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TOXIC SUBSTANCES

December 7, 1998

MEMORANDUM

SUBJECT: ERROR CORRECTION. Response to Comments on EPA's Methyl Parathion Draft Health Effects Division Chapter of the Reregistration Eligibility Decision Document. PC Code: 053501, Case # 818931.

FROM: Diana Locke, Ph.D.  
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THRU: Alan Nielsen, Branch Senior Scientist  
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Al Nielsen 12/9/98

TO: Mark Wilhite, Acting Chief  
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Special Review and Reregistration Division (7508W)

The attached errata list for methyl parathion was generated in response to the document *Comments on EPA's Methyl Parathion Draft Health Effects Division Chapter of the Reregistration Eligibility Decision Document* (November 6, 1998) submitted by Cheminova Agro A/S in Phase 1 of the Public Participation Process. The errata list is to accompany the HED chapter and its attached discipline chapters. Some of the comments concern issues and/or Agency policy and will more appropriately be dealt with during Phase 4. The registrant needs to work with the Agency on changes and/or clarification of label language before a re-evaluation of the risk can be made.

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December 7, 1998

## METHYL PARATHION ERRATA

This memo serves to correct errors (Phase 2) made in the disciplinary chapters written for the methyl parathion Reregistration Eligibility Document (RED), completed September 1998. This is in response to comments made on errors in Phase 1 of the Public Participation Process. Some of the comments made by the registrants do not address errors, but rather issues and policy, and will be addressed, as appropriate, in Phase 4.

### A. Use Patterns for Methyl Parathion (p. 12-13 of Comments on EPA's Methyl Parathion)

1. The Agency concurs that Cheminova and Griffin Corporation are producers and Elf Atochem is a formulator.
2. This issue is deferred until Phase 4.
3. The Agency concurs.
4. All the registrant's labels do not clearly and specifically prohibit uses around the home by certified applicators. The registrants will need to work with the Agency to develop acceptable label language prohibiting use around dwellings.
5. The Agency does not consider the inclusion of kohlrabi in its preliminary risk assessments an error. Methyl parathion is currently registered for use on kohlrabi and a tolerance for residues of methyl parathion is currently established in/on kohlrabi at 1 ppm (40 CFR 180.121). HED, via the Residue Chemistry Chapter to the Methyl Parathion Reregistration Eligibility Decision (RED) document (7/11/98), has recommended in favor of establishing a crop group tolerance for residues of methyl parathion in/on Vegetables, leafy, Brassica (cole) at 1 ppm concomitant with the revocation of individual tolerances currently established on broccoli, Brussels sprouts, cabbage, cauliflower, collards, kale, kohlrabi, and mustard greens. The Vegetables, leafy, Brassica (cole) tolerance, if established, would cover residues of methyl parathion in/on kohlrabi.

### B. HED Chapter (p. 13 of Comments on EPA's Methyl Parathion)

1. The Agency concurs that Cheminova and Griffin Corporation are producers and Elf Atochem is a formulator.
2. This is not an error. Agency policy directs that acute dietary endpoints be expressed as acute RfD.

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3-4. A number of studies have been received by the Agency and are in review. These data will be addressed during Phase 4, as appropriate.

5. The Agency does not consider residue data requirements for sorghum forage and rape forage as errors, if uses of methyl parathion on grain sorghum and rape are being supported under reregistration. Methyl parathion is currently registered for use on sorghum (unspecified) and rape and tolerances for residues of methyl parathion are currently established in/on sorghum (0.1 ppm), sorghum fodder (3 ppm), sorghum forage (3 ppm), and rape seed (0.2 ppm).

**C. Toxicology Chapter** (p. 14 of Comments on EPA's Methyl Parathion)

1. The procedures should be clarified as follows; ppm should be changed to mg/kg every other day and the route of administration should be stated as oral.
2. Citations for Fuchs (1976), Gupta (1985), and Benke (1975) should list these years.
3. The dose should be expressed as "7.5 mg/kg/d or higher."
4. A developmental neurotoxicity study is required.

**D. Hazard Identification Document** (p. 14 of Comments on EPA's Methyl Parathion)

- 1,2,4. The errors are the same as in the Toxicology Chapter.
3. 7.5 mg/kg/d should be changed to 2.5 mg/kg/d.

