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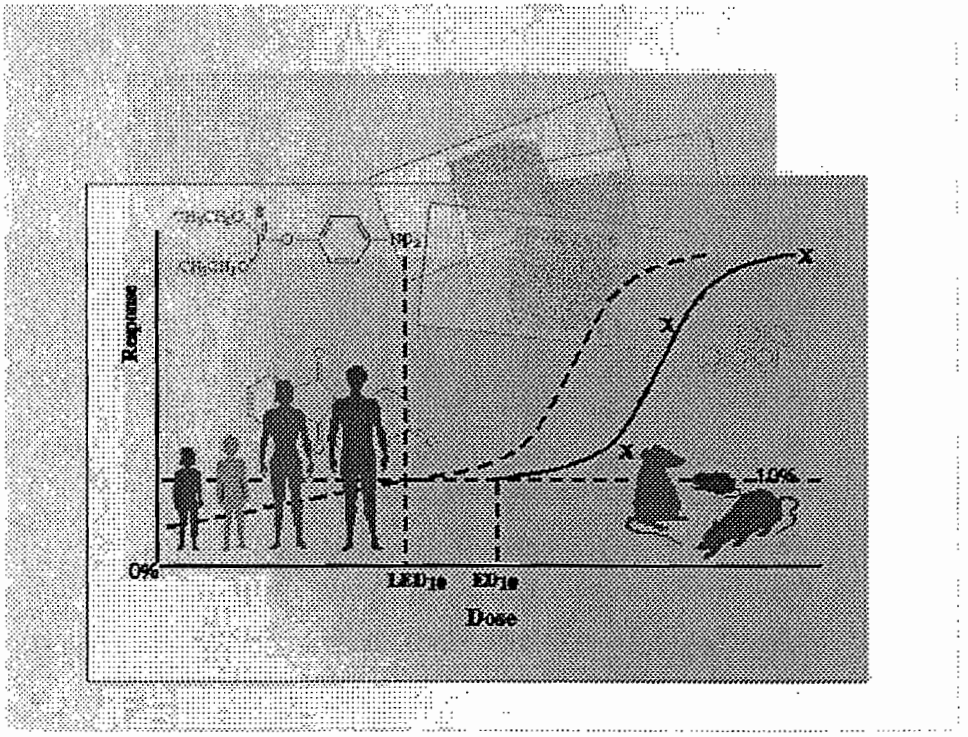
HUMAN HEALTH RISK ASSESSMENT

Methyl Parathion



U.S. Environmental Protection Agency
Office of Pesticide Programs
Health Effects Division (7509C)

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HUMAN HEALTH RISK ASSESSMENT

Methyl Parathion

Phase 4

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METHYL PARATHION REVISED RISK ASSESSMENT

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METHYL PARATHION

Executive Summary

Uses

Methyl parathion, O, O-Dimethyl O-(4-nitrophenyl) phosphorothioate, is an acaricide and an insecticide registered for use on a variety of food and feed crops. Methyl parathion is a restricted use pesticide that is formulated as a microencapsulate [20.9% active ingredient (ai)], and an emulsifiable concentrate (ranges from 11.2 to 54.8% ai). Currently, a granular formulation is available but is not being supported for reregistration and is not included in the risk assessment. Methyl parathion is sold in the U.S. by Cheminova Agro A/S and Griffin Corporation, the basic producers, under the trade name Methyl Parathion, and by Elf Atochem North America, a formulator for Penncap-M®. Methyl parathion can be applied with aerial equipment, and an airblast sprayer (microencapsulated formulation only), by chemigation (microencapsulated formulation only), and with groundboom equipment. Both the registrant's proposed maximum application rates and the current label maximum application rates were used in this assessment. These application rates vary from 0.25 to 3.0 lbs. ai/A. Methyl parathion is formulated with several other active ingredients including ethyl parathion, malathion, and endosulfan.

Methyl parathion is a restricted-use pesticide and is available for retail sale to, and for use by, certified applicators (or persons under their direct supervision), and only for those uses covered by the certified applicator's certification. There are no labeled uses for homeowners. However, residential exposure could occur via agricultural spray drift from the use of methyl parathion on fields adjacent to residences or from the use of methyl parathion as a mosquito control agent. A mosquito control use (larvicide) is not being supported for reregistration by the primary data-submitter, Cheminova. The Agency contacted Health and Human Services and determined that methyl parathion has not been for many years, nor is, in use for mosquito control. A quantitative exposure and risk assessment for residential exposure via agricultural spray drift has not been completed as part of this risk assessment as the methodology for this assessment is still under development by the Agency.

Endpoints

The toxicity endpoints selected for the risk assessment are based primarily on neurotoxic effects, including neuropathology and cholinesterase (ChE) inhibition in the brain, red blood cell (RBC), and plasma, as well as behavioral effects and systemic toxicity (decreased hematocrit and erythrocyte levels). In addition, a single oral exposure to methyl parathion (7.5 mg/kg) in rodents resulted in peripheral nerve demyelination (tibial and sural nerves, dorsal and ventral root fibers). Additional effects of chronic exposure include retinal degeneration and sciatic nerve degeneration. No evidence of carcinogenicity was seen in any study.

An uncertainty factor (UF) of 100 was applied to the doses selected for risk assessment to account for both interspecies extrapolation and intraspecies variability. An additional factor of 10X was retained in accordance with the FQPA for the dietary risk assessment. In accordance with current HED guidance, the FQPA factor is not retained for the occupational risk assessment.

The Agency conducted the human health risk assessment for all registered uses of methyl parathion which were being supported under reregistration, plus hops, as well as for the use changes which reflect mitigation measures.

Dietary Assessment

Current tolerances for methyl parathion are based on the parent compound alone. This is consistent with Codex. The methyl parathion residues of concern that are included in this dietary risk assessment, based on ChE inhibition, are methyl parathion and its oxygen analog, methyl paraoxon. A dietary exposure assessment for methyl parathion residues from animal commodities was not performed since there are no tolerances currently established for residues of methyl parathion in meat, milk, poultry, and eggs. Residues of methyl parathion were not detected in ruminant tissue, milk, and egg samples collected from the ruminant and poultry metabolism studies. The pre-mitigation dietary exposure assessment was limited to those agricultural uses of methyl parathion which were being supported under reregistration. The United States Department of Agriculture (USDA) was contacted and any agricultural uses that USDA - IR4 wished to retain were included in the assessment. It was determined that hops were the only IR4 crop of agricultural interest that Cheminova would not support. Therefore, hops were included in the assessment. Dietary exposure estimates were refined to include monitoring data, percent crop treated data, and available processing and cooking data.

The acute dietary risk assessment (probabilistic), based on USDA's Continuing Survey of Food Intake by Individuals (CSFII) food consumption survey and using an acute Population Adjusted Dose (aPAD) of 0.00011 mg/kg/d, shows that acute dietary exposure to all population subgroups prior to mitigation measures exceeded the aPAD at the 99.9th percentile estimated exposure level (U.S. population 378% aPAD, children 1-6 years 881% aPAD). Children 1-6 years were identified as the most highly exposed population subgroup. Acute dietary exposure to children 1-6 years exceeded the aPAD at the 99th and 95th percentile also. Dietary exposure to children 1-6 years did not exceed the aPAD at the 90th percentile. Dietary risk estimates that reflect mitigation measures show that exposures from food do not exceed the aPAD for any population subgroup at the 99.9th percentile (U.S. population 60% aPAD, children 1-6 years 78% aPAD). Several crops were identified as making substantial contributions to the dietary risk. In other words, residues measured on these crops and the surveyed consumption of these crops by the different population subgroups, factored together, results in these crops making a large contribution to the overall estimated exposure. For methyl parathion, the largest contributors to the acute dietary exposure were identified as apples, peaches, grapes, and pears. It should be noted that only the use of the

microencapsulate (Mcap) formulation of methyl parathion on pome and stone fruits (apples, peaches, pears, and grapes) was being supported under reregistration, not the emulsifiable concentrate (EC).

Based on a refined pre-mitigation chronic dietary exposure analysis and using a chronic PAD (cPAD) of 0.00002 mg/kg/d, chronic dietary exposure to all population subgroups did not exceed the cPAD (U.S. population 17% cPAD, children 1-6 years 47% cPAD). Dietary risk estimates that reflect mitigation measures further reduced exposures from food and do not exceed the cPAD for any population subgroup (U.S. population 3% aPAD, children 1-6 years 8% aPAD)

Drinking Water Assessment

Ready to drink, treated drinking water data for methyl parathion, or "at the tap" water data, are not available. While the Agency's Office of Water (OW) has established a lifetime health advisory (HA) of 2 ppb, methyl parathion does not have an established Maximum Contaminant Level, and it is not included on the OW's Unregulated Contaminant Monitoring List. Therefore, public drinking water supply systems are not required to analyze for methyl parathion. Consequently, EFED relied on simulation models and some very limited surface-water monitoring data for this risk assessment. The monitoring data represent only a very small range of conditions (regional weather, streamflow, application rates and methods) and it cannot be assumed that they represent surface water concentrations or conditions across the United States. None of the monitoring data included analysis for the methyl paraoxon metabolite. Although the Agency considers it unlikely that drinking water concentrations "at the tap," will make the largest, or a significant, contribution to the total dietary burden, there is sufficient information from the available monitoring data and the models to warrant close monitoring of potential surface and ground water sources of methyl parathion exposure.

Occupational Assessment

HED has determined that there are potential occupational exposures of concern to mixers, loaders, applicators, and other handlers associated with uses of methyl parathion. Calculations of occupational risk were based on combined dermal and inhalation exposures, a No Observable Adverse Effect Level (NOAEL) = 0.11 mg/kg/day, and 100% dermal and inhalation absorption. The risk calculations indicate that the Margins of Exposure (MOE) less than 100 with maximum risk reduction measures for nearly all of the supported short- and intermediate-term occupational exposure scenarios (many less than 1). Depending on crop and postapplication activities, calculated re-entry intervals (REI) for workers, that would not be of concern, were estimated to range from 30 to 33 days for Mcap formulations, and from 7 to 9 days for EC formulations. Current labels show 48-72 hours REI. Mitigation measures have eliminated many of the activities involving hand harvesting and therefore, have reduced occupational risks.

Risk estimates of residential dermal and inhalation exposures were not estimated. The Agency is currently developing methods to assess residential risks, and these risks will be assessed in the future when these new methods are available. However, based on available information, HED remains concerned about residential risks from methyl parathion spray drift.

Aggregate Assessment

Under the Food Quality Protection Act, the Agency considers contributions to risk from various exposure sources, specifically, food, drinking water, and residential. Methyl parathion has no registered residential uses, therefore only exposures through food and drinking water were considered in the aggregate risk assessment. The acute aggregate risk estimate for all registered uses, pre-mitigation, indicated that there is no room for exposure to methyl parathion in drinking water because risk from food sources alone exceed the Agency's level of concern (> 100% aPAD). The acute aggregate risk estimate which reflects mitigation measures may still be of concern. Though acute exposure to methyl parathion from food sources alone, with mitigation measures, does not exceed the Agency's level of concern (< 100% aPAD), limited surface water monitoring data indicate potential exposures at unacceptable levels. However, without actual drinking water monitoring data, it is difficult to draw any conclusions about actual residues in drinking water. The chronic aggregate risk assessment is not of concern, pre- or post-mitigation measures.

The Agency is in the process of formulating guidance for conducting cumulative risk assessment. When the guidance is finalized, methyl parathion and other organophosphates will be revisited to assess the cumulative effects of exposure to multiple organophosphates.

Reported Incidents

A review of the published incident data indicates that in outdoor agricultural uses, the primary activities associated with poisoning are application and spray drift (Attachment 11). Methyl parathion is associated with less poisoning compared to other organophosphate or carbamate pesticides when adjusted for the number of incidents per amount of use (lbs ai/A).

Hazard Characterization

A. Hazard Profile

The toxicological database is complete pending submission of a developmental neurotoxicity study. In summary, methyl parathion is acutely toxic (category 1) for oral, dermal, and inhalation routes, is slightly-moderately irritating to the eyes and skin, and is not a dermal sensitizer. The toxicity endpoints selected for the risk assessment are based primarily on neurotoxic effects, including neuropathology and ChE inhibition in the brain, RBC, and plasma, as well as behavioral effects and systemic toxicity. A single exposure to methyl parathion (7.5 mg/kg) in rodents results in peripheral nerve demyelination (tibial and sural nerves, dorsal and ventral root fibers). Chronic exposure at a dose level of 2.21 mg/kg/d results in retinal degeneration and sciatic nerve degeneration. There are no notable differences in sensitivity to methyl parathion between male and female animals. No evidence of carcinogenicity was seen in any study. Methyl parathion is classified as a "Group E" carcinogen, indicating no evidence of carcinogenicity in humans; i.e., the chemical is characterized as "Not Likely" to be carcinogenic in humans via relevant routes of exposure. This classification is supported by the lack of mutagenic activity. There is evidence suggesting that methyl parathion may function as an endocrine disruptor (Attachment 3).

Table 1. summarizes the acute toxicity data for the technical methyl parathion.

Table 1. Acute Toxicity Data for Methyl Parathion (Technical)

Guideline No.	Study Type	MRID #	Results	Toxicity Category
81-1	Acute Oral (rat)		LD_{50} = 4.5-24 mg/kg	I
81-2	Acute Dermal (rat)		LD_{50} = 6 mg/kg	I
81-3	Acute Inhalation (rat)	256961	LC_{50} < 0.163 mg/L (< 7 mg/kg)	I
81-4	Primary Eye Irritation	256966, 40542602	Irritation clear by 7 days	III
81-5	Primary Skin Irritation	256962	Max. score = 2.0; 72 h = 0.5	IV
81-6	Dermal Sensitization	256963	Negative	
81-8	Acute Neurotoxicity Delayed Hen	41606801	Negative	

No dermal absorption study was available. Although there was a 21-day dermal toxicity study in rabbits available, it was not selected to generate a dermal toxicity endpoint for the following reasons: 1) The rabbit is less sensitive than the rat to this chemical (for example, in the rabbit developmental study, the 3.0 mg/kg/d dose resulted in only minimally significant ChE inhibition, and in the rat, maternal deaths occurred in the developmental toxicity study at the same dose), 2) several endpoints (including neurotoxicity and neuropathology) occurring at low doses in the acute oral rat study were not measured in the dermal rabbit study, 3) oral and dermal effects seen in other acute studies occurred at similar doses (Attachments 1 and 2), so there is no reason to believe that neurotoxic effects might not occur at low dermal doses, and 4) because of physiological and biochemical factors, unique to the rabbit, which might result in an underestimation of the dermal toxicity of organophosphorus pesticides belonging to the thiophosphate subgroup (R. Zendzian, HED, memo dated March 1997). Therefore, based on available information, including comparison of toxicity following oral and dermal exposure, dermal absorption was estimated to be 100% (i.e. equivalent toxicity is expected after oral or dermal exposure to a given amount of methyl parathion). This decision was reevaluated and reaffirmed in the Hazard Identification Assessment Review Committee (HIARC) meeting of March 4, 1999 (Attachment 2). Cheminova submitted a 5-day dermal toxicity study in rats (06/03/99) and it is in review.

B. Endpoint Selection

Previously, the HIARC selected a NOAEL = 0.025 mg/kg/d from an acute neurotoxicity study for use in acute dietary and short-term occupational risk assessment (Attachment 1). The dose spacing in Cheminova's submitted acute neurotoxicity study was very broad and the NOAEL of 0.025 mg/kg/d was believed to possibly be an artifact of the doses selected for the study (LOAEL = 7.5 mg/kg/d). Following a review of the comments submitted by Cheminova in Phase 3 of the Public Participation Process, the HIARC reevaluated the endpoints on March 4, 1999, and determined that the acute dietary, as well as the dermal and inhalation short- and intermediate-term occupational endpoints should be based on a NOAEL of 0.11 mg/kg/d for inhibition of plasma, brain, and RBC ChE and neuropathology seen in a 1 year dietary study in rats at the LOAEL of 0.53 mg/kg/d (Attachment 2). The NOAEL of 0.11 mg/kg/d is still considerably lower than the LOAEL from the previously selected acute neurotoxicity study (7.5 mg/kg/d).

Cheminova submitted an acute dietary risk assessment (conducted by Novigen Sciences, Inc.) on 3/16/99. The acute dietary endpoint used was based on a NOAEL = 1 mg/kg/day for inhibition of RBC ChE at 1.5 mg/kg/day (the LOAEL) in Cheminova's newly conducted acute feeding study in the rat.

This acute feeding study has recently been submitted (05/99) to the Agency and is in review. Cheminova's acute feeding study was conducted using a novel protocol, not previously submitted to the Agency (not guideline), and will undergo peer review (Science Advisory Panel) following internal review.

The HIARC did consider the registrant's proposals for the other endpoints but reaffirmed that the NOAEL = 0.02 mg/kg/d from the 2-year chronic oral study in the rat should be used for the chronic dietary risk assessment. The HIARC also reaffirmed that the dermal absorption factor for methyl parathion would continue to be 100% for risk assessment purposes (Attachment 2). Due to the high toxicity seen in the submitted acute inhalation study, 100% absorption is considered appropriate. Details of the HIARC's findings and rationale can be found in the attached Revised Toxicology chapter (Attachment 3), the addendum to the HIARC memo (Attachment 2), and the original HIARC endpoint selection document (Attachment 1).

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Table 2. Revised Methyl Parathion Endpoints (3/4/99)

Exposure Duration	Exposure Route	Endpoint		Comments
		Dose	Effect	
Acute - PAD	Dietary	aPAD = 0.00011 mg/kg/d	Neuropathology and inhibition of brain, plasma, and RBC ChE	NOAEL = 0.11 mg/kg/d. Based on neurotoxicity, neuropathology and inhibition of brain, plasma, and RBC ChE occurring at 0.53 mg/kg/d. One year dietary study in rats. UF of 100 applied for intra and inter species differences and an additional safety factor of 10X retained by the FQPA Safety Factor Committee for FQPA.
Chronic - PAD	Dietary	cPAD = 0.00002 mg/kg/d	Systemic toxicity, neuropathology, and inhibition of RBC ChE at the LOAEL	NOAEL = 0.02 mg/kg/d. Based on systemic toxicity, neuropathology, and RBC ChE inhibition occurring at 0.21 mg/kg/d. Inhibition of plasma and brain ChE occurred at higher doses. Retinal degeneration and clinical signs occurred at the highest dose. 2-Yr chronic feeding study in rats. UF of 100 applied for intra and inter species differences and an additional safety factor of 10X retained by the FQPA Safety Factor Committee for FQPA.
Short-term (1-7 days) Occupational	Dermal	NOAEL = 0.11 mg/kg/d	Neuropathology and inhibition of brain, plasma, and RBC ChE	Same endpoint as aPAD. Although a 21-day dermal study in the rabbit is available, it was not selected. See Hazard ID SARC memo 12/01/97. Dermal absorption rate estimated to be 100% (Revisited 02/14/99, 03/04/99). UF of 100 applied for intra and inter species differences.
Intermediate- term (7 - 90 days) Occupational	Dermal	NOAEL = 0.11 mg/kg/d	Neuropathology and inhibition of brain, plasma, and RBC ChE	Same endpoint as aPAD. Long term dermal study not available. Dermal absorption rate estimated to be 100%. UF of 100 applied for intra and inter species differences.
Short- & Intermediate-term Occupational	Inhalation	NOAEL = 0.11 mg/kg/d	Neuropathology & inhibition of brain, plasma, and RBC ChE	Same endpoint as aPAD. Due to high toxicity seen in acute inhalation study, 100% absorption is estimated. UF of 100 applied for intra and inter species differences.

C. FQPA Considerations

The decision to retain the full 10X FQPA Safety Factor was based on a substantial data gap that can be filled with the submission of a Developmental Neurotoxicity Test. The data that were instrumental in this decision are discussed below.

Neuropathology reported in acceptable studies submitted by the registrant:

- ❑ Neuropathology seen in experimental animals in the guideline acute neurotoxicity study;
- ❑ Neuropathology seen in experimental animals in the guideline chronic/carcinogenicity study;
- ❑ Neuropathology seen in experimental animals in the non-guideline, but acceptable one year neurotoxicity study.

Fetal/neonate susceptibility reported in open literature citations which were retrieved and reviewed by the Agency:

- ❑ An open literature citation which assessed postnatal functional toxicity following prenatal exposure reported the inhibition of acetyl cholinesterase and other neurochemical biomarkers in pups which persisted to day 28 and impaired behavioral parameters (Gupta *et. al.* 1985);
- ❑ Additional open,literature citations reported that neonates were more sensitive to acute lethality from methyl parathion than adults and that significant compound-related and age-related differences in duration of ChE inhibition can occur (Pope *et al.* 1991, Pope and Chakraborti 1992);
- ❑ Possible endocrine disruption in mammals (Dhondup and Basavanneppa 1997, Lukaszewica-Hussain, Moniuszko-Jakoniuk and Pawlowska 1985).

Fetal/neonate sensitivity/susceptibility reported in studies submitted by the registrant during the comment period:

- ❑ Decreased survival and convulsions in the surviving F_{1b} pups were reported in a non-guideline multi-generation reproduction study in rats;
- ❑ Embryotoxicity or fetotoxicity was observed at non-maternally toxic levels

in an additional supplementary developmental study in rats which had previously been submitted to the Agency.

The standard guideline studies for developmental and reproductive toxicity, which have been submitted by the registrant and are acceptable, are not required to measure cholinesterase inhibition, behavioral effects, neuropathology, or increased sensitivity to lethal effects in pups. Thus, these studies are silent on effects that have been reported in the open literature. Even though the open literature studies have a number of deficiencies, the fact that *several* studies have reported adverse effects on neonates raises concern. The suggestive evidence of possible endocrine disruption, although not heavily weighted, was also taken into account. If the information from these studies is considered together with the reported neuropathology seen in adult animals after a single and multiple doses of methyl parathion and the results from the supplementary developmental and reproduction studies submitted by the registrant which demonstrate fetal and neonate sensitivity, the concern for effects on the developing organism increases. Thus all of these data, taken *in toto* require that the 10X FQPA Safety Factor be retained until such time as the Agency receives an acceptable Developmental Neurotoxicity Test. When this study is received and reviewed, the final decision on the retention, reduction, or removal of the 10X FQPA Safety Factor will be made based upon the weight of the evidence.

II. Exposure Characterization

A. Registered Uses

Methyl parathion is registered for use on a variety of fruits, vegetables, and feed crops. Methyl parathion is sold in the U.S. by Cheminova Agro A/S and Griffin, the basic producers, under the trade name Methyl Parathion, and by Elf Atochem North America, a formulator for Penncap-M®. Registered formulations for use on food and feed crops include Mcap and EC formulations. Currently, a granular formulation is available but is not being supported for reregistration. Methyl parathion can be applied with aerial equipment and an airblast sprayer (Mcap formulation only), by chemigation (Mcap formulation only), and with groundboom equipment. Methyl parathion is formulated with several other active ingredients including ethyl parathion, malathion, and endosulfan.

The following uses (1-4) are currently being supported by the registrant and are included in this assessment:

1. Food, Forage, Feed, and Fiber Crops

Alfalfa, artichoke, barley, beans, broccoli, Brussels sprouts, cabbage, canola, carrot, cauliflower, celery, collards, corn, cotton, grass forage/fodder/hay, hops, kale, lentils, lettuce, mustard greens, oats, onion, pastures, peas, potato, rangeland, rice, rye, soybeans, spinach, sugar beet, sunflower, sweet potato, tomato, turnip, wheat, and yam.

2. Fruits and Nuts

Almond, walnut, peanut, pecan, apple, cherry, grapes, nectarine, peach, pear, and plum.

3. Ornamental Plants and Forest Trees

Christmas tree plantations, forest trees, ornamental and/or shade trees, pine trees, field-grown ornamental herbaceous plants, and field-grown ornamental woody shrubs and vines.

4. Non-agriculture Land and Pastures

Rights-of-way and grazing lands.

The crops included in the post mitigation uses of methyl parathion differ

from the above list. The following crops were added: dried beans and dried peas. The following crops were taken out: apple, artichoke, broccoli, Brussels sprouts, carrots, cauliflower, celery, cherry, collards, forest trees, garden beets, grapes, grasses grown for seed, kale, kohlrabi, lettuce, mustard, nectarine, non-agricultural land (mosquito use), ornamentals, pastures, peach, pears, plums, prunes, rangeland, spinach, succulent beans, succulent peas, tomatoes, and turnips.

B. Dietary Exposure

1. Food Exposure

The HED Metabolism Assessment Review Committee (Attachment 5) tentatively concluded that methyl parathion residues of concern in plant commodities include methyl parathion, methyl paraoxon, and *p*-nitrophenol, and that methyl parathion residues of concern in animal commodities include methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl. The tolerance expression for plant and animal commodities is based on the parent methyl parathion only (U.S. tolerance definition is compatible with Codex). The methyl parathion residues of concern for plant and animal commodities included in this risk assessment are based on ChE inhibition, and are methyl parathion and methyl paraoxon. Residues of *p*-nitrophenol are not included in the tolerance expression, nor considered in the aggregate risk assessment for methyl parathion with respect to cholinesterase inhibition, but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol in the future. There is concern for the amino-paraoxon-methyl metabolite due to neuropathy of unknown etiology. Once outstanding livestock feeding studies have been submitted, the Agency will determine whether to include amino-paraoxon-methyl metabolite in the risk assessment.

Tolerances for residues of methyl parathion have been established on a variety of fruit, vegetable, and field crops. Additional magnitude of the residue and processing data remain outstanding. Anticipated residue (AR) estimates of methyl parathion and methyl paraoxon in/on plant commodities and processed commodities have been included in the dietary risk assessment for methyl parathion. Anticipated residue estimates are highly refined and are based on available monitoring and magnitude of the residue data. These estimates have been refined to include concentration/reduction factors determined from available processing data along with percent crop treated information.

No tolerances for residues of methyl parathion have been established in animal commodities (meat, milk, poultry, and eggs); although, tolerances for residues of methyl parathion have been established on numerous animal feed items. Therefore, the dietary exposure assessment may possibly underestimate dietary risks. Residues of methyl parathion were not detected in ruminant tissue, milk, and egg samples collected from the ruminant and poultry metabolism studies. Residues of methyl paraoxon were also not detected in any of the samples. Residues of methyl parathion were not detected in USDA monitored samples (1304 samples) of milk (1996-1998). Residues of methyl parathion detected in poultry tissue samples collected from the poultry metabolism study were very low. Based on available data, it is uncertain if finite residues of methyl parathion and methyl paraoxon are likely to occur in animal commodities; hence, AR estimates for residues of methyl parathion and methyl paraoxon in animal commodities were not included in the dietary risk assessment for methyl parathion. If required, appropriate tolerances for methyl parathion residues in animal commodities will be determined once data are available from outstanding livestock feeding studies.

2. Drinking Water Exposure

When the preliminary HED chapter (09/01/98) was written, potential exposure and risk from methyl parathion in drinking water were assessed using modeled estimates, and limited monitoring data. EFED provided HED with a Tier 2 surface water exposure assessment derived from the PRZMS3 model, which simulates the erosion and runoff from an agricultural field, and the EXAMS model, which simulates fate in a surface water body. A Tier 1 ground water exposure assessment was derived from the SCI-GROW screening model only, with no refinements. No further refinements can be made by EFED without ground water monitoring data.

Ready to drink, treated drinking water data for methyl parathion, or "at the tap" water data, are not available. While the Agency's OW has established a lifetime HA of 2 ppb, methyl parathion does not have an established Maximum Contaminant Level, and is not included on the OW's Unregulated Contaminant Monitoring List. Therefore, public drinking water supply systems are not required to analyze for methyl parathion. Consequently, EFED has relied on simulation models and other surface- and ground-water monitoring data for this revised risk assessment.

a. Surface Water

The surface-water concentrations estimated from the PRZM-EXAMS screening model (Tier 2) for human health risk assessments are: acute- 254 ppb (μg/L) and chronic- 4.2 ppb. However, these screening estimates are significantly higher than the concentrations seen in monitoring studies that have been obtained by EFED since the Preliminary HED chapter was issued (09/01/98). Data from targeted monitoring studies such as those in California, and the Mississippi River basin may provide a better estimate of possible acute drinking water concentrations than the models. In addition, Cheminova supplied supplementary information during Phase 3 of the Public Participation Process and suggested alternative input parameters for the modeled estimates.

Prior to a mitigation program instituted by California EPA's Department of Pesticide Regulation (CDPR) in the early 1990's, peak concentrations of methyl parathion in the Colusa Basin Drain were measured as high as 6 ppb. Although monitoring data are more realistic than modeling results, they do not necessarily reflect the use scenarios most vulnerable to contamination. For instance, the CDPR monitoring of the Colusa Basin Drain targeted methyl parathion use on rice. Application rates and the number of applications for many crops are higher than those for rice. In addition, current mitigation measures incorporating retention of water on treated fields is relevant only to rice, and not other crops to which methyl parathion is applied. Mitigation measures such as holding ponds lower the expected surface water concentrations, but to what extent is unknown, and it is not applicable to other crops.

Since EFED's preliminary chapter was issued, EFED has obtained targeted surface-water monitoring data collected by the United States Geological Survey (USGS) from rivers in the Mississippi Embayment cotton-growing region. Samples were drawn from five rivers in 1996 and 1997, and methyl parathion was detected in all five. Detected concentrations reached up to 0.42 ppb. The site with the highest frequency of detections in this study had 8 detections in 17 samples during water year (WY) 1996, and 8 detections in 37 samples during WY1997. However, the rivers sampled are not known drinking-water sources. Mississippi derives its drinking water almost exclusively from ground water, and of the five stations sampled for methyl parathion, only one was within 25 miles of a surface-water body used for drinking water. Usage data provided by Cheminova indicates that the Mississippi

Embayment cotton-growing region represents the area with the greatest density of methyl parathion use in the country.

In another 1996 monitoring program in the Mississippi Embayment region, the USGS detected methyl parathion in 18% of the 60 samples it collected from tributaries of the Mississippi River. The highest concentration detected was about 0.12 ppb, and the 50th percentile concentration was about 0.05 ppb.

The maximum acute surface water concentration simulated by PRZM/EXAMS was 214 ppb, for use on cotton at the maximum label rates. Cotton was chosen since it also has the highest application rate of all the use sites. When the input parameters, suggested by Cheminova in Phase 3 of the Public Participation Process, were considered in a hypothetical scenario, the peak concentration estimated for cotton was 17.8 ppb. Though somewhat refined, this is still considered a conservative estimate. Given the fact that the 0.42 and 6 ppb detections came from very limited, targeted surface-water monitoring studies on cotton and rice, respectively, and that the data represent only a very small range of conditions (a year or two of weather, streamflow, application rates and methods), insufficient evidence exists to determine how nationally representative these exposure concentrations are.

EFED has obtained some closer-to-the-tap targeted chronic monitoring data from Jefferson Parish, Louisiana, drawn at two intakes of a surface water derived drinking water plant on the Mississippi River. Weekly composites (continuous slow sampling to a refrigerated container over one week) were drawn for 52 weeks of the year. In 1994, raw water drawn at one intake had 18 detections of methyl parathion out of the 52 composite samples. At another intake in the same year, there were 21 out of 52 detections. The average for both plants was 0.009 ppb (detection limit) with highs of 0.03 and 0.04 ppb, respectively.

b. Ground Water

Using the screening model SCI-GROW, EFED calculated a ground water concentration of 0.6 ppb (Tier 1) for human health risk assessment. Data collected from a variety of sources did not identify any known instance in which a ground-water concentration higher than 0.6 ppb was detected, although individual detections have been within the same order of magnitude. Therefore, EFED suggests that 0.6 ppb is a reasonable conservative modeled estimate of possible acute concentrations of methyl parathion in drinking water derived from ground water. EFED does not have a model for estimating Tier 2 ground water concentrations for dietary

risk assessments.

C. Non-Dietary Exposure

1. Occupational Handler Exposure

HED has determined that there are potential short- and intermediate-term exposures to mixers, loaders, applicators, and other handlers during the usual use-patterns associated with methyl parathion. Based on the use patterns of methyl parathion, twelve major exposure scenarios were identified: (1a) mixing/loading liquids (EC) for aerial application; (1b) mixing/loading liquids (EC) for groundboom application; (2a) mixing/loading liquids (Mcap) for aerial/chemigation application; (2b) mixing/loading liquids (Mcap) for groundboom application; (2c) mixing/ loading liquids (Mcap) for airblast application; (3) applying sprays with aerial equipment (EC); (4) applying sprays with aerial equipment (Mcap); (5) applying sprays with groundboom equipment (EC); (6) applying sprays with groundboom equipment (Mcap); (7) applying sprays with airblast sprayer (Mcap); (8) flagging sprays (EC); and (9) flagging sprays (Mcap).

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted to the Agency in support of the reregistration of methyl parathion. It is the policy of the HED to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that are utilized to ensure consistency in exposure assessments. See Tables 2-6 in the revised Occupational and Residential Exposure and Risk Assessment Chapter (Attachment 14).

2. Postapplication Occupational Exposure

Chemical-specific postapplication exposure and/or environmental fate data have not been submitted by the registrants in support of reregistration of all formulation types of methyl parathion. In lieu of these data, a potential range of postapplication exposures were estimated to determine potential risks for the representative crops used in the handler exposure assessment section.

The surrogate assessment on pre mitigation uses for the Mcap formulation uses a typical transfer coefficient (Tc) for tree crops (peaches, apples and pears) of 10,000 cm^2/hr (based on HED's Exposure Science Assessment Committee Policy No. 3, "Agricultural Default Transfer Coefficients," May 7, 1998), from activities such as harvesting and pruning, and a typical Tc for grapes of 15,000 cm^2/hr, from activities such as harvesting and hand girdling. The dislodgeable foliar residue (DFR) is derived from the various application rates using an estimated 20% of the rate applied as initial dislodgeable residues, and an estimated 25% dissipation rate per day. The dissipation half-life of the Mcap formulation is 1 to 2 days (based on environmental fate data supplied by EFED). A half-life of 1 to 2 days has also been suggested for methyl paraoxon, depending upon the crop and climate. The estimated dissipation rate of 25% per day is intended to approximate this half-life. For grapes, the registrant's proposed application rate is 1.5 lbs ai/A and the current maximum label rate is 3.0 lbs ai/A. For apples, pears, and peaches the application rate is 2.0 lbs ai/A.

The surrogate assessment on post-mitigation uses for the Mcap formulation uses a typical transfer coefficient (Tc) for nut crops (almonds, walnuts, and pecans) of 10,000 cm^2/hr (based on HED's Exposure Science Assessment Committee Policy No. 3, "Agricultural Default Transfer Coefficients," May 7, 1998), from activities such as harvesting and pruning, and a typical Tc for grapes of 15,000 cm^2/hr, from activities such as shaking, raking, pole and picking up. The dislodgeable foliar residue (DFR) is derived from the various application rates using an estimated 20% of the rate applied as initial dislodgeable residues, and an estimated 25% dissipation rate per day. The dissipation half-life of the Mcap formulation is 1 to 2 days (based on environmental fate data supplied by EFED). A half-life of 1 to 2 days has also been suggested for methyl paraoxon, depending upon the crop and climate. The estimated dissipation rate of 25% per day is intended to approximate this half-life. For nut crops, the application rate is 2.0 lbs ai/A.

The post application assessment for the emulsifiable concentrate formulation is the same for the pre-mitigation uses and the post-mitigation uses. The surrogate assessment for the EC formulation uses a typical Tc for cotton of 1,000 cm^2/hr for scouting in the early season and 4,000 cm^2/hr for scouting in the late season. Since the dissipation rate is chemical specific, the DFR data were obtained from an open literature study done with methyl parathion. The DFR data were derived by combining the amount of methyl parathion with the amount of methyl paraoxon that were present on the foliage each day, after an initial

application of 1.0 lb ai/A. Since the maximum application rate for cotton is 3.0 lbs ai/A and is greater than 1.0 lb ai/A, the initial amount found on the leaf on day 0 was multiplied by the application rate of the crop. The data were log transferred and a regression analysis was done. The dissipation was determined from the regression data to be 63% per day. The predicted DFR from the regression analysis were then determined using this dissipation rate, starting at day 0 and then used to obtain the dose for each day.

3. Residential

Although methyl parathion is a restricted use pesticide that is only to be applied by certified applicators, HED believes that residential exposures may occur in several situations. First, residential exposures may occur from the use of methyl parathion as a mosquito control agent (as permitted on some current labels). Second, even though methyl parathion is a restricted use pesticide and some (but not all) labels state "Not for home use", the possibility exists for residential postapplication exposure from commercial application of methyl parathion to private orchards. Finally, residential exposures may result from spray drift from the aerial application of methyl parathion to agricultural fields adjacent to residential areas.

HED did not quantitatively assess the exposures and risks to individuals who live adjacent to farm fields and that could potentially be exposed to methyl parathion from spray drift. Methods to assess these risks are currently being developed by the Agency, and these assessments will be conducted in the future when these methods are available. However, based on current information, HED remains concerned about the potential risks from this source.

III. Risk Assessment/Characterization

Risk is a function of exposure multiplied by hazard (Risk = Exposure x Hazard). Exposure may be measured or modeled, depending on the available data. Ideally the exposure data would be chemical specific occupational or residential monitoring data, at the tap drinking water data, and close to the plate food residue data on all crops. In the absence of an ideal data set, surrogate data, and other factors are incorporated into the exposure assessments (dietary and non-dietary) to present a reasonable exposure picture based on the best available data. The hazard portion of the risk equation has several layers of safety built into it to provide a cushion between exposure and the dose at which adverse effects were seen in an animal study. Generally, endpoints are based on the dose at which **no** observable adverse effect is seen in an animal study. This is the No Observable Adverse Effect Level (NOAEL). The Lowest Observable Adverse Effect Level (LOAEL) is the next highest dose in an animal study, up from the NOAEL, at which the adverse effect of concern is seen. Levels of ChE inhibition which are of concern to the Agency do not always manifest themselves in clinical signs. In humans, the initial signs of organophosphate poisoning are headache, hypersecretion, muscle twitching, nausea, and diarrhea. Many of these symptoms are often confused with flu-like symptoms. Since the toxicity studies used for endpoint selection are conducted in animals, and there are differences between individual humans, additional uncertainty factors for inter- and intra-species variability are integrated into the hazard portion of the risk equation. Since the passage of the FQPA, an additional layer of protection is factored in (when appropriate) to provide an even greater safety cushion between exposure and toxic effects for particularly sensitive populations. It is in this light that expressions of risk (risk numbers) should be viewed with an understanding that they are not portrayals of imminent toxic effects to humans but as a measure of the distance between potential exposure and possible toxic effects.

In accordance with current HED policy (effective 03/11/99) the acute and chronic dietary endpoints are expressed as acute Population Adjusted Dose (aPAD) and chronic PAD (cPAD), and no longer as an adjusted Reference Dose (RfD).

$$\text{RfD} = \frac{\text{acute or chronic NOAEL}}{\text{Uncertainty Factor (UF)}}$$

Generally, an UF of 100 is applied for intra- and inter-species differences.

$$\text{PAD} = \frac{\text{acute or chronic RfD}}{\text{FQPA factor}}$$

The use of the PAD will apply whether the FQPA factor is retained (10x or 3x) or not (1x). When a PAD is used, such as in the dietary assessment, the risk is expressed as a percentage of the PAD which is equal to the measured exposure divided by the PAD and then multiplied by 100 or:

$$\text{Risk (\% PAD)} = \frac{\text{Exposure}}{\text{PAD}} \times 100$$

Occupational, residential (when applicable), and the aggregate risk (when appropriate) will still be expressed as the Margin of Exposure (MOE).

$$\text{MOE} = \frac{\text{NOAEL}}{\text{Exposure}}$$

Current HED policy requires that FQPA safety factors be retained for dietary and non-occupational exposures, when appropriate, not occupational exposures. Therefore, an MOE of $\geq$ 100 is needed in the occupational exposure risk assessment. However, when a risk assessment for residential uses is conducted in the future, an MOE $\geq$ 1000 will be needed.

A. Dietary Risk

HED has completed a revision of the dietary risk assessment for methyl parathion using available data and updated methods for estimating acute dietary exposure. Based on the results of the HIARC, hazard endpoints have been selected for both acute (one day) and chronic (long term) exposure intervals. Acute and chronic risk assessments were conducted for all methyl parathion food uses combined, and additional risk assessments were conducted minus individual commodities or commodity subgroups depending on their estimated contribution to the overall dietary exposure. Risk estimates are provided for the average U.S. population and various subgroups, with the major emphasis placed on the exposure estimates for infants and children. This assessment concluded that for the pre-mitigation methyl parathion registered uses, the acute dietary risk estimates exceeded the aPAD for all population subgroups. However, the risk estimates for the post-mitigation remaining uses do not exceed the aPAD for any population subgroup. The assessment also concluded that for pre- and post-mitigation uses, the chronic risk estimates did not exceed the cPAD.

1. Endpoints/Doses for Dietary Risk Assessment

Estimates for one-day, or acute, dietary exposure(s) are compared to an aPAD of 0.00011 mg/kg bw/d, based on a NOAEL of 0.11 mg/kg/d and an uncertainty factor of 1,000. The NOAEL was established in a one-year oral gavage study in rats which demonstrated plasma, RBC, and brain ChE inhibition and neuropathology at 0.53 mg/kg/d. Based on evidence of neuropathology in 3 submitted studies and literature reports (see FQPA Considerations) of sensitivity in young animals (triggering a requirement for a developmental neurotoxicity study), the FQPA safety factor of 10 has been retained and added to the UF of 100 used to account for intraspecies variability and interspecies extrapolation. Acute risk is expressed as a percentage of the aPAD.

Estimates for chronic exposure(s) are compared to a cPAD of 0.00002 mg/kg bw/d, based on a NOAEL of 0.02 mg/kg/d and an uncertainty factor of 1,000. The NOAEL was established in a 2-year rat feeding study which demonstrated RBC ChE inhibition, neuropathology, and systemic toxicity at 0.21 mg/kg/d. Based on evidence of neuropathology in 3 submitted studies and literature reports of sensitivity in young animals, the FQPA safety factor of 10 has been retained and added to the UF of 100 used to account for intraspecies variability and interspecies extrapolation. Risk is expressed as a percentage of the cPAD.

2. Usage Data

Dietary risk estimates were based, in part, on estimates of the percent usage of methyl parathion on each registered food commodity. BEAD estimated methyl parathion use (I. Yusuf and T. Kiely memo, 4/13/99) based on available pesticide survey usage data for the years 1987 through 1997. BEAD estimates were provided to HED as a weighted average, and as a maximum. To be consistent with HED guidance and to avoid underestimating exposure, this risk assessment assumed 1 % crop treated for any BEAD estimate less than 1% (including zero), and also used the estimated maximum percent crop treated (%CT) for each commodity for both the acute and chronic risk assessments. Percent crop treated estimates varied from less than 1% to a maximum of 39% for peaches (Attachments 10 and 11).

3. Residue Data Sources

Methyl parathion residue estimates in this assessment are based primarily on three data sources:

① field trial data, submitted by the registrant to support tolerances;

② USDA Pesticide Data Program (PDP) food sampling data; and

③ Food and Drug Administration (FDA) Surveillance Monitoring data.

The order of preference for the purpose of risk assessment is PDP data > FDA data > field trial data. PDP data are preferred over FDA data because of the statistical design of the PDP program specific for dietary risk assessment, and because the foods are prepared before analysis as they would typically be before consumption (peeling, washing). Methyl parathion commodities not sampled by the PDP program are assessed based on translation of data from PDP sampled commodities in the same crop group, FDA surveillance data, or field trial data. Field trial residue data are generally considered by HED as the upper-end of possible residue more suited to the requirements of tolerance setting than to the requirements of dietary risk assessment (when the most realistic estimate is desired).

When using crop field trial data in this assessment, all data were handled similarly except the data for cottonseed meal. Due to a low pre-harvest interval (PHI) for some special local needs (SLN) on cottonseed grown in Texas, the crop field trial studies were used for cottonseed meal and incorporated Texas %CT only for cotton grown in Texas, as well as the U.S. %CT for cotton grown in all other states, so as not to overestimate the risk (Attachments 10 and 11).

a. Acute exposure

Single Serving Commodities with PDP/FDA Detections: The PDP and FDA databases report detected residues as residues found in 5 lb. composite samples. This manner of reporting may not be representative of possible high-end residues that could be found if individual units of fruits and vegetables were analyzed. This assessment has used a statistical methodology for applying existing (composite) information to acute dietary risk assessments. This methodology consists of extrapolating data on pesticide residues in composite samples of fruits and vegetables to residue

levels in single servings of fruits and vegetables. Given the composite sample mean, the composite sample variance, the number of units in each composite sample, and assuming a log normal distribution, it is possible to *estimate* the mean and variance of the pesticide residues present on single servings of fruits and vegetables. These parameters can then be applied to generate information on the level of residue in fruits and vegetables (and calculate a theoretical distribution). This information can be incorporated into a probabilistic exposure estimation model, such as the Monte Carlo method. This methodology has a higher degree of accuracy when more than 30 composite samples have detectable residues. Commodities that are blended (such as juices) or are smaller than single unit servings (peas) were not decomposited since the measured PDP levels were assumed representative of the actual range of residue.

b. Chronic exposure

For chronic risk assessment, reported residues were averaged, whether based on PDP, FDA, or field trials. If a commodity had no reported detections by the PDP and FDA programs, and the expectation of no detection was confirmed by field trial data, the weighted average of the Limits of Detection (LOD) were used to account for possible exposure that could not be more precisely quantified (½ LOD methyl parathion + ½ LOD methyl paraoxon).

c. Methyl Paraoxon

This assessment assumes that methyl paraoxon is of equal toxicity as the parent methyl parathion and has accounted for the possibility of this metabolite occurring in treated foods. In general, field trial studies have included analysis for methyl paraoxon, as has FDA surveillance. The PDP program has not analyzed for methyl paraoxon. For the commodities that methyl paraoxon was detected in the field trial data, but not detected by FDA surveillance, paraoxon is accounted for by an assumption of ½ LOD. For commodities with no detection of methyl paraoxon in FDA or field trial data, the assumption was zero residue, and ½ LOD was not incorporated.

d. Processing Factors

Methyl parathion residues may be concentrated, or reduced, by the activities of drying (raisins etc.), processing (juice, catsup etc.), washing, peeling, and cooking. If methyl parathion was measured prior to any of these processes, the predicted effect of the process has been applied to the estimated final residue at consumption. This assessment used factors to account for various processing, but most significantly, for the effect of cooking. This assessment reduced all food-forms designated as boiled, or canned by a factor of 95% (0.05), which was established in a submitted canned snap bean study (MRID 44812901). Other processing factors, including DEEM™ default factors that were used in this assessment are listed in Attachment 12.

4. Consumption Data/DEEM™ Software

The DEEM™ Program: HED is currently using software developed by Novigen Sciences, Inc., named the *Dietary Exposure Evaluation Model*, or DEEM™, to calculate acute and chronic dietary risk estimates for the general U.S. population and various population subgroups. The food consumption data used in the program is taken from the *USDA Continuing Survey of Food Intake by Individuals* (CSFII). The Agency is currently using 1989-92 consumption data. Consumption data are averaged for the entire U.S. population, and within population subgroups such as "all infants" to support chronic risk assessment, but retained as individual consumption data points to support acute risk assessment (which is based on distributions of consumption estimates for either deterministic- or probabilistic-type exposure estimates). The DEEM software is capable of calculating probabilistic (Monte Carlo) type risk assessments when appropriate residue data (distributions of residue) are available.

For acute risk assessments, one-day consumption data are summed and a food consumption distribution is calculated for each population subgroup of interest. The consumption distribution can be multiplied by a residue point estimate for a deterministic (Tier I/II type) exposure/risk assessment, or used with a residue distribution in a probabilistic (Monte Carlo) type risk assessment.

For chronic risk assessments, residue estimates for foods (e.g. apples) or food-forms (apple juice) of interest are multiplied by the averaged consumption estimate of each food/food-form of each population subgroup. Exposure estimates are expressed in mg/kg bw/d and as a percent of the cPAD.

5. Dietary (Food) Risk Results

a. Acute Dietary Risk Before Mitigation Measures

Based on the acute dietary exposure analysis as described above and using an aPAD of 0.00011 mg/kg/d, acute dietary exposure to all population subgroups, pre-mitigation, exceeded the aPAD at the 99.9th exposure percentile. Children 1-6 years were identified as the most highly exposed population subgroup. Estimated acute dietary exposure to children 1-6 years exceeded the aPAD at the 99th and 95th exposure percentiles (See Table 3 following), but did not exceed the aPAD at the 90th exposure percentile. A complete listing of the acute dietary results are in attachment 6.

Several crops were identified as making substantial contributions to the dietary risk. Residues measured on these crops and the surveyed consumption of these crops, factored together, results in these crops taking up a substantial percentage of the "risk cup" and thereby, making substantial contributions to the risk. Theoretically, the risk cup is full when the aggregate risk (food + water + residential) $\geq$ 100% PAD. A number of crops had significant residues from PDP data **and** are high consumption items (e.g. peaches, apples). The acute substantial contributors have been identified as apples, cottonseed, peaches, grapes, and pears. For all the substantial contributors, except cottonseed oil, PDP and/or FDA monitoring data have shown measurable residues of methyl parathion, some greater than half the tolerance. The FDA monitoring data used for cottonseed oil showed no detectable residues; however, there were only two samples of oil analyzed. The Agency believes that residues are not likely to be found in cottonseed oil since there are no detectable residues found in cottonseed. Therefore, FDA monitoring data were used so as not to overestimate the potential risk from cottonseed oil.

The acute summary table below shows the acute dietary risks to the U.S. population, infants, and children from exposures to all the supported crops, pre-mitigation (See Attachment 6).

Table 3. Pre-mitigation Acute Dietary Risk Estimates

Population	(95th percentile)		(99th percentile)		(99.9th percentile)	
	Exposure	% aPAD	Exposure	% aPAD	Exposure	% aPAD
U.S. Population	0.000044 mg/kg/day	40	0.000121 mg/kg/day	110	0.000416 mg/kg/day	378
All Infants <1 year	0.000095 mg/kg/day	86	0.000169 mg/kg/day	153	0.000415 mg/kg/day	377
Children 1-6 years	0.000132 mg/kg/day	**120**	0.000273 mg/kg/day	**249**	0.000969 mg/kg/day	**881**
Children 7-12 years	0.000061 mg/kg/day	55	0.000129 mg/kg/day	117	0.000428 mg/kg/day	388

b. Chronic Dietary Risk Before Mitigation Measures

Based on the chronic pre-mitigation dietary exposure analysis as described above and using an cPAD of 0.00002 mg/kg/d, chronic dietary exposure to all population subgroups did **not** exceed the cPAD (See Table 4 following). Children 1-6 years were identified as the most highly exposed population subgroup. The chronic summary table below shows the chronic dietary risks to the U.S. population, infants, and children from exposures to all the supported crops, pre-mitigation, for which methyl parathion is registered (Attachment 7). The chronic substantial contributors have been identified as apples, peaches, grapes, cottonseed oil, and pears. For all the substantial contributors, except cottonseed oil, PDP and/or FDA monitoring data have shown measurable residues of methyl parathion. The FDA monitoring data used for cottonseed oil showed no detectable residues; however, there were only two samples of oil analyzed.; however, there are not sufficient USDA/FDA monitoring data reported for residues of methyl parathion in/on cottonseed oil. Since monitoring data showed significant residues on cottonseed meal (feed use), the Agency believed it likely that residues could be found in cottonseed oil. Therefore, field trial data were used so as not to underestimate the potential risk. The crop field trial studies were used for cottonseed oil incorporating Texas %CT for cotton grown in TX, and U.S. %CT for cotton grown in all other states (Attachment 7).

Table 4. Pre-mitigation Chronic Dietary Risk Estimates

Population	Exposure (mg/kg/day)	% Chronic PAD
U.S. Population	0.000003	17
All Infants (<1 year)	0.000006	29
Children 1-6 years	**0.000009**	**47**
Children 7-12 years	0.000005	22

6. Dietary Risk Reflecting Mitigation Measures

a. Recent Use Changes - Remaining Uses

The uses for methyl parathion reflecting mitigation measures include almonds, barley, dried beans, cabbage, canola oil (rape seed oil), field corn, sweet corn, cottonseed, lentils, oats, onions, peanuts, dried peas, pecans, potatoes, rice, rye, soybeans, sugar beets, sunflowers, sweet potatoes, walnuts, and wheat.

b. Acute Dietary Risk Reflecting Mitigation Measures

Based on the acute dietary exposure analysis as described above and using an aPAD of 0.00011 mg/kg/d, acute dietary exposure to all population subgroups, acute dietary risks reflecting mitigation measures, do not exceed the aPAD at the 99.9th exposure percentile (Table 5). A complete listing of the acute dietary risk calculation results are in attachment 8.

Table 5. Post-mitigation Acute Dietary Risk Estimates

Population	(95th percentile)		(99th percentile)		(99.9th percentile)	
	Exposure	% aPAD	Exposure	% aPAD	Exposure	% aPAD
U.S. Population	0.000027 mg/kg/day	24	0.000042 mg/kg/day	38	0.000068 mg/kg/day	60
All Infants <1 year	0.000033 mg/kg/day	30	0.000051 mg/kg/day	47	0.000067 mg/kg/day	61
Children 1-6 years	0.000043 mg/kg/day	**39**	0.000056 mg/kg/day	**50**	0.000086 mg/kg/day	**78**
Children 7-12 years	0.000032 mg/kg/day	29	0.000042 mg/kg/day	38	0.000087 mg/kg/day	78

c. Chronic Dietary Risk Reflecting Mitigation Measures

Based on the chronic dietary exposure analysis reflecting mitigation measures and using a cPAD of 0.00002 mg/kg/d, chronic dietary risk to all population subgroups does **not** exceed the cPAD (See Table 6 following). A complete listing of the chronic dietary risk calculation results are in attachment 9.

Table 6. Post-mitigation Chronic Dietary Risk Estimates

Population	Exposure (mg/kg/day)	% Chronic PAD
U.S. Population	0.000001	3
All Infants (<1 year)	0.000001	3
Children 1-6 years	**0.000002**	**8**
Children 7-12 years	0.000001	5

7. Conclusions

Apples, peaches, grapes, and pears were found to be substantial contributors to both the acute and chronic dietary risk based on PDP detects and high consumption. Decomposited PDP data were used for the residue distribution file for peach residues. The decomposited data were truncated to eliminate the highest 25 residues and no substantial effect on the exposure was found indicating that the high residues obtained as a result of decompositing are minimally reflected in the overall exposure.

The mitigation measures **remove many of the substantial contributors**, particularly commodities consumed by children, and greatly lower the potential dietary exposures to both adults and children.

B. Drinking Water Risk

1. Acute Drinking Water Risk Per Pre-mitigation Measures

Generally, the Agency calculates Drinking Water Levels of Comparison (DWLOC) for comparison to measured or modeled drinking water concentrations for the risk analysis. The DWLOC is the concentration in drinking water, as part of the aggregate exposure, that occupies no more than 100% of the PAD. The dietary exposure and DWLOC together, cannot be greater than 100% of the PAD. Any measured or modeled drinking water estimates that are less than the DWLOC are not of concern.

Acute exposures from methyl parathion in drinking water may add to the dietary risk. The DWLOC for acute exposure was calculated to be zero since the acute exposure from food alone on all registered use sites is > 100% of the aPAD.

2. Chronic Drinking Water Risk from Surface Water Per Pre-mitigation Measures

Non-targeted surface water survey studies performed over the past 30 years have not shown concentrations of methyl parathion at levels predicted in the chronic modeling assessments (4.2 ppb). The average reported value from the Louisiana composites of intake water is 0.009 ppb. A chronic DWLOC ($DWLOC_{chronic}$) was calculated using the following formulae:

$$DWLOC_{chronic}\ (\mu g/L) = \frac{\text{chronic water exposure (mg/kg/d) x body weight (kg)}}{\text{consumption (L/d) x } 10^{-3}\ mg/\mu g}$$

chronic water exposure (mg/kg/d) = [cPAD - chronic food (mg/kg/d)]

The current Agency default body weight and consumption values are 10 kg and 1 liter/day, respectively, for all infants and children, 70 kg and 2 liters/day for adult males, and 60 kg and 2 liters/day for adult females. These default values and others are presently under review in the Agency. If at a future time the Agency decides to change the default assumptions used, the impact of the changes on the methyl parathion risk assessment will be considered.

Table 7. Chronic Surface Water

Population	Monitoring Data (ug/L)	cPAD (mg/kg/d)	Chronic Food Exposure (mg/kg/d)	Chronic H_2O Exposure (mg/kg/d)	$DWLOC_{chronic}$ (ug/L)
Adult Male	0.009	0.00002	0.000002	0.000018	0.63
Adult Female	0.009	0.00002	0.000005	0.000015	0.45
Infants <1 yr	0.009	0.00002	0.000006	0.000014	0.14
Children 1-6	0.009	0.00002	0.000009	0.000011	0.11

Concentrations from available monitoring studies were well below the OW's 2 ppb HA. Although the available chronic monitoring data do not allow a comprehensive assessment, EFED believes that chronic concentrations of methyl parathion in surface water will be below the 2 ppb HA. The table above shows the limited monitoring concentration of 0.009 ppb does not exceed the $DWLOC_{chronic}$. As mentioned earlier, these data do not represent concentrations after drinking water treatment and may actually be lower.

3. Chronic Drinking Water Risk from Ground Water Per Pre-mitigation Measures

It is uncertain whether chronic exposures from ground water would pose a risk concern without any targeted monitoring studies. No model exists for specifically estimating chronic ground water concentrations. Therefore, a highly conservative modeled ground water concentration of 0.6 ppb (from the acute model) is the default concentration. However, EFED believes it is very unlikely that chronic exposures would be as high as 0.6 ppb. The $DWLOCs_{chronic}$ are the same as for surface water concentrations.

4. Drinking Water Risks Reflecting Use Mitigation Measures

Based on use changes reflecting mitigation measures, the acute and chronic exposures to methyl parathion in food have been reduced. The Agency recalculated the DWLOCs for chronic risk analysis to reflect these changes. Since the acute exposures from food no longer exceed the aPAD, $DWLOCs_{acute}$ were also calculated.

Surface water monitoring data range between 6 ppb from methyl parathion applications to rice fields in California to 0.42 ppb from applications to cotton in Mississippi. After the monitoring data were recorded in California, the state instituted a number of its own mitigation

measures to reduce contamination of surface waters and therefore, present-day concentrations would be expected to be lower. As a result, EFED has more confidence in the surface water concentrations from Mississippi (0.42 ppb) and it should be noted that cotton has the highest application rate for methyl parathion than any other remaining uses.

Table 8. Acute Surface Water Reflecting Use Mitigation Measures

Population	Monitoring Data (ug/L)	aPAD (mg/kg/d)	Acute Food Exposure (mg/kg/d)	Acute H_2O Exposure (mg/kg/d)	$DWLOC_{acute}$ (ug/L)
Adult Male	0.42	0.00011	0.000067	0.000043	1.51
Adult Female	0.42	0.00011	0.000075	0.000035	1.05
Infants <1 yr	0.42	0.00011	0.000067	0.000043	0.43
Children 1-6	0.42	0.00011	0.000087	0.000023	0.23

Though comparisons between the untreated surface water monitoring data and the $DWLOC_{acute}$ for children 1-6 years of age raise some concerns, it is uncertain what the actual "at the tap" drinking water residues would be after dilution from the source to the tap and after treatment. Since these Mississippi monitoring data come from come from a high use region (cotton has the highest application rate), the Agency believes that they are somewhat conservative though recognizably limited.

Table 9. Chronic Surface Water Reflecting Use Mitigation Measures

Population	Monitoring Data (ug/L)	aPAD (mg/kg/d)	Acute Food Exposure (mg/kg/d)	Acute H_2O Exposure (mg/kg/d)	$DWLOC_{chronic}$ (ug/L)
Adult Male	0.009	0.00002	0.000001	0.000019	0.67
Adult Female	0.009	0.00002	0.000001	0.000019	0.57
Infants <1 yr	0.009	0.00002	0.000001	0.000019	0.19
Children 1-6	0.009	0.00002	0.000002	0.000018	0.18

Based on the limited chronic drinking water data, potential residues of methyl parathion in water are not of concern. The chronic monitoring data were collected closer to the tap (drinking water intake) over a period of a year from a high use area and therefore, are approaching what may be actual residues in "at the tap" drinking water.

It is uncertain whether exposures from ground water would pose a

risk concern without any targeted monitoring studies. The highly conservative modeled ground water concentration of 0.6 ppb from the acute model is the estimated concentration for both the acute and chronic ground water drinking water estimates. However, EFED believes it is very unlikely that any ground water exposures would be as high as 0.6 ppb, based on fate information. The $DWLOCs_{acute}$ and $DWLOCs_{chronic}$ are the same as for surface water concentrations.

5. Considerations

There are several things to consider when weighing the potential contribution to the total dietary risk from drinking water contaminated with methyl parathion. The limited monitoring data available to the Agency indicate that exposures would be expected to be lower than the modeled estimates. In addition, neither the models nor the monitoring data reflect concentrations after dilution (from source to treatment to tap) or drinking water treatment. Methyl parathion is a compound that can be absorbed onto activated carbon as a water treatment method. However, Granulated Activated Carbon (GAC) is not a commonly used technology, and it is expensive to install and maintain. Less than 1% of the 55,000 community water treatment systems in the United States use GAC filters. A community water treatment system is defined as serving more than 25 people or having 15 or more service connections. GAC is most often used to remove pesticides, to control odor, and taste problems. There are currently little data on the efficacy of other more common treatment technologies in removing methyl parathion.

When the available monitoring data were gathered, methyl parathion was measured, but they did not look for methyl paraoxon. EFED does not have any data available with which to predict the rate of formation, or the half-life of, methyl paraoxon. Though there are data to show that another organophosphate, malathion, degrades to its oxon metabolite during drinking water treatment, it is unknown if methyl parathion would behave in a similar manner.

Given the fact that the monitoring data represent only a very small range of conditions (regional weather, streamflow, application rates and methods), it cannot be assumed that they represent surface water concentrations or conditions elsewhere in the United States, and the Agency still does not have any ground water monitoring data. The data collected closest to the tap (treatment plant intake) in Louisiana do not indicate exposures that would be of concern. Though the Agency considers it unlikely that drinking water concentrations "at the tap," will

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make the largest, or a significant, contribution to the total dietary burden, there is sufficient information from available monitoring data and models to warrant close monitoring of potential surface and ground water sources of methyl parathion exposure.

C. Occupational/Residential Risk

1. Combined Dermal and Inhalation Risk from Handler Exposures

While the MOEs for the pre mitigation uses and the post mitigation uses vary, the scenarios that pose a risk of concern are the same for both. Dermal and inhalation exposures were combined and risk was calculated for each exposure scenario using the short- and intermediate-term dermal and inhalation NOAEL of 0.11 mg/kg/day and 100% dermal absorption and inhalation absorption. An MOE $\geq$ 100 is needed for the risk to be acceptable. Overall, there is moderate to high confidence in the PHED data from which the occupational exposures used in the assessment were derived. See Tables 2-4 in Attachment 14 for details. The calculations of risk based on combined dermal and inhalation exposure indicate that the MOEs are less than 100 even with maximum risk reduction measures (inside the cab of a truck) for all of the short and intermediate term scenarios listed except for the flagging at the lowest application rates.

- Flagging aerial spray applications with engineering controls for the EC formulation at the 0.375 lbs ai/A application rate (MOE = 260).

- Flagging aerial spray applications with engineering controls for the Mcap formulation at the 0.5 lbs ai/A application rate (MOE = 190).

One of the registrants has stated that they are not supporting the use of human flaggers. However, HED has included the risk to flaggers in this assessment because some current labels allow the use of flaggers.

2. Postapplication Risk

a. Microencapsulated Formulation

The surrogate postapplication assessment for pre mitigation uses indicates that following applications of methyl parathion to grapes at 1.5 lbs ai/A and 3.0 lbs ai/A workers cannot reenter the fields for 30 and 33 days, respectively, without being exposed to levels of methyl parathion that would result in MOEs of less than

100:

- ❑ MOEs $\geq$ 100 for grapes at the registrant suggested application rate of 1.5 lbs ai/A with a dermal transfer of 15,000 cm^2/hr at the **30th day following application**.

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- ❑ MOEs ≥ 100 for grapes at the current label application rate of 3.0 lbs ai/A with a dermal transfer of 15,000 cm^2/hr at the **33rd day following application**.

- ❑ MOEs ≥ 100 for tree crops such as pears, apples, and peaches with a dermal transfer of 10,000 cm^2/hr at the **30th day following application** (2.0 lbs ai/A).

The surrogate postapplication assessment for the post mitigation uses indicates that:

- ❑ MOEs ≥ 100 for nut crops including pecans, almonds and walnuts with a dermal transfer of 10,000 cm^2/hr at the **30th day following application**.

b. Emulsifiable Concentrate Formulation

The post application assessment for the emulsifiable concentrate formulation is the same for the pre mitigation uses and the post mitigation uses. The surrogate postapplication assessment indicates that:

- ❑ MOEs ≥ 100 for cotton - early season, with a dermal transfer of 1,000 cm^2/hr on the **7th day after application** (3.0 lbs ai/A).

- ❑ MOEs ≥ 100 for cotton - late season, with a dermal transfer of 4,000 cm^2/hr on the **9th day after application** (3.0 lbs ai/A).

3. Residential Risk

Risk estimates of residential dermal and inhalation exposures were not estimated. The Agency is currently developing methods to assess residential risks, and these risks will be assessed in the future when these new methods are available. However, based on available information, HED remains concerned about residential risks from methyl parathion spray drift.

D. Aggregate Risk

Under the Food Quality Protection Act, the Agency considers contributions to risk from various exposure sources, specifically, food, drinking water, and residential. Methyl parathion has no registered residential uses, therefore only exposures through food and drinking water were considered in the aggregate risk assessment.

The potential for other non-occupational exposures to individuals living in or near agricultural areas where methyl parathion is being used were not included in the aggregate risk assessment but will be addressed at a later time when methodologies to perform such assessments are in place.

The acute aggregate risk estimate for all registered uses, pre-mitigation, indicated that there is no room for exposure to methyl parathion in drinking water because risk from food sources alone exceed the Agency's level of concern (i.e. > 100% acute PAD). The acute aggregate risk estimate which reflects mitigation measures may still be of concern. Though acute exposure to methyl parathion from food sources alone, with mitigation measures, does not exceed the Agency's level of concern (i.e. < 100% acute PAD), limited surface water monitoring data indicate potential exposures at unacceptable levels. However, as discussed earlier, the monitoring data are not nationally representative, do not represent dilution from the source to the tap, and do not reflect water treatment. Without actual drinking water monitoring data, it is difficult to draw any conclusions about actual residues in drinking water.

The chronic aggregate risk assessment is not of concern, pre- or post-mitigation measures. In particular, chronic exposures reflecting mitigation measures to methyl parathion from food sources alone are well below the Agency's level of concern (i.e. < 100% chronic PAD). Limited drinking water monitoring data indicate drinking water exposures may be very low. In addition, fate data show that methyl parathion is not persistent.

E. Cumulative Risk

The Agency is in the process of formulating guidance for conducting cumulative risk assessment. When the guidance is completed, peer reviewed, and finalized, methyl parathion and other organophosphates will be revisited to assess the cumulative effects of exposure to multiple organophosphates.

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IV. Data Needs

A. Developmental Neurotoxicity Study

A Developmental Neurotoxicity Study is required.

B. Tolerance Reassessment Data

Data needs for the tolerance reassessment and dietary risk assessment are summarized as follows:

1. Plant and Animal Metabolism Data

Pending acceptance of recently submitted lettuce metabolism data, and additional goat and hen metabolism data, which are under review, no additional plant and animal metabolism data will be required to support the reregistration of methyl parathion. The registrant should resubmit the goat and hen metabolism data cited above through the MRID process.

The Agency continues to recommend that future plant and animal magnitude of the residue studies include data depicting residues of *p*-nitrophenol resulting from the use of methyl parathion.

2. Analytical Methods - Plant and Animal

Since the proposed enforcement method(s) is/are the FDA multiresidue testing protocol(s), an independent laboratory validation (ILV) is not required.

