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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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January 29, 1998

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MEMORANDUM

SUBJECT: **Phorate** (057201) Evaluation of Novigen Chronic and Acute Monte-Carlo Analyses
DP Barcode: D241656; No MRID No.; Rereg. Case No. 0103.

FROM: David J. Miller, HSO, U.S. Public Health Service
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THRU: Susan V. Hummel, Branch Senior Scientist
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TO: Chris Olinger, Chemist/Chemical Review Manager
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Health Effects Division (7508W)

CEB2 has been asked to review a Monte-Carlo submission from American Cyanamid for the pesticide chemical phorate. Novigen performed this analysis dated November 21, 1997. CBRS previously completed a Residue Chemistry Chapter for the Phorate Reregistration Eligibility Document (RED) which preceded acute and chronic dietary (food only) analyses performed by DRES (D. Miller, 1/17/96, CBRS No. 16525, DP Barcode No. D220570). Based in part on the information provided in the Residue Chemistry Chapter of the RED, DRES determined chronic risk from food only was **not** of concern, but that acute risk from food only was potentially of concern with calculated MOEs of 12.5, 8.3, 8.3, and 12.5 for the U.S. general population, infants <1, children 1-6, and males (13+), respectively. No MOE was calculated for females (13+). These MOEs reflect CEB2's recommended changes in tolerance and/or recommended canceled uses (see the Tolerance Reassessment Table in the Phorate Residue Chemistry Chapter) and represent food uses only (no drinking water is included).

As of this date, the Hazard ID Committee has not formally decided that the default FQPA

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uncertainty factor of 10 should be retained, reduced, or removed. Nevertheless, we anticipate that a decision will be made in the near future to reduce this factor to "3" and this memorandum has been written under the assumption that this reduction will be made. This means that the final uncertainty factor for both acute and chronic endpoints will be 300. If the Hazard ID Committee chooses instead to select a different uncertainty factor, then the calculations performed and conclusions reached in this memorandum should be appropriately adjusted.

Novigen, in its present submission, estimated chronic and acute dietary *aggregate* (food and water) exposures using the Dietary Exposure Evaluation Module (DEEM) software. CBRS has reviewed this report. We make the following comments and recommendations with respect to the chronic and acute aggregate risks:

CHRONIC AGGREGATE RISK

Conclusion: Based on the Agency's chronic DRES run conducted in March, 1996 (see B. Steinwand memo dated 3/8/96), the adjustments made to these calculations as detailed below and presented in Attachment 1 of this memo, and the EFED-supplied 1-in-10 year average annual concentrations in surface and ground waters, CEB2 concludes that chronic aggregate exposures (through food and water) are below a level generally judged to be of concern: specifically, the %RfD occupied for the three subgroups for which risk is currently aggregated (General U.S. Population, females 13+, and infants/children) are all below the 37% of the RfD occupied for infants/children. We make the following comments and observations with respect to this conclusion:

1. CEB2 has not reviewed and has no comments on the chronic portion of the Novigen run (which showed no chronic dietary risks at levels of concern to the Agency), since the Agency's previous DRES analysis showed that chronic risks from food only are not at a level of concern.

2. EFED has modeled both surface- and ground- water chronic concentrations using PRZM/EXAMS and SCI-GROW, respectively, and indicated that the limited monitoring data available are inadequate for use in risk assessment (J. Breithaupt, 10/3/97 memorandum entitled "Drinking Water Assessment for Phorate"). They state that the surface water Drinking Water Expected Concentration (DWEC) which should be used for chronic human health risk assessment is 0.5 ppb: this concentration was obtained from a 36-year PRZM/EXAMS modeling run (MS cotton scenario) and represents a one-in-ten year (90th percentile) annual average concentration. For the corresponding chronic ground water assessment, a DWEC was calculated to be 0.015 ppb: this represents a concentration derived from a SCI-GROW analysis (peanut scenario).

3. Based on the chronic DRES run described in an 3/8/96 DRES memo, the manual

(2)

adjustment made to these calculations as presented in Attachment 1 of this memo[1], and the drinking water concentrations provided to HED by EFED in J. Breithapt's 10/3/97 memorandum, we calculate a chronic Drinking Water Level of Concern ($DWLOC_{chronic}$) of 1 ppb for infants/children.[2] DWLOC's for the general U.S. population and females 13+ (i.e., the two other subgroups for which we currently aggregate risks) would be expected to be higher. In no case does the modeled concentration exceed the $DWLOC_{chronic}$ (see above); we therefore conclude with reasonable certainty, after taking into account those uses which CEB2 has recommended reregistration in its 1/17/96 Residue Chemistry Chapter, that residues of phorate in drinking water (when considered along with other sources of exposure for which OPP has reliable data) will result in acceptable levels of aggregate chronic human health risk at this time. We note that both anticipated residues and %CT information were used in this determination and that this information may be required to be re-verified at a later time as per Section 408(b)(2)E and 408(b)(2)F of FQPA.

ACUTE AGGREGATE RISK

Conclusion: Despite several deficiencies in the Novigen Monte-Carlo (acute) analysis, CEB2 concurs with Novigen's analysis and calculation of the MOEs associated with acute exposure to phorate residues in food alone. For the general U.S. population and all subpopulations of concern, these calculated MOEs are lower than that level generally considered to represent negligible risk for this pesticide (i.e., an MOE of 300). The residues and exposures incorporated into this analysis are not considered to be worst-case: they represent the actual field trial data

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[1]The estimates reported in this memorandum are based on a "manually-adjusted" DRES run which takes into account information on processing factors, cooking factors, and BEAD's new percent crop treated data. These adjustments were based upon the DRES crop contribution analysis shown in Attachment 1 of this memorandum. Children 1-6 were determined to be the subgroup most exposed in terms of %RfD occupied. Therefore, manual adjustments were made for this group only.

