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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

MAR 13 1995

SUBJECT: OCCUPATIONAL AND RESIDENTIAL EXPOSURE ASSESSMENT AND RECOMMENDATIONS FOR THE REREGISTRATION ELIGIBILITY DECISION DOCUMENT FOR PHORATE

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Please find the OREB review of Phorate.

DP Barcode:	D220555
Pesticide Chemical Codes:	057201
EPA Reg. Nos.:	34704-259, 9779-293, 241-259, 34704-712, 241-53, 2935-361
LUIS Report Date:	11/2/95
PHED:	Yes, Version 1.1

OCCUPATIONAL AND RESIDENTIAL EXPOSURE CHAPTER

In this document, which is for use in EPA's development of the phorate Reregistration Eligibility Decision Document (RED), EPA presents the results of its review of the potential human health effects of occupational and residential exposure to phorate. Included is a discussion of the adequacy of the occupational and residential exposure data that have been submitted in support of the reregistration of phorate.

(RED SECTION III - TOXICITY, EXPOSURE, AND RISK)

(EXPOSURE)

Occupational and Residential

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.

OR9500027 Label?

Use Summary

Use Patterns

Phorate, O,O-dimethyl S-[(ethylthio)methyl] phosphorodithioate, is an organophosphate insecticide and nematicide formulated as a granular (6.5 to 20 percent ai) and as an emulsifiable concentrate manufacturing product (92 to 95 percent ai).[1,2] Phorate is used on non-domestic terrestrial and aquatic food/feed crops.[1,2] The LUIS report indicates that there is a greenhouse commercial nursery stock (both outdoor and greenhouse) use, however data from BEAD, the registrant and SRRD state that there are to be no greenhouse or indoor uses of phorate. **Although the greenhouse/nursery uses are not included in this assessment, confirmation that there are no such uses registered is necessary. The fact that phorate is not currently marketed for greenhouse/nursery uses does not mean that such uses are not currently registered and could, therefore, be activated at any time.**

Phorate can be applied by aircraft and ground equipment (soil band treatment, soil in-furrow treatment, soil drill treatment, soil side dress treatment). The maximum application rates range from 1.3 to 3.9 lb ai/acre.[1] Only one application per season is allowed for most of the uses. Two applications per season are allowed for irrigated cotton, sorghum, peanuts and sugarbeets. The interval between applications range from 1 to 2 months.

Occupational-use products and homeowner-use products

At this time products containing phorate are intended primarily for occupational uses and not for homeowner uses.

(2)

Acute Toxicity

The toxicological data base for phorate is adequate and will support reregistration. Guideline studies for acute toxicity indicate that the technical grade of phorate is classified as category I for acute oral toxicity, category I for acute dermal toxicity, and category I for acute inhalation toxicity.[3] Eye irritation potential, and dermal irritation, and skin sensitizer toxicity studies were waived due to the high acute toxicity of phorate.[3]

Other Endpoints of Concern

The *Toxicity Endpoint Selection Document* dated January 30, 1996, indicates that there are toxicological endpoints of concern for phorate.[3] The toxicology endpoints and dose levels identified for short-term and intermediate-term, inhalation, and chronic term exposure assessments are a NOEL of 0.05 mg/kg/day based on RBC and brain cholinesterase inhibition (one year feeding study in dogs). Because no dermal absorption study is available, a 100 percent dermal absorption factor is used. Phorate has two metabolites of concern, phorate sulfoxide and phorate sulfone. Terrestrial field dissipation studies suggest that these metabolites may be somewhat more persistent than phorate.[6] Although not likely an issue for handler exposures, the role of these metabolites in post application exposures is of concern.

Poisoning Incident Data

The following data bases were consulted for poisoning incident data on the active ingredient phorate: OPP Incident Data System (IDS); Poison Control Centers - (data received in response to 1993 Data-Call-In covering the years 1985 to 1992); California Department of Food and Agriculture (Replaced by Department of Pesticide Regulation 1991); and National Pesticide Telecommunication Network (NPTN).