In conjunction with the ruminant and poultry feeding studies, the registrants must provide data validating the analytical method(s) used for determining methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl in meat, milk, poultry, and eggs. If the feeding studies indicate that tolerances are necessary for residues in animal commodities, then the registrants must propose an enforcement method for determining the residues of concern in animal commodities which must be regulated.

3. Storage Stability Data

HED acknowledges receipt of the new storage stability data on plants submitted in support of the reregistration of methyl parathion (Attachment 4). These data are under review and pending acceptance of these new data to satisfy guideline requirements, no additional storage stability data on plant commodities will be required to support the

reregistration of methyl parathion.

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Data depicting the storage stability of methyl parathion residues of concern in animal commodities are required in conjunction with the ruminant and poultry feeding.

4. Magnitude of the Residue Data - Plant Commodities

HED acknowledges receipt of new residue chemistry data submitted in support of the reregistration of methyl parathion (Attachment 4), which are under review and which have been used in the residue chemistry science assessments and dietary risk assessment analyzes for methyl parathion as the Agency deems appropriate.

HED understands that Cheminova has committed to generate alfalfa field trial data (Received 05/99), grass field trial data (Received 05/99), cotton gin by-product magnitude of the residue data, and sunflower seed processing data in support of the registration of the EC formulation of methyl parathion.

HED understands that Elf Atochem has committed to generate potato field trial data, onion field trial data, soybean field trial data, plum field trial data, cotton gin by-product magnitude of the residue data, and plum processing data in support of the reregistration of the Mcap formulation of methyl parathion. Potato data will be translated to support the use of the Mcap formulation of methyl parathion on sweet potatoes and yams.

Additional residue chemistry data are required to support the reregistration of methyl parathion which the registrants (Cheminova and Elf Atochem) have not committed to generate. Additional sugar beet top, turnip top, wheat forage, and wheat hay magnitude of the residue data are required to support the reregistration of the EC formulation of methyl parathion. Additional pear field trial data and rice straw magnitude of the residue data are required to support the reregistration of the Mcap formulation of methyl parathion.

5. Magnitude of the Residue Data - Animal Commodities

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs remain outstanding. No tolerances have been established for residues of methyl parathion in animal commodities, although tolerances have been established on numerous animal feed items. HED understands that the registrants have committed to generate these data.

C. Occupational Handler Exposure/Risk Data

The occupational handler risks for all but one exposure scenario are of concern. Specific exposure studies and data needs will be addressed after risk/risk mitigation concerns are addressed.

D. Occupational Post-application Exposure/Risk Data

The occupational post-application risks for the EC and Mcap formulations are of concern. Specific post-application exposure studies and data needs will be addressed after risk/risk mitigation concerns are addressed.

E. Dioxin Data

Product analyzes for dioxins at LOQ = 0.1 ppb as requested by 6/87 DCI.

V. List of Attachments

1 - Methyl Parathion (O,O-dimethyl O-p-nitrophenyl phosphorothioate): Hazard Identification Committee Report (George Ghali, December 1, 1997)

2 - Methyl Parathion - Re-evaluation of Dietary Endpoint and Non-dietary Endpoint Selection and Dermal Absorption Factor; Report of the Hazard Identification Assessment Review Committee (Kathleen Raffaele, March 23, 1999)

3 - Revised Toxicology Chapter (Kathleen Raffaele, 06/01/99)

4 - Revised Residue Chemistry Chapter for the Methyl Parathion Reregistration Eligibility Decision (RED) Document (Bonnie Cropp-Kohlligian, 05/12/99)

5 - Methyl Parathion (053501). The Outcome of the HED Metabolism Assessment Review Committee Meeting Held on March 11, 1998 (Bonnie Cropp-Kohlligian, May 21, 1998)

6 - Pre-mitigation Acute Dietary Monte Carlo Assessment

7 - Pre-mitigation Chronic Dietary Assessment

8 - Post-mitigation Acute Dietary Monte Carlo Assessment

9- Post-mitigation Chronic Dietary Assessment

10- Raw Data Table

11- Anticipated Residue Determination for Acute Dietary Assessment

12 - DEEM memo

13 - Residue Data Files

14 - Revised Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Methyl Parathion (Jonathan Becker and Renee Sandvig, 07/30/99)

15 - Review of Methyl Parathion Incident Reports (Jerome Blondell and Monica Spann, February 5, 1998)

16 - Revised Product Chemistry Chapter for the Methyl Parathion Reregistration Eligibility Decision (RED) Document (Ken Dockter, 05/25/99).

Attachment 1: Hazard Identification Committee Report

DATE STAMPED: 12/01/97
HED Doc. No.: 012406

MEMORANDUM:

SUBJECT: **Methyl Parathion** (O,O-dimethyl O-p-nitrophenyl phosphorothioate: Hazard Identification Committee Report.

CASRN: 298-00-0
PC Code: 053501
Caswell: 372

FROM: George Z. Ghali, PhD.
Executive Secretary, Hazard Identification Committee
Health Effects Division (7509C)

Thru: Clark Swentzel
Chairman, Hazard Identification Committee
Health Effects Division (7509C)

Michael Metzger
Co-Chair, Hazard Identification Committee
Health Effects Division (7509C)

To: Tina Levine, PM 4
Insecticide-Rodenticide Branch
Registration Division (7505C)

The Health Effects Division-Hazard Identification Committee met on September 25, 1997 to evaluate the existing and/or recently submitted toxicology data in support of methyl parathion re-registration, identify toxicological endpoints and dose levels of concern appropriate for use in risk assessments for different exposure routes and duration, and assess/reassess the reference dose for this chemical.

Material available for review consisted of data evaluation records (DERs) for combined chronic toxicity-carcinogenicity studies in rats **(83-5)**, chronic toxicity studies in dogs **(83-1b)**, a carcinogenicity study in mice **(83-2b)**, a reproductive toxicity study in rats **(83-4)**, developmental toxicity studies in rats and rabbits **(83-3a and -3b)**, subchronic studies in rodents and non-rodent species **(82-1a and 82-1b)**, a 21-day dermal toxicity study in rabbits **(82-2)**, acute and subchronic oral neurotoxicity study in rats **(81-8ss and 82-)**, acute inhalation toxicity studies in rats **(81-3)**, and a battery of

mutagenicity studies **(84-2)**.

INDIVIDUALS IN ATTENDANCE

Hazard Identification Committee members present were David Anderson, Karl Baetcke (Senior Science Advisor, HED), William Burnam (Chief, SAB, HED), George Ghali (Executive Secretary, Hazard Identification Committee, HED), Susan Makris, Nancy McCarroll, Kathleen Raffaele, John Redden, Jess Rowland, Clark Swentzel (Chairman, Hazard Identification Committee, HED).

Others in attendance were William Sette, Diana Locke, Emily Mitchel, William Dykstra, Stephen Dapson and Steven Knizner as observers.

Scientific reviewer(s) (Committee or non-committee member(s) responsible for data presentation; signature(s) indicate technical accuracy of panel report and concurrence with the hazard identification assessment review unless otherwise stated.

Kathleen Raffaele _____

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IV. REFERENCES

I. TOXICOLOGY PROFILE:

A. Carcinogenicity:

Three carcinogenicity studies were considered by the committee; two studies in rats and one in mice. One of the two rat studies and the mouse study showed no evidence of increases in tumors. The second rat study showed slight, but not statistically significant, increases in C-cell adenomas in the thyroid, and slight increases in pituitary adenoma, significant in females only. The incidence of pituitary adenomas in females was found to be at the upper end of the historical control range. The Committee concluded, based on the results of statistical analysis, and comparison with historical control data, that these apparent increases were not biologically significant, and do not support a finding that methyl parathion is carcinogenic.

Based on the toxicology data available, the Hazard Identification Committee determined that methyl-parathion did not alter the spontaneous tumor profile in rats and mice under the testing conditions. Therefore, it was recommended that methyl-parathion be classified as a **"Group E"**, indicating evidence of non-carcinogenicity for humans; i.e., the chemical is characterized as **"Not Likely"** to be carcinogenic in humans via relevant routes of exposure. This weight of the evidence judgement is largely based on the absence of significant tumor increases in two adequate carcinogenicity studies in rats (MRID No: 252501-252503) and mice (MRID No. 42216401, 00127239).

This classification is also supported by the lack of mutagenic activity (MRID Nos. 00132949, 00124901, 00124901).

It should be noted, however, that designation of an agent as being in **"Group E"** or **"Not Likely"** is based on the available evidence and should not be interpreted as a definitive conclusion that the agent will not be a carcinogen under any circumstances.

B. Reproductive and Developmental Toxicity:

The following evaluation of the chemical methyl parathion is provided to address FQPA considerations on the sensitivity of infants and children.

1. Reproductive Toxicity:

A two-generation reproduction study was conducted with Sprague-Dawley rats (15 males and 30 females/group) (MRID 00119087; Doc. 005095, 005588) in which methyl parathion (93.65%) was administered in the diet at levels of 0.5, 5, or 25 ppm (0.04, 0.38, or 2.0 mg/kg/day for males and 0.04, 0.44, or 2.3 mg/kg/day for females). The parental (systemic) NOEL was 5 ppm (0.44 mg/kg/day), and the parental LOEL

was 25 ppm (2.3 mg/kg/day), based on decreased premating body weight for F1 females and decreased maternal body weight during lactation in females of both generations. No parental reproductive toxicity was observed at any dose level; however, the offspring/developmental NOEL was 5 ppm (0.44 mg/kg/day), based upon decreased pup survival in early lactation and on decreased body weight gain and increased food consumption in the period immediately following weaning. The developmental LOEL was 25 ppm (2.3 mg/kg/day). It was noted that cholinesterase activity was not measured in either adults or offspring in this study.

2. Developmental Toxicity:

In a prenatal developmental toxicity study in Wistar rats (MRID 41136101; Doc. 008118, 009526), doses of 0.3, 1.0, or 3.0 mg/kg/day methyl parathion (97%) were administered by gavage in a dose volume of 10 ml/kg of 0.5% aqueous Cremophor on gestation days 6-15. Each group consisted of 25 rats; 10 additional rats each were assigned to the control and high-dose groups for maternal cholinesterase measurements. Cesarean section was performed on gestation day 21. The maternal NOEL was 1.0 mg/kg/day, with a maternal LOEL of 3.0 mg/kg/day, based upon increased mortality; adverse clinical signs (somnolence, ataxia, dyspnea, ventral recumbency, and repeated chewing behavior); decreased body weight, body weight gain, and food consumption; and decreased plasma, erythrocyte, and brain cholinesterase activity. The developmental NOEL was also 1.0 mg/kg/day; the developmental LOEL (3.0 mg/kg/day) was based on increased postimplantation loss (early resorptions), decreased fetal body weight, and increased incidence of delayed ossification (3rd cervical vertebra, proximal phalanx of the 2nd right digit, and 1st metatarsal of both hindlimbs).

In a prenatal developmental toxicity study conducted in Himalayan rabbits (15/group) (MRID 259403, 259404, 259405; Doc. 004997, 007614), methyl parathion (95.7%) was administered by gavage in 0.5% aqueous Cremophor at dose levels of 0.3, 1.0, or 3.0 mg/kg/day on days 6-18 of gestation. These dose levels were based upon a previously conducted study with rabbits (MRID 41046101) in which plasma and erythrocyte cholinesterase inhibition was observed at a dose of 3.0 mg/kg/day, and for that reason they were considered adequate, although cholinesterase activity was not measured in this study. No evidence of either maternal or developmental toxicity was observed (NOEL $\geq$3.0 mg/kg/day).

3. Literature Information:

Although these studies were not submitted to the Agency by the Registrant in support of registration or reregistration, they can be considered in weight-of-the-evidence determinations for methyl parathion.

a. Effects on gestation and morphological development following *in utero* exposure:

In a study by Fuchs et al. (1975), methyl parathion (3 ppm) was administered in the diet to Wistar rats on gestation days (5-9 and 11-15) or (5-9 and 11-19). Growth retardation and increased incidence of resorptions were noted in the treated group, although malformations were not observed.

In a study by Sunil Kamar and Devi (1996), pregnant inbred Wistar rats (10/group) were administered methyl parathion (98% a.i.) on gestation days 6 through 15 at gavage doses of 0.5, 1, and 1.5 mg/kg/day. The dams were killed on gestation day 20 and fetuses were examined for external and visceral anomalies. At 1.5 mg/kg/day, there was a significant decrease in maternal body weight gain during gestation; at the same dose, an increase in resorptions and a decrease in fetal and placental weight were observed. There was no increase in skeletal or viscera abnormalities; however, a significant increase in the incidence of "hemorrhagic spots" in the brain (ventricles) and upper body were observed in pups from dams treated with 1.5 mg/kg/day methyl parathion.

b. Assessment of postnatal functional toxicity following prenatal exposure:

In a study by Gupta et al. (1984), male Fischer 344 rats were mated to Wistar-Furth females. The dams were administered 1.0 mg/kg/day of methyl parathion in peanut butter (0.1 g/25 g body weight) as a dietary dose consumed in <2 minutes, or 1.5 mg/kg/day of methyl parathion by gavage in peanut oil (at a volume of 0.1 ml/50g body weight). Treatment was administered daily from gestation day 6 through 20. The dams were allowed to litter normally, and pups were placed with foster mothers within 24 hours of birth. Pups and dams were killed at intervals (postnatal days 1, 7, 14, 21, and 28 for pups, and at gestation day 19 for dams). Their brains were removed, weighed, dissected, and processed for analysis of acetylcholinesterase (Ache) and choline acetyltransferase (CAT) activity and of [^{3}H]quinuclididinyl benzilate (^{3}H-QNB) binding to muscarinic receptors. Frontal cortex and brainstem were collected on postnatal days 1 and 7, while striatum and hippocampus were also obtained on postnatal days 14, 21, and 28. Tissues from two pups per litter were pooled, and the litter was used as the unit of analysis. Behavioral evaluation of the pups was performed: preweaning reflexive behaviors (postnatal days 1-25); startle response (days 1-25 and 4 months); passive avoidance, rotarod performance, and accommodated locomotor activity (2 months); cage emergence (3 months); shuttle box avoidance (4 months); and operant behavior (3-6 months). Morphological analysis of the cornuammonis in the hippocampus and of the cerebellar culmen was performed in 4 control and 4 high-dose pups at 28 days of age.

The following treatment-related effects were noted: At 1.5 mg/kg/day, clinical signs of toxicity included muscle fasciculations and tremors, decreased maternal body weight gain and increased late resorptions. On postnatal day 1, litter size, body weight, and pup brain weight were similar between control and treated groups. Prenatal exposure to 1.5 mg/kg/day reduced Ache and increased CAT activity in all brain regions at each developmental period and in maternal brain. Similar exposure to 1.0 mg/kg/day caused a significant but smaller and less persistent reduction in Ache activity but no change in brain CAT activity of the offspring. Both dose levels decreased the B_{max} of ^{3}H-QNB binding in maternal frontal cortex but did not alter the postnatal pattern of ^{3}H-QNB binding. Cage emergence, accommodated locomotor activity, and operant behavior in a mixed paradigm were impaired in rats exposed to 1.0 but not to 1.5 mg/kg/day. The study authors concluded that "subchronic prenatal exposure to methyl parathion altered postnatal development of cholinergic neurons and caused subtle alterations in selected behaviors of the offspring."

c. Comparison of the neurotoxic response of adults and neonatal or weanling animals:

In a study by Benke and Murphy (1974), the effects of methyl parathion and methyl paraoxon were studied in male and female Holtzman rats ranging in age as follows: 1, 12-13, 23-24, 35-40, and 56-63 days of age. The test substances were administered by i.p. injection in corn oil at a volume of 1 ml/kg over a range of doses. It was found that there was a gradual decrease in susceptibility to methyl parathion with increasing age for both sexes as measured by the value of the LD50. For methyl parathion, the LD50 ranges from 1 mg/kg at postnatal day 1 to 6-8 mg/kg on postnatal day 56-63. Age differences in susceptibility were not related to differences in sensitivity of cholinesterase to inhibition by methyl paraoxon *in vitro*. LD50 values were calculated for the different ages; in general, changes in LD50 values with age for methyl parathion correlated better with changes in rates of reactions which represented detoxification pathways for methyl paraoxon than for reactions which represented direct metabolism of the parent compound. Both male and female rats became less sensitive to the acute lethal effects of methyl paraoxon with increasing age. This is consistent with a hypothesis that changes in LD50 values of methyl parathion with age are due to changes in rates of metabolism of the oxygen analogs.

In a study by Pope et al. (1991), the time course of cholinesterase inhibition and recovery in whole brain was compared between neonatal (postnatal day 7) and adult (80-100 days of age) Sprague-Dawley rats after acute treatment (by subcutaneous injection) with maximum tolerated doses of methyl parathion and other organophosphate pesticides (chlorpyrifos and parathion). The neonates were more sensitive clinically than adults to chlorpyrifos exposure: the MTD for neonates was 7.8 mg/kg s.c., while for adults the MTD was 18 mg/kg s.c. In general, maximal brain ChE inhibition was similar (>78%) in both age groups, but ChE activity recovered faster in

neonates. Plasma and RBC ChE activities correlated relatively well with brain ChE activity in neonatal rats at all time points between 4 hours and 7 days posttreatment, but similar correlations between circulating and brain ChE activities in adults were more variable. The study authors concluded that neonatal rats are more sensitive to acute lethality from methyl parathion (and other OP) exposure than are adults, and that MTD exposures produced extensive brain ChE inhibition in both age groups. Following OP exposures, however, significant compound-related and age-related differences in the duration of ChE inhibition can occur.

In a study by Pope and Chakraborti (1992), dose-related inhibition of both brain and plasma cholinesterase activity was examined in neonatal and adult rats exposed to methyl parathion and other organophosphate pesticides (chlorpyrifos and parathion) by subcutaneous injection in corn oil at 1-2 ml/kg. It was found that ED_{50} estimates for both brain and plasma cholinesterase correlated highly with previously derived MTD values. The correlation between the extent of brain and plasma cholinesterase inhibition across dose in neonatal rats was high but lower in adults. The study authors concluded that in vivo inhibitory potency, towards either brain or plasma ChE activity, of methyl parathion and the other organophosphate pesticides tested, is highly correlated with sensitivity to acute toxicity in both neonatal and adult rats.

4. Developmental Neurotoxicity:

There was no developmental neurotoxicity study available for review by the Committee. The Committee determined that a developmental neurotoxicity study should be required for methyl parathion. It was further recommended that the protocol should include comparative measurements of cholinesterase inhibition in adults and offspring. The weight-of-evidence used in arriving at this conclusion is presented below:

a. Evidence that support requiring a developmental neurotoxicity study:

Methyl parathion is a neurotoxic chemical (methyl parathion is an organophosphate compound, administration of methyl parathion to various species including rat, mouse, dog, and rabbit results in plasma, RBCs, and brain cholinesterase inhibition sometimes accompanied by cholinergic symptoms (e.g., lacrimation, salivation, miosis, tremors, convulsions, muscle fasciculation, muscle weakness, ataxia) as observed in rats in an acute neurotoxicity study at a gavage dose of 7.5 mg/kg and other cholinergic symptoms (e.g., tremors, slow pupillary constriction, and decreased hindlimb grip strength were observed at 50 ppm (3.02/3.96 mg/kg/day in M/F) in the subchronic neurotoxicity study.

Neuropathological findings observed in the acute neurotoxicity study in rats (at 7.5 mg/kg) included focal demyelination of the dorsal and ventral root fibers of the

cervical and lumbar spinal cord and focal demyelination of the sural and tibial nerves. In the subchronic neurotoxicity study, the incidences of degenerative lesions of peripheral nerves at 50 ppm (3.02/3.96 mg/kg/day in M/F) were equivocal. In the two-year chronic study in Sprague-Dawley rats, loss of myelinated sciatic nerve fibers and retinal atrophy were observed at 50 ppm (2.5 mg/kg/day).

There is evidence of the developmental neurotoxic potential of methyl parathion in the open literature. In a study by Gupta, et al. (1985), it was demonstrated that both maternal and fetal neurobiochemical markers are affected by treatment with 1.0 or 1.5 mg/kg/day from gestation days 6-20, and that altered postnatal development of cholinergic neurons and alteration of select behaviors of the offspring resulted.

Methyl parathion is extremely toxic on acute basis; the oral LD50 in rats is approximately 4.0 mg/kg (males) and 6.3 mg/kg (females).

b. Evidence that do not support asking for a developmental neurotoxicity study:

Brain weight was increased in the three-month study in mice at 60 ppm (13.5/16.2 mg/kg/day in M/F) and in the two-year chronic study in rats at 50 ppm (2.5 mg/kg/day). These effects were, however, not statistically significant and were not considered to be biologically meaningful. In a study from the open literature (Gupta et al., 1985) it was reported that pup brain weights (Day 1) were not affected following *in utero* exposure to methyl parathion (gestation days 6-20). Furthermore, delayed neuropathy was not observed in the hen.

No evidence of abnormalities in the development of the fetal nervous system was observed in the prenatal developmental toxicity studies in either rats, or rabbits, at maternal gavage doses up to 3.0 mg/kg/day. In the two-generation reproduction study in rats, no clinical evidence suggestive of neurotoxicity was observed grossly in pups, which had been administered methyl parathion *in utero* and during early and late postnatal development, generally mediated by maternal dietary exposure, but also available in the diet to late lactation pups.

There is no evidence that endocrine function is disrupted by administration of methyl parathion.

C. <u>FQPA Considerations</u>:

Under the Food Quality Protection Act (FQPA), P.L. 104-170, which was promulgated in 1996 as an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), the Agency was directed to "ensure that there is a reasonable certainty that no harm will

result to infants and children" from aggregate exposure to a pesticide chemical residue. The law further states that in the case of threshold effects, for purposes of providing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such margin will be safe for infants and children."

Pursuant to the language and intent of the FQPA directive regarding infants and children, the applicable toxicity database for methyl parathion was evaluated by the Hazard Identification Committee.

Adequacy of data package: The data package included an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits, meeting the basic data requirements, as defined for a food-use chemical by 40 CFR Part 158. A developmental neurotoxicity study was requested.

Susceptibility issues: The submitted guideline study data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methyl parathion. In the two-generation reproduction study in rats, offspring toxicity occurred at the same dose as parental toxicity; the offspring developmental and parental systemic NOELs and LOELs were 5 ppm (0.25 mg/kg/day) and 25 ppm (1.25 mg/kg/day), respectively. In the prenatal developmental toxicity study in rats, developmental toxicity was observed only in the presence of maternal toxicity; the maternal and developmental NOELs and LOELs were equivalent at 1.0 and 3.0 mg/kg/day, respectively. In the prenatal developmental toxicity study in rabbits, neither maternal nor developmental toxicity was observed, although, based upon the results of a previous study in rabbits, the doses were judged to be adequate to elicit plasma and erythrocyte cholinesterase inhibition in the maternal animals.

An assessment of the differential response of fetuses versus adults to cholinesterase inhibition following oral administration of methyl parathion was studied by Gupta, et al. (1985). No indication of additional sensitivity of the offspring was suggested by the data, since offspring effects were noted concurrently with maternal effects. Specifically, it was demonstrated that both maternal and fetal neurobiochemical markers are affected by treatment with 1.0 or 1.5 mg/kg/day from gestation days 6-20, and that altered postnatal development of cholinergic neurons and alteration of select behaviors of the offspring resulted.

In addition, in studies by Benke and Murphy (1974), Pope et al. (1991), and

Pope and Chakraborti (1992), evidence of increased sensitivity of young rats to the effects of methyl parathion, as compared to adults, were reported. Although these studies used non-oral methods of test substance administration, and were conducted at the maximum tolerated dose in order to establish LD50 values, they indicate that there should be a concern for the effects of methyl parathion on young animals.

Uncertainty factor: Based on the following concerns, the Committee determined that for methyl parathion the 10-fold uncertainty factor for the protection of infants and children is appropriate:

1. The data base for methyl parathion is complete with regard to the standard studies required by 40 CFR Part 158 for a food-use chemical. Acceptable prenatal developmental toxicity studies in rats and rabbits, and an acceptable multigeneration reproduction study in rats have been received by the Agency. Although delayed neuropathy was not observed in a study in hens, a single-dose acute neurotoxicity study in rats demonstrated neuropathology at a relatively low dose level (2.5 mg/kg). Also, there was evidence of the developmental neurotoxic potential of methyl parathion in the open literature (Gupta et al., 1985); in this study, altered postnatal development of cholinergic neurons and alteration of select behaviors of the offspring resulted following *in utero* exposure. A developmental neurotoxicity study is required with methyl parathion; in the absence of this study, substantial uncertainties remain regarding the effect of methyl parathion on functional development.

2. Although differential sensitivity to young animals was not revealed in standard prenatal developmental and multigeneration reproductive toxicity studies, qualitative evidence of increased sensitivity to perinatal rats has been identified in the open literature. In these studies, a) lethality at doses at or near the maximum tolerated dose and b) cholinesterase inhibition were used as biomarkers of sensitivity. Methyl parathion was administered to the rats in these studies by subcutaneous injection (Pope et al., 1991; Pope and Chakraborti, 1992), intraperitoneal injection (Benke and Murphy, 1974), or oral (Gupta, 1984) routes. This evidence of increased sensitivity to the offspring cannot be quantified, however data from another organophosphorus pesticide, chlorpyrifos, has demonstrated differences in sensitivity in the offspring of up to 10-fold.

D. Mutagenicity:

Seven studies sponsored by the USEPA under contract Nos. 68-02-2947 or EPA-600/1-7-028 were available for review. The following are summaries and the committee's conclusion for these studies (with MRID/Accession and/or Document Control Numbers):

1. Gene mutations:

a) Salmonella typhimurium reverse gene mutation assay (MRID No. 00124901; Doc. No. 005095): The test is negative in S. typhimurium strains TA1535, TA1537, TA1538 and TA100 up to 1000 µg/plate +/-S9, the highest dose tested (HDT). Due to the lack of cytotoxicity at the HDT and other technical deficiencies, the study was classified as Unacceptable. However, the standard protocol used in this assay required testing up to 10,000 µg/plate +/-S9, unless solubility or cytotoxic prevent testing up to this level. The Committee, therefore, concluded that methyl parathion was assayed up to an appropriate high dose and found to be negative. It was further concluded that the assay should be upgraded.

b) Escherichia coli reverse gene mutation assay (MRID No. 00124901; Doc. No. 005095): The test is negative in E. coli WP2 up to the HDT (1000 µg/plate +/-S9). Due to the lack of cytotoxicity at the HDT and other technical deficiencies, the study was classified as Unacceptable. For reasons similar to those stated above, the Committee concluded that the assay should be upgraded.

c) Saccharomyces cerevisiae D7 reverse gene mutation, mitotic gene conversion and mitotic crossing-over assay (MRID No. 00132949; Doc. No. 005095): Independent test are negative at all three endpoints up to severely cytotoxic levels (≥1.0% +/-S9, equivalent to ≈10,000 µg/mL).

d) L5178Y TK $^{+/-}$ mouse lymphoma cell forward gene mutation assay (MRID No. ?; Doc. No. 005095/005588): Confirmed positive; dose-related mutagenic effects at 80-200 µg/mL with S9 activation. Positive responses were also seen in the absence of S9 activation; however, the effect was not clearly dose-related and reproducible increases in the mutation frequency were only seen at ≥150 µg/mL. (Colony sizing was not performed).

2. Chromosomal Aberrations:

a) Mouse Dominant lethal assay (MRID No. 00124901; Doc. Nos. 005095/005588): The test is negative in the germinal cells of male ICR/SIM mice receiving dietary administrations of 0, 20, 40 or 80 ppm methyl parathion for 7 weeks. No overt toxicity or cytotoxicity to the target organ occurred at the HDT. It was noted, however, that body weight reductions (4-20%) were seen at all weeks in males mice receiving dietary levels of 10, 30 or 60 ppm methyl parathion in the subchronic mouse study conducted with methyl parathion (MRID No. 00072513). Based on these findings, the Committee concluded that dosing was adequate in the dominant lethal assay.

3. Other Mutagenic Mechanisms:

a) In vitro sister chromatid exchange (SCE) in Chinese hamster ovary cell assay (MRID No. ?; Doc. No. ?): The test is positive in the presence of S9 activation; dose related increases in SCEs were obtained at 50-200 µg/mL. Without S9 activation the test is negative up to cytotoxic levels (≥40 µg/mL).

b) Unscheduled DNA synthesis in cultured human fibroblasts (WI-38) assay (MRID No. 00124901; Doc. No. 005095/005588): The test is negative up to a precipitating dose (10^{-3} M +/- S9).

4. Conclusions:

Methyl parathion was negative for gene mutations in S. typhimurium, E. coli and S. cerevisiae. It also did not cause mitotic recombination or gene conversion in S. cerevisiae or DNA damage in a human cell line. Gene mutations and SCE were, however, induced in cultured mammalian cells and the effect was more clearly demonstrated in the presence of S9 activation. The only acceptable in vivo study in the Agency's files indicated that methyl parathion was not active in the mouse dominant lethal assay. Nevertheless, positive dose-related increases in micronuclei induction have been reported in the literature in mice receiving methyl parathion orally (Mathew et al., 1990) and in rats following intraperitoneal injection (Grover and Malhi, 1985). Structural chromosome aberrations have also been reported in bone marrow cells harvested from treated rats (Malhi and Grover 1987).

The relevance of the positive findings from both the in vitro and in vivo mutagenicity studies is not clear in light of the negative cancer studies and the lack of an effect in germinal cells in the dominant lethal assay. The Committee concluded, therefore, that nothing further would be gained by requiring additional testing. Based on these deliberations, the available acceptable studies satisfies the pre-1991 mutagenicity initial testing battery guidelines. No further testing is required at this time.

E. Dermal Absorption:

No dermal absorption study was available. Because of relatively high dermal toxicity, dermal absorption should be assumed to be 100%.

II. HAZARD IDENTIFICATION:

Based on comprehensive evaluation of the toxicology data available on methyl parathion, toxicology endpoints and dose levels of concern have been identified for use in risk assessments corresponding to the categories indicated below.

Where no appropriate data have been identified for a particular duration or exposure scenario, or if a risk assessment is not warranted, this is noted. Levels of uncertainties associated with intraspecies variability, interspecies extrapolation, route to route conversion, or variable durations extrapolation are also addressed.

Based on the exposure/use profile for methyl parathion, the Committee determined that the risk assessments indicated below are required.

A. Chronic Dietary Exposure-Reference Dose (RfD):

Reference Dose (R_fD): 0.00002 mg/kg/day mg/kg/day.
Critical Study: A Two Year Chronic Feeding Study of Methyl Parathion in Rats (83-1a), MRID No 252501-252503.

Executive Summary: Methyl Parathion (purity 93.7%) was administered to Sprague Dawley rats (60/sex/group) at 0, 0.5, 5, and 50 ppm in the diet (mean compound intake approximately 0, 0.02, 0.21, and 2.21 mg/kg/day for males and 0, 0.03, 0.29, and 3.34 for females [from the original study report, based on nominal concentrations]) for 26 (males) or 28 (females) months. Body weights and food consumption were recorded weekly to week 14, and biweekly thereafter. Ophthalmic examinations were performed at pretest, 3, 12, and 24 months and on females only at 28 months. Clinical chemistry and hematological parameters were determined, and urinalysis was performed at 6, 12, 18, and 24 months (10 animals/sex/group). Plasma and RBC Cholinesterase inhibition were also measured at 6, 12, and 18 months and at termination (10 rats/sex/group), on different animals from those used for other blood measures. Brain cholinesterase was measured at termination. All study animals received gross postmortem examination and histopathological evaluations. Five animals/sex/dose received additional histopathological examination of neural tissues (brain, spinal cord, and sciatic nerve).

No carcinogenic effects were seen at 50 ppm (highest dose) in either sex. Doses were considered adequate to test for carcinogenicity.

Effects seen at the 5.0 ppm dose were abnormal gait in one female, significant decreases in hematocrit and erythrocyte levels in males at 24 months, slight decreases in erythrocyte cholinesterase activity in both sexes (+4.4 to -11.3% inhibition).

Additional effects seen at 50 ppm were significant decreases in hemoglobin,

hematocrit, and erythrocyte levels in females (at all time points), significant decreases in activity of plasma (67-89% inhibition), erythrocyte (0-20% inhibition), and brain cholinesterase (76-79% inhibition) at multiple time points (males and females), increased incidence of alopecia (more pronounced in females), bilateral retinal degeneration and posterior subcapsular cataract (females only, at 24 months), decreased mean body weight and increased food consumption (both sexes), irritability (both sexes), tremors (largely in females), increased incidence of ano-genital staining, decreased incidence of chromodacryorrhea, and soft stools. There was also a slight apparent increase in survival in 50 ppm females.

Neurological changes (in particular sciatic nerve degeneration) were most pronounced in animals receiving 50 ppm, but lesions in low and mid-dose males were slightly more severe than those seen in control animals. Although the original DER found no NOEL for these effects, upon re-evaluation a NOEL can be determined at the low dose (0.5 ppm).

The LOEL for neurological effects in this study, based on increases in lesion severity (sciatic nerve degeneration, males) was established at 5.0 ppm (0.21 mg/kg/day in males, 0.29 mg/kg/day in females); the NOEL was established at 0.5 ppm (0.02 mg/kg/day for males, 0.03 mg/kg/day for females). Based on other effects seen in this study (decreased hematocrit and erythrocyte levels), the systemic LOEL was established at 5.0 ppm (0.21 mg/kg/day in males, 0.29 mg/kg/day in females); the NOEL was established at 0.5 ppm (0.02 mg/kg/day in males, 0.03 mg/kg/day in females). The LOEL for cholinesterase inhibition (decreased erythrocyte cholinesterase activity in both sexes) was established at 5.0 ppm (0.21 mg/kg/day in males, 0.29 mg/kg/day in females); the NOEL was established at 0.5 ppm (0.02 mg/kg/day in males, 0.03 mg/kg/day in females).

This study is classified as Acceptable for carcinogenicity and Acceptable for chronic toxicity in rats.

Endpoint and Dose selected for use in risk assessment: 0.02 mg/kg/day was the NOEL for this study, based on systemic toxicity, neuropathology, and RBC cholinesterase inhibition occurring at 0.21 mg/kg/day.

Uncertainty Factor (UF): An uncertainty factor of 100 was applied to account for both interspecies extrapolation and intraspecies variability. The use of a UF of 100 was justified based on the availability of a chronic toxicity study in a second species (MRID Nos.) and a reproductive toxicity study in rats (MRID No. 00119087) in accordance with the rules established by the Agency-Integration Risk Information System (IRIS) Work Group.

The Committee recommended that the additional UF of 10, required for the

protection of infants and children in accordance with the FQPA, be retained in addition to the traditional Uncertainty Factor (see Section I-C, above).

Comments: This study is appropriate for use in risk assessment for this type of exposure and duration concern.

B. Acute Dietary Exposure (one day):

Critical Study: Acute Neurotoxicity (81-8), MRID No.: 43254401.

Executive Summary: In this acute neurotoxicity study, male and female Sprague-Dawley rats (10 animals/sex/group) were orally gavaged once with methyl parathion at doses of 0, 0.025, 7.5, 10 (males only), or 15 (females only) mg/kg. Neurobehavioral evaluations, consisting of FOB and motor activity, were conducted at pre-study, at the peak time of effect (1.5 hrs post-dosing) on Day 0 and on Days 7 and 14. At 15 $\pm$ 3 days animals were euthanized and neuropathological examination performed on control and high-dose animals (6/dose/sex). Plasma and erythrocyte (RBC) cholinesterase activities were determined at Day -2; plasma, RBC and brain (six different regions) activities were measured at the peak time of effect and at Day 14.

No significant differences were noted in the mean body weights of the treated animals; body weight gain in high-dose males was significantly lower than controls.

Neurobehavioral evaluation revealed treatment-related FOB and motor activity findings at the mid- and high-dose levels. The effects were transient and observed only at the peak time of effect. Neurobehavioral findings are consistent with those observed following cholinesterase inhibition (i.e. lacrimation, salivation, miosis, tremors/convulsions, muscle fasciculations, muscle weakness, and ataxia).

No treatment-related gross pathological findings were observed. Neuropathological findings consisted of focal demyelination in the dorsal root fibers of the cervical spine in 3/6 high-dose males and lumbar spine in 3/6 low-, 4/6 mid- and 5/6 high-dose males. Focal demyelination was also observed in the ventral root fibers of the cervical spine in 2/6 high-dose males and of the lumbar spine in control (males, 2/6; females, 1/6), low- (males, 3/6), mid- (males, 4/6), and high- (males, 4/6; females, 3/6) dose groups. Focal demyelination of the lumbar spinal cord and spinal nerve were observed in high-dose males; the incidence of each of these observations was only 1/6. Focal demyelination was observed in the tibial nerves of 1/6 mid- and 3/6 high-dose males and in the sural nerves of 2/6 high-dose males.

In summary, systemic toxicity was observed in high-dose males (decreased body weight gain) and females (increased incidence of clinical signs). Neurotoxic effects (abnormal FOB findings, decreased motor activity, inhibition cholinesterase activities,

and neuro-pathological findings) were observed in mid- and high-dose males and females.

Based on the results of this study, the systemic LOEL was 10 mg/kg (males) and 15 mg/kg (females); the systemic NOEL was 7.5 mg/kg. In males and females, the LOEL for neurotoxicity was 7.5 mg/kg; the NOEL for neurotoxicity was 0.025 mg/kg.

This study is classified as Core-Guideline and satisfies guideline requirements (81-8) for an acute neurotoxicity screening battery in the rat.

Endpoint and Dose Selected for Use in Risk Assessment: 0.025 mg/kg was the NOEL for this study, based on neurotoxicity and cholinesterase inhibition occurring at 7.5 mg/kg.

Comments and Rationale: Effects seen in this study occurred after a single dose, appropriate for use in risk assessment for this type of exposure and duration concern.

Uncertainty Factor (UF): The Committee recommended that the additional UF of 10, required for the protection of infants and children in accordance with the FQPA, be retained in addition to the traditional Uncertainty Factor.

C. Short Term Occupational or Residential Exposure (1-7 days):

Critical Study: Acute Neurotoxicity (81-8), MRID No.: 43254401.

Executive Summary: See Section II-B, above.

Endpoint and Dose Level selected for use in risk assessment: Same as for acute oral, 0.025 mg/kg, based on neurotoxicity and cholinesterase inhibition occurring at 7.5 mg/kg.

Comments: Although there was a 21-day dermal study in rabbit available, it was not selected for the following reasons: 1) The rabbit is less sensitive than the rat to this chemical (for example, in the rabbit developmental study, 3.0 mg/kg doses resulted in only minimally significant cholinesterase inhibition); 2) several endpoints (including neurotoxicity and neuropathology) occurring at low doses in the acute oral study were not measured in the dermal study; 3) oral and dermal effects seen in other acute studies occurred at similar doses (see Acute Toxicity Endpoints), so there is no reason to believe that neurotoxic effects might not occur at low dermal doses, and 4) because of physiological and biochemical factors, unique to the rabbit, which might result in underestimation of the dermal toxicity of organophosphorus pesticides belonging to the thiophosphate subgroup (R. Zendzian, HED, memo dated March 1997). Dermal

absorption rate was assumed to be 100%.

Uncertainty Factor (UF): The Committee recommended that an additional UF of 10 be applied in addition to the traditional Uncertainty Factor (see Section I-C, above).

D. **Intermediate Term Occupational or Residential Exposure (one week to several months):**

Critical Study: A Two Year Chronic Feeding Study of Methyl Parathion in Rats (83-1a), MRID No 252501-252503.

Executive Summary: See Section II-A, above.

Endpoint and Dose Level Selected for Use in Risk Assessment: 0.02 mg/kg/day was the NOEL for this study, based on systemic toxicity, neuropathology, and RBC cholinesterase inhibition occurring at 0.21 mg/kg/day.

Comments: Long term dermal study is not available. Since there is evidence of cumulative neurotoxic effects, the acute neurotoxicity study is not of sufficient duration to cover this type of exposure.
Dermal absorption rate was assumed to be 100%.

Uncertainty Factor (UF): The Committee recommended that the an additional UF of 10 be applied in addition to the traditional Uncertainty Factor (see Section I-C, above).

E. **Chronic Occupational or Residential Exposure (several months to life time):**

Critical Study: A Two Year Chronic Feeding Study of Methyl Parathion in Rats (83-1a), MRID No 252501-252503.

Executive Summary: See Section II-A, above.

Endpoint and Dose Selected for Use in Risk Assessment: 0.02 mg/kg/day was the NOEL for this study, based on systemic toxicity, neuropathology, and RBC cholinesterase inhibition occurring at 0.21 mg/kg/day.

Uncertainty Factor (UF): The Committee recommended that the additional UF of 10 be applied in addition to the traditional Uncertainty Factor (see Section I-C, above).

Comments: Long term dermal study is not available. Therefore, a chronic oral toxicity study was used and a 100% dermal absorption rate was recomended.

F. **Inhalation Exposure (variable duration):**

* *Use the same format as the dermal if appropriate studies are available for the 3 exposure time periods. If appropriate studies are NOT available for the 3 time periods then use the following format.*

Critical Study: A Two Year Chronic Feeding Study of Methyl Parathion in Rats (83-1a), MRID No 252501-252503.

Executive Summary: See Section II-A, above.

Endpoint and Dose Level Selected for Use in Risk Assessment: 0.02 mg/kg/day was the NOEL for this study, based on systemic toxicity, neuropathology, and RBC cholinesterase inhibition occurring at 0.21 mg/kg/day.

Comments: Due to high toxicity seen in acute inhalation study, 100% absorption should be assumed.

Uncertainty Factor (UF): The Committee recommended that the additional UF of 10, required for the protection of infants and children in accordance with the FQPA, be retained in addition to the traditional Uncertainty Factor (see Section II-A, above).

G. Aggregate Risk:

The Comittee recomended that the aggregate risk be performed by adding the exposures together and using the oral endpoint. As previously stated, the dermal absorption rate was assumed to be 100%.

III. APPENDIX:

A. Acute Toxicity:

Guideline No.	Study Type	MRID #(S).	Results	Toxicity Category
81-1	Acute Oral (rat)		LD_{50} = 4.5-24 mg/kg	I
81-2	Acute Dermal (rat)		$LD_{50=}$ 6 mg/kg	I
81-3	Acute Inhalation (rat)	256961	LC_{50} <0.163 mg/L	I
81-4	Primary Eye Irritation	256966, 40542602	Irritation clear by 7 days	III
81-5	Primary Skin Irritation	256962	Max. score=2.0; 72 h=0.5	IV
81-6	Dermal Sensitization	256963	Negative	
81-8	Acute Neurotoxicity Delayed Hen	41606801	Negative	--

IV. REFERENCES:

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cc: Stephanie Irene, Kathleen Raffaele, Clark Swentzel, Diana Locke, Karen Whitby, Jess Rowland, Amal Mahfouz (OW), Hazard ID file, Caswell File

Attachment 2: Re-evaluation of Dietary Endpoint and Non-dietary Endpoint Selection and Dermal Absorption Factor; Report of the Hazard Identification Assessment Review Committee

HED DOC. NO. 013285

DATE: March 23, 1999

MEMORANDUM

SUBJECT: ***METHYL PARATHION*** - Re-evaluation of Dietary Endpoint and Non-dietary Endpoint Selection and Dermal Absorption Factor; Report of the Hazard Identification Assessment Review Committee

FROM: Kathleen Raffaele
Toxicology Branch 2
Health Effects Division (7509C)

THROUGH: Pauline Wagner, Co-Chairman
Hazard Identification Assessment Review Committee
Health Effects Division (7509C)
and
Jess Rowland, Co-Chairman
Hazard Identification Assessment Review Committee
Health Effects Division (7509C)

TO: Diana Locke, Risk Assessor
Reregistration Branch 2
Health Effects Division (7509C)

PC Code: 053501

On March 4, 1999 the Health Effects Division's Hazard Identification Assessment Review Committee (HIARC) reevaluated the endpoints selected for dietary and non-dietary risk assessment and the dermal absorption factor for methyl parathion. The HIARC's conclusions are presented in this report.

ACUTE REFERENCE DOSE (RfD)

Previously, the Committee had selected the acute oral neurotoxicity study for use in acute dietary risk assessment (HIARC Report, 12/1/97). Effects seen at 7.5 mg/kg (the mid-dose) in this study included cholinesterase inhibition, changes in functional observation battery and motor activity, and neuropathology. Therefore, the NOAEL from this study was set at 0.025 mg/kg (the low dose). Because the mid and low doses used in this study differed by a factor of 300, the registrant requested reconsideration of this endpoint, and suggested several possible alternatives.

On March 4, 1999, the Committee evaluated available data for methyl parathion, and concluded the only appropriate study demonstrating a higher NOAEL for the endpoints measured in the acute neurotoxicity study was the special one year chronic neurotoxicity study. The study included a dose intermediate between the LOAEL and NOAEL of the guideline subchronic neurotoxicity study (0.295 and 0.029 mg/kg/day, respectively, based on red blood cell cholinesterase inhibition), and critical endpoints identified in the acute oral neurotoxicity study (cholinesterase inhibition and neuropathology) were evaluated.

In the one year special neurotoxicity study, methyl parathion was administered in the diet at 0, 0.5, 2.5, 12.5, and 50 ppm (0, 0.02, 0.107, 0.533, and 2.207 mg/kg/day for males, 0, 0.026, 0.138, 0.697, and 3.088 mg/kg/day for females) for one year. The NOAEL for the study was 2.5 ppm (0.107 mg/kg/day for males, 0.138 mg/kg/day for females), and the LOAEL 12.5 ppm (0.533 or 0.697 mg/kg/day for males or females, respectively), based on inhibition of plasma, brain, and red blood cell cholinesterase (in one or both sexes) and neuropathology seen in both sexes. The Committee felt that use of this study for acute dietary risk assessment would not underestimate the risk for that type of exposure, due to the longer duration of the selected study (one year vs. a single exposure) and the evaluation of the critical effects (cholinesterase inhibition and neuropathology). The Committee felt that use of a NOEL from a long term (one year) study would be protective for a single exposure.

Calculation of Acute RfD:

NOAEL = 0.11 mg/kg

Uncertainty Factors: 10 (interspecies) X 10 (intraspecies)
= 100

Acute RfD = 0.0011 mg/kg/day

CHRONIC REFERENCE DOSE (RfD)

The Committee also considered the registrant's proposal that the one year special chronic neurotoxicity study be used for the chronic dietary risk assessment. The current chronic RfD, 0.0002 mg/kg/day, is based the NOAEL of 0.02 mg/kg/day in a 2-year chronic rat study; red blood cell cholinesterase inhibition, neuropathology, and hematologic effects were seen at the LOAEL of 0.2 mg/kg/day (see HIARC report, 12/1/97). The NOAEL from the one year neurotoxicity study (0.11 mg/kg/day) is higher than the NOAEL in the chronic study, but lower than the LOAEL for that study. However, hematologic effects (seen at the LOAEL in the 2 year chronic study) were not evaluated in the one year study, therefore the Committee could not be sure that these effects did not occur at levels lower than the NOAEL for the one year study. Thus, the Committee determined that there should be no change in the chronic RfD, which will remain at 0.02 mg/kg/day.

Calculation of Chronic RfD:

NOAEL = 0.02 mg/kg/day

Uncertainty Factors: 10 (interspecies) X 10 (intraspecies)
= 100

Chronic RfD = 0.0002 mg/kg/day

DERMAL TOXICITY ENDPOINTS

For reasons described in the previous HIARC report (12/1/97), it was determined that the 21-day rabbit dermal toxicity studies were not appropriate for use as dermal toxicity endpoints. Previously, the acute oral neurotoxicity study was selected for use as the short term dermal endpoint, the two-year chronic rat study was selected for both intermediate and long term dermal endpoints.

Based on the rationale outlined above, the Committee selected the one-year chronic neurotoxicity study for use in short and intermediate-term dermal risk assessment. There is no change in the endpoint selected for long term dermal risk assessment. Since oral values were selected, a dermal absorption factor of 100% should be used for risk assessments.

Short- and Intermediate-Term Dermal Risk Assessment:

NOAEL = 0.11 mg/kg
MOE = 100

Long Term Dermal Risk Assessment:

As determined previously, the Committee reaffirmed that the 2-year chronic rat study will be used for long term dermal risk assessment.

NOAEL = 0.02 mg/kg/day
MOE = 100

Dermal Absorption Factor:

The Committee reaffirmed that the dermal absorption factor for methyl parathion would be 100% (assume equivalent dermal and oral absorption). The decision was based on the following data, some of which has been submitted since the previous HIARC meeting (see Table 1).

Table 1. Comparison of cholinesterase inhibition at selected doses in females from oral and dermal studies in rats and rabbits.

Study type	MRID No.	Dose (mg/kg/day)	Percent Inhibition in various compartments		
			Red Blood Cell	Plasma	Brain
Rabbit					
Oral Developmental	?	3	19	12	---
Oral Developmental	44691004	3	43	---	ND
Oral Developmental	44691004	9	75	50	ND
21-Day Dermal	42263701	10	30	---	---
21-Day Dermal	42263701	100	38	15	---
Rat					
Oral Developmental	41136101	3	71	59	22
Acute Oral Neurotoxicity (peak effect time)	43254401	7.5	57	71	80
Acute Oral Neurotoxicity (peak effect time)	43254401	15	58	76	90
Subchronic Oral Neurotoxicity (4 week time point)	43490501	3.96	64	80	80
Two-week Dermal Neurotoxicity (preliminary data submission)	44680200	3.5 (a.i.)	72	38	60
Two-week Dermal Neurotoxicity (preliminary data submission)	44680200	7.5 (a.i.)	85	50	80

ND=not done; ---=no inhibition found

Although the rabbit appeared to demonstrate less cholinesterase inhibition after dermal doses than oral doses (compare oral developmental at 9 mg/kg/day with dermal at 10 mg/kg/day), the rat showed comparable inhibition after similar oral and dermal doses (compare oral developmental at 3 mg/kg/day with two week dermal neurotoxicity study at 3.5 mg/kg/day). The Committee believes that these data support the use of an assumption of 100% dermal absorption (e.g. equivalent dermal and oral absorption).

In addition, the Committee noted the similarity in the doses selected for the new short term rat dermal and oral studies currently being conducted by the registrant (oral study will use 0, 1, 1.5, 3, and 12 mg/kg; dermal study will use 0, 1, 2, and 3 mg/kg/day). Use of similar doses in the oral and dermal studies supports the assumption of similar

toxicity by the oral and dermal routes.

The Committee also noted the preliminary nature of the data from the two week dermal neurotoxicity study and the pending completion of the two new studies. The above conclusions will be reevaluated if indicated when complete data from these studies are received.

INHALATION ENDPOINTS

The Committee determined that inhalation risk assessments should be conducted using the same oral values used in acute and chronic dietary risk assessment, for the appropriate time frames. As specified in the previous report, the inhalation exposure should be converted to oral dose, which is then compared with the appropriate endpoints as described above.

FQPA FACTOR

As determined previously, the 10x FQPA safety factor was retained for methyl parathion (see HIARC report, 7/7/98, FQPA Safety Factor Committee report 8/6/98).

SUMMARY OF TOXICOLOGY ENDPOINT SELECTION

The doses and toxicological endpoints selected for various exposure scenarios are summarized below:

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	NOAEL= 0.11 mg/kg UF = 100	Based on Plasma, RBC, and Brain ChEI and neuropathology	Chronic Neurotoxicity in rat
	Acute RfD = 0.0011 mg/kg		
Chronic Dietary	NOAEL = 0.02 mg/kg/day UF = 100	Based on Plasma, RBC, and Brain ChEI; neuropathology; and hematological effects	Two-year chronic toxicity/oncogenicity in rat
		Chronic RfD = 0.0002 mg/kg day	
Short-Term[1] (Dermal)	Oral NOAEL= 0.11 mg/kg	Based on Plasma, RBC, and Brain ChEI and neuropathology	Chronic Neurotoxicity in rat
Intermediate-Term[1] (Dermal)	Oral NOAEL= 0.11 mg/kg	Based on Plasma, RBC, and Brain ChEI and neuropathology	Chronic Neurotoxicity in rat
Long-Term (Dermal)[1]	Oral NOAEL= 0.02 mg/kg/day	Based on Plasma, RBC, and Brain ChEI; neuropathology; and hematological effects	Two-year chronic toxicity/oncogenicity in rat
Short Term[2] (Inhalation)	Oral NOAEL= 0.11 mg/kg	Based on Plasma, RBC, and Brain ChEI and neuropathology	Chronic Neurotoxicity in rat
Intermediate Term[2] (Inhalation)	Oral NOAEL= 0.11 mg/kg	Based on Plasma, RBC, and Brain ChEI and neuropathology	Chronic Neurotoxicity in rat
Long Term[2] (Inhalation)	Oral NOAEL= 0.02 mg/kg/day	Based on Plasma, RBC, and Brain ChEI; neuropathology; and hematological effects	Two-year chronic toxicity/oncogenicity in rat

Attachment 3: Revised Toxicology Chapter

MEMORANDUM

TO: Diana Locke
Toxicologist, Reregistration Branch 2/HED (7509C)

FROM: Kathleen C. Raffaele, Ph.D.
Toxicologist, Toxicology Branch 2/HED (7509C)

THRU: Stephen C. Dapson, Ph.D.
Senior Scientist, Toxicology Branch 2/HED (7509C)

Chemical: Methyl Parathion
Case #
Pesticide Chemical Code 053501
CAS Reg No. 298-00-0

Attached is the Toxicology Chapter for the Methyl Parathion RED

In a second acute inhalation study (MRID No. 142803), Albino rats (strain Hsd:(SD) BR), 5/sex/group, were exposed by inhalation to Methyl Parathion Technical (purity, composition, and stability not provided) as follows: 0.163 mg/l for 4 hours, or 1.06 mg/l for 1.5 h. All animals died during the study. Necropsy findings included discoloration of lungs, lungs edematous, adrenal glands enlarged, corneal opacity, and changes in the gastrointestinal tract. Clinical observations included decreased activity, body tremors, chromodacryorrhea, convulsions, constricted pupils, labored breathing, salivation, lacrimation, piloerection, etc. No NOEL could be determined based on this study. All animals demonstrated cholinergic signs and died prior to completion of study. The LC50 for methyl parathion technical is <0.163 mg/l. The study is classified as tentatively acceptable.

b. Subchronic Toxicity

Available studies are adequate to satisfy subchronic testing requirements for this chemical.

Subchronic toxicity in mice

In a three month feeding study in mice (MRID No. 72513), Methyl parathion (purity 93.7%) was administered to mice (15/sex/group) in the diet at 0, 10, 30, or 60 ppm (approximately 0, 2.1, 6.5, 13.5 mg/kg/day for males; 0, 2.5, 8.6, 16.2 mg/kg/day for females, respectively) for 90 days. There was a significant decrease in body weight of high dose males throughout the study (4-20% less than controls; body weight was 94% of controls at study termination). Absolute brain weights of high dose males and females were slightly increased (significant increase in brain/body weight ratio for high dose males only). Testes weights of all treated males were decreased in a dose-related manner (significant only as testes/brain weight ratio in high dose males). Ovary weights of mid and high dose females were slightly decreased (significant only as ovary/brain weight ratio in high dose females). There were no compound-related histopathological findings (peripheral nerve was not microscopically examined). The systemic LOEL is 60 ppm (13.5 mg/kg/day for males, 16.2 mg/kg/day for females), based on decreased body weight in males and decreased testes/brain weight ratio; decreased ovary/brain weight ratio in females. The systemic NOEL is 30 ppm (6.5 mg/kg/day for males, 8.6 mg/kg/day for females).

This nonguideline [82-1] subchronic feeding study in mice is classified as Acceptable, although cholinesterase inhibition, clinical chemistry, and hematology were not measured, and histopathological evaluation was limited. There is a long-term [carcinogenicity] study in the mouse available.

Subchronic toxicity in rats

In a three month feeding study in rats (MRID No. 74299), Methyl parathion (purity 93.7%) was administered to Sprague-Dawley CD rats (20/sex/group) in the diet at 0, 2.5, 25, or 75 ppm for three months (mean daily intake, corrected for compound stability, was approximately 0.12, 1.24, 4.46 mg/kg/day for males, 0.16, 1.55, 5.15 mg/kg/day for females, respectively). In the high dose group, 14 females and 1 male died or were sacrificed (due to extreme morbidity) during the first 4 weeks of study. The study report stated that all high dose females and some high dose males exhibited tremors and emaciation (data not provided). The following additional effects were found: significantly reduced body weight at all time points (high dose males (16-23% less than controls) and females (24-35% less than controls); increased food consumption (significant at week 4 and all subsequent weeks, high dose males (18-37% greater) and females (12-30% greater); significantly decreased hemoglobin (mid- and high dose males, high dose females), hematocrit (high dose males and females), and red blood cell count (high dose females); changes in several clinical chemistry parameters, including increased alkaline phosphatase (high dose males and mid- and high dose females), increased SGOT (high dose females), increased BUN (high dose females), decreased glucose (high dose males and females), decreased total protein (high dose males and females), decreased albumin (high dose males), decreased globulin (high dose males and females), increased A/G ratio (mid and high dose males, females at all dose levels); apparently increased specific gravity in urinalysis (high dose males and females; note that neither statistical analysis nor summary data were provided in the report).

Plasma cholinesterase was significantly inhibited in high dose males (9-27%) and in the mid- and high doses for females (29-39% and 54-68%, respectively); RBC cholinesterase was significantly inhibited in mid, and high dose males (41-43%, and 9-48%, respectively) and mid and high dose females (33-48% and 31-63%, respectively). At 3 months, brain cholinesterase was significantly inhibited in mid- and high dose females (32% and 81%, respectively) and in high dose males (74%).

Absolute organ weights were decreased in high dose males (heart, kidneys, and liver) and females (ovaries, heart, and liver). Relative organ/body weights were increased in high dose males (brain, testes, heart, kidneys) and females (brain, ovaries, heart, kidneys). These changes were probably due, at least in part, to decreased body weight in high dose animals.

Apparently treatment-related histopathological lesions included (results refer to high dose groups unless otherwise noted): acute gastritis, acanthosis and hyperkeratosis in the cardia (stomach, mid- and high dose males and females), focal tubular regeneration in the kidneys (males), posterior synechia (eye, female), lymphocytic necrosis and lymphocytic depletion (spleen, female), cellular necrosis (salivary gland, female), lung

congestion (female), lymphocytic necrosis (thymus, female), liver congestion (female), hypocellularity (bone marrow, female). Note that, since 14 of the high dose females died after less than 4 weeks of exposure, histopathological results may not be comparable between this group and the other groups.

Based on the results of this study, the LOEL for systemic effects (hematological changes, stomach lesions) was 25 ppm (1.24 mg/kg/day for males, 1.55 mg/kg/day for females), and the NOEL for systemic effects was 2.5 ppm (0.16 mg/kg/day for males, 0.12 mg/kg/day for females). The LOEL for cholinesterase inhibition (brain, plasma, and erythrocyte) was established at 25 ppm (1.24 mg/kg/day for males, 1.55 mg/kg/day for females), the NOEL was 2.5 ppm (0.16 mg/kg/day for males, 0.12 mg/kg/day for females).

This guideline [82-1] study was classified as Acceptable.

Subchronic toxicity in dogs

In a ninety day feeding study in dogs (MRID No. 72512), Methyl parathion (purity 94.3%) was administered in diet to beagle dogs (4/sex/group) at 0, 0.3, 1.0, and 3.0 mg/kg/day for 90 days. No differences between control and treated animals were found with respect to food consumption, body weight gain, or clinical signs. Pulse rate was significantly decreased at 13 weeks for high dose females only (control rate was 161, high dose females was 121). No biologically relevant effects were found on clinical chemistry parameters or hematological parameters (scattered significant effects were not dose-related or consistent across time). No treatment-related effects were seen on analysis of urine samples. No treatment-related effects were seen on organ weights, or histopathologically.

Plasma cholinesterase activity was significantly decreased in mid-dose males at 13 weeks (72% of control) and in high dose males and females at 6 and 13 weeks (37-53% of control). RBC cholinesterase activities were significantly decreased in high dose males and females at 6 and 13 weeks (23-34% of control), and in mid-dose males and females at 13 weeks (63-64% of control). Brain cholinesterase activity was significantly decreased in high dose males and females at 13 weeks (the only time point measured; 36-44% of control).

Based on the results of this study, the LOEL for cholinesterase inhibition (plasma and RBC), was established at 1.0 mg/kg/day; the NOEL was established at 0.3 mg/kg/day. The LOEL for brain cholinesterase inhibition was 3.0 mg/kg/day; the NOEL was established at 1.0 mg/kg/day. For systemic effects (decreased pulse rate in females), the LOEL was 3.0 mg/kg/day, with a NOEL of 1.0 mg/kg/day.

This guideline [82-1] study was classified as Acceptable.

Dermal toxicity in rabbits

In a 21-day dermal study in rabbits (MRID No. 42263701), Methyl parathion was evaluated at dosages of 0 (vehicle control, 1% carboxymethylcellulose), 1, 5, 10, and 100 mg/kg/day. There were no mortalities or clinical signs of toxicity during the study. No adverse effects were apparent based on body weight, body weight gain, food consumption, clinical pathology parameters or organ weights. Histopathologic evaluations of the kidneys, liver and skin from high-dose rabbits did not reveal any treatment-related effects. Treatment-related RBC cholinesterase inhibition was seen in 10 and 100 mg/kg/day males and females.

No dermal effects were seen in treated males, however, slight erythema and edema was induced in 1, 5, and 10 mg/kg/day females; one 10 mg/kg/day female also had slight fissuring. The severity of these reactions did not increase with dosage. No dermal reactions were reported in 100 mg/kg/day females. Although no dermal effects were seen in treated males, the noted effects in females obviate the establishment of a NOEL for local dermal toxicity in this study.

The LOEL for systemic toxicity was 10 mg/kg/day based on RBC cholinesterase inhibition in both sexes and the NOEL was 5 mg/kg/day under the conditions of this study. A definitive NOEL for local dermal toxicity could not be determined in this study.

This guideline [82-2] study was rated Acceptable.

c. Chronic Toxicity and Carcinogenicity

Available studies are adequate to satisfy chronic toxicity and carcinogenicity testing requirements for this chemical.

Chronic toxicity in dogs

In a one-year study in dogs (MRID No. 93895), Purebred beagle dogs (8/sex/group) were administered methyl parathion (purity 93.7%) in the diet at 0, 0.03, 0.1, or 0.3 mg/kg body weight/day. Plasma and RBC cholinesterase activity were sporadically (significantly) depressed at all dose levels, at different time points. The decreases were not always dose-related, but the variance was high. At 12 months, RBC cholinesterase was significantly decreased at all dose levels for both sexes (males: 68-81% of control; females: 71-78% of control). Plasma cholinesterase levels in treated animals ranged from 66-83% of control for males, 52-81% of control for females. Brain cholinesterase was not significantly depressed at any dose level (it was significantly increased in high dose males), but again the variance was very high.

There was no compound-related effect on body weight, feed consumption, urinalysis,

clinical chemistry, or histological findings. Absolute liver weights were slightly, but significantly, increased in high dose males; in the absence of body weight changes, liver specific enzyme changes, or histopathology this effect was not considered toxicologically significant. No treatment-associated clinical signs were reported, but the clinical observations were not included in the report.

Based on the results of this study, the LOEL for RBC and plasma cholinesterase inhibition was established at 0.03 mg/kg/day; the NOEL for cholinesterase inhibition was not established. The LOEL for brain cholinesterase inhibition was established at $\geq$ 0.3 mg/kg/day, the NOEL was established at 0.3 mg/kg/day. For systemic effects, the LOEL was $\geq$ 0.3 mg/kg/day, the NOEL was 0.3 mg/kg/day.

This study was classified as Unacceptable and does not satisfy guideline requirements by itself, but was upgraded to acceptable upon submission of the 90-day dog bridging study.

In a subchronic bridging study in dogs (MRID No. 413354-01), Beagle dogs (8/sex/group, 4 of which were sacrificed after a 4-week recovery period) were treated with methyl parathion (purity 94.9%) in the diet at 0, 0.03, 0.3, or 3.0 mg/kg/day for 13 weeks. Two high dose males exhibited emaciation, dehydration, and thin appearance from study weeks 11-13, one low-dose male appeared thin from weeks 9-13 and throughout recovery period. Mean body weight gains of high dose males and females were depressed throughout dosing period (31% of control for males, 66% of control for females), with no change in food consumption. No treatment-related effects were seen in the ophthalmological examinations or ocular histopathology.

Plasma and erythrocyte cholinesterase were depressed in high dose males and females at weeks 6 and 13 (the decrease was significant except for males (erythrocyte) at week 13), but not at week 17 (recovery). Plasma cholinesterase inhibition ranged from 47-59%, erythrocyte inhibition ranged from 18-23%. Brain cholinesterase (pons and cerebellum) was significantly inhibited in high dose males and females at week 13 (43-55% inhibition), but not at week 17 (recovery).

Based on the results of this study (decrease in weight gain), the systemic LOEL was established at 3.0 mg/kg/day; the systemic NOEL was established at 0.3 mg/kg/day. For cholinesterase inhibition (brain, plasma, and erythrocyte), the LOEL was 3.0 mg/kg/day, the NOEL was 0.3 mg/kg/day.

This study is classified as Acceptable and does not satisfy guideline requirements for a subchronic study in dogs. This study includes bridging data which allow the classification of the 1 year chronic feeding study in dogs to be upgraded to Acceptable (Guideline 83-1).

An additional non-guideline, chronic dog study was submitted during the comment period (MRID 44674201). Methyl parathion (purity 96.5%) was administered to dogs in the diet at 0.3, 1.0, 3.0, 3.5, or 4.5 mg/kg/day for up to one year. Preliminary review indicates the results of this study will not change the risk assessment.

Chronic toxicity/carcinogenicity in rats

In a chronic toxicity/carcinogenicity study in rats (Accession Nos. 257513, 257514), Methyl parathion (purity 94.8%) was administered to Wistar rats (50/sex/group for treatment groups, 100/sex/group for controls) at doses of 0, 2, 10, or 50 ppm (approximately 0.09, 0.46, 2.6 mg/kg/day for males, 0.14, 0.71, and 4.97 mg/kg/day for females, respectively) for 2 years. Interim sacrifices of an additional 10 animals/sex/group were performed at 6 and 12 months.

Cholinergic symptoms were observed in some high dose animals, and 9 animals in the high dose group (3M, 6F) died in the first two weeks of the study. Body weights were significantly decreased in high dose animals only, food consumption was increased in high dose females. Hemoglobin and hematocrit were slightly but significantly decreased in high dose males and females at 24 months; reticulocyte counts were significantly increased in high dose males and females at 6 months and in high dose females at 24 months. Urinary protein was increased in 50 ppm females (significantly at 1 and 6 months). Serum protein was significantly decreased in high dose females at all time points. Brain cholinesterase was significantly decreased in both sexes at 50 ppm (37% of control for females, 50% of control for males), and in males at 10 ppm (78% of control). Erythrocyte cholinesterase was significantly decreased at all time points, both sexes, at 50 ppm (58-79% of control), all time points except week 1, both sexes, at 10 ppm (73-83% of control), and sporadically at 2 ppm (week 13 for females only, week 52 for both sexes; 83-89% of controls). Plasma cholinesterase was significantly decreased at all time points, both sexes at 50 ppm (9-41% of controls) and sporadically in both sexes at 10 ppm (61-111% of controls).

Significant decreases in organ weight at 2 years in the high dose group (heart, lung, liver, spleen, kidney for males and females, adrenal for males only) were probably due to decreases in body weight; relative organ/body weight ratios did not vary among groups. Slight increases in incidences of thyroid adenomas, pituitary adenomas, Leydig cell tumors, and uterine adenocarcinomas were found not to be biologically significant. Non-neoplastic lesions included an increase in PAS-positive material in cortical tubules of the kidney in 2 and 10 ppm groups only, and an increase in ORO-positive material in hepatocytoplasm of 10 ppm and 50 ppm males.

Based on the results of this study (liver histopathology), the LOEL for systemic effects was established at 10 ppm (0.46 mg/kg/day for males, 0.71 mg/kg/day in females); the NOEL was established at 2 ppm (0.09 mg/kg/day for males, 0.14 mg/kg/day for females). There was no indication that methyl parathion induced neoplastic lesions. For cholinesterase inhibition (brain, plasma and RBC in both sexes), the LOEL was established at 10 ppm (0.46 mg/kg/day for males, 0.71 mg/kg/day in females); the NOEL was established at 2 ppm (0.09 mg/kg/day for males, 0.14 mg/kg/day for females).