[2] This is calculated as follows for infants/children assuming a NOEL of 0.05 mg/kg/day an UF of 300, and an RfD of 0.0001667:

Chronic water exposure = RfD - (chronic food + chronic residential)
= 0.0001667 mg/kg/day - (0.00006203 mg/kg/day+ 0 mg//kg/day)
= 0.0001047 mg/kg/day

$DWLOC_{chronic}$ = (chronic water exposure x Body Weight)/(Consumption x 10-3 mg/ug)
= 0.0001047 mg/kg/day x 10 kg/(1 L x 10-3 mg/ug)
= 1.0 ppb

This DWLOC of 1 ppb is a level in drinking water such that the RfD will not be exceeded. A similar calculation can be performed for the general U.S. population and females 13+ using the standard body weight/drinking water assumptions of 70 kg/2 L and 60 kg/2 L, respectively. These DWLOCs are expected to be greater than the corresponding DWLOC calculated for children 1-6.

from composite samples and incorporate percent of crop treated, processing factors, and cooking factors where appropriate. Given these exposure levels and the nature of the analysis conducted, CEB2 recommends that either mitigation procedures and/or site cancellations be required OR that a Tier 4 analysis be initiated. It is likely that potatoes and/or fresh sweet corn are the primary contributors to the acute risk and any Tier 4 analysis should therefore concentrate on determining residues in single-serving sized (non-composited) potato samples obtained in a market-basket survey. Incorporation of a cooking factor for fresh sweet corn (corn on the cob) and a processing factor for processed (canned) sweet corn may also be advantageous to the registrant. The registrant may also wish to incorporate a processing factor of 1.2 for dry potatoes (potato granules) instead of relying on the default 6.5 factor present in the DEEM and DRES software. In addition, the registrant may wish to consider incorporating the *distribution* of percent crop treated (%CT) instead of only incorporating BEAD high-end %CT estimates. The extent and nature of these required actions will depend upon the results of a subsequent Monte-Carlo analysis which incorporates the recommendations of this memorandum and aggregates drinking water exposures. The results of these re-analyses should aid in determining which labels will require modification and/or which use sites may be required to be dropped. We make the following comments and observations with respect to this conclusion:

4. For the acute analyses performed by Novigen, the Monte-Carlo simulations were performed using consumption data from the 1989-1992 USDA CSFII data, information on the percent of crop treated, and data from field trial studies.

5. Novigen obtained its percent crop treated estimate from the Residue Chemistry chapter and (for the most part) used the "likely maximum" figure (generated by the Biological and Economic Analysis Division) as its estimate of %CT. This information (and new data provided by BEAD in December 1997) is summarized on the following page in Table 1.

Table 1. Comparison of Novigen and EPA Percent Crop Treated Estimates, by Crop

Commodity	Percent Crop Treated Estimate				
	Novigen	EPA (BEAD) Estimates			
		Residue Chemistry Chapter[b]		Revised Estimate[c]	
		Likely Average	Likely Maximum	Likely Average	Likely Maximum
Beans (dry and succulent)	1	Dry: 1	Dry: 2	1	3
		Green: 3	Green: 6	2	4
Coffee	10	–[a]	–[a]	<1	3
Corn, field	2	1	2	2	3
Corn, sweet	8	3	5	Fresh: 10	19
				Processed: 2	6
Cotton	6	4	6	4	7
Peanuts	12	6	12	9	11
Potatoes	24	24	29	20	24
Grain Sorghum	1	<1	<1	<1	<1
Soybeans	1	<1	<1	<1	<1
Sugar Beets	3	2	3	2	5
Sugarcane	4	10	11	4	10
Wheat	1	<1	<1	<1	<1

[a] no estimate provided
[b] original BEAD estimate as reported in Residue Chemistry Chapter
[c] revised BEAD estimate dated 1/8/98 (Jihad Alsadek)

As can be seen from the above Table, Novigen's estimates of percent crop treated for each crop are appropriate in that they in general used close to the latest maximum likely estimates provided by BEAD for all crops except beans, sweet corn, and sugarcane[3]. BEAD has provided an estimate of %CT for coffee of

[3] Note that for sugarcane, any difference in %CT estimates is immaterial since the residues are destroyed during sugarcane processing (see 1988 FRSTR)

<1%, with 3% as an upper bound estimate (pers. communication, D. Miller, 1/5/98). We are recommending that the Monte-Carlo analysis be re-run (see below) with these %CT adjustments made. Alternatively, the registrant may wish to use a *distribution* of %CT estimates if this information is available and can be confirmed by BEAD.

6. Adequate background information was provided about Novigen's DEEM software used to analyze the consumption and residue data and the specific algorithms used to perform the MC analyses. Briefly, DEEM is a dietary exposure analysis system which can be used to estimate exposure to constituents in foods comprising the diets of the U.S. population, including population subgroups. DEEM expresses the expected risk relative to either the RfD (for chronic endpoints) or NOEL (for acute endpoints) entered by the user. In the case of chronic endpoints (and assumed chronic exposure), the average concentration in food commodities is used. With acute endpoints, average concentration in food commodities is used only for those foods which are blended (e.g.,sugarcane, soybeans, etc) prior to consumption; for those commodities which are not blended, a randomly selected value from the field trials is used during each iteration.

