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

MAR 2 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

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

FROM: Laura Morris, Environmental Scientist Laura Morris

TO: Esther Saito, Chief
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THRU: Alan P. Nielsen, Section Head Laura Morris for
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Please find the OREB review of fenamiphos.

DP Barcode: D187031

Pesticide Chemical Codes: 100601

EPA Reg. Nos.: 003125-00236, 003125-00237, 003125-00283, 3125-333, 3125-269

EPA MRID Nos.: 419017-01

LUIS Report Date: Updated Report 6/8/93 (7/15/93 Cover Memorandum) [replaces initial Report 5/14/92 (5/20/92 Cover Memorandum)

PHED: Yes

This memorandum presents the OREB science chapter review for the Fenamiphos Reregistration Eligibility Document (RED). Occupational and residential exposure data requirements to support the reregistration of fenamiphos are discussed in this chapter. A

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WPS/PPE labelling evaluation has been completed for the active ingredient. Some of the application parameters used to calculate daily exposure levels were based on the professional judgement of the OREB staff. If the risk levels are unacceptable, the Biological Economics and Analysis Division (BEAD) should be requested to further refine the use information for this exposure assessment. The toxicology endpoints used in this assessment are based on cholinesterase inhibition as demonstrated in a 21 day dermal study in rabbits and the maternal toxicity noted in the developmental study. Both studies resulted in NOELs of 0.5 mg/kg/day (memorandum dated 1/14/94 from M. Van Gemert/HED to E. Saito/HED).

Occupational and Residential Exposure

Fenamiphos (Ethyl 3-methyl-4-(methylthio)phenyl-1-(methylethyl) phosphoramidate) is an organophosphate insecticide/nematicide. End-use products include granulars and emulsifiable concentrates[1]. The granular formulations contain 10 and 15 percent active ingredient, respectively. The emulsifiable concentrate formulation contains 35 percent active ingredient.

Fenamiphos is labelled for use on terrestrial food, non-food, and food and feed crops.[1] Use sites are quite varied and include: low, mid-height, and orchard type agricultural crops; turf uses; and ornamental uses. More specifically, agricultural use sites include: low crops (i.e., asparagus, beets, brussel sprouts, cabbage, chinese cabbage, eggplant, garlic, okra, unspecified peanuts, peppers, pineapples, and strawberries); mid-level crops (i.e., cotton, grapes, kiwi, black and red raspberry, and tobacco); and orchard type crops (i.e., apple, cherry, citrus, unspecified deciduous fruit trees, nectarine, unspecified orchards, peaches, and tree nuts). Turf use sites include commercial/industrial lawns; ornamental lawns and turf; sod farms and golf courses. Additionally, ornamental uses include: ornamental and/or shade trees; ornamental herbaceous plants; ornamental nonflowering plants; and ornamental woody shrubs and vines. All uses appear to be outdoors except for some of the ornamental uses which may be inside of greenhouses. Further clarification is needed from BEAD to adequately assess the use of fenamiphos in greenhouses. Fenamiphos controls several varieties of nematodes, thrips, beetles, aphids, and root borers.[1] [Note: There are no residential turf uses allowable for fenamiphos at this time for any label or end-use-product.]

Applications can be made using ground equipment or chemigation. Additionally, a majority of the available labels preclude the use of any knapsack/backpack type equipment. Application types include: chemigation (i.e., low pressure irrigation and solid set irrigation); soil band treatments (i.e., granulars and emulsifiable concentrates); broadcast treatments (i.e., granulars and emulsifiable concentrates); in-furrow treatments; soil injection; and spray/foliar treatments.[1] A majority of the labelled uses require that the applications are soil incorporated and/or watered-in via irrigation or natural rainfall. Additionally, the timing for a majority of applications is at or near planting or the dormant stage for most of the labelled targets (i.e., timing for most application scenarios: posttransplant, postharvest, preemergence, pretransplant, preplant, or at planting). Chemigation application rates (i.e., E.C. formulation only) range up to 4.5 lb ai/acre for typical low pressure irrigation and up to 12 lb ai/acre for solid set irrigation techniques. Rates for ground-based applications of the emulsifiable concentrate formulations range up to: 20 lb ai/acre for broadcast applications; 10 lb ai/acre for soil banding and spray applications; 3 lb ai/acre for soil injection applications and 2.175 lb ai/acre for in-furrow treatments.[1] Rates for the ground-based application of the granular formulations range up to: 10.05 lb ai/acre for banding (i.e., other banding rates were specified based on the row length -