This study is classified as Acceptable for carcinogenicity ([Guideline 83-2] classification upgraded following submission of supplementary information) and Unacceptable for chronic toxicity (due to inadequate presentation of clinical data, lack of ophthalmic observations, insufficient numbers of animals used for clinical laboratory studies and cholinesterase determinations, and other deficiencies).

In a second chronic toxicity/carcinogenicity study in rats (Acc. No. 252501, 252502, 252503, 253346, 253372, 253373, 253374), Methyl Parathion (purity 93.7%) was administered to Sprague Dawley rats (60/sex/group) at 0, 0.5, 5, and 50 ppm in the diet (mean compound intake approximately 0, 0.02, 0.21, and 2.21 mg/kg/day for males and 0, 0.03, 0.29, and 3.34 for females) for 26 (males) or 28 (females) months.

Effects seen at the 5.0 ppm dose were abnormal gait in one female, significant decreases in hematocrit and erythrocyte levels in males at 24 months, slight decreases in erythrocyte cholinesterase activity in both sexes (+4.4 to -11.3% inhibition). Additional effects seen at 50 ppm were significant decreases in hemoglobin, hematocrit, and erythrocyte levels in females (at all time points), significant decreases in activity of plasma (67-89% inhibition), erythrocyte (0-20% inhibition), and brain cholinesterase (76-79% inhibition) at multiple time points (males and females), increased incidence of alopecia (more pronounced in females), bilateral retinal degeneration and posterior subcapsular cataract (females only, at 24 months), decreased mean body weight and increased food consumption (both sexes), irritability (both sexes), tremors (largely in females), increased incidence of ano-genital staining, decreased incidence of chromodacryorrhea, and soft stools. There was also a slight apparent increase in survival in 50 ppm females.

Neurological changes (in particular sciatic nerve degeneration) were most pronounced in animals receiving 50 ppm, but lesions in low and mid-dose males were slightly more severe than those seen in control animals.

No oncogenic effects were seen at 50 ppm (highest dose) in either sex. Doses were considered adequate to test for carcinogenicity.

The LOEL for neurological effects in this study, based on increases in lesion severity (sciatic nerve degeneration, males) was established at 5.0 ppm (0.21 mg/kg/day in males, 0.29 mg/kg/day in females); the NOEL was established at 0.5 ppm (0.02 mg/kg/day for males, 0.03 mg/kg/day for females). Based on other effects seen in this study (decreased hematocrit and erythrocyte levels), the systemic LOEL was established at 5.0 ppm (0.21 mg/kg/day in males, 0.29 mg/kg/day in females); the NOEL was established at 0.5 ppm (0.02 mg/kg/day in males, 0.03 mg/kg/day in females). The LOEL for cholinesterase inhibition (decreased erythrocyte cholinesterase activity in both sexes) was established at 5.0 ppm (0.21 mg/kg/day in males, 0.29 mg/kg/day in females); the NOEL was established at 0.5 ppm (0.02

mg/kg/day in males, 0.03 mg/kg/day in females).

This study [Guideline 83-2] is classified as Acceptable for oncogenicity and Acceptable for chronic toxicity.

Chronic toxicity/carcinogenicity in mice

In a chronic toxicity/carcinogenicity study in mice (MRID No. 42216401), Methyl parathion (purity 95.5%) was administered in diet to mice (50/sex/group in main 2 year study, 15/sex/group in the 12 month satellite study) at levels of 0, 1, 7, and 50 ppm (mean intakes of 0, 0.2, 1.6, and 9.2 mg/kg/day in males; 0, 0.3, 2.1, and 13.7 mg/kg/day in females) for 2 years.

There was no dose-related difference in survival among groups. Body weights were significantly increased in the high dose groups of both sexes (107-119% of control), overall food consumption was decreased in these groups. No treatment-related effect was found on hematology parameters; serum cholesterol levels were significantly increased in 50 ppm males at 12 months and in 7 and 50 ppm females at 24 months. Plasma cholinesterase was significantly decreased at 50 ppm in both males (71-75% inhibited) and females (62-65% inhibited) at 12 and 24 months; erythrocyte and brain cholinesterase were significantly decreased for 7 and 50 ppm groups in both males and females at 12 and 24 months (erythrocyte ChE: 41-57% inhibited at 7 ppm, 76-89% inhibited at 50 ppm; brain ChE: 0.6-37% inhibited at 7 ppm; 46-85% inhibited at 50 ppm).

Slight increases in absolute liver and kidney weights were seen at 12 or 24 month sacrifices, high dose males and females only. An increase in adipose tissue was also found in high dose males and females at study termination. Histopathological examination found no neoplastic or nonneoplastic changes related to treatment in either sex (non-neoplastic findings were attributed to age).

Based on the results of this study, the LOEL for systemic effects was established at 7 ppm (increased serum cholesterol levels in females) (1.6 mg/kg/day for males, 2.1 mg/kg/day for females), and the systemic NOEL was established at 1 ppm (0.2 mg/kg/day for males, 0.3 mg/kg/day for females). The LOEL for cholinesterase inhibition (brain and erythrocyte cholinesterase inhibition) was established at 7 ppm (1.6 mg/kg/day in males, 2.1 mg/kg/day in females); the NOEL was established at 1 ppm (0.2 mg/kg/day in males, 0.3 mg/kg/day in females). There was no treatment-related increase in tumors in either sex.

This guideline [83-2] carcinogenicity study in mice is classified as Acceptable.

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d. Developmental Toxicity

Available developmental toxicity studies are adequate to satisfy guideline requirements, however the Committee determined the need for a developmental neurotoxicity study (see below).

Developmental toxicity in rats

In a developmental study in rats (MRID No. 41136101), Methyl parathion (purity 97%) at 0, 0.3, 1.0, and 3.0 mg/kg/day was administered by oral gavage (in water mixed with Cremophor EL) to female pregnant Wistar/HAN rats (25/group, main group) from days 6 through 15 of gestation. An additional 10 rats (subgroup) at 0 and 3.0 mg/kg/day were similarly treated and sacrificed on day 16 of gestation for determination of plasma, erythrocyte, and brain cholinesterase inhibition.

Signs of maternal toxicity were seen in high dose only, including mortality (5 maternal deaths), decreased body weight, body weight gain, and food consumption, and increased clinical signs. In the 3.0 mg/kg/day subgroup, plasma, red blood cell, and brain cholinesterase activities were significantly decreased (59%, 29%, and 78% of control levels, respectively); cholinesterase inhibition was not measured in lower dose groups or in fetal tissue.

Developmental toxicity was also seen only in the high dose group: increased post-implantation loss and embryonic resorptions, decreased group mean fetal body weight and litter mean body weight, and an increase in delayed ossification.

Based on the results of this study (decreased maternal weight gain and clinical signs), the maternal LOEL was established at 3.0 mg/kg/day, the maternal NOEL was 1.0 mg/kg/day; the developmental LOEL (based on increased post-implantation loss, embryonic resorptions, and decreased fetal weight) was established at 3.0 mg/kg/day, the developmental NOEL was established at 1.0 mg/kg/day. Cholinesterase inhibition was demonstrated at 3.0 mg/kg/day, but was not measured at lower doses, so no NOEL for that effect can be established.

This study is classified as Acceptable-Guideline [83-3].

Developmental toxicity in rabbits

In a developmental toxicity study in rabbits (MRID No. unknown), Methyl parathion (purity 95.7%) was administered orally, by gavage, to 15 mated female Himalayan rabbits (strain CHBB:HM), on days 6-18 of gestation at 0, 0.3, 1.0, and 3.0 mg/kg. The study was terminated on day 29.

No toxic signs or changes in maternal weight gain related to treatment were observed in the dams during gestation. Fetal and placental weights were comparable across treatment groups. No treatment-related effects on any measured parameter were observed in the fetuses.

Supplementary data (MRID No. 41046101) subsequently documented inhibition of plasma and RBC cholinesterase on gestation day 14 (9.3% and 24.8% inhibited, respectively) and gestation day 19 (12.5% and 19.5% inhibited, respectively) in mated females at the 3.0 mg/kg/day dose (statistically significant in RBC, only). Brain cholinesterase was not inhibited in any treatment group (112% of control on day 19 for 3.0 mg/kg/day dose group).

Based on the results of this study, the maternal LOEL for cholinesterase inhibition (plasma and RBC cholinesterase inhibition) was established at 3.0 mg/kg/day; the NOEL was established at 1.0 mg/kg. The developmental LOEL was >3.0 mg/kg/day, with a NOEL of 3.0 mg/kg/day. Maternal systemic NOEL was >3.0 mg/kg/day.

This study was classified as Acceptable-Guideline [83-3].

An additional guideline developmental study in rabbits was submitted during the comment period (MRID 44691004). Methyl parathion (purity 95.7%) was administered by gavage at doses of 0, 0.3, 3, or 9 mg/kg to artificially inseminated rabbits on gestation days 6-18. Preliminary review indicates that no developmental effects were seen at any dose. In does, RBC cholinesterase inhibition was seen at all doses, and plasma cholinesterase inhibition was seen at 9 mg/kg (measured in does at 2 h post-dosing on gestation day 18). Cholinesterase inhibition was not measured in pups. Preliminary review indicates that the results of this study will not change the risk assessment.

e. Reproductive Toxicity

Available studies are adequate to satisfy the guideline requirements for reproductive toxicity testing, but the Committee determined the need for developmental neurotoxicity testing (see below).

Reproductive toxicity in rats

In a two-generation reproduction study in rats (MRID No. 00119087), Methyl parathion (purity 93.7%) was administered in the diet at 0, 0.5, 5.0, and 25 ppm to CD rats (30 females and 15 males per dose group) (mean compound intake approximately 0.04, 0.38, 2.0 mg/kg/day for males, 0.04, 0.44, and 2.3 mg/kg/day for females, respectively). Treatment was begun at age 6 weeks for F0 rats and continued throughout mating/gestation, and lactation. F0 rats were sacrificed at weaning of F1, at which time

the F1 parental rats were selected (remaining F1 weanlings were sacrificed) and treatment was continued throughout growth, mating/gestation, and lactation. F1 parents were sacrificed 30 days after weaning of F2 pups, and F2 pups were sacrificed at weaning.

No treatment-related histopathological effects were found, nor were there any significant effects on reproductive parameters, except for maternal weight gain during lactation. Body weight gain of F0 and F1 females was significantly decreased during lactation, for the 25 ppm group only (gain was 19 g for control; at 25 ppm gain was -3 g for F0, and -7 g for F1). Body weight of F1 females receiving 25 ppm methyl parathion was significantly lower than that of control females for approximately 2 months post-weaning (89-93% of control), while food intake was consistently increased (107-121% of control; significantly increased on multiple occasions) during that same period. At the start of gestation, body weight was no longer significantly depressed, but maternal weight gain during lactation was significantly decreased for the 25 ppm treatment group only, starting on lactation day 14. In addition, there was a significant decrease in survival of F2 pups in the 25 ppm treatment group, from postnatal day 0 to postnatal day 4.

Based on the results of this study, the LOEL for reproductive and developmental effects (decreased pup survival) was established at 25 ppm (2.0 mg/kg/day for males, 2.3 mg/kg/day for females); the NOEL was established at 5 ppm (0.38 mg/kg/day for males, 0.44 mg/kg/day for females). The LOEL for parental (systemic) toxicity (decreased body weight gains during lactation and post-weaning) was established at 25 ppm (2.0 mg/kg/day for males, 2.3 mg/kg/day for females); the NOEL was established at 5 ppm (0.38 mg/kg/day for males, 0.44 mg/kg/day for females). Cholinesterase inhibition was not measured in this study.

This study is classified as Acceptable-Guideline [83-4].

f. Mutagenicity

Seven studies sponsored by the USEPA under contract Nos. 68-02-2947 or EPA-600/1-7-028 were available for review. Summaries of the acceptable studies (with MRID/Accession and/or Document Control Numbers) follow:

Gene Mutations

1) Salmonella typhimurium reverse gene mutation assay (MRID No. 00124901; Doc. No. 005095): The test is negative in S. typhimurium strains TA1535, TA1537, TA1538 and TA100 up to 1000 µg/plate +/-S9, the highest dose tested (HDT). Due to the lack of cytotoxicity at the HDT and other technical deficiencies, the study was classified as Unacceptable. However, the standard protocol used in this assay required testing up

to 10,000 µg/plate +/-S9, unless solubility or cytotoxic prevent testing up to this level. The Committee, therefore, concluded that methyl parathion was assayed up to an appropriate high dose and found to be negative. It was further concluded that the assay should be upgraded.

2) Escherichia coli reverse gene mutation assay (MRID No. 00124901; Doc. No. 005095): The test is negative in E. coli WP2 up to the HDT (1000 µg/plate +/-S9). Due to the lack of cytotoxicity at the HDT and other technical deficiencies, the study was classified as Unacceptable. For reasons similar to those stated above, the Committee concluded that the assay should be upgraded.

3) Saccharomyces cerevisiae D7 reverse gene mutation, mitotic gene conversion and mitotic crossing-over assay (MRID No. 00132949; Doc. No. 005095): Independent test are negative at all three endpoints up to severely cytotoxic levels (≥1.0% +/-S9, equivalent to ≈10,000 µg/mL).

4) L5178Y TK $^{+/-}$ mouse lymphoma cell forward gene mutation assay (MRID No. not available; Doc. No. 005095/005588): Confirmed positive; dose-related mutagenic effects at 80-200 µg/mL with S9 activation. Positive responses were also seen in the absence of S9 activation; however, the effect was not clearly dose-related and reproducible increases in the mutation frequency were only seen at ≥150 µg/mL. (Colony sizing was not performed).

Chromosome Aberrations

5) Mouse Dominant lethal assay (MRID No. 00124901; Doc. Nos. 005095/005588): The test is negative in the germinal cells of male ICR/SIM mice receiving dietary administrations of 0, 20, 40 or 80 ppm methyl parathion for 7 weeks. No overt toxicity or cytotoxicity to the target organ occurred at the HDT. It was noted, however, that body weight reductions (4-20%) were seen at all weeks in males mice receiving dietary levels of 10, 30 or 60 ppm methyl parathion in the subchronic mouse study conducted with methyl parathion (MRID No. 00072513). Based on these findings, the Committee concluded that dosing was adequate in the dominant lethal assay.

Other mutagenic mechanisms

6) In vitro sister chromatid exchange (SCE) in Chinese hamster ovary cell assay (MRID No. not available; Doc. No. 005095/005588): The test is positive in the presence of S9 activation; dose related increases in SCEs were obtained at 50-200 µg/mL. Without S9 activation the test is negative up to cytotoxic levels (≥40 µg/mL).

7) Unscheduled DNA synthesis in cultured human fibroblasts (WI-38) assay (MRID No. 00124901; Doc. No. 005095/005588): The test is negative up to a precipitating dose

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(10^{-3} M +/- S9).

Conclusions

In vitro, methyl parathion was negative for gene mutations in S. typhimurium, E. coli and S. cerevisiae. It also did not cause mitotic recombination or gene conversion in S. cerevisiae or DNA damage in a human cell line. Gene mutations and SCE were, however, induced in cultured mammalian cells and the effect was more clearly demonstrated in the presence of S9 activation. The only acceptable in vivo study in the Agency's files indicated that methyl parathion was not active in the mouse dominant lethal assay. Nevertheless, positive dose-related increases in micronuclei induction have been reported in the literature in mice receiving methyl parathion orally (Mathew et al., 1990) and in rats following intraperitoneal injection (Grover and Malhi, 1985). Structural chromosome aberrations have also been reported in bone marrow cells harvested from treated rats (Malhi and Grover 1987).

The relevance of the positive findings from both the in vitro and in vivo mutagenicity studies is not clear in light of the negative cancer studies and the lack of an effect in germinal cells in the dominant lethal assay. The Committee concluded, therefore, that nothing further would be gained by requiring additional testing. Based on these deliberations, the available acceptable studies satisfies the Pre-1991 mutagenicity initial testing battery guidelines. No further testing is required at this time.

g. Metabolism

In a metabolism study in rats (MRID No. 41001407), Methyl parathion (U-^{14}C-phenyl-labeled) was administered orally to male and female rats in order to follow the absorption, distribution, excretion and metabolism of the radio-labeled molecule after single oral administration of the test material at 2 dose levels and after repeated oral (14x) pre-treatment using the non-radioactive test material followed by single oral administration of the ^{14}C-labeled material.

The data showed that a large proportion of the administered radioactivity was absorbed from the gastro-intestinal tract and excreted in the urine. Within 8 hours, 61.8 to 94% of the radioactivity was excreted in the urine of male and female rats. After 48 hours the corresponding values were 75.7 to 99.2% and, at this interval, 3.2 to 9.3 of the administered radioactivity was excreted in feces. Only negligible amounts of administered radioactivity was found in organs, tissues, blood (<0.1-1.0%) and expired air (<0.01%). Total average recoveries for both sexes ranged from 95.6 to 104.2%.

Repeated oral (14x) administration of non-labeled methyl parathion had no apparent effect on the rate of absorption and excretion of the ^{14}C-labeled material or on the levels of residual radioactivity in organs/tissues and blood.

Similar metabolic patterns were found in urine and feces regardless of the dose of test

material administered.

Seven metabolites were detected in urine, 5 of which were characterized. The characterized metabolites represented up to 94.7% of the radioactivity recovered in urine. The two major urinary metabolites were the sulphate conjugate of para-nitrophenol (60.6 to 79.3% of urinary radioactivity) and the glucuronide conjugate of para-nitro-phenol (up to 15% of urinary radioactivity). Three minor metabolites detected were para-nitrophenol, P-O-desmethyl-paraoxon-methyl and P-O-desmethyl-parathion-methyl; small amounts of the latter 2 metabolites ere also found in feces. Although only 2 of the 6 metabolites detected in fecal extracts were characterized, the total radioactivity recovered in feces was quite low (1.0 to 4.2% of administered dose). The parent compound was not detected in either urine or feces.

Core classification: minimum.

h. Neurotoxicity

Available neurotoxicity studies were adequate to satisfy the guideline requirements, however the Committee determined the need for a developmental neurotoxicity study (see below).

Acute neurotoxicity in hens

In an acute delayed neurotoxicity study in hens (MRID No. 41606801), Methyl parathion (purity 95.8%) was administered to hens (10/group, followed by an additional 6 in the methyl parathion group, because of high mortality in the initial dose group) via oral intubation, one acute dose of 0 or 250 mg/kg, redosed at 0 or 215 mg/kg on day 21 (intra-muscular atropine sulfate was administered concurrently, as needed). TOCP at 600 mg/kg was the positive control.

A total of 6 (out of 16) hens died following the first dose of methyl parathion; 2 additional deaths followed the second dose. Cholinergic signs (including lethargy, loss of coordination, salivation, shallow and rapid respiration) were seen for up to 8 days following the first dose and 6 days following the second dose. One hen displayed left leg stiffness after the second dose until study termination; other birds were normal after acute signs had resolved. No signs of ataxia typical of delayed neurotoxic effects were seen in control or methyl parathion-treated birds after either dose, nor were neural degenerative changes were observed histologically. TOCP-treated birds displayed behavior and histopathological changes typical of delayed peripheral neuropathy.

Based on the results of this study the NOEL for acute delayed neurotoxicity in laying hen was established at 215 mg/kg. A NOEL for systemic toxicity was not established.

The initial study report did not include verification of concentration of dosing solutions, and so the study was initially rated supplementary. After dose verification data was

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received, the study was upgraded to Core-minimum [Guideline 81-7].

In their memo of July 7, 1998, the Committee requested submission of a confirmatory NTE study for methyl parathion, since NTE inhibition was not measured in the above study. During the comment period, registrant submitted a literature reference (Ohkawa, H., H. Oshita, and J. Miyamoto, 1980) that included an evaluation of NTE inhibition by methyl parathion. Hens were evaluated for acetylcholinesterase and NTE inhibition (in the brain) 2 days after oral dosing with 100 mg/kg methyl parathion. Acetylcholinesterase was found to be 85% inhibited, while NTE inhibition was only 12%. The submitted data, taken together with the negative hen study, are sufficient to demonstrate that methyl parathion does not cause acute delayed neuropathy. A confirmatory NTE study will not be required.

Acute neurotoxicity in rats

In an acute neurotoxicity study (MRID No.: 43254401), male and female Sprague-Dawley rats (10 animals/sex/group) were orally gavaged once with methyl parathion at doses of 0, 0.025, 7.5, 10 (males only), or 15 (females only) mg/kg.

Neurobehavioral evaluation revealed treatment-related FOB and motor activity findings at the mid- and high-dose levels (lacrimation, salivation, miosis, tremors/convulsions, muscle fasciculations, muscle weakness, and ataxia).

Neuropathological findings consisted of focal demyelination in the dorsal root fibers of the cervical spine in 3/6 high-dose males and lumbar spine in 3/6 low-, 4/6 mid- and 5/6 high-dose males. Focal demyelination was also observed in the ventral root fibers of the cervical spine in 2/6 high-dose males and of the lumbar spine in control (males, 2/6; females, 1/6), low- (males, 3/6), mid- (males, 4/6), and high- (males, 4/6; females, 3/6) dose groups. Focal demyelination of the lumbar spinal cord and spinal nerve were observed in high-dose males; the incidence of each of these observations was only 1/6. Focal demyelination was observed in the tibial nerves of 1/6 mid- and 3/6 high-dose males and in the sural nerves of 2/6 high-dose males.

In summary, systemic toxicity was observed in high-dose males (decreased body weight gain) and females (increased incidence of clinical signs). Neurotoxic effects (abnormal FOB findings, decreased motor activity, inhibition ChEase activities, and neuro-pathological findings) were observed in mid- and high-dose males and females.

Based on the results of this study, the systemic LOEL was 10 mg/kg (males) and 15 mg/kg (females); the systemic NOEL was 7.5 mg/kg. In males and females, the LOEL for neurotoxicity was 7.5 mg/kg; the NOEL for neurotoxicity was 0.025 mg/kg.

This study is classified as Core-Guideline and satisfies guideline requirements (81-8)

for an acute neurotoxicity screening battery in the rat.

Subchronic neurotoxicity in rats

In a subchronic neurotoxicity screening battery (MRID No. 43490501), methyl parathion was administered to groups of Crl:CD BR (Sprague-Dawley) male and female rats for 13 weeks at dietary concentrations of 9 (basal diet), 0.5, 5 or 50 ppm (equivalent to 0, 0.029, 0.295, or 3.02 mg/kg/day, males; 0, 0.037, 0.365, or 3.96 mg/kg/day, females).

No treatment-related differences were noted in motor activity or the incidence of gross and neuropathological lesions at any dose level. No treatment-related effects were observed at 0.5 ppm.

At 5 ppm, inhibition in RBC ChE activities in males (-19 to -33%) at weeks 4, 8, and 14 and in females (-23 to -24%) were observed at weeks 8 and 14.

At 50 ppm, females showed significant decreases in mean body weights (-6.6 to -11.4%) during weeks 2 to 6 and a significant decrease (-13.5%) in mean body weight gain for weeks 1 to 13. FOB findings consisted of tremors in females at weeks 4 and 8, partial (absent) pupillary response in males and females during the week 4 evaluation, slow pupillary constriction in males and females during weeks 8 and 13, and significant decreases in hindlimb grip strength in females at weeks 4 and 13. Plasma (-61 to -66%, males; -80 to -35%, females), RBC (-52 to -66%, males; -55 to -64%, females) and regional brain (-38 to -75%, males; -66 to -93%, females) ChE activities were all inhibited. During the treatment-free recovery period, plasma ChE showed complete recovery in males and females. RBC ChE and regional brain (excluding cerebral cortex and cerebellum in males, which showed nearly complete recovery) ChE activities in males and females showed partial recovery but were still significantly lower than concurrent control values.

Based on the results of this study (inhibition of RBC ChE), the LOEL was established at 5 ppm (0.295 mg/kg/day, males, 0.365 mg/kg/day, females); the NOEL was established at 0.5 ppm (0.029 mg/kg/day, males; 0.037 mg/kg/day, females).

This study is classified as Acceptable and satisfies guideline requirements (section 82-7) for a subchronic neurotoxicity screening battery in the rat.

Chronic neurotoxicity in rats

In a twelve month oral neurotoxicity study in rat (MRID No. 41853801, 44204501), Methyl parathion (purity 94.6%) was administered to Sprague Dawley rats (70/sex/group; 50 primarily for neuropathology, 20 primarily for ocular effects) in feed at 0, 0.5, 2.5, 12.5, and 50 ppm (daily intake was 0, 0.02, 0.107, 0.533, and 2.207 mg/kg/day for males, 0, 0.026, 0.138, 0.697, and 3.088 mg/kg/day for females).

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No ocular effects were seen at any dose level.

Compound-associated clinical signs (e.g. aggressiveness, tremors, abnormal gait, decreased body weight and body weight gain, increased food consumption, etc.) were seen at 50 ppm dose only. Plasma, erythrocyte, and brain cholinesterase activity were significantly decreased in males and females at 12.5 ppm and 50 ppm doses (at various time points). For erythrocyte cholinesterase, inhibition ranged from 3-13% at 12.5 ppm, 13-20% at 50 ppm; for plasma cholinesterase, inhibition ranged from 25-36% at 12.5 ppm, 52-79% at 50 ppm; for brain cholinesterase, inhibition ranged from 4-25% at 12.5 ppm, 57-75% at 50 ppm. Increased neuropathology in the spinal cord (lumbosacral spine, neuronal degeneration) was seen in males and females at 50 ppm dose only. Increased neuropathology in peripheral nerve preparations was seen in both sexes at all doses, however the dose at which the changes are compound-associated or toxicologically relevant was determined to be 12.5 ppm, with a NOEL of 2.5 ppm.

Based on the results of this study, the NOEL for ocular effects was > 50 ppm (2.2 mg/kg/day), the LOEL for systemic effects (decreased body weight, increased food consumption, and clinical signs) was 50 ppm (2.2 mg/kg/day), NOEL was 12.5 ppm (0.53 mg/kg/day). The LOEL for cholinesterase inhibition was 12.5 ppm (0.53 mg/kg/day), with a NOEL of 2.5 ppm (0.11 mg/kg/day); the LOEL for neuropathological effects was 12.5 ppm (0.53 mg/kg/day), with a NOEL of 2.5 ppm (0.11 mg/kg/day).

This study is classified as acceptable and is not a guideline study.

I. Dermal absorption

No study was available. Based on available information, including comparison of toxicity following oral and dermal exposure, dermal absorption was estimated to be 100% (i.e. equivalent toxicity is expected after oral or dermal exposure to a given amount of methyl parathion). This decision was reevaluated and reaffirmed in the HIARC meeting of March 4, 1999 (see HIARC memo of 3/23/99).

j. Reference Dose (RfD) for Chronic Oral Exposure

The Chronic RfD for methyl parathion was established at 0.0002 mg/kg/day, based on systemic toxicity, neuropathology, and RBC cholinesterase inhibition occurring at a LOEL of 0.21 mg/kg/day in the two year chronic rat study (MRID No. 252501-252503). The NOEL of 0.02 mg/kg/day will be used for risk assessment. An uncertainty factor of 100 was applied to account for both interspecies extrapolation and intraspecies variability. An additional Safety Factor of 10, required for the protection of infants and children in accordance with the FQPA, will be retained in addition to the traditional Uncertainty Factor (see discussion below). The Population Adjusted Dose (PAD) was established at 0.00002 mg/kg/day.

Based on the toxicology data available, including two carcinogenicity studies in rats (MRID No. 252501-252503, Accession Nos. 257513, 257514), and one in mice (MRID No. 42216401), the Hazard Identification Committee determined that methyl parathion did not alter the spontaneous tumor profile in rats and mice under the testing conditions. Therefore, it was recommended that methyl parathion be classified as a **"Group E"**, indicating evidence of non-carcinogenicity for humans; i.e., the chemical is characterized as **"Not Likely"** to be carcinogenic in humans via relevant routes of exposure.

k. Uncertainty Factor/FQPA Considerations

The following evaluation of the chemical methyl parathion is provided to address FQPA considerations on the sensitivity of infants and children.

Summary of reproductive and developmental toxicity (see also above):

A two-generation reproduction study was conducted with Sprague-Dawley rats (15 males and 30 females/group) (MRID 00119087; Doc. 005095, 005588) in which methyl parathion (93.65%) was administered in the diet at levels of 0.5, 5, or 25 ppm (0.04, 0.38, or 2.0 mg/kg/day for males and 0.04, 0.44, or 2.3 mg/kg/day for females). The parental (systemic) NOEL was 5 ppm (0.44 mg/kg/day), and the parental LOEL was 25 ppm (2.3 mg/kg/day), based on decreased premating body weight for F1 females and decreased maternal body weight during lactation in females of both generations. No parental reproductive toxicity was observed at any dose level; however, the offspring/developmental NOEL was 5 ppm (0.44 mg/kg/day), based upon decreased pup survival in early lactation and on decreased body weight gain and increased food consumption in the period immediately following weaning. The developmental LOEL was 25 ppm (2.3 mg/kg/day). It was noted that cholinesterase activity was not measured in either adults or offspring in this study. (Daly and Hogan, 1982)

In a prenatal developmental toxicity study in Wistar rats (MRID 41136101; Doc. 008118, 009526), doses of 0.3, 1.0, or 3.0 mg/kg/day methyl parathion (97%) were administered by gavage in a dose volume of 10 ml/kg of 0.5% aqueous Cremophor on gestation days 6-15. Each group consisted of 25 rats; 10 additional rats each were assigned to the control and high-dose groups for maternal cholinesterase measurements. Cesarean section was performed on gestation day 21. The maternal NOEL was 1.0 mg/kg/day, with a maternal LOEL of 3.0 mg/kg/day, based upon increased mortality; adverse clinical signs (somnolence, ataxia, dyspnea, ventral recumbency, and repeated chewing behavior); decreased body weight, body weight gain, and food consumption; and decreased plasma, erythrocyte, and brain cholinesterase activity. The developmental NOEL was also 1.0 mg/kg/day; the developmental LOEL (3.0

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mg/kg/day) was based on increased postimplantation loss (early resorptions), decreased fetal body weight, and increased incidence of delayed ossification (3rd cervical vertebra, proximal phalanx of the 2nd right digit, and 1st metatarsal of both hindlimbs). (Becker et al., 1987)

In a prenatal developmental toxicity study conducted in Himalayan rabbits (15/group) (MRID 259403, 259404, 259405; Doc. 004997, 007614), methyl parathion (95.7%) was administered by gavage in 0.5% aqueous Cremophor at dose levels of 0.3, 1.0, or 3.0 mg/kg/day on days 6-18 of gestation. These dose levels were based upon a previously conducted study with rabbits (MRID 41046101) in which plasma and erythrocyte cholinesterase inhibition was observed at a dose of 3.0 mg/kg/day, and for that reason they were considered adequate, although cholinesterase activity was not measured in this study. No evidence of either maternal or developmental toxicity was observed (NOEL $\geq$3.0 mg/kg/day). (Renhof, 1984)

Additional information submitted by Cheminova during the comment period:

In their response to HED's preliminary risk assessment, Cheminova submitted additional information regarding several toxicity studies relevant to FQPA considerations. HED's assessment of that additional information is summarized below:

An additional guideline developmental study in rabbits was submitted during the comment period (MRID 44691004). Methyl parathion (purity 95.7%) was administered by gavage at doses of 0, 0.3, 3, or 9 mg/kg to artificially inseminated rabbits on gestation days 6-18. Preliminary review indicates that no developmental effects were seen at any dose. In does, RBC cholinesterase inhibition was seen at all doses, and plasma cholinesterase inhibition was seen at 9 mg/kg (measured in does at 2 h post-dosing on gestation day 18). Cholinesterase inhibition was not measured in pups.

An additional non-guideline multi-generation reproduction study in rats was also submitted during the comment period (MRID 44768201). Methyl parathion (purity 95%) was administered to Wistar rats in the diet at 2, 10, or 50 ppm. Administration was continued through three generations, two matings per generation. There was a large decrease in pup survival at 50 ppm, such that no third generation matings could be conducted at that dose. There was a slight, sporadically statistically significant, decrease in pup survival at 10 ppm. No effects were seen at 2 ppm. In addition, although no effects on fertility or gestation were seen, surviving F_{1b} animals receiving 50 ppm suffered occasional convulsions (not noted in F_0 parents at this dose). No F_{2b} pups survived to adult at 50 ppm. Doses used in this study were intermediate to those used in the submitted Guideline reproduction study (see above), and results seen in this study do not conflict with those noted previously. However, the effects seen at 50 ppm in the current study (decreased survival and convulsions) support the request for a developmental neurotoxicity study (see below).

An additional developmental study in rats (MRID 00143747) was also cited by

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Cheminova in their comments. This study has been previously reviewed (HED Doc. No. 005095) and found to be supplementary due to reporting deficiencies. Based on the previous HED review, it was found that maternal toxicity was not established, but that methyl parathion was "embryotoxic or fetotoxic at 1.0 mg/kg, but not at 0.3 mg/kg." Based on the many deficiencies cited in the HED review, we do not consider the study suitable for use in risk assessment, however we note that the results of the earlier review do not support Cheminova's contention that "fetal toxicity (decreased body weight) was evident only in the presence of maternal toxicity."

Additional information from the literature: (Although these studies were not submitted to the Agency by the Registrant in support of registration or reregistration, they can be considered in weight-of-the-evidence determinations for methyl parathion.)

Effects on gestation and morphological development following *in utero* exposure:

Fuchs, V., S. Golbs, M. Kuehnert, and F. Osswald. (1976) Untersuchungen zur praenatal-toxischen wirkung von parathion-methyl an Wistarratten im vergleich zu cyclophosphamid und trypanblau. *Archives of Experimental Veterinary Medicine (Leipzig)* 30(Mai3):343-350.

Methyl parathion (0.1, 1.0, or 3 mg/kg) was administered orally to Wistar rats on gestation days (5-9 and 11-15) or (5-9 and 11-19 [3.0 mg/kg dose only]), at intervals of 2 days. Growth retardation and increased incidence of resorptions were noted in the 3.0 mg/kg dose group, although malformations were not observed. Maternal toxicity (decreased body weight and clinical signs) was also seen at the 3.0 mg/kg dose.

Sunil Kumar, K.B. and K.S. Devi. (1996) Methyl parathion induced teratological study in rats. *Journal of Environmental Biology* 17(1):51-57.

Pregnant inbred Wistar rats (10/group) were administered methyl parathion (98% a.i.) on gestation days 6 through 15 at gavage doses of 0.5, 1, and 1.5 mg/kg/day. The dams were killed on gestation day 20 and fetuses were examined for external and visceral anomalies. At 1.5 mg/kg/day, there was a significant decrease in maternal body weight gain during gestation and clinical signs indicative of cholinesterase inhibition were seen in some dams; at the same dose, an increase in resorptions and a decrease in fetal and placental weight were observed. There was no increase in skeletal or viscera abnormalities; however, a significant increase in the incidence of "hemorrhagic spots" in the brain (ventricles) and upper body were observed in pups from dams treated with 1.5 mg/kg/day methyl parathion.

Assessment of postnatal functional toxicity following prenatal exposure:

Gupta, R.C., R.H. Rech, K.L. Lovell, F. Welsch, and J.E. Thornburg. (1985) Brain Cholinergic, behavioral, and morphological development in rats exposed *in utero* to methyl parathion. *Toxicology and Applied Pharmacology* 77:405-413.

In this study, male Fischer 344 rats were mated to Wistar-Furth females. The dams were administered 0 or 1.0 mg/kg/day of methyl parathion in peanut butter (0.1 g/25 g body weight) as a dietary dose consumed in <2 minutes, or 0 or 1.5 mg/kg/day of methyl parathion by gavage in peanut oil (at a volume of 0.1 ml/50g body weight). Treatment was administered daily from gestation day 6 through 20. The dams were allowed to litter normally, and pups were placed with foster mothers within 24 hours of birth.

At specified intervals (gestation day 19 for dams, postnatal days 1, 7, 14, 21, and 28 for pups), brains were removed, weighed, dissected, and processed for analysis of acetylcholinesterase (AChE) and choline acetyltransferase (CAT) activity and of [^{3}H]quinuclididinyl benzilate (^{3}H-QNB) binding to muscarinic receptors. For pups, frontal cortex and brainstem were collected on postnatal days 1 and 7, while striatum and hippocampus were also obtained on postnatal days 14, 21, and 28. Tissues from two pups per litter were pooled, and the litter was used as the unit of analysis. In addition, morphological analysis (cell counts) of the cornuammonis in the hippocampus (pyramidal cells) and of the cerebellar culmen (granule cells) was performed in 4 control and 4 high-dose pups at 28 days of age.

Behavioral evaluation of the pups was performed as follows: preweaning reflexive behaviors (postnatal days 1-25); startle response (days 1-25 and 4 months); passive avoidance, rotarod performance, and accommodated locomotor activity (2 months); cage emergence (3 months); shuttle box avoidance (4 months); and operant behavior (3-6 months).

The following treatment-related effects were noted in dams: at 1.5 mg/kg/day, clinical signs of toxicity in dams included muscle fasciculations and tremors, decreased maternal body weight gain and increased late resorptions; no clinical signs were seen at 1.0 mg/kg/day. At gestation day 19 (the only time point measured), there was a dose-dependent decrease in AChE activity, an increase in cortical CAT activity, and a reduction in ^{3}H-QNB binding sites (B_{max}) with no alteration of K_D.

On postnatal day 1, litter size, body weight, and pup brain weight were similar between control and treated groups. Prenatal exposure to 1.5 mg/kg/day reduced AChE and increased CAT activity in all brain regions at all

developmental periods (post-natal days 1, 7, 14, 21, and 28). Similar exposure to 1.0 mg/kg/day caused a significant but smaller and less persistent reduction in AChE activity (statistically significant in the frontal cortex only on post-natal day 1, in brainstem on post-natal days 1-21, but not day 28) but no change in brain CAT activity of the offspring. Neither dose level altered the ^{3}H-QNB binding in frontal cortex or striatum on post-natal day 28 (the only time point for which results were reported). Cage emergence, accommodated locomotor activity, and operant behavior in a mixed paradigm were impaired in rats exposed to 1.0 but not to 1.5 mg/kg/day. The reason for the apparent lack of a dose-response relationship for the behavioral parameters was not clear.

Comparison of the neurotoxic response of adults and neonatal or weanling animals:

Benke, G.M. and S.D. Murphy. (1975) The influence of age on the toxicity and metabolism of methyl parathion in male and female rats. *Toxicology and Applied Pharmacology* 31:254-269.

The effects of methyl parathion and methyl paraoxon were studied in male and female Holtzman rats ranging in age as follows: 1, 12-13, 23-24, 35-40, and 56-63 days of age. The test substances were administered by i.p. injection in corn oil at a volume of 1 ml/kg over a range of doses. It was found that there was a gradual decrease in susceptibility to methyl parathion with increasing age for both sexes as measured by the value of the LD50. For methyl parathion, the LD50 ranges from 1 mg/kg at postnatal day 1 to 6-8 mg/kg on postnatal day 56-63. Age differences in susceptibility were not related to differences in sensitivity of cholinesterase to inhibition by methyl paraoxon *in vitro*. LD50 values were calculated for the different ages; in general, changes in LD50 values with age for methyl parathion correlated better with changes in rates of reactions which represented detoxification pathways for methyl paraoxon than for reactions which represented direct metabolism of the parent compound. Both male and female rats became less sensitive to the acute lethal effects of methyl paraoxon with increasing age. This is consistent with a hypothesis that changes in LD50 values of methyl parathion with age are due to changes in rates of metabolism of the oxygen analogs.

Pope, C.N., T.K. Chakraborti, M.L. Chapman, J.D. Farrar, and D. Arthun. (1991) Comparison of in vivo cholinesterase inhibition in neonatal and adult rats by three organophosphorothioate insecticides. *Toxicology* 68:51-61.

The time course of cholinesterase inhibition and recovery in whole brain was compared between neonatal (postnatal day 7) and adult (80-100 days of age) Sprague-Dawley rats after acute treatment (by subcutaneous injection) with maximum tolerated doses of methyl parathion and other organophosphate

pesticides (chlorpyrifos and parathion). The neonates were more sensitive clinically than adults to chlorpyrifos exposure: the MTD for neonates was 7.8 mg/kg s.c., while for adults the MTD was 18 mg/kg s.c. In general, maximal brain ChE inhibition was similar (>78%) in both age groups, but ChE activity recovered faster in neonates. Plasma and RBC ChE activities correlated relatively well with brain ChE activity in neonatal rats at all time points between 4 hours and 7 days posttreatment, but similar correlations between circulating and brain ChE activities in adults were more variable. The study authors concluded that neonatal rats are more sensitive to acute lethality from methyl parathion (and other OP) exposure than are adults, and that MTD exposures produced extensive brain ChE inhibition in both age groups. Following OP exposures, however, significant compound-related and age-related differences in the duration of ChE inhibition can occur.

Pope, C.N. and T.K. Chakraborti. (1992) Dose-related inhibition of brain and plasma cholinesterase in neonatal and adult rats following sublethal organophosphate exposures. *Toxicology* 73:35-43.

Dose-related inhibition of both brain and plasma cholinesterase activity was examined in neonatal and adult rats exposed to methyl parathion and other organophosphate pesticides (chlorpyrifos and parathion) by subcutaneous injection in corn oil at 1-2 ml/kg. It was found that ED_{50} estimates for both brain and plasma cholinesterase correlated highly with previously derived MTD values. The correlation between the extent of brain and plasma cholinesterase inhibition across dose in neonatal rats was high but lower in adults. The study authors concluded that in vivo inhibitory potency, towards either brain or plasma ChE activity, of methyl parathion and the other organophosphate pesticides tested, is highly correlated with sensitivity to acute toxicity in both neonatal and adult rats.

Additional information submitted by World Wildlife Fund during the comment period:

In their comments, World Wildlife Fund (WWF) has submitted a large number of articles in support of their contention that there is evidence indicating that methyl parathion may function as an endocrine disrupter. Two of the articles (Lukaszewica-Hussain, Moniuszko-Jakoniuk, and Pawlowska; and Dhondup and Kaliwal) concerned possible effects in mammals (rats). This issue is discussed more fully in the EFED Chapter.

Recommendation for a developmental neurotoxicity study: The Committee determined that a developmental neurotoxicity study should be required for methyl

parathion. It was further recommended that the protocol should include comparative measurements of cholinesterase inhibition in adults and offspring. The weight-of-evidence used in arriving at this conclusion is presented below:

Evidence that support requiring a developmental neurotoxicity study:

Methyl parathion is a neurotoxic chemical.

- SAR: Methyl parathion is an organophosphate chemical.
- Administration to various species (rat, mouse, dog, rabbit) results in ChE inhibition in the plasma, RBCs, and brain.
- Neurobehavioral effects (e.g., lacrimation, salivation, miosis, tremors, convulsions, muscle fasciculation, muscle weakness, ataxia) were observed in rats in an acute neurotoxicity study at a gavage dose of 7.5 mg/kg. In the subchronic neurotoxicity study, tremors, slow pupillary constriction, and decreased hindlimb grip strength were observed at 50 ppm (3.02/3.96 mg/kg/day in M/F).
- Neuropathological findings observed in the acute neurotoxicity study in rats (at doses of 7.5 mg/kg or higher) included focal demyelination of the dorsal and ventral root fibers of the cervical and lumbar spinal cord and focal demyelination of the sural and tibial nerves. In a one-year neurotoxicity study in rats, neuropathological findings were observed in peripheral nerves and/or spinal cord at doses of 12.5 ppm or higher (0.5 mg/kg/day or higher). In the two-year chronic study in Sprague-Dawley rats, loss of myelinated sciatic nerve fibers and retinal atrophy were observed at 50 ppm (2.5 mg/kg/day); increased severity of sciatic nerve degeneration (in males only) was also seen at 5 ppm (0.3 mg/kg/day).

There is evidence of the developmental neurotoxic potential of Methyl parathion in the open literature. In a study by Gupta, et al. (1985), it was demonstrated that both maternal and fetal neurobiochemical markers are affected by treatment with 1.0 or 1.5 mg/kg/day from gestation days 6-20. Behavioral alterations were detected at 1.0 mg/kg/day only. Although the behavioral alterations detected are difficult to interpret, due to the lack of a dose-response relationship, the changes in neurochemical parameters were dose-related and persistent. In particular, decreases in acetylcholinesterase and increases in choline acetyltransferase seen at 1.5 mg/kg/day (exposure to dams only, during gestation days 6-20) persisted throughout the study period, and remained statistically significantly different from control values 28 days after cessation of exposure.

In studies by Benke and Murphy (1975), Pope et al. (1991), and Pope and Chakraborti (1992), increased sensitivity of young rats to acute effects of methyl parathion, as compared to adults, was observed.

In submitted reproduction studies (MRID 00119087, MRID 44768201) decreased survival of pups was seen at doses causing less severe effects in adults. At 50 ppm (MRID 44768201), convulsions were noted in surviving F_{1b} offspring; no such effects were noted in F_0 adults.

Submitted articles from the open literature (see above) raise the possibility that methyl parathion may disrupt endocrine function.

Evidence that do not support asking for a developmental neurotoxicity study:

Brain weight was increased in the three-month study in mice at 60 ppm (13.5/16.2 mg/kg/day in M/F) and in the two-year chronic study in rats at 50 ppm (2.5 mg/kg/day). These effects were, however, not statistically significant and were not considered to be biologically meaningful. In a study from the open literature (Gupta et al., 1985) it was reported that pup brain weights (Day 1) were not affected following *in utero* exposure to Methyl parathion (gestation days 6-20).

Delayed neuropathy was not observed in the hen.

No evidence of abnormalities in the development of the fetal nervous system was observed in the prenatal developmental toxicity studies in either rats, or rabbits, at maternal gavage doses up to 3.0 mg/kg/day. In the two-generation reproduction study in rats (MRID 00119087), no clinical evidence suggestive of neurotoxicity was observed grossly in pups, which had been administered Methyl parathion *in utero* and during early and late postnatal development, generally mediated by maternal dietary exposure, but also available in the diet to late lactation pups.

FQPA assessment of additional sensitivity for infants and children:

Under the Food Quality Protection Act (FQPA), P.L. 104-170, which was promulgated in 1996 as an amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), the Agency was directed to "ensure that there is a reasonable certainty that no harm will result to infants and children" from aggregate exposure to a pesticide chemical residue. The law further states that in the case of threshold effects, for purposes of providing this reasonable certainty of no harm, "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide residue only if, on the basis of reliable data, such margin will be safe for infants and children."

Pursuant to the language and intent of the FQPA directive regarding infants and

children, the applicable toxicity database for Methyl parathion was evaluated by the Hazard Identification SARC.

Adequacy of data package: The data package included an acceptable two-generation reproduction study in rats and acceptable prenatal developmental toxicity studies in rats and rabbits, meeting the basic data requirements, as defined for a food-use chemical by 40 CFR Part 158. The Committee determined that a developmental neurotoxicity study should be required for methyl parathion.

Susceptibility issues: The submitted guideline study data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to Methyl parathion. In the prenatal developmental toxicity study in rats, developmental toxicity was observed only in the presence of maternal toxicity; the maternal and developmental NOELs and LOELs were equivalent at 1.0 and 3.0 mg/kg/day, respectively. In the prenatal developmental toxicity study in rabbits, neither maternal nor developmental toxicity was observed, although, based upon the results of a previous study in rabbits, the doses were judged to be adequate to elicit plasma and erythrocyte cholinesterase inhibition in the maternal animals. In the two-generation reproduction study in rats, offspring toxicity occurred at the same dose as parental toxicity; the offspring developmental and parental systemic NOELs and LOELs were 5 ppm (0.25 mg/kg/day) and 25 ppm (1.25 mg/kg/day), respectively.

An assessment of the differential response of fetuses versus adults to cholinesterase inhibition following oral administration of Methyl parathion was studied by Gupta, et al. (1985). No indication of additional sensitivity of the offspring was suggested by the data, since offspring effects were noted concurrently with maternal effects. Specifically, it was demonstrated that both maternal and fetal neurobiochemical markers are affected by treatment with 1.0 or 1.5 mg/kg/day from gestation days 6-20, and that neurochemical markers in exposed pups remained significantly different from those of control pups for as long as 28 days after cessation of exposure.

In addition, in studies by Benke and Murphy (1975), Pope et al. (1991), and Pope and Chakraborti (1992), evidence of increased sensitivity of young rats to the effects of methyl parathion, as compared to adults, was reported. Although these studies used non-oral methods of test substance administration, and were conducted at the maximum tolerated dose in order to establish LD50 values, they indicate that there should be a concern for the effects of methyl parathion on young animals. This concern is reinforced by the marginal decrease in survival seen in an additional reproduction study at a dose of 10 ppm; no effects were seen in adults at that dose (MRID 44768201).

Uncertainty factor: The Committee determined that for methyl parathion the 10-fold uncertainty factor for the protection of infants and children is appropriate, based upon the following concerns:

1. The data base for methyl parathion is complete with regard to the standard studies required by 40 CFR Part 158 for a food-use chemical. Acceptable prenatal developmental toxicity studies in rats and rabbits, and an acceptable multigeneration reproduction study in rats have been received by the Agency. Delayed neuropathy was not observed in a study in hens. A single-dose acute neurotoxicity study in rats demonstrated neuropathology in males at 7.5 mg/kg; more severe effects were seen in males at 10 mg/kg and in females at 15 mg/kg. Neuropathology was also seen in the one year neurotoxicity study in rats at doses of 0.53 mg/kg/day and above, and increased severity of neuropathological lesions was seen in a two-year chronic toxicity study in rats at doses of 0.2 mg/kg/day and above. There was evidence of the developmental neurotoxic potential of Methyl parathion in the open literature (Gupta et al., 1985); in this study, alterations in neurochemical markers of pups persisted for at least 28 days following *in utero* exposure. A developmental neurotoxicity study is required with methyl parathion; in the absence of this study, substantial uncertainties remain regarding the effect of methyl parathion on functional development.
2. Although differential sensitivity to young animals was not revealed in standard prenatal developmental and multigeneration reproductive toxicity studies, qualitative evidence of increased sensitivity to perinatal rats has been identified in the open literature. In these studies, a) lethality at doses at or near the maximum tolerated dose and b) cholinesterase inhibition were used as biomarkers of sensitivity. Methyl parathion was administered to the rats in these studies by subcutaneous injection (Pope et al., 1991; Pope and Chakraborti, 1992), intraperitoneal injection (Benke and Murphy, 1975), or oral (Gupta, 1985) routes. This evidence of increased sensitivity to the offspring cannot be quantified.

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Pope, C.N. and T.K. Chakraborti. (1992) Dose-related inhibition of brain and plasma cholinesterase in neonatal and adult rats following sublethal organophosphate exposures. *Toxicology* 73:35-43.

Sunil Kumar, K.B. and K.S. Devi. (1996) Methyl parathion induced teratological study in rats. *Journal of Environmental Biology* 17(1):51-57.

I. Toxicity End-Point Selection

1. DERMAL ABSORPTION FACTOR

No study was available. Based on available information, including comparison of toxicity following oral and dermal exposure, dermal absorption was estimated to be 100% (i.e. equivalent toxicity is expected after oral or dermal exposure to a given amount of methyl parathion). This decision was reevaluated and reaffirmed in the HIARC meeting of March 4, 1999 (see HIARC memo of 3/23/99).

2. REFERENCE DOSE FOR ACUTE EXPOSURE (ONE DAY)

For acute dietary exposure, the one year rat neurotoxicity study (MRID No.: 41853801, 44204501) was selected, based on neuropathology and cholinesterase inhibition occurring at a LOEL of 0.53 mg/kg/day. The NOEL of 0.11 mg/kg/day will be used for

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risk assessment. An UF of 100 will be used, resulting in an acute dietary RfD of 0.0011 mg/kg/day. An additional Safety Factor of 10, required for the protection of infants and children in accordance with the FQPA, will be retained in addition to the traditional Uncertainty Factor. The Population Adjusted Dose (PAD) was established at 0.00011 mg/kg/day.

Previously, the HIARC had selected the acute oral neurotoxicity study for use in acute dietary risk assessment (HIARC Report, 12/1/97). Effects seen at 7.5 mg/kg (the mid-dose) in this study included cholinesterase inhibition, changes in functional observation battery and motor activity, and neuropathology. Therefore, the NOAEL from this study was set at 0.025 mg/kg (the low dose). Because the mid and low doses used in this study differed by a factor of 300, the registrant requested reconsideration of this endpoint, and suggested several possible alternatives.

On March 4, 1999, the Committee evaluated available data for methyl parathion, and concluded the only appropriate study demonstrating a higher NOAEL for the endpoints measured in the acute neurotoxicity study was the special one year chronic neurotoxicity study. The study included a dose intermediate between the LOAEL and NOAEL of the guideline subchronic neurotoxicity study (0.295 and 0.029 mg/kg/day, respectively, based on red blood cell cholinesterase inhibition), and critical endpoints identified in the acute oral neurotoxicity study (cholinesterase inhibition and neuropathology) were evaluated. The Committee felt that use of this study for acute dietary risk assessment would not underestimate the risk for that type of exposure, due to the longer duration of the selected study (one year vs. a single exposure) and the evaluation of the critical effects (cholinesterase inhibition and neuropathology). The Committee felt that use of a NOEL from a long term (one year) study would be protective for a single exposure.

3. SHORT TERM OCCUPATION EXPOSURE (1 TO 7 DAYS)

For short term occupational or residential exposure, the one year rat neurotoxicity study (MRID No.: 41853801, 44204501) was selected, based on neuropathology and cholinesterase inhibition occurring at a LOEL of 0.53 mg/kg/day. The NOEL of 0.11 mg/kg/day will be used for risk assessment. An UF of 100 will be used.

4. INTERMEDIATE TERM OCCUPATIONAL EXPOSURE (1 WEEK TO SEVERAL MONTHS)

For intermediate term occupational exposure, the one year rat neurotoxicity study (MRID No.: 41853801, 44204501) was selected, based on neuropathology and cholinesterase inhibition occurring at a LOEL of 0.53 mg/kg/day. The NOEL of 0.11 mg/kg/day will be used for risk assessment. An UF of 100 will be used.

5. CHRONIC OCCUPATIONAL EXPOSURE (SEVERAL MONTHS TO LIFETIME)

For chronic occupational exposure, the two-year chronic feeding study in rats (Acc. No. 252501, 252502, 252503, 253346, 253372, 253373, 253374) was selected, based on systemic toxicity, neuropathology, and cholinesterase inhibition occurring at the LOEL of 0.21 mg/kg/day. The NOEL of 0.02 mg/kg/day will be used for risk assessment. An UF of 100 will be used.

6. INHALATION EXPOSURE:

For short or intermediate term inhalation exposure, the one year rat neurotoxicity study (MRID No.: 41853801, 44204501) was selected, based on neuropathology and cholinesterase inhibition occurring at a LOEL of 0.53 mg/kg/day. The NOEL of 0.11 mg/kg/day will be used for risk assessment. An UF of 100 will be used.

For long term inhalation exposure, the two-year chronic feeding study in rats (Acc. No. 252501, 252502, 252503, 253346, 253372, 253373, 253374) was selected, based on systemic toxicity, neuropathology, and cholinesterase inhibition occurring at the LOEL of 0.21 mg/kg/day. The NOEL of 0.02 mg/kg/day will be used for risk assessment. Due to high toxicity seen in an acute inhalation study, 100% absorption should be assumed. An UF of 100 will be used.

Attachment 4: Revised Residue Chemistry Chapter

May 12, 1999

MEMORANDUM

SUBJECT: **REVISED Residue Chemistry Chapter for the Methyl Parathion Reregistration Eligibility Decision (RED) Document.**
DP Barcode No.: D255926
Chemical No.: 053501
Reregistration Case No.: 0153

FROM: Bonnie Cropp-Kohlligian, Environmental Scientist
Reregistration Branch II
Health Effects Division [7509C]

THROUGH: Alan P. Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division [7509C]

TO: Diana Locke, Risk Assessor
Reregistration Branch II
Health Effects Division [7509C]

A Residue Chemistry Chapter for the Methyl Parathion Reregistration Eligibility Decision (RED) Document was completed 6/11/98. Attached is the most recent revision of this RED Chapter hereafter referred to as the Residue Chemistry Chapter for the Methyl Parathion RED Document (REV 5/99).

Subsequent to the completion of the Residue Chemistry Chapter for the Methyl Parathion Reregistration Eligibility Decision (RED) Document (6/11/98), the Agency issued a Preliminary Human Health Risk Assessment entitled, "Methyl Parathion. The HED Chapter of the Reregistration Eligibility Decision Document (RED)" (completed 9/1/98). In response to the Agency's Preliminary Human Health Risk Assessment of Methyl Parathion (completed 9/1/98), Jellinek, Schwartz & Connolly, Inc. submitted extensive comments (dated 11/6/98 and 2/16/99) to the Agency on behalf of

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Cheminova and Elf Atochem. In their 11/6/98 and 2/16/99 responses to the Agency's Preliminary Human Health Risk Assessment of Methyl Parathion (completed 9/1/98), the registrants clarified the food/feed uses of methyl parathion which they wish to support under reregistration. They also committed to generate certain additional residue chemistry data in support of the reregistration of methyl parathion.

The information contained in this document outlines the current residue chemistry science assessment with respect to the reregistration of methyl parathion and takes into account the responses of Cheminova and Elf Atochem (dated 11/6/98 and 2/16/99) to the Agency's Preliminary Human Health Risk Assessment of Methyl Parathion (completed 9/1/98). It also takes into account the following new residue chemistry data submitted by the registrants and IR-4, in support of the reregistration of methyl parathion, which are under review: (i) lettuce metabolism data (MRID 44669501), (ii) additional goat and hen metabolism data (letter dated 2/2/98), (iii) storage stability data on apple, grape, and peach commodities (MRIDs 44643602, 44413301, and 44413403), (iv) apple field trial data (MRIDs 44413501 and 44413502), (v) bean field trial data (MRID 43967301), (vi) cherry field trial data (MRIDs 44622501 and 44622502), (vii) cottonseed field trial data (MRID 44430601), (viii) field corn field trial data (MRID 44398301), (ix) grape field trial data (MRIDs 44413401 and 44413402), (x) hops field trial data (MRID 44501201), (xi) pecan field trial data (MRID 43760901), (xii) peanut field trial data (MRIDs 44620301 and 44620302), (xiii) rice field trial data (MRID 44643601), (xiv) wheat forage, hay, and straw magnitude of the residue data (MRID 41818502), and (xv) magnitude of the residue data on aspirated grain fractions (AGF) of wheat (MRID 44794501).

Attachment: Residue Chemistry Chapter for the Methyl Parathion RED Document (REV 5/99)

cc w/attachment: BLCKohlligian (RRB2), Methyl Parathion Reg. Std. File, Methyl Parathion SF, RF.

7509C:RRB2:BLCKohlligian:CM#2:Rm 712N:703-305-7462: 5/12/99.

RESIDUE CHEMISTRY CHAPTER
for the
METHYL PARATHION RED DOCUMENT
(REV 5/99)

INTRODUCTION

Methyl parathion [*O,O*-dimethyl-*O*-*p*-nitrophenylthiophosphate] is an insecticide/acaricide registered for use on a variety of fruits, vegetables, and field crops (see Table A). Cheminova Agro A/S and Griffin L.L.C. are the basic producers of methyl parathion technical in the U.S. Methyl parathion is sold in the U.S. by Cheminova, Inc. and Elf Atochem North America under the trade names Methyl Parathion and Penncap-M®, respectively. Formulations of methyl parathion registered for use on food/feed crops subject to reregistration include microencapsulated (Mcap) and emulsifiable concentrate (EC) formulations. Methyl parathion may be applied using aerial and ground equipment via foliar, dormant, and delayed dormant treatments. Multiple Active Ingredient (MAI) formulations of methyl parathion are registered in combination with ethyl parathion or endosulfan or malathion.

REGULATORY BACKGROUND

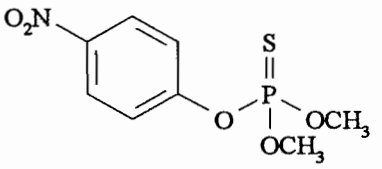
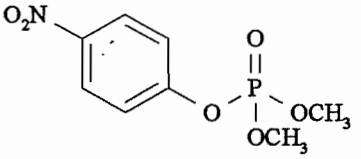
Methyl parathion is a list A reregistration chemical that was the subject of a Reregistration Standard (completed 11/8/95), a Guidance Document (completed 12/8/86), a Reregistration Standard Update (completed 11/24/92), a Residue Chemistry Chapter for the Methyl Parathion Reregistration Eligibility Decision (RED) Document (completed 6/11/98), and a Preliminary Human Health Risk Assessment entitled, "Methyl Parathion. The HED Chapter of the Reregistration Eligibility Decision Document (RED)" (completed 9/1/98). In response to the Agency's Preliminary Human Health Risk Assessment of Methyl Parathion (completed 9/1/98), Jellinek, Schwartz & Connolly, Inc. submitted extensive comments (dated 11/6/98 and 2/16/99) to the Agency on behalf of Cheminova and Elf Atochem. In their 11/6/98 and 2/16/99 responses to the Agency's Preliminary Human Health Risk Assessment of Methyl Parathion (completed 9/1/98), the registrants clarified the food/feed uses of methyl parathion which they wish to support under reregistration. They also committed to generate certain additional residue chemistry data in support of the reregistration of methyl parathion. The information contained in this document outlines the current residue chemistry science assessment with respect to the reregistration of methyl parathion and takes into account the responses of Cheminova and Elf Atochem (dated 11/6/98 and 2/16/99) to the Agency's Preliminary Human Health Risk Assessment of Methyl Parathion (completed 9/1/98).

Tolerances for residues of ethyl parathion or its methyl homolog (methyl parathion) in/on raw agricultural commodities (RACs) have been established under 40 CFR §180.121(a) and §180.319, and tolerances for residues of methyl parathion *per se* have been established under 40 CFR §180.121(b). No tolerances for residues of methyl parathion have been established for animal commodities or processed food/feed commodities.

The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) has tentatively concluded that methyl parathion residues of concern in plant commodities include methyl parathion, methyl paraoxon, and *p*-nitrophenol and that methyl parathion residues of concern in animal commodities include methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl. The tolerance expression for plant and animal commodities may be based on methyl parathion only. Methyl parathion residues of concern to be included in the risk assessments based on cholinesterase inhibition for plant and animal commodities will include methyl parathion and methyl paraoxon. Residues of *p*-nitrophenol do not have to be included in the tolerance expression or considered in the aggregate risk assessment for methyl parathion with respect to cholinesterase inhibition, but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol. Toxicology deems amino-paraoxon-methyl of concern due to neuropathy of unknown origin and not due to cholinesterase inhibition. Once outstanding livestock feeding studies have been submitted, the Agency will determine how to include amino-paraoxon-methyl in the risk assessment.

The chemical names and structures of methyl parathion and methyl paraoxon are depicted in Figure A.

Figure A. Chemical names and structures of methyl parathion and methyl paraoxon.

Common Name/Chemical Name	Chemical Structure
Methyl parathion *O,O*-dimethyl-*O*-*p*-nitrophenyl thiophosphate	
Methyl paraoxon *O,O*-dimethyl-*O*-*p*-nitrophenyl phosphate	

SUMMARY OF SCIENCE FINDINGS

OPPTS GLN 860.1200: Directions for Use

A search of the Reference Files System (REFS) conducted 4/19/99 identified 3 methyl parathion end-use products with food/feed uses that are currently registered to Cheminova, Inc. (hereafter referred to as Cheminova) or Elf Atochem and which the registrants have committed to support under reregistration according to their responses (dated 11/6/98 and 2/16/99) to the Agency's Preliminary Human Health Risk Assessment of Methyl Parathion (completed 9/1/98). These end-use products are presented below.

EPA Reg No.	Label Acceptance Date	Formulation Class	Product Name
4581-292 [a]	7/98	2 lb/gal Mcap	Penncap-M Microencapsulated Insecticide
67760-39 [b]	5/98	3 lb/gal EC	Ethyl-Methyl Parathion 6-3 EC
67760-29 [c]	3/97	4 lb/gal EC	Cheminova Methyl Parathion 4 EC

[a]Includes Special Local Needs (SLN) Registration Nos. AL97000300, CA97002400, ID84001000, IN88000200, IN88000700, LA96000100, MN97000100, MO95000100, MS97000600, NM82000400, WA82005400, and WI95000500.
[b]This is a MAI formulation containing 6 lb ai/gal of parathion in addition to 3 lb ai/gal of methyl parathion.
[c]Includes SLN Registration Nos. ID97001300, OR9700200, TX97000600, and WA97003400.

The search of REFS also identified several 5 lb/gal EC formulations of methyl parathion with food/feed uses which are currently registered to companies other than Cheminova and Elf Atochem (EPA Reg. Nos. 2935-527, 5481-175, and 34704-795) and 3 Special Local Needs (SLN) registrations which were issued under products not registered to Cheminova or Elf Atochem. These SLN registrations are: (I) TX97000900 under EPA Reg. No. 2935-528, (ii) NV97000100 under EPA Reg. No. 2935-527, and (iii) WA97001800 under EPA Reg. No. 2935-527.

The Agency has determined that the following food/feed crops for methyl parathion are subject to reregistration: alfalfa (grown for forage and hay), almonds, apples, artichokes (globe), barley, beans (dried and succulent, excluding cowpeas), broccoli, Brussels sprouts, cabbage, canola, carrots, cauliflower, celery, cherries, collards, corn (sweet, field, and pop), cotton, grapes, grass (grown for forage and hay), hops, kale, lentils, lettuce (head and leaf), mustard greens, nectarines, oats, onions, peaches, peanuts, pears, peas (dried and succulent, excluding field peas), pecans, plums, potatoes, rice, rye, soybeans, spinach, sugar beets, sunflower, sweet potatoes, tomatoes, turnips, walnuts, wheat, and yams. ULV applications of methyl parathion on cotton are also subject to reregistration. A summary of the food/feed use sites, patterns, and restrictions subject to reregistration for methyl parathion is provided in Table A.

Cheminova and Elf Atochem have submitted the majority of the residue chemistry data in support of the reregistration of methyl parathion. The food/feed use sites, patterns, and restrictions which they wish to support, according to their responses (dated 11/6/98 and 2/16/99) to the Agency's Preliminary Human Health Risk Assessment of Methyl Parathion (completed 9/1/98), are consistent with the food/feed use sites and restrictions prescribed by the Agency, herein, and consistent with the food/feed use patterns prescribed by the Agency, herein, with the following exceptions: almonds, apples, cherries, lettuce, pears, spinach, and all of the *Brassica* Leafy Vegetables. The use patterns prescribed by the Agency for these crops are based on the use pattens supported by the available residue chemistry data. Cheminova plans to support the use of the EC formulation of methyl parathion on alfalfa and grass but did not specify use patterns for these crops in their responses (dated 11/6/98 and 2//16/99) to the Agency's Preliminary Human Health Risk Assessment of Methyl Parathion (completed 9/1/98). The Agency's prescribed use patterns for alfalfa and grass are based on current label use rates for the use of the EC formulation of methyl parathion on alfalfa and grass. See Table A for details concerning the Agency's prescribed food/feed use sites, patterns, and restrictions for methyl parathion.

IR-4 has submitted the residue chemistry data in support of the use of methyl parathion on hops. The use pattern which the Agency understands that IR-4 wishes to support on hops is consistent with the use pattern prescribed by the Agency. See Table A for details concerning the Agency's prescribed food/feed use sites, patterns, and

restrictions for methyl parathion.

A tabular summary of the residue chemistry science assessment for reregistration of methyl parathion is presented in Table B. The conclusions listed in Table B regarding the reregistration eligibility of methyl parathion food/feed uses are predicated on the use sites, pattens, and restrictions prescribed by the Agency and summarized in Table A. When end-use product DCIs are developed (e.g., at issuance of the RED), the Registration Division (RD) should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the food/feed use sites, patterns, and restrictions specified in Table A.