**E. Residue Chapter** (p. 15-16 of Comments on EPA's Methyl Parathion)

1. The word "respectively" should be added.
- 2-3. A number of studies have been received by the Agency and are in review. These data will be addressed during Phase 4, as appropriate.
4. The Agency acknowledges that this was an incomplete statement which had no impact on the risk assessment but which will be corrected during Phase 4, as appropriate.
5. This is not an error.
6. The Agency does not consider residue data requirements for sweet potatoes an error. For clarification, data are required depicting methyl parathion residues of concern in/on potatoes and sweet potatoes resulting from the maximum use rates of the microencapsulated (Mcap) formulation of methyl parathion. The Agency understands that these uses are being supported by

Elf Atochem. No data are currently available to support the use of the Mcap formulation of methyl parathion on potatoes or sweet potatoes. However, if potato field trial data are generated using the Mcap formulation, then these data might be acceptable for translation to support the use of the Mcap formulation on sweet potatoes as well.

7. This is an issue deferred until Phase 4.

**F. Metabolism** (p. 16 of Comments on EPA's Methyl Parathion)

1. This is not an error and is consistent with Agency policy.

**G. Occupational Exposure** (p. 16-17 of Comments on EPA's Methyl Parathion)

1. This is a standard Agency title for the exposure chapter.
2. As was clearly stated in the cover memo for the HED chapter and attachments, the decision to not apply the FQPA factor to occupational exposures was made by the FQPA Safety Factor Committee after the exposure chapter was completed.
3. This is not an error.
4. The Agency concurs that "Min Rate" should be "Max Rate."
5. The Agency concurs that the maximum rate should be 20,000 cm<sup>2</sup>/hr.
6. As was clearly stated in the cover memo for the HED chapter and attachments, the exposure chapter was completed prior to finalization of the registrants' decision to not support granular formulations.

September 1, 1998

## METHYL PARATHION

### Executive Summary

Methyl parathion (O,O-dimethyl-O-p-nitrophenyl thiophosphate) is an acaricide and an insecticide registered for use on a variety of food and feed crops, ornamentals, and nonagricultural sites to control a number of biting or sucking pests. This restricted use pesticide is formulated as a microencapsulate (Mcap, 20.9% ai) and as an emulsifiable concentrate (EC, 11.2 to 70.74% ai). Currently, a granular formulation is available but is not being supported for reregistration. Methyl parathion is sold in the U.S. by Cheminova Agro A/S and Elf Atochem North America, the basic producers, under the trade names Methyl Parathion and Penncap-M®. Methyl parathion may be applied using aerial and ground equipment via foliar, dormant, and delayed dormant treatments. Methyl parathion is formulated with several other active ingredients including malathion, endosulfan, and parathion.

An errata list is attached in response to the document *Comments on EPA's Methyl Parathion Draft Health Effects Division Chapter of the Reregistration Eligibility Decision Document* (November 6, 1998) submitted by Cheminova Agro A/S in Phase 1 of the Public Participation Process. The errata list is to accompany the HED chapter and its attached discipline chapters. Some of the comments concern issues and/or Agency policy and will more appropriately be dealt with during Phase 4. The registrant needs to work with the Agency on changes and/or clarification of label language before a re-evaluation of the risk can be made.

The toxicity endpoints selected for the risk assessment are based on neurotoxic effects, primarily but not exclusively, neuropathology and cholinesterase (ChE) inhibition in the brain, red blood cell, and plasma, as well as behavioral effects and systemic toxicity (decreased hematocrit and erythrocyte levels). In addition, a single exposure to methyl parathion (7.5 mg/kg) 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.

Two of the active ingredients with which methyl parathion is formulated, malathion and parathion, are also cholinesterase-inhibiting organophosphates. Experiments have shown that certain cholinesterase-inhibiting pesticides, when fed together to test animals, are more toxic than the sum of their individual toxicities when fed separately (40 CFR 180.35 Tests for Potentiation). At this time, it is unknown whether potentiation would occur following exposure to these multiple active ingredient formulations. The potential for potentiation, or any other interaction, may need to be addressed at a later date.