IDS (as of 12/95) received 18 separate incident reports, most involving wildlife and ecological adverse effects. Poison Control Centers Data (1985 to 1992)) showed 109 cases of occupational and 82 cases of non-occupational exposure to phorate. California data (1982-1993) showed 22 cases of adverse reactions to phorate. NPTN (1985-1991) handled 116 calls on phorate involving 39 incidents (29 humans and 5 animals) . A detailed discussion of these data is in OREB's review, *Phorate - A review of Pesticide Poisoning Incident Data (V. Dobozy, 1/30/96).*

Handler Exposures & Assumptions

EPA has determined that there are potential exposures to loaders, applicators, or other handlers during usual use-patterns associated with phorate. Based on the use patterns and potential exposures described above, four major exposure scenarios were identified for phorate: (1a) loading the granular formulation for aerial application; (1b) loading the granular formulation for ground applications; (2) applying the granular formulation with aerial equipment; (3) ground applications of the granular formulation; and, (4) flagging for the aerial application of the granular formulation. The minimum and maximum application rates (1.0 and 3.9 lb ai/A, respectively) were used in this assessment to represent the range of all crops. **It should be noted that this handler exposure/risk assessment may not encompass worse-case for all crops. If applications to soybeans, peanuts, or potatoes may be made**

(3)

aerially, the potential exposure to loaders and applicators would exceed that for aerial corn applications, since the rates per acre for those crops is double to triple that for corn.

Short-term and intermediate-term exposure assessments are presented in Table 1. Table 2 presents the corresponding risk assessment for short-term and intermediate-term exposures, while Table 3 summarizes the caveats and parameters specific to each exposure scenario and corresponding risk assessment. No chronic exposure scenarios were identified. The exposure assessments are based on PHED V1.1 data.

Table 1. Short-Term and Intermediate-Term Exposure of Phorate

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Crop and Application Rate[c] (lb ai/acre)	Daily Acres Treated[d]	Daily Dermal Exposure[e] (mg/day)	Daily Inhalation Exposure[f] (mg/day)	Daily Total Exposure[g] (mg/day)
Loader Exposure							
Granular Formulation for Aerial Application (1a)	0.0048	1.7	Corn = 1.0	500	2.4	0.9	3.3
Granular Formulation for 6 & 8 Row Planters (1b)	0.0048	1.7	Typical Acres Treated at Maximum Rates				
			Sugarcane = 4.0	69	1.32	0.47	1.79
				100	1.92	0.68	2.60
			Wheat = 1.0	69	0.33	0.12	0.45
				100	0.48	0.17	0.65
			Maximum Acres Treated at Maximum Rates				
			Sugarcane = 4.0	213	4.1	1.4	5.5
			Wheat = 1.0	213	1.0	0.36	1.36
Applicator Exposure							
Aerial - Fixed-Wing - enclosed cockpit (2)	No data - see engineering controls	No data - see engineering controls	Corn = 1.0	500	No data - see engineering controls	No data - see engineering controls	No data - see engineering controls
Granular Formulation for 6 & 8 Row Planters (3)	No data - see engineering controls	No data - see engineering controls	Typical Acres Treated at Maximum Rates				
			Sugarcane = 4.0	69	No data - see engineering controls	No data - see engineering controls	No data - see engineering controls
				100	No data - see engineering controls	No data - see engineering controls	No data - see engineering controls
			Wheat = 1.0	69	No data - see engineering controls	No data - see engineering controls	No data - see engineering controls
				100	No data - see engineering controls	No data - see engineering controls	No data - see engineering controls
			Maximum Acres Treated as Maximum Rate				
			Sugarcane =4.0	213	No data - see engineering controls	No data - see engineering controls	No data - see engineering controls
			Wheat = 1.0	213	No data - see engineering controls	No data - see engineering controls	No data - see engineering controls
Flagger Exposure							