NOTE: The Agency's prescribed food/feed use sites, patterns, and restrictions for methyl parathion summarized in Table A are specific to each of the methyl parathion formulations discussed above (hereafter referred to as 5 lb/gal EC, 4 lb/gal EC, 3 lb/gal EC, and 2 lb/gal Mcap). Detailed summaries of the Agency's prescribed food/feed use sites, patterns, and restrictions specified to each of the methyl parathion formulations are provided in Appendix A (5 lb/gal EC and 4 lb/gal EC), Appendix B (3 lb/gal EC), and Appendix C (2 lb/gal Mcap). These appendices to not include SLN registrations, since no amendments are required for existing SLN registrations with the exception of SLN IN88000700.

OPPTS GLN 860.1300: Nature of the Residue in Plants

The qualitative nature of the residue in plants is not adequately understood. Acceptable metabolism studies are available for cotton and potatoes; however, the previously submitted lettuce metabolism study has been deemed inadequate. The Agency has required a new lettuce metabolism study.

The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) has tentatively concluded that based on available plant metabolism and magnitude of the residue data, methyl parathion residues of concern in/on plant commodities are methyl parathion, methyl paraoxon, and *p*-nitrophenol. Methyl parathion residues of concern to be included in the risk assessment for plant commodities based on cholinesterase inhibition will include methyl parathion and methyl paraoxon. The tolerance expression may be based on methyl parathion only since detectable levels of methyl paraoxon have not been found in/on commodities tested by FDA monitoring. Residues of *p*-nitrophenol do not have to be included in the tolerance expression or considered in the aggregate risk assessment for methyl parathion with respect to cholinesterase inhibition, but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol. The risk assessment for *p*-nitrophenol will be based on its own toxicological endpoints (rather than cholinesterase inhibition) and should include exposure to *p*-nitrophenol from its

use as a fungicide on leather. Residues of methyl parathion, methyl paraoxon, and *p*-nitrophenol should be determined in/on plant samples collected in future plant magnitude of the residue studies.

The registrant (Cheminova) has submitted a new lettuce metabolism study (MRID 44669501) which is under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the dietary exposure estimates used in the dietary risk assessments for methyl parathion. No new methyl parathion residues of concern were identified in the subject study. Pending acceptance of the new lettuce metabolism data to satisfy this guideline requirement, no additional plant metabolism data are required to support the reregistration of methyl parathion.

OPPTS GLN 860.1300: Nature of the Residue in Livestock

The qualitative nature of the residue in animals is understood based upon adequate ruminant and poultry metabolism studies. The following additional data are required to validate the experimental methods for the poultry and ruminant metabolism studies: (I) the in-life portion of the study, including total feeds consumed to determine theoretical dietary intake of methyl parathion, as ppm, in the feed; (ii) the storage intervals for goat tissue and milk, and hen tissue and egg samples; and (iii) for the ruminant study only, the specific fraction or matrix used for Soxhlet extraction, acid hydrolysis, and enzyme hydrolysis; flow charts must be provided to indicate at what point these procedures were used.

The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) has tentatively concluded that based on available animal metabolism data, methyl parathion residues of concern in animal commodities are methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl. [Note: Livestock feeding studies remain outstanding.] As with plants, methyl parathion residues of concern to be included in the risk assessment for animal commodities based on cholinesterase inhibition will include methyl parathion and methyl paraoxon. The tolerance expression may be based on methyl parathion only. Residues of *p*-nitrophenol do not have to be included in the tolerance expression or considered in the aggregate risk assessment for methyl parathion with respect to cholinesterase inhibition, but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol. The risk assessment for *p*-nitrophenol will be based on its own toxicological endpoints (rather than cholinesterase inhibition) and should include exposure to *p*-nitrophenol from its use as a fungicide on leather. Toxicology deems amino-paraoxon-methyl of concern due to neuropathy of unknown origin and not due to cholinesterase inhibition. Once outstanding livestock feeding studies have been submitted, the Agency will determine how to include amino-paraoxon-methyl in the risk assessment. Residues of methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl should be

determined in meat, milk, poultry, and egg tissue samples from the required livestock feeding studies.

In a letter dated 2/2/98, the registrant (Cheminova) has submitted the additional data required to validate the experimental methods for the poultry and ruminant metabolism studies concerning: (I) the in-life portion of the study, including total feeds consumed to determine theoretical dietary intake of methyl parathion, as ppm, in the feed; (ii) the storage intervals for goat tissue and milk, and hen tissue and egg samples; and (iii) for the ruminant study only, the specific fraction or matrix used for Soxhlet extraction, acid hydrolysis, and enzyme hydrolysis; flow charts must be provided to indicate at what point these procedures were used. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the dietary exposure estimates used in the dietary risk assessments for methyl parathion. Pending acceptance of these data to validate the experimental methods for the poultry and ruminant metabolism studies and satisfy this guideline requirement, no additional animal metabolism data are required to support the reregistration of methyl parathion.

OPPTS GLN 860.1340: Residue Analytical Methods

Pesticide Analytical Manual (PAM) Vol. II lists Methods I(a) and I(b) (PAM, Vol. I multiresidue methods for organophosphates), I(c), I(d), and II for parathion. Methyl parathion is also recovered under these methods.

The proposed enforcement method(s) employed to determine methyl parathion and methyl paraoxon in plant commodities are the FDA multiresidue testing protocol(s). Therefore, an independent laboratory validation (ILV) is not required.

In conjunction with the ruminant and poultry feeding studies, the registrants must provide data validating the analytical method(s) used for determining methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl in meat, milk, poultry, and eggs. If the feeding studies indicate that tolerances are necessary for residues in animal commodities, then the registrants must propose an enforcement method for determining the residues of concern in animal commodities which must be regulated.

OPPTS GLN 860.1360: Multiresidue Method Testing

The FDA PESTDATA database indicates that methyl parathion is completely recovered using FDA Multiresidue Protocols D (nonfatty), E (nonfatty), and F (fatty). Methyl paraoxon is not recovered by Protocols E and F. The recovery of methyl paraoxon by Protocol D has not been determined.

OPPTS GLN 860.1380: Storage Stability Data

Acceptable storage stability data are available indicating that methyl parathion *per se* is stable at -20 C for up to 24 months in turnip roots and tops, green onions, lettuce, cabbage, mustard greens, celery, soybeans, beans (snap and dry), peas (dry seed and succulent pods), pea forage and straw, corn grain, forage and fodder, wheat grain, forage and straw, grass hay, and clover forage; for up to 18 months in sunflower seeds; for up to 14 months in canola seed, oil, meal, and processing waste; for up to 12 months in almonds, almond hulls, and walnuts; and for up to 6 months in tomato wet pomace, puree, juice, and catsup.

Data are also available indicating that the metabolite, methyl paraoxon, is stable at -20 C for up to 24 months in turnip roots and tops, mustard greens, cabbage, celery, beans (snap and dry), peas (dry seed), pea forage and straw, corn grain, forage and fodder, wheat grain, forage and straw, grass hay, and clover forage; for up to 18 months in green onions and sunflower seeds; for up to 14 months in canola oil and processing waste; for up to 12 months in almond hulls; for up to 6 months in lettuce and canola meal; and for up to 1 month in almonds, soybeans, succulent pea pods, canola seeds, and walnuts.

With the exceptions of residues of methyl paraoxon in lettuce, soybeans, succulent pea pods, canola seeds, and nuts, the storage stability data indicate that residues of methyl parathion and methyl paraoxon are stable in plant commodities for the intervals and under the conditions that test samples were stored in the residue chemistry studies. Although methyl paraoxon is unstable in selected plant matrices, additional field trial data will not be required to replace the available residue data on these commodities as methyl paraoxon did not comprise a sizable portion of the terminal residue in the plant metabolism studies and was only observed at detectable/significant levels in a limited number of crops.

New stability data have been submitted demonstrating the stability of methyl parathion residues of concern in apples (MRID 44643602), peaches (MRID 44413301), and grapes (MRID 44413403) which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the dietary exposure estimates used in the dietary risk assessments for methyl parathion. Pending acceptance of these storage stability to satisfy guideline requirements, no additional data depicting the storage stability of methyl parathion residues of concern in plant commodities are required to support the reregistration of methyl parathion.

Data depicting the storage stability of methyl parathion residues of concern in animal commodities are required in conjunction with the ruminant and poultry feeding.

<u>OPPTS GLN 860.1500: Magnitude of the Residue in Plants</u>

Residue chemistry data depicting methyl parathion residues of concern are not required on the following food/feed crops which the Agency understands are not being supported under the reregistration process: apricots, avocados, birdsfoot trefoil, blackberries, blueberries (huckleberries), boysenberries, citrus fruits, clover, cowpeas, cranberries, cucumbers, currants, dates, dewberries, eggplants, endive (escarole), field peas, figs, filberts, garden beets, garlic, gooseberries, guar beans, guavas, kohlrabi, Loganberries, mangoes, melons, mustard seed, okra, olives, parsley, parsnips, peppers, pineapples, pumpkins, quinces, radishes, rapeseed, raspberries, rutabagas, safflower seed, sorghum, squash, strawberries, sugarcane, Swiss chard, tobacco, vetch, and Youngberries. Likewise, residue chemistry data depicting methyl parathion residues of concern are not required on the following food/feed commodities which the Agency understands are not being supported under the reregistration process: alfalfa grown for seed, grass grown for seed, soybean forage, and soybean hay.

Residue chemistry data depicting methyl parathion residues of concern are required on the following food/feed crops which the Agency understands are being supported under the reregistration process: alfalfa (grown for forage and hay), almonds, apples, artichokes (globe), barley, beans (dried and succulent, excluding cowpeas), broccoli, Brussels sprouts, cabbage, canola, carrots, cauliflower, celery, cherries, collards, corn (sweet, field, and pop), cotton, grapes, grass (grown for forage and hay), hops, kale, lentils, lettuce (head and leaf), mustard greens, nectarines, oats, onions, peaches, peanuts, pears, peas (dried and succulent, excluding field peas), pecans, plums, potatoes, rice, rye, soybeans, spinach, sugar beets, sunflower, sweet potatoes, tomatoes, turnips, walnuts, wheat, and yams. ULV applications of methyl parathion on cotton are also subject to reregistration. A summary of the food/feed use sites, patterns, and restrictions subject to reregistration for methyl parathion is provided in Table A.

Provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, patterns, and restrictions as specified in Table A (and further clarified for each formulation in Appendices A, B, and C), reregistration requirements for magnitude of the residue data are fulfilled for the use of methyl parathion on the following crops: almonds, artichokes (globe), beans (dried, excluding coowpeas), broccoli, cabbage, canola, carrots, celery, lentils, lettuce (head and leaf), mustard greens, peaches, peas (dried and succulent, excluding field peas), sunflower, spinach, tomatoes, and walnuts. Likewise, reregistration requirements for magnitude of the residue data are fulfilled for the use methyl parathion on the following crop commodities: sugar beet roots, turnip roots, and wheat grain. The residue chemistry data on broccoli, cabbage, and mustard greens (representative commodities of the *Brassica* Vegetables crop group) will be translated to satisfy magnitude of the residue data requirements in support of the use of the EC formulations of methyl parathion on Brussels sprouts, cauliflower, collards, and kale. The residue chemistry data on peaches will be translated to nectarines.

In support of the reregistration of the Mcap formulations of methyl parathion the registrant (Elf Atochem) has submitted the following new field trial data: (i) apple field trial data (MRIDs 44413501 and 44413502), (ii) beans field trial data (MRID 43967301), (iii) cherry field trial data (MRID 44622501 and 44622502), (iv) cottonseed field trial data (MRID 44430601), (v) field corn field trial data (MRID 44398301), (vi) grape field trial data (MRIDs 44413401 and 44413402), (vii) pecan field trial data (MRID 43760901), (viii) peanut field trial data (MRIDs 44620301 and 44620302), (ix) rice field trial data (MRID 44643601), and (x) wheat forage, hay, and straw magnitude of the residue data (MRID 41818502). These data are under review. Pending acceptance of these data to fulfill guideline requirements and provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, patterns, and restrictions as specified in Table A (and further clarified for each formulation in Appendices A, B, and C), no additional magnitude of the residue data are required to support the reregistration of the Mcap formulations of methyl parathion on the following crops: apples, beans (succulent, excluding cowpeas), cherries, corn (sweet, field, and pop), grapes, pecans, and peanuts. Likewise, no additional magnitude of the residue data will be required on the following crop commodities: cottonseed, rice grain, and wheat straw.

In support of the reregistration of the EC formulations of methyl parathion, IR-4 has submitted new hops field trial data (MRID 44501201) which are under review. Pending acceptance of these data to fulfill guideline requirements and provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, patterns, and restrictions as specified in Table A (and further clarified for each formulation in Appendices A, B, and C), no additional hops magnitude of the residue data are required to support the reregistration of methyl parathion.

In support of the reregistration of the EC formulations of methyl parathion, the registrant (Cheminova) has submitted new magnitude of the residue data on the aspirated grain fractions (AGF) of wheat (MRID 44794501). These data are under review. Pending acceptance of these data to fulfill guideline requirements and provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, patterns, and restrictions as specified in Table A (and further clarified for each formulation in Appendices A, B, and C), no additional aspirated grain fractions (AGF) magnitude of the residue data are required to support the reregistration of methyl parathion.

For the purposes of reregistration, additional magnitude of the residue data are required to support the use of the EC formulations of methyl parathion on the following crop commodities:
alfalfa (forage and hay), cotton gin byproducts, grass (forage and hay), sugar beet tops, turnip tops, wheat forage, and wheat hay.

For the purposes of reregistration, additional magnitude of the residue data are required to support the use of the Mcap formulation of methyl parathion on the following crop commodities: cotton gin byproducts, onions, pears, plums, potatoes, rice straw, and soybeans.

Once the additional data are received and accepted, residue chemistry data on potatoes will be translated to sweet potatoes and yams. Residue chemistry data on wheat will be translated to barley, oats, and rye commodities.

OPPTS GLN 860.1520: Magnitude of the Residue in Processed Food/Feed

In support of the reregistration of methyl parathion, processing data are required on the following food/feed crop commodities: apples, canola seed, field corn grain, cottonseed, grapes, oat grain, peanuts, plums/prunes, potatoes, rice grain, rye grain, soybeans, sugar beet roots, sunflower seeds, tomatoes, and wheat grain. Reregistration requirements for magnitude of the residue in processed food/feed crop commodities are fulfilled for apples, canola seed, corn grain, cottonseed, grapes, potatoes, rice grain, soybeans, sugar beet roots, tomato, and wheat grain. Data from the processing study on wheat grain will be used to determine the need for tolerances on barley grain, oat grain, and rye grain processed commodities. Processing studies on peanuts, plums/prunes, and sunflower seeds are required.

Based on the available processing studies, tolerances are not required for residues in processed crop commodities of canola seed, corn grain, cottonseed, grapes, potatoes, sugar beet roots, and tomatoes. Residues did not concentrate in commodities processed from corn grain, cottonseed, grapes, and tomatoes bearing detectable residues. Residues were nondetectable in potatoes and sugar beet roots treated at 5x the maximum label rate and in the commodities processed from these crops.

Residues of methyl parathion did not concentrate in canola meal, but concentrated by 2x in refined canola oil processed from canola seed treated at 5x. Residues of methyl parathion were below the LOQ (0.05 ppm) in/on canola seed from all field trials. When residues in oil are adjusted for the degree of exaggeration, the maximum expected residues in oil would be <0.2 ppm. As the Agency is not proposing to decrease the current 0.2 ppm tolerance for residues of methyl parathion in/on canola seed, residues in oil would be covered by the current tolerance. Therefore, a separate tolerance is not required for canola oil.

In rice grain, residues of methyl parathion did not concentrate in brown rice, polished rice, or rice bran, but concentrated by 4.7x in rice hulls. Based upon the highest average field trial (HAFT) value for residues of methyl parathion in/on rice grain (2.35 ppm), a tolerance of 12 ppm for residues of methyl parathion in rice hulls should be established.

In apples, residues of methyl parathion did not concentrated in apple juice, but concentrated by 5.3x in wet apple pomace. Apple field trial data (including those under review (MRIDs 44413501 and 44413502) indicate that the currently established tolerance for residues of methyl parathion in/on apples (1 ppm) is just adequate to cover residues likely to occur in/on apples resulting from the maximum use rate of the Mcap formulation of methyl parathion on apples. Hence, a tolerance of 5 ppm should be established for residues of methyl parathion in apple, wet pomace.

In soybeans, residues of methyl parathion did not concentrate significantly in hulls and meal, but concentrated by 3x in refined oil. Based upon the reassessed tolerance for residues of methyl parathion in/on soybeans (0.05 ppm), a tolerance of 0.2 ppm for residues of methyl parathion in refined soybean oil should be established. [Note: Additional soybean magnitude of the residue data are required to support the use of the Mcap formulations of methyl parathion on soybeans. These data are considered confirmatory.]

In wheat grain, residues of methyl parathion did not concentrate in flour, but concentrated by ca 2x in wheat bran, shorts, and germ. Based upon the HAFT value for residues of methyl parathion (5.09 ppm) in/on wheat grain, a tolerance of 10 ppm for residues of methyl parathion in wheat bran, shorts, and germ should be established. In addition, these data should be translated to establish tolerances for residues of methyl parathion in barley bran and rye bran at 10 ppm.

New peanut processing data are required to support the use of the Mcap formulation of methyl parathion on peanuts. The registrant (Elf Atochem) has submitted new peanut processing data (MRID 44620303) to support the use of the Mcap formulation of methyl parathion on peanuts. The subject peanut processing data are under review. A preliminary evaluation of these data indicates that residues of methyl parathion do not concentrate in/on peanut meal and refined oil processed from peanuts treated with methyl parathion. It is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or any dietary exposure estimates used in the dietary risk assessment for methyl parathion. Pending acceptance of the subject peanut processing data to support the use of the Mcap formulation of methyl parathion on peanuts, no additional peanut processing data are required to support the reregistration of methyl parathion.

New plum/prune processing data are required to support the use of the Mcap formulation of methyl parathion on plums. New sunflower seed processing data are required to support the use of the EC formulation of methyl parathion on sunflowers.

OPPTS GLN 860.1480: Magnitude of the Residue in Meat, Milk, Poultry, and Eggs

Reregistration requirements for magnitude of the residue in meat, milk, poultry, and eggs remain outstanding. No tolerances have been established for residues of methyl parathion in animal commodities, although tolerances have been established on numerous animal feed items.

For the required feeding studies, ruminants and poultry should be dosed orally at 1x, 3x, and 10x the maximum expected dietary burden for a minimum of 28 days or until residues plateau in milk and eggs if they have not done so by 28 days. Animals should be sacrificed within 24 hours of receiving the final dose. Milk and eggs should be collected through the study, and samples of muscle, fat, liver, and kidney (ruminants only) should be collected at sacrifice for analysis. Samples should be analyzed for residues of methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl. In addition, these studies must be supported by data depicting the storage stability of methyl parathion residues of concern in animal commodities. For additional guidance, the registrants should refer to OPPTS GLN. 860.1480.

Based upon the established or reassessed tolerances for residues of methyl parathion in/on animal feed items, the calculated maximum theoretical dietary burdens for livestock are presented below:

Feed Commodity	% Dry Matter [a]	% Diet [a]	Tolerance (ppm) [b]	Dietary Contribution (ppm) [c]
Beef Cattle				
corn stover	83	25	30	9.0
corn forage	40	40	10	10.0
wheat grain	89	35	5	2.0
TOTAL BURDEN		100		**21**
Dairy Cattle				
corn stover	83	15	30	5.4
corn forage	40	50	10	12.5
wheat grain	89	35	5	2.0
TOTAL BURDEN		100		**20**
Poultry				
wheat grain	NA	80	5	4.0
rice hulls	NA	15	12	1.8
rice bran [d]	NA	5	0.2	0.15
TOTAL BURDEN		100		**6**

[a]Table 1, OPPTS GLN 860.1000.
[b]Established or reassessed tolerances from Table C.
[c]Contribution = [tolerance / %DM (if cattle)] X % diet).
[d]Based on the reassessed tolerance for rice grain (3 ppm) and a concentration value of 1x for methyl parathion in rice bran.

OPPTS GLN 860.1400: Magnitude of the Residue in Water, Fish, and Irrigated Crops
Methyl parathion is not being support under reregistration for direct use on potable water and label restrictions for the use of methyl parathion on rice preclude the need for residue chemistry data under these guideline topics.

OPPTS GLN 860.1460: Magnitude of the Residue in Food-Handling Establishments
Methyl parathion is not being support under reregistration for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

OPPTS GLN 860.1850: Confined Accumulation in Rotational Crops

The Agency has requried a new confined rotational crop study. A new confined rotational crop study (MRID 43127609) has been submitted and is under review. Pending acceptance of these data to satisfy guideline requirements, no additional confined rotational crop data are required to support the reregistration of methyl parathion.

OPPTS GLN 860.1900: Field Accumulation in Rotational Crops

The need for field rotational crop data will be determined once the new confined rotational crop data (MRID 43127609) are reviewed.

TABLE A. FOOD/FEED USE SITES, PATTERNS, and RESTRICTIONS SUPPORTED UNDER THE REREGISTRATION PROCESS FOR METHYL PARATHION (CASE 0153). Note: The conclusions listed in Table B regarding the reregistration eligibility of methyl parathion food/feed uses are predicated on the use information summarized in this Table.

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
ROOT and TUBER VEGETABLE GROUP							
Carrots							
Broadcast application Ground and aerial equipment	4 lb/gal EC [c] 5 lb/gal EC	1.0 lb/A	6	2	7	15	
Potatoes							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.5 lb/A	6	2	7	5	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap [d]	1.5 lb/A	6	2	7	5	
Sugar Beets							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	0.38 lb/A	6	2	7	20	
Sweet potatoes							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	0.75 lb/A	8	2	7	5	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap [AL97000300] [LA96000100] [MS97000600]	0.75 lb/A	8	NS	NS	5	
Turnips							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	0.75 lb/A	6	2	7	15	

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
Yams							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	0.75 lb/A	8	2	7	5	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap [AL97000300] [LA96000100] [MS97000600]	0.75 lb/A	8	NS	NS	5	
BULB VEGETABLES GROUP							
Onions							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.0 lb/A	6	2	7	15	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	1.0 lb/A	6	2	7	15	
LEAFY VEGETABLES GROUP							
Celery							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.0 lb/A	2	2	14	15	
Lettuce (head and leaf)							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.0 lb/A	6	2	7	21	

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
Spinach							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	<0.5 lb/A	6	2	7	15	
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	0.5 - 1.0 lb/A	6	2	7	21	
***BRASSICA* LEAFY VEGETABLES GROUP**							
Broccoli, Brussels sprouts, Cabbage, Cauliflower, Collards, Kale, and Mustard Greens							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.5 lb/A	6	2	7	21	A PHI of 10-days is permitted if the last application is <0.05 lb ai/A. For use on broccoli, Brussels sprouts, cabbage, cauliflower, collards, kale, and mustard greens only. Use on kohlrabi is prohibited.
LEGUME VEGETABLES GROUP							
Beans, dried (excluding cowpeas)							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.5 lb/A	6	2	7	15	Use on cowpeas is prohibited.
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	1.0 lb/A	6	2	7	15	

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
Beans, succulent (excluding cowpeas)							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.5 lb/A	6	2	7	15	Use on cowpeas is prohibited.
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	1.0 lb/A	6	2	7	7	
Beans, succulent							
Broadcast application Ground equipment	2 lb/gal Mcap [MN97000100] [WI95000500]	0.75 lb/A	4	NS	4	7	For applications <0.05 lb ai/A/application a 3-day PHI is specified.
Broadcast application Ground equipment	2 lb/gal Mcap [MO95000100]	0.50 lb/A	6	NS	4	7	For applications <0.05 lb ai/A/application a 3-day PHI is specified.
Lentils							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	0.5 lb/A	3	2	11	14	
Broadcast application Aerial equipment	2 lb/gal Mcap [ID84001000] [WA82005400]	0.5 lb/A	NS	5	NS	15	Do not harvest for forage or graze treated areas. Aerial applications only.

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
Peas, dried and succulent (excluding field peas)							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.0 lb/A	6	2	7	15	A PHI of 10-day sis permitted if the last application is <0.5 lb ai/A. Use on field peas is prohibited.
Broadcast application Ground and aerial equipment	4 lb/gal EC [ID97001300] [OR97002000] [WA97003400]	<0.5 lb/A	NS	NS	NS	10	
Broadcast application Ground and aerial equipment	4 lb/gal EC [ID97001300] [OR97002000] [WA97003400]	0.5 - 1.0 lb/A	NS	NS	NS	15	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	0.5 lb/A	2	2	7	15	Use on field peas is prohibited.
Soybeans							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	0.5 lb/A	2	2	5	14	Do not feed green immature growing plants to livestock. Do not harvest for livestock feed.
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	1.0 lb/A	2	2	7	30	Do not feed green immature growing plants to livestock. Do not harvest for livestock feed.
Broadcast application Ground and aerial equipment	2 lb/gal Mcap [IN88000700]	0.5 lb/A	2	NS	7	20	This SLN registration must be amended to include the following restriction: Do not feed green immature growing plants to livestock. Do not harvest for livestock feed.
Broadcast application Aerial equipment	3 lb/gal EC [e]	0.20 lb/A	2	2	7	20	Aerial applications only. Do not feed green immature growing plants to livestock. Do not harvest for livestock feed.
FRUITING VEGETABLES GROUP							

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
Tomatoes							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	1.0 lb/A	5	2	6	15	
POME FRUITS GROUP							
Apples and Pears							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	2.0 lb/A	5	10	7	30	
STONE FRUITS GROUP							
Cherries							
Broadcast applications Ground and aerial equipment	2 lb/gal Mcap	1.5 lb/A	4	10	7	21	
Nectarines and Peaches							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	<0.75 lb/A	6	10	7	21	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	0.75 - 2.0 lb/A	6	10	7	30	
Plums and Prunes							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	1.5 lb/A	4	10	7	15	
TREE NUTS GROUP							
Almonds							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	2.0 lb/A	6	10	21	28	

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
Pecans							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	2.0 lb/A	8	10	13	51	
Walnuts							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap [CA97002400]	2.0 lb/A	4	10	21	14	
CEREAL GRAINS GROUP							
Barley							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.25 lb/A	6	2	7	15	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	0.75 lb/A	3	2	7	14	
Broadcast application Aerial equipment	3 lb/gal EC	0.25 lb/A	6	2	7	15	Aerial applications only.
Corn, field and pop							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.0 lb/A	6	2	7	12	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	1.0 lb/A	5	2	14	12	
Broadcast application Aerial equipment	3 lb/gal EC	0.2 lb/A	6	2	5	12	Aerial applications only.
Broadcast application Ground and aerial equipment	2 lb/gal Mcap [IN88000200]	0.75	NS	NS	NS	NS	

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
Corn, sweet							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	0.5 lb/A	6	2	3	3	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	1.0 lb/A	5	2	14	12	
Broadcast application Aerial equipment	3 lb/gal EC	0.2 lb/A	6	2	5	12	Aerial applications only.
Broadcast application Ground and aerial equipment	2 lb/gal Mcap [IN88000200]	0.75	NS	NS	NS	NS	
Oats							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.25 lb/A	6	2	7	15	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	0.75 lb/A	3	2	7	14	
Rice							
Broadcast application Aerial equipment	4 lb/gal EC 5 lb/gal EC	0.75 lb/A	6	2	7	15	Aerial applications only. NEED LABEL RESTRICTIONS
Broadcast application Aerial equipment	2 lb/gal Mcap	0.75 lb/A	3	2	21	15	Aerial applications only. NEED LABEL RESTRICTIONS
Rye							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.25 lb/A	6	2	7	15	
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	0.75 lb/A	3	2	7	14	

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CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
Wheat							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.25 lb/A	6	2	7	15	
	2 lb/gal Mcap	0.75 lb/A	3	2	7	14	
	2 lb/gal Mcap [NM82000400]	0.5 lb/A	NS	NS	NS	15	
Broadcast application Aerial equipment	3 lb/gal EC	0.25 lb/A	6	2	7	15	Aerial applications only.
GRASS FORAGE, FODDER, and HAY GROUP							
Grass							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	0.75 lb/A	6	1	NS	15	Apply in a minimum of 3 gal/A of water using ground equipment or 1 gal/A using aerial equipment.
NON-GRASS ANIMAL FEEDS GROUP							
Alfalfa							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC 5 lb/gal EC [NV97000100][f]	1 lb/A	2 per cutting	1	Not Specified (NS)	15	Maximum application rate of 0.38 lb ai/A/application is specified for CA and NV only (except SLN NV97000100). Apply in a minimum of 3 gal/A of water using ground equipment or 1 gal/A of water using aerial equipment.
Broadcast application Aerial equipment	3 lb/gal EC	0.25 lb/A	2	2	7	15	Aerial applications only. Do not apply more than 0.5 lb ai/A/cutting. Do not apply more than 0.14 lb ai/A/cutting in CA and NV.

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CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
MISCELLANEOUS							
Artichokes (globe)							
Broadcast application **Ground and aerial equipment**	4 lb/gal EC 5 lb/gal EC	1.0 lb/A	4	2	7	7	
Canola (oilseed crop only)							
Broadcast application **Ground and aerial equipment**	4 lb/gal EC 5 lb/gal EC 5 lb/gal EC [WA97001800][f]	0.5 lb/A	2	3	7	28	Not for use on rapeseed. Do not graze treated fields or feed treated forage or threshings to livestock.
Broadcast application **Aerial equipment**	3 lb/gal EC	0.25 lb/A	NS	3	NS	28	Aerial applications only. Not for use on rapeseed. Do not graze treated fields or feed treated forage or threshings to livestock.
Cotton							
Broadcast application **Ground and aerial equipment**	4 lb/gal EC 5 lb/gal EC	3.0 lb/A	10	2	3	7	
ULV aerial application	4 lb/gal EC [TX97000600]	3.0 lb/A	NS	1	4-5	1	Dilute in 1 quart of refined vegetable oil (such as cottonseed).
ULV aerial application	4 lb/gal EC [TX97000900][g]	1.0 lb/A	NS	1	3-7	NS	Dilute in 1 quart of refined vegetable oil (such as cottonseed).
Broadcast application **Aerial equipment**	3 lb/gal EC	0.6 lb/A	6	2	7	7	Aerial applications only.
Broadcast application **Ground and aerial equipment**	2 lb/gal Mcap	1.0 lb/A	8	2	5	14	
ULV aerial application	2 lb/gal Mcap	1.0 lb/A	8	1	5	14	
Grapes							

CROP GROUP Crop Application Type Application Timing Application Equipment	Formulation Class [SLN Reg. No.]	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Minimum Spray Volume [b] (gal/A)	Minimum Retreatment Interval (Days)	Pre-Harvest Interval (Days)	Use Restrictions
Broadcast Application Ground and aerial equipment	2 lb/gal Mcap	1.0 lb/A	2	2	7	28	Not for use in CA.
Post-harvest, dormant, delayed dormant, and prebloom applications. Ground and aerial equipment	2 lb/gal Mcap	1.5 lb/A	2	2	7	150	CA only.
Hops							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.0 lb/A	3	10	7	15	
Peanuts							
Broadcast application Ground and aerial equipment	2 lb/gal Mcap	1.0 lb/A	4	2	14	15	
Sunflowers							
Broadcast application Ground and aerial equipment	4 lb/gal EC 5 lb/gal EC	1.0 lb/A	3	2	7	30	
Broadcast application Aerial equipment	3 lb/gal EC	0.33 lb/A	3	2	5	30	Aerial applications only.

[a]Maximum number of applications at the maximum single application rate.
[b]Diluent is water unless otherwise specified under restrictions.
[c]4 lb/gal emulsifiable concentrate (EC) formulation; Cheminova Methyl Parathion 4 EC; EPA Reg. No. 67760-29. Includes SLN registration Nos. ID97001300, OR9700200, TX97000600, and WA97003400.
[d]2 lb/gal microencapsulated (Mcap) formulation; Penncap-M Microencapsulated Insecticide; EPA Reg. No. 4581-292. Includes SLN Registration Nos. AL97000300, CA97002400, ID84001000, IN88000200, IN88000700, LA96000100, MN97000100, MO95000100, MS97000600, NM82000400, WA82005400, and WI95000500.
[e]3 lb/gal emulsifiable concentrate (EC) formulation; Ethyl-Methyl Parathion 6-3EC; EPA Registration No. 67760-39. This is a multiple active ingredient (MAI) formulation containing 6 lb ai/gal of ethyl parathion in addition to 3 lb ai/gal of methyl parathion.
[f]Under EPA Reg. No. 2935-527.
[g]Under EPA Reg. No. 2935-528.

Table B. Residue Chemistry Science Assessments for Reregistration of Methyl Parathion.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
860.1200: Directions for Use	N/A	Yes[4]	See Table A.
860.1300: Plant Metabolism	N/A	No[5]	41001401 41001403 41001404 42914601[6] 44669501[3]
860.1300: Animal Metabolism	N/A	No[7]	**00128039** 41001405 41001406 Letter dated 2/2/98[5]
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	No[8]	**00003724 00035330 00073196 00080018 00085260 00085261 00085262 00101100 00101122 00101124 00101213 00102312 00102367 00102376 00102414 00113173 05004211** 42241601[9] 42281001[7] 42307901[7] 42307902[7] 42690001[10] 42717601[11] 42717602[9] 42844601[12] 42844602[10] 42844603[10] 42844604[10]
- Animal commodities	N/A	Yes[13]	**00047726 00105217**
860.1360: Multiresidue Methods	N/A	No	
860.1380: Storage Stability Data	N/A	Yes[14]	**00102314** 42230901[7] 42291901[7] 42307001[7] 43685601[15] 43758801[16] 44159702[14] 44632602[17] 44643602[12] 44413301[12] 44413403[12]
860.1500: Crop Field Trials			
Root and Tuber Vegetables Group			
- Beets, garden, roots	1 [§180.121(a)]	No[18]	
- Carrots	1 [§180.121(a)]	No	41395105

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
- Parsnips	1 [§180.121(a)]	No[16]	**00101095 00102356**
- Potatoes	0.1 (N) [§180.121(a)]	Yes[19]	**00101095 00102356** 41438102
- Radishes	1 [§180.121(a)]	No[16]	**00101095 00102356**
- Rutabagas	1 [§180.121(a)]	No[16]	
- Sugar beet roots	0.1 (N) [§180.121(a)]	No[20]	**00101095 00102418** 41379306
- Sweet potatoes	0.1 (N) [§180.121(a)]	No[21]	**00031669**
- Turnips roots	1 [§180.121(a)]	No[22]	**00102418** 41717806
- Yams	None	No[23]	
Leaves of Root and Tuber Vegetables Group			
- Beets garden greens	1 [§180.121(a)]	No[16]	
- Parsnip greens	1 [§180.121(a)]	No[16]	
- Radish tops	1 [§180.121(a)]	No[16]	
- Rutabaga tops	1 [§180.121(a)]	No[16]	
- Sugar beet tops	0.1 (N) [§180.121(a)]	Yes[24]	**00101095 00102418** 41379306
- Turnip greens	1 [§180.121(a)]	Yes[25]	**00102418** 41717806
Bulb Vegetables (*Allium spp.*) Group			
- Garlic	1 [§180.121(a)]	No[16]	
- Onions	1 [§180.121(a)]	Yes[26]	**00102356** 41395104 41596203

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GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
Leafy Vegetables (Except Brassica Vegetables) Group			
- Celery	1 [§180.121(a)]	No[27]	41717802
- Endive	1 [§180.121(a)]	No[16]	
- Lettuce	1 [§180.121(a)]	No[28]	41379302 41596204
- Parsley	1 [§180.121(b)]	No[16]	
- Spinach	1 [§180.121(a)]	No[29]	41359906
- Swiss Chard	1 [§180.121(a)]	No[16]	
Brassica (Cole) Leafy Vegetables Group	1.0 [§180.121(b)]	No[30]	
- Broccoli	1 [§180.121(a)]	No	41379305
- Brussels Sprouts	1 [§180.121(a)]	No	
- Cabbage	1 [§180.121(a)]	No	00061199 41379304 42844602[10]
- Cauliflower	1 [§180.121(a)]	No	00102356
- Collards	1 [§180.121(a)]	No	
- Kale	1 [§180.121(a)]	No	
- Kohlrabi	1 [§180.121(a)]	No[16]	
- Mustard Greens	1 [§180.121(a)]	No	41359901

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
Legume Vegetables (Succulent or Dried) Group			
- Beans succulent and dried	1 [§180.121(a)]	No[31]	**00009821 00009822 00031669 00102417 00102370 00137986** 41438101 41457901 41517102 41560005 41596206 43967301[29]
- Guar beans	0.2 [§180.121(b)]	No[16]	**00161146 00161188**
- Lentils	1 [§180.121(b)]	No[32]	42307902[7]
- Peas succulent and dried	1 [§180.121(a)]	No[33]	**00102417** 41596207 42241601[7]
- Soybeans	0.1 [§180.121(a)]	Yes[34]	**00101100 00102314 00102367** 41379303
Foliage of Legume Vegetables Group			
- Beans forage and hay	None	No[35]	41517102
- Peas vines and hay	1 (forage) [§180.121(a)]	No[36]	41596207 42241601[7]
- Soybeans forage and hay	1 (hay) [§180.121(a)]	No[37]	**00101100 00102356 00102367** 41560003
Fruiting Vegetables (Except Cucurbits) Group			
- Eggplant	1 [§180.121(a)]	No[16]	
- Peppers	1 [§180.121(a)]	No[16]	**00102418**
- Tomatoes	1 [§180.121(a)]	No[38]	**00102292 00102415 00102417** 42844604[10]
Cucurbit Vegetables Group			
- Cucumbers	1 [§180.121(a)]	No[16]	**00102356**
- Melons	1 [§180.121(a)]	No[16]	**00102356**
- Pumpkins	1 [§180.121(a)]	No[16]	

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GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
- Squash (summer/winter)	1 [§180.121(a)]	No[16]	00102356
Citrus Fruits Group	1 [§180.121(a)]	No[16]	
Pome Fruits Group			
- Apples	1 [§180.121(a)]	No[39]	00047726 00051649 00086695 00102355 42844601[10]44413501[37] 44413502[37]
- Pears	1 [§180.121(a)]	Yes[40]	00051649
- Quince	1 [§180.121(a)]	No[16]	
Stone Fruits Group			
- Apricots	1 [§180.121(a)]	No[16]	00102356
- Cherries	1 [§180.121(a)]	No[41]	00102356 44622501[39] 44622502[39]
- Nectarines	1 [§180.121(a)]	No[42]	
- Peaches	1 [§180.121(a)]	No[43]	00047726 00102356 44159901[14]
- Plums (fresh prunes)	1 [§180.121(a)]	Yes[44]	00102356
Berries Group			
- Blackberries	1 [§180.121(a)]	No[16]	
- Blueberries (huckleberries)	1 [§180.121(a)]	No[16]	
- Boysenberries	1 [§180.121(a)]	No[16]	
- Currants	1 [§180.121(a)]	No[16]	
- Dewberries	1 [§180.121(a)]	No[16]	

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
- Gooseberries	1 [§180.121(a)]	No[16]	
- Loganberries	1 [§180.121(a)]	No[16]	
- Raspberries	1 [§180.121(a)]	No[16]	
- Youngberries	1 [§180.121(a)]	No[16]	
Tree Nuts Group			
- Almonds	0.1 (N) [§180.121(a)]	No[45]	**00102418** 44632601[15]
- Filberts	0.1 (N) [§180.121(a)]	No[16]	
- Pecans	0.1 (N) [§180.121(a)]	No[46]	43760901[44]
- Walnuts	0.1 (N) [§180.121(a)]	No[47]	44159701[14]
Cereal Grains Group			
- Barley	1 [§180.121(a)]	No[48]	**00051649 00072376 00086695**
- Corn	1 [§180.121(a)]	No[49]	**00051649 00085259 00085260 00085261** 41560002 41717803 41717804 41717805 44398301[47]
- Oats	1 [§180.121(a)]	No[46]	**00051649 00072376 00086695**
- Rice	1 [§180.121(a)]	No[50]	**00051649** 41379307 41560004 44643601[48]
- Rye	0.5 [§180.319]	No[46]	**00101096**
- Sorghum	0.1 (N) [§180.121(a)]	No[16]	**00053436 00081419 00101098 00101213** 41517103
- Wheat	1 [§180.121(a)]	No[51]	**00051649 00072376 00086695** 41560001 41596209

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GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
Forage Fodder and Straw of Cereal Grains			
- Barley hay and straw	None	No[46, 52]	
- Corn forage and stover	1 (forage) [§180.121(a)]	No[52]	**00051649 00085261** 41717803 41717805 42307901[7] 44398301[50]
- Oat forage, hay and straw	None	No[46, 52]	
- Rice straw	None	Yes[53]	41379307
- Rye forage and straw	None	No[46, 52]	
- Sorghum forage and stover	3 (forage and fodder) [§180.121(a)]	No[16]	**00053436 00081419 00101098 00101213** 41517103
- Wheat forage, hay and straw	None	Yes[54]	**00051649 00072376** 41596209 41818502[52]
Grass Forage Fodder and Hay Group			
- Grass forage and hay	1 (forage) [§180.121(a)]	Yes[55]	**00102417** 41359902 41359903 41359905 43479501[14]
Non-grass Animal Feeds			
- Alfalfa (fresh)	1.25 [§180.121(a)]	Yes[56]	**00035330 00035332 00035890 00047726 00072376 00101221 00102356 00104198** 41517101
- Alfalfa hay	5 [§180.121(a)]	Yes[54]	**00035330 00035332 00035890 00047726 00072376 00101221 00102356 00104198** 41517101
- Clover	1 [§180.121(a)]	No[16]	**00102356 00104198** 41439601
- Trefoil forage	1.25 [§180.121(b)]	No[16]	
- Trefoil hay	5 [§180.121(b)]	No[16]	
- Vetch forage and hay	1 [§180.121(a)]	No[16]	
Miscellaneous Commodities			

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GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
- Artichokes	1 [§180.121(a)]	No[57]	**00102415** 41717801
- Aspirated Grain Fractions	None	No[58]	44794501[56]
- Avocados	1 [§180.121(a)]	No[16]	
- Cottonseed	0.75 [§180.121(a)]	No[59]	**00008516 00080018 00086695 00099011 00101100 00101122 00101226 00101489 00102291 00102314 00102362 00102376 00105217 00113173** 41395103 41457904 44430601[57]
- Cotton, gin byproducts	None	Yes[60]	
- Cranberries	1 [§180.121(a)]	No[16]	
- Dates	1 [§180.121(a)]	No[16]	
- Figs	1 [§180.121(a)]	No[16]	
- Grapes	1 [§180.121(a)]	No[61]	**00102417** 41457902 42844603[10]44413401[59] 44413402[59]
- Guavas	1 [§180.121(a)]	No[16]	
- Hops	1 [§180.121(a)]	No[62]	44501201[60]
- Mangoes	1 [§180.121(a)]	No[16]	
- Mustard seed	0.2 [§180.121(a)]	No[16]	**00003724**
- Okra	1 [§180.121(a)]	No[16]	
- Olives	1 [§180.121(a)]	No[16]	
- Peanuts	1 [§180.121(a)]	No[63]	**00102418** 44620301[61] 4462302[61]

GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
- Pineapples	1 [§180.121(a)]	No[16]	
- Rape seed	0.2 [§180.121(a)]	No[64]	**00003724** 42717601[65]
- Safflower seed	0.1 (N) [§180.121(a)]	No[16]	
- Strawberries	1 [§180.121(a)]	No[16]	**00102418**
- Sugarcane	0.1 (N) [§180.121(a)]	No[16]	
- Sunflower seed	0.2 [§180.121(a)]	No[66]	**00031669 00102312** 41359904
- Tobacco	None	No[16]	**00102356**
860.1520: Processed Food/Feed			
- Apples	None	No[67]	42479101[68]
- Barley	None	No[69]	
- Citrus	None	No[16]	
- Corn (field)	None	No[70]	41717804
- Cottonseed	None	No[68]	**00101122 00102362** 41596201
- Figs	None	No[16]	
- Grapes	None	No[68]	41457903
- Oats	None	No[67]	
- Olives	None	No[16]	
- Peanuts	None	No[71]	44620303[69]
- Pineapple	None	No[16]	
- Plums/prunes	None	Yes[72]	
- Potato	None	No[68]	41438102
- Rapeseed	None	No[73]	42717602[62]
- Rice	None	No[74]	**00051649** 41596205
- Rye	None	No[67]	
- Safflower seed	None	No[16]	

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GLN: Data Requirements	Current Tolerances, ppm [40 CFR]	Must Additional Data Be Submitted?	References [3]
- Sorghum	None	No[16]	
- Soybeans	None	No[75]	41517104 42690001[8]
- Sugar beets	None	No[68]	41379306
- Sugarcane	None	No[16]	
- Sunflower seed	None	Yes[76]	
- Tomatoes	None	No[68]	42281001[7]
- Wheat	None	No[77]	41596209
860.1480: Meat Milk Poultry Eggs			
- Milk and the Fat Meat and Meat Byproducts of Cattle Goats Hogs Horses and Sheep	None	Yes[78]	
- Eggs and the Fat Meat and Meat Byproducts of Poultry	None	Yes[76]	
860.1400: Water Fish and Irrigated Crops	None	N/A	
860.1460: Food Handling	None	N/A	
860.1850: Confined Rotational Crops	N/A	No[79]	41596301 4312760977
860.1900: Field Rotational Crops	None	N/A[77]	

1. Use 100% Dermal Absorption for Route-to-Route Extrapolation

2. Use 100% Absorption for Route-to-Route Extrapolation

3. **Bolded** references were reviewed in the Residue Chemistry Chapter of the Methyl Parathion Reregistration Standard dated 11/8/85; non-bolded references were reviewed in the Residue Chemistry Chapter of the Methyl Parathion Reregistration Standard Update dated 11/24/92. All other references were reviewed as noted.

4. Registrants must amend all Section 3 end-use product labels for the EC formulations of methyl parathion containing 4 lb/gal of methyl parathion or more, as necessary, to conform to the Agency prescribed food/feed use sites, patterns, and restrictions specified in Appendix A.

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Registrants must amend all Section 3 end-use product labels for the EC formulations of methyl parathion containing 3 lb/gal of methyl parathion and 6 lb/gal of ethyl parathion, as necessary, to conform to the Agency's prescribed food/feed use sites, patterns, and restrictions specified in Appendix B. [Note: Since, the use of methyl parathion on sorghum is not being supported under reregistration, all end-use product labels for the EC formulations of methyl parathion containing 3 lb/gal of methyl parathion and 6 lb/gal of ethyl parathion must be amended to prohibit the use of methyl parathion on sorghum.]

Registrants must amend all Section 3 end-use product labels for the Mcap formulations of methyl parathion containing 2 lb/gal of methyl parathion, as necessary, to conform to the Agency's prescribed food/feed use sites, patterns, and restrictions specified in Appendix C.

No label amendments are required for existing Special Local Needs (SLN) registrations listed in Table A with the exception of the SLN for the use of the Mcap formulation of methyl parathion on soybeans (IN88000700) which must be amended to prohibit the feeding or grazing of treated soybean forage or hay to livestock.

5. The registrant (Cheminova) has submitted a new lettuce metabolism study (MRID 44669501) which is under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the dietary exposure estimates used in the dietary risk assessments for methyl parathion. No new methyl parathion residues of concern were identified in the subject study. Pending acceptance of the new lettuce metabolism data to satisfy this guideline requirement, no additional plant metabolism data are required to support the reregistration of methyl parathion.

6. CBRS No. 12731, DP Barcode D195379, 5/6/94, R. Perfetti.

7. In a letter dated 2/2/98, the registrant (Cheminova) has submitted the additional data required to validate the experimental methods for the poultry and ruminant metabolism studies concerning: (I) the in-life portion of the study, including total feeds consumed to determine theoretical dietary intake of methyl parathion, as ppm, in the feed; (ii) the storage intervals for goat tissue and milk, and hen tissue and egg samples; and (iii) for the ruminant study only, the specific fraction or matrix used for Soxhlet extraction, acid hydrolysis, and enzyme hydrolysis; flow charts must be provided to indicate at what point these procedures were used. These data are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the dietary exposure estimates used in the dietary risk assessments for methyl parathion. Pending acceptance of these data to validate the experimental methods for the poultry and ruminant metabolism studies and

satisfy this guideline requirement, no additional animal metabolism data are required to support the reregistration of methyl parathion.

8. The proposed enforcement method(s) employed to determine methyl parathion and methyl paraoxon in plant commodities are the FDA multiresidue testing protocol(s). Therefore, an independent laboratory validation (ILV) is not required.

9. CBRS Nos. 9854, 9856, 9857, 9958, 9967, and 10,074; DP Barcodes D177993, D177987, D177985, D178858, D178854, and D179067; 12/18/92; R. Perfetti.

10. CBRS No. 11616, DP Barcode D189381, 9/10/93, R. Perfetti.

11. CBRS No. 12024, DP Barcode D192316, 9/7/93, S. Knizner.

12. CBRS No. 12454, DP Barcode D194342, 1/4/94, R. Perfetti.

13. In conjunction with the ruminant and poultry feeding studies, the registrants must provide data validating the analytical method(s) used for determining methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl in meat, milk, poultry, and eggs. If the feeding studies indicate that tolerances are necessary for residues in animal commodities, then the registrants must propose an enforcement method for determining residues of methyl parathion in animal commodities.

14. New storage stability data have been submitted demonstrating the stability of methyl parathion residues of concern in apples (MRID 44643602), peaches (MRID 44413301), and grapes (MRID 44413403) which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any of the dietary exposure estimates used in the dietary risk assessments for methyl parathion. Pending acceptance of these storage stability to satisfy guideline requirements, no additional data depicting the storage stability of methyl parathion residues of concern in plant commodities are required to support the reregistration of methyl parathion.

    Data depicting the storage stability of methyl parathion residues of concern in animal commodities are required in conjunction with the ruminant and poultry feeding studies.

15. DP Barcode D216966, 9/24/97, B. Cropp-Kohlligian.

16. DP Barcodes D225636, D225672, D235833, D235837; 9/19/97, B. Cropp-Kohlligian.

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17. DP Barcode D249726, 4/8/99, B. Cropp-Kohlligian.

18. The Agency understands that the use of methyl parathion on this commodity is not being supported under reregistration. Hence, no residue chemistry data are required and the associated tolerance(s) should be revoked.

19. The available data are adequate to support the use of the EC formulation of methyl parathion on potatoes and indicate that the currently established tolerance for residues of methyl parathion in/on potatoes should be decreased from 0.1 ppm to 0.05 ppm.

    No data are available to support the use of the Mcap formulation of methyl parathion on potatoes. Data are required depicting methyl parathion residues of concern in/on potatoes harvested 5 days following the last of 6 foliar applications of the Mcap formulation of methyl parathion at 1.5 lb ai/A/application. The registrant should refer to OPPTS GLN 860.1500 for information on the number and location of field trials required. These data are considered confirmatory. [Note: The registrant (Elf Atochem) has committed to generate the subject data.]

20. The available data are adequate and support decreasing the tolerance for residues of methyl parathion in/on sugar beet roots from 0.1 ppm to 0.05 ppm.

21. Potato field trial data required to support the use of the Mcap formulation of methyl parathion on potatoes will be translated to support the use of the Mcap formulation of methyl parathion on sweet potatoes and yams. Available potato field trial data generated with an EC formulation of methyl parathion indicate that the tolerance for residues of methyl parathion in/on sweet potatoes should be decreased from 0.1 ppm to 0.05 ppm.

22. The available data are adequate and support decreasing the tolerance for residues of methyl parathion in/on turnip roots from 1 ppm to 0.05 ppm.

23. No residue chemistry data are required. Furthermore, since a tolerance for residues of methyl parathion is currently established in/on sweet potatoes, a tolerance for residues of methyl parathion in/on yams is not required. [Separate tolerances are not required for sweet potatoes and yams as specified under 40 CFR §180.1(h).]

24. Data are required depicting methyl parathion residues of concern in/on sugar beet tops harvested 20 days following the last of 6 foliar applications of an EC formulation of methyl parathion at 0.38 lb ai/A/application. The registrant should refer to OPPTS GLN 860.1500 for information on the number and location of field trials required. These data are considered confirmatory. [Note: The registrant (Cheminova) has <u>not</u> committed to generate the subject data.]

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Based on available turnip top data (MRID 41717806), residues of methyl parathion in/on sugar beet tops are likely to exceed the currently established tolerance in/on sugar beet tops (0.1 ppm) resulting from the maximum use rate of methyl parathion on sugar beets. Residues of methyl parathion in/on turnip tops harvested 21 days following the last of 6 foliar applications of methyl parathion at 0.8 lb ai/A/application were 0.05 ppm - 1.82 ppm and 0.05 ppm - 3.83 ppm in/on turnip tops harvested 7 days following 4 foliar applications of methyl parathion at 0.8 lb ai/A/application plus 2 foliar applications at 0.5 lb ai/A/application. Based on the translation of the turnip top data to sugar beet tops, the currently established tolerance for residues of methyl parathion in/on sugar beet tops should be increased from 0.1 ppm to 2 ppm.

25. Data are required depicting methyl parathion residues of concern in/on turnip tops harvested 15 days after the last of 6 foliar applications of the EC formulation of methyl parathion at 0.75 lb ai/A/application. The registrant should refer to OPPTS GLN 860.1500 for information on the number and location of field trials required. These data are considered confirmatory. {Note: The registrant (Cheminova) has not committed to generate the subject data.]

Based on available turnip top data (MRID 41717806), residues of methyl parathion in/on turnip tops are likely to exceed the currently established tolerance (1 ppm) in/on turnip greens resulting from the maximum use rate of methyl parathion on turnips. Residues of methyl parathion in/on turnip tops harvested 21 days following the last of 6 foliar applications of methyl parathion at 0.8 lb ai/A/application were 0.05 ppm - 1.82 ppm and 0.05 ppm - 3.83 ppm in/on turnip tops harvested 7 days following 4 foliar applications of methyl parathion at 0.8 lb ai/A/application plus 2 foliar applications at 0.5 lb ai/A/application. Based on these data, the currently established tolerance for residues of methyl parathion in/on turnip greens should be increased from 1 ppm to 4 ppm.

26. The available data are adequate to support the use of the EC formulation of methyl parathion on onions and indicate that the currently established tolerance for residues of methyl parathion in/on onions (1 ppm) is appropriate.

No data are available to support the use of the Mcap formulation of methyl parathion on onions. Data are required depicting methyl parathion residues of concern in/on onions harvested 15 days following the last of 6 foliar applications of the Mcap formulation of methyl parathion at 1.0 lb ai/A/application. The registrant should refer to OPPTS GLN 860.1500 for information on the number and location of field trials required. These data are considered confirmatory. [Note: The registrant (Elf Atochem) has committed to generate the subject data.]

27. The available data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on celery should be increased from 1 ppm to 5 ppm.

28. The available data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on lettuce should be increased from 1 ppm to 2 ppm.

29. The available data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on spinach should be decreased from 1 ppm to 0.5 ppm.

30. Adequate broccoli, cabbage, and mustard green data are available and support the 1.0 ppm tolerance in/on *Brassica* Vegetables Crop Group. Individual tolerances for members of this group should be revoked.

31. The available dried bean residue chemistry data are adequate and support a tolerance of 0.05 ppm for residues of methyl parathion in/on beans, dried seed.

    The available succulent bean residue chemistry data are adequate and support a tolerance of 1 ppm for residues of methyl parathion in/on succulent beans.

    Additional succulent bean field trial data are required to support existing Special Local Needs (SLN) registrations in MN (MN97000100), WI (WI95000500), and MO (MO95000100) for the use of the Mcap formulation of methyl parathion on succulent beans. The registrant (Elf Atochem) has submitted additional succulent bean field trial data (MRID 43967301) to support the subject SLN registrations which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or dietary exposure estimates used in the dietary risk assessments for methyl parathion. Pending acceptance of the subject succulent bean field trial data to support the existing Special Local Needs (SLN) registrations in MN (MN97000100), WI (WI95000500), and MO (MO95000100) for the use of the Mcap formulation of methyl parathion on succulent beans, no additional bean field trial data are required to support the reregistration of methyl parathion.

32. The available lentil field trial data are adequate and support decreasing the tolerance for residues of methyl parathion in/on lentil seeds from 1 ppm to 0.05 ppm

33. The available pea field trial data (succulent and dried) are adequate and support the establishment of separate tolerances for residues of methyl parathion in/on dried pea seeds at 0.5 ppm and in/on succulent peas at 1 ppm.

Note: Although pea field trial data were not submitted to support the reregistration of the Mcap formulation of methyl parathion, available pea field trial data that were conducted using the EC formulation are sufficient since the proposed maximum use rate for the Mcap formulation of methyl parathion on peas (2 applications/season at 0.5 lb ai/A/application with a 15-day PHI) is significantly less than the maximum use rate for the EC formulation of methyl parathion on peas (6 applications/season at 1.0 lb ai/A/application with a 15-day PHI).

34. The available data are adequate to support the use of the EC formulation of methyl parathion on soybeans and indicate that the currently established tolerance for residues of methyl parathion in/on soybeans should be decreased from 0.1 ppm to 0.05 ppm.

    Data are required depicting methyl parathion residues of concern in/on soybeans harvested 30 days following the last of 2 applications of the Mcap formulation of methyl parathion at 1.0 lb ai/A/application. The registrant is referred to OPPTS GLN 860.1500 for information on the location and number of field trials required. These data are considered confirmatory. [Note: The registrant (Elf Atochem) has committed to generate the subject data.]

35. Bean vines and hay are no longer listed as RACs of beans. The only bean cultivar having foliage RACs is cowpeas for which forage and hay are RACs used as livestock feeds. The use of methyl parathion in/on cowpeas is not being supported under reregistration. Hence, no residue data on bean vines and forage are required to support the reregistration of methyl parathion. No tolerances for residues of methyl parathion in/on bean vines or bean forage are needed.

36. Pea vines and hay are no longer listed as RACs of peas. The only pea cultivar having foliage RACs is field peas for which forage and hay are RACs used as livestock feeds. The use of methyl parathion in/on field peas is not being supported under reregistration. Hence, no residue chemistry data on peas vines and hay are required to support the reregistration of methyl parathion. No tolerances for residues of methyl parathion in/on pea vines or pea hay are needed.

37. Provided the registrants amend all end-use product labels, including SLN registration labels (SLN Reg. No. IN88000700) to prohibit the feeding or grazing of treated soybean forage and hay to livestock, no residue chemistry soybean forage and hay are required to support the reregistration of methyl parathion. No tolerances for residues of methyl parathion in/on soybean forage or soybean hay are needed.

38. The available data are adequate and support decreasing the tolerance for residues of methyl parathion in/on tomatoes from 1 ppm to 0.5 ppm.

39. Additional apple field trial data are required to support the use of the Mcap formulation of methyl parathion on apples. The available apple field trial data indicate that a tolerance of 1 ppm in/on apples would be appropriate.

    The registrant (Elf Atochem) has submitted new apple field trial data (MRIDs 44413501 and 44413502) to support the use of the Mcap formulation of methyl parathion on apples which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or change any dietary exposure estimates used in the dietary risk assessment for methyl parathion. Pending acceptance of the subject apple field trial data to support the use of the Mcap formulation of methyl parathion on apples, no additional apple field trial data are required to support the reregistration of methyl parathion.

40. Data are required depicting methyl parathion residues of concern in/on pears resulting from the maximum use rate of the Mcap formulation of methyl parathion on pears. Apple field trial data will not be translated to pears. The registrant should refer to OPPTS GLN 860.1500 for information on the number and location of field trials required. These data are considered critical to tolerance reassessment. [Note: The registrant (Elf Atochem) has not committed to generate the subject data.]

41. Additional cherry field trial data are required to support the use rate of the Mcap formulation of methyl parathion on cherries. The registrant (Elf Atochem) has submitted new cherry field trial data (MRIDs 44622501 and 44622502 to support the use of the Mcap formulation of methyl parathion on cherries which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to increase any dietary exposure estimates used in the dietary risk assessment for methyl parathion; however, these data do indicate that it may be appropriate to increase the currently established tolerance for residues of methyl parathion in/on cherries from 1 ppm to 4 ppm. Pending acceptance of the subject cherry field trial data to support the use of the Mcap formulation of methyl parathion on cherries, no additional cherry field trial data are required to support the reregistration of methyl parathion.

42. The available peach field trial data will be translated to support the use of methyl parathion on nectarines.

43. The available data are adequate and support the established 1 ppm tolerance for residues of methyl parathion in/on peaches.

44. Data are required depicting methyl parathion residues of concern in/on plums/fresh prunes reflecting the maximum use of the Mcap formulation of methyl parathion on plums/fresh prunes The registrant is referred to OPPTS GLN 860.1500 for information on the location and number of field trials required. These data are considered critical to tolerance reassessment. [Note: The registrant (Elf Atochem) has committed to generate these data.]

45. The available data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on almonds (0.1 ppm) is appropriate and that the currently established tolerance for residues of methyl parathion in/on almond hulls should be increased from 3 ppm to 25.

46. Additional pecan field trial data are required to support the use of the Mcap formulation of methyl parathion on pecans. The registrant (Elf Atochem) has submitted new pecan field trial data (MRID 43760901) to support the use of the Mcap formulation of methyl parathion on pecans which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any dietary exposure estimates used in the dietary risk assessment for methyl parathion; however, these data do indicate that it may be appropriate to decrease the currently established tolerance for residues of methyl parathion in/on pecans from 0.1 ppm to 0.05 ppm. Pending acceptance of the subject pecan field trial data to support the use of the Mcap formulation of methyl parathion on pecans, no additional pecan field trial data are required to support the reregistration of methyl parathion.

47. Data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on walnuts should be decreased from 0.1 ppm to 0.05 ppm.

48. Residue chemistry data on wheat grain, forage, hay, and straw will be translated to support uses on barley (grain, hay, and straw), oats (grain, forage, hay, and straw), and rye (grain, forage and straw).

49. The available data are adequate and support the establishment of separate tolerances for residues of methyl parathion in/on sweet corn (K+CWHR), field corn grain, and pop corn grain at 0.2 ppm.

    The registrant (Elf Atochem) has submitted new field corn data (MRID 44398301) depicting methyl parathion residues of concern in/on grain, forage, and fodder resulting from treatment with the Mcap formulation of methyl

parathion which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or any exposure estimates used in the dietary risk assessment for methyl parathion.

50. The available data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on rice should be increased from 1 ppm to 3 ppm. The registrant (Elf Atochem) has submitted new rice field trial data (MRID 44643601) which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or change any dietary exposure estimates used in the dietary risk assessment for methyl parathion.

51. The available data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on wheat grain should be increased from 1 ppm to 5 ppm. [Note: Since wheat grain data are being translated to barley, oats, and rye grains, these grain tolerances should also be increased to 5 ppm.]

52. The available data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on corn forage should be increased from 1 ppm to 10 ppm. The available data also indicate that a tolerance for residues of methyl parathion in/on corn stover should be established and that an appropriate level would be 30 ppm.

    The registrant (Elf Atochem) has submitted new field corn data (MRID 44398301) depicting methyl parathion residues of concern in/on grain, forage, and fodder resulting from treatment with the Mcap formulation of methyl parathion which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or any exposure estimates used in the dietary risk assessment for methyl parathion.

53. The available rice straw data are adequate to support the use of the EC formulation of methyl parathion on rice and indicate that a tolerance for residues of methyl parathion in/on rice straw should be established and that an appropriate level would be 9 ppm.

    The available rice straw data are <u>not</u> adequate to support the use of the Mcap formulation of methyl parathion on rice. Data are required depicting methyl parathion residues of concern in/on rice straw harvested 15 days following the

last of 3 foliar applications of the Mcap formulation of methyl parathion to rice at 0.75 lb ai/A/application. The registrant should refer to OPPTS GLN 860.1500 for information on the number and location of field trials required. These data are considered confirmatory. [Note: The registrant (Elf Atochem) has not committed to generate the subject data.]

54. The available wheat straw magnitude of the residue data are adequate and indicate a tolerance for residues of methyl parathion in/on wheat straw should be established and that an appropriate level would be 11 ppm. Since wheat straw data are being translated to barley straw, oat straw, and rye straw, tolerances for residues of methyl parathion in/on these straw RACs of barley, oats, and rye should also be established at 11 ppm.

Data are required depicting methyl parathion residues of concern in/on wheat forage and hay reflecting the maximum use rate of the EC formulation of methyl parathion on wheat. The registrants should refer to OPPTS GLN 860.1500 for information on the number and location of trials required. These data are considered confirmatory. [Note: The registrant (Cheminova) has not committed to generate the subject data.]

The available wheat forage and hay data (MRID 41596209), which were generated at a use rate which is slightly lower than the maximum use rate of the EC formulation of methyl parathion on wheat, indicate that tolerances for residues of methyl parathion in/on wheat forage and hay should be established and that appropriate levels would be 2 ppm and 3 ppm, respectively. Since wheat forage and hay data are being translated to barley hay, oat forage, oat hay, and rye forage, tolerances for residues of methyl parathion in/on these forage and hay RACs of barley, oats, and rye should also be established at 2 ppm and 3 ppm, respectively.

The registrant (Elf Atochem) has submitted new whet forage, hay, and straw magnitude of the residue data (MRID 41818502) which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or change any dietary exposure estimates used in the dietary risk assessment for methyl parathion.

55. Data are required depicting methyl parathion residues of concern in/on grass forage (at a 0-day PHI/PGI) and hay reflecting the maximum use rate of the EC formulation of methyl parathion on grass. The registrants should refer to OPPTS GLN 860.1500 for information on the number and location of trials required. These data are deemed critical to tolerance reassessment. [Note: The registrant (Cheminova) has committed to generate the subject data.]

56. Data are required depicting methyl parathion residues of concern in/on alfalfa forage and hay reflecting the maximum use rate of the EC formulation of methyl parathion on alfalfa. The registrants should refer to OPPTS GLN 860.1500 for information on the number and location of trials required. These data are considered critical to tolerance reassessment. [Note: The registrant (Cheminova) has committed to generate the subject data.]

57. The available data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on artichokes should be increased from 1 ppm to 2 ppm.

58. Data are required depicting methyl parathion residues of concern in aspirated grain fractions (AGF) of wheat grain treated with the EC formulation of methyl parathion at the maximum use rate for methyl parathion on wheat. The registrant (Cheminova) has submitted new magnitude of the residue data (MRID 44794501) depicting methyl parathion residues of concern in the AGF of wheat grain treated with the EC formulation of methyl parathion at the maximum use rate. These data are under review. A preliminary evaluation of these data indicates that residues of methyl parathion are not likely to concentrate in AGF of wheat grain treated with methyl parathion. Based upon the highest average residue (HAFT) value for residues of methyl parathion in/on wheat grain (5.09 ppm) and the average concentration factor from the subject study (ca 1x), a tolerance of 5 ppm for residues of methyl parathion in aspirated grain fractions would be appropriate. Pending acceptance of these data to satisfy guideline requirements, no additional AGF data are required to support the reregistration of methyl parathion.

59. The available residue chemistry data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on cottonseed should be increased from 0.75 ppm to 5 ppm. Note: A tolerance level of 5 ppm for residues of methyl parathion in/on cottonseed is required to cover residues of methyl parathion likely to be incurred in/on cottonseed resulting from multiple ULV applications of the EC formulation of methyl parathion to cotton grown in TX at 3.0 lb ai/A/application with a 1-day PHI (SLN Reg. No. TX97000600).

Additional cottonseed field trial data are required to support the maximum use rate of the Mcap formulation of methyl parathion on cotton. The registrant (Elf Atochem) has submitted new cottonseed field trial data (MRID 44430601) which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or change any dietary exposure estimates used in the dietary risk assessment for methyl parathion. Pending acceptance of the subject cottonseed field trial data to support the use of the Mcap formulation of methyl parathion on cotton, no

submitted new peanut processing data (MRID 44620303) to support the use of the Mcap formulation of methyl parathion on peanuts. The subject peanut processing data are under review. A preliminary evaluation of these data indicates that residues of methyl parathion do not concentrate in/on peanut meal and refined oil processed from peanuts treated with methyl parathion. Therefore, it is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or any dietary exposure estimates used in the dietary risk assessment for methyl parathion. Pending acceptance of the subject peanut processing data to support the use of the Mcap formulation of methyl parathion on peanuts, no additional peanut processing data are required to support the reregistration of methyl parathion.