7. The raw field trial data used in the simulation was provided as was a description of the application scenarios tested (e.g., application rate, PHI, number of applications, etc.). Except as specifically noted below, CEB2 has confirmed that these application scenarios correspond to current label rates as summarized in the Phorate Residue Chemistry Chapter. In addition, Novigen provided an indication of which field trial residues were *excluded* from the analysis and the reasons for these exclusions. CEB2 makes the following observations concerning Novigen's selection of specific field trial residue values to include/exclude and Monte-Carlo practices:

   Dry Beans The registrant appropriately assumed that dry beans are a blended commodity and used the mean concentration of 0.05 ppm calculated from field trials and a %CT estimate of 1%. Based on a review dated 2/06/97 (D. Miller, 2/06/97 DP Barcode D223644; CBRS No. 17023), CEB2 has verified the residue data used as input values to the Monte-Carlo analysis and has judged these to be substantially complete and appropriate. We do note that Novigen inappropriately calculated an average from field trials which did not match label rate or label PHI and normalized these values for the 1x rate. We emphasize that use of data from field trials which do not mimic the maximum application scenario is not appropriate and normalizing the data to the label rate is not acceptable without data demonstrating that the residues are directly proportional to the application rate. Nevertheless, the final residue estimate used in the input data file for the analysis (i.e., 0.05 ppm with 1% CT) does not appear to underestimate

potential residues and is acceptable; we do, however, recommend that the %CT be increased to 3% in any subsequent run to agree with the "maximum likely"estimates provided by BEAD. This increase, however, is unlikely to have a significant effect on the exposure and risk estimates.

Beans, succulent: Succulent beans are not considered a blended commodity and therefore Novigen used the individual field trial residue values in its Monte-Carlo analysis rather than the average values which would be appropriate for blended commodities. Residue data from trials conducted at PHIs of 48 to 60 days (with a recommended label PHI of 50 days as indicated in the D. Miller 2/6/97 memorandum) and application rates ranging up to 4.5x the maximum label rate. All residues were normalized by the registrant to the 1x rate. This normalization is not appropriate without data demonstrating that the residues are directly proportional to the application rate. Nevertheless, the final residues used in the input data file for the analysis (i.e., residues ranging from 0.02-0.05 ppm) do not appear to significantly underestimate potential residues based on the D. Miller 2/6/97 review and are acceptable; we do, however, recommend that the %CT be increased from 1% to 4% in any subsequent run to agree with the maximum estimates provided by BEAD.

Coffee: The registrant appropriately assumed that coffee is a blended commodity and used the tolerance of 0.02 ppm and a %CT estimate of 10%. Although little effect would be expected, the registrant may wish to decrease the %CT to the 3% maximum estimated by BEAD. In any case, CEB2 has verified the data used as input to the Monte-Carlo analysis and has judged these to be substantially complete and appropriate.

Field Corn: Field corn is a blended commodity and it is therefore appropriate to use average field trial residues. Field trial data from studies conducted at a PHI of 30 days were used to calculate a mean residue for use in the acute MC analysis. We do note that Novigen inappropriately calculated an average from field trials which did not match the label rate and normalized these residues to the 1x rate. We also note that the text indicates that data were normalized to a 2.6 lb ai/A rate, but a rate as high as 3.0 lb ai/A exists as a broadcast application (SLN OR840038 and WA840041). These SLNs should therefore be withdrawn (as was recommended in Residue Chemistry Chapter). We emphasize that use of data from field trials which do not mimic the maximum application scenario is not appropriate and normalizing these values is normally not acceptable. Nevertheless, the residues used as final input to the Monte-Carlo analysis (i.e., 0.007 ppm with 1% CT) do not appear to underestimate potential residues and is acceptable given the low percent crop treated. We also note

that both poultry and ruminant commodities have been previously declared to be a 180.6(a)(3) situation.

Sweet Corn: The registrant used residue data from trials conducted at a PHI of 37 days (with a label PHI of 30 days) and application rates of 1x, 2x, and 5x. There is only one trial conducted at the 1x rate, and all trials were conducted at the same location in FL. In addition, all 2x and 5x values were normalized by the registrant to the 1x rate. Again, normalization is not appropriate and the analysis should be re-run with the reassessed tolerance (0.05 ppm) used and EPA's %CT estimate since so few data points are available. The registrant should note that BEAD's estimates of %CT have been refined: while the registrant estimated that 8% of the sweet corn crop is treated with phorate, BEAD's refined analysis indicates that up to 20% for fresh sweet corn (corn on the cob) and up to 6% of the processed sweet corn are treated. These refined %CT estimates should be incorporated into any subsequent Monte-Carlo analysis. These changes may have a significant effect on the final estimated exposures and MOEs.

Cotton: The registrant appropriately assumed that cottonseed is a blended commodity and used the mean concentration of 0.03 ppm from the field trials and a %CT estimate of 6%. We do note that Novigen inappropriately calculated an average from field trials which did not match label rate and normalized these values for the 1x rate. We again emphasize that use of data from field trials which do not mimic the maximum application scenario is not appropriate and normalizing these values is normally not acceptable. Nevertheless, the residues used as final input to the Monte-Carlo analysis do not appear to underestimate potential residues and the final residue estimate used in the input data file for the analysis (i.e., 0.03 ppm with 6% CT) and the analysis is acceptable.

Peanuts: The registrant appropriately assumed that peanuts are a blended commodity and used the mean concentration of 0.09 ppm from the field trials and a %CT estimate of 12%. Novigen inappropriately calculated an average from field trials which did not match label rate and normalized these values for the 1x rate; nevertheless, the values used as final input to the Monte-Carlo analysis do not appear to underestimate potential residues and the final residue used in the input data file for the analysis (i.e., 0.09 ppm with 12% CT) is acceptable.

Potatoes: Potatoes are not a blended commodity and it is therefore appropriate to use the actual field trial data in the Monte-Carlo assessment for potato consumption. The registrant used residue data from trials

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conducted at PHIs of 91 to 104 days (with a label PHI of 90 days) and application rates of 1x or 2x. All 2x values were normalized by the registrant to the 1x rate. This is not appropriate and the analysis should be re-run with these data points eliminated. Given that potatoes have some of the highest phorate residues, are single-serving commodities, and have a sizable percentage of the crop treated (up to 24% per BEAD's latest revised estimates), elimination of these inappropriately-normalized data may have a significant affect on the final estimated MOEs. The registrant should also provide copies of two cited reports (60914-85-T01A and B and C-3311) from which the residue data are derived: these are not referenced in the 1983 Phorate Registration Standard, the 1988 FRSTR, or the 1996 Residue Chemistry Chapter. With respect to Report Number C-3311, we would expect in any subsequent re-analysis to see more complete substantiation of the referenced 0.004 ppm LOD values used as Monte-Carlo input. We note, also, that none of the study data referenced in the 1983 Phorate Registration Standard or the 1988 Phorate FRSTR are referenced (or presumably used) in the Novigen analysis. Finally, as no sample numbers or identifications were included in the Novigen report, the registrant should insure that "duplicate" or "replicate" analyses are not present in the Monte Carlo input data set.