Exposure Scenario (Scen. #)	Baseline Dermal Unit Exposure[a] (mg/lb ai)	Baseline Inhalation Unit Exposure[b] (μg/lb ai)	Crop and Application Rate[c] (lb ai/acre)	Daily Acres Treated[d]	Daily Dermal Exposure[e] (mg/day)	Daily Inhalation Exposure[f] (mg/day)	Daily Total Exposure[g] (mg/day)
Granular Applications (4)	0.00025	0.15	Corn = 1.0	500	1.25	0.08	1.33

a Baseline dermal unit exposures represent long pants, long sleeve shirts, no gloves, open loading, enclosed cockpit for aerial application, open cab tractor.
b Baseline inhalation unit exposure does not include the use of a respirator.
c Application rate from phorate labels (EPA Reg. Nos. 34704-259 and 9779-293, 34704-712).
d Acres treated are based on the Corn Insecticide Cluster Risk Assessment, Nov/1993.
e Daily Dermal Exposure (mg/day) = Dermal Unit Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/acre) * Max. Treated (acres).
f Daily Inhalation Exposure (ug/day) = Inhalation Unit Exposure (mg/lb ai) * (1mg/1000ug) conversion * Max. treated
g Daily Total Exposure (mg/day) = Daily Dermal Exposure + Daily Inhalation Exposure.

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Table 2: Short-Term and Intermediate-Term Risk from Phorate

Exposure Scenario (Number)	Crop	Baseline Total Dose (mg/kg/day)[a]	Baseline Dermal MOE[b]	Risk Mitigation Measures							
				Additional PPE[c]				Engineering Controls[d]			
				Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (ug/lb ai)	Daily Total Dose (mg/kg/day)[a]	Total MOE[b]	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (ug/lb ai)	Daily Total Dose (mg/kg/day)[a]	Total MOE[b]
Loader Risk											
Granular Formulation for Aerial Application (1a)	Corn	0.047	1	0.00155	0.425	0.01	5	0.0001	0.034	0.001	50
Granular Formulation for 6 and 8 Row Planters (1b)	Typical Acres Treated at Maximum Rates[e]										
	Sugarcane	0.03	2	0.00155	0.425	0.0078	6	0.0001	0.034	0.00041	122
		0.04	1	0.00155	0.425	0.011	5	0.0001	0.034	0.00077	65
	Wheat	0.006	8	0.00155	0.425	0.002	25	0.0001	0.034	0.0001	500
		0.009	5	0.00155	0.425	0.003	17	0.0001	0.034	0.0002	250
	Maximum Acres Treated at Maximum Rates[f]										
	Sugarcane	0.08	0.63	0.00155	0.425	0.024	2	0.0001	0.034	0.0016	31
	Wheat	0.02	3	0.00155	0.425	0.006	8	0.0001	0.034	0.0004	125
Applicator Risk											
Aerial- Fixed-wing - enclosed cockpit (2)	Corn	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	0.0017	1.32	0.023	2
Granular Formulation with 6 and 8 Row Planters (3)	Typical Acres Treated at Maximum Rates[e]										
	Sugarcane	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	0.0022	0.22	0.0095	5
										0.014	4
	Wheat	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	0.0022	0.22	0.0024	21
										0.0035	14

(2)

Exposure Scenario (Number)	Crop	Baseline Total Dose (mg/kg/day)[a]	Baseline Dermal MOE[b]	Risk Mitigation Measures							
				Additional PPE[c]				Engineering Controls[d]			
				Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (ug/lb ai)	Daily Total Dose (mg/kg/day)[a]	Total MOE[b]	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (ug/lb ai)	Daily Total Dose (mg/kg/day)[a]	Total MOE[b]
Granular Formulation with 6 & 8 Row Planters (3)	Maximum Acres Treated at Maximum Rates[f]										
	Sugarcane	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	0.0022	0.22	0.029	2
	Wheat	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	No data see engineering controls	0.0022	0.22	0.0074	7
Flagger Risk											
Granular Applications (4)	Corn	0.019	3	0.00125	0.038	0.009	6	0.00005	0.003	0.00038	132

a Total dose = (daily dermal exposure + daily inhalation exposure)/70 kg.
b. MOE = NOEL (0.05 mg/kg/day)/daily dermal dose.
c Additional PPE is represented by double layer of clothing, chemical resistant gloves and dust/mist respirator.
d Engineering Controls is represented by closed system (i.e., lock'n load and enclosed cabs and cockpits); single layer clothing and no gloves.
e 69 acres/day and 100 acres/day, respectively - refer to Table 1.
f 213 acres/day - refer to Table 1.