72. Data are required depicting the potential for the concentration of methyl parathion residues of concern in/on prunes processed from plums bearing detectable residues. [Note: The registrant (Elf Atochem) has committed to generate the subject data.]

73. The available data are adequate and indicate that tolerances for residues of methyl parathion are not required for the processed commodities of canola seed. Residues of methyl parathion did not concentrate in canola meal, but concentrated by 2x in refined canola oil processed from canola seed treated at 5x. Residues of methyl parathion were below the LOQ (0.05 ppm) in/on canola seed from all field trials. When residues in oil are adjusted for the degree of exaggeration, the maximum expected residues in oil would be <0.2 ppm. As the Agency is not proposing to decrease the current 0.2 ppm tolerance for residues of methyl parathion in/on canola seed, residues in oil would be covered by the current tolerance. Therefore, a separate tolerance is not required for canola oil.

74. The available data are adequate and indicate that a tolerance for residues of methyl parathion in rice hulls is required and that an appropriate level would be 12 ppm. In rice grain, residues of methyl parathion did not concentrate in brown rice, polished rice, or rice bran, but concentrated by 4.7x in rice hulls. Based upon the highest average field trial (HAFT) value for residues of methyl parathion in/on rice grain (2.35 ppm), a tolerance of 12 ppm for residues of methyl parathion in rice hulls should be established.

75. The available data are adequate and indicate that a tolerance for residues of methyl parathion in soybean oil is required and that an appropriate level would be 0.2 ppm. In soybeans, residues of methyl parathion did not concentrate significantly in hulls and meal, but concentrated by 3x in refined oil. Based upon the reassessed tolerance for residues of methyl parathion in/on soybeans (0.05 ppm), a tolerance of 0.2 ppm for residues of methyl parathion in refined soybean oil should be established. [Note: Additional soybean magnitude of the residue

additional cottonseed magnitude of the residue data are required to support the reregistration of methyl parathion.

60. New cotton gin byproducts magnitude of the residue data are required to support the maximum use rates of the EC and Mcap formulations of methyl parathion on cotton. The registrants should refer to OPPTS GLN 860.1500 for information on the number and location of trials required. These data are considered critical to tolerance reassessment. [Note: The registrants (Cheminova and Elf Atochem) have committed to generate the subject data.]

61. Additional grape field trial data are required to support the use of the Mcap formulation of methyl parathion on grapes. The available grape field trial data indicate that a tolerance of 1 ppm for residues of methyl parathion in/on grapes would be appropriate.

    The registrant (Elf Atochem) has submitted new grape field trial data (MRIDs 44413401 and 44413402) which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any tolerance recommendations made herein or change any exposure estimates used in the dietary risk assessment for methyl parathion. Pending acceptance of the subject grape field trial data to support the use of the Mcap formulation of methyl parathion on grapes, no additional grape field trial data are required to support the reregistration of methyl parathion.

62. Data are required depicting methyl parathion residues of concern in/on dried hops treated with the EC formulation of methyl parathion at the maximum use rate of methyl parathion on hops. IR-4 has submitted new hops field trial data (MRID 44501201) to support the use of the EC formulation of methyl parathion on hops which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to change any tolerance reassessment recommendations made herein or change any dietary exposure estimates used in the dietary risk assessment for methyl parathion. Pending acceptance of these data to satisfy guideline requirements, no additional hops field trial data are required to support the reregistration of methyl parathion.

63. Additional peanut field trial data are required to support the use of the Mcap formulation of methyl parathion on peanuts. The registrant (Elf Atochem) has submitted new peanut field trial data (MRIDs 44620301 and 44620302) to support the use of the Mcap formulation of methyl parathion on peanuts which are under review. A preliminary evaluation of these data indicates that it is unlikely that a thorough review of these data will precipitate the need to increase dietary exposure estimates used in the dietary risk assessment for methyl

parathion; however, these data do indicate that it may be appropriate to decrease the currently established tolerance for residues of methyl parathion in/on peanuts from 1 ppm to 0.05 ppm and establish a tolerance in/on peanut hay at 6 ppm. Pending acceptance of the subject peanut field trial data to support the use of the Mcap formulation of methyl parathion on peanuts, no additional peanut field trial data are required to support the reregistration of methyl parathion.

64. Provided the registrants amend all end-use product labels to specify applications to canola (oilseed crop) only, the available data are adequate and support the currently established 0.2 ppm tolerance for residues of methyl parathion in/on canola seed.

65. CBRS No. 12024, DP Barcode D192316, 9/7/93, S. Knizner.

66. The available data are adequate and indicate that the currently established tolerance for residues of methyl parathion in/on sunflower seeds should be decreased from 0.2 ppm to 0.05 ppm.

67. The available data are adequate and indicate that a tolerance for residues of methyl parathion in apple, wet pomace should be established and that an appropriate level would be 5 ppm. In apples, residues of methyl parathion did not concentrated in apple juice, but concentrated by 5.3x in wet apple pomace. Apple field trial data (including those under review (MRIDs 44413501 and 44413502) indicate that the currently established tolerance for residues of methyl parathion in/on apples (1 ppm) is just adequate to cover residues likely to occur in/on apples resulting from the maximum use rate of the Mcap formulation of methyl parathion on apples. Hence, a tolerance of 5 ppm should be established for residues of methyl parathion in apple, wet pomace.

68. CBRS No. 10687, DP Barcode D183212, 3/2/93, A. Aikens.

69. Processing data from wheat grain will be translated to determine the need for tolerances in processed commodities of barley grain, oat grain, and rye grain.

70. The available data are adequate and indicate that tolerances are not required for residues of methyl parathion in processed commodities of corn grain, cottonseed, grapes, potatoes, sugar beet roots, and tomatoes. Residues did not concentrate in commodities processed from corn grain, cottonseed, grapes, and tomatoes bearing detectable residues. Residues were nondetectable in potatoes and sugar beet roots treated at 5x the maximum label rate and in the commodities processed from these crops.

71. New peanut processing data are required to support the use of the Mcap formulation of methyl parathion on peanuts. The registrant (Elf Atochem) has

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of methyl parathion are expressed in terms of parathion or its methyl homolog (methyl parathion) [40 CFR §180.121 (a) and §180.319] or in terms of methyl parathion *per se* [40 CFR §180.121 (b)]. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) has tentatively determined that the tolerance expression for methyl parathion residues of concern in/on plant commodities may be based on residues of methyl parathion only. Tolerances for residues of parathion should be moved from 40 CFR §180.121 (a) and listed under a separate 40 CFR §180.XXX (a) section. The tolerance definition for methyl parathion listed under 40 CFR §180.121 (a) should be changed to read as follows:

> Tolerances are established for the residues of methyl parathion [*O,O*-dimethyl-*O*-*p*-nitrophenylthiophosphate] in/on the following commodities:

The appropriate tolerances for methyl parathion residues in animal commodities will be determined once data are available from outstanding livestock feeding studies. The HED Metabolism Assessment Review Committee (memo by B. Cropp-Kohlligian dated 5/21/98) has tentatively determined that the tolerance expression for methyl parathion residues of concern in/on animal commodities, if tolerances are needed, may be based on residues of methyl parathion only.

A summary of the methyl parathion tolerance reassessment and recommended modifications in commodity definitions are presented in Table C.

Tolerances Listed Under 40 CFR §180.121 (a) and (b):

In support of the reregistration of methyl parathion, the registrants (Cheminova and Elf Atochem) and IR-4 have submitted the following new field trial data: (i) apple field trial data (MRIDs 44413501 and 44413502), (ii) beans field trial data (MRID 43967301), (iii) cherry field trial data (MRIDs 44622501 and 44622502), (iv) cottonseed field trial data (MRID 44430601), (v) field corn field trial data (MRID 44398301), (vi) grape field trial data (MRIDs 44413401 and 44413402), (vii) hops field trial data (MRID 44501201), (viii) pecan field trial data (MRID 43760901), (ix) peanut field trial data (MRIDs 44620301 and 44620302), (x) rice field trial data (MRID 44643601), (xi) wheat forage, hay, and straw magnitude of the residue data (MRID 41818502), and (xii) magnitude of the residue data on aspirated grain fractions (AGF) of wheat (MRID 44794501). These data are under review.

Pending acceptance of the new residue chemistry data detailed above to fulfill data guideline requirements and provided the registrants amend all end-use product labels, as necessary, to conform to the Agency's prescribed food/feed use sites, patterns, and restrictions as specified in Table A (and further clarified for each formulation in

Table C. Tolerance Reassessment Summary for Methyl Parathion.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	*Correct Commodity Definition* Comments
Tolerances listed under 40 CFR §180.121 (a):			
Alfalfa, Fresh	1.25	TBD [a]	*Alfalfa, forage* Data deemed critical to tolerance reassessment remain outstanding.
Alfalfa, Hay	5	TBD	*Alfalfa, hay* Data deemed critical to tolerance reassessment remain outstanding.
Almonds	0.1(N)	0.1	
Almonds, hulls	3	25	
Apples	1	1	New apple field trial data (MRIDs 44413501 and 44413502) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on apples may be appropriate.
Apricots	1	Revoke	Not supported under reregistration
Artichokes	1	2	
Avocados	1	Revoke	Not supported under reregistration
Barley	1	5	*Barley, grain* Translated from wheat grain.
Beans	1	1	*Beans, succulent* New succulent bean field trial data (MRID 43967301) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on succulent beans may be appropriate.
		0.05	*Beans, dried seed*
Beets greens (alone)	1	Revoke	Not supported under reregistration
Beets (with or without tops)	1	Revoke	Not supported under reregistration
Beets, sugar	0.1(N)	0.05	*Sugar beets, roots*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	*Correct Commodity Definition* Comments
Beets, sugar (tops)	0.1(N)	2	*Sugar beets, tops* Translated from turnip top data. Additional sugar beet top magnitude of the residue data are required. These data are considered confirmatory.
Blackberries **Blueberries (huckleberries)** **Boysenberries** **Dewberries** **Gooseberries** **Loganberries** **Raspberries** **Youngberries**	1	Revoke	Not supported under reregistration
Broccoli **Brussels sprouts** **Cabbage** **Cauliflower** **Collards** **Kale** **Kohlrabi** **Mustard greens**	1	Revoke	Concomitant with the establishment of a Vegetables, leafy, Brassica (cole) crop group tolerance at 1 ppm under §180.121 (a).
Carrots	1	1	*carrot, root*
Celery	1	5	
Cherries	1	4	New cherry field trial data (MRIDs 44622501 and 44622502) are under review. A preliminary evaluation of these data indicates that it may be appropriate to increase the currently established tolerance in/on cherries from 1 ppm to 4 ppm.
Citrus Fruits	1	Revoke	Not supported under reregistration
Clover	1	Revoke	Not supported under reregistration
Corn	1	0.2	*Corn, field, grain* New corn field trial data (MRID 44398301) are under review. A preliminary evaluation of these data indicates that the reassessed tolerances in/on field corn grain and pop corn grain are appropriate.
		0.2	*Corn, pop, grain*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	*Correct Commodity Definition* Comments
		0.2	*Corn, sweet: K+CWHR*
Corn, Forage	1	10	*Corn, forage* New corn field trial data (MRID 44398301) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on corn forage is are appropriate.
Cottonseed	0.75	5	*Cotton, undelinted seed* New cottonseed field trial data (MRID 44430601) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on cottonseed may be appropriate.
Cranberries	1	Revoke	Not supported under reregistration
Cucumbers **Melons** **Pumpkins** **Squash** **Summer squash**	1	Revoke	Not supported under reregistration
Currants	1	Revoke	Not supported under reregistration
Dates	1	Revoke	Not supported under reregistration
Eggplant	1	Revoke	Not supported under reregistration
Endive (escarole)	1	Revoke	Not supported under reregistration
Figs	1	Revoke	Not supported under reregistration
Filberts	0.1(N)	Revoke	Not supported under reregistration
Garlic	1	Revoke	Not supported under reregistration
Grapes	1	1	New grape field trial data (MRIDs 44413401 and 44413402) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on grapes may be appropriate.
Grass (forage)	1	TBD	*Grass, forage* Data deemed critical to tolerance reassessment remain outstanding.

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Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	*Correct Commodity Definition* Comments
		TBD	*Grass, hay* Data deemed critical to tolerance reassessment remain outstanding.
Guavas	1	Revoke	Not supported under reregistration
Hops	1	1	*Hops cones, dried* New hops field trial data (MRID 44501201) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on hops may be appropriate.
Lettuce	1	2	*Lettuce, head and leaf*
Mangoes	1	Revoke	Not supported under reregistration
Mustard seed	0.2	Revoke	Not a RAC of mustard
Nectarines	1	1	Translated from peach field trial data.
Oats	1	5	*Oat, grain* Translated from wheat grain data.
Okra	1	Revoke	Not supported under reregistration
Olives	1	Revoke	Not supported under reregistration
Onions	1	1	Additional onion field trial data are required. These data are considered confirmatory.
Parsnips (with or without tops)	1	Revoke	Not supported under reregistration
Parsnip greens (alone)	1	Revoke	Not supported under reregistration
Peaches	1	1	
Peanuts	1	0.05	New peanut field trial data (MRIDs 44620301 and 44620302) are under review. A preliminary evaluation of these data indicates that it may be appropriate to decrease the currently established tolerance in/on peanuts from 1 ppm to 0.05 ppm.
Pears	1	TBD	It is uncertain if the currently established tolerance is appropriate. Data deemed critical to tolerance reassessment remain outstanding.
Peas	1	1	*Pea, succulent*

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	*Correct Commodity Definition* Comments
		0.5	*Peas, dried seed*
Peas forage	1	Revoke	Not a significant livestock feed item
Pecans	0.1(N)	0.05	New pecan field trial data (MRID 43760901) are under review. A preliminary evaluation of these data indicate that it may be appropriate to decrease the currently established tolerance in/on pecans from 0.1 ppm to 0.05 ppm.
Peppers	1	Revoke	Not supported under reregistration
Pineapples	1	Revoke	Not supported under reregistration
Plums (Fresh Prunes)	1	TBD	It is uncertain if the currently established tolerance is appropriate. Data deemed critical to tolerance reassessment remain outstanding.
Potatoes	0.1(N)	0.05	*Potato, tuber* Additional potato field trial data are required. These data are considered confirmatory.
Quinces	1	Revoke	Not supported under reregistration
Radishes (with or without tops)	1	Revoke	Not supported under reregistration
Radish, tops	1	Revoke	Not supported under reregistration
Rape seed	0.2	0.2	*Canola seed*
Rice	1	3	*Rice, grain* New rice field trial data (MRID 44643601) are under review. A preliminary evaluation of these data indicate that the reassessed tolerance in/on rice grain may be appropriate.
Rutabagas (with or without tops)	1	Revoke	Not supported under reregistration
Rutabaga tops	1	Revoke	Not supported under reregistration
Safflower seed	0.1(N)	Revoke	Not supported under reregistration
Sorghum	0.1(N)	Revoke	Not supported under reregistration
Sorghum fodder	3	Revoke	Not supported under reregistration

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Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	*Correct Commodity Definition* Comments
Sorghum forage	3	Revoke	Not supported under reregistration
Soybean	0.1	0.05	*Soybean, seed* Additional soybean field trial data are required. These data are considered confirmatory.
Soybean hay	1	Revoke	Not supported under reregistration
Spinach	1	0.5	
Strawberries	1	Revoke	Not supported under reregistration
Sugarcane	0.1(N)	Revoke	Not supported under reregistration
Sugarcane fodder	0.1(N)	Revoke	Not supported under reregistration
Sugarcane forage	0.1(N)	Revoke	Not supported under reregistration
Sunflower seed	0.2	0.05	
Sweet Potatoes	0.1(N)	0.05	*Sweet potato, root* Translated from available potato data. Additional potato field trial data are required. These data are considered confirmatory.
Swiss Chard	1	Revoke	Not supported under reregistration
Tomatoes	1	0.5	
Turnips (with or without tops)	1	0.05	*Turnip, roots*
Turnip greens	1	4	*Turnip, tops* Additional turnip top magnitude of the residue data are required. These data are considered confirmatory.
Vetch	1	Revoke	Not supported under reregistration
Walnuts	0.1(N)	0.05	
Wheat	1	5	*Wheat, grain*
Tolerances listed under 40 CFR §180.121 (b):			
Birdsfoot trefoil forage	1.25	Revoke	Not supported under reregistration
Birdsfoot trefoil hay	5	Revoke	Not supported under reregistration
Guar beans	0.2	Revoke	Not supported under reregistration

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	*Correct Commodity Definition* Comments
Lentils	1	Revoke	Concomitant with the establishment of a tolerance on *lentil, seed* at 0.05 ppm under 180.121(a)
Parsley	1	Revoke	Not supported under reregistration
Vegetables, leafy, *Brassica* (cole)	1.0	Revoke	Concomitant with the establishment of a tolerance on Vegetables, leafy, *Brassica* (cole) at 1 ppm under 180.121(a)
Tolerances listed under 40 CFR §180.319:			
Rye	0.5	Revoke	Temporary tolerance no longer in effect.
Tolerances needed under 40 CFR §180.121 (a)			
Apple, wet pomace	None	5	Based on a concentration factor of 5.3x and apple field trial data which indicate that the currently established tolerance on apples (1 ppm) is just adequate.
Aspirated grain fractions	None	5	New aspirated grain fractions magnitude of the residue data (MRID 44794501) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on aspirated grain fractions would be appropriate.
Barley, bran	None	10	Translated from wheat bran.
Barley, hay	None	3	Translated from wheat hay. Additional wheat hay magnitude of the residue data are required.
Barley, straw	None	11	Translated from wheat straw.
Corn, stover	None	30	New corn field trial data (MRID 44398301) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on corn stover is appropriate.
Cotton gin byproducts	None	TBD	Data deemed critical to tolerance reassessment remain outstanding.
Lentil, seed	None	0.05	

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	*Correct Commodity Definition* Comments
Oat, forage	None	2	Translated from wheat forage. Additional wheat forage data are required.
Oat, hay	None	3	Translated from wheat hay. Additional wheat hay magnitude of the residue data are required.
Oat, straw	None	11	Translated from wheat straw.
Peanut hay	None	6	New peanut field trial data (MRIDs 44620301 and 44620302) are under review. A preliminary evaluation of these data indicates that it may be appropriate to establish a tolerance in/on peanut hay and that 6 ppm may be appropriate.
Rice, hulls	None	12	Based on an average concentration factor of 4.7x and a HAFT value of 2.35 ppm in/on rice grain.
Rice, straw	None	9	Additional rice straw magnitude of the residue data are required. These data are considered confirmatory.
Rye, bran	None	10	Translated from wheat bran.
Rye, grain	None	5	Translated from wheat grain.
Rye, forage	None	2	Translated from wheat forage. Additional wheat forage data are required.
Rye, straw	None	11	Translated from wheat straw.
Soybean, refined oil	None	0.2	Based on a concentration factor of 3x and the reassessed tolerance for residues of methyl parathion in/on soybeans (0.05 ppm).
Vegetables, leafy, *Brassica* (cole)	None	1	
Wheat, bran	None	10	Based on a concentration factor of 2x and a HAFT value of 5.09 ppm in/on wheat grain.

Commodity	Current Tolerance (ppm)	Tolerance Reassessment (ppm)	*Correct Commodity Definition* Comments
Wheat, forage	None	2	Additional wheat forage magnitude of the residue data (MRID 41818502) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on wheat forage is appropriate. Additional wheat forage magnitude of the residue data are required. These data are considered confirmatory.
Wheat, germ	None	10	Based on a concentration factor of 2x and a HAFT value of 5.09 ppm in/on wheat grain.
Wheat, hay	None	3	Additional wheat hay magnitude of the residue data (MRID 41818502) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on wheat hay is appropriate. Additional wheat hay magnitude of the residue data are required. These data are considered confirmatory.
Wheat, shorts	None	10	Based on a concentration factor of 2x and a HAFT value of 5.09 ppm in/on wheat grain.
Wheat, straw	None	11	Additional wheat straw magnitude of the residue data (MRID 41818502) are under review. A preliminary evaluation of these data indicates that the reassessed tolerance in/on wheat straw is appropriate.

[a]TBD = To be determined.

CODEX HARMONIZATION

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for methyl parathion residues in/on various plant commodities (see *Guide to Codex Maximum Limits For Pesticide Residues, Part A.1, 1995*). Codex MRLs for methyl parathion are currently expressed in terms of the parent. The U.S. tolerance definition will be compatible with Codex. A comparison of the Codex MRLs and the corresponding U.S. tolerances is presented in Table D.

Table D. Codex MRLs for Parathion-methyl and applicable U.S. tolerances.

Codex			Reassessed U.S. Tolerance (ppm)	Recommendations and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Artichoke globe	2	3	2	
Bean forage (green)	1	3	None	
Beans (dry)	0.05 * [a]	3	0.05	
Brassica vegetables	0.2	CXL	1	
Broccoli	0.2	3(a)	None	
Cabbages, Head	0.2	3(a)	None	
Carrot	1	3	1	
Celery	5	3	5	
Cherries	0.01 *	CXL	4	
Clover	10	3	None	
Common bean (pods and/or immature seeds)	0.05 *	3	1	U.S. commodity definition is "Beans, succulent".
Garden pea (young pods)	1	3	1	U.S. commodity definition is "Peas, succulent".
Gooseberry	0.01 *	CXL	None	
Hay or fodder (dry) of grasses	5	3	TBD [b]	U.S. commodity definitions are "Grass, forage" and "Grass, hay".
Hops, Dry	1.0	3(a)	1	
Lettuce, Leaf	0.05 *	3	2	
Lettuce, Head	0.5	3	2	
Lima bean (young pods and/or immature beans)	0.05 *	3	1	U.S. commodity definition is "Beans, succulent".

Codex			Reassessed U.S. Tolerance (ppm)	Recommendations and Comments
Commodity (As Defined)	MRL (mg/kg)	Step		
Mustard greens	0.5	3	None	
Peas (dry)	0.2	3	0.5	U.S. commodity definition is "Peas, dried seed".
Plums (including prunes)	0.01 *	CXL	TBD	
Potato	0.05 *	3	0.05	U.S. commodity definition is "Potato, tuber".
Raspberries, Red, Black	0.01 *	CXL	None	
Rice	3	3	3	U.S. commodity definition is "Rice, grain".
Rice straw and fodder, Dry	10	3	9	U.S. commodity definition is "Rice, straw".
Rice, Husked	1	3	3	U.S. commodity definition is "Rice, grain".
Spinach	0.5	3	0.5	
Sugar beet	0.05 *	CXL	0.05	U.S. commodity definition is "Sugar beet, roots".
Sugar beet leaves or tops	0.05 *	3	2	U.S. commodity definition is "Sugar beet, tops".
Turnip greens	2	3	4	U.S. commodity definition is "Turnip, tops".
Turnip, Garden	0.05 *	3	0.05	U.S. commodity definition is "Turnip, roots".
Wheat	5	3	5	U.S. commodity definition is "Wheat, grain".
Wheat bran, Unprocessed	10	3	10	U.S. commodity definition is "Wheat, bran".
Wheat straw and fodder, Dry	10	3	11	U.S. commodity definition is "Wheat, straw".

[a]An asterisk (*) signifies that the MRL was established at or about the limit of detection.
[b]TBD = To be determined; additional data are required before the U.S. tolerance can be determined.

APPENDIX A

As a condition of reregistration, all end-use product labels (Sections 3 registrations only) for the 4 lb/gal EC and 5 lb/gal EC formulations of methyl parathion must be amended, as necessary, to conform to the following prescribed food/feed use sites, patterns, and restrictions.

CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
ROOT and TUBER VEGETABLE GROUP						
Carrots						
Broadcast application Ground and aerial equipment	1.0 lb/A	6	2	7	15	
Potatoes						
Broadcast application Ground and aerial equipment	1.5 lb/A	6	2	7	5	
Sugar Beets						
Broadcast application Ground and aerial equipment	0.38 lb/A	6	2	7	20	
Turnips						
Broadcast application Ground and aerial equipment	0.75 lb/A	6	2	7	15	
BULB VEGETABLES GROUP						
Onions						
Broadcast application Ground and aerial equipment	1.0 lb/A	6	2	7	15	
LEAFY VEGETABLES GROUP						
Celery						
Broadcast application Ground and aerial equipment	1.0 lb/A	2	2	14	15	
Lettuce (head and leaf)						
Broadcast application Ground and aerial equipment	1.0 lb/A	6	2	7	21	

CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
Spinach						
Broadcast application Ground and aerial equipment	<0.5 lb/A	6	2	7	15	
Broadcast application Ground and aerial equipment	0.5 - 1.0 lb/A	6	2	7	21	
***BRASSICA* LEAFY VEGETABLES GROUP**						
Broccoli, Brussels sprouts, Cabbage, Cauliflower, Collards, Kale, and Mustard Greens						
Broadcast application Ground and aerial equipment	1.5 lb/A	6	2	7	21	A PHI of 10-days is permitted if the last application is <0.05 lb ai/A. For use on broccoli, Brussels sprouts, cabbage, cauliflower, collards, kale, and mustard greens only. Use on kohlrabi is prohibited.
LEGUME VEGETABLES GROUP						
Beans, dried (excluding cowpeas)						
Broadcast application Ground and aerial equipment	1.5 lb/A	6	2	7	15	Use on cowpeas is prohibited.
Beans, succulent (excluding cowpeas)						
Broadcast application Ground and aerial equipment	1.5 lb/A	6	2	7	15	Use on cowpeas is prohibited.
Peas, dried and succulent (excluding field peas)						
Broadcast application Ground and aerial equipment	1.0 lb/A	6	2	7	15	A PHI of 10-day sis permitted if the last application is <0.5 lb ai/A. Use on field peas is prohibited.
Soybeans						
Broadcast application Ground and aerial equipment	0.5 lb/A	2	2	5	14	Do not feed green immature growing plants to livestock. Do not harvest for livestock feed.
CEREAL GRAINS GROUP						
Barley						
Broadcast application Ground and aerial equipment	1.25 lb/A	6	2	7	15	

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CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
Corn, field and pop						
Broadcast application Ground and aerial equipment	1.0 lb/A	6	2	7	12	
Corn, sweet						
Broadcast application Ground and aerial equipment	0.5 lb/A	6	2	3	3	
Oats						
Broadcast application Ground and aerial equipment	1.25 lb/A	6	2	7	15	
Rice						
Broadcast application Aerial equipment	0.75 lb/A	6	2	7	15	Aerial applications only. NEED LABEL RESTRICTIONS
Rye						
Broadcast application Ground and aerial equipment	1.25 lb/A	6	2	7	15	
Wheat						
Broadcast application Ground and aerial equipment	1.25 lb/A	6	2	7	15	
GRASS FORAGE, FODDER, and HAY GROUP						
Grass						
Broadcast application Ground and aerial equipment	0.75 lb/A	6	1	NS	15	Apply in a minimum of 3 gal/A of water using ground equipment or 1 gal/A using aerial equipment.
NON-GRASS ANIMAL FEEDS GROUP						
Alfalfa						
Broadcast application Ground and aerial equipment	1 lb/A	2 per cutting	1	Not Specified (NS)	15	Maximum application rate of 0.38 lb ai/A/application is specified for CA and NV only (except SLN NV97000100). Apply in a minimum of 3 gal/A of water using ground equipment or 1 gal/A of water using aerial equipment.

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CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
MISCELLANEOUS						
Artichokes (globe)						
Broadcast application Ground and aerial equipment	1.0 lb/A	4	2	7	7	
Canola (oilseed crop only)						
Broadcast application Ground and aerial equipment	0.5 lb/A	2	3	7	28	No for use on rapeseed. Do not graze treated fields or feed treated forage or threshings to livestock.
Cotton						
Broadcast application Ground and aerial equipment	3.0 lb/A	10	2	3	7	
Hops						
Broadcast application Ground and aerial equipment	1.0 lb/A	3	10	7	15	
Sunflowers						
Broadcast application Ground and aerial equipment	1.0 lb/A	3	2	7	30	

[a]Maximum number of applications at the maximum single application rate.
[b]Diluent is water unless otherwise specified under restrictions.

20823.17

APPENDIX B

As a condition of reregistration, all end-use product labels (Section 3 registrations only) for the 3 lb/gal EC formulations of methyl parathion must be amended, as necessary, to conform to the following prescribed food/feed/use sites, patterns, and restrictions.

CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
LEGUME VEGETABLES GROUP						
Soybeans						
Broadcast application Aerial equipment	0.20 lb/A	2	2	7	20	Aerial applications only. Do not feed green immature growing plants to livestock. Do not harvest for livestock feed.
CEREAL GRAINS GROUP						
Barley						
Broadcast application Aerial equipment	0.25 lb/A	6	2	7	15	Aerial applications only.
Corn, field and pop						
Broadcast application Aerial equipment	0.2 lb/A	6	2	5	12	Aerial applications only.
Corn, sweet						
Broadcast application Aerial equipment	0.2 lb/A	6	2	5	12	Aerial applications only.
Wheat						
Broadcast application Aerial equipment	0.25 lb/A	6	2	7	15	Aerial applications only.
NON-GRASS ANIMAL FEEDS GROUP						
Alfalfa						
Broadcast application Aerial equipment	0.25 lb/A	2	2	7	15	Aerial applications only. Do not apply more than 0.5 lb ai/A/cutting. Do not apply more than 0.14 lb ai/A/cutting in CA and NV.
MISCELLANEOUS						
Canola (oilseed crop only)						
Broadcast application Aerial equipment	0.25 lb/A	NS	3	NS	28	Aerial applications only. Not for use on rapeseed. Do not graze treated fields or feed treated forage or threshings to livestock.

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CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
Cotton						
Broadcast application Aerial equipment	0.6 lb/A	6	2	7	7	Aerial applications only.
Sunflowers						
Broadcast application Aerial equipment	0.33 lb/A	3	2	5	30	Aerial applications only.

[a] Maximum number of applications at the maximum single application rate.

[b] Diluent is water unless otherwise specified under restrictions.

2103577

APPENDIX C

As a condition of reregistration, all end-use product labels (Section 3 registrations only) for the 2 lb/gal Mcap formulations of methyl parathion must be amended, as necessary, to conform to the following food/feed use sites, patterns, and restrictions.

CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
ROOT and TUBER VEGETABLE GROUP						
Potatoes						
Broadcast application Ground and aerial equipment	1.5 lb/A	6	2	7	5	
Sweet potatoes						
Broadcast application Ground and aerial equipment	0.75 lb/A	8	2	7	5	
Yams						
Broadcast application Ground and aerial equipment	0.75 lb/A	8	2	7	5	
BULB VEGETABLES GROUP						
Onions						
Broadcast application Ground and aerial equipment	1.0 lb/A	6	2	7	15	
LEGUME VEGETABLES GROUP						
Beans, dried (excluding cowpeas)						
Broadcast application Ground and aerial equipment	1.0 lb/A	6	2	7	15	Use on cowpeas is prohibited.
Beans, succulent (excluding cowpeas)						
Broadcast application Ground and aerial equipment	1.0 lb/A	6	2	7	7	Use on cowpeas is prohibited.
Lentils						
Broadcast application Ground and aerial equipment	0.5 lb/A	3	2	11	14	
Peas, dried and succulent (excluding field peas)						
Broadcast application Ground and aerial equipment	0.5 lb/A	2	2	7	15	Use on field peas is prohibited.

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CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
Soybeans						
Broadcast application Ground and aerial equipment	1.0 lb/A	2	2	7	30	Do not feed green immature growing plants to livestock. Do not harvest for livestock feed.
FRUITING VEGETABLES GROUP						
Tomatoes						
Broadcast application Ground and aerial equipment	1.0 lb/A	5	2	6	15	
POME FRUITS GROUP						
Apples and Pears						
Broadcast application Ground and aerial equipment	2.0 lb/A	5	10	7	30	
STONE FRUITS GROUP						
Cherries						
Broadcast applications Ground and aerial equipment	1.5 lb/A	4	10	7	21	
Nectarines and Peaches						
Broadcast application Ground and aerial equipment	<0.75 lb/A	6	10	7	21	
Broadcast application Ground and aerial equipment	0.75 - 2.0 lb/A	6	10	7	30	

2129317

CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
Plums and Prunes						
Broadcast application Ground and aerial equipment	1.5 lb/A	4	10	7	15	
TREE NUTS GROUP						
Almonds						
Broadcast application Ground and aerial equipment	2.0 lb/A	6	10	21	28	
Pecans						
Broadcast application Ground and aerial equipment	2.0 lb/A	8	10	13	51	
Walnuts						
Broadcast application Ground and aerial equipment	2.0 lb/A	4	10	21	14	
CEREAL GRAINS GROUP						
Barley						
Broadcast application Ground and aerial equipment	0.75 lb/A	3	2	7	14	
Corn, field and pop						
Broadcast application Ground and aerial equipment	1.0 lb/A	5	2	14	12	
Corn, sweet						
Broadcast application Ground and aerial equipment	1.0 lb/A	5	2	14	12	
Oats						
Broadcast application Ground and aerial equipment	0.75 lb/A	3	2	7	14	
Rice						
Broadcast application Aerial equipment	0.75 lb/A	3	2	21	15	Aerial applications only. NEED LABEL RESTRICTIONS

CROP GROUP Crop Application Type Application Timing Application Equipment	Maximum Single Application Rate (ai)	Max. # Apps. [a]	Min. Spray Volume [b] (gal/A)	RTI (Days)	PHI (Days)	Use Restrictions
Rye						
Broadcast application Ground and aerial equipment	0.75 lb/A	3	2	7	14	
Wheat						
	0.75 lb/A	3	2	7	14	
MISCELLANEOUS						
Cotton						
Broadcast application Ground and aerial equipment	1.0 lb/A	8	2	5	14	
ULV aerial application	1.0 lb/A	8	1	5	14	
Grapes						
Broadcast Application Ground and aerial equipment	1.0 lb/A	2	2	7	28	Not for use in CA.
Post-harvest, dormant, delayed dormant, and prebloom applications. Ground and aerial equipment	1.5 lb/A	2	2	7	150	CA only.
Peanuts						
Broadcast application Ground and aerial equipment	1.0 lb/A	4	2	14	15	

[a]Maximum number of applications at the maximum single application rate.
[b]Diluent is water unless otherwise specified under restrictions.

Attachment 5: The Outcome of the HED Metabolism Assessment Review Committee Meeting

May 21, 1998

MEMORANDUM

Subject: **Methyl Parathion (053501).** The Outcome of the HED Metabolism Assessment Review Committee Meeting Held on March 11, 1998. DP Barcode: D245127

From: Bonnie Cropp-Kohlligian, Environmental Scientist
Reregistration Branch II
Health Effects Division [7509C]

Through: Alan P. Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division [7509C]

And

Alberto Protzel, Branch Senior Scientist
Toxicology Branch I
Health Effects Division [7509C]

And

Richard Loranger, Chair
Metabolism Assessment Review Committee
Health Effects Division [7509C]

To: George Kramer, Executive Secretary
Metabolism Assessment Review Committee
Health Effects Division [7509C]

Background

Methyl parathion was previously discussed by the HED Metabolism Committee on 3/11/92. Available plant metabolism, animal metabolism, and plant magnitude of the residue data were presented and discussed. Livestock feeding studies were not available. The Committee concluded the following (memo by R. Perfetti dated 3/16/92):

- The terminal residue of concern in the extractable portion of the TRR in the methyl parathion plant metabolism studies was tentatively determined to be parent and paraoxon, pending submission of additional information required in the update. The Committee decided that *p*-nitrophenol need

not be regulated because it is not a cholinesterase inhibitor as is methyl parathion. Also, the no observable effect level for cholinesterase inhibition for methyl parathion is low so that protection for any possible systemic effects arising from exposure to *p*-nitrophenol would be provided (Note: This does not mean that toxicity data for *p*-nitrophenol may not be required in the future.).

- In the case of milk, eggs, and animal tissues, if it is determined that tolerances are needed for these commodities, then the parent and paraoxon are to be regulated. Therefore, feeding studies for ruminants and poultry are needed. These experiments should reflect feeding of parathion *per se* at 1, 3, and 10X the maximum expected dietary burden for the subject species. However, in addition to analysis for parent and paraoxon, the following compounds should also be determined in milk, egg, and tissue samples; *p*-nitrophenol, *p*-aminophenol, and conjugates of these compounds.

Current Considerations

In light of FQPA requirements to perform cumulative risk assessments and the associated issue of addressing common metabolites, previous conclusions reached by the HED Metabolism Committee on 3/11/92 concerning *p*-nitrophenol and *p*-aminophenol needed to be reconsidered since they are also metabolites of parathion. Moreover, to insure consistency between methyl parathion and parathion, the HED Metabolism Assessment Review Committee* met on 3/11/98 to consider both chemicals and reconsider the question of what residues of methyl parathion need to be regulated/included in the risk assessment from plant and animal commodities.

Available plant metabolism, animal metabolism, and plant magnitude of the residue data were presented and discussed. [Note: No new plant metabolism, animal metabolism, or animal magnitude of the residue data had been submitted since the previous meeting of the HED Metabolism Committee on 3/11/92.] The HED Chapter of the Paranitrophenol Reregistration Eligibility Decision (RED) document was briefly discussed. The Committee tentatively concluded the following:

- Based on available plant metabolism and magnitude of the residue data, methyl parathion residues of concern in/on plant commodities are methyl parathion, methyl paraoxon, and *p*-nitrophenol. [Note: A new lettuce metabolism study remains outstanding.] Methyl parathion residues of concern to be included in the risk assessment for plant commodities based on cholinesterase inhibition will include methyl parathion and methyl paraoxon. The tolerance expression may be based on methyl parathion only since detectable levels of methyl paraoxon have not been

found in/on commodities tested by FDA monitoring. Residues of *p*-nitrophenol do not have to be included in the tolerance expression or considered in the aggregate risk assessment for methyl parathion with respect to cholinesterase inhibition, but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol. The risk assessment for *p*-nitrophenol will be based on its own toxicological endpoints (rather than cholinesterase inhibition) and should include exposure to *p*-nitrophenol from its use as a fungicide on leather. Residues of methyl parathion, methyl paraoxon, and *p*-nitrophenol should be determined in/on plant samples collected in future plant magnitude of the residue studies.

- Based on available animal metabolism data, methyl parathion residues of concern in animal commodities are methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl. [Note: Livestock feeding studies remain outstanding.] As with plants, methyl parathion residues of concern to be included in the risk assessment for animal commodities based on cholinesterase inhibition will include methyl parathion and methyl paraoxon. The tolerance expression may be based on methyl parathion only. Residues of *p*-nitrophenol do not have to be included in the tolerance expression or considered in the aggregate risk assessment for methyl parathion with respect to cholinesterase inhibition, but should be considered in conjunction with the cumulative risk assessment for *p*-nitrophenol. The risk assessment for *p*-nitrophenol will be based on its own toxicological endpoints (rather than cholinesterase inhibition) and should include exposure to *p*-nitrophenol from its use as a fungicide on leather. Toxicology deems amino-paraoxon-methyl of concern due to neuropathy of unknown origin and not due to cholinesterase inhibition. Once outstanding livestock feeding studies have been submitted, the Agency will determine how to include amino-paraoxon-methyl in the risk assessment. Residues of methyl parathion, methyl paraoxon, *p*-nitrophenol, and amino-paraoxon-methyl should be determined in meat, milk, poultry, and egg tissue samples from the required livestock feeding studies.

- For the aggregate risk assessment for methyl parathion with respect to cholinesterase inhibition, the residues of concern in drinking water are methyl parathion and methyl paraoxon. Residues of *p*-nitrophenol in drinking water should be included in the cumulative risk assessment for *p*-nitrophenol.

Committee Members in Attendance:

R. Loranger, C. Olinger, G. Kramer, A. Protzel, L. Cheng, K. Farwell, J. Peggins

cc: HED Metabolism Assessment Review Committee file (G. Kramer),
BLCKohlligian, Methyl Parathion Reg. Std. File, Methyl Parathion SF, RF.
7509C:RRB2:BLCKohlligian:CM#2:Rm 804E:703-305-7462:4/10/98.

Attachment 6: Pre-mitigation Acute Dietary Monte Carlo Assessment

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

All infants (<1 year)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000026	0.000029
Standard Deviation	0.000090	0.000095
Margin of Exposure	4,233	3,818
Percent of aRfD	23.62	26.19

Percent of Person-Days that are User-Days = 90.19%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000004	3.73	26,780	90.00	0.000053	48.13	2,077
20.00	0.000007	6.63	15,071	95.00	0.000093	84.59	1,182
30.00	0.000013	11.74	8,516	97.50	0.000109	98.74	1,012
40.00	0.000016	14.34	6,973	99.00	0.000180	163.84	610
50.00	0.000021	19.06	5,246	99.50	0.000241	219.51	455
60.00	0.000024	21.53	4,644	99.75	0.000278	252.96	395
70.00	0.000029	26.74	3,740	99.90	0.000426	386.88	258
80.00	0.000034	31.05	3,220				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.08	>1,000,000	90.00	0.000051	46.27	2,161
20.00	0.000005	4.11	24,323	95.00	0.000089	80.62	1,240
30.00	0.000009	7.85	12,731	97.50	0.000107	97.20	1,028
40.00	0.000014	12.65	7,908	99.00	0.000175	159.12	628
50.00	0.000018	16.49	6,063	99.50	0.000235	213.45	468
60.00	0.000023	20.46	4,888	99.75	0.000274	249.32	401
70.00	0.000028	25.04	3,993	99.90	0.000415	377.17	265
80.00	0.000033	30.11	3,320				

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Pre-mitigation Acute Dietary Monte Carlo Assessmemt

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day
MC iterations = 1000 MC list in residue file MC seed = 1
File Comment: Revised Risk Assessment (All Crops)

Summary calculations:

	95th Percentile			99th Percentile			99.9th Percentile		
	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
U.S. pop - all seasons:	0.000044	40.37	2477	0.000121	109.77	911	0.000416	378.21	264
All infants (<1 year):	0.000089	80.62	1240	0.000175	159.12	628	0.000415	377.17	265
Nursing infants (<1 year):	0.000025	22.35	4473	0.000166	150.70	663	0.001523	1384.35	72
Non-nursing infants (<1 yr):	0.000095	86.41	1157	0.000169	153.23	652	0.000391	355.18	281
Children (1-6 years):	0.000132	120.15	832	0.000273	248.63	402	0.000969	880.75	113
Children (7-12 years):	0.000061	55.24	1810	0.000129	116.87	855	0.000428	388.74	257
Females (13+/preg/not nsg):	0.000035	31.95	3129	0.000078	70.99	1408	0.000334	303.22	329
Females (13+/nursing):	0.000052	47.23	2117	0.000134	122.22	818	0.000624	567.06	176
Females (13-19 yrs/np/nn):	0.000032	29.52	3387	0.000062	56.56	1768	0.000213	193.63	516
Females (20+ years/np/nn):	0.000026	23.93	4179	0.000062	56.04	1784	0.000285	259.11	

385
Females (13-50 years):
0.000028 25.88 3863 0.000064 58.39 1712 0.000261 237.55
420
Males (13-19 years):
0.000031 28.45 3515 0.000063 56.86 1758 0.000189 171.69
582
Males (20+ years):
0.000030 27.40 3650 0.000063 56.85 1759 0.000243 220.94
452
Seniors (55+):
0.000026 23.66 4226 0.000066 60.26 1659 0.000326 296.32
337
Pacific Region:
0.000047 42.52 2351 0.000126 114.53 873 0.000699 635.51
157

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day
MC iterations = 1000 MC list in residue file MC seed = 1
File Comment: Revised Risk Assessment (All Crops)

U.S. pop - all seasons

Daily Exposure Analysis 1/ (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000015	0.000015
Standard Deviation	0.000045	0.000045
Margin of Exposure 2/	7,132	7,110
Percent of aRfD	14.02	14.06

Percent of Person-Days that are User-Days = 99.69%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.60	38,436	90.00	0.000029	25.95	3,854
20.00	0.000004	3.96	25,278	95.00	0.000044	40.41	2,474
30.00	0.000006	5.18	19,309	97.50	0.000071	64.28	1,555
40.00	0.000007	6.46	15,469	99.00	0.000121	109.86	910
50.00	0.000009	7.93	12,603	99.50	0.000165	150.07	666
60.00	0.000011	9.82	10,184	99.75	0.000242	219.57	455
70.00	0.000014	12.41	8,055	99.90	0.000416	378.53	264
80.00	0.000018	16.66	6,000				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.53	39,542	90.00	0.000029	25.92	3,858
20.00	0.000004	3.92	25,495	95.00	0.000044	40.37	2,477
30.00	0.000006	5.15	19,408	97.50	0.000071	64.20	1,557
40.00	0.000007	6.44	15,527	99.00	0.000121	109.77	911
50.00	0.000009	7.91	12,639	99.50	0.000165	149.94	666
60.00	0.000011	9.80	10,208	99.75	0.000241	219.36	455
70.00	0.000014	12.39	8,071	99.90	0.000416	378.21	264

80.00	0.000018	16.64	6,010

1/ Analysis based on all three-day participant records in CSFII 1989-92 survey.
2/ Margin of Exposure = NOEL/ Dietary Exposure

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Nursing infants (<1 year)

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000013	0.000019
Standard Deviation	0.000157	0.000192
Margin of Exposure	8,722	5,842
Percent of aRfD	11.46	17.12

Percent of Person-Days that are User-Days = 66.98%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	2.22	45,116	90.00	0.000016	14.84	6,739
20.00	0.000004	3.61	27,716	95.00	0.000033	29.66	3,371
30.00	0.000004	3.85	26,000	97.50	0.000091	82.75	1,208
40.00	0.000004	4.08	24,484	99.00	0.000202	183.95	543
50.00	0.000005	4.80	20,833	99.50	0.000365	331.57	301
60.00	0.000006	5.39	18,542	99.75	0.000742	674.75	148
70.00	0.000010	9.20	10,868	99.90	0.001905	1731.63	57
80.00	0.000012	10.95	9,133				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000014	12.92	7,739
20.00	0.000000	0.00	>1,000,000	95.00	0.000025	22.35	4,473
30.00	0.000000	0.00	>1,000,000	97.50	0.000062	56.58	1,767
40.00	0.000003	2.28	43,937	99.00	0.000166	150.70	663
50.00	0.000004	3.74	26,769	99.50	0.000285	258.81	386
60.00	0.000005	4.10	24,362	99.75	0.000556	505.60	197
70.00	0.000006	5.11	19,572	99.90	0.001523	1384.35	72
80.00	0.000010	9.23	10,839				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Non-nursing infants (<1 yr)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000032	0.000032
Standard Deviation	0.000033	0.000033
Margin of Exposure	3,480	3,478
Percent of aRfD	28.73	28.75

Percent of Person-Days that are User-Days = 99.96%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000010	8.71	11,476	90.00	0.000063	57.09	1,751
20.00	0.000015	13.26	7,539	95.00	0.000095	86.42	1,157
30.00	0.000017	15.16	6,595	97.50	0.000109	98.90	1,011
40.00	0.000021	18.84	5,307	99.00	0.000169	153.24	652
50.00	0.000024	21.71	4,606	99.50	0.000216	196.77	508
60.00	0.000027	24.93	4,011	99.75	0.000247	224.49	445
70.00	0.000031	28.31	3,532	99.90	0.000391	355.22	281
80.00	0.000036	33.11	3,020				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000010	8.68	11,518	90.00	0.000063	57.08	1,752
20.00	0.000015	13.25	7,547	95.00	0.000095	86.41	1,157
30.00	0.000017	15.16	6,598	97.50	0.000109	98.89	1,011
40.00	0.000021	18.83	5,310	99.00	0.000169	153.23	652
50.00	0.000024	21.70	4,607	99.50	0.000216	196.76	508
60.00	0.000027	24.92	4,012	99.75	0.000247	224.48	445
70.00	0.000031	28.30	3,533	99.90	0.000391	355.18	281
80.00	0.000036	33.11	3,020				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Children (1-6 years)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000043	0.000043
Standard Deviation	0.000094	0.000094
Margin of Exposure	2,584	2,583
Percent of aRfD	38.69	38.70

Percent of Person-Days that are User-Days = 99.97%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000009	8.10	12,352	90.00	0.000094	85.37	1,171
20.00	0.000013	11.60	8,620	95.00	0.000132	120.16	832
30.00	0.000016	14.89	6,716	97.50	0.000174	158.29	631
40.00	0.000020	17.97	5,563	99.00	0.000274	248.65	402
50.00	0.000024	21.56	4,638	99.50	0.000438	398.61	250
60.00	0.000028	25.58	3,909	99.75	0.000686	623.31	160
70.00	0.000036	33.00	3,030	99.90	0.000969	880.80	113
80.00	0.000055	49.77	2,009				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000009	8.07	12,385	90.00	0.000094	85.36	1,171
20.00	0.000013	11.59	8,626	95.00	0.000132	120.15	832
30.00	0.000016	14.88	6,719	97.50	0.000174	158.28	631
40.00	0.000020	17.97	5,565	99.00	0.000273	248.63	402
50.00	0.000024	21.56	4,639	99.50	0.000438	398.57	250
60.00	0.000028	25.57	3,910	99.75	0.000686	623.24	160
70.00	0.000036	32.99	3,030	99.90	0.000969	880.75	113
80.00	0.000055	49.76	2,009				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Children (7-12 years)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000023	0.000023
Standard Deviation	0.000045	0.000045
Margin of Exposure	4,774	4,772
Percent of aRfD	20.94	20.95

Percent of Person-Days that are User-Days = 99.96%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000007	6.13	16,303	90.00	0.000043	39.53	2,529
20.00	0.000009	8.33	11,998	95.00	0.000061	55.24	1,810
30.00	0.000011	10.26	9,742	97.50	0.000089	80.63	1,240
40.00	0.000013	12.12	8,253	99.00	0.000129	116.88	855
50.00	0.000016	14.29	6,999	99.50	0.000177	160.63	622
60.00	0.000018	16.64	6,008	99.75	0.000266	241.37	414
70.00	0.000022	20.09	4,977	99.90	0.000428	388.78	257
80.00	0.000028	25.50	3,920				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000007	6.11	16,366	90.00	0.000043	39.53	2,529
20.00	0.000009	8.33	12,009	95.00	0.000061	55.24	1,810
30.00	0.000011	10.26	9,748	97.50	0.000089	80.62	1,240
40.00	0.000013	12.11	8,256	99.00	0.000129	116.87	855
50.00	0.000016	14.28	7,002	99.50	0.000177	160.62	622
60.00	0.000018	16.64	6,010	99.75	0.000265	241.34	414
70.00	0.000022	20.09	4,978	99.90	0.000428	388.74	257
80.00	0.000028	25.50	3,921				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (13+/preg/not nsg)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000013	0.000013
Standard Deviation	0.000042	0.000042
Margin of Exposure	8,715	8,715
Percent of aRfD	11.47	11.47

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	3.00	33,370	90.00	0.000022	19.91	5,021
20.00	0.000005	4.20	23,818	95.00	0.000035	31.95	3,129
30.00	0.000006	5.20	19,237	97.50	0.000049	44.65	2,239
40.00	0.000007	6.12	16,346	99.00	0.000078	70.99	1,408
50.00	0.000008	7.18	13,918	99.50	0.000116	105.21	950
60.00	0.000009	8.57	11,674	99.75	0.000181	164.14	609
70.00	0.000011	10.19	9,817	99.90	0.000334	303.22	329
80.00	0.000015	13.59	7,360				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	3.00	33,370	90.00	0.000022	19.91	5,021
20.00	0.000005	4.20	23,818	95.00	0.000035	31.95	3,129
30.00	0.000006	5.20	19,237	97.50	0.000049	44.65	2,239
40.00	0.000007	6.12	16,346	99.00	0.000078	70.99	1,408
50.00	0.000008	7.18	13,918	99.50	0.000116	105.21	950
60.00	0.000009	8.57	11,674	99.75	0.000181	164.14	609
70.00	0.000011	10.19	9,817	99.90	0.000334	303.22	329
80.00	0.000015	13.59	7,360				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (13+/nursing)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000018	0.000018
Standard Deviation	0.000050	0.000050
Margin of Exposure	6,038	6,038
Percent of aRfD	16.56	16.56

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	2.15	46,492	90.00	0.000031	28.22	3,543
20.00	0.000004	3.66	27,326	95.00	0.000052	47.23	2,117
30.00	0.000005	4.54	22,048	97.50	0.000120	109.13	916
40.00	0.000008	7.23	13,833	99.00	0.000134	122.22	818
50.00	0.000011	9.55	10,472	99.50	0.000175	158.96	629
60.00	0.000013	11.65	8,582	99.75	0.000276	250.90	398
70.00	0.000017	15.20	6,580	99.90	0.000624	567.06	176
80.00	0.000021	19.04	5,252				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	2.15	46,492	90.00	0.000031	28.22	3,543
20.00	0.000004	3.66	27,326	95.00	0.000052	47.23	2,117
30.00	0.000005	4.54	22,048	97.50	0.000120	109.13	916
40.00	0.000008	7.23	13,833	99.00	0.000134	122.22	818
50.00	0.000011	9.55	10,472	99.50	0.000175	158.96	629
60.00	0.000013	11.65	8,582	99.75	0.000276	250.90	398
70.00	0.000017	15.20	6,580	99.90	0.000624	567.06	176
80.00	0.000021	19.04	5,252				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (13-19 yrs/np/nn)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000012	0.000012
Standard Deviation	0.000026	0.000026
Margin of Exposure	9,508	9,490
Percent of aRfD	10.52	10.54

Percent of Person-Days that are User-Days = 99.81%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	3.13	31,909	90.00	0.000021	18.82	5,312
20.00	0.000005	4.30	23,241	95.00	0.000032	29.54	3,384
30.00	0.000006	5.25	19,060	97.50	0.000039	35.83	2,790
40.00	0.000007	6.43	15,556	99.00	0.000062	56.58	1,767
50.00	0.000008	7.59	13,182	99.50	0.000083	75.35	1,327
60.00	0.000010	8.84	11,318	99.75	0.000111	100.66	993
70.00	0.000012	10.54	9,483	99.90	0.000213	193.75	516
80.00	0.000014	12.79	7,819				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	3.08	32,457	90.00	0.000021	18.81	5,315
20.00	0.000005	4.29	23,337	95.00	0.000032	29.52	3,387
30.00	0.000006	5.23	19,105	97.50	0.000039	35.82	2,791
40.00	0.000007	6.41	15,589	99.00	0.000062	56.56	1,768
50.00	0.000008	7.57	13,201	99.50	0.000083	75.32	1,327
60.00	0.000010	8.83	11,330	99.75	0.000111	100.61	993
70.00	0.000012	10.53	9,492	99.90	0.000213	193.63	516
80.00	0.000014	12.78	7,824				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (20+ years/np/nn)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000010	0.000010
Standard Deviation	0.000034	0.000034
Margin of Exposure	10,735	10,702
Percent of aRfD	9.32	9.34

Percent of Person-Days that are User-Days = 99.70%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	2.00	50,044	90.00	0.000018	16.63	6,012
20.00	0.000003	3.08	32,473	95.00	0.000026	23.95	4,175
30.00	0.000004	4.04	24,748	97.50	0.000038	34.60	2,890
40.00	0.000005	4.98	20,079	99.00	0.000062	56.08	1,783
50.00	0.000007	5.99	16,708	99.50	0.000091	82.84	1,207
60.00	0.000008	7.19	13,910	99.75	0.000158	143.59	696
70.00	0.000010	8.77	11,398	99.90	0.000285	259.34	385
80.00	0.000012	11.19	8,932				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	1.94	51,435	90.00	0.000018	16.62	6,018
20.00	0.000003	3.05	32,749	95.00	0.000026	23.93	4,179
30.00	0.000004	4.02	24,872	97.50	0.000038	34.56	2,893
40.00	0.000005	4.96	20,148	99.00	0.000062	56.04	1,784
50.00	0.000007	5.97	16,750	99.50	0.000091	82.76	1,208
60.00	0.000008	7.17	13,938	99.75	0.000158	143.41	697
70.00	0.000010	8.76	11,417	99.90	0.000285	259.11	385
80.00	0.000012	11.18	8,944				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (13-50 years)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000011	0.000011
Standard Deviation	0.000033	0.000033
Margin of Exposure	10,200	10,167
Percent of aRfD	9.80	9.83

Percent of Person-Days that are User-Days = 99.68%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	2.11	47,486	90.00	0.000019	17.72	5,642
20.00	0.000004	3.33	30,001	95.00	0.000028	25.91	3,859
30.00	0.000005	4.36	22,954	97.50	0.000040	36.51	2,738
40.00	0.000006	5.34	18,711	99.00	0.000064	58.44	1,711
50.00	0.000007	6.51	15,353	99.50	0.000089	81.17	1,231
60.00	0.000009	7.78	12,848	99.75	0.000141	128.07	780
70.00	0.000010	9.45	10,587	99.90	0.000262	237.78	420
80.00	0.000013	12.07	8,287				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	2.05	48,897	90.00	0.000019	17.71	5,648
20.00	0.000004	3.30	30,287	95.00	0.000028	25.88	3,863
30.00	0.000005	4.33	23,076	97.50	0.000040	36.48	2,741
40.00	0.000006	5.33	18,778	99.00	0.000064	58.39	1,712
50.00	0.000007	6.49	15,397	99.50	0.000089	81.10	1,233
60.00	0.000009	7.77	12,875	99.75	0.000141	127.92	781
70.00	0.000010	9.43	10,605	99.90	0.000261	237.55	420
80.00	0.000013	12.05	8,299				

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DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Males (13-19 years)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000013	0.000013
Standard Deviation	0.000027	0.000027
Margin of Exposure	8,173	8,171
Percent of aRfD	12.24	12.24

Percent of Person-Days that are User-Days = 99.97%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000004	3.88	25,763	90.00	0.000024	21.66	4,617
20.00	0.000006	5.30	18,877	95.00	0.000031	28.45	3,514
30.00	0.000007	6.42	15,576	97.50	0.000045	41.12	2,432
40.00	0.000009	7.78	12,854	99.00	0.000063	56.86	1,758
50.00	0.000010	9.47	10,557	99.50	0.000089	80.83	1,237
60.00	0.000012	10.91	9,163	99.75	0.000106	96.13	1,040
70.00	0.000014	12.94	7,729	99.90	0.000189	171.70	582
80.00	0.000017	15.55	6,430				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000004	3.87	25,822	90.00	0.000024	21.66	4,617
20.00	0.000006	5.29	18,888	95.00	0.000031	28.45	3,515
30.00	0.000007	6.42	15,581	97.50	0.000045	41.11	2,432
40.00	0.000009	7.78	12,858	99.00	0.000063	56.86	1,758
50.00	0.000010	9.47	10,559	99.50	0.000089	80.83	1,237
60.00	0.000012	10.91	9,164	99.75	0.000106	96.12	1,040
70.00	0.000014	12.94	7,729	99.90	0.000189	171.69	582
80.00	0.000017	15.55	6,430				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Males (20+ years)

	Daily Exposure Analysis (mg/kg body-weight/day) per Capita	per User
Mean	0.000011	0.000011
Standard Deviation	0.000028	0.000028
Margin of Exposure	9,601	9,588
Percent of aRfD	10.42	10.43

Percent of Person-Days that are User-Days = 99.87%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.57	38,936	90.00	0.000021	19.37	5,163
20.00	0.000004	3.77	26,545	95.00	0.000030	27.41	3,648
30.00	0.000005	4.87	20,546	97.50	0.000041	37.29	2,681
40.00	0.000007	5.96	16,773	99.00	0.000063	56.87	1,758
50.00	0.000008	7.13	14,032	99.50	0.000085	77.26	1,294
60.00	0.000009	8.53	11,728	99.75	0.000131	119.41	837
70.00	0.000011	10.38	9,636	99.90	0.000243	221.03	452
80.00	0.000014	13.18	7,588				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.54	39,387	90.00	0.000021	19.36	5,165
20.00	0.000004	3.75	26,631	95.00	0.000030	27.40	3,650
30.00	0.000005	4.86	20,588	97.50	0.000041	37.28	2,682
40.00	0.000007	5.95	16,797	99.00	0.000063	56.85	1,759
50.00	0.000008	7.12	14,047	99.50	0.000085	77.24	1,294
60.00	0.000009	8.52	11,737	99.75	0.000131	119.35	837
70.00	0.000011	10.37	9,642	99.90	0.000243	220.94	452
80.00	0.000014	13.17	7,592				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Seniors (55+)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000011	0.000011
Standard Deviation	0.000035	0.000035
Margin of Exposure	10,448	10,433
Percent of aRfD	9.57	9.58

Percent of Person-Days that are User-Days = 99.86%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.28	43,897	90.00	0.000018	16.19	6,176
20.00	0.000004	3.27	30,538	95.00	0.000026	23.67	4,224
30.00	0.000005	4.19	23,875	97.50	0.000038	34.97	2,859
40.00	0.000006	5.11	19,570	99.00	0.000066	60.28	1,658
50.00	0.000007	6.09	16,408	99.50	0.000104	94.87	1,054
60.00	0.000008	7.31	13,684	99.75	0.000176	159.85	625
70.00	0.000010	8.83	11,322	99.90	0.000326	296.45	337
80.00	0.000012	11.14	8,973				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	2.25	44,472	90.00	0.000018	16.18	6,179
20.00	0.000004	3.26	30,645	95.00	0.000026	23.66	4,226
30.00	0.000005	4.18	23,927	97.50	0.000038	34.96	2,860
40.00	0.000006	5.10	19,600	99.00	0.000066	60.26	1,659
50.00	0.000007	6.09	16,427	99.50	0.000104	94.82	1,054
60.00	0.000008	7.30	13,697	99.75	0.000176	159.76	625
70.00	0.000010	8.83	11,330	99.90	0.000326	296.32	337
80.00	0.000012	11.14	8,978				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: MPFINALV2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-21-1999/17:26:24 Residue file dated: 07-21-1999/15:30:32/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Pacific Region

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000017	0.000017
Standard Deviation	0.000059	0.000059
Margin of Exposure	6,605	6,583
Percent of aRfD	15.14	15.19

Percent of Person-Days that are User-Days = 99.66%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.36	42,387	90.00	0.000030	26.91	3,715
20.00	0.000004	3.72	26,914	95.00	0.000047	42.57	2,348
30.00	0.000005	4.97	20,138	97.50	0.000069	62.72	1,594
40.00	0.000007	6.32	15,818	99.00	0.000126	114.64	872
50.00	0.000009	8.02	12,475	99.50	0.000196	178.17	561
60.00	0.000011	10.23	9,778	99.75	0.000394	358.08	279
70.00	0.000014	13.10	7,634	99.90	0.000700	636.14	157
80.00	0.000019	17.70	5,651				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.29	43,714	90.00	0.000030	26.88	3,719
20.00	0.000004	3.68	27,181	95.00	0.000047	42.52	2,351
30.00	0.000005	4.94	20,258	97.50	0.000069	62.65	1,596
40.00	0.000007	6.29	15,887	99.00	0.000126	114.53	873
50.00	0.000009	7.99	12,520	99.50	0.000196	177.96	561
60.00	0.000011	10.20	9,807	99.75	0.000393	357.48	279
70.00	0.000014	13.07	7,651	99.90	0.000699	635.51	157
80.00	0.000019	17.66	5,661				

Attachment 7: Pre-mitigation Chronic Dietary Assessment

Pre-mitigation Chronic Dietary Assessment

U.S. Environmental Protection Agency Ver. 6.76
DEEM Chronic analysis for METHYL PARATHION (1989-92 data)
Residue file name: D:\Methyl Parathion\R-96\053501-1cr.R96
Adjustment factor #2 NOT used.
Analysis Date 07-28-1999/11:20:04 Residue file dated: 07-28-1999/11:19:14/8
Reference dose (RfD, CHRONIC) = .00002 mg/kg bw/day
COMMENT 1: Revised Risk Assessment (All Crops)

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.000003	16.6%
U.S. Population (spring season)	0.000003	14.1%
U.S. Population (summer season)	0.000005	23.7%
U.S. Population (autumn season)	0.000003	14.7%
U.S. Population (winter season)	0.000003	13.2%
Northeast region	0.000004	20.1%
Midwest region	0.000003	13.7%
Southern region	0.000003	14.7%
Western region	0.000004	19.6%
Hispanics	0.000003	15.6%
Non-hispanic whites	0.000003	17.3%
Non-hispanic blacks	0.000002	12.0%
Non-hisp/non-white/non-black)	0.000004	20.9%
All infants (< 1 year)	0.000006	28.9%
Nursing infants	0.000008	39.8%
Non-nursing infants	0.000005	24.3%
Children 1-6 yrs	0.000009	46.7%
Children 7-12 yrs	0.000004	22.2%
Females 13-19 (not preg or nursing)	0.000002	8.4%
Females 20+ (not preg or nursing)	0.000003	13.5%
Females 13-50 yrs	0.000002	12.3%
Females 13+ (preg/not nursing)	0.000003	15.3%
Females 13+ (nursing)	0.000005	25.4%
Males 13-19 yrs	0.000002	9.7%

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Males 20+ yrs	0.000002	11.1%
Seniors 55+	0.000003	15.1%
Pacific Region	0.000004	21.6%

-

Attachment 8: Post-mitigation Acute Dietary Monte Carlo Assessment

Post-mitigation Acute Dietary Monte Carlo Assessment

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day
MC iterations = 1000 MC list in residue file MC seed = 1
Run Comment: Revised Risk Assessment (Registrant Proposal w/Dried Peas and Hops)

Summary calculations:

	95th Percentile			99th Percentile			99.9th Percentile	
	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE	Exposure	% aRfD	MOE
U.S. pop - all seasons:	0.000027	24.21	4130	0.000041	37.61	2658	0.000066	60.41	1655
All infants (<1 year):	0.000033	30.06	3326	0.000052	47.02	2126	0.000067	60.86	1643
Children (1-6 years):	0.000043	38.66	2586	0.000055	50.36	1985	0.000086	78.10	1280
Children (7-12 years):	0.000031	28.61	3495	0.000042	38.11	2624	0.000086	78.53	1273
Females (13+/preg/not nsg):	0.000016	14.57	6865	0.000020	17.96	5568	0.000026	23.22	4306
Females (13+/nursing):	0.000023	20.57	4860	0.000029	26.14	3825	0.000075	67.88	1473
Females (13-19 yrs/np/nn):	0.000019	17.33	5771	0.000032	28.87	3463	0.000065	59.25	1687
Females (20+ years/np/nn):	0.000016	14.44	6927	0.000025	22.59	4426	0.000049	44.38	2253
Females (13-50 years):	0.000018	15.96	6264	0.000028	25.57	3911	0.000062	55.97	1786
Males (13-19 years):									

0.000024	21.54	4641	0.000034	30.98	3227	0.000059	53.79	1859
Males (20+ years):								
0.000021	19.17	5216	0.000036	32.79	3049	0.000065	59.17	1690
Seniors (55+):								
0.000015	13.68	7309	0.000023	21.27	4701	0.000041	37.21	2687

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day
MC iterations = 1000 MC list in residue file MC seed = 1
Run Comment: Revised Risk Assessment (Registrant Proposal w/Dried Peas and Hops)

U.S. pop - all seasons

Daily Exposure Analysis 1/ (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000010	0.000010
Standard Deviation	0.000009	0.000009
Margin of Exposure 2/	10,980	10,942
Percent of aRfD	9.11	9.14

Percent of Person-Days that are User-Days = 99.65%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.39	41,834	90.00	0.000020	18.57	5,383
20.00	0.000004	3.63	27,583	95.00	0.000027	24.23	4,126
30.00	0.000005	4.70	21,294	97.50	0.000033	29.59	3,379
40.00	0.000006	5.79	17,272	99.00	0.000041	37.63	2,657
50.00	0.000008	6.99	14,301	99.50	0.000049	44.40	2,252
60.00	0.000009	8.42	11,874	99.75	0.000056	51.17	1,954
70.00	0.000011	10.36	9,650	99.90	0.000066	60.43	1,654
80.00	0.000015	13.21	7,568				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.32	43,191	90.00	0.000020	18.56	5,389
20.00	0.000004	3.59	27,848	95.00	0.000027	24.21	4,130
30.00	0.000005	4.67	21,413	97.50	0.000033	29.57	3,381
40.00	0.000006	5.77	17,340	99.00	0.000041	37.61	2,658
50.00	0.000008	6.97	14,344	99.50	0.000049	44.38	2,253
60.00	0.000009	8.40	11,902	99.75	0.000056	51.15	1,955

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70.00	0.000011	10.34	9,669	99.90	0.000066	60.41	1,655
80.00	0.000015	13.19	7,580				

1/ Analysis based on all three-day participant records in CSFII 1989-92 survey.
2/ Margin of Exposure = NOEL/ Dietary Exposure.