Grain Sorghum: Grain sorghum is a blended commodity and it is therefore appropriate to use average field trial residues. Field trial data from studies conducted at a PHI of 30 days were used to calculate a mean residue for use in the acute MC analysis (sorghum is a blended commodity). Novigen inappropriately calculated an average from several field trial studies which did not match label rate and normalized these values for the 1x rate. We again emphasize that use of data from field trials which do not mimic the maximum application scenario is not appropriate to derive a point estimate and normalizing these values is not acceptable. Nevertheless, the residue estimates used as final input to the Monte-Carlo analysis do not appear to underestimate potential residues and the final value used in the input data file for the analysis (i.e., 0.03 ppm with 1% CT) is acceptable.

Soybeans: Soybeans are a blended commodity and it is therefore acceptable to use average field trial residues. Field trials conducted at up to a 4x rate showed no detectable phorate residues at a 0.05 ppm detection limit (see 1983 Registration Standard and 1988 FRSTR). The registrant appropriately assumed that soybeans are a blended commodity and used an LOD of 0.001 ppm from the field trials and a 1% crop treated assumption. Although soybeans are unlikely to be a significant contributor to risk, the source of the 0.001 ppm LOD is unclear and should be more thoroughly referenced and documented.

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Sugar Beets: The Agency has stated in the 1996 Residue Chemistry Chapter and the 1988 FRSTR that phorate residues are destroyed by the lime and carbonation process which occurs during the manufacture of beet sugar. Therefore, Novigen appropriately assumed that no phorate residues would be present in processed commodities of sugar beets.

Sugarcane: As with sugar beets, phorate residues are destroyed in the lime and carbonation process which occurs during the manufacture of cane sugar (see 1988 FRSTR). Therefore, Novigen appropriately assumed that no phorate residues would be present in processed commodities of sugar cane.

Wheat: The registrant appropriately assumed that wheat is a blended commodity and used the mean concentration of 0.02 ppm from the field trials and a %CT estimate of 1%. Novigen inappropriately calculated an average from field trials which did not match label rate and normalized these values for the 1x rate; nevertheless, the residues used as final input to the Monte-Carlo analysis do not appear to underestimate potential residues and the final value used in the input data file for the analysis (i.e., 0.01 ppm with 1% CT) is acceptable.

8. Novigen elected to use experimentally-determined processing factors in its Monte-Carlo analysis for the following commodities: coffee beans (roasted beans), corn (deodorized oil), and potatoes (baked with peel, baked without peel, boiled without peel, fried, and peeled). Specifically, the processing factors shown below in Table 2 were used:

Table 2. Processing Factors used in Novigen's Acute Monte-Carlo Analysis for Phorate

RAC Commodity	Item	Processing Factor	MRID Source or Report No.
Coffee	roasted beans	0.06	--
Corn	deodorized oil	0.81	40000602
Potatoes	baked w/ peel	0.46	C-3895 and C-3896
	baked w/o peel	0.44	
	boiled w/o peel	0.27	
	fried	0.49	
	peeled	0.26	
	dry	6.5[a]	

[a] This factor is intrinsic to DRES, and was not determined experimentally

CBRS has examined these data and finds their use appropriate. We do note, however, that the concentration factor for *deodorized* (as opposed to refined) corn oil was used. Specifically, a processing factor of 0.81 was used for deodorized oil as opposed to the value of 5.81 determined for refined oil as per the 1988 FRSTR.[4] In addition, Novigen used a default processing factor of 6.5 for dry potatoes. A processing study is available which indicates that for processed potato granules (essentially, dry potatoes) the processing factor is only 1.2 (see MRID No. 42597001 and D. Miller, 9/12/95, CBRS No. 15173, DP Barcode No. D212457).

9. Based on the Monte-Carlo input values provided by Novigen, Table 3 presents the exposures from food-only and the corresponding MOEs for each of the relevant groups:

Table 3. Novigen-Calculated Exposures and MOEs for Food Only at 99th-, 99.5th-, and 99.9th Percentiles of Exposure.

Subgroup	Percentile	Exposure (mg/kg/day)	MOE
General U.S. Population	99	0.00013	384
	99.5	0.000192	260
	99.9	0.000405	124
Children (1-6)	99	0.000307	163
	99.5	0.000401	125
	99.9	0.00078	64
Children (7-12)	99	0.000196	255
	99.5	0.000262	191
	99.9	0.000489	102
Infants	99	0.000084	598
	99.5	0.000149	336
	99.9	0.000441	113
Females 13+	99	0.000091	547
	99.5	0.000128	390

[4]To confirm that use of a processing factor for *deodorized* oil is appropriate, we contacted the Corn Refiners Association. This organization confirmed that all food grade oils are deodorized prior to human consumption.

	99.9	0.000257	195

Although CEB2 has recommended that certain modifications be made in the inputs used in the Monte-Carlo analysis, it is unlikely that these changes would substantially increase the 99.9th percentile MOE's. Since a minimum MOE of 300 is required at the 99.9th percentile, CEB2 concludes that there is an inadequate MOE for the general U.S. population and all subgroups of concern for phorate residues in food only. When exposure from water is incorporated into this analysis (see below), these MOE's would be expected to be lower.