- maximum reported was 0.1725 lb ai/1000 linear feet); and 10 lb ai/acre for broadcast (with the exception of 20 lb ai/acre for pineapples) and in-furrow applications.[1]

Exposure data requirements are triggered based on the potential for exposure and the toxicological significance of the active ingredient. Preliminary exposure analyses for the use/activity patterns associated with fenamiphos have been completed for each handler (i.e., mixer/loader/applicator) scenario of concern to the Agency in order to identify specific exposure scenarios as well as any associated data gaps.

Mixer/Loader/Applicator (Handler) Exposure:

Mixer/loader/applicator (i.e., handler) exposure issues are addressed by Subdivision U of the Pesticide Assessment Guidelines. Mixer/loader/applicator (M/L/A) exposure data were not required by the Registration Standard for Products Containing Fenamiphos.[2]

Based on the use patterns described above, several exposure scenarios are plausible as defined by the types of application equipment and procedures that might be employed by fenamiphos handlers. Each scenario is presented in **Table 1. Summary Exposure Values** along with a corresponding exposure assessment. Each scenario was defined by the types of potential mixing/loading and application equipment that could be employed based on the major use groups for fenamiphos described above.[1] Mixer/loader exposure during chemigation and ground applications is of concern. Applicator exposure is a concern when using ground equipment applications (e.g., broadcast, banding, injection applications, etc.). Exposure values were calculated based on the Pesticide Handlers Exposure Database (PHED).[3] No chemical specific mixer/loader/applicator exposure data were submitted in support of the reregistration of fenamiphos.

Additionally, to clarify the "**Summary Exposure Values**" (Table 1), **Table 2. Exposure Scenario Descriptions for Fenamiphos** is included. This table summarizes the caveats and parameters specific to each exposure scenario. This table also includes a description of the sources for each data point as well as general information pertaining to the techniques used to calculate the corresponding exposure values. The "Data Source" indicates the derivation of the measurements. The "Clothing Scenario" represents the clothing worn by test subjects during the generation of the referenced exposure values. "Equipment" describes the application techniques used to generate the referenced data. The "Formulation" represents which end-use products are addressed. "Standard Assumptions" represent the use scenarios employed by EPA to estimate daily exposure levels. [Note: Assumptions are based on the maximum use rates allowable by the current fenamiphos labels.] The "Comments" section includes any other critical descriptions of the data including information pertaining to the quality of the exposure data (i.e., notations are only included to indicate if the data are in any way considered circumspect).

Data Quality is a critical parameter in the interpretation of the results of any exposure assessment. As indicated above, only PHED exposure data were used to develop the exposure assessments in the "**Summary Exposure Values**" table. Data contained in PHED are assigned grades (A through E) based on the overall quality of the analytical recovery data generated concurrently with actual data points (i.e., laboratory recovery, field recovery and stability data). All PHED-based exposure assessments were based on the **Surrogate Unit Exposure Values for REDs Table** currently being used by OREB as a standard source of exposure values. The

TABLE 1. SUMMARY EXPOSURE VALUES FOR FENAMIPHOS[A]

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (ug/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (μg/kg/day)	MOE Dermal[H,**]
Mixer/Loader Exposure Levels											
Open Mixing Granulars (I)	Nemacur 10 G Nemacur 15 G	All open mixing operations	Variable, see below	Variable, see below	10.0*	100 Acres	0.006	2.4	0.1	40	5.0
Open Mixing Emulsifiable Concentrates (II)	Nemacur 3	All open mixing operations	Variable, see below	Variable, see below	20.0	80	0.15	0.40	4.0	10.7	0.1
Open Mixing For Chemigation (III) [Only ECs are used for chemigation]	