Table 3: Exposure Scenario Descriptions for Uses of Phorate

Exposure Scenario (Number)	Data Source	Standard Assumptions (8-hr work day)	Comments
Loader Exposure			
Loading Granulars (1a and 1b)	PHED V1.1	For aerial application - 500 acres. For 6 and 8 row planters 69, 100, and 213 acres	**Baseline:** "Best Available" grades: Dermal and inhalation acceptable grades, hand exposure all grades. Dermal = 29 to 36 replicates; inhalation = 58 replicates; hand = 10 replicates. Low confidence in dermal data, high confidence in inhalation data. **PPE:** Dermal, inhalation and hand acceptable grades. Dermal = 29 to 36 replicates; inhalation = 58 replicates; hand = 45 replicates. Medium confidence in dermal data, high confidence in inhalation data. PHED data used for baseline, no protection factors (PFs) were necessary. For additional PPE, a 50% PF was used for the addition of coveralls. For engineering controls, a 98% PF was applied to the baseline for closed mixing.
Applicator Exposure			
Aerial-Fixed Wing -- enclosed cockpit -- Granular (2)	PHED V1.1	500 acres.	**Baseline/Engineering Controls:** "Best Available" grades: Dermal exposure grade C data; inhalation and hand exposure all grades. Dermal = 9 to 13 replicates; inhalation = 13 replicates; hand = 4 replicates. Low confidence in dermal and inhalation data. PHED data used for baseline/engineering, no PFs were necessary.
Granular 6 and 8 Row Planters (3)	PHED V1.1	69, 100, and 213 acres.	**Engineering Control:** "Best Available" grades: Dermal, inhalation and hand exposure acceptable grades. Dermal = 27 to 30 replicates; inhalation = 37 replicates; hands = 24 replicates. High confidence in dermal and inhalation data. PHED data used for engineering controls, no PFs were necessary.
Flagger			
Flagging - Granulars (4)	PHED V1.1	500 acres.	**Baseline:** "Best Available" grades: Dermal, inhalation and hand exposure all grades. Dermal = 16 to 20 replicates; inhalation = 4 replicates; and, hand = 4 replicates. Low confidence in dermal and inhalation data. PHED data used for baseline, or 50% PF was applied to total deposition.

Post Application Exposures & Assumptions

EPA has determined that there is potential exposure to persons entering treated sites after application is complete. Postapplication exposures may occur to agricultural workers following applications to the crops identified in the use summary during routine crop-production tasks. There are two chemical-specific studies available for phorate. Two soil residue studies were conducted on potatoes and peanuts. These studies show that residues of phorate and it's metabolites (phorate sulfoxide and phorate sulfone) are detectable in soil up to 93 days after the application. Unfortunately, there is no concurrent human exposure study to accompany these residue dissipation studies. From the residue data, it seems likely that there would be post-application exposure to workers, including harvesters and others exposed to the soil-subsurfaces, following applications of phorate to potatoes, peanuts and other crops. A summary of the studies follows.

Study 1: CL 35,024 (phorate/15G): Residues of CL 35,024, CL 18,177, and CL 18,161 in Soil from a Peanut Plot at-Harvest. MRID No. 416161-02.

The purpose of this study was to assess soil dissipation data at various depths for phorate applied to peanuts as Thimet 15G. This study was conducted at a peanut farm in Chula, GA. Thimet 15G was applied twice, once at planting (July 8, 1989) and once at pegging (August 23, 1989) 46 days later using a John Deere 71 Flexi-unit, a tractor and a Gandy assembly. The application rate was 1.0 lb ai/acre at planting and 2.0 lb ai/acre at pegging. Samples were only collected after the second application at soil depths of 0 to 6 inches, 6 to 12 inches and 12 to 18 inches. Samples were analyzed for phorate, phorate sulfoxide, and phorate sulfone residues. Samples were taken 0, 0.1 and 1, 19, 52, 72, 89, 90, and 93 days after the final application. The residues of phorate in soil were not detected on DAT 72. However for phorate sulfoxide residues were detected on DAT 93 (the last day tested) and phorate sulfone residues were detected up to DAT 89.