10. Novigen also incorporated water estimates in its acute Monte-Carlo analysis using USGS NAWQA data and information about phorate usage and population distribution in the U.S. Based on this information, Novigen water concentration input to the Monte-Carlo analysis were as follows: 200 zero entries representing phorate concentrations in non-use areas, 1620 entries at the LOD of 0.000002 ppm, and 10 detects ranging from 0.000012 to 0.000108 ppm. The Agency emphasizes (and has repeatedly emphasized) that treatment of water in this manner is inappropriate: it assumes that water is a nationally distributed commodity and exposures in any given area will occur in a random fashion in a manner which mimics the national distribution of exposures. In reality, exposures are auto-correlated and localized; there are small subpopulations which (by dint of localized pest pressure, location, climate, geology, precipitation patterns, soil type, etc.) can be exposed to high concentrations of a pesticide in their drinking water on a regular basis. Daily exposures to these small geographically-localized subpopulations are NOT properly represented simply by a random sample from nationwide pesticide contaminant data, but rather by a random sample from a high-end subset of data. In any case, EFED has determined that inadequate monitoring data are available for use in quantitative risk assessment. On this basis, HED has determined that it is appropriate to calculate a DWLOC acute and compare this value with the PRZM/EXAMS model values (see point #11) as per HED/EFED's Drinking Water SOP.

11. EFED has provided PRZM/EXAMS- and SCI-GROW- generated acute residue concentrations in surface and ground waters (J. Breithaupt). For surface waters, the 1-in-10 year maximum concentration is 22.8 ppb, while the 1-in-10 year maximum concentration for ground waters is 0.015 ppb. Per the Drinking Water SOP, the former surface water concentration is appropriate for comparison with the $DWLOC_{acute}$ which is calculated as a

negative concentration[5] indicating that an inadequate MOE exists when food alone is considered.

cc: RF, SF, List A File, SRRD (Jason Robertson), DJM.
RDI: Team: ✔; SHummel:1/28/98

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[5]This is calculated as follows for infants/children assuming a NOEL of 0.05 mg/kg/day and a required MOE of 300:

Acute water exposure = NOEL/MOE - acute food exposure
= (0.05 mg/kg/day)/300 - 0.00078
=-0.001 mg/kg/day

$DWLOC_{chronic}$ = (chronic water exposure x Body Weight)/(Consumption x 10-3 mg/ug)
=-0.001 mg/kg/day x 10 kg/(1 L x 10-3 mg/ug)
= -6.1 ppb

The negative value in the above calculation arises since food only exposure provides an MOE of less than the required 300. This indicates that even with no exposure through water, an inadequate MOE exists when food alone is considered. A similar calculation can be performed for the general U.S. population and females 13+ using the standard body weight/drinking water assumptions of 70 kg/2 L and 60 kg/2 L, respectively. Corresponding food only exposures (from the Novigen DEEM run) at the 99.9th percentile are 0.000405 mg/kg/day and 0.000259 mg/kg/day for the U.S. population and females 13+, respectively. When these calculations are performed, the $DWLOC_{acute}$'s are also both negative, indicating that for these groups, an inadequate MOE exists.

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 12/05/97

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Phorate (Thimet) Caswell #660 CAS No. 298-02-2 A.I. CODE: 057201 CFR No. 180.206	1yr feeding- dog NOEL= 0.0500 mg/kg 0.00 ppm LEL= 0.2500 mg/kg 0.00 ppm ONCO: E (RfD/PR Committee)	Brain ChE inhibition; slight tremors in M&F, marginal inhibition of body weight gain in M. No evidence of carcinogenicity in rats or mice.	ADI UF -->1000 OPP RfD= 0.000050 EPA RfD= 0.000050	No data gaps. RfD Pending RAC approval of RAF ChE report.	WHO reviewed 1985 HED reviewed 09/25/97 HED reviewed 09/25/97 RfD/PR reviewed 09/25/97

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.000518	0.000518	1036.152000	0.000000	0.000078	155.18400
U.S. POPULATION - SPRING SEASON	0.000509	0.000509	1017.206000	0.000000	0.000076	151.04600
U.S. POPULATION - SUMMER SEASON	0.000514	0.000514	1028.320000	0.000000	0.000075	150.25600
U.S. POPULATION - FALL SEASON	0.000525	0.000525	1049.730000	0.000000	0.000080	160.00000
U.S. POPULATION - WINTER SEASON	0.000520	0.000520	1039.902000	0.000000	0.000080	159.33600
NORTHEAST REGION	0.000490	0.000490	979.214000	0.000000	0.000073	146.04600
NORTH CENTRAL REGION	0.000551	0.000551	1101.798000	0.000000	0.000086	171.14600
SOUTHERN REGION	0.000530	0.000530	1059.522000	0.000000	0.000079	157.45800
WESTERN REGION	0.000482	0.000482	963.016000	0.000000	0.000070	140.02800
HISPANICS	0.000526	0.000526	1051.492000	0.000000	0.000077	153.50600
NON-HISPANIC WHITES	0.000520	0.000520	1039.428000	0.000000	0.000079	157.58000
NON-HISPANIC BLACKS	0.000505	0.000505	1009.986000	0.000000	0.000073	145.42000
NON-HISPANIC OTHERS	0.000424	0.000424	847.620000	0.000000	0.000055	110.36600
NURSING INFANTS (< 1 YEAR OLD)	0.000199	0.000199	397.672000	0.000000	0.000024	48.80200
NON-NURSING INFANTS (< 1 YEAR OLD)	0.000693	0.000693	1386.306000	0.000000	0.000096	191.19600
FEMALES (13+ YEARS, PREGNANT)	0.000353	0.000353	706.466000	0.000000	0.000052	103.59400
FEMALES 13+ YEARS, NURSING	0.000404	0.000404	807.610000	0.000000	0.000057	114.81600
CHILDREN (1-6 YEARS OLD)	0.001111	0.001111	2222.142000	0.000000	0.000157	313.55400
CHILDREN (7-12 YEARS OLD)	0.000815	0.000815	1630.076000	0.000000	0.000117	233.13600
MALES (13-19 YEARS OLD)	0.000577	0.000577	1153.446000	0.000000	0.000086	171.26400
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000479	0.000479	958.110000	0.000000	0.000071	142.50600
MALES (20 YEARS AND OLDER)	0.000421	0.000421	842.162000	0.000000	0.000066	131.31400
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000346	0.000346	692.114000	0.000000	0.000055	110.08000