246377

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

All infants (<1 year)

Daily Exposure Analysis (mg/kg body-weight/day)

	per Capita	per User
Mean	0.000015	0.000017
Standard Deviation	0.000012	0.000011
Margin of Exposure	7,446	6,589
Percent of aRfD	13.43	15.18

Percent of Person-Days that are User-Days = 88.49%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000004	3.68	27,160	90.00	0.000031	28.50	3,508
20.00	0.000006	5.11	19,563	95.00	0.000033	30.29	3,301
30.00	0.000009	8.13	12,293	97.50	0.000038	34.82	2,872
40.00	0.000012	11.33	8,823	99.00	0.000053	48.18	2,075
50.00	0.000015	14.01	7,135	99.50	0.000061	55.64	1,797
60.00	0.000018	16.63	6,013	99.75	0.000065	59.01	1,694
70.00	0.000022	20.29	4,928	99.90	0.000067	61.04	1,638
80.00	0.000027	24.29	4,116				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000000	0.00	>1,000,000	90.00	0.000031	27.96	3,577
20.00	0.000004	3.53	28,318	95.00	0.000033	30.06	3,326
30.00	0.000006	5.38	18,582	97.50	0.000038	34.23	2,921
40.00	0.000010	8.84	11,317	99.00	0.000052	47.02	2,126
50.00	0.000013	12.27	8,149	99.50	0.000060	54.67	1,829
60.00	0.000017	15.27	6,549	99.75	0.000064	58.57	1,707
70.00	0.000021	18.86	5,301	99.90	0.000067	60.86	1,643
80.00	0.000026	23.25	4,300				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Children (1-6 years)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000021	0.000021
Standard Deviation	0.000013	0.000013
Margin of Exposure	5,304	5,302
Percent of aRfD	18.85	18.86

Percent of Person-Days that are User-Days = 99.96%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000008	6.93	14,419	90.00	0.000036	32.35	3,091
20.00	0.000011	10.28	9,728	95.00	0.000043	38.66	2,586
30.00	0.000014	12.67	7,892	97.50	0.000048	43.85	2,280
40.00	0.000016	14.89	6,717	99.00	0.000055	50.36	1,985
50.00	0.000019	17.26	5,793	99.50	0.000062	56.50	1,770
60.00	0.000022	19.82	5,046	99.75	0.000070	63.57	1,573
70.00	0.000025	22.70	4,405	99.90	0.000086	78.11	1,280
80.00	0.000029	26.31	3,801				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000008	6.91	14,465	90.00	0.000036	32.35	3,091
20.00	0.000011	10.27	9,737	95.00	0.000043	38.66	2,586
30.00	0.000014	12.66	7,896	97.50	0.000048	43.84	2,280
40.00	0.000016	14.88	6,719	99.00	0.000055	50.36	1,985
50.00	0.000019	17.26	5,794	99.50	0.000062	56.49	1,770
60.00	0.000022	19.81	5,047	99.75	0.000070	63.57	1,573
70.00	0.000025	22.69	4,406	99.90	0.000086	78.10	1,280
80.00	0.000029	26.30	3,801				

2489577

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Children (7-12 years)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000015	0.000015
Standard Deviation	0.000010	0.000010
Margin of Exposure	7,187	7,184
Percent of aRfD	13.91	13.92

Percent of Person-Days that are User-Days = 99.96%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000006	5.63	17,757	90.00	0.000026	23.96	4,173
20.00	0.000008	7.64	13,091	95.00	0.000031	28.61	3,495
30.00	0.000010	9.29	10,767	97.50	0.000036	32.98	3,032
40.00	0.000012	10.81	9,254	99.00	0.000042	38.11	2,623
50.00	0.000014	12.41	8,058	99.50	0.000047	43.11	2,319
60.00	0.000016	14.28	7,003	99.75	0.000058	52.94	1,889
70.00	0.000018	16.24	6,157	99.90	0.000086	78.54	1,273
80.00	0.000021	19.20	5,208				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000006	5.61	17,826	90.00	0.000026	23.96	4,173
20.00	0.000008	7.63	13,103	95.00	0.000031	28.61	3,495
30.00	0.000010	9.28	10,773	97.50	0.000036	32.98	3,032
40.00	0.000012	10.80	9,258	99.00	0.000042	38.11	2,624
50.00	0.000014	12.41	8,060	99.50	0.000047	43.10	2,319
60.00	0.000016	14.28	7,005	99.75	0.000058	52.93	1,889
70.00	0.000018	16.24	6,158	99.90	0.000086	78.53	1,273
80.00	0.000021	19.20	5,208				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (13+/preg/not nsg)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000007	0.000007
Standard Deviation	0.000004	0.000004
Margin of Exposure	14,854	14,854
Percent of aRfD	6.73	6.73

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.69	37,115	90.00	0.000013	11.87	8,423
20.00	0.000004	3.63	27,574	95.00	0.000016	14.57	6,865
30.00	0.000005	4.53	22,083	97.50	0.000018	16.36	6,112
40.00	0.000006	5.20	19,237	99.00	0.000020	17.96	5,568
50.00	0.000007	5.92	16,889	99.50	0.000022	20.05	4,988
60.00	0.000008	6.99	14,307	99.75	0.000024	21.87	4,573
70.00	0.000009	8.17	12,244	99.90	0.000026	23.22	4,306
80.00	0.000010	9.42	10,614				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.69	37,115	90.00	0.000013	11.87	8,423
20.00	0.000004	3.63	27,574	95.00	0.000016	14.57	6,865
30.00	0.000005	4.53	22,083	97.50	0.000018	16.36	6,112
40.00	0.000006	5.20	19,237	99.00	0.000020	17.96	5,568
50.00	0.000007	5.92	16,889	99.50	0.000022	20.05	4,988
60.00	0.000008	6.99	14,307	99.75	0.000024	21.87	4,573
70.00	0.000009	8.17	12,244	99.90	0.000026	23.22	4,306
80.00	0.000010	9.42	10,614				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (13+/nursing)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000010	0.000010
Standard Deviation	0.000008	0.000008
Margin of Exposure	11,194	11,194
Percent of aRfD	8.93	8.93

Percent of Person-Days that are User-Days =100.00%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	1.85	54,126	90.00	0.000019	17.02	5,873
20.00	0.000004	3.38	29,548	95.00	0.000023	20.57	4,860
30.00	0.000005	4.29	23,327	97.50	0.000026	23.30	4,291
40.00	0.000006	5.82	17,178	99.00	0.000029	26.14	3,825
50.00	0.000009	8.04	12,445	99.50	0.000031	28.12	3,556
60.00	0.000010	9.51	10,519	99.75	0.000040	36.25	2,758
70.00	0.000012	11.31	8,841	99.90	0.000075	67.88	1,473
80.00	0.000016	14.15	7,066				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	1.85	54,126	90.00	0.000019	17.02	5,873
20.00	0.000004	3.38	29,548	95.00	0.000023	20.57	4,860
30.00	0.000005	4.29	23,327	97.50	0.000026	23.30	4,291
40.00	0.000006	5.82	17,178	99.00	0.000029	26.14	3,825
50.00	0.000009	8.04	12,445	99.50	0.000031	28.12	3,556
60.00	0.000010	9.51	10,519	99.75	0.000040	36.25	2,758
70.00	0.000012	11.31	8,841	99.90	0.000075	67.88	1,473
80.00	0.000016	14.15	7,066				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (13-19 yrs/np/nn)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000009	0.000009
Standard Deviation	0.000007	0.000007
Margin of Exposure	12,382	12,358
Percent of aRfD	8.08	8.09

Percent of Person-Days that are User-Days = 99.81%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.98	33,566	90.00	0.000016	14.18	7,049
20.00	0.000005	4.13	24,201	95.00	0.000019	17.33	5,769
30.00	0.000006	5.00	19,980	97.50	0.000024	21.84	4,577
40.00	0.000007	5.93	16,874	99.00	0.000032	28.88	3,462
50.00	0.000008	7.02	14,246	99.50	0.000036	32.95	3,034
60.00	0.000009	8.06	12,402	99.75	0.000049	44.47	2,248
70.00	0.000010	9.48	10,547	99.90	0.000065	59.27	1,687
80.00	0.000012	11.14	8,980				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.93	34,142	90.00	0.000016	14.18	7,052
20.00	0.000005	4.11	24,303	95.00	0.000019	17.33	5,771
30.00	0.000005	4.99	20,026	97.50	0.000024	21.84	4,579
40.00	0.000007	5.92	16,904	99.00	0.000032	28.87	3,463
50.00	0.000008	7.01	14,266	99.50	0.000036	32.95	3,035
60.00	0.000009	8.05	12,414	99.75	0.000049	44.45	2,249
70.00	0.000010	9.47	10,556	99.90	0.000065	59.25	1,687
80.00	0.000012	11.13	8,985				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (20+ years/np/nn)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000007	0.000007
Standard Deviation	0.000006	0.000006
Margin of Exposure	15,858	15,805
Percent of aRfD	6.31	6.33

Percent of Person-Days that are User-Days = 99.67%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	1.82	54,843	90.00	0.000013	11.75	8,513
20.00	0.000003	2.80	35,738	95.00	0.000016	14.44	6,923
30.00	0.000004	3.66	27,312	97.50	0.000020	18.03	5,547
40.00	0.000005	4.47	22,357	99.00	0.000025	22.60	4,424
50.00	0.000006	5.30	18,862	99.50	0.000030	27.03	3,699
60.00	0.000007	6.26	15,970	99.75	0.000037	33.66	2,971
70.00	0.000008	7.41	13,486	99.90	0.000049	44.41	2,251
80.00	0.000010	8.97	11,151				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	1.77	56,553	90.00	0.000013	11.74	8,519
20.00	0.000003	2.77	36,076	95.00	0.000016	14.44	6,927
30.00	0.000004	3.64	27,464	97.50	0.000020	18.01	5,551
40.00	0.000005	4.46	22,439	99.00	0.000025	22.59	4,426
50.00	0.000006	5.29	18,912	99.50	0.000030	27.02	3,701
60.00	0.000007	6.25	16,002	99.75	0.000037	33.64	2,973
70.00	0.000008	7.40	13,507	99.90	0.000049	44.38	2,253
80.00	0.000010	8.96	11,164				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Females (13-50 years)

	Daily Exposure Analysis (mg/kg body-weight/day) per Capita	per User
Mean	0.000008	0.000008
Standard Deviation	0.000007	0.000007
Margin of Exposure	14,485	14,436
Percent of aRfD	6.90	6.93

Percent of Person-Days that are User-Days = 99.66%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	1.93	51,917	90.00	0.000014	12.72	7,862
20.00	0.000003	3.05	32,777	95.00	0.000018	15.98	6,259
30.00	0.000004	4.00	25,001	97.50	0.000021	19.40	5,155
40.00	0.000005	4.90	20,405	99.00	0.000028	25.58	3,909
50.00	0.000006	5.82	17,189	99.50	0.000035	31.65	3,159
60.00	0.000008	6.89	14,516	99.75	0.000041	37.12	2,693
70.00	0.000009	8.15	12,267	99.90	0.000062	56.02	1,785
80.00	0.000011	9.85	10,157				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	1.87	53,572	90.00	0.000014	12.71	7,868
20.00	0.000003	3.02	33,113	95.00	0.000018	15.96	6,264
30.00	0.000004	3.98	25,145	97.50	0.000021	19.39	5,158
40.00	0.000005	4.88	20,482	99.00	0.000028	25.57	3,911
50.00	0.000006	5.80	17,236	99.50	0.000035	31.63	3,161
60.00	0.000008	6.87	14,547	99.75	0.000041	37.10	2,695
70.00	0.000009	8.14	12,286	99.90	0.000062	55.97	1,786
80.00	0.000011	9.83	10,169				

U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Males (13-19 years)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000011	0.000011
Standard Deviation	0.000007	0.000007
Margin of Exposure	10,018	10,016
Percent of aRfD	9.98	9.98

Percent of Person-Days that are User-Days = 99.97%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000004	3.75	26,673	90.00	0.000019	17.25	5,796
20.00	0.000006	5.06	19,750	95.00	0.000024	21.54	4,641
30.00	0.000007	6.14	16,299	97.50	0.000028	25.77	3,880
40.00	0.000008	7.33	13,645	99.00	0.000034	30.98	3,227
50.00	0.000010	8.81	11,346	99.50	0.000045	41.06	2,435
60.00	0.000011	10.17	9,831	99.75	0.000054	48.79	2,049
70.00	0.000013	11.78	8,489	99.90	0.000059	53.79	1,859
80.00	0.000016	14.16	7,063				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000004	3.74	26,734	90.00	0.000019	17.25	5,796
20.00	0.000006	5.06	19,760	95.00	0.000024	21.54	4,641
30.00	0.000007	6.13	16,304	97.50	0.000028	25.77	3,880
40.00	0.000008	7.33	13,649	99.00	0.000034	30.98	3,227
50.00	0.000010	8.81	11,348	99.50	0.000045	41.05	2,435
60.00	0.000011	10.17	9,832	99.75	0.000054	48.79	2,049
70.00	0.000013	11.78	8,490	99.90	0.000059	53.79	1,859
80.00	0.000016	14.16	7,063				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Males (20+ years)

	Daily Exposure Analysis (mg/kg body-weight/day) per Capita	per User
Mean	0.000009	0.000009
Standard Deviation	0.000008	0.000008
Margin of Exposure	12,629	12,613
Percent of aRfD	7.92	7.93

Percent of Person-Days that are User-Days = 99.87%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.37	42,246	90.00	0.000016	14.71	6,799
20.00	0.000004	3.48	28,767	95.00	0.000021	19.18	5,215
30.00	0.000005	4.44	22,510	97.50	0.000027	24.85	4,024
40.00	0.000006	5.45	18,351	99.00	0.000036	32.80	3,048
50.00	0.000007	6.41	15,608	99.50	0.000043	39.29	2,545
60.00	0.000008	7.55	13,237	99.75	0.000055	49.72	2,011
70.00	0.000010	8.97	11,153	99.90	0.000065	59.18	1,689
80.00	0.000012	10.90	9,172				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000003	2.34	42,735	90.00	0.000016	14.70	6,802
20.00	0.000004	3.46	28,860	95.00	0.000021	19.17	5,216
30.00	0.000005	4.43	22,554	97.50	0.000027	24.84	4,025
40.00	0.000006	5.44	18,377	99.00	0.000036	32.79	3,049
50.00	0.000007	6.40	15,623	99.50	0.000043	39.28	2,545
60.00	0.000008	7.55	13,247	99.75	0.000055	49.71	2,011
70.00	0.000010	8.96	11,159	99.90	0.000065	59.17	1,690
80.00	0.000012	10.90	9,176				

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U.S. Environmental Protection Agency Ver. 6.78
DEEM ACUTE analysis for METHYL PARATHION (1989-92 data)
Residue file: mpproposal2.R96 Adjustment factor #2 NOT used.
Analysis Date: 07-29-1999/09:43:45 Residue file dated: 07-29-1999/08:18:22/8
Acute Reference Dose (aRfD) = 0.000110 mg/kg body-wt/day
NOEL (Acute) = 0.110000 mg/kg body-wt/day

Seniors (55+)

Daily Exposure Analysis (mg/kg body-weight/day)	per Capita	per User
Mean	0.000007	0.000007
Standard Deviation	0.000006	0.000006
Margin of Exposure	16,179	16,151
Percent of aRfD	6.18	6.19

Percent of Person-Days that are User-Days = 99.83%

Estimated percentile of user-days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	2.04	48,903	90.00	0.000012	11.12	8,989
20.00	0.000003	2.95	33,921	95.00	0.000015	13.69	7,307
30.00	0.000004	3.70	26,998	97.50	0.000018	16.45	6,077
40.00	0.000005	4.50	22,234	99.00	0.000023	21.27	4,700
50.00	0.000006	5.29	18,919	99.50	0.000027	24.52	4,077
60.00	0.000007	6.20	16,128	99.75	0.000032	29.30	3,413
70.00	0.000008	7.32	13,661	99.90	0.000041	37.22	2,686
80.00	0.000010	8.74	11,438				

Estimated percentile of per-capita days exceeding calculated exposure in mg/kg body-wt/day and corresponding

Perc.	Exposure	% aRfD	MOE	Perc.	Exposure	% aRfD	MOE
10.00	0.000002	2.01	49,678	90.00	0.000012	11.12	8,993
20.00	0.000003	2.94	34,066	95.00	0.000015	13.68	7,309
30.00	0.000004	3.69	27,065	97.50	0.000018	16.45	6,079
40.00	0.000005	4.49	22,275	99.00	0.000023	21.27	4,701
50.00	0.000006	5.28	18,944	99.50	0.000027	24.52	4,078
60.00	0.000007	6.19	16,145	99.75	0.000032	29.29	3,414
70.00	0.000008	7.31	13,672	99.90	0.000041	37.21	2,687
80.00	0.000010	8.74	11,445				

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Attachment 9: Post-mitigation Chronic Dietary Assessment

Post-mitigation Chronic Dietary Assessment

U.S. Environmental Protection Agency Ver. 6.76
DEEM Chronic analysis for METHYL PARATHION (1989-92 data)
Residue file name: D:\Methyl Parathion\R-96\053501proposal2-cr.R96
Adjustment factor #2 NOT used.
Analysis Date 07-29-1999/08:20:30 Residue file dated: 07-29-1999/08:19:50/8
Reference dose (RfD, CHRONIC) = .00002 mg/kg bw/day
COMMENT 1: Revised Risk Assessment (Registrant Proposal w/ Dried Peas and Hops)

Total exposure by population subgroup

Population Subgroup	Total Exposure mg/kg body wt/day	Total Exposure Percent of Rfd
U.S. Population (total)	0.000001	3.4%
U.S. Population (spring season)	0.000001	3.3%
U.S. Population (summer season)	0.000001	3.8%
U.S. Population (autumn season)	0.000001	3.3%
U.S. Population (winter season)	0.000001	3.1%
Northeast region	0.000001	3.4%
Midwest region	0.000001	3.4%
Southern region	0.000001	3.2%
Western region	0.000001	3.7%
Hispanics	0.000001	3.0%
Non-hispanic whites	0.000001	3.4%
Non-hispanic blacks	0.000001	3.0%
Non-hisp/non-white/non-black)	0.000001	4.6%
All infants (< 1 year)	0.000001	2.5%
Nursing infants	0.000000	0.7%
Non-nursing infants	0.000001	3.3%
Children 1-6 yrs	0.000002	7.5%
Children 7-12 yrs	0.000001	5.2%
Females 13-19 (not preg or nursing)	0.000001	2.8%
Females 20+ (not preg or nursing)	0.000001	2.5%
Females 13-50 yrs	0.000001	2.8%
Females 13+ (preg/not nursing)	0.000000	2.3%
Females 13+ (nursing)	0.000001	4.0%

Males	13-19 yrs	0.000001	3.4%
Males	20+ yrs	0.000001	2.7%
Seniors	55+	0.000000	2.3%
Pacific	Region	0.000001	3.6%

Attachment 10: Raw Data Table

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
ROOT and TUBER VEGETABLES										
Carrots (Parent only)	PDP - Parent	1994	687	6	0.004-0.052	0.002-0.013	0.0028	1%	RDF 9	0.00016
		1995	701	3		0.002-0.034			Canned: 0.00016	
		1996	500	0		0.002-0.013				
Potatoes (Parent Only)	PDP - Parent	1994	694	0	No Detectable Residues	0.002-0.013	0.0021	2%	RDF 27	0.000042
		1995	707	0		0.002-0.006				
	* FDA - Parent	1994	215	0		0.0033			Dried: 0.0021	
		1995	277	0						
		1996	309	0					Canned: 0.000042	
		1997	189	0						
Sweet Potatoes (Parent Only)	PDP - Parent	1996	507	0	0.003-0.014	0.002-0.013	0.0019	21%	RDF 30	0.00037
		1997	695	2		0.002-0.013				
	* FDA - Parent	1994	32	0		0.0033			Canned:0.00 037	
		1995	39	0						
		1996	53	0						
		1997	55	0						
Sugar Beets (Parent + Metabolite)	Field Trial Data[11]	N/A	26	0	No Detectable Residues	0.0167	0.0084	1%	0.000167	0.000167
Turnips (Parent + Metabolite)	*Translated from Carrots*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	1%	RDF 33	0.000054
Turnip Greens (Parent + Metabolite)	Field Trial Data[13]	N/A	15	8	0.12-3.96	0.008	0.004	7%	RDF 32	0.000467
									Canned: 0.000467	
BULB VEGETABLES										

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
Bulb Onions (Parent + Metabolite)	FDA - Parent + Metabolite	1994 1995 1996 1997	158/0	0	No Detectable Residues	0.0033	0.0017	9%	RDF 6 Canned: 0.00033	0.00033
GreenOnions (Parent + Metabolite)	Field Trial Data[5]	N/A	11	11	0.05-0.71	0.05	0.025		RDF 7	0.0254

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
LEAFY VEGETABLES (EXCEPT BRASSICA)										
Celery (Parent + Metabolite)	PDP - Parent	1994	176	1	0.05	0.002-0.008	0.0024	1%	RDF 11	0.00009
	* FDA - Parent + Metabolite	1994	51/26	1		0.0033			Canned: 0.00009	
		1995	72/31	0						
		1996	61/45	0						
		1997	70/31	0						
Lettuce (Parent + Metabolite)	PDP - Parent	1994	691	0	No Detectable Residues	0.002-0.013	0.0026	1%	RDF 23	0.00005
	* FDA - Parent + Metabolite	1994	207/106	0		0.0033			Canned: 0.00005	
		1995	285/202	2						
		1996	276/160	0						
		1997	179/73	0						
Spinach (Parent + Metabolite)	PDP - Parent	1995	609	0	0.03	0.002-0.034	0.0038	5%	RDF 28	0.00040
		1996	516	0		0.002-0.013				
		1997	780	1		0.002-0.013				
	* FDA - Parent + Metabolite	1994	75/27	0		0.0033				
		1995	62/30	0						
		1996	78/32	0						
		1997	56/22	0						
Canned Spinach	PDP - Parent	97	168	0	No Detectable Residues	0.002-0.034	0.003		RDF 29	0.00032

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
BRASSICA (COLE) LEAFY VEGETABLES										
Broccoli (Parent + Metabolite)	PDP - Parent	1994	637	0	No Detectable Residues	0.002-0.013	0.0022	1%	RDF 4	0.000049
	* FDA - Parent + Metabolite	1994	100/14	0		0.0033			Canned:	
		1995	81/20	0						
		1996	77/18	0						
		1997	79/25	0						
Brussels Sprouts (Parent + Metabolite)	*Translated From Lettuce*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	1%	RDF 5	0.00008
	* FDA - Parent + Metabolite	1994	41/19	0		0.0033				
		1995		0						
		1996		0						
		1997		0						
Cabbage (Parent + Metabolite)	*Translated From Lettuce*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	/	4%	RDF 8	0.00032
	* FDA - Parent + Metabolite	1994	375/110	0		0.0033	*See Above*		Canned: 0.00032	
		1995		1						
		1996		0						
		1997		0						
Cauliflower (Parent + Metabolite)	*Translated from Broccoli*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	1%	RDF 10	0.00005
Collards (Parent + Metabolite)	*Translated from Spinach*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	3%	RDF 13	0.00024

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
	* FDA - Parent + Metabolite	1994	80/11	0		0.0033			Canned:	
		1995		0						
		1996		0						
		1997		0						
Kale (Parent + Metabolite)	*Translated from Spinach*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	2%	RDF 22	0.00016
	* FDA - Parent + Metabolite	1994	69/41	0		0.0033			Canned: 0.00016	
		1995								
		1996								
		1997								
Mustard Greens (Parent + Metabolite)	*Translated from Spinach*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	2%	RDF 24	0.00016
	* FDA - Parent + Metabolite	1994	49/9	0		0.0033				
		1995								
		1996								
		1997								

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
LEGUME VEGETABLES										
Dried Beans (Parent + Metabolite)	FDA - Parent + Metabolite	1994	436/33	0	No Detectable Residues	0.0033	0.0017	3%	0.0033	0.00013
		1995		0						
		1996		0						
Succulent Beans (Parent + Metabolite)	PDP - Parent	1994	591	0	0.0249-0.0449	0.002-0.013	0.0057	4%	RDF 18	0.00026
		1995	587	0		0.002-0.013				
		1998	359	15		0.002-0.013				
	* FDA - Parent + Metabolite	1994	237/57	2		0.0033			Canned: 0.00026	
		1995	199/82	2						
		1996	181/58	6						
		1997	252/72	6						
Frozen Succulent Beans	PDP - Parent frozen	1996	531	18	0.0079-0.0169	0.002-0.013	0.0057		RDF 19	0.00156
		1997	707	33		0.002-0.013				
Succulent Lima Beans (Parent + Metabolite)	*Translated from Succulent Beans, Fresh and Frozen*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	4%	RDF 18	0.00026
									Canned: 0.00026	
Frozen Lima Beans		*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*		RDF 19	0.00156
Dried Lima Beans (Parent + Metabolite)	*Translated from Dried Beans*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	3%	0.0033	0.00013
Lentils (Parent + Metabolite)	*Translated from Soybean*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	1%	0.0036	0.000045

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
Dried Peas (Parent + Metabolite)	*Translated from Dried Beans*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	3%	0.006	0.00018
	* FDA - Parent + Metabolite	1994	47/6	0						
		1995		0						
		1996		0						
Succulent Peas (Parent + Metabolite)	FDA - Parent + Metabolite	1994	296/51	0	0.004-0.007	0.0033	0.0050	4%	RDF 26	0.00020
		1995	175/63	0						
		1996	197/59	1					Canned: 0.00020	
		1997	198/70	0						
Soybean Grain (Parent)	PDP - Parent	1997	159	0	No Detectable Residues	0.0036	0.0018	1%	0.0018	0.000023
	* FDA - Parent	1994	28	0		0.0033				
		1995	18	0						
		1996	26	0						
		1997	20	0						
FRUITING VEGETABLES										
Tomatoes (Parent + Metabolite)	PDP - Parent	1996	174	0	0.012	0.002-0.013	0.0024	1%	RDF 31	0.000062
		1997	706	1		0.002-0.013				
	* FDA - Parent + Metabolite	1994	310/0	1		0.0033			Canned and Processed: 0.000062	
		1995	430/148	1						
		1996	582/259	1						
		1997	470/233	1						

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
POME FRUITS										
Apples (Parent + Metabolite)	*Translated from Single Serving Pear Data*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	25%	RDF 35	0.00171
	* PDP-Parent	1994	687	45		0.002-0.013			Canned: 0.00171	
		1995	693	33		0.002-0.034				
		1996	530	30		0.002-0.013				
Apple Juice	PDP-Parent	1996	177	0	0.003	0.002-0.013	0.0033		RDF 2	0.00118
		1997	683	2		0.002-0.013				
Pear (Parent + Metabolite)	Single Serving PDP - Parent	1998	222	50	0.0141-0.0241	0.002-0.013	0.0033	14%	RDF 1	0.00139
	*PDP - Parent	1997	708	37		0.002-0.013				
	* FDA - Parent + Metabolite	1994	633/225	7		0.0033			Canned: 0.00139	
		1995								
		1996								
		1997								
Pear Juice	*Translated from Apple Juice Data*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*		RDF 2	0.00118

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
STONE FRUITS										
Cherries (Parent + Metabolite)	FDA - Parent + Metabolite	1994	90/6	3	0.005-0.23	0.0033	0.0017	11%	RDF 12	0.00287
		1995	84/11	3						
		1996	43/10	0						
		1997	70/6	1						
	* Field Trial Data[3]	N/A	N/A	N/A					Canned and Juice: 0.00287	
Nectarines (Parent + Metabolite)	*Translated from Fresh Peaches*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	18%	RDF 25	0.00793
	* FDA - Parent + Metabolite	1994	59/0	15						
		1995	42/22	3						
		1996	44/30	7						
		1997	23/8	0						
Peaches (Parent + Metabolite)	PDP - Parent	1994	396	117	Decomp.: 0.0002-1.9924	0.002-0.013	0.0035	39%	RDF 14	0.01703
		1995	367	104		0.002-0.013				
		1996	324	82		0.002-0.013				
	* FDA - Parent + Metabolite	1994	287/13	76		0.0033			Juice: 0.01703	
		1995	251/67	46						
		1996	166/38	35						
		1997	192/32	37						
Canned Peaches	PDP - Parent canned	1997	892	0	No Detectable Residues	0.002-0.013	0.0030		RDF 15	0.00234
Plums (Parent + Metabolite)	FDA - Parent + Metabolite	1994	44/10	0	No Detectable Residues	0.0033	0.0017	31%	RDF 20	0.00102
		1995	39/10	0						

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
		1996	50/30	0					Canned and Juice:0.001	
		1997	21/6	0						
TREE NUTS										
Almonds (Parent + Metabolite)	Field Trial Data[1]	N/A	6	1	0.18	0.05	0.025	2%	RDF 36	0.001
Pecans (Parent)	Field Trial Data[8]	N/A	4	0	No Detectable Residues	0.016	0.008	2%	RDF 37	0.00016
Walnuts (Parent)	Field Trial Data[14]	N/A	6	0	No Detectable Residues	0.016	0.008	12%	RDF 38	0.00096
CEREAL GRAINS										
Barley (Parent + Metabolite)	*Translated from Wheat*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	1%	0.00722	0.000095
Sweet Corn (Parent Only)	PDP - Parent frozen/can	1994	462	0	No Detectable Residues	0.002-0.013	0.0015	7%	RDF 17	0.000175
		1995	671	0		0.002-0.013				
		1996	173	0		0.002-0.013				
	FDA - Parent fresh	1994	432	0	No Detectable	0.0033			RDF 16	0.00010
		1995		0						
		1996		0						
		1997		0						
Field Corn (Parent Only)	FDA - Parent	1994	137/0	0	No Detectable Residues	0.0033	0.00167	7%	0.00167	0.00010
		1995								
		1996								
		1997								
Popped Corn (Parent Only)	*Translated from Field*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	*See Above*	7%	0.00167	0.00010

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Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
	Corn									
Oats (Parent + Metabolite)	*Translated from Wheat*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	1%	0.00722	0.000095
Polished Milled and Brown Rice (Parent + Metabolite)	FDA - Parent + Metabolite	1994	18/0	0	0.068-3.3	0.008	0.004	12%	0.00430	0.00169
		1995	53/0	1						
		1996	54/0	1						
		1997	53/0	2						
	* Field Trial Data[10]	N/A	21	20						
Crop	**Source of Data**	**Year**	**# of Samples Par/Met**	**Detects for Parent**	****Range of Detectable Residues (ppm)**	**Range of LOD's (ppm)**	**Weighted ½ LOD (ppm)**	**% Crop Treated**	**Ave. Acute Residue Conc. (ppm)**	**Ave. Chronic Residue Conc. (ppm)**
Rye (Parent + Metabolite)	*Translated from Wheat*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	*See Below*	1%	0.00722	0.000095
Wheat (Parent + Metabolite)	PDP - Parent	1995	600	0	0.01-0.31	0.006	0.0036	2%	0.00722	0.00016
		1996	340	1		0.006				
		1997	623	1		0.006				
	* FDA - Parent +	1994	197/0	0		0.0033				
		1995	153/6	0						
		1996	157/0	0						
		1997	163/4	1						

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
MISCELLANEOUS CROPS										
Artichokes (Parent + Metabolite)	Field Trial Data[2]	N/A	N/A	11	0.435-1.795	0.05	0.025	1%	RDF 3	0.01165
Cottonseed Meal (Parent + Metabolite)	Field Trial Data[4]	N/A	17	13	N/A	0.0167	0.0083	TX-6% US-17%	0.25	0.25
Cottonseed Oil (Parent)	FDA for Oil - Parent***	1995	1	0	N/A	0.0033	0.0017	17%	0.02	0.003
		1996	1	0						
Grapes (Parent + Metabolite)	PDP - Parent	1994	669	14	0.005-0.503	0.002-0.013	0.0024	2%	RDF 21	0.00165
		1995	690	2		0.002-0.013				
		1996	525	0		0.002-0.013				
	* FDA - Parent + Metabolite	1994	186/84	6		0.0033			Canned Grapes, Grape Wine and Sherry: 0.00165	
		1995	248/181	1						
		1996	230/202	0						
		1997	57/85	1						
Grape Juice	FDA - Parent + Metabolite	1994	33	0	No Detectable Residues	0.0033	0.0017		RDF 34	0.0001
		1995								
		1996								
Hops (Parent + Metabolite)	Field Trial Data - IR-4[6]	N/A	13	13	0.010-3.6	0.008	0.004	1%	0.00968	0.00968
Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)

Crop	Source of Data	Year	# of Samples Par/Met	Detects for Parent	**Range of Detectable Residues (ppm)	Range of LOD's (ppm)	Weighted ½ LOD (ppm)	% Crop Treated	Ave. Acute Residue Conc. (ppm)	Ave. Chronic Residue Conc. (ppm)
MISCELLANEOUS CROPS cont.										
Rapeseed (Canola) (Parent + Metabolite)	Field Trial Data[9]	N/A	16	2	0.05-0.062	0.05	0.025	5%	0.00271	0.00271
Peanuts (Parent + Metabolite)	Field Trial Data[7]	N/A	18	0	No Detectable Residues	0.0017	0.008	1%	0.00017	0.00017
Sunflowers (Parent + Metabolite)	Field Trial Data[12]	N/A	6	0	No Detectable Residues	0.0017	0.008	1%	0.00017	0.00017

One asterisk (*) signifies supporting data only. These supporting data are not used for the calculation of anticipated residues in this assessment.

Two aterick (**): This column shows the range of residue values used in this assessment, not the residues found in all supporting data.

Three asterisk (***): The FDA data for cottonseed shows 39 samples with no detectable residues.

1. Almond Field Trial Data - MRID No.: 44632601.
2. Artichoke Field Trial Data - MRID Nos.: 41379301 and 41717801.
3. Cherry Field Trial Data - MRID No.: 44622501.
4. Cottonseed Field Trial Data - MRID Nos.: 41395103, 41457904, 41560001, and 44430601.
5. Green Onion Field Trial Data - MRID Nos.: 41395104 and 41596203.
6. Hops IR-4 Trial Data - MRID No.: 44501201.
7. Peanuts Field Trial Data - MRID No.: 42606001.
8. Pecan Field Trial Data - MRID No.: 43760901.
9. Rapeseed (Canola) Field Trial Data - MRID Nos.: 42709101 and 42717601.
10. Rice Field Trial Data - MRID Nos.: 41379307 and 41560004.
11. Sugar Beets Field Trial Data: MRID No.: 41379306.
12. Sunflower Field Trial Data - MRID No.: 41359904.
13. Turnip Greens Field Trail Data - MRID Nos.: 41395101 and 41717806.
14. Walnut Field Trial Data - MRID No.: 44159701.

Attachment 11: Anticipated Residue Determination for Acute Dietary Assessment

Crop	Source of Data	Residue Data Used	% Crop Treated	Acute Residue (ppm)	Adjustment Factor (ppm)
ROOT and TUBER VEGETABLES					
Carrots (Parent only)	PDP -Parent	The composite PDP data is directly input incorporating %CT.	1%	RDF 9	Adjustment Factor[1]
Canned Carrots	Fresh Carrot PDP Data	Canned carrots uses an average of composite PDP data incorporating %CT.		0.00016	
Potatoes (Parent Only)	PDP -Parent * FDA - Parent	No detectable residues found in PDP data. ½ LOD is used for all non-detects incorporating %CT.	2%	RDF 27	Adjustment Factor[1]
Canned and Dried Potatoes	Fresh Potato PDP Data	Average of composite PDP data is used with no further adjustment for %CT.		Canned: 0.000042 Dried: 0.0021	
Sweet Potatoes (Parent Only)	PDP -Parent * FDA - Parent	The composite PDP data is directly input incorporating %CT.	21%	RDF 30	Adjustment Factor[1]
Canned Sweet Potatoes	Fresh Sweet Potato PDP Data	Canned sweet potatoes uses an average of composite PDP data incorporating %CT.		0.00037	
Sugar Beets (Parent + Metabolite)	Field Trial Data	No detectable residues found in field trial data. LOD is used incorporating %CT.	1%	0.000167	Adjustment Factor[1]
Turnips (Parent + Metabolite)	*Translated from Carrots*	*The composite carrot PDP data is directly input incorporating turnip %CT.*	1%	RDF 33	Adjustment Factor[1]
Turnip Greens (Parent + Metabolite)	Field Trial Data	Turnip FT data is used incorporating %CT.	7%	RDF 32	Adjustment Factor[1]
Canned Turnip Greens	Fresh Turnip Green FT Data	Average of field trial data is used incorporating %CT.		0.000467	

Crop	Source of Data	Residue Data Used	% Crop Treated	Acute Residue (ppm)	Adjustment Factor (ppm)
BULB VEGETABLES					
Bulb Onions (Parent + Metabolite)	FDA -Parent + Metabolite	No detectable residues found in FDA data. ½ LOD is used for all non-detects incorporating %CT.	9%	RDF 6	Adjustment Factor[1]
Canned Onion	Fresh Bulb Onion FDA Data	Average of composite bulb onion FDA data is used incorporating %CT.		0.00033	
Green onions (Parent + Metabolite)	Field Trial Data	Green onion FT data is used incorporating %CT.	9%	RDF 7	Adjustment Factor[1]
LEAFY VEGETABLES (EXCEPT BRASSICA)					
Celery (Parent + Metabolite)	PDP -Parent * FDA - Parent + Metabolite	The composite PDP data is directly input incorporating %CT.	1%	RDF 11	Adjustment Factor[1]
Canned Celery and Celery Juice	Fresh Celery PDP data	Average of composite celery PDP data is used incorporating %CT.1%		0.00009	
Lettuce (Parent + Metabolite)	PDP -Parent * FDA - Parent + Metabolite	No detectable residues found in PDP data. ½ LOD is used for all non-detects incorporating %CT.	1%	RDF 23	Adjustment Factor[1]
Canned Lettuce	Fresh Lettuce PDP Data	Average of composite lettuce PDP data is used incorporating %CT.		0.00005	
Spinach (Parent + Metabolite)	PDP -Parent * FDA - Parent + Metabolite	The composite PDP data is directly input incorporating %CT.	5%	RDF 28	Adjustment Factor[1]
Canned Spinach	PDP -Parent canned	The composite PDP data is directly input incorporating %CT.		RDF 29	

Crop	Source of Data	Residue Data Used	% Crop Treated	Acute Residue (ppm)	Adjustment Factor (ppm)
BRASSICA (COLE) LEAFY VEGETABLES					
Broccoli (Parent + Metabolite)	PDP -Parent * FDA - Parent + Metabolite	No detectable residues found in PDP data. LOD is used for all non-detects incorporating %CT.	1%	RDF 4	Adjustment Factor[1]
Canned Broccoli	Fresh Broccoli PDP Data	Average of composite broccoli fresh PDP data is used incorporating %CT.		0.000049	
Brussels Sprouts (Parent + Metabolite)	*Translated from Spinach* * FDA - Parent + Metabolite	*The composite spinach PDP data is directly input incorporating brussels sprouts %CT.*	1%	RDF 5	Adjustment Factor[1]
Cabbage (Parent + Metabolite)	*Translated from Spinach* * FDA - Parent + Metabolite	*The composite spinach PDP data is directly input incorporating cabbage %CT.*	4%	RDF 8	Adjustment Factor[1]
Canned Cabbage	*Translated from Spinach*	*Average of composite spinach PDP data is used incorporating cabbage %CT.*		0.00032	
Cauliflower (Parent + Metabolite)	*Translated from Broccoli*	*No detectable residues found on broccoli. LOD is used for all non-detects incorporating cauliflower %CT.*	1%	RDF 10	Adjustment Factor[1]
Collards (Parent + Metabolite)	*Translated from Spinach*	*The composite spinach PDP data is directly input incorporating collard %CT.*	2%	RDF 13	Adjustment Factor[1]
Canned Collards	*Translated from Spinach*	*Average of composite spinach PDP data is used incorporating collard %CT.*		0.00024	
Kale (Parent + Metabolite)	*Translated from Spinach*	*The composite spinach PDP data is directly input incorporating kale %CT.*	2%	RDF 22	Adjustment Factor[1]
Canned Kale	*Translated from Spinach*	*Average of composite spinach PDP data is used incorporating kale %CT.*		0.00016	
Mustard Greens (Parent + Metabolite)	*Translated from Spinach*	*The composite spinach PDP data is directly input incorporating mustard green %CT.*	2%	RDF 24	Adjustment Factor[1]

Crop	Source of Data	Residue Data Used	% Crop Treated	Acute Residue (ppm)	Adjustment Factor (ppm)
LEGUME VEGETABLES					
Dried Beans (Parent + Metabolite)	FDA - Parent + Metabolite	No detectable residues found in FDA data. ½ LOD is used incorporating %CT.	3%	0.0033	Adjustment Factor[1]
Succulent Beans (Parent + Metabolite)	PDP -Parent * FDA -Parent + Metabolite	The composite green bean PDP data is directly input incorporating succulent bean %CT.	4%	RDF 18	Adjustment Factor[1]
Frozen Succulent Beans	PDP -Parent frozen only	The composite frozen green bean PDP data is directly input incorporating succulent bean %CT.		RDF 19	
Canned Succulent Beans	Fresh Green Bean PDP Data	Average of composite green bean PDP data is used incorporating succulent bean %CT.		0.00026	
Dried Lima Beans (Parent + Metabolite)	*Translated from Dried Beans*	*No detectable residues found in dried bean FDA data. ½ LOD is used incorporating %CT.*	3%	0.0033	Adjustment Factor[1]
Succulent Lima Beans (Parent + Metabolite)	*Translated from Succulent Beans*	*The composite green bean PDP data is directly input incorporating succulent bean %CT.*	4%	RDF 18	Adjustment Factor[1]
Frozen Succulent Lima Beans	*Translated From Frozen Succulent Beans*	*The composite frozen green bean PDP data is directly input incorporating succulent lima bean %CT.*		RDF 19	
Canned Succulent Lima Beans	*Translated from Succulent Beans*	*Average of composite green bean PDP data is used incorporating succulent bean %CT.*		0.00026	
Lentils (Parent + Metabolite)	*Translated from Soybean*	*No detectable residues found on soybeans. LOD is used with no further adjustment for %CT.*	1%	0.0036	Adjustment Factor[1]
Dried Peas (Parent + Metabolite)	FDA - Parent + Metabolite	Average of composite dried bean FDA data is used with no further adjustment for %CT.	3%	0.006	Adjustment Factor[1]

Crop	Source of Data	Residue Data Used	% Crop Treated	Acute Residue (ppm)	Adjustment Factor (ppm)
Succulent Peas (Parent + Metabolite)	PDP -Parent * FDA -Parent + Metabolite	The composite PDP data is directly input incorporating %CT.	4%	RDF 26	Adjustment Factor[1]
Canned Succulent Peas	PDP -Parent frozen/can	The composite frozen/canned peas PDP data is directly input incorporating %CT.		0.00020	
Crop	**Source of Data**	**Residue Data Used**	**% Crop Treated**	**Acute Residue (ppm)**	**Adjustment Factor (ppm)**
Soybean Grain (Parent)	PDP -Parent * FDA - Parent + Metabolite	No detectable residues found. ½ LOD is used for all non-detects with no further adjustment for %CT.	1%	0.0018	Soybean Meal[2]: 0.3x Refined Soybean Oil[2]: 3x
FRUITING VEGETABLES					
Tomatoes (Parent + Metabolite)	PDP -Parent * FDA - Parent + Metabolite	The composite PDP data is directly input incorporating %CT.	1%	RDF 31	Adjustment Factor[1] Juice[2]: 0.06x Puree[2]: 0.12x Catsup[2]: 0.06x Paste[2]: 0.12x
Canned and Processed Tomatoes	Fresh Tomato PDP Data	Average of composite PDP data is used incorporating %CT.		0.000062	
POME FRUITS					
Apples (Parent + Metabolite)	*Translated from Single Serving Pear PDP Data*	*The single serving pear PDP data is directly input incorporating apple %CT.*	25%	RDF 35	Adjustment Factor[1]
Canned Apples	Composite Apple PDP Data	Average of composite fresh apple PDP data is used incorporating %CT.		0.00171	
Apple Juice (Parent + Metabolite)	PDP- Parent	The composite PDP data is input directly with no further adjustment for %CT.		RDF 2	Adjustment Factor[1] Juice[3]: 1x Conc.[3]: 3x

Crop	Source of Data	Residue Data Used	% Crop Treated	Acute Residue (ppm)	Adjustment Factor (ppm)
Pear(Parent + Metabolite)	PDP -Parent Single Serving	The single serving PDP data is input directly incorporating %CT.	14%	RDF 1	Adjustment Factor[1]
	*PDP-Parent Composite				
	*FDA-Parent + Metabolite				
Canned Pear	Composite Pear PDP Data	Average of composite fresh pear PDP data is used incorporating %CT.		0.00139	
Pear Juice (Parent + Metabolite)	*Translated from Apple Juice Data*	*The composite apple juice PDP data is directly input incorporating pear %CT.*		RDF 2	Adjustment Factor[1] Juice[3]: 1x Conc.[3]: 3x
		STONE FRUITS			
Cherries (Parent + Metabolite)	FDA - Parent + Metabolite	The composite FDA data is directly input incorporating %CT.	11%	RDF 12	Adjustment Factor[1]
	* Field Trial Data				
Canned Cherries and Cherry Juice	Fresh Cherry FDA Data	Average of composite fresh cherry FDA data is used incorporating %CT.	11%	0.00287	Adjustment Factor[1]
Nectarines (Parent + Metabolite)	*Translated from Fresh Peaches*	*The composite fresh peach PDP data is decomposited incorporating nectarine %CT.*	18%	RDF 25	Default Concentration Factor
Peaches (Parent + Metabolite)	PDP -Parent	The composite PDP data is decomposited incorporating %CT.	39%	RDF 14	Adjustment Factor[1]
	* FDA - Parent + Metabolite				
Peach Juice	Fresh Peach PDP Data	Average of composite peach PDP data is used incorporating %CT.		0.01703	
Canned Peaches	PDP -Parent canned	No detectable residues found. LOD is used for all non-detects incorporating %CT.		RDF 15	
				0.00234	

Crop	Source of Data	Residue Data Used	% Crop Treated	Acute Residue (ppm)	Adjustment Factor (ppm)
Plums (Parent + Metabolite)	FDA - Parent + Metabolite	No detectable residues found. LOD is used for all non-detects incorporating %CT.	31%	RDF 20	Adjustment Factor[1]
Canned Plums and Prune Juice	Fresh Plum FDA Data	No detectable residues found. LOD is used incorporating %CT.		0.00102	
		TREE NUTS			
Almonds (Parent + Metabolite)	Field Trial Data	Almond FT data is used incorporating %CT.	2%	RDF 36	Adjustment Factor[1]
Pecans (Parent)	Field Trial Data	No detectable residues found in Pecan FT data. ½ LOD is used incorporating %CT.	2%	RDF 37	Adjustment Factor[1]
Walnuts (Parent)	Field Trial Data	No detectable residues found in walnut FT data. ½ LOD is used incorporating %CT.	12%	RDF 38	Adjustment Factor[1]
		CEREAL GRAINS			
Barley (Parent + Metabolite)	*Translated from Wheat*	*Average of composite wheat PDP data is used with no further adjustment for %CT.*	1%	0.00722	Adjustment Factor[1]
Sweet Corn (Parent Only)	PDP -Parent frozen/can	No detectable residues found. ½ LOD is used for all non-detects incorporating %CT.	7%	RDF17	Adjustment Factor[1]
	FDA-Parent fresh	No detectable residues found. ½ LOD is used for all non-detects incorporating %CT.		RDF 16	
Oats (Parent + Metabolite)	*Translated from Wheat*	*Average of composite wheat PDP data is used with no further adjustment for %CT.*	1%	0.00722	Adjustment Factor[1]
Polished Milled and Brown Rice (Parent + Metabolite)	FDA - Parent + Metabolite * Field Trial Data	Average of composite FDA data is used incorporating LOD for all non-detects with no further adjustment for %CT.	12%	0.00430	Adjustment Factor[1] Polished Milled Rice[4]: 0.04x Brown Rice[4]: 0.18x
Rye (Parent + Metabolite)	*Translated from Wheat*	*Average of composite wheat PDP data is used incorporating LOD with no further adjustment for %CT.*	1%	0.00722	Adjustment Factor[1] Germ[2]: 2x

Crop	Source of Data	Residue Data Used	% Crop Treated	Acute Residue (ppm)	Adjustment Factor (ppm)
Wheat (Parent + Metabolite)	PDP -Parent * FDA - Parent + Metabolite	Average of composite PDP data is used incorporating LOD for all non-detects with no further adjustment for %CT.	2%	0.00722	Adjustment Factor[1] Germ[2]: 2x Flour[2]: 0.4x
MISCELLANEOUS CROPS					
Artichokes (Parent + Metabolite)	Field Trial Data	Artichoke FT data is used incorporating %CT.	1%	RDF3	Adjustment Factor[1]
Cottonseed Meal (Parent + Metabolite)	Field Trial Data	Average FT data is used, 3.0ppm for TX and 1.15ppm for US, incorporating the TX %CT, US %CT, and portions of the crop grown in each area.	TX 6% US 17%	0.25	Adjustment Factor[1] Seed Meal[5]: 0.09x
Cottonseed Oil (Parent)	FDA - Parent	No detectable residues found. ½ LOD is used for all non-detects with no further adjustment for %CT. (Note: Only 2 samples were found for seed oil, but 39 samples were found for seed.)	17%	0.02	Seed Oil: 1x
Grapes (Parent + Metabolite)	PDP - Parent * FDA - Parent + Metabolite	Composite PDP data is input directly incorporating %CT.	2%	RDF 21	Adjustment Factor[1] Juice[3]: 1x Conc.[3]: 3x
Canned Grapes, Grape Wine and Sherry	Fresh Grape PDP Data	Average of composite grape PDP data is used incorporating %CT.		0.00165	
Grape Juice	Grape Juice FDA Data	No detectable residues found. ½ LOD is used for all non-detects with no further adjustment for %CT.		RDF 34	
Hops (Parent + Metabolite)	Field Trial Data	Average of FT data is used incorporating %CT.	1%	0.00968	Adjustment Factor[1]
Rapeseed (Canola) (Parent + Metabolite)	Field Trial Data	Average of FT data is used incorporating %CT.	5%	0.00271	Adjustment Factor[1] Canola Oil[6]: 2x

Crop	Source of Data	Residue Data Used	% Crop Treated	Acute Residue (ppm)	Adjustment Factor (ppm)
Peanuts (Parent + Metabolite)	Field Trial Data	Average of FT data is used incorporating %CT.	1%	0.00017	Adjustment Factor[1] Peanut Oil[7]: 1x PeanutButter[7]: 1x
Sunflowers (Parent + Metabolite)	Field Trial Data	Average of FT data is used incorporating %CT.	1%	0.00017	Default Adjustment Factor

An asterisk (*) signifies supporting data only. These supporting data are not used for the calculation of anticipated residues in this assessment.

The FDA monitoring data used for cottonseed oil was not standard policy due to the limited number of samples.

The application rate for wheat will be increased requiring a raise in tolerance to 5ppm; therefore, the anticipated residue used in this assessment for wheat may underestimate the risk.

. All commodities containing boiled, canned, or cooked (NFS) food forms incorporate an adjustment factor of 0.05x for those food orms. Snap Beans Canning Study - MRID No.: 44812901.
. Residue Chemistry Chapter for the Methyl Parathion Reregistration Eligibility Decision (RED) Document. Bonnie Cropp-Kohlligian. 1/June/98.
. The default processing factors are adjusted to incorporate the actual juice data, maintaining the default juice/juice concentrate ratio.
Rice Processing Study - MRID No.: 41596205.
Cottonseed Processing Study - MRID No.: 41596201. The anticipated residue for cottonseed are adjusted for the proposed SLN's Texas.
Rapeseed (Canola) Processing Study - MRID No.: 42717601 and 42717602.
Peanut Processing Study - MRID No.: 42606003.

Attachment 12: DEEM Memo

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

August 2, 1999

MEMORANDUM

SUBJECT: Acute and Chronic Dietary Exposure and Risk Analysis for Methyl Parathion.
Reregistration Case No.: 0153.
PC code: 053501.
DP Barcode No.: D256996.

FROM: Sherrie L. Mason, Chemist
Reregistration Branch II
Health Effects Division (7509C)
And
John Punzi Ph.D., Chemist
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division (7509C)
And
Richard Griffin, Biologist
Felicia Fort, Chemist
Dietary Exposure Science Advisory Council
Health Effects Division (7509C)

TO: Diana Locke, Risk Assessor
Reregistration Branch II
Health Effects Division (7509C)
And
Dennis Deziel, Chemical Review Manager
Reregistration Branch I
Special Review and Reregistration Division (7508W)

Action Requested

A probabilistic Tier 3 (Monte-Carlo) acute dietary exposure and a chronic dietary exposure assessment for methyl parathion was requested to estimate the dietary risks associated with the reregistration of methyl parathion. It was requested that this acute assessment be done incorporating results from the United States Department of Agriculture's (USDA) Pesticide Data Program (PDP) when available. Methyl parathion residue estimates used in this assessment include percent crop treated estimates reported by Biological and Economic Analysis Division (BEAD) and are based primarily on three data sources: 1) USDA Pesticide Data Program food sampling data; 2) Food and Drug Administration (FDA) Surveillance Monitoring data; and 3) field trial data, submitted by the registrant to support tolerances.

Executive Summary

HED has completed a revision of the dietary risk assessment for methyl parathion using updated methods for estimating acute dietary exposure. Based on the deliberations of the Hazard Identification Assessment Review Committee (HIARC), hazard endpoints have been selected for both acute (one day) and chronic (long term) exposure intervals.

An uncertainty factor (UF) of 100 was applied to the risk assessment to account for inter- and intraspecies variability. The FQPA Safety Factor (as required by the Food Quality Protection Act of August, 1996) has been retained (10x) for the organophosphorous pesticide, methyl parathion.

The acute and chronic risk assessments were conducted for all methyl parathion food uses combined. Risk estimates are provided for the average U.S. population and various subgroups, with the major emphasis placed on the exposure estimates for infants and children. This assessment concludes that for all supported registered commodities, the acute risk estimates are above the Agency's level of concern (100% aPAD[2]) at the 99.9th percentile for the average U.S. population (378% of the aPAD) and all population subgroups. This assessment also concludes that for all commodities, the chronic risk estimates are below the Agency's level of concern (100% cPAD[1]) at the 99.9th percentile for the U.S. population (17% of the cPAD) and all population subgroups.

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[2]aPAD/cPAD = acute/chronic Population Adjusted Dose = $\frac{\text{Acute or Chronic RfD}}{\text{FQPA Safety Factor}}$

Toxicological Information

The toxicological database is complete pending submission of a developmental neurotoxicity (DNT) study. In summary, methyl parathion is acutely toxic (category 1) for oral, dermal, and inhalation routes of exposure, is slightly-moderately irritating to the eyes and skin, and is not a dermal sensitizer. The toxicity endpoints selected for the risk assessment are based primarily on neurotoxic effects, including neuropathology and cholinesterase (ChE) inhibition in the brain, red blood cell (RBC), and plasma, as well as behavioral effects and systemic toxicity. A single exposure to methyl parathion (7.5 mg/kg) in rodents results in peripheral nerve demyelination (tibial and sural nerves, dorsal and ventral root fibers). Chronic exposure at a dose level of 2.21 mg/kg/day in rodents results in retinal degeneration and sciatic nerve degeneration. There are no notable differences in sensitivity to methyl parathion between male and female animals. No evidence of carcinogenicity was seen in any study. Methyl parathion is classified as a "Group E" carcinogen, indicating no evidence of carcinogenicity in humans; i.e., the chemical is characterized as "Not Likely" to be carcinogenic in humans via relevant routes of exposure. This classification is supported by the lack of mutagenic activity; however, there is evidence suggesting that methyl parathion may function as an endocrine disrupter.

Table 1: Revised Methyl Parathion Toxicological Endpoints

REVISED METHYL PARATHION ENDPOINTS 03/04/99				
Exposure Duration	Exposure Route	Endpoint		Comments
		Dose	Effect	
Acute - aPAD	Dietary	aPAD = 0.00011 mg/kg/d	Neuropathology and inhibition of brain, plasma, and RBC ChE	NOAEL = 0.11 mg/kg/d. Based on neurotoxicity, neuropathology and inhibition of brain, plasma, and RBC ChE occurring at 0.53 mg/kg/d. One year dietary study in rats. UF of 100 applied for intra and inter species differences and an additional safety factor of 10X retained by the FQPA Safety Factor Committee for FQPA.
Chronic - cPAD	Dietary	cPAD = 0.00002 mg/kg/d	Systemic toxicity, neuropathology, and inhibition of RBC ChE at the LOAEL	NOAEL = 0.02 mg/kg/d. Based on systemic toxicity, neuropathology, and RBC ChE inhibition occurring at 0.21 mg/kg/d. Inhibition of plasma and brain ChE occurred at higher doses. Retinal degeneration and clinical signs occurred at the highest dose. 2-Yr chronic feeding study in rats. UF of 100 applied for intra and inter species differences and an additional safety factor of 10X retained by the FQPA Safety Factor Committee for FQPA.

Residue Information

Methyl Parathion Usage:

Methyl parathion is registered for use (direct application during the growing season to the raw agricultural commodity) on a variety of fruits, vegetables, and feed crops. The published tolerances for methyl parathion are listed in 40 CFR §180.189.

Residue Estimates:

Dietary risk estimates are based, in part, on estimates of the percent usage of methyl parathion on each registered food commodity. BEAD estimated methyl parathion use (I. Yusuf and T. Kiely memo, 4/13/99) based on available pesticide survey usage data for the years 1987 through 1997. BEAD estimates are provided to HED as a weighted average, and as a maximum. To avoid underestimating exposure, this risk assessment assumed 1% crop treated for any BEAD estimate less than 1% (including zero), and also used the estimated maximum percent crop treated (%CT) for each commodity for both the acute and chronic risk assessments. Percent crop treated estimates varied from less than 1%CT to the highest level of 39%CT for peaches (Attachment 1 and 2).

Methyl parathion residue estimates, or anticipate residues (ARs) in this assessment are based primarily on three data sources: 1) field trial data, submitted by the registrant to support tolerances; 2) USDA Pesticide Data Program (PDP) food sampling data; and 3) Food and Drug Administration (FDA) Surveillance Monitoring data. The order of preference for the purpose of risk assessment is PDP data > FDA data > field trial data. PDP data are preferred over FDA data because the statistical design of the PDP program is specific for dietary risk assessment (i.e. sampling is done at grocery store distribution points instead of directly from the field), and because the foods are prepared before analysis as they would typically be before consumption (i.e. peeling, washing). Many methyl parathion treated commodities not sampled by the PDP program are assessed based on translation of data from PDP sampled commodities in the same crop group, FDA surveillance data, or field trial data. Field trial residue data are generally considered by HED as conservative or worse case scenario of possible residue and are more suited to the requirements of tolerance setting, because it requires highest rates of application and shortest PHI, than to the requirements of dietary risk assessment (when the most realistic estimate is desired).

When using crop field trial data in this assessment, all data were handled similarly except the data for cottonseed meal. Due to a low PHI for some special local needs (SLN) on cottonseed grown in Texas, the crop field trial studies were used for cottonseed meal incorporating Texas %CT for cotton grown in TX, and

U.S. %CT for cotton grown in all other states so as to not overestimate the risk (Attachment 2).

Acute Assessment:

Single Serving Commodities with PDP/FDA Detections: The PDP and FDA databases report most detected residues as residues found in 5 lb. composite samples. This manner of reporting may not be representative of possible high-end residues that could be found if individual units of fruits and vegetables were analyzed. This assessment uses a statistical methodology for applying existing (composite) information to acute dietary risk assessments. This methodology consists of extrapolating data on pesticide residues in composite samples of fruits and vegetables to residue levels in single servings of fruits and vegetables. Given the composite sample mean, the composite sample variance, the number of units in each composite sample, and assuming a lognormal distribution, it is possible to *estimate* the mean and variance of the pesticide residues present on single servings of fruits and vegetables. These parameters can then be applied to generate information on the level of residue in fruits and vegetables (and calculate a theoretical distribution). This information was incorporated into a probabilistic exposure estimation model, the Monte-Carlo method. This methodology has a higher degree of accuracy when more than 30 composite samples have detectable residues (Use of Pesticide Data Program in Acute Risk Assessment - sent to Federal Register May,1999). Commodities that are blended (such as grains) or are smaller than single unit servings (peas) were not decomposited since the measured PDP levels were assumed representative of the actual range of residue.

Chronic Assessment:

For chronic risk assessment, reported residues were averaged, whether based on PDP, FDA, or field trials. If a commodity had no reported detections by the PDP and FDA programs, and the expectation of no detection was confirmed by field trial data, the weighted average of the Limits of Detection (LOD) were used to account for possible exposure that could not be more precisely quantified (½ LOD methyl parathion + ½ LOD methyl paraoxon).

Methyl Paraoxon:

This assessment assumes that methyl paraoxon is equal in toxicity to the parent methyl parathion and accounts for the possibility of this metabolite occurring in treated foods. In general, field trial studies have included analysis for methyl paraoxon, as have FDA surveillance data. The PDP program did not analyze for methyl paraoxon (1994-1998). For the commodities in which methyl paraoxon was detected in the field trial analyses, but not detected by FDA surveillance, paraoxon is accounted for by an assumption of ½ LOD. For commodities with no detection of methyl paraoxon in FDA or field trial data, the assumption was zero

residue, and ½ LOD was not incorporated.

Processing Factors:

Methyl parathion residues may be either concentrated or reduced by the activities of drying (prunes etc.), processing (juice, catsup etc.), washing, peeling, and cooking. If methyl parathion was measured prior to any of these processes, the predicted effect of the process has been applied to the estimated final residue at consumption. This assessment used factors to account for various processing, but most significantly, for the effect of cooking. This assessment reduced all food-forms designated as boiled or canned by a factor of 95% (0.05), which was established in a submitted canned snap bean study (MRID 44812901). Other processing factors (Methyl Parathion Residue Chemistry Chapter; REV. 5/99; Bonnie Cropp-Kohlligian; May 12, 1999; D255926) including DEEM™ default factors that were used in this assessment are listed in attachment 2.

Consumption Data and Dietary Risk Analysis

The DEEM™ Program: HED is currently using software developed by Novigen Sciences, Inc., named the *Dietary Exposure Evaluation Model* , or DEEM™ , to calculate acute and chronic dietary risk estimates for the general U.S. population and various population subgroups. The food consumption data used in the program are taken from the *USDA Continuing Survey of Food Intake by Individuals* (CSFII). The Agency is currently using 1989-92 consumption data. Consumption data are averaged for the entire U.S. population, and within population subgroups such as "all infants" to support chronic risk assessment, but retained as individual daily consumption data points to support acute risk assessment (which is based on distributions of consumption estimates for either deterministic- or probabilistic-type exposure estimates). The DEEM™ software is capable of calculating probabilistic (Monte Carlo) type risk assessments when appropriate residue data (distribution of residues) are available.

For acute risk assessments, one-day consumption data are summed and a food consumption distribution is calculated for each population subgroup of interest. The consumption distribution can be multiplied by a residue point estimate for a deterministic (Tier I/II type) exposure/risk assessment, or used with a residue distribution in a probabilistic (Monte Carlo) type risk assessment.

For chronic risk assessments, residue estimates for foods (e.g. apples) or food-forms (e.g. apple juice) of interest are multiplied by the averaged consumption estimate of each food/food-form of each population subgroup. Exposure estimates are expressed in mg/kg bw/d and as a percent of the cPAD.

Results and Discussion

Acute Probabilistic Exposure Analysis: (Monte-Carlo)

Based on the acute dietary exposure analysis as described above and using an aPAD of 0.00011 mg/kg/d, acute dietary exposure to all population subgroups exceeds the aPAD at the 99.9th exposure percentile (see Table 2). Estimated methyl parathion exposure to infants and children, as well as the general U.S. population, also exceeds the aPAD at the 99th percentile. Children 1-6 years have been identified as the most highly exposed population subgroup. Estimated acute dietary exposure to children 1-6 years exceeds the aPAD at the 95th, 99th, and 99.9th exposure percentiles. A complete listing of the acute dietary results are in attachment 4.

Several crops have been identified as making significant contributions to the dietary risk. Residues measured on these crops and the surveyed consumption of these crops, factored together, results in these crops taking up a significant percentage of the aPAD and thereby, making significant contributions to the risk. Theoretically, the overall risk exceeds the Agency's level of concern when the aggregate risk (food + water + residential) $\geq$ 100% PAD. A number of crops had significant residues from PDP data and are high consumption items (e.g. peaches, apples). The significant acute contributors have been identified as apples, cottonseed, peaches, grapes, and pears. Apples and peaches alone exceed the Agency's level of concern. For all the significant contributors, except cottonseed oil, PDP and/or FDA monitoring data have shown measurable residues of methyl parathion, some greater than half the tolerance. The FDA monitoring data used for cottonseed oil showed no detectable residues; however, there were only two samples of oil analyzed. The Agency believed that residues are not likely to be found in cottonseed oil since there are no detectable residues found in seed. Therefore, FDA monitoring data were used so as not to overestimate the potential risk from cottonseed oil.

The acute summary table below shows the acute dietary risks to the U.S. population, infants, and children from exposures to all the supported crops. A complete listing of the acute dietary results are in attachment 4.

Table 2: Acute Dietary Risk Estimates

Population	(95th percentile)		(99th percentile)		(99.9th percentile)	
	Exposure	% aPAD	Exposure	% aPAD	Exposure	% aPAD
U.S. Population	0.000044 mg/kg/day	40	0.000121 mg/kg/day	110	0.000416 mg/kg/day	378
All Infants <1 year	0.000095 mg/kg/day	86	0.000169 mg/kg/day	153	0.000415 mg/kg/day	377
Children 1-6 years	0.000132 mg/kg/day	**120**	0.000273 mg/kg/day	**249**	0.000969 mg/kg/day	**881**
Children 7-12 years	0.000061 mg/kg/day	55	0.000129 mg/kg/day	117	0.000428 mg/kg/day	388

Chronic Exposure Analysis:

Based on the chronic dietary exposure analysis as described above and using a cPAD of 0.00002 mg/kg/d, chronic dietary exposure to all population subgroups does not exceed the cPAD (see Table 3). Children 1-6 years have been identified as the most highly exposed population subgroup. The chronic summary table below shows the chronic dietary risks to the U.S. population, infants, and children from exposures to all the supported crops for which methyl parathion is registered. A complete listing of the chronic dietary results is in attachment 6. The chronic significant contributors have been identified as apples, peaches, grapes, cottonseed oil, and pears. For all the significant contributors, except cottonseed oil, PDP and/or FDA monitoring data have shown measurable residues of methyl parathion. The FDA monitoring data used for cottonseed oil showed no detectable residues; however, there were only two samples of oil analyzed. The Agency believed that residues are not likely to be found in cottonseed oil since there are no detectable residues found in seed. Therefore, FDA monitoring data were used so as not to overestimate the potential risk from cottonseed oil.