Study 2: CL 35,024 (phorate/20G): Residues of CL 35,024, CL 18,177, and, CL 18, 161 in Soil from a Potato Plot at Harvest. MRID No. 416161-03.

The purpose of this study was to assess soil dissipation data at various depths for phorate applied to potatoes as Thimet 20G. This study was conducted at a potato farm near American Falls, Idaho. Thimet 20G was applied once at planting (July 29, 1989) using a four-row curl potato planter attached with a John Deere 71 Flexi-unit. Phorate was applied at 3.1 lb ai/acre. Samples were only collected after the application at soil depths of 0 to 6 inches, 6 to 12 inches and 12 to 18 inches. Samples were analyzed for phorate, phorate sulfoxide, and phorate sulfone residues. Samples were taken 0, 0.1 and 20, 50, 70, and 90 days after the final application. Residues of phorate, phorate sulfoxide, and phorate sulfone were all detectable on DAT 90 (final sample date).

(RISK)

Occupational and Residential

Risk From Handler Exposures

The daily dose is calculated using the following formula:

$$Daily\ Dose\left(\frac{mg}{Kg\ Day}\right) = Daily\ Exposure\left(\frac{mg}{Day}\right) \cdot \left(\frac{1}{Body\ Weight\ (Kg)}\right)$$

These calculations of daily dose of phorate received by handlers are used to assess the risk to those handlers. The Short-Term and Intermediate-Term MOE was calculated using the following formula:

$$MOE = \frac{NOEL\left(\frac{mg}{kg\ day}\right)}{Daily\ Dose\left(\frac{mg}{kg\ day}\right)}$$

The calculations of risk indicate that the MOEs are less than 100 despite maximum mitigation measures (**engineering controls**) for short-term risk and intermediate-term risk for all but two of the exposure scenarios. The MOEs are equal or greater than 100 with **engineering controls** for short-term risk and intermediate-term risk for following scenarios:

- (1b) Loading the granular formulation into ground application equipment;
- (4) Flagging for aerial application of granular formulation (for corn only).

OREB REQUESTS A MEETING WITH THE REGISTRANT TO DISCUSS RISK MITIGATION OPTIONS FOR HANDLERS. UNDER THE PRESENT RISK ASSESSMENT PHORATE USES REPRESENT UNACCEPTABLE RISKS FOR HANDLERS.

Risk from Post Application:

OREB REQUESTS A MEETING WITH THE REGISTRANT TO DISCUSS RISK MITIGATION OPTIONS FOR POST-APPLICATION EXPOSURES. IF RISK MITIGATION MEASURES ALLOW THE APPLICATION OF PHORATE, THEN POST-APPLICATION EXPOSURES AND RISKS MUST BE ADDRESSED.

Data Requirements:

THIS DETERMINATION HAS BEEN POSTPONED PENDING THE OUTCOME OF THE HANDLER AND POST-APPLICATION RISK-MITIGATION DECISIONS.

References:

1) Phorate labels.

2) U.S. EPA 1995. LUIS report of Phorate dated 11/2/95

3) U.S. EPA 1996. Toxicology Endpoint Selection Document, dated 1/30/96.

4) CL 35,024 (phorate/15G): Residues of CL 35,024, CL 18,177, and CL 18,161 in Soil from a Peanut Plot at-Harvest. MRID No. 416161-02.

5) CL 35,024 (phorate/20G): Residues of CL 35,024, CL 18,177, and, CL 18, 161 in Soil from a Potato Plot at Harvest. MRID No. 416161-03.

6) U.S. EPA 1996. Phorate RED Candidate, EFGWB Science Chapter. Memo from John Hunt Jordan, Ph.D.

7) U.S. EPA 1996. Phorate - Review of Pesticide Poisoning Incident Data. Memo from Virginia A. Dobozy, V.M.D.