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Phorate (Thimet) Caswell #660 CAS No. 298-02-2 A.I. CODE: 057201 CFR No. 180.206	1yr feeding- dog NOEL= 0.0500 mg/kg 0.00 ppm LEL= 0.2500 mg/kg 0.00 ppm ONCO; E (RfD/PR Committee)	Brain ChE inhibition; slight tremors in M&F, marginal inhibition of body weight gain in M. No evidence of carcinogenicity in rats or mice.	ADI UF -->1000 OPP RfD= 0.000050 EPA RfD= 0.000050	No data gaps. RfD Pending RAC approval of RAF ChE report.	WHO reviewed 1985 HED reviewed 09/25/97 HED reviewed 09/25/97 RfD/PR reviewed 09/25/97

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
15027AA	BEANS-UNSPEC	21 COOKED-NFS	8F0727	P 0.050000	0.050000		6.00	0.003000
15029AA	SOYBEAN-SPROUTED	00 NOT SPECIFIED (NO CONSUMPTION)	NOPET#	P 0.050000	0.050000		1.00	0.000500
15030AA	BEANS-DRY-HYAC	00 NOT SPECIFIED (NO CONSUMPTION)	8F0727	P 0.050000	0.050000		2.00	0.001000
15030AB	BEANS-SUCC-HYAC	00 NOT SPECIFIED (NO CONSUMPTION)	8F0727	P 0.050000	0.050000		6.00	0.003000
15031AA	BLKEYE PEAS-DRY	21 COOKED-NFS	8F0727	P 0.050000	0.050000		2.00	0.001000
15032AA	BEANS-DRY	21 COOKED-NFS	8F0727	P 0.050000	0.050000		2.00	0.001000
15032AA	BEANS-DRY	31 COOKED-FRESH OR CANNED	8F0727	P 0.050000	0.050000		2.00	0.001000
24002EA	CORN,GRAIN-ENDO	10 RAW-FRESH OR NFS	7F0521	P 0.050000	0.050000		2.00	0.001000
24002EA	CORN,GRAIN-ENDO	21 COOKED-NFS	7F0521	P 0.050000	0.050000		2.00	0.001000
24002EA	CORN,GRAIN-ENDO	22 COOKED-FRESH-BAKED	7F0521	P 0.050000	0.050000		2.00	0.001000
24002EA	CORN,GRAIN-ENDO	23 COOKED-FRESH-BOILED	7F0521	P 0.050000	0.050000		2.00	0.001000
24002HA	CORN,GRAIN-BRAN	00 NOT SPECIFIED (NO CONSUMPTION)	7F0521	P 0.050000	0.050000		2.00	0.001000
24002SA	CORN SUGAR	10 RAW-FRESH OR NFS	7F0521	P 0.050000	0.050000		2.00	0.001000
24002SA	CORN SUGAR	21 COOKED-NFS	7F0521	P 0.050000	0.050000		2.00	0.001000
24002SA	CORN SUGAR	22 COOKED-FRESH-BAKED	7F0521	P 0.050000	0.050000		2.00	0.001000
24006AA	SORGHUM	00 NOT SPECIFIED (NO CONSUMPTION)	8F0723	P 0.050000	0.050000		1.00	0.000500
24007AA	WHEAT-ROUGH	10 RAW-FRESH OR NFS	0F0938	P 0.050000	0.050000		1.00	0.000500
24007AA	WHEAT-ROUGH	21 COOKED-NFS	0F0938	P 0.050000	0.050000		1.00	0.000500
24007AA	WHEAT-ROUGH	22 COOKED-FRESH-BAKED	0F0938	P 0.050000	0.050000		1.00	0.000500
24007AA	WHEAT-ROUGH	23 COOKED-FRESH-BOILED	0F0938	P 0.050000	0.050000		1.00	0.000500
24007GA	WHEAT-GERM	10 RAW-FRESH OR NFS	0F0938	P 0.050000	0.050000		1.00	0.000500
24007GA	WHEAT-GERM	22 COOKED-FRESH-BAKED	0F0938	P 0.050000	0.050000		1.00	0.000500
24007HA	WHEAT-BRAN	10 RAW-FRESH OR NFS	0F0938	P 0.050000	0.050000		1.00	0.000500
24007HA	WHEAT-BRAN	21 COOKED-NFS	0F0938	P 0.050000	0.050000		1.00	0.000500
24007HA	WHEAT-BRAN	22 COOKED-FRESH-BAKED	0F0938	P 0.050000	0.050000		1.00	0.000500
24007WA	WHEAT-FLOUR	10 RAW-FRESH OR NFS	0F0938	P 0.050000	0.050000		1.00	0.000500
24007WA	WHEAT-FLOUR	21 COOKED-NFS	0F0938	P 0.050000	0.050000		1.00	0.000500
24007WA	WHEAT-FLOUR	22 COOKED-FRESH-BAKED	0F0938	P 0.050000	0.050000		1.00	0.000500
24007WA	WHEAT-FLOUR	25 COOKED-FRESH-FRIED	0F0938	P 0.050000	0.050000		1.00	0.000500
25002SA	BEET SUGAR	10 RAW-FRESH OR NFS	378	P 0.300000	0.300000		3.00	0.009000
25002SA	BEET SUGAR	21 COOKED-NFS	378	P 0.300000	0.300000		3.00	0.009000
25002SA	BEET SUGAR	22 COOKED-FRESH-BAKED	378	P 0.300000	0.300000		3.00	0.009000
25002SA	BEET SUGAR	31 COOKED-FRESH OR CANNED	378	P 0.300000	0.300000		3.00	0.009000
25003SA	CANE SUGAR	10 RAW-FRESH OR NFS	8F0723	P 0.050000	0.050000		11.00	0.005500
25003SA	CANE SUGAR	21 COOKED-NFS	8F0723	P 0.050000	0.050000		11.00	0.005500
25003SA	CANE SUGAR	22 COOKED-FRESH-BAKED	8F0723	P 0.050000	0.050000		11.00	0.005500
25003SA	CANE SUGAR	31 COOKED-FRESH OR CANNED	8F0723	P 0.050000	0.050000		11.00	0.005500
25003SB	SUGAR-MOLASSES	10 RAW-FRESH OR NFS	8F0723	P 0.050000	0.050000		11.00	0.005500
25003SB	SUGAR-MOLASSES	21 COOKED-NFS	8F0723	P 0.050000	0.050000		11.00	0.005500
25003SB	SUGAR-MOLASSES	22 COOKED-FRESH-BAKED	8F0723	P 0.050000	0.050000		11.00	0.005500