Table 3: Chronic Dietary Risk Estimates

Population	Exposure (mg/kg/day)	% Chronic PAD
U.S. Population	0.000003	17
All Infants (<1 year)	0.000006	29
Children 1-6 years	**0.000009**	**47**
Children 7-12 years	0.000005	22

Attachment 13: Residue Data Files

Methyl Parathion Residue Data Files (RDF)

Almonds
TOTALNZ=0
TOTALZ=98
TOTALLOD=2
LODRES=0.05

Fresh Apples
TOTALNZ=50
TOTALZ=172
TOTALLOD=0
LODRES=0.0033
0.0141
0.0061
0.0061
0.0171
0.0111
0.0111
0.0061
0.0111
0.0811
0.0163
0.0161
0.0821
0.0171
0.0061
0.0061
0.0061
0.0331
0.0061
0.0231
0.0211
0.0071
0.0071
0.0071
0.0071
0.0071
0.0111
0.0071
0.0071
0.0071
0.0161
0.0121
0.0071
0.0121
0.0071
0.0071
0.0071
0.0071
0.0121
0.0121
0.0232
0.0261
0.0121
0.0121
0.0121
0.0191
0.0351
0.0271
0.0231
0.0241
0.0241

Apple Juice
TOTALNZ=2
TOTALZ=0
TOTALLOD=862
LODRES=0.0046
0.003
0.003

Artichokes
TOTALNZ=11
TOTALZ=1100
TOTALLOD=0
LODRES=0.05
1.1145
0.895
1.285
1.005
1.075
1.185
1.795
0.435
1.655
1.445
0.895

Fresh Green Beans
TOTALNZ=15
TOTALZ=1527
TOTALLOD=47
LODRES=0.0057
0.0249
0.0129
0.0349
0.0129
0.0129
0.0369
0.0079
0.0459
0.0809
0.0379
0.0269
0.0569
0.0329
0.0079
0.0449

Frozen Green Beans
TOTALNZ=51
TOTALZ=1137
TOTALLOD=50
TOTALDRES=0.0057
0.0079
0.0129
0.0389
0.0199
0.0129
0.0109
0.0079
0.0129
0.0129
0.0349
0.0119
0.0079
0.0129
0.0339
0.0059
0.0109
0.0819
0.0109
0.0249
0.0059
0.0119
0.0059
0.0189
0.0209
0.0579
0.0249
0.2329
0.0419
0.1129
0.0129
0.0129
0.0219
0.0379
0.0699
0.0249
0.0129
0.0249
0.0249
0.0079
0.0949
0.0129
0.0059
0.0079
0.0249
0.2729
0.0129
0.0129
0.0269
0.3829
0.0129
0.0169

Broccoli
TOTALNZ=0
TOTALZ=634
TOTALLOD=7
LODRES=0.0044

Brussels Sprouts
TOTALNZ=0
TOTALZ=1555
TOTALLOD=16
LODRES=0.00796

Carrots
TOTALNZ = 9
TOTALZ = 1869
TOTALLOD = 10
LODRES = 0.0028
0.008
0.01
0.004
0.02
0.004
0.004
0.005
0.01
0.052

Cauliflower
TOTALNZ=0
TOTALZ=634
TOTALLOD=7
LODRES=0.0044

Celery
TOTALNZ=1
TOTALZ=174
TOTALLOD=2
LODRES=0.0048
0.005

Cherries
TOTALNZ = 7
TOTALZ = 255
TOTALLOD = 25
LODRES = 0.0033
0.2317
0.2317
0.2317
0.0067
0.0067
0.0067
0.0287

Collards
TOTALNZ=0
TOTALZ=1555
TOTALLOD=47
LODRES=0.00796

Fresh Sweet Corn
TOTALNZ = 0
TOTALZ = 93
TOTALLOD = 7
LODRES = 0.0015

Frozen Sweet Corn
TOTALNZ = 0
TOTALZ = 93
TOTALLOD = 7
LODRES = 0.0025

Grapes
TOTALNZ = 23
TOTALZ = 1846
TOTALLOD = 15
LODRES = 0.00476
0.483
0.019
0.253
0.163
0.103
0.133
0.021
0.503
0.263
0.413

Methyl Parathion Residue Data Files (RDF)

0.008
0.153
0.163
0.07
0.055
0.094
0.024
0.008
0.006
0.005
0.046
0.024
0.02

Grape Juice
TOTALNZ = 0
TOTALZ = 0
TOTALLOD = 34
LODRES = 0.0033

Kale
TOTALNZ=0
TOTALZ=1555
TOTALLOD=31
LODRES=0.00796

Lettuce
TOTALNZ=0
TOTALZ=684
TOTALLOD=7
LODRES=0.0052

Mustard Greens
TOTALNZ=0
TOTALZ=1555
TOTALLOD=31
LODRES=0.00796

Bulb Onions
TOTALNZ=0
TOTALZ=89
TOTALLOD=11
LODRES=0.0033

Green Onions
TOTALNZ=11
TOTALZ=122
TOTALLOD=0
LODRES=0.05
0.56
0.71
0.14
0.15
0.10
0.21
0.05
0.05
0.25
0.11
0.21

Canned Peaches
TOTALNZ = 0
TOTALZ = 544
TOTALLOD = 348
LODRES = 0050

Pears
TOTALNZ=50
TOTALZ=172
TOTALLOD=0
LODRES=0.0033
0.0141
0.0061
0.0061
0.0171
0.0111
0.0111
0.0061
0.0111
0.0811
0.0163
0.0161
0.0821
0.0171
0.0061
0.0061
0.0061
0.0331
0.0061
0.0231
0.0211
0.0071
0.0071
0.0071
0.0071
0.0071
0.0111
0.0071
0.0071
0.0071
0.0161
0.0121
0.0071
0.0121
0.0071
0.0071
0.0071
0.0071
0.0121
0.0121
0.0232
0.0261
0.0121
0.0121
0.0121
0.0191
0.0351
0.0271
0.0231
0.0241
0.0241

Peas
TOTALNZ=12
TOTALZ=0
TOTALLOD=1449
LODRES=0.005
0.004
0.004
0.004
0.004
0.005
0.004
0.005
0.005
0.005
0.007
0.007
0.004

Pecans
TOTALNZ=0
TOTALZ=98
TOTALLOD=2
LODRES=0.008

Plums
TOTALNZ = 0
TOTALZ = 106
TOTALLOD = 48
LODRES = 0.0033

Potatoes
TOTALNZ = 0
TOTALZ = 1373
TOTALLOD = 28
LODRES = 0.0021

Fresh Spinach
TOTALNZ=1
TOTALZ=1555
TOTALLOD=78
LODRES=0.00796
0.003

Canned Spinach
TOTALNZ=0
TOTALZ=1596
TOTALLOD=84
LODRES=0.00604

Sweet Potatoes
TOTALNZ = 2
TOTALZ = 974
TOTALLOD = 226
LODRES = 0.0019
0.014
0.003

Tomatoes
TOTALNZ = 1
TOTALZ = 871
TOTALLOD = 8
LODRES = 0.0047
0.017

Turnip Greens
TOTALNZ = 8
TOTALZ = 199
TOTALLOD = 7
LODRES = 0.008
0.228
1.05
1.07
3.96
2.64
0.168
0.208
0.12

Turnip Roots
TOTALNZ = 9
TOTALZ = 1869
TOTALLOD = 10
LODRES = 0.0028
0.0108
0.0128
0.0068
0.0228
0.0068
0.0068
0.0078
0.0128
0.0548

Walnuts
TOTALNZ=0
TOTALZ=78
TOTALLOD=12
LODRES=0.008

Nectarines
TOTALNZ = 1000
TOTALZ = 6307
TOTALLOD = 385
LODRES = 0.0070
2.2423
1.5901
1.3802
1.3005
0.9859
0.9053
0.8144
0.8088
0.7392
0.72
0.657
0.6386
0.5677
0.5606
0.5295
0.5161
0.492
0.4917
0.4504
0.4414
0.4112
0.4071
0.3901
0.3876

2178377

Methyl Parathion Residue Data Files (RDF)

0.3794	0.144	0.0863	0.059
0.374	0.1408	0.086	0.0587
0.3574	0.1405	0.085	0.0586
0.3553	0.139	0.0848	0.0578
0.3319	0.1381	0.0835	0.0578
0.3266	0.1361	0.0834	0.0573
0.3139	0.1347	0.0828	0.0573
0.3138	0.1336	0.0824	0.0567
0.304	0.1318	0.0818	0.0566
0.3012	0.1314	0.0812	0.0564
0.2975	0.1297	0.0807	0.0559
0.2945	0.1288	0.0806	0.0553
0.2858	0.1273	0.0792	0.0553
0.2815	0.1257	0.0789	0.0551
0.2745	0.1253	0.0784	0.0548
0.2733	0.1242	0.0781	0.0545
0.2656	0.1239	0.0772	0.0543
0.2645	0.1225	0.0771	0.0538
0.2507	0.1213	0.0767	0.0537
0.2487	0.1202	0.0759	0.0535
0.2458	0.1196	0.0752	0.0532
0.2436	0.1182	0.0751	0.0527
0.2385	0.1177	0.0744	0.0525
0.2357	0.1162	0.0741	0.0522
0.2314	0.1151	0.074	0.052
0.2311	0.1136	0.0736	0.0517
0.2238	0.1134	0.0729	0.0514
0.2215	0.1126	0.0726	0.0512
0.2164	0.112	0.072	0.0512
0.2146	0.1105	0.0715	0.0508
0.2109	0.1102	0.0713	0.0504
0.2074	0.109	0.0708	0.05
0.2053	0.1082	0.0704	0.0499
0.2027	0.107	0.07	0.0497
0.1961	0.1058	0.0692	0.0495
0.1956	0.1051	0.0692	0.049
0.1932	0.105	0.0687	0.049
0.1929	0.1033	0.0685	0.0488
0.1896	0.1032	0.0678	0.0484
0.1881	0.1018	0.0675	0.0483
0.1834	0.1011	0.0671	0.048
0.1814	0.1007	0.0671	0.0477
0.1804	0.0996	0.066	0.0477
0.1777	0.0988	0.0658	0.0474
0.1753	0.0988	0.0656	0.0474
0.1739	0.0977	0.0654	0.0469
0.171	0.0975	0.0648	0.0468
0.1687	0.0964	0.0644	0.0465
0.1662	0.0958	0.0639	0.0462
0.1648	0.0949	0.0638	0.0457
0.1631	0.0942	0.0633	0.0457
0.1614	0.0935	0.0631	0.0456
0.1597	0.0926	0.0624	0.0453
0.158	0.0924	0.0623	0.0449
0.1573	0.0921	0.0618	0.0448
0.1563	0.0909	0.0617	0.0445
0.1542	0.0903	0.0614	0.0445
0.152	0.0898	0.0609	0.0441
0.1493	0.0895	0.0607	0.0441
0.1486	0.0884	0.0607	0.0437
0.1477	0.0882	0.06	0.0435
0.1475	0.0873	0.0599	0.0432
0.1446	0.0867	0.0591	0.0432

Methyl Parathion Residue Data Files (RDF)

0.043	0.0324	0.025	0.0194
0.0428	0.0321	0.0249	0.0192
0.0425	0.0321	0.0247	0.0192
0.0425	0.032	0.0247	0.0191
0.0423	0.0318	0.0245	0.019
0.0421	0.0317	0.0245	0.019
0.0418	0.0317	0.0244	0.0189
0.0415	0.0315	0.0243	0.0188
0.0415	0.0313	0.0241	0.0188
0.0412	0.0312	0.024	0.0187
0.0411	0.031	0.0239	0.0186
0.0408	0.0309	0.0239	0.0185
0.0406	0.0308	0.0238	0.0185
0.0406	0.0307	0.0237	0.0184
0.0403	0.0307	0.0235	0.0183
0.0403	0.0304	0.0235	0.0183
0.0397	0.0302	0.0233	0.0183
0.0397	0.0301	0.0233	0.0181
0.0396	0.0301	0.0231	0.018
0.0396	0.0299	0.0231	0.018
0.0392	0.0299	0.023	0.0179
0.0391	0.0295	0.0229	0.0178
0.0386	0.0295	0.0228	0.0178
0.0386	0.0294	0.0227	0.0177
0.0385	0.0293	0.0226	0.0176
0.0384	0.0291	0.0226	0.0175
0.0379	0.0291	0.0225	0.0175
0.0379	0.0289	0.0224	0.0174
0.0378	0.0289	0.0223	0.0173
0.0377	0.0286	0.0222	0.0173
0.0375	0.0285	0.0221	0.0172
0.0375	0.0283	0.022	0.0171
0.037	0.0283	0.0219	0.0171
0.037	0.0281	0.0218	0.017
0.0367	0.0281	0.0217	0.0169
0.0366	0.0279	0.0217	0.0169
0.0365	0.0279	0.0216	0.0168
0.0363	0.0277	0.0215	0.0167
0.0361	0.0276	0.0214	0.0166
0.0361	0.0275	0.0213	0.0166
0.0359	0.0275	0.0212	0.0166
0.0356	0.0273	0.0211	0.0165
0.0355	0.0272	0.0211	0.0165
0.0353	0.0271	0.021	0.0164
0.0352	0.0269	0.0209	0.0163
0.0352	0.0267	0.0208	0.0162
0.0348	0.0267	0.0207	0.0161
0.0348	0.0266	0.0206	0.016
0.0346	0.0266	0.0205	0.016
0.0344	0.0264	0.0205	0.0159
0.0344	0.0263	0.0204	0.0159
0.0343	0.0261	0.0203	0.0158
0.0339	0.026	0.0203	0.0158
0.0339	0.0259	0.0202	0.0157
0.0337	0.0258	0.0201	0.0157
0.0335	0.0256	0.02	0.0156
0.0334	0.0256	0.0199	0.0156
0.0332	0.0256	0.0198	0.0155
0.0331	0.0255	0.0198	0.0154
0.0329	0.0253	0.0197	0.0154
0.0328	0.0252	0.0196	0.0153
0.0328	0.0251	0.0196	0.0152
0.0325	0.0251	0.0194	0.0151

Methyl Parathion Residue Data Files (RDF)

0.0151	0.0118	0.0091	0.0068
0.015	0.0117	0.009	0.0068
0.015	0.0117	0.0089	0.0068
0.015	0.0116	0.0089	0.0067
0.0149	0.0116	0.0089	0.0067
0.0148	0.0115	0.0088	0.0067
0.0147	0.0115	0.0088	0.0067
0.0147	0.0114	0.0088	0.0066
0.0146	0.0114	0.0087	0.0066
0.0146	0.0113	0.0087	0.0066
0.0145	0.0113	0.0087	0.0065
0.0145	0.0112	0.0087	0.0064
0.0144	0.0112	0.0086	0.0064
0.0144	0.0111	0.0085	0.0064
0.0143	0.0111	0.0085	0.0064
0.0142	0.011	0.0085	0.0064
0.0142	0.011	0.0084	0.0063
0.0141	0.011	0.0084	0.0063
0.0141	0.0109	0.0084	0.0063
0.014	0.0109	0.0083	0.0062
0.0139	0.0109	0.0083	0.0062
0.0139	0.0108	0.0083	0.0062
0.0139	0.0108	0.0082	0.0062
0.0139	0.0106	0.0082	0.0061
0.0137	0.0106	0.0081	0.0061
0.0137	0.0106	0.0081	0.0061
0.0136	0.0106	0.008	0.006
0.0136	0.0105	0.008	0.006
0.0135	0.0105	0.008	0.006
0.0135	0.0104	0.008	0.006
0.0134	0.0104	0.0079	0.0059
0.0134	0.0103	0.0079	0.0059
0.0132	0.0103	0.0079	0.0059
0.0132	0.0103	0.0078	0.0058
0.0132	0.0102	0.0078	0.0058
0.0131	0.0102	0.0078	0.0058
0.0131	0.0101	0.0077	0.0058
0.013	0.0101	0.0077	0.0057
0.013	0.01	0.0077	0.0057
0.0129	0.01	0.0077	0.0056
0.0129	0.01	0.0076	0.0056
0.0128	0.0099	0.0075	0.0056
0.0127	0.0099	0.0075	0.0056
0.0127	0.0098	0.0075	0.0055
0.0126	0.0098	0.0075	0.0055
0.0126	0.0097	0.0074	0.0055
0.0126	0.0097	0.0074	0.0055
0.0125	0.0097	0.0073	0.0054
0.0125	0.0096	0.0073	0.0054
0.0125	0.0096	0.0073	0.0053
0.0124	0.0096	0.0073	0.0053
0.0124	0.0095	0.0072	0.0053
0.0123	0.0095	0.0072	0.0053
0.0123	0.0094	0.0072	0.0053
0.0122	0.0094	0.0071	0.0052
0.0121	0.0093	0.0071	0.0052
0.0121	0.0093	0.007	0.0052
0.012	0.0093	0.007	0.0051
0.012	0.0093	0.007	0.0051
0.0119	0.0092	0.007	0.0051
0.0119	0.0092	0.0069	0.0051
0.0119	0.0091	0.0069	0.0051
0.0118	0.0091	0.0068	0.005

Methyl Parathion Residue Data Files (RDF)

0.005
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0.0004
0.0003
0.0003
0.0002
0.0002
0.0002
0.0001

Fresh Peaches
TOTALNZ = 1000
TOTALZ = 2178
TOTALLOD = 393
LODRES = 0.0070
1.9924
1.7971
1.2104
1.2032
1.0593
1.0414
0.814
0.7277
0.7207
0.6667
0.6468
0.6362
0.602
0.584
0.5734
0.5414
0.475
0.4603
0.4392
0.4354
0.3963
0.3945
0.3864
0.3661
0.3646
0.3589
0.3442

Methyl Parathion Residue Data Files (RDF)

0.3365	0.1214	0.0736	0.0481
0.3344	0.1194	0.0728	0.0481
0.3202	0.1169	0.0717	0.0479
0.3168	0.1162	0.0716	0.0478
0.3063	0.1161	0.0708	0.0476
0.3039	0.1155	0.0706	0.0474
0.3007	0.1143	0.0702	0.0474
0.2986	0.114	0.0689	0.0469
0.285	0.1135	0.0685	0.0468
0.2773	0.1115	0.0683	0.0463
0.2649	0.1101	0.0671	0.0459
0.264	0.1092	0.0667	0.0458
0.2626	0.1088	0.066	0.0458
0.2554	0.1085	0.0658	0.0448
0.2513	0.1076	0.0655	0.0447
0.2446	0.1063	0.0642	0.0445
0.2396	0.1061	0.0636	0.0445
0.2363	0.1036	0.0635	0.044
0.2357	0.1026	0.0631	0.0438
0.2259	0.1014	0.063	0.0436
0.2156	0.1003	0.0627	0.0431
0.2109	0.1002	0.0627	0.043
0.208	0.1002	0.0626	0.0428
0.2049	0.1002	0.0617	0.0426
0.199	0.0997	0.0616	0.0426
0.1981	0.0986	0.061	0.0423
0.1981	0.0985	0.0605	0.0419
0.196	0.0977	0.0599	0.0416
0.196	0.0975	0.059	0.0407
0.189	0.0962	0.0589	0.0404
0.1876	0.0955	0.0584	0.0403
0.1869	0.0943	0.0582	0.04
0.1856	0.0942	0.0575	0.0399
0.1819	0.0909	0.0574	0.0396
0.1756	0.0905	0.0567	0.0395
0.1747	0.0898	0.0566	0.0394
0.1725	0.0884	0.056	0.0393
0.1695	0.088	0.0556	0.0393
0.1606	0.0878	0.055	0.0393
0.1606	0.0871	0.0548	0.039
0.1549	0.086	0.0548	0.039
0.1508	0.0853	0.0547	0.0386
0.1507	0.085	0.0544	0.0384
0.1488	0.0846	0.0536	0.0381
0.1473	0.0837	0.0521	0.038
0.1452	0.0825	0.0521	0.038
0.1441	0.0821	0.052	0.0379
0.1399	0.0819	0.0516	0.0377
0.139	0.081	0.0515	0.0371
0.1379	0.0806	0.051	0.037
0.1373	0.0801	0.0506	0.0369
0.1369	0.0797	0.0506	0.0367
0.1347	0.0796	0.0505	0.0365
0.1329	0.0796	0.0504	0.0361
0.1325	0.0782	0.0497	0.036
0.1308	0.0771	0.0495	0.0359
0.1281	0.0767	0.0493	0.0357
0.1266	0.0767	0.0491	0.0354
0.1263	0.0767	0.049	0.0354
0.1262	0.0761	0.0487	0.0354
0.1225	0.076	0.0487	0.0354
0.1224	0.0752	0.0486	0.0352
0.1222	0.0746	0.0481	0.0349

Methyl Parathion Residue Data Files (RDF)

0.0348	0.0265	0.0209	0.0164
0.0348	0.0264	0.0208	0.0164
0.0345	0.0264	0.0208	0.0163
0.0344	0.0263	0.0207	0.0163
0.0342	0.0263	0.0204	0.0163
0.0337	0.0262	0.0204	0.0161
0.0335	0.0262	0.0204	0.016
0.0335	0.0261	0.0203	0.016
0.0328	0.026	0.0203	0.016
0.0324	0.0259	0.0199	0.0157
0.0319	0.0259	0.0198	0.0157
0.0317	0.0257	0.0198	0.0156
0.0316	0.0256	0.0197	0.0156
0.0315	0.0255	0.0197	0.0155
0.0313	0.0254	0.0197	0.0155
0.0312	0.0253	0.0197	0.0155
0.0312	0.0251	0.0196	0.0154
0.0311	0.025	0.0194	0.0153
0.0309	0.0248	0.0193	0.0153
0.0306	0.0248	0.0193	0.0153
0.0304	0.0247	0.0193	0.0152
0.0304	0.0246	0.019	0.0151
0.0303	0.0246	0.0189	0.015
0.0301	0.0245	0.0188	0.0148
0.0299	0.0245	0.0188	0.0147
0.0299	0.0244	0.0187	0.0147
0.0296	0.0242	0.0187	0.0147
0.0296	0.0241	0.0186	0.0147
0.0295	0.024	0.0184	0.0147
0.0294	0.0238	0.0183	0.0146
0.0292	0.0235	0.0183	0.0146
0.0292	0.0232	0.0181	0.0146
0.0292	0.0232	0.018	0.0145
0.0292	0.0232	0.018	0.0143
0.0291	0.0231	0.0179	0.0143
0.029	0.0231	0.0179	0.0142
0.029	0.0231	0.0179	0.0142
0.0289	0.0229	0.0179	0.0141
0.0289	0.0229	0.0178	0.0141
0.0289	0.0228	0.0177	0.0138
0.0289	0.0228	0.0175	0.0138
0.0287	0.0228	0.0175	0.0137
0.0287	0.0228	0.0175	0.0136
0.0284	0.0227	0.0173	0.0135
0.0283	0.0226	0.0173	0.0135
0.0283	0.0226	0.0172	0.0135
0.0281	0.0223	0.0171	0.0134
0.0277	0.0223	0.017	0.0134
0.0275	0.0222	0.017	0.0134
0.0275	0.0221	0.017	0.0134
0.0274	0.0221	0.017	0.0133
0.0274	0.0218	0.0169	0.0133
0.0274	0.0218	0.0169	0.0133
0.0274	0.0218	0.0169	0.0133
0.0273	0.0217	0.0169	0.0132
0.0273	0.0216	0.0168	0.013
0.0272	0.0216	0.0168	0.0129
0.0271	0.0215	0.0166	0.0129
0.0271	0.0214	0.0166	0.0129
0.0271	0.0212	0.0166	0.0128
0.027	0.0212	0.0166	0.0127
0.027	0.0212	0.0165	0.0127
0.0268	0.0212	0.0164	0.0127

Methyl Parathion Residue Data Files (RDF)

0.0126	0.01	0.0073	0.0056
0.0126	0.01	0.0072	0.0056
0.0126	0.01	0.0072	0.0056
0.0126	0.0099	0.0072	0.0056
0.0125	0.0099	0.0071	0.0055
0.0124	0.0098	0.0071	0.0055
0.0124	0.0096	0.0071	0.0055
0.0124	0.0096	0.0071	0.0055
0.0123	0.0096	0.0071	0.0055
0.0123	0.0094	0.007	0.0054
0.0123	0.0093	0.007	0.0054
0.0123	0.0092	0.007	0.0054
0.0122	0.0092	0.007	0.0054
0.0122	0.0091	0.007	0.0053
0.0122	0.0091	0.0069	0.0053
0.0122	0.009	0.0069	0.0053
0.0121	0.009	0.0069	0.0053
0.012	0.009	0.0068	0.0053
0.012	0.0089	0.0068	0.0052
0.012	0.0088	0.0068	0.0052
0.012	0.0088	0.0068	0.0052
0.012	0.0087	0.0068	0.0051
0.0119	0.0087	0.0066	0.0051
0.0118	0.0086	0.0065	0.005
0.0118	0.0086	0.0065	0.005
0.0118	0.0086	0.0065	0.005
0.0117	0.0086	0.0065	0.005
0.0116	0.0085	0.0063	0.005
0.0116	0.0084	0.0063	0.005
0.0115	0.0084	0.0063	0.0049
0.0115	0.0084	0.0063	0.0049
0.0114	0.0084	0.0063	0.0049
0.0113	0.0084	0.0063	0.0049
0.0113	0.0083	0.0063	0.0049
0.0113	0.0083	0.0063	0.0049
0.0112	0.0083	0.0062	0.0049
0.0112	0.0082	0.0062	0.0048
0.0112	0.0082	0.0061	0.0048
0.0111	0.0082	0.0061	0.0048
0.0111	0.0082	0.0061	0.0048
0.0111	0.0082	0.006	0.0047
0.011	0.0081	0.006	0.0047
0.011	0.008	0.006	0.0047
0.011	0.008	0.006	0.0047
0.0109	0.0079	0.006	0.0046
0.0109	0.0079	0.006	0.0046
0.0109	0.0077	0.0059	0.0046
0.0108	0.0077	0.0059	0.0045
0.0107	0.0077	0.0059	0.0044
0.0107	0.0077	0.0058	0.0044
0.0107	0.0077	0.0058	0.0044
0.0105	0.0077	0.0058	0.0043
0.0104	0.0076	0.0058	0.0043
0.0104	0.0076	0.0058	0.0043
0.0104	0.0076	0.0057	0.0043
0.0104	0.0076	0.0057	0.0043
0.0103	0.0075	0.0057	0.0043
0.0102	0.0074	0.0057	0.0043
0.0102	0.0074	0.0057	0.0042
0.0102	0.0074	0.0057	0.0042
0.0102	0.0074	0.0057	0.0042
0.0101	0.0074	0.0057	0.0042
0.01	0.0074	0.0056	0.0042

Methyl Parathion Residue Data Files (RDF)

0.0042	0.0029	0.0017	0.0006
0.0041	0.0029	0.0017	0.0006
0.0041	0.0029	0.0017	0.0005
0.0041	0.0029	0.0016	0.0005
0.004	0.0028	0.0016	0.0004
0.004	0.0028	0.0016	0.0004
0.004	0.0028	0.0016	0.0003
0.004	0.0028	0.0016	0.0003
0.004	0.0028	0.0016	0.0003
0.0039	0.0028	0.0016	0.0002
0.0039	0.0026	0.0016	0.0002
0.0038	0.0026	0.0015	
0.0038	0.0026	0.0015	
0.0038	0.0026	0.0015	
0.0038	0.0025	0.0015	
0.0038	0.0025	0.0015	
0.0038	0.0024	0.0014	
0.0038	0.0024	0.0014	
0.0038	0.0024	0.0014	
0.0038	0.0024	0.0014	
0.0038	0.0024	0.0014	
0.0037	0.0024	0.0014	
0.0036	0.0024	0.0014	
0.0036	0.0024	0.0013	
0.0036	0.0024	0.0013	
0.0035	0.0024	0.0013	
0.0035	0.0023	0.0013	
0.0035	0.0023	0.0013	
0.0035	0.0023	0.0013	
0.0035	0.0023	0.0013	
0.0034	0.0022	0.0012	
0.0034	0.0022	0.0012	
0.0034	0.0022	0.0012	
0.0034	0.0022	0.0012	
0.0034	0.0022	0.0012	
0.0033	0.0022	0.0012	
0.0033	0.0021	0.0012	
0.0033	0.0021	0.0012	
0.0033	0.0021	0.0011	
0.0033	0.0021	0.0011	
0.0032	0.0021	0.0011	
0.0032	0.002	0.001	
0.0032	0.002	0.001	
0.0032	0.002	0.001	
0.0031	0.002	0.001	
0.0031	0.0019	0.001	
0.0031	0.0019	0.0009	
0.0031	0.0019	0.0009	
0.0031	0.0019	0.0009	
0.0031	0.0019	0.0009	
0.0031	0.0019	0.0009	
0.0031	0.0018	0.0009	
0.0031	0.0018	0.0008	
0.0031	0.0018	0.0008	
0.003	0.0018	0.0008	
0.003	0.0017	0.0008	
0.003	0.0017	0.0008	
0.003	0.0017	0.0008	
0.0029	0.0017	0.0007	
0.0029	0.0017	0.0007	
0.0029	0.0017	0.0006	
0.0029	0.0017	0.0006	

Attachment 14: Revised Occupational and Residential Exposure

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 30, 1999

MEMORANDUM

SUBJECT: OCCUPATIONAL AND RESIDENTIAL EXPOSURE AND RISK ASSESSMENT AND RECOMMENDATIONS FOR THE REREGISTRATION ELIGIBILITY DECISION DOCUMENT FOR METHYL PARATHION. (PC 053501 and DP Barcode D239744)

FROM: Jonathan Becker, Ph.D., Environmental Health Scientist
Renee Sandvig, Environmental Protection Specialist
Reregistration Branch II
Health Effects Division (7509C)

TO: Dennis Deziel
Reregistration Branch I
Special Review and Reregistration Division (7508W)

THRU: Al Nielsen, Senior Scientist
Reregistration Branch II
Health Effects Division (7509C)

Please find attached a revised occupational exposure and risk assessment for the use of methyl parathion. The original risk assessment has been updated to address public comments received during Phase 4.

DB Barcode: D239744

Pesticide Chemical Code: 053501

EPA Reg Nos: 279-2149, 279-2609, 1812-399, 1812-405, 2935-482, 2935-527, 2935-528, 4581-292, 4787-28, 5481-175, 5481-307, 5481-437, 5905-198, 5905-515, 5905-528, 9779-344, 19713-37, 19713-281, 19713-322, 19713-324, 34704-715, 34704-794, 34704-795, 51036-284, 67760-29, and 67760-39.

PHED: Yes, Version 1.1

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EXECUTIVE SUMMARY

Methyl parathion, O, O-Dimethyl O-(4-nitrophenyl) phosphorothioate, is an acaricide and an insecticide registered for use on a variety of crops. It is a restricted use pesticide that is formulated as a microencapsulate (20.9 percent active ingredient), and an emulsifiable concentrate (ranges from 11.2 to 54.8 percent active ingredient). Methyl parathion can be applied with aerial equipment, airblast sprayer (microencapsulated formulation only), chemigation (microencapsulated formulation only), and groundboom equipment. Both the registrant's proposed maximum application rates and the current label maximum application rates were used in this assessment. These application rates vary from 0.25 to 3.0 pounds active ingredient per acre depending upon the exposure scenario and crop. Additionally, the recent mitigation measures for methyl parathion were included in this assessment.

At this time, products containing methyl parathion are intended for occupational uses. Methyl parathion is a restricted-use pesticide and is only available for retail sale to and for use by certified applicators (or persons under their direct supervision) and only for those uses covered by the certified applicator's certification. There are no homeowner uses, however, residential exposure could occur via agricultural spray drift from the use of methyl parathion on adjacent fields or from the use of methyl parathion as a mosquito control agent.

HED has determined that there are potential exposures to mixers, loaders, applicators, and other handlers during usual use-patterns associated with methyl parathion. Based on the use patterns of methyl parathion, twelve major exposure scenarios were identified: (1a) mixing/loading liquids (emulsifiable concentrate) for aerial application; (1b) mixing/loading liquids (emulsifiable concentrate) for groundboom application; (2a) mixing/loading liquids (microencapsulated) for aerial/chemigation application; (2b) mixing/loading liquids (microencapsulated) for groundboom application; (2c) mixing/loading liquids (microencapsulated) for airblast application; (3) applying sprays with aerial equipment (emulsifiable concentrate); (4) applying sprays with aerial equipment (microencapsulated); (5) applying sprays with groundboom equipment (emulsifiable concentrate); (6) applying sprays with groundboom equipment (microencapsulated); (7) applying sprays with airblast sprayer (microencapsulated); (8) flagging sprays (emulsifiable concentrate); and (9) flagging sprays (microencapsulated).

Calculations of risk based on combined dermal and inhalation exposure indicate that the MOEs are **not more than 100** even with maximum risk reduction measures for **all** of the short and intermediate term occupational exposure scenarios listed above **except** for two flagger exposure scenarios with engineering controls at the lowest application rates.

Depending on crop and postapplication activities, re-entry intervals are estimated to range up to 30 days for microencapsulated formulations and from 7 to 9 days for emulsifiable concentrate formulations.

Although methyl parathion is a restricted use pesticide that is only to be applied by certified applicators, HED believes that residential exposures may occur in several situations. First, residential exposures may occur from the use of methyl parathion as a mosquito control agent. Second, even though methyl parathion is a restricted use pesticide and some (but not all) labels state "Not for home use", the possibility exists for residential post-application exposure from commercial application of methyl parathion to homeowner orchards. HED believes that this occurs infrequently and that the risks from this situation may be best addressed by changes in label language to explicitly state that the use of methyl parathion around residences is prohibited. Finally, residential exposures may result from spray drift from the aerial application of methyl parathion to agricultural fields. HED believes that these exposures may occur frequently with increasing urban encroachment on agricultural lands.

Risk estimates of residential dermal and inhalation exposures were not estimated. The Agency is currently developing methods to assess residential risks, and these risks will be assessed in the future when these new methods are available. However, based on available information, HED remains concerned about residential risks from methyl parathion spray drift.

A quantitative exposure and risk assessment for mosquito control has not be completed as part of this document. The magnitude of the occupational and residential cannot currently be estimated because HED lacks necessary data. Guideline studies needed to fill these data gaps include those related to applicator exposure (3 studies), postapplication exposure (5 studies), and spray drift (3 studies).

OCCUPATIONAL AND RESIDENTIAL EXPOSURE AND RISK ASSESSMENT FOR THE USE OF METHYL PARATHION

In this document, which is for use in the Agency's development of the Methyl Parathion Reregistration Eligibility Decision Document (RED), HED presents the results of its occupational exposure and risk assessment for the use of methyl parathion.

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete.

Occupational and Residential Use Patterns

Methyl parathion, O, O-Dimethyl O-(4-nitrophenyl) phosphorothioate, is an acaricide and an insecticide registered for use on a variety of crops. Methyl parathion, a restricted use pesticide, is formulated as a microencapsulate (20.9 percent active ingredient), and an emulsifiable concentrate (ranges from 11.2 to 54.8 percent active ingredient).[1] Methyl parathion's emulsifiable concentration is also formulated with ethyl parathion, endosulfan, and malathion.

Methyl parathion can be applied with aerial equipment, airblast sprayer (microencapsulated formulation only), chemigation (microencapsulated formulation only), and groundboom equipment. Both the registrant's proposed maximum application rates and the current label maximum application rates were used in this assessment. These application rates vary from 0.25 to 3.0 pounds active ingredient per acre depending upon the exposure scenario and crop.

This chapter includes all the pre mitigation uses for methyl parathion as well as the post mitigation uses for methyl parathion. The following crops are being supported by the registrant and include all pre mitigation uses:

Food, Forage, Feed and Fiber Crops: Alfalfa, artichoke, barley, beans, beets, broccoli, brussel sprouts, cabbage, carrot, cauliflower, celery, collards, corn, cotton, grass forage/fodder/hay, hops, kale, lentils, lettuce, mustard, oats, onion, pastures, peas, peanuts, potato, rangeland, rape, rice, rye, soybeans, spinach, sugar beet, sunflower, sweet potato, tomato, turnip, wheat, and yam.[1,2]

Fruits and Nuts: Almond, apple, cherry, grapes, nectarine, peach, pear, pecan, plum, prune, and walnuts.

Ornamental Plants and Forest Trees: Christmas tree plantations, forest trees, ornamental and/or shade trees, pine trees, field-grown ornamental herbaceous plants, field-grown ornamental woody shrubs and vines, and rights-of-way.[1,2]

Non-agriculture Land and Pastures.

The crops included in the post mitigation uses of methyl parathion differ from the above list. The following crops were added: dried beans and dried peas. The following crops were taken out: apple, artichoke, broccoli, brussel sprouts, carrots, cauliflower, celery, cherry, collards, forest trees, garden beets, grapes, grasses grown for seed, kale, kohlrabi, lettuce, mustard, nectarine, non-agricultural land (mosquito use), ornamentals, pastures, peach, pears, plums, prunes, rangeland, spinach, succulent beans, succulent peas, tomatoes, and turnips.

Occupational use Products and Homeowner Use Products

At this time, products containing methyl parathion are intended for occupational uses. Methyl parathion is a restricted-use pesticide and is only available for retail sale to and for use by certified applicators (or persons under their direct supervision) and only for those uses covered by the certified applicator's certification.[1] There are no homeowner uses, however, residential exposure could occur via agricultural spray drift from the use of methyl parathion on adjacent fields or from the use of methyl parathion as a mosquito control agent.

Summary of Toxicity Concerns

Acute Toxicology Categories

The toxicological data base for methyl parathion is adequate and will support reregistration. Guideline studies for acute toxicity indicate that the technical grade of methyl parathion classified as category I for acute oral toxicity, category I for acute dermal toxicity, category I for inhalation toxicity, category III for primary eye irritation, and category IV for primary skin irritation. Methyl parathion is not classified as a dermal sensitizer.[3]

Toxicological Endpoints of Concern

The methyl parathion hazard identification committee report, dated March 23, 1999, indicates that there are toxicological endpoints of concern for methyl parathion. Dermal and inhalation endpoints of concern have been identified for short-term and intermediate-term exposure durations. These endpoints are listed in Table 1.

An uncertainty factor (UF) of 100 was applied to account for both interspecies extrapolation (10X) and intraspecies variability (10X). An additional factor of 10X was retained in accordance with the FQPA. This is justified because toxicity studies demonstrate neuropathology at relatively low dose levels and because evidence of developmental neurotoxic potential was seen in open literature studies. Target MOEs

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are 100 for occupational exposures and 1000 for residential exposures.

Since both the dermal and inhalation NOAELs were based on identical endpoints, the doses were combined in this risk assessment to identify a total MOE for the short and intermediate-term. No chronic exposure scenarios were identified.

Table 1. Methyl Parathion Hazard Endpoints and Uncertainty Factors.

Route / Duration	NOAEL (mg/kg/day)	Effect	Study	Uncertainty Factors	Comments
Dermal (short and intermediate term)	0.11	Neuropathology & inhibition of brain, plasma, & RBC ChE	1-year dietary rat study	Interspecies: 10x Intraspecies: 10x FQPA: 10x (res.)	100 percent dermal absorption
Inhalation (short and intermediate term)	0.11	Neuropathology & inhibition of brain, plasma, & RBC ChE	1-year dietary rat study	Interspecies: 10x Intraspecies: 10x FQPA: 10x (res.)	100 percent inhalation absorption

Epidemiological Information

Incident reports for methyl parathion were extracted from four databases with the following results:

OPP Incident Data System (IDS): Twelve anecdotal or alleged incidents were reported in IDS.

Poison Control Centers(PCC) -- Occupational and Non-occupational Exposure: 274 methyl parathion cases were recorded in the PCC database from 1985 through 1992. Of these, 102 cases resulted from occupational exposure (91 involved exposure to methyl parathion alone) and 146 cases resulted from non-occupational exposure (133 involved exposure to methyl parathion alone). Including exposure to multiple chemicals, methyl parathion had the fifth highest percent of occupational cases seen in a health care facility. On other measures of hazard (percent hospitalized, percent with symptoms or life-threatening symptoms) methyl parathion had results similar to the median for other cholinesterase inhibitors.

From 1993 through 1996 there were 132 exposures reported to Poison Control Centers. Of these 91 occurred in a residential setting and 26 occurred at the workplace. Another 12 cases occurred in a public area and 3 occurred at an unknown location. Children or teenagers were involved in 43 of the exposures. Of the residential cases, 43 received follow-up to determine medical outcome, of which 23 reported minor symptoms, 7 with moderate symptoms, and one case that was classified as life-threatening. Thirty-six of the residential cases were seen in a health care facility, including five that were hospitalized and 2 that were seen in an intensive care unit. Of the occupational cases, 8 had minor symptoms, 3 had moderate outcome.

Seventeen of the occupational cases were seen in a health care facility of which two were hospitalized.

Poison Control Centers(PCC) -- California Data for Ratio of Poisoning to Number of Applications: Methyl parathion had very low ratios of handler and field worker poisonings per 1,000 applications in California from 1982 through 1989. Only two pesticides (*Bacillus thuringiensis* and permethrin) had lower ratios.

Poison Control Centers(PCC) -- Ratios of Poisoning based on U.S. Poison Control Data: Among pesticides used exclusively in agriculture, methyl parathion had the third lowest ratio of exposures, poisonings, and treatment to estimated pounds of active ingredient used. It also had the second lowest ratio of hospitalized cases per estimated pounds used.

Poison Control Centers(PCC) -- Exposure in Children: For methyl parathion, 26 incidents were reported in children under five years of age from 1985-1992. No further analyses were conducted.

California Department of Food and Agriculture (1982 through 1995): Methyl parathion ranked 90th as a cause of systemic poisonings in California. It was the sole active ingredient in seven of the 18 reported cases. Workers took from two to five days off work as a result of their illness.

National Pesticide Telecommunications Network (NPTN): Methyl parathion was not reported on the list of the top 200 chemicals involved in human incidents.

OCCUPATIONAL AND RESIDENTIAL EXPOSURE AND RISKS

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted to the Agency in support of the reregistration of methyl parathion. It is the policy of the HED to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available.[4]

PHED was designed by a task force of representatives from the U.S. EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association. PHED is a software system consisting of two parts -- a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates)

Users select criteria to subset the PHED database to reflect the exposure scenario being evaluated. The subsetting algorithms in PHED are based on the central assumption that the magnitude of handler exposures to pesticides are primarily a function of activity (e.g., mixing/loading, applying), formulation type (e.g., wettable powders, granulars), application method (e.g., aerial, groundboom), and clothing scenarios (e.g., gloves, double layer clothing).

Once the data for a given exposure scenario have been selected, the data are normalized (i.e., divided by) by the amount of pesticide handled resulting in standard unit exposures (milligrams of exposure per pound of active ingredient handled). Following normalization, the data are statistically summarized. The distribution of exposure values for each body part (e.g., chest, upper arm) is categorized as normal, lognormal, or "other" (i.e., neither normal nor lognormal). A central tendency value is then selected from the distribution of the exposure values for each body part. These values are the arithmetic mean for normal distributions, the geometric mean for lognormal distributions, and the median for all "other" distributions. Once selected, the central tendency values for each body part are composited into a "best fit" exposure value representing the entire body.

The unit exposure values calculated by PHED generally range from the geometric mean to the median of the selected data set. To add consistency and quality control to the values produced from this system, the PHED Task Force has evaluated all data within the system and has developed a set of grading criteria to characterize the quality of the original study data. The assessment of data quality is based on the number of observations and the available quality control data. While data from PHED provide the best available information on handler exposures, it should be noted that some aspects of the included studies (e.g., duration, acres treated, pounds of active ingredient handled) may not accurately represent labeled uses in all cases. HED has developed a series of tables of standard unit exposure values for many occupational scenarios that can be utilized to ensure consistency in exposure assessments.[5]

Handler Exposures & Assumptions

HED has determined that there are potential exposures to mixers, loaders, applicators, and other handlers during usual use-patterns associated with methyl parathion. Based on the use patterns of methyl parathion, twelve major exposure scenarios were identified: (1a) mixing/loading liquids (emulsifiable concentrate) for aerial application; (1b) mixing/loading liquids (emulsifiable concentrate) for groundboom application; (2a) mixing/loading liquids (microencapsulated) for aerial/chemigation application; (2b) mixing/loading liquids (microencapsulated) for groundboom application; (2c) mixing/loading liquids (microencapsulated) for airblast application; (3) applying sprays with aerial equipment (emulsifiable concentrate); (4) applying sprays with aerial equipment (microencapsulated); (5) applying sprays with groundboom equipment (emulsifiable concentrate); (6) applying sprays with groundboom equipment (microencapsulated); (7) applying sprays with airblast sprayer (microencapsulated); (8) flagging sprays (emulsifiable concentrate); and (9) flagging

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sprays (microencapsulated).

Short-term and intermediate-term exposures and doses at baseline for the pre mitigation use patterns (developed using PHED Version 1.1 surrogate data) are presented in Table 2. The short- and intermediate term MOEs with mitigation methods for pre mitigation use patterns are presented in Table 3. Table 4 discusses the short-term and intermediate-term exposures and doses at baseline for post mitigation uses of methyl parathion. Table 5 discusses the short- and intermediate term MOEs with mitigation methods for post mitigation uses to methyl parathion. Table 6 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment The short and intermediate term MOEs are identical since they have the same endpoint.

The following general assumptions are made:

- Average body weight of an adult handler is 70 kg.
- Average work day interval represents an 8 hour workday (e.g., the acres treated or volume of spray solution prepared in a typical day).
- Calculations of the handler scenarios for the pre mitigation uses and the post mitigation uses both take into account the application rates proposed by one of the registrants. The various crop groupings found in the application rate column of the tables (i.e., cotton, rice, etc.) are assigned in a way to try to simplify the exposure assessments for this chemical. The crop groupings are developed based on different ranges of application rates.
- PHED Version 1.1 data were used for to estimate exposures for all scenarios.[5]
- Due to a lack of scenario-specific data, HED calculated unit exposure values using generic data from the Pesticide Handler Exposure Database (PHED) and, in lieu of PHED data for a scenario, using protection factors that are applied to represent various risk mitigation options (i.e., the use of personal protective equipment (PPE) and engineering controls). See Table 4 for detailed descriptions.
- Area treated in each scenario: 350 acres for aerial and chemigation applications (including flaggers supporting aerial applications); 80 acres for groundboom applications; and 40 acres for airblast application.
- The labels indicate that a ground or aerial sprayer can be used for field-grown ornamentals. Exposure and risk assessments for handheld equipment were not conducted. Ornamental use is not included in the

post mitigation uses.

- No PHED data were available for microencapsulant formulations; therefore, PHED data for liquids was used as a surrogate for this formulation.

Potential daily dermal exposure is calculated using the following formula:

$$\text{Daily Dermal Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right) = \text{Unit Exposure}\left(\frac{\text{mg ai}}{\text{lb ai}}\right) \times \text{Use Rate}\left(\frac{\text{lb ai}}{\text{A}}\right) \times \text{Daily Acres Treated}\left(\frac{\text{A}}{\text{day}}\right)$$

Potential daily inhalation exposure is calculated using the following formula:

$$\text{Daily Inhalation Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right) =$$
$$\text{Unit Exposure}\left(\frac{\mu\text{g ai}}{\text{lb ai}}\right) \times \text{Conversion Factor}\left(\frac{1\text{mg}}{1{,}000\ \mu\text{g}}\right) \times \text{Use Rate}\left(\frac{\text{lb ai}}{\text{A}}\right) \times \text{Daily Acres Treated}\left(\frac{\text{A}}{\text{day}}\right)$$

Dermal and inhalation absorption is assumed to be 100 percent. The daily dermal and inhalation dose is calculated using a 70 kg body weight for both short-term and intermediate-term exposure as follows:

$$\text{Daily Inhalation Dose}\left(\frac{\text{mg ai}}{\text{kg/day}}\right) = \text{Daily Inhalation Exposure}\left(\frac{\text{mg ai}}{\text{day}}\right) \times \left(\frac{1}{\text{Body Weight (kg)}}\right)$$

$$\text{Daily Dermal Dose}\left(\frac{\text{mg ai}}{\text{Kg/Day}}\right) = \text{Daily Dermal Exposure}\left(\frac{\text{mg ai}}{\text{Day}}\right) \times \left(\frac{1}{\text{Body Weight (Kg)}}\right)$$

$$\text{Total Daily Dose} = \text{Daily Dermal Dose}\left(\frac{\text{mg}}{\text{kg/day}}\right) + \text{Daily Inhalation Dose}\left(\frac{\text{mg}}{\text{kg/day}}\right)$$

These calculations of both the daily dermal dose and the daily inhalation dose of methyl parathion received by handlers are used to assess the total risk to handlers. The short-term and intermediate-term total MOEs were calculated using a NOAEL of 0.11 mg/kg/day. The following formula describes the calculation of a total MOE:

$$\text{Total MOE} = \frac{\text{NOEL}\left(\frac{mg}{kg/day}\right)}{\text{Total Daily Dose}\left(\frac{mg}{kg/day}\right)}$$

e 2. Occupational Short-Term and Intermediate-Term Dermal and Inhalation Exposure to Methyl Parathion and Doses at Baseline for ³re Mitigation Uses of Methyl Parathion.

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Maximum Application Rate (lb ai/acre)[c]	Crop[d]	Daily Acres Treated[e]	Daily Dermal Exposure (mg/day)[f]	Daily Inhalation Exposure (mg/day)[g]	Baseline Dermal Dose (mg/kg/day)[h]	Baseline Inhalation Dose (mg/kg/day)[i]	Baseline Total Dose (mg/kg/day)[j]	Total Short and Int-term MOE[k]
Mixer/Loader Exposure											
xing/Loading Liquids ulsifiable concentrate) Aerial Application (1a)	2.9	1.2	0.375	sugar beets	350	380	0.16	5.4	0.0023	5.4	0.020
			1.5	broccoli		1500	0.63	22	0.0090	22	0.0051
			3.0	cotton		3000	1.3	44	0.018	44	0.0025
xing/Loading Liquids ulsifiable concentrate) for Groundboom Application (1b)			0.375	sugar beets	80	87	0.036	1.2	0.00051	1.2	0.088
			1.5	broccoli		350	0.14	5.0	0.0021	5.0	0.022
			3.0	cotton		670	0.29	9.9	0.0041	9.9	0.011
xing/Loading Liquids icroencapsulated) for Aerial/Chemigation Application (2a)	2.9	1.2	0.5	peas	350	510	0.21	7.3	0.003	7.3	0.015
			1.5	cherries		1500	0.63	22	0.0090	22	0.0051
			2.0	pears		2000	0.84	29	0.012	29	0.0038
			3.0 (L)	grapes		3000	1.3	44	0.018	44	0.0025
xing/Loading Liquids icroencapsulated) for undboom Application (2b)			0.5	peas	80	120	0.048	1.7	0.00069	1.7	0.066
			1.0	corn		230	0.096	3.3	0.0014	3.3	0.033
			1.5	potatoes		350	0.14	5.0	0.0021	5.0	0.022
			3.0 (L)	grapes		700	0.29	9.9	0.0041	9.9	0.011
xing/Loading Liquids icroencapsulated) for Airblast Sprayer (2c)			1.5	cherries	40	170	0.072	2.5	0.0010	2.5	0.044
			2.0	pears		230	0.096	3.3	0.0014	3.3	0.033
			3.0 (L)	grapes		350	0.14	5.0	0.0021	5.0	0.022

Exposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Maximum Application Rate (lb ai/acre)[c]	Crop[d]	Daily Acres Treated[e]	Daily Dermal Exposure (mg/day)[f]	Daily Inhalation Exposure (mg/day)[g]	Baseline Dermal Dose (mg/kg/day)[h]	Baseline Inhalation Dose (mg/kg/day)[i]	Baseline Total Dose (mg/kg/day)[j]	Total Short and Int-term MOE[k]
Applicator Exposure											
plying Liquids with Aerial Equipment ulsifiable concentrate) (3)	See Eng. Controls	See Eng. Controls	0.375	sugar beets	350	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls
			1.5	broccoli							
			3.0	cotton							
plying Liquids with Aerial Equipment croencapsulated) (4)	See Eng. Controls	See Eng. Controls	0.5	peas	350	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls
			1.5	cherries							
			2.0	pears							
			3.0 (L)	grapes							
plying Liquids with a oundboom Sprayer ulsifiable concentrate) (5)	0.014	0.74	0.375	sugar beets	80	0.42	0.022	0.00060	0.00032	0.0063	17
			1.5	broccoli		1.7	0.089	0.024	0.0013	0.025	4.4
			3.0	cotton		3.4	0.18	0.048	0.0025	0.051	2.2
plying Liquids with a oundboom Sprayer croencapsulated) (6)	0.014	0.74	0.5	potatoes	80	0.56	0.030	0.0080	0.00042	0.0084	13
			1.0	corn		1.1	0.059	0.016	0.00085	0.017	6.5
			1.5	potatoes		1.7	0.089	0.024	0.0013	0.025	4.4
			3.0 (L)	grapes		3.4	0.18	0.048	0.0025	0.051	2.2
lying Sprays with an Airblast Sprayer croencapsulated) (7)	0.36	4.5	1.5	cherries	40	22	0.27	0.31	0.0039	0.31	0.35
			2.0	pears		29	0.36	0.41	0.0051	0.42	0.26
			3.0 (L)	grapes		43	0.54	0.62	0.0077	0.62	0.18

xposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Maximum Application Rate (lb ai/acre)[c]	Crop[c]	Daily Acres Treated[d]	Daily Dermal Exposure (mg/day)[f]	Daily Inhalation Exposure (mg/day)[g]	Baseline Dermal Dose (mg/kg/day)[h]	Baseline Inhalation Dose (mg/kg/day)[i]	Baseline Total Dose (mg/kg/day)[j]	Total Short and Int-term MOE[k]
Flagger Exposures											
igging Aerial Spray ications (emulsifiable concentrate) (8)	0.011	0.35	0.375	sugar beets	350	1.4	0.046	0.021	0.00066	0.021	5.2
			1.5	broccoli		5.8	0.18	0.083	0.0026	0.085	1.3
			3.0	cotton		12	0.37	0.17	0.0053	0.17	0.65
igging Aerial Spray Applications :roencapsulated) (9)	0.011	0.35	0.5	peas		1.9	0.061	0.028	0.00088	0.028	3.9
			1.5	cherries		5.8	0.18	0.083	0.0026	0.085	1.3
			2.0	pears		7.7	0.25	0.11	0.0035	0.11	0.97
			3.0 (L)	grapes		12	0.37	0.17	0.0053	0.17	0.65

notes

Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab tractor. Baseline data are not available for aerial equipment.

Baseline inhalation exposure represents no respirator.

Application rates are a range of maximum application rates proposed by the registrant and on the labels. If rates are not equal, they are designated with a R for registrant proposed or a L for label.

Emulsifiable concentrate formulation

Crop listed (max. app. rate (lbs ai/acre))	Also represents (max. app. rate (lbs ai/acre))
sugar beets (0.375)	canola (0.5 R, 0.25 L), soybeans (0.5 R, 1.0 L), grass and turnips (0.75)
broccoli (1.5)	alfalfa (1 R, 1.25 L), onions (1 R, 0.78 L), rice (0.75), corn (1 R, 0.5 L). soybeans (0.5R, 1.0L), artichoke, carrots, celery, hops,ornamentals, lettuce, sunflowers, spinach, and peas (1). barley, oats, wheat and rye (1.25 R, 0.75 L). cauliflower, brussel sprouts, cabbage, dried beans, kale, collards, mustard greens, green beans, and potatoes (1.5)
cotton (3)	none

Microencapsulate formulation

Crop listed (max. app. rate (lbs ai/acre))	Also represents (max. app. rate (lbs ai/acre))
peas (0.5) (aerial and groundboom)	onions (1 R, 0.5 L), lentils (0.5), barley, oats, grass, rye, yams, rice, sweet potatoes, and wheat (0.75)
cherries (1.5) (aerial)	alfalfa, corn, dried beans, green beans, peanuts, soybeans, and tomatoes (1). cotton (1.0R, 1.5L), potatoes (1.5), plums (1.5 R, 2L). grapes (1.5 R).
pears (2) (aerial and airblast)	almonds, nectarines, pecans, walnuts, apples and peaches (2)
corn (1) (groundboom)	alfalfa, corn, dried beans, green beans, peanuts, soybeans, and tomatoes (1).
potatoes (1.5) (groundboom)	cotton (1.0R, 1.5L), potatoes (1.5). grapes (1.5R)

cherries (1.5) (airblast)	plums (1.5 R, 2.0 L) and grapes (1.5R)
grapes (L) (3.0) (airblast and groundboom)	none

Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure ario of concern.

Daily dermal exposure (mg/day) = Dermal Unit Exposure (mg/lb ai) * Application rate (lb ai/acre) * Acres treated (acres/day).

Daily inhalation exposure (mg/day) = Inhalation Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion factor * Application rate (lb ai/A) * Acres treated (acres/day).

Baseline dermal dose (mg/kg/day) = Daily dermal exposure / Body weight (70 kg).

Baseline inhalation dose (mg/kg/day) = Daily inhalation exposure / Body weight (70 kg).

Total Dose(mg/kg/day) = Inhalation dose (mg/kg/day) + dermal dose (mg/kg/day).

Total Short and Intermediate Term MOE = Short and intermediate term NOAEL (0.11 mg/kg/day)/baseline total dose (mg/kg/day).

› 3. Occupational Short and Intermediate Term Combined Inhalation and Dermal MOEs for Methyl Parathion with Mitigation Measures
ccupational Exposures for the Pre Mitigation Uses of Methyl Parathion.

Exposure Scenario (Scenario #)	Crop	Additional Mitigation Measures										
		Additional PPE					Engineering Controls					
		Unit Dermal Exposure[a] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Daily Inhalation Dose[c] (mg/kg/day)	Total Dose[d]	Total MOE[e]	Unit Dermal Exposure[f] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Unit Inhalation Exposure[f] (µg/lb ai)	Daily Inhalation Dose[b] (mg/kg/day)	Total Dose[d]	Total MOE[e]
Mixer/Loader Exposure and Dose Levels												
Mixing/Loading Liquids ifiable concentrate) for Aerial Application (1a)	sugar beets	0.017	0.032	0.00045	0.032	3.4	0.0086 (gloves)	0.016	0.083	0.00016	0.016	6.8
	broccoli		0.13	0.0018	0.13	0.85		0.065		0.00062	0.065	1.7
	cotton		0.26	0.0036	0.26	0.43		0.13		0.0013	0.13	0.84
Mixing/Loading Liquids ulsifiable concentrate) for undboom Application (1b)	sugar beets		0.0073	0.00010	0.0074	15		0.0037		0.000036	0.0037	30
	broccoli		0.029	0.00041	0.030	3.7		0.015		0.00014	0.015	7.4
	cotton		0.058	0.00082	0.059	1.9		0.029		0.00028	0.030	3.7
Mixing/Loading Liquids microencapsulated) for Chemigation Application (2a)	peas	0.017	0.043	0.00060	0.043	2.6	0.0086 (gloves)	0.022	0.83	0.00021	0.022	5.1
	cherries		0.013	0.0018	0.13	0.85		0.064		0.00062	0.065	1.7
	pears		0.17	0.0024	0.17	0.64		0.086		0.00083	0.087	1.3
	grapes		0.26	0.0036	0.26	0.43		0.13		0.0013	0.13	0.84
Mixing/Loading Liquids microencapsulated) for undboom Application (2b)	peas		0.0097	0.00014	0.0099	11		0.0049		0.000047	0.0050	22
	corn		0.019	0.00027	0.020	5.6		0.0098		0.000095	0.0099	11
	potatoes		0.029	0.00041	0.030	3.7		0.015		0.00014	0.015	7.4
	grapes		0.059	0.00082	0.059	1.9		0.029		0.00028	0.030	3.7
Mixing/Loading Liquids roencapsulated) for Airblast Sprayer (2c)	cherries		0.015	0.00027	0.015	7.4		0.0074		0.000071	0.0074	15
	pears		0.019	0.00027	0.020	5.6		0.0098		0.000095	0.0099	11
	grapes		0.029	0.00041	0.030	3.7		0.015		0.00014	0.015	7.4

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Exposure Scenario (Scenario #)	Crop	Additional Mitigation Measures										
		Additional PPE					Engineering Controls					
		Unit Dermal Exposure[a] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Daily Inhalation Dose[c] (mg/kg/day)	Total Dose[d]	Total MOE[e]	Unit Dermal Exposure[f] (mg/lb ai)	Daily Dermal Dose[g] (mg/kg/day)	Unit Inhalation Exposure[f] (µg/lb ai)	Daily Inhalation Dose[h] (mg/kg/day)	Total Dose[d]	Total MOE[e]
Applicator Exposure, Dose, and Risk Levels												
olying Liquids with Aerial quipment (emulsifiable concentrate) (3)	sugar beets	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.005	0.0094	0.068	0.00013	0.0095	12
	broccoli							0.038		0.00051	0.038	2.9
	cotton							0.075		0.0010	0.076	1.4
olying Liquids with Aerial nent (microencapsulated) (4)	peas	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.005	0.013	0.068	0.00017	0.013	8.7
	cherries							0.038		0.00051	0.038	3.0
	pears							0.05		0.00068	0.051	2.2
	grapes							0.075		0.0010	0.076	1.4
Applying Liquids with a dboom Sprayer (emulsifiable concentrate) (5)	sugar beets	0.011	0.0047	0.00006	0.0048	23	0.005	0.0021	0.043	0.000018	0.0022	51
	broccoli		0.019	0.00025	0.019	5.8		0.0086		0.000074	0.0086	13
	cotton		0.038	0.00051	0.038	2.9		0.017		0.00015	0.017	6.4
Applying Liquids with a Groundboom Sprayer microencapsulated) (6)	potatoes		0.0063	0.00008	0.0064	17		0.0029		0.000025	0.0029	38
	corn		0.0013	0.00017	0.013	8		0.0057		0.000049	0.0058	19
	potatoes		0.019	0.00025	0.019	5.8		0.0086		0.000074	0.0086	13
	grapes		0.038	0.00051	0.038	2.9		0.017		0.00015	0.017	6.4
ng Liquids Using an Airblast yer (microencapsulated) (7)	cherries	0.22	0.19	0.00077	0.20	0.58	0.019 (gloves)	0.016	0.45	0.00039	0.017	6.6
	pears		0.25	0.0010	0.25	0.44		0.022		0.00051	0.022	4.9
	grapes		0.38	0.0015	0.38	0.29		0.033		0.00077	0.033	3.3

Exposure Scenario (Scenario #)	Crop	Additional Mitigation Measures										
		Additional PPE					Engineering Controls					
		Unit Dermal Exposure[a] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Daily Inhalation Dose[c] (mg/kg/day)	Total Dose[d]	Total MOE[e]	Unit Dermal Exposure[f] (mg/lb ai)	Daily Dermal Dose[g] (mg/kg/day)	Unit Inhalation Exposure[f] (µg/lb ai)	Daily Inhalation Dose[h] (mg/kg/day)	Total Dose[d]	Total MOE[e]
Flagger Exposure												
g Aerial Spray Applications lsifiable concentrate) (8)	sugar beets	0.010	0.019	0.00013	0.019	5.8	0.00022	0.00041	0.007	0.000013	0.00043	260
	broccoli		0.075	0.00053	0.076	1.5		0.0017		0.000053	0.0017	65
	cotton		0.15	0.0011	0.15	0.73		0.0033		0.00011	0.0034	32
g Aerial Spray Applications icroencapsulated) (9)	peas		0.025	0.00018	0.025	4.4		0.00055		0.000018	0.00057	190
	cherries		0.075	0.00053	0.076	1.5		0.0017		0.000053	0.0017	65
	pears		0.10	0.00070	0.10	1.1		0.0022		0.000070	0.0023	48
	grapes		0.15	0.0011	0.15	0.73		0.0033		0.00011	0.0034	32

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Additional PPE for all dermal scenarios includes double layer of clothing (50% Protection Factor for clothing) and chemical resistant s.

Daily Dermal Dose (mg/kg/day) = ((Dermal Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)) / Body Weight (70 kg))

Daily Inhalation Dose (Baseline Inhalation Dose)/ 5) [Additional PPE for all inhalation scenarios includes a dust/mist respirator for a 5-fold Protection Factor].

Total Dose (mg/kg/day) = Inhalation dose (mg/kg/day) + Dermal Dose (mg/kg/day).

Total MOE = Short and Intermediate term MOE (0.11 mg/kg/day) / total dose (mg/kg/day).

Scenario Number	Engineering Controls
1a / 1b / 1c / 2a / 2b / 2c	Closed mixing / loading, single layer clothing, chemical resistant gloves.
3, 4, 5, 6, 7	Enclosed cab, single layer clothing, no gloves.
8, 9	Enclosed truck (98% Protection Factor), single layer clothing, no gloves.

Daily Inhalation Dose (mg/kg/day) = ((Inhalation Unit Exposure (mg/lb ai) * Application Rates (lb ai/A) * Area Treated per day (acres)) / Body Weight (70 kg))

4. Occupational Short-Term and Intermediate-Term Dermal and Inhalation Exposure to Methyl Parathion and Doses at Baseline for Mitigation Uses.

posure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Maximum Application Rate (lb ai/acre)[c]	Crop[d]	Daily Acres Treated[e]	Daily Dermal Exposure (mg/day)[f]	Daily Inhalation Exposure (mg/day)[g]	Baseline Dermal Dose (mg/kg/day)[h]	Baseline Inhalation Dose (mg/kg/day)[i]	Baseline Total Dose (mg/kg/day)[j]	Total Short and Int-term MOE[k]
Mixer/Loader Exposure											
ng/Loading Liquids ifiable concentrate) for ial Application (1a)	2.9	1.2	0.375	sugar beets	350	380	0.16	5.4	0.0023	5.4	0.020
			1.5	cabbage		1500	0.63	22	0.0090	22	0.0051
			3.0	cotton		3000	1.3	44	0.018	44	0.0025
ing/Loading Liquids ifiable concentrate) for lboom Application (1b)			0.375	sugar beets	80	87	0.036	1.2	0.00051	1.2	0.088
			1.5	cabbage		350	0.14	5.0	0.0021	5.0	0.022
			3.0	cotton		700	0.29	9.9	0.0041	9.9	0.011
ing/Loading Liquids roencapsulated) for erial/Chemigation Application (2a)	2.9	1.2	0.5	peas	350	510	0.21	7.3	0.003	7.3	0.015
			1.0	alfalfa		1000	0.42	15	0.006	15	0.0076
			1.5	potatoes		1500	0.63	22	0.0090	22	0.0051
			2.0	pecans		2000	0.84	29	0.012	29	0.0038
ing/Loading Liquids roencapsulated) for lboom Application (2b)			0.5	peas	80	120	0.048	1.7	0.00069	1.7	0.066
			1.0	alfalfa		230	0.096	3.3	0.0014	3.3	0.033
			1.5	potatoes		350	0.14	5.0	0.0021	5.0	0.022
ing/Loading Liquids roencapsulated) for blast Sprayer (2c)			2.0	pecans	40	230	0.01	3.3	0.0014	3.3	0.033

xposure Scenario (Scenario #)	Baseline Dermal Unit Exposure (mg/lb ai)[a]	Baseline Inhalation Unit Exposure (µg/lb ai)[b]	Maximum Application Rate (lb ai/acre)[c]	Crop[d]	Daily Acres Treated[e]	Daily Dermal Exposure (mg/day)[f]	Daily Inhalation Exposure (mg/day)[g]	Baseline Dermal Dose (mg/kg/day)[h]	Baseline Inhalation Dose (mg/kg/day)[i]	Baseline Total Dose (mg/kg/day)[j]	Total Short and Int-term MOE[k]
Applicator Exposure											
ring Liquids with Aerial uipment (emulsifiable concentrate) (3)	See Eng. Controls	See Eng. Controls	0.375	sugar beets	350	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls
			1.5	cabbage							
			3.0	cotton							
ring Liquids with Aerial Equipment croencapsulated) (4)	See Eng. Controls	See Eng. Controls	0.5	peas	350	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls
			1.0	alfalfa							
			1.5	potatoes							
			2.0	pecans							
plying Liquids with a roundboom Sprayer sifiable concentrate) (5)	0.014	0.74	0.375	sugar beets	80	0.42	0.022	0.00060	0.00032	0.0063	17
			1.5	cabbage		1.7	0.089	0.024	0.0013	0.025	4.4
			3.0	cotton		3.4	0.18	0.048	0.0025	0.051	2.2
plying Liquids with a roundboom Sprayer croencapsulated) (6)	0.014	0.74	0.5	peas	80	0.56	0.030	0.0080	0.00042	0.0084	13
			1.0	alfalfa		1.1	0.059	0.016	0.00085	0.017	6.5
			1.5	potatoes		1.7	0.089	0.024	0.0013	0.025	4.4
olying Sprays with an Airblast Sprayer icroencapsulated) (7)	0.36	4.5	2.0	pecans	40	29	0.36	0.41	0.0051	0.42	0.26
Flagger Exposures											
agging Aerial Spray lications (emulsifiable concentrate) (8)	0.011	0.35	0.375	sugar beets	350	1.4	0.046	0.021	0.00066	0.021	5.2
			1.5	cabbage		5.8	0.18	0.083	0.0026	0.085	1.3
			3.0	cotton		12	0.37	0.17	0.0053	0.17	0.65
agging Aerial Spray Applications croencapsulated) (9)	0.011	0.35	0.5	peas		1.9	0.061	0.028	0.00088	0.028	3.9
			1.0	alfalfa		3.9	0.12	0.055	0.0018	0.057	1.9
			1.5	potatoes		5.8	0.18	0.083	0.0026	0.085	1.3
			2.0	pecans		7.7	0.25	0.11	0.0035	0.11	0.97

tnotes

Baseline dermal unit exposure represents long pants, long sleeved shirt, no gloves, open mixing/loading, open cab tractor. Baseline data are not available for aerial equipment.