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 Food Quality Protection Act (FQPA) for the dietary risk assessment only.

The preliminary (Tier 1) acute dietary risk assessment, based on food consumption only, indicates unacceptable risk estimates for all population subgroups examined with estimates that exceed 10,000% of the acute Reference Dose (RfD). This assessment is based on an acute RfD of 0.000025 mg/kg/d and assumes exposure to upper bound ChE inhibiting residue levels of methyl parathion and methyl paraoxon based on available magnitude of the residue data. Dietary exposure is limited to only those agricultural uses of methyl parathion which are being supported under reregistration and dietary exposure estimates are refined to include available processing data.

The preliminary chronic dietary risk assessment, based on food consumption only, indicates unacceptable risk estimates for all population subgroups examined with estimates that exceed 11,000% of the chronic RfD. This Tier 2 assessment is based on a chronic RfD of 0.00002 mg/kg/d and the same dietary exposure estimates used in the acute risk dietary assessment, while incorporating percent crop treated data. The chronic dietary risk assessment indicates that the most highly exposed population is non-nursing infants < 1 year of age. Pome fruits (>5,000% RfD), primarily apple juice, stone fruits (>2,000% RfD), primarily peaches, and cereal grains (>1,000% RfD), primarily milled white rice, contribute the greatest dietary burden to the chronic risk for this age group. It should be noted that only the use of the microencapsulate formulation of methyl parathion on apples and peaches is being supported under reregistration.

Potential exposure and risk from methyl parathion and methyl paraoxon in drinking water was assessed using models and limited surface water monitoring data. The measured or modeled drinking water exposures are expected to contribute very little to the overall dietary exposure. Since, the preliminary dietary risk assessments, based on exposures from food alone, are well above HED's level of concern, aggregation of the food and drinking water exposure components was not deemed necessary at this time.

Since there are no registered residential uses, an aggregate exposure and risk assessment for methyl parathion includes consideration of exposures from dietary sources only.

The calculations of handler risk based on combined dermal and inhalation occupational exposure estimates indicate that the Margins of Exposure (MOE) are **not more than 100** even with maximum risk reduction measures (PPE and engineering controls) for all of the short- and intermediate-term scenarios assessed, except one. Many scenarios indicate MOEs less than 1. No chemical-specific handler data were submitted. Occupational exposure assessments are based on surrogate data. Overall, there is moderate to high confidence in the PHED data from which the occupational exposures were derived. With maximum risk reduction measures applied, the only short- and intermediate-term occupational exposure scenario with a MOE **more**

than 100 is flagging aerial spray applications at the 0.1 lb ai/A application rate.

The surrogate rangefinding post-application assessment used the minimum and maximum application rates according to application rates found on existing labels. The resulting surrogate post-application assessment indicates that 1) **MOEs equal or exceed 100** for crops/activities with low exposure potential (dermal transfer of 500 cm<sup>2</sup>/hr) at the **23rd day** following applications at a rate of 0.1 lbs ai/A to pastures (microencapsulated and EC formulations), and 2) **MOEs equal or exceed 100** for crops/activities with high exposure potential (dermal transfer of 20,000 cm<sup>2</sup>/hr) at the **48th day** following applications at a rate of 3.0 lbs ai/A to grapes (microencapsulated formulation only). Based on the findings of the surrogate agricultural assessment, the occupational post-application risks for the EC and microencapsulated formulations are of concern. The existing labels for active registrations of EC and microencapsulated formulations allow 48 hour reentry intervals.

A review of the published incident data indicates that in outdoor agricultural situations, the primary activities associated with poisoning are application and spray drift (see Attachment 7, Review of Methyl Parathion Incident Reports, Jerome Blondell, February 5, 1998). Compared to other organophosphate and carbamate pesticides, methyl parathion is associated with less poisoning than these other pesticides when adjusted for incident per amount of use. HED believes that, to some extent, the similarity (in terms of poisonings and deaths even after adjusting for use) between methyl parathion and the more toxic ethyl parathion may have resulted in workers handling any product with the "parathion" name with greater care. Illegal interior home use of methyl parathion 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. Additional reported cases in Ohio, Mississippi, and Louisiana have not been well documented or confirmed with ChE level testing.