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CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Phorate (Thimet) Caswell #660 CAS No. 298-02-2 A.I. CODE: 057201 CFR No. 180.206	1yr feeding- dog NOEL= 0.0500 mg/kg 0.00 ppm LEL= 0.2500 mg/kg 0.00 ppm ONCO: E (RfD/PR Committee)	Brain ChE inhibition; slight tremors in M&F, marginal inhibition of body weight gain in M. No evidence of carcinogenicity in rats or mice.	ADI UF -->1000 OPP RfD= 0.000050 EPA RfD= 0.000050	No data gaps. RfD Pending RAC approval of RAF ChE report.	WHO reviewed 1985 HED reviewed 09/25/97 HED reviewed 09/25/97 RfD/PR reviewed 09/25/97

COMMODITY CONTRIBUTION BY RAC FOR: CHILDREN (1-6 YEARS OLD)

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TMRC TYPE	TMRC (UG/KG/DAY)	%RFD	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD
GRAND TOTALS FOR CHILDREN (1-6 YEARS OLD)				1.111071	2222.142		0.156777	313.554

TOLERANCE TYPE: N=NEW; A=PENDING; P=PUBLISHED
TMRC=THEORETICAL MAXIMUM RESIDUE CONTRIBUTION
ARC = ANTICIPATED RESIDUE CONTRIBUTION
RFD = REFERENCE DOSE

3.136.

3.36

$\Sigma_{Grand} = 6.203E-2$

or

0.06203 ug/kg/dy

or 0.00006203

Assuming UF = 300

$\%RfD = \frac{Exposure}{(NOEL/UF)}$

$\frac{0.06203 \text{ ug/kg/dy} \times 10^{-3} \text{ mg/ug}}{(0.05/300)} = 37\%$

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Phorate (Thimet) Caswell #660 CAS No. 298-02-2 A.I. CODE: 057201 CFR No. 180.206	1yr feeding- dog NOEL= 0.0500 mg/kg 0.00 ppm LEL= 0.2500 mg/kg 0.00 ppm ONCO: E (RfD/PR Committee)	Brain ChE inhibition; slight tremors in M&F, marginal inhibition of body weight gain in M. No evidence of carcinogenicity in rats or mice.	ADI UF -->1000 OPP RfD= 0.000050 EPA RfD= 0.000050	No data gaps. RfD Pending RAC approval of RAF ChE report.	WHO reviewed 1985 HED reviewed 09/25/97 HED reviewed 09/25/97 RfD/PR reviewed 09/25/97

COMMODITY CONTRIBUTION BY RAC FOR: CHILDREN (1-6 YEARS OLD)

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TYPE	TMRC (UG/KG/DAY)	%RFD	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD
15022AB	BEANS-SUCCULENT-BROADBEANS(IMMAT. SEED)	0.050	P	0.000000	0.000			
	00 NOT SPECIFIED (NO CONSUMPTION)					0.00300	0.000000	0.000
15023AA	BEANS-DRY-PIGEON BEANS	0.050	P	0.000000	0.000			
	21 COOKED-NFS					0.00100	0.000000	0.000
15027AA	BEANS-UNSPECIFIED	0.050	P	0.000537	1.074			
	21 COOKED-NFS					0.00300	0.000032	0.064
15029AA	SOYBEANS-SPROUTED SEEDS	0.050	P	0.000000	0.000			
	00 NOT SPECIFIED (NO CONSUMPTION)					0.00050	0.000000	0.000
15030AA	BEANS-DRY-HYACINTH(MATURE SEEDS)	0.050	P	0.000000	0.000			
	00 NOT SPECIFIED (NO CONSUMPTION)					0.00100	0.000000	0.000
15030AB	BEANS-SUCCULENT-HYACINTH(YOUNG PODS)	0.050	P	0.000000	0.000			
	00 NOT SPECIFIED (NO CONSUMPTION)					0.00300	0.000000	0.000
15031AA	BEANS-DRY-BLACKEYE PEAS(COWPEAS)	0.050	P	0.000175	0.350			
	21 COOKED-NFS					0.00100	0.000004	0.008
15032AA	BEANS-DRY-GARBANZO(CHICK PEA)	0.050	P	0.000058	0.116			
	21 COOKED-NFS					0.00100	0.000001	0.002
	31 COOKED-FRESH OR CANNED					0.00100	0.000000	0.000
270070A	PEANUTS-OIL	0.100	P	0.000834	1.668			
	18 PROCESSED OIL					0.01200	0.000100	0.200
270100A	SOYBEANS-OIL	0.050	P	0.029868	59.736			
	18 PROCESSED OIL					0.00050	0.000299	0.598
28023AA	SOYBEANS-UNSPECIFIED	0.050	P	0.000030	0.060			
	21 COOKED-NFS					0.00050	0.000000	0.000
28023AB	SOYBEANS-MATURE,SEEDS DRY	0.050	P	0.000037	0.074			
	10 RAW-FRESH OR NFS					0.00050	0.000000	0.000
	21 COOKED-NFS					0.00050	0.000000	0.000
	23 COOKED-FRESH-BOILED					0.00050	0.000000	0.000
	25 COOKED-FRESH-FRIED					0.00050	0.000000	0.000
	31 COOKED-FRESH OR CANNED					0.00050	0.000000	0.000
28023WA	SOYBEANS-FLOUR, FULL FAT	0.050	P	0.000346	0.692			
	21 COOKED-NFS					0.00050	0.000001	0.002
	22 COOKED-FRESH-BAKED					0.00050	0.000002	0.004
	31 COOKED-FRESH OR CANNED					0.00050	0.000001	0.002
28023WB	SOYBEANS-FLOUR, LOW FAT	0.050	P	0.000059	0.118			
	21 COOKED-NFS					0.00050	0.000001	0.002
28023WC	SOYBEANS-FLOUR,DEFATTED	0.050	P	0.001468	2.936			
	10 RAW-FRESH OR NFS					0.00050	0.000000	0.000
	21 COOKED-NFS					0.00050	0.000001	0.002
	22 COOKED-FRESH-BAKED					0.00050	0.000006	0.012
	51 COOKED-CANNED					0.00050	0.000003	0.006
	53 COOKED-CANNED-BOILED					0.00050	0.000005	0.010