Baseline inhalation exposure represents no respirator.

Application rates are a range of maximum application rates proposed by the registrant and on the labels. If rates are not equal, they are designated with a R for registrant proposed or a L for label.

Emulsifiable concentrate formulation

Crop listed (max. app. rate (lbs ai/acre))	Also represents (max. app. rate (lbs ai/acre))
sugar beets (0.375)	Rape seed (0.5 R, 0.25 L), soybeans (0.5 R, 1.0 L), sweet potato and grass (0.75)
cabbage (1.5)	alfalfa (1 R, 1.25 L), onions (1 R, 0.78 L), rice (0.75), corn (1 R, 0.5 L). hops and dried peas (1). barley, oats, wheat and rye (1.25 R, 0.75 L). dried beans and white potatoes (1.5)
cotton (3)	none

Microencapsulate formulation

Crop listed (max. app. rate (lbs ai/acre))	Also represents (max. app. rate (lbs ai/acre))
peas (0.5) (aerial and groundboom)	onions (1 R, 0.5 L). lentils and dried peas (0.5). barley, oats, grass, rice, sweet potatoes, and wheat (0.75)
alfalfa (1) (aerial and groundboom)	alfalfa, corn, dried beans, peanuts, and soybeans (1).
Potatoes (1.5) (aerial and groundboom)	cotton (1.0R, 1.5L). white potatoes (1.5).
pecans (2) (aerial and airblast)	almonds and walnuts (2)

Daily acres treated values are from the EPA HED estimates of acreage that could be treated in a single day for each exposure ario of concern.

Daily dermal exposure (mg/day) = Dermal Unit Exposure (mg/lb ai) * Application rate (lb ai/acre) * Acres treated (acres/day).

Daily inhalation exposure (mg/day) = Inhalation Unit Exposure (µg/lb ai) * (1mg/1000 µg) Conversion factor * Application rate (lb ai/A) * Acres treated (acres/day).

Baseline dermal dose (mg/kg/day) = Daily dermal exposure / Body weight (70 kg).

Baseline inhalation dose (mg/kg/day) = Daily inhalation exposure / Body weight (70 kg).

Total Dose(mg/kg/day) = Inhalation dose (mg/kg/day) + dermal dose (mg/kg/day).

Total Short and Intermediate Term MOE = Short and intermediate term NOAEL (0.11 mg/kg/day)/baseline total dose (mg/kg/day).

5. Occupational Short and Intermediate Term Combined Inhalation and Dermal MOEs for Methyl Parathion with Mitigation Measures
cupational Exposures for Post Mitigation Uses.

Exposure Scenario (Scenario #)	Crop	Additional Mitigation Measures										
		Additional PPE					Engineering Controls					
		Unit Dermal Exposure[a] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Daily Inhalation Dose[c] (mg/kg/day)	Total Dose[d]	Total MOE[e]	Unit Dermal Exposure[f] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Unit Inhalation Exposure[f] (µg/lb ai)	Daily Inhalation Dose[b] (mg/kg/day)	Total Dose[d]	Total MOE[e]
Mixer/Loader Exposure and Dose Levels												
Loading Liquids (emulsifiable rate) for Aerial Application (1a)	sugar beets	0.017	0.032	0.00045	0.032	3.4	0.0086 (gloves)	0.016	0.083	0.00016	0.016	6.8
	cabbage		0.13	0.0018	0.13	0.85		0.065		0.00062	0.065	1.7
	cotton		0.26	0.0036	0.26	0.43		0.13		0.0013	0.13	0.84
Loading Liquids (emulsifiable centrate) for Groundboom Application (1b)	sugar beets		0.0073	0.00010	0.0074	15		0.0037		0.000036	0.0037	30
	cabbage		0.029	0.00041	0.030	3.7		0.015		0.00014	0.015	7.4
	cotton		0.058	0.00082	0.059	1.9		0.029		0.00028	0.030	3.7
Mixing/Loading Liquids microencapsulated) for Chemigation Application (2a)	peas	0.017	0.043	0.00060	0.043	2.6	0.0086 (gloves)	0.022	0.83	0.00021	0.022	5.1
	alfalfa		0.085	0.0012	0.086	1.3		0.043		0.00042	0.043	2.5
	potatoes		0.013	0.0018	0.13	0.85		0.064		0.00062	0.065	1.7
	pecans		0.17	0.0024	0.17	0.64		0.086		0.00083	0.087	1.3
Mixing/Loading Liquids ncapsulated) for Groundboom Application (2b)	peas		0.0097	0.00014	0.0099	11		0.0049		0.000047	0.0050	22
	alfalfa		0.019	0.00027	0.020	5.6		0.0098		0.000095	0.0099	11
	potatoes		0.029	0.00041	0.030	3.7		0.015		0.00014	0.015	7.4
Mixing/Loading Liquids roencapsulated) for Airblast Sprayer (2c)	pecans		0.019	0.00027	0.020	5.6		0.0098		0.000095	0.0099	11
Applicator Exposure, Dose, and Risk Levels												
plying Liquids with Aerial nent (emulsifiable concentrate) (3)	sugar beets	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.005	0.0094	0.068	0.00013	0.0095	12
	cabbage							0.038		0.00051	0.038	2.9
	cotton							0.075		0.0010	0.076	1.4
plying Liquids with Aerial ment (microencapsulated) (4)	peas	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	See Eng. Controls	0.005	0.013	0.068	0.00017	0.013	8.7
	alfalfa							0.025		0.00034	0.025	4.3
	potatoes							0.038		0.00051	0.038	3.0
	pecans							0.05		0.00068	0.051	2.2

Exposure Scenario (Scenario #)	Crop	Additional Mitigation Measures										
		Additional PPE					Engineering Controls					
		Unit Dermal Exposure[a] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Daily Inhalation Dose[c] (mg/kg/day)	Total Dose[d]	Total MOE[e]	Unit Dermal Exposure[f] (mg/lb ai)	Daily Dermal Dose[b] (mg/kg/day)	Unit Inhalation Exposure[f] (µg/lb ai)	Daily Inhalation Dose[h] (mg/kg/day)	Total Dose[d]	Total MOE[e]
g Liquids with a Groundboom (emulsifiable concentrate) (5)	sugar beets	0.011	0.0047	0.00006	0.0048	23	0.005	0.0021	0.043	0.000018	0.0022	51
	cabbage		0.019	0.00025	0.019	5.8		0.0086		0.000074	0.0086	13
	cotton		0.038	0.00051	0.038	2.9		0.017		0.00015	0.017	6.4
g Liquids with a Groundboom yer (microencapsulated) (6)	peas		0.0063	0.00008	0.0064	17		0.0029		0.000025	0.0029	38
	alfalfa		0.0013	0.00017	0.013	8		0.0057		0.000049	0.0058	19
	potatoes		0.019	0.00025	0.019	5.8		0.0086		0.000074	0.0086	13
ing Liquids Using an Airblast yer (microencapsulated) (7)	pecans	0.22	0.25	0.0010	0.25	0.43	0.019 (gloves)	0.022	0.45	0.00051	0.022	5.0
Flagger Exposure												
ng Aerial Spray Applications ulsifiable concentrate) (8)	sugar beets	0.010	0.019	0.00013	0.019	5.8	0.00022	0.00041	0.007	0.000013	0.00043	260
	cabbage		0.075	0.00053	0.076	1.5		0.0017		0.000053	0.0017	65
	cotton		0.15	0.0011	0.15	0.73		0.0033		0.00011	0.0034	32
ing Aerial Spray Applications microencapsulated) (9)	peas		0.025	0.00018	0.025	4.4		0.00055		0.000018	0.00057	190
	alfalfa		0.05	0.00035	0.05	2.2		0.0011		0.000035	0.0011	97
	potatoes		0.075	0.00053	0.076	1.5		0.0017		0.000053	0.0017	65
	pecans		0.10	0.00070	0.10	1.1		0.0022		0.000070	0.0023	48

notes

Additional PPE for all dermal scenarios includes double layer of clothing (50% Protection Factor for clothing) & chem. resistant
s

Daily Dermal Dose (mg/kg/day) = ((Dermal Unit Exposure (mg/lb ai) x Application Rates (lb ai/A and lb ai/sq. ft.) x Area Treated per day (acres)) / Body Weight (70 kg))

Daily Inhalation Dose (Baseline Inhalation Dose)/ 5) [Additional PPE for all inhalation scenarios includes a dust/mist respirator for a 5-fold Protection Factor].

Total Dose (mg/kg/day) = Inhalation dose (mg/kg/day) + Dermal Dose (mg/kg/day).

Total MOE = Short and Intermediate term MOE (0.11 mg/kg/day) / total dose (mg/kg/day).

Scenario Number	Engineering Controls
1a / 1b / 1c / 2a / 2b / 2c	Closed mixing / loading, single layer clothing, chemical resistant gloves.
3, 4, 5, 6, 7	Enclosed cab, single layer clothing, no gloves.
8, 9	Enclosed truck (98% Protection Factor), single layer clothing, no gloves.

Daily Inhalation Dose (mg/kg/day) = ((Inhalation Unit Exposure (mg/lb ai) * Application Rates (lb ai/A) * Area Treated per day (acres)) / Body Weight (70 kg))

6: Occupational Exposure Scenario Descriptions for the Use of Methyl Parathion

Exposure Scenario (Number)	Data Source	Standard Values[a] (8-hr work day)	Comments[b]
Mixer/Loader Exposure			
Mixing/Loading Liquid ɔrmulations (1 a and 1b) mulsifiable concentration formulation)	PHED V1.1	350 acres for aerial and 80 acres for groundboom,	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation based on acceptable grades. Dermal = 25 to 122 replicates; hands = 53 replicates; and inhalation= 85 replicates. High confidence in all data. **PPE:** "Best Available" grades: Hands, dermal, and inhalation = acceptable grades. Dermal = 25 to 122 replicates; hands = 59 replicates; and inhalation = 85 replicates. High confidence in all data. **Engineering Controls:** "Best Available" grades: Hands, dermal, and inhalation = acceptable grades; Dermal = 16 to 22 replicates; hands = 31 replicates; and inhalation = 27 replicates. High confidence in all data. PHED data were used for baseline, no protection factors (PFs) were necessary. A 50% PF was added to simulate coveralls for PPE. An 80% PF was used for PPE for inhalation to represent a dust/mist respirator. Engineering Controls data were monitored with chemical resistant gloves.
Mixing/Loading Liquid Formulations (2a, 2b, 2c) (microencapsulated formulation)	PHED V1.1	350 acres for aerial and chemigation, 80 acres for groundboom, and 40 acres for airblast.	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation based on acceptable grades. Dermal = 25 to 122 replicates; hands = 53 replicates; and inhalation= 85 replicates. High confidence in all data. **PPE:** "Best Available" grades: Hands, dermal, and inhalation = acceptable grades. Dermal = 25 to 122 replicates; hands = 59 replicates; and inhalation = 85 replicates. High confidence in all data. **Engineering Controls:** "Best Available" grades: Hands, dermal, and inhalation = acceptable grades; Dermal = 16 to 22 replicates; hands = 31 replicates; and inhalation = 27 replicates. High confidence in all data. PHED data were used for baseline, no protection factors (PFs) were necessary. A 50% PF was added to simulate coveralls for PPE. An 80% PF was used for PPE for inhalation to represent a dust/mist respirator. Engineering Controls data were monitored with chemical resistant gloves. No PHED data was available for microencapsulate formulations; therefore, PHED for liquids was used as a surrogate.

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Exposure Scenario (Number)	Data Source	Standard Values[a] (8-hr work day)	Comments[b]
Applicator Exposure			
)plying Liquids with Aerial Equipment (3, 4)	PHED V1.1	350 acres	**Engineering controls:** "Best Available" grades: Dermal and inhalation = ABC grades; and hands = acceptable grades. Dermal = 24 to 48 replicates; hands = 34 replicates; and inhalation = 23 replicates. Medium confidence in all data. PHED data were used for baseline, no PFs were necessary.
oundboom Application (5, 6)	PHED V1.1	80 acres	**Baseline:** "Best Available" grades: Hands and dermal, and inhalation = acceptable grades. Dermal = 32 to 42 replicates; hands = 29 replicates; and inhalation = 22 replicates. High confidence in all data. **PPE:** "Best Available" grades: Dermal and inhalation= acceptable grades; hands = ABC grades. Dermal = 32 to 42 replicates; hands = 21 replicates; and inhalation= 22 replicates. Medium confidence in dermal and hands data. High confidence in inhalation data. **Engineering Controls:** "Best Available" grades: Dermal and hands = ABC grades. Dermal = 20 to 31 replicates; hands = 16 replicates. Medium confidence in dermal and hands data. High confidence in inhalation data. PHED data were used for baseline, no PFs were necessary. A 50% PF was added to the PPE scenario only to simulate coveralls.
Applying Liquids with an Airblast Sprayer (7)	PHED V1.1	40 acres	**Baseline:** "Best Available" grades = Hands, dermal, and inhalation = acceptable grades. Dermal = 32 to 49 replicates; hands = 22 replicates; and inhalation = 47 replicates. High confidence in all data. **PPE:** "Best Available" grades = Hands, dermal, and inhalation = acceptable grades. Dermal = 32 to 49 replicates; hands = 18 replicates; and inhalation = 47 replicates. High confidence in all data. **Engineering Controls:** "Best Available" grades: Hands and dermal = acceptable grades; and inhalation= ABC grades. Dermal = 20 to 30 replicates; hands = 20 replicates; and inhalation = 9 grades. High confidence in dermal data. Low confidence in inhalation data. No PFs were used for baseline data. A 50 percent PF was used for PPE to simulate coveralls. Engineering Controls data were monitored with chemical resistant gloves. 80% PF for the addition of a dust/mist respirator.

Exposure Scenario (Number)	Data Source	Standard Values[a] (8-hr work day)	Comments[b]
Flagger Exposure			
Flagging Aerial Spray Applications (8, 9)	PHED V1.1	350 acres	**Baseline:** "Best Available" grades: Hands, dermal, and inhalation = acceptable grades. Hands = 16 replicates; dermal = 16 to 18 replicates; and inhalation = 18 replicates. High confidence in dermal, hands, and inhalation data. **PPE:** "Best Available" grades: Hands, dermal, and inhalation = acceptable grades. Hands = 2 replicates; dermal = 16 to 18 replicates; and inhalation = 18 replicates. High confidence in dermal and inhalation data. Low confidence in hands data. **Engineering Controls:** Same as baseline. PHED data were used for baseline, no PFs were necessary. A 50% PF was added for PPE to represent coveralls. 80% PF for addition of a dust/mist respirator. A 98 percent PF was applied to baseline to simulate engineering controls.

notes

Standard Values based on an 8-hour work day as estimated by EPA. BEAD data were not available.

"Best Available" grades are defined by EPA SOP for meeting Subdivision U Guidelines. Acceptable grades are matrices with grades A and B data. Data confidence are assigned as follows:

High = grades A and B and 15 or more replicates

Medium = grades A, B, and C and 15 or more replicates

Low = grades A, B, C, D, and E or any combination of grades with less than 15 replicates

Post Application:

Chemical-specific postapplication exposure and/or environmental fate data have not yet been submitted by the registrant in support of reregistration of all formulation types of methyl parathion. In lieu of these data, a surrogate rangefinder postapplication assessment was conducted to determine potential risks for the representative crops used in the handler exposure assessment section. Current restricted-entry intervals are set in accordance with the Worker Protection Standard, 40 CFR Part 170, for most formulations. These interim restricted-entry intervals are 48 hour, except for areas receiving less than 25 inches of average rainfall per year. In these low rainfall areas the restricted-entry interval is 72 hours.

Microencapsulate Formulation

Pre Mitigation Uses

The surrogate assessment uses a typical transfer coefficient (Tc) for tree crops (peaches, apples and pears) of 10,000 cm^2/hr, from activities such as harvesting and pruning, a typical transfer coefficient for grapes of 15,000 cm^2/hr, from activities such as harvesting and hand girdling[6]. The dislodgeable foliar residue (DFR) value is derived from the various application rates using an estimated 20 percent of the rate applied as initial dislodgeable residues, and an estimated 25 percent dissipation rate per day. The dissipation half-life of the microencapsulated formulation is 1 to 2 days (based on environmental fate data supplied by EFED). A half-life of 1 to 2 days has also been suggested for the oxon of methyl parathion, depending upon the crop and climate.[7] The estimated dissipation rate of 25 percent per day is intended to approximate this half-life. For grapes the registrant's proposed application rate is 1.5 lbs ai/acre and the current maximum label rate is 3.0 lbs/acre, and for apples, pears and peaches is 2.0 lbs ai/acre. The equations used for the calculations in Table 7 are presented below:

$$DFR\left(\frac{\mu g}{cm^2}\right) = AR\left(\frac{lb\ ai}{A}\right) \times CF\left(\frac{\mu g/cm^2}{lb\ ai/A}\right) \times F \times (1-DR)^t$$

Where:

AR = Application rate is 1.5 and 3.0 lb ai/A for grapes and 2.0 lb/A for tree crops
DR = Daily dissipation rate (25 percent / day)
t = Days after treatment
CF = Conversion factor (11.2 lb per cm^2/lb per A)
F = Fraction retained on foliage (20 percent)

$$Dose\ (mg/kg/d) = \frac{DFR\ (\mu g/cm^2) \times Tc\ (cm^2/hr) \times CF\left(\frac{1\ mg}{1{,}000\ \mu g}\right) \times Abs \times ED\ (hrs)}{BW\ (kg)}$$

Where:

DFR = Initial DFR or daily DFR (μg/cm^2)
Tc = Transfer coefficient (10,000 cm^2/hr or 15,000 cm^2/hr)
CF = Conversion factor (1 mg/1,000 μg)
Abs = Dermal absorption (100 percent)
ED = Exposure duration (8 hours per day)
BW = Body weight (70 kg)

$$MOE = \frac{NOEL\ (mg/kg/d)}{Dose\ (mg/kg/d)}$$

Where:

NOAEL = 0.11 mg/kg/day
Dose = Calculated dose

Table 7. Methyl Parathion Intermediate-Term Surrogate Postapplication Assessment for Tree Crops and Grapes (Range Finder).

DAT[a]	DFR (μg/cm^2)[b]			Dermal Dose (mg/kg/day)[c]			MOE[d]		
	Pears, Apples, and Peaches	Grapes[a]		Pears, Apples, and Peaches	Grapes[a]		Pears, Apples, and Peaches	Grapes[a]	
		Registrant	Label		Registrant	Label		Registrant	Label
0	4.5	3.4	6.7	5.1	5.8	12	0	0	0
30	0.00080	0.00060	0.0012	0.0009	0.00010	0.0021	107	120	53
33	NA	NA	0.00051	NA	NA	0.00087	NA	NA	130

NA = Not applicable
[a] DAT = Days after treatment
[b] Initial DFR (μg/cm^2) = Application rate (1.5 and 3/0 lb ai/A for grapes and 2.0 lb ai/A for tree crops) x Conversion factor (1 lb ai/acre= 11.209 ug/cm2) x Fraction of initial ai retained on foliage

$$Daily\ Dissipation\ DFR = AR\left(\frac{lb\ ai}{A}\right) \times (1 - daily\ DFR)^{(1\ -\ D)^T} \times CF\left(\frac{\mu g\ per\ cm^2}{lb\ per\ A}\right) \times FI$$

Where: Assumed percent DFR after initial treatment is 20%, and each day after the percent dissipation per day is 25%.

[c] Dose = DFR ($\mu g/cm^2$) x Transfer coefficient (10,000 for tree crops, 15,000 cm^2/hr for grapes) x Conversion factor (1mg/1000 ug) x Dermal absorption (1) x Hrs worked per day (8 hrs) / Body weight (70 kg)
[d] MOE = NOAEL (mg/kg/day) / Dermal dose (mg/kg/day). Where: NOAEL is 0.11 mg/kg/day.
[e] Both the registrant's proposed application rate of 1.5 lbs ai/acre and the maximum label application rate of 3.0 lbs ai/acre were used for grapes.

Post Mitigation Uses

The surrogate assessment uses a typical transfer coefficient (Tc) for nut crops (pecans, walnuts and almonds) of 10,000 cm^2/hr, from activities such as harvesting (i.e. shaking, raking, pole and picking up) and pruning[6]. The dislodgeable foliar residue (DFR) value is derived from the various application rates using an estimated 20 percent of the rate applied as initial dislodgeable residues, and an estimated 25 percent dissipation rate per day. The dissipation half-life of the microencapsulated formulation is 1 to 2 days (based on environmental fate data supplied by EFED). A half-life of 1 to 2 days has also been suggested for the oxon of methyl parathion, depending upon the crop and climate.[7] The estimated dissipation rate of 25 percent per day is intended to approximate this half-life. The application rate for pecans, walnuts, and almonds is 2.0 lbs ai/acre. The equations used for the calculations in Table 8 are presented below:

$$DFR\left(\frac{\mu g}{cm^2}\right) = AR\left(\frac{lb\ ai}{A}\right) \times CF\left(\frac{\mu g/cm^2}{lb\ ai/A}\right) \times F \times (1-DR)^t$$

Where:

AR = Application rate is 2.0 lb/A for nut crops
DR = Daily dissipation rate (25 percent / day)
t = Days after treatment
CF = Conversion factor (11.2 lb per cm^2/lb per A)
F = Fraction retained on foliage (20 percent)

$$Dose\ (mg/kg/d) = \frac{(DFR\ (\mu g/cm^2) \times Tc\ (cm^2/hr) \times CF\left(\frac{1\ mg}{1{,}000\ \mu g}\right) \times Abs \times ED\ (hrs)}{BW\ (kg)}$$

Where:

DFR = Initial DFR or daily DFR (μg/cm^2)
Tc = Transfer coefficient (10,000 cm^2/hr)
CF = Conversion factor (1 mg/1,000 μg)
Abs = Dermal absorption (100 percent)
ED = Exposure duration (8 hours per day)
BW = Body weight (70 kg)

$$MOE = \frac{NOEL\ (mg/kg/d)}{Dose\ (mg/kg/d)}$$

Where:

NOAEL = 0.11 mg/kg/day
Dose = Calculated dose

Table 8. Methyl Parathion Intermediate-Term Surrogate Postapplication Assessment for Nut Crops (Range Finder).

DAT[a]	DFR (µg/cm^2)[b]	Dermal Dose (mg/kg/day)[c]	MOE[d]
	Walnuts, Pecans, and Almonds	Walnuts, Pecans, and Almonds	Walnuts, Pecans, and Almonds
0	4.5	5.1	0
30	0.00080	0.0009	107

NA = Not applicable
[a] DAT = Days after treatment
[b] Initial DFR (μg/cm^2) = Application rate (2.0 lb ai/A for nut crops) x Conversion factor (1 lb ai/acre= 11.209 ug/cm2) x Fraction of initial ai retained on foliage

$$Daily\ Dissipation\ DFR = AR\left(\frac{lb\ ai}{A}\right) x\ (1 - daily\ DFR)^{(1\ -\ D)T}\ x\ CF\left(\frac{\mu g\ per\ cm^2}{lb\ per\ A}\right) x\ FI$$

Where: Assumed percent DFR after initial treatment is 20%, and each day after the percent dissipation per day is 25%.

[c] Dose = DFR (μg/cm^2) x Transfer coefficient (10,000 for nut crops) x Conversion factor (1mg/1000 ug) x Dermal absorption (1) x Hrs worked per day (8 hrs) / Body weight (70 kg)
[d] MOE = NOAEL (mg/kg/day) / Dermal dose (mg/kg/day). Where: NOAEL is 0.11 mg/kg/day.

Emulsifiable Concentrate Formulation

The post application assessment for the emulsifiable concentrate formulation is the same for the pre mitigation uses and the post mitigation uses. The surrogate assessment uses a typical transfer coefficient (Tc) for cotton of 1,000 cm^2/hr for scouting in the early season and 4,000 cm^2/hr for scouting in the late season[6]. Since dissipation rate is chemical specific, the DFR date was derived from a open literature study done with methyl parathion[8]. The DFR data were derived by combining the amount of methyl parathion with the amount of methyl paraoxon that was present on the foliage each day, after an initial application of 1.0 lbs ai/acre. Since the application rates for cotton is 3.0 lbs ai/acre, are greater than 1.0 lbs ai/acre, the initial amount found on the leaf on day 0 was multiplied by the application rate of the crop. The data were log transferred and a regression analysis was done. The dissipation was determined from the regression data to be 63 percent per day. The predicted DFR were then determined using this dissipation rate, starting at day 0. The predicted DFR data were then used to obtain the dose for each day. The equations used for the calculations in Table 9 are presented below:

$$Dose\ (mg/kg/d) = \frac{(DFR\ (\mu g/cm^2)\ x\ Tc\ (cm^2/hr)\ x\ CF\left(\frac{1\ mg}{1{,}000\ \mu g}\right)\ x\ Abs\ x\ ED\ (hrs)}{BW\ (kg)}$$

Where:

DFR = Initial DFR or daily DFR ($\mu g/cm^2$)
Tc = Transfer coefficient (1,000 cm^2/hr and 4,000 cm^2/hr)
CF = Conversion factor (1 mg/1,000 μg)
Abs = Dermal absorption (100 percent)
ED = Exposure duration (8 hours per day)
BW = Body weight (70 kg)

$$MOE = \frac{NOEL\ (mg/kg/day)}{Dose\ (mg/kg/day)}$$

Where:

NOAEL = 0.11 mg/kg/day
Dose = Calculated dose

Table 9. Methyl Parathion Intermediate-Term Surrogate Postapplication Assessment for Cotton (Range Finder).

DAT[a]	DFR (µg/cm²)[b]	Dermal Dose (mg/kg/day)[c]		MOE[d]	
	Cotton	Cotton, scouting - early season	Cotton, scouting - late season	Cotton, scouting - early season	Cotton scouting - late season
0	9.2	1.1	4.2	0.1	0.0
7	0.0090	0.001	0.0041	110	27
9	0.0012	N/A	0.00056	N/A	200

Footnotes

NA = Not applicable

[a] DAT is "days after treatment"

[b] Predicted DFR was obtained through study data of the insecticide residues on cotton foliage[6]. The natural log was taken of the actual data and a regression analysis was done. This produced a dissipation rate and the predicted DFR values.

[c] Dose = DFR ($\mu g/cm^2$) x Transfer coefficient (1,000 and 4,000 cm^2/hr) x Conversion factor (1mg/1000 g) x Dermal absorption (1) x Hrs worked per day (8 hrs) / Body weight (70 kg)

[d] MOE = NOAEL (mg/kg/day) / Dermal dose (mg/kg/day). Where: intermediate NOAEL is 0.11 mg/kg/day.

Summary

Combined Dermal and Inhalation Risk from Handler Exposures

While the MOEs for the pre mitigation uses and the post mitigation uses vary, the scenarios that are a risk of concern are the same for both dermal and inhalation exposures were combined and risk was calculated for each exposure scenario using the short and intermediate term dermal and inhalation NOAEL of 0.11 mg/kg/day The acceptable MOE is 100. The calculations of risk based on combined dermal and inhalation exposure indicate that the MOEs are **not more than 100** even with maximum risk reduction measures for **all** of the short and intermediate term scenarios listed **except** the following:

- Flagging aerial spray applications with engineering controls for the emulsifiable concentration formulation at the 0.375 lbs ai/acre application rate (MOE = 260).

- Flagging aerial spray applications with engineering controls for the microencapsulated formulation at the 0.5 lbs ai/acre application rate (MOE = 190).

One of the registrants has stated that they are not supporting the use of human flaggers. However, HED has included the risk to flaggers in this assessment because some current labels allow the use of flaggers. In order for this assessment to be dropped, all labels must be modified to specify that human flaggers are prohibited.

Post-application Exposure

Microencapsulate Formulation

The resulting surrogate postapplication assessment for pre mitigation uses indicates that:

- MOEs equal or exceed 100 for grapes at the registrant suggested application rate of 1.5 lb ai/A with a dermal transfer of 15,000 cm^2/hr at the 30th day following application.

- MOEs equal or exceed 100 for grapes at the current label application rate of 3.0 lb ai/A with a dermal transfer of 15,000 cm^2/hr at the 33rd day following application.

- MOEs equal or exceed 100 for tree crops such as pears, apples and peaches with a dermal transfer of 10,000 cm^2/hr at the 30th day following application.

The resulting surrogate postapplication assessment for the post mitigation uses indicates that:

- MOEs equal or exceed 100 for nut crops including pecans, almonds and walnuts with a dermal transfer of 10,000 cm^2/hr at the 30th day following application.

Emulsifiable Concentrate Formulation

The post application assessment for the emulsifiable concentrate formulation is the same for the pre mitigation uses and the post mitigation uses. The surrogate postapplication assessment indicates that:

- MOEs equal or exceed 100 for cotton - early season, with a dermal transfer of 1,000 cm^2/hr on the 7th day after application.

- MOEs equal or exceed 100 for cotton - late season, with a dermal transfer of 4,000 cm^2/hr on the 9th day after application.

Residential Exposure and Risk Assessment for the Use of Methly Parathion

Although methyl parathion is a restricted use pesticide that is only to be applied by certified applicators, HED believes that residential exposures may occur in several situations. First, residential exposures may occur from the use of methyl parathion as a mosquito control agent. These exposures and risks are addressed later in this document. Second, even though methyl parathion is a restricted use pesticide and some (but not all) labels state "Not for home use", the possibility exists for residential post-application exposure from commercial application of methyl parathion to homeowner orchards. HED believes that this occurs infrequently and that the risks from this situation may be best addressed by changes in label language to explicitly state that the use of methyl parathion around residences is prohibited. Finally, residential exposures may result from spray drift from the aerial application of methyl parathion to agricultural fields. HED believes that these exposures may occur frequently with increasing urban encroachment on agricultural lands.

HED did not quantitatively assess the exposures and risks to individuals who live adjacent to farm fields and that could potentially be exposed to methyl parathion from spray drift. Methods to assess these risks are currently being developed by the Agency, and these assessments will be conducted in the future when these methods are available. However, based on current information, HED remains concerned about the potential risks from this source.

Mosquito Control

A quantitative exposure and risk assessment for mosquito control has not be completed as part of this document. The magnitude of the occupational and residential cannot currently be estimated because HED lacks necessary data. Guideline studies that would fill in these data gaps are as follows:

Applicator Exposure

- 875.1100 Dermal Exposure -- Outdoor
- 875.1300 Inhalation Exposure -- Outdoor
- 875.1500 Biological Monitoring

Postapplication Exposure

- 875.2100 Foliar Dislodgeable Residue Dissipation
- 875.2200 Soil Residue Dissipation
- 875.2400 Dermal Exposure
- 875.2500 Inhalation Exposure
- 875.2600 Biological Monitoring

Spray Drift

- 835.1100 Spray Droplet Size Spectrum
- 835.4100 Field Volatility From Soil
- 835.4200 Spray Drift Field Deposition

References

1) Methyl parathion labels.

2) U.S. EPA. Methyl parathion LUIS Table for Exposure Assessors. PRD Report, July 2, 1997; Report Run, August 22, 1997.

3) Methyl parathion (o,o-dimethyl o-p-nitrophenyl phosphorothioate): Hazard Identification Committee Report, Health Effects Division, Office of Pesticide Program, March 23, 1999.

4) HED Science Advisory Council for Exposure, Policy 007, *Use of Values from the PHED Surrogate Table and Chemical-Specific Data.* Health Effects Division, Office of Pesticide Programs, January 1999.

5) PHED Surrogate Exposure Guide. Health Effects Division, Office of Pesticide Program, August 1998.

6) HED Science Advisory Council for Exposure, Policy 003. *Agricultural Default Transfer Coefficients.* Health Effects Division, Office of Pesticide Programs, May 7, 1998.

7) Popendorf, W. 1985. Reentry Simulation Study, Phase 1. Draft Report.

8) Buck, N.A., B.J. Estesen, and G.W. Ware. Dislodgable Residues on Cotton Foliage: Fenvalarate, Permethrin, Sulprofos, Chlorpyrifos, Methyl Parathion, EPN, Oxymyl, and Profenfos. Bulletin of Environmental Contaminant Toxicology. Volume 24. Pages 283-288. 1980.

cc: Diana Locke, OPP/HED/RRB2
OREB Files

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Attachment 15: Review of Methyl Parathion Incident Reports

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

February 5, 1998

SUBJECT: Review of Methyl Parathion Incident Reports
DP Barcode D242333, Chemical #053501, Reregistration Case#0153

FROM: Jerome Blondell, Ph.D., Health Statistician
Chemistry and Exposure Branch 2
Health Effects Division (7509C)

Monica F. Spann, MPH, Environmental Health Scientist
Chemistry and Exposure Branch 2
Health Effects Division (7509C)

THRU: Susan V. Hummel, Senior Scientist
Chemistry and Exposure Branch 2
Health Effects Division (7509C)

TO: Jonathan Becker, Environmental Health Specialist
Reregistration Branch 2
Health Effects Division (7509C)

BACKGROUND

The following data bases have been consulted for the poisoning incident data on the active ingredient Methyl Parathion (PC Code: 053501):

1) OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation risk mitigation measures may be suggested.

2) Poison Control Centers - as the result of Data-Call-Ins issued in 1993, OPP received Poison Control Center data covering the years 1985 through 1992 for 28

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organophosphate and carbamate chemicals. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System which obtains data from about 70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings, involving drugs, household products, pesticides, etc.

3) California Department of Food and Agriculture (replaced by the Department of Pesticide Regulation in 1991) - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.

4) National Pesticide Telecommunications Network (NPTN) - NPTN is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive has been prepared. The total number of calls was tabulated for the categories human incidents, animal incidents, calls for information, and others.

METHYL PARATHION REVIEW

I. Incident Data System

Please note that the following cases from the IDS do not have documentation confirming exposure or health effects unless otherwise noted.

Incident# 000578 001

A pesticide incident occurred in 1993, when nineteen workers were exposed to methyl parathion and two other pesticides when entering an apple orchard two or three days after application to thin the fruit. The other two pesticides, calcium chloride and Systhane/Mycloburanil, are not cholinesterase inhibitors. They all reported experiencing some combination of headaches, diarrhea, nausea, and one worker had a bloody nose. In another incident in the same field, sixteen workers (perhaps of the original 19) re-entered the area 49 hours after methyl parathion (Penncap M) was sprayed and a few complained of illness. The next day all sixteen workers were complaining of illness (headache, nausea, diarrhea) and left the field. No one sought medical treatment, so blood cholinesterase was not measured. No further information on the disposition of the case was reported.

Incident# 000894 004

A pesticide incident occurred in 1992, when several inspectors found more than 200 gallons of methyl parathion in a basin and experienced burning throats, sore eyes, and fatigue. No further information on the disposition of the case was reported.

Incident# 001280 004

A pesticide incident occurred in 1994, when a veterinarian smelled a container with methyl parathion and became ill. No further information on the disposition of the case was reported.

Incident# 001769 001

A pesticide incident occurred in 1994, when a woman was sprayed with methyl parathion by an aerial applicator and experienced blurred vision, disorientation, weakening in the legs, and memory lapses. She reported that the symptoms persisted for eleven months.

Incident# 002225 001

A pesticide incident occurred in 1995, when an individual was packaging containers of methyl parathion and experienced nausea. No further information on the disposition of the case was reported.

Incident# 002431 001

A pesticide incident occurred in 1995, when a three year old boy was exposed to methyl parathion after a pig rooted out a hole in the ground which had previously been an old farm surrounded by a fence. The boy played in this same area and experienced vomiting. No further information on the disposition of the case was reported.

Incident# 002479 001

A pesticide incident occurred in 1995, when a man was sprayed with methyl parathion that was applied aerially and two weeks later experienced convulsions and seizures. Symptoms during the two week period were not reported. No further information on the disposition of the case was reported.

Incident# 002922 001

A pesticide incident occurred in 1995, when a man was accidentally sprayed with methyl parathion that was applied aerially to a cotton field. Specific symptoms were not mentioned. No further information on the disposition of the case was reported.

Incident# 003599 001

The Minnesota Department of Agriculture surveyed state enforcement agencies to determine what pesticides were involved in spray drift. Among the thirty-two states responding to the survey, there was a total of 2,681 cases of drift complaints related to

specific pesticides. Methyl parathion was responsible for 7 complaints or less than one percent of the total.

Incident# 003976 001

A pesticide incident occurred in 1996, when a crop advisor, who was scouting corn fields 48 hours after spraying with methyl parathion. He experienced nausea, blurred vision, and excessive salivation. He did not see a doctor but remained in bed several days. No further information on the disposition of the case was reported.

Incident# 004420 001

A pesticide incident occurred in 1996, when a woman and her son were sitting on their back porch and were sprayed with methyl parathion. The woman experienced nausea, chest tightness, soreness over her entire body, and body tremors. The son experienced diarrhea, skin irritation, and headaches. No further information on the disposition of the case was reported.

Incident# 004439 142

A pesticide incident occurred in 1996, when an individual was drenched with methyl parathion and died. Despite repeated follow-up no information could be obtained to verify this incident.

II. Poison Control Center Data

Methyl Parathion was one of 28 chemicals for which Poison Control Center (PCC) data were requested. The following text and statistics are taken from an analysis of these data; see December 5, 1994 memo from Jerome Blondell to Joshua First.

The 28 chemicals were ranked using three types of measures: (A) number and percent occupational and non-occupational adult exposures reported to PCCs requiring treatment, hospitalization, displaying symptoms or serious life-threatening effects; (B) California data for handlers and field workers comparing number of agricultural poisonings to reported applications; and (C) ratios of poisonings and hospitalization for PCC cases to estimated pounds reported in agriculture for pesticides used primarily in agriculture.

A. Occupational and Non-occupational Exposure

There were a total of 274 methyl parathion cases in the PCC data base. Of these, 102 cases were occupational exposure; 91 (89%) involved exposure to methyl parathion alone and 11 (11%) involved exposure to multiple chemicals, including methyl parathion. There were a total of 146 adult non-occupational exposures; 113 (77%) involved this chemical alone and 33 (23%) were attributed to multiple chemicals.[3] In this analysis, four measures of hazard were developed based on the Poison Control

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[3]Workers who were indirectly exposed (not handlers) were classified as non-occupational cases.

Center data, as listed below.

1. Percent of all accidental cases that were seen in or referred to a health care facility (HCF).

2. Percent of these cases (seen in or referred to HCF) that were admitted for medical care.

3. Percent of cases reporting symptoms based on just those cases where the medical outcome could be determined.

4. Percent of those cases that had a major medical outcome which could be defined as life-threatening or resulting in permanent disability.

Exposure to methyl parathion alone or in combination with other chemicals was evaluated for each of these categories, giving a total of 8 measures. A ranking of the 28 chemicals was done based on these measures with the lowest number being the most frequently implicated in adverse effects. Table 1 presents the analyses for occupational and non-occupational exposures.

Table 1: Measures of Risk From Occupational and Non-occupational Exposure to Methyl Parathion Using Poison Control Center Data from 1985-1992[a]

	Occupational Exposure	Non-occupational Exposure
Percent Seen in HCF		
Single chemical exposure	81.3[5] (68.2)	58.4* (44.0)
Multiple chemical exposure	82.4[5] (69.8)	63.7*[6] (46.1)
Percent Hospitalized		
Single chemical exposure	9.5* (12.2)	9.1* (9.9)
Multiple chemical exposure	13.1* (14.3)	14.0* (12.6)
Percent with Symptoms		
Single chemical exposure	72.7* (85.8)	80.0* (74.0)
Multiple chemical exposure	75.0* (85.8)	81.3*[7] (75.2)
Percent with Life-threatening Symptoms		
Single chemical exposure	0.0 (0.0)	0.0* (0.0)
Multiple chemical exposure	1.2 (0.5)	0.0* (0.05)

a Extracted from Tables 2, 3, 5 and 6 in December 5, 1994 memo from Jerome Blondell to Joshua First; number in parentheses is median score for that category

* Top 25% of chemicals are ranked with a superscript of 1 to 7

Including exposure to multiple chemicals, methyl parathion had the fifth highest percent of occupational cases seen in a health care facility (Table 1). On other measures of hazard (percent hospitalized, percent with symptoms or life-threatening symptoms), methyl parathion had percents similar to the median for other cholinesterase-inhibitors, sometimes higher and sometimes lower.

B. Ratios of poisoning - California Data

The incidence of **systemic poisoning cases** in agricultural workers reported to the California was compared to the number of applications of methyl parathion. Those calculations, along with the median score for a total of 29 pesticides, are presented in the Table 2 below.

Table 2: Systemic Poisonings/1,000 Applications in Selected Agricultural Workers Exposed to Methyl Parathion in California, 1982-1989[a]

Pesticide	Number of Appl.	Poisonings/1,000 Appl. (N) Primary Pesticide Only			Poisonings/1,000 Appl.(N) Multiple Pesticide Exposure		
		Handlers	Field Workers	Total	Handlers	Field Workers	Total
Methyl Parathion	45,597	.04 (2)	.00 (0)	.04 (2)	.09 (4)	.04 (2)	.13 (6)
Median		.21	.20	.41	.44	.50	1.02

a Extracted from Table A5 in December 5, 1994 memo from Jerome Blondell to Joshua First; number in parentheses is the observed number of poisoned cases.

Methyl Parathion had much lower ratios of handler poisonings and field worker poisonings per 1,000 applications in California, regardless of whether exposures to mixtures were included or not. For total poisoning per 1,000 applications where methyl parathion was deemed the primary cause of the incident, only two other pesticides (bacillus thuringiensis and permethrin) had lower ratios. This is an unusually good record for an organophosphate insecticide, suggesting that worker practices in place in California from 1982 through 1989 were both safe and effective.

C. Ratios of Poisoning - U.S. Poison Control Data

Active registrations of methyl parathion are for agricultural use exclusively. Ratios of the number of occupational Poison Control Center exposures to the reported pounds of the chemical used[4] were calculated. The results for methyl parathion and the median for the 15 agricultural chemicals included in the analysis are presented in

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[4]Gianessi, L.P., Puffer, C.A. Insecticide Use in U.S. Crop Production. Resources for the Future, Washington, D.C., 1992.

the Table 3 below.

Table 3: Ratios of Methyl Parathion Poisonings (PCC Data, 1985-1992) to Reported Use[a]

Pesticide	Exposure Per Use	Poisonings Per Use	Health Care Referral Per Use	Hospital Admitted Cases Per Use
Methyl Parathion	.013*	.008*	.010*	.001*
Median	.033	.013	.027	.004

a Extracted from Table 9 in the December 5, 1994 memo from Jerome Blondell to Joshua First

* Top 33% of chemicals are ranked with a superscript of 1 to 5

Among pesticides used exclusively in agriculture, methyl parathion had the third lowest ratio of exposures, poisonings, and treatment to estimated pounds active ingredient reported in use (Table 3). Methyl parathion had second lowest ratio of hospitalized cases per estimated pounds used. Based on these measures, methyl parathion appears to be much less likely to be involved in potential poisonings than other organophosphate and carbamate insecticides.

D. Exposure in Children

A separate analysis of the number of exposures in children five years of age and under from 1985-1992 was conducted. For methyl parathion, there were 26 incidents; 23 involved exposure to methyl parathion alone and 3 involved other pesticides as well. Because of the relatively small number of cases, no statistical comparisons were made with other organophosphates and carbamates.

E. Environmental and Misuse accidents

The American Association of Poison Control Centers (AAPCC) provided data on over 100,000 exposures from 1985 through 1992 for 28 pesticides. A search was performed on this data for those pesticides with no significant home use, but large agricultural use (n = 15). Only exposures where the residence was the site of the exposure and the pesticide product was the sole product involved in the exposure were included in the analysis. The table below shows the results where reason was environmental or misuse. AAPCC defines these terms as follows:

Environmental: any passive exposure that results from man-made contamination of the environment, e.g. exposures to contaminated water resulting from improper disposal of chemicals, passive inhalation of toxic fumes or gases as a result of discharge at a plant or a "HazMat" incident.

Misuse: An accidental exposure which results from the improper or incorrect use of a substance where therapeutic or beneficial results were intended.

The other commonly used "reason" categories are general, occupational, unknown, and intentional (includes suicide and abuse). General is defined as: all unintended poisonings or exposures that are not specifically defined by other categories, including most accidental exposures to children, bites, stings, plant exposures and unintentional food poisoning.

Obviously there is considerable 'gray area' between these categories and many scenarios can be imagined where different poison specialists would assign different categories. For example, spray drift could be counted as environmental or misuse and probably accounts for the majority of cases recorded. The purpose of this analysis was to find out if it might be used to identify agricultural pesticides illegally applied in the home environment.

The other key problem with AAPCC data, particularly severe in this case, is the lack of representation in certain states. Thirteen states had little or no coverage by AAPCC during the time period of interest. They were Nevada, Oklahoma, Texas, Arkansas, Mississippi, Illinois, Iowa, North Carolina, South Carolina, Delaware, Connecticut, Vermont and Maine. In particular, the absence of data from Mississippi, the Carolina, Arkansas, Texas and Oklahoma is likely to miss a substantial portion of misuse problems due to methyl parathion.

Table 4. AAPCC exposures for agricultural pesticides reported in residences due to environmental exposure or misuse, 1985-1992 (ratio = environmental + misuse/ pounds active ingredient).

Pesticide	Environ-mental	Misuse	Env. + Misuse	Pounds ai 1989-91	E+M/P ratio
aldicarb	30	6	36	5000	7.2
azinphosmethyl	16	3	19	3000	6.3
carbofuran	12	19	31	1500	20.7
dicrotophos	2	2	4		
ethoprop	2	0	2	750	2.7
fenamiphos	0	0	0	800	0.0
fonophos	12	1	13		
methamidophos	15	0	15	1230	12.2
methidathion	1	1	2	520	3.8
methyl parathion	29	5	34	8180	4.2
mevinphos	3	0	3	420	7.1
phorate	3	5	8	2902	2.8
profenofos	0	0	0	900	0.0
sulfotepp	7	0	7		
terbufos	4	4	8		

The conclusion from examining Table 4 is that the categories for environment and misuse can not be used to identify agricultural pesticides, like methyl parathion, that may be applied indoors.

III. California Data - 1982 through 1995

Detailed descriptions of 18 cases submitted to the California Pesticide Illness Surveillance Program (1982-1995) were reviewed. In 7 of these cases, methyl parathion was used alone and was judged to be responsible for the health effects. Only cases with a definite, probable or possible relationship were reviewed. Methyl parathion ranked 90th as a cause of systemic poisoning in California (1982-1994). Table 5 presents the types of illnesses reported by year. Table 6 gives the total number of workers that took time off work as a result of their illness and how many were hospitalized and for how long.

Table 5. Cases Due to Methyl Parathion Exposure in California Reported by Type of Illness and Year, 1982-1995

Year	Illness Type				
	Systemic[a]	Eye	Skin	Respiratory	Total
1982	1	1	-	-	2
1983	1	-	-	-	1
1984	-	-	-	-	-
1985	-	-	-	-	-
1986	-	-	-	-	-
1987	1	-	-	-	1
1988	-	-	-	-	-
1989	-	-	-	-	-
1990	2	-	-	-	2
1991	-	-	-	-	-
1992	1	-	-	-	1
1993	-	-	-	-	-
1994	-	-	-	-	-
1995	6.00	1.00	0.00	0.00	7.00
Total	0.00	0.00	0.00	0.00	0.00

[a]Category includes cases where skin, eye, or respiratory effects were also reported

A total of 6 persons had systemic illnesses or 86% of 7 cases. Five of these workers took between two and five days off work as a result of their illness as shown in Table 6 below. One worker was hospitalized for four days after spraying the insecticide inside a greenhouse. A variety of worker activities were associated with exposure to methyl parathion as illustrated in Table 7 below.

Table 6. Number of Persons Disabled (taking time off work) or Hospitalized for Indicated Number of Days After Methyl Parathion Exposure in California, 1986-1995.

	Number of Persons Disabled	Number of Persons Hospitalized
One day	-	-
Two days	2	-
3-5 days	3	1
6-10 days	-	-
more than 10 days	-	-
Unknown	-	-

Table 7. Illnesses by Activity Categories for Methyl Parathion Exposure in California, 1986-1995

Activity Category[a]	Illness Category				
	Systemic[b]	Eye	Skin	Respiratory	Total
Applicator	2	1	-	-	3
Driftexp	2	-	-	-	2
Other	2	-	-	-	2
Total	6.00	1.00	0.00	0.00	7.00

[a]Driftexp= exposure to pesticide that has drifted from intended targets; Other= other occupational exposure

[b]Category includes cases where skin, eye, or respiratory effects were also reported

According to the above activity categories, applicators (two by hand and one by spray rig) were associated with three illnesses. The most serious case experienced muscle spasms, vomiting, diarrhea, and abdominal pain and was hospitalized for four days. One of the cases classified as other was a person downwind from a spill, similar to the two drift exposure cases. These cases reported symptoms of headaches, difficulty breathing, nausea, diarrhea, vomiting, weakness, sweating, and itching around the mouth.

IV. NPTN

On the list of the top 200 chemicals for which NPTN received calls from 1984-1991 inclusively, methyl parathion was not reported to be involved in human incidents.

V. Literature Review

Two incidents involving deaths have been reported in Mississippi from misuse of methyl parathion inside homes. The first incident reported in 1977 involved seven of 13 members in one family who developed weakness, abdominal pain, nausea, vomiting, difficulty seeing, excessive sweating and salivation. The father of the rural farm family had taken some concentrated methyl parathion from a discarded drum and placed it in a nebulizer and then sprayed his home for cockroaches. A 26 year old died as a result of organophosphate poisoning confirmed by cholinesterase testing.

In the second incident, the male live-in companion sprayed the house to control spiders. He had obtained a nearly empty container of methyl parathion from the farm he worked on and added water to it. He used a hand sprayer to spray the solution on the inside upper walls of three of the four rooms (excluding the kitchen) in the house. The concentration in the hand sprayer was found to be three times that used for outdoor agricultural application. It was suspected that methyl parathion got into the food and drinking water, as well as being present in the air and on surfaces. All seven children in the home became ill and were hospitalized with confirmed cholinesterase inhibition. Two of the five children, a four year old and an eleven year old, died.

Numerous cases of exposure inside homes have been documented in Ohio, Michigan, Mississippi, Louisiana and elsewhere. These exposures have occurred due to illegal application by PCOs going door to door. Total number of people exposed from these applications number in the thousands and over 1,000 people have had to be relocated while their home were decontaminated. The estimated cost of clean up exceeds $70 million. There have been reports of symptomatic human cases and pets that have been adversely affected or died. However, these cases have not been confirmed by cholinesterase testing and the reported cases have not been published in the scientific literature.

VI. Conclusions

Exposure to methyl parathion can lead to systemic illness. In outdoor agricultural situations, the primary activities associated with poisoning are application and spray drift. Compared to other organophosphate and carbamate insecticides, methyl parathion is associated with less poisoning when adjusted for amount of use. To some extent the similarity between the methyl parathion and the far more toxic ethyl parathion (in terms of poisonings and deaths even after adjusting for use), may have resulted in workers handling any product with the 'parathion' name with greater care.

Interior home use of methyl parathion has resulted in deaths in two separate incidents in Mississippi. Food or water contamination and an unusually high concentration used in the application probably contributed to these deaths which occurred in the 1970s and early 1980s. The more recent cases exposed primarily in Ohio, Mississippi, and Louisiana have not been well documented or confirmed with

cholinesterase testing.

VII. Recommendations

Numerous actions have already been taken to prevent use of methyl parathion in homes. For outdoor use, protective measures required for other organophosphate and carbamate insecticides should be considered. Special attention should be given to protecting pesticide handlers and preventing spray drift.

cc: Correspondence
Methyl parathion file (chemical no. 053501)
SRRD - Emily Mitchell (7508W)

RDI: BRSrSci:SHummel:

Attachment 16: Revised Product Chemistry Chapter

5/25/99

MEMORANDUM

SUBJECT: **Methyl Parathion**. PC Code 053501. List A Reregistration Case 0153. **Revised Product Chemistry Chapter for the Reregistration Eligibility Decision**. DP Barcode D252912.

FROM: K. Dockter, Chemist
Reregistration Branch 2
Health Effects Division [7509C]

THRU: Alan Nielsen, Branch Senior Scientist
Reregistration Branch 2
Health Effects Division [7509C]

TO: Dennis Deziel
Special Review and Reregistration Division [7508 C]

Attached is the revised Product Chemistry Chapter for the methyl parathion [O,O-dimethyl O-*p*-nitrophenyl phosphorothioate] RED. The chapter was assembled by Dynamac Corporation under the supervision of RRB2, HED. The data assessment has undergone secondary and tertiary review and has been revised to reflect Agency policies. Many product chemistry data requirements remain outstanding.

Attachment: Reregistration Eligibility Decision: Product Chemistry Considerations

cc: RF, Reg. Std. File, SF, Dockter, Locke, Cropp-Kohlligian, Dennis Deziel; SRRD.

RD/I: RRB2/T2 Methyl parathion RED Team: D. Locke, [the TL], B. Cropp-Kohlligian, K. Raffaele, R. Griffin.

7509C:RRB2:CM2:Rm712N:57886:KD/kd

METHYL PARATHION.RED[896]

METHYL PARATHION
PC Code 053501; Case 0153
(DP Barcode D252912)

Reregistration Eligibility Decision: Product Chemistry Considerations

May 20, 1999

Contract No. 68-D4-0010

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
2275 Research Boulevard
Rockville, MD 22850-3268

METHYL PARATHION

REREGISTRATION ELIGIBILITY DECISION:

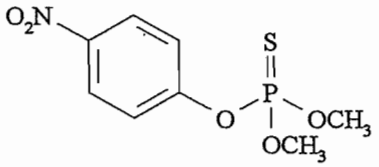
PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 053501; Case No. 0153

DP Barcode D252912

DESCRIPTION OF CHEMICAL

Methyl parathion [O,O-dimethyl O-*p*-nitrophenyl phosphorothioate] is an insecticide used on a variety of vegetables, fruits, and field crops.



Empirical Formula:	$C_8H_{10}O_5NPS$
Molecular Weight:	263.2
CAS Registry No.:	298-00-0
PC Code:	053501

IDENTIFICATION OF ACTIVE INGREDIENT

Pure methyl parathion is a white crystalline solid with a melting point of 35-36 C, bulk density of 1.358 g/mL at 25 C, vapor pressure of 9.7×10^{-6} mm Hg at 20 C, and octanol/water partition coefficient (P_{ow}) of 3300. Methyl parathion is only slightly soluble in water (55-60 mg/L at 20 C); readily soluble in dichloromethane, 2-propanol, and toluene; and practically insoluble in n-hexane. Methyl parathion is formulated with inert ingredients for manufacturing use to produce an 80% tan-colored liquid.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 5/19/99 identified two methyl parathion manufacturing-use products (MPs) registered under PC Code 053501: an 80% formulation intermediate (FI; EPA Reg. No. 1812-399) registered to Griffin L.L.C. and an 80% FI (EPA Reg. No. 4787-28) registered to Cheminova Agro

A/S. We note that REFS identifies these products as technical products (Ts); however, based on their CSFs, both are formulated from unregistered TGAIs and are thus appropriately identified as FIs. The Cheminova 80% FI was registered to replace an identical product (EPA Reg. No. 4787-4) which was voluntarily canceled by Cheminova on 7/21/98. Only the Griffin and Cheminova unregistered TGAIs and 80% FIs (EPA Reg. Nos. 1812-399 and 4787-28) are subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

The Science Chapter of the Methyl Parathion Reregistration Standard dated 11/8/85 and the Methyl Parathion Guidance Document dated 12/8/86 required additional generic and product-specific product chemistry data for the registered methyl parathion MPs. The Methyl Parathion Reregistration Standard Update dated 11/24/92 reviewed data submitted in response to the Guidance Document and summarized the product chemistry database in support of the reregistration of methyl parathion. The Update required additional product chemistry data concerning OPPTS 830.1600-1650, 1670, 7000, 6314, 6315, 6316, 6317, 6319, 6320, and 7100 for the Cheminova TGAI and 80% FI (EPA Reg. No. 4787-4). Although the Cheminova 80% FI (EPA Reg. No. 4787-28) was registered following issuance of the Methyl Parathion Update, data submitted for EPA Reg. No. 4787-4 will apply to data requirements for EPA Reg. No. 4787-28 because the products are identical. The full complement of product chemistry data pertaining to the Griffin 80% FI (EPA Reg. No. 1812-399), which was also registered (4/20/98) following issuance of the Update, have been submitted and are under review.

A Data Call-In dated 6/87 was issued to registrants of methyl parathion MPs requiring data concerning the potential for formation of halogenated dibenzo-p-dioxins/dibenzofurans during the manufacture of methyl parathion. Data remain outstanding.

The current status of the product chemistry data requirements for the Griffin and Cheminova methyl parathion unregistered TGAIs and MPs is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All product chemistry data requirements except dissociation constant, octanol/water partition coefficient, solubility, and vapor pressure (OPPTS 830.7370, 7550, 7840, and 7950) remain unfulfilled for the Griffin unregistered TGAI and 80% FI pending review of data submitted for this product. Pertinent data requirements remain unfulfilled for the Cheminova unregistered TGAI and 80% FI; additional data are required concerning the potential for formation of dioxins (OPPTS 830.1600, and 1620-1670) and physical/chemical characteristics including stability, oxidation/reduction, flammability,

explodability, storage stability, miscibility, corrosion characteristics, pH, UV/visible absorption, and viscosity (OPPTS 830.6313, 6314, 6315, 6316, 830.6317, 6319, 6320, 7000, 7050, and 7100). When the outstanding dioxin data have been received, the Agency will determine if further analytical quantitation of halogenated dibenzo-p-dioxins/dibenzofurans is required. Provided that the registrants submit the data required in the attached data summary tables for the unregistered TGAIs and 80% FIs, and either certify that the suppliers of beginning materials and the manufacturing processes for the methyl parathion MPs have not changed since the last comprehensive product chemistry reviews or submit complete updated product chemistry data packages, HED has no objections to the reregistration of methyl parathion with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).:	3107
Subject:	EPA Reg. No. 4787-4. Methyl Parathion Product Chemistry in Response to the Methyl Parathion Registration Standard Data Gaps.
From:	S. Malak
To:	A. Rispin/D. Edwards
Dated:	2/11/88
MRID(s):	40406601

CBRS No(s).:	3280
Subject:	Methyl Parathion MP - EPA Registration No. 4787-4 Cheminova - Response to the Product Chemistry Chapter.
From:	G. Makhijani
To:	D. Edwards and A. Rispin
Dated:	3/25/88
MRID(s):	40482401

CBRS No(s).:	3804
Subject:	Methyl Parathion MP - EPA Registration No. 4787-4 Cheminova - Response to the Product Chemistry Chapter.
From:	G. Makhijani
To:	D. Edwards and A. Rispin
Dated:	5/25/88
MRID(s):	40601501

CBRS No(s).: 4023
Subject: Methyl Parathion - Technical. EPA Registration No. 4787-4 - Cheminova - Response to the Product Chemistry Chapter.
From: G. Makhijani
To: D. Edwards and A. Rispin
Dated: 8/3/88
MRID(s): None

CBRS No(s).: 6491
Subject: Product Chemistry Data Review for Technical Methyl Parathion to Determine the Potential for Halogenated Dibenzo-p-Dioxin/Dibenzofuran Formation.
From: S. Funk
To: E. Feris
Dated: 6/20/90
MRID(s): 40482401 and 40601501

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00055859 A/S Cheminova (1980) [Chemical Analysis of Methyl parathion]: Pr-4; CDL:243416-A)

00055860 A/S Cheminova (1980) Physical and Chemical Properties: [Methyl parathion]: Pr-Ch-mp-3. (Unpublished study received Sep 22, 1980 under 4787-4; CDL:243416-B)

00055866 A/S Cheminova (1980) Product Chemistry: Methyl parathion Technical: Pr-Ch-mp-3. (Unpublished study received Sep 22, 1980 under 4787-4; CDL:243416-M)

40406601 A/S Cheminova (1987) Product Chemistry - Methyl Parathion Technical: Study No. KLy/870625-MP3. Unpublished study. 17 p.

40482401 A/S Cheminova (1987) Product Chemistry - Methyl Parathion Technical ... Supplementary Information ...: Study No. MVF/01.12.87-MP-3. Unpublished study prepared by A/S Cheminova in association with the Ministry of the Environment, Denmark. 42 p.

40601501 A/S Cheminova (1987) Product Chemistry - Methyl Parathion Technical ...: Supplementary Information: Submission/Pr-Ch-MP-3-conf/-5/04.19.88. Unpublished study. 14 p.

The following MRIDs have been referenced by Griffin in support of the 80% FI (EPA Reg. No. 1812-399) and are currently under review:

42365505 Orr, G. (1992) Griffin Corporation Test Methods: Physical and Chemical Characteristics of Pesticide Products. Unpublished study prepared by Griffin Corp. 25 p.

42869302 Hand, O. (1993) Griffin Corporation Test Methods: Physical and Chemical Characteristics of Pesticide Products: Kocide LF. Unpublished study prepared by Griffin Corp. 14 p

44279801 Harris, M. (1997) GX 507: Product Identity and Composition. Unpublished study prepared by Griffin Corp. 30 p. {830.1550, 830.1600, 830.1620, 830.1670}

44279802 Harris, M. (1997) GX 507: Physical and Chemical Properties: Lab Project Number: 97-003: P97-003. Unpublished study prepared by Griffin Corp. 28 p. {OPPTS 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7000, 830.7050, 830.7100, 830.7200, 830.7220, 830.7300, 830.7520}.

44279803 Harris, M. (1997) GX 507: Report Amendment: (Density). Unpublished study prepared by Griffin Corp. 6 p. {OPPTS 830.7300}.

44279804 Harris, M. (1997) Griffin Analytical Methods: Methyl Parathion in Technical and Formulated Products: Capillary GLC Assay Method: Lab Project Number: TM-1198. Unpublished study prepared by Griffin Corp. 18 p. {OPPTS 830.1800}.

44317801 Harris, M. (1997) GX 507: Analysis and Certification of Product Ingredients: Lab Project Number: 97-003: P97-003. Unpublished study prepared by Griffin Corp. 19 p. {OPPTS 830.1700, 830.1750}.

Case No. 0153
PC Code 053501

Case Name: Methyl Parathion
Registrant: Griffin L.L.C.
Product(s): Unregistered TGAI and 80% FI (EPA Reg. No. 1812-399)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N	*44279801*
830.1600	Description of materials used to produce the product	N	*44317801*
830.1620	Description of production process	N	*44317801*
830.1670	Discussion of formation of impurities	N	*44279801*
830.1700	Preliminary analysis	N	*44317801*
830.1750	Certified limits	N	*44317801*
830.1800	Enforcement analytical method	N	*44279804*
830.6302	Color	N	*44279802, 42365505*
830.6303	Physical state	N	*44279802, 42365505*
830.6304	Odor	N	*44279802*
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N	*44279802*
830.6314	Oxidation/reduction: chemical incompatability	N	*44279802, 42365505*
830.6315	Flammability	N	*44279802*
830.6316	Explodability	N	*44279802*
830.6317	Storage stability	N	*44279802, 42365505*
830.6319	Miscibility	N	*44279802*
830.6320	Corrosion characteristics	N	*44279802, 42365505*
830.7000	pH	N	*44279802, 42365505*
830.7050	UV/Visible absorption	N	*44279802*
830.7100	Viscosity	N	*44279802, 42869302*
830.7200	Melting point/melting range	N	*44279802*
830.7220	Boiling point/boiling range	N	*44279802*
830.7300	Density/relative density/bulk density	N	*44279802, 42869302*

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Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.7370	Dissociation constants in water	Y	40406601 [3]
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	**00055860**
830.7840	Water solubility: column elution method; shake flask method	Y	40406601 [3]
830.7950	Vapor pressure	Y	**00055860**

[1]Y = Yes; N = No; N/A = Not Applicable. Data submitted by Cheminova pertaining to 830.7370, 7550, 7840, and 7950 were referenced by Griffin; these data may be used to fulfill requirements for the Griffin product provided their use has been approved by Cheminova.

[2]*Italicized* references are currently under review; **bolded** references were reviewed in the Methyl Parathion Reregistration Standard Science Chapter dated 11/8/85; and all other references were reviewed as noted.

[3]CBRS No. 3107, 2/11/88, S. Malak.

215211

Case No. 0153
PC Code 053501

Case Name: Methyl Parathion
Registrant: Cheminova Agro A/S
Product(s): Unregistered TGAI and 80% FI (EPA Reg. No. 4787-28)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	Y	40482401 [3], CSF 6/16/88 [4], CSF 1/17/97 [5]
830.1600	Description of materials used to produce the product	N [6]	**00055859, 00055866,** 40406601 [7]
830.1620	Description of production process	N [6]	**00055859, 00055866,** 40406601 [7]
830.1670	Discussion of formation of impurities	N [8]	**00055859**
830.1700	Preliminary analysis	Y [9]	**00055859,** 40482401 [3,10], 40601501 [10]
830.1750	Certified limits	Y	40482401 [3], CSF 6/16/88 [4] CSF 1/17/97 [5]
830.1800	Enforcement analytical method	Y	**00055859,** 40482401 [3,10], 40601501 [10,11]
830.6302	Color	Y	40406601 [7]
830.6303	Physical state	Y	40406601 [7]
830.6304	Odor	Y	40406601 [7]
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N [12]	40406601 [7]
830.6314	Oxidation/reduction: chemical incompatability	N	
830.6315	Flammability	N	
830.6316	Explodability	N	
830.6317	Storage stability	N	
830.6319	Miscibility	N	
830.6320	Corrosion characteristics	N	
830.7000	pH	N [13]	40406601 [7]

37608?

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.7050	UV/Visible absorption	N [14]	
830.7100	Viscosity	N	
830.7200	Melting point/melting range	Y	40406601 [7,5]
830.7220	Boiling point/boiling range	Y	40406601 [7]
830.7300	Density/relative density/bulk density	Y	40406601 [7], 40482401 [3]
830.7370	Dissociation constants in water	Y	40406601 [7]
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	**00055860**
830.7840	Water solubility: column elution method; shake flask method	Y	40406601 [7]
830.7950	Vapor pressure	Y	**00055860**

[1]Y = Yes; N = No; N/A = Not Applicable. Data were originally submitted in support of the Cheminova 80% FI (EPA Reg. No. 4787-4) which has been canceled. Because EPA Reg. No. 4787-28 is identical to EPA Reg. No. 4787-4, all submitted data are applicable to the new FI.

[2]**Bolded** references were reviewed in the Methyl Parathion Reregistration Standard Science Chapter dated 11/8/85, and all other references were reviewed as noted.

[3]CBRS No. 3280, 3/25/88, G. Makhijani.

[4]CBRS No. 4023, 8/3/88, G. Makhijani.

[5]The CSF was obtained from the product jacket.

[6]Additional information is required by the Dioxin DCI dated 6/87 concerning the manufacturing conditions and starting materials which may promote the possible formation of halogenated dibenzo-p-dioxins/dibenzofurans during the manufacturing process.

[7]CBRS No. 3107, 2/11/88, S. Malak.

[8]Additional discussion is required by the Dioxin DCI dated 6/87 concerning the potential for formation of halogenated dibenzo-p-dioxins/dibenzofurans.

[9]On receipt of the outstanding manufacturing information and discussion of formation of impurities for dioxins, the Agency will determine if further analytical quantitation of halogenated dibenzo-p-dioxins/dibenzofurans is required.

[10]CBRS No. 6491, 6/20/90, S. Funk (for dioxins).

[11]CBRS No. 3804, 5/25/88, G. Makhijani.

[12]Additional data concerning the stability of the TGAI in the presence of metals and metal ions are required.

[13]Data concerning the pH of the MP are required.

[14]The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

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