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TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS

DATE: 12/05/97 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Phorate (Thimet) Caswell #660 CAS No. 298-02-2 A.I. CODE: 057201 CFR No. 180.206	1yr feeding- dog NOEL= 0.0500 mg/kg 0.00 ppm LEL= 0.2500 mg/kg 0.00 ppm ONCO; E (RfD/PR Committee)	Brain ChE inhibition; slight tremors in M&F, marginal inhibition of body weight gain in M. No evidence of carcinogenicity in rats or mice.	ADI UF -->1000 OPP RfD= 0.000050 EPA RfD= 0.000050	No data gaps. RfD Pending RAC approval of RAF ChE report.	WHO reviewed 1985 HED reviewed 09/25/97 HED reviewed 09/25/97 RfD/PR reviewed 09/25/97

COMMODITY CONTRIBUTION BY RAC FOR: CHILDREN (1-6 YEARS OLD)

FOOD CODE	FOODNAME/FOODFORM	TOLERANCE (PPM)	TYPE	TMRC (UG/KG/DAY)	%RFD	ANTICIPATED RESIDUE (PPM)	ARC (UG/KG/DAY)	%RFD	%CT	PF	AR
07002AA	COFFEE 21 COOKED-NFS	0.020	P	0.000024	0.048						
08020AA	HOPS 21 COOKED-NFS	2.000	P	0.000043	0.086	0.02000	0.000024	0.048	10% 100%	0.06	1442
25003SA	CANE SUGAR 10 RAW-FRESH OR NFS 21 COOKED-NFS 22 COOKED-FRESH-BAKED 31 COOKED-FRESH OR CANNED	0.050	P	0.090652	181.304	0.04000 0.00550 0.00550 0.00550 0.00550	0.000001 0.000895 0.002215 0.001378 0.004984	0.002 1.790 4.430 3.756 9.968		0 0 0 0	0 0 0 0
25003SB	SUGAR-MOLASSES 10 RAW-FRESH OR NFS 21 COOKED-NFS 22 COOKED-FRESH-BAKED 31 COOKED-FRESH OR CANNED	0.050	P	0.001172	2.344	0.00550 0.00550 0.00550 0.00550	0.000000 0.000035 0.000068 0.000026	0.000 0.070 0.136 0.052		0 0 0 0	0 0 0 0
26011AA	GUAR BEANS 00 NOT SPECIFIED (NO CONSUMPTION)	0.050	P	0.000000	0.000						
270030A	COTTONSEED-OIL 18 PROCESSED OIL	0.050	P	0.001818	3.636	0.00300	0.000000	0.000			
27003MA	COTTONSEED-MEAL 18 PROCESSED OIL	0.050	P	0.000026	0.052	0.00300 0.00300	0.000109 0.000002	0.218 0.004	7% 6% 7% 6%		1.272 2.33E
	CROP GROUP TOTALS FOR UNSPECIFIED:			0.093735	187.470		0.010237	20.474			
14013AA	POTATOES(WHITE)-WHOLE 10 RAW-FRESH OR NFS 21 COOKED-NFS 22 COOKED-FRESH-BAKED	0.200	P	0.115997	231.994	0.05800 0.05800 0.05800	0.004620 0.015108 0.013911	9.240 30.216 27.822	24% 24% 29%	- - 0.46	3.82E 1.25E 5.29E
14013AB	POTATOES(WHITE)-UNSPECIFIED 22 COOKED-FRESH-BAKED	0.200	P	0.000039	0.078						
14013AC	POTATOES(WHITE)-PEELED 21 COOKED-NFS 22 COOKED-FRESH-BAKED 23 COOKED-FRESH-BOILED 25 COOKED-FRESH-FRIED	0.200	P	0.329707	659.414	0.05800 0.05800 0.05800 0.05800 0.05800	0.000011 0.000972 0.004521 0.050418 0.031704	0.022 17.944 9.042 100.836 63.408	29% 24% 29%	0.46 0.26 0.44 0.27 0.29	4.19E 1.93E 1.64E 1.36E 1.29E
14013DA	POTATOES(WHITE)-DRY 10 RAW-FRESH OR NFS 31 COOKED-FRESH OR CANNED	0.200	P	0.004424	8.848	0.05800 0.05800	0.000672 0.000611	1.344 1.222	24% 28%	1.2/65 1.2/65	1.02E 9.35E
14013HA	POTATOES(WHITE)-PEEL ONLY 22 COOKED-FRESH-BAKED	0.200	P	0.000000	0.000						
25002SA	BEET SUGAR 10 RAW-FRESH OR NFS	0.300	P	0.245515	491.030	0.05800 0.00900	0.000000 0.000661	0.000 1.322	24%/47%	- -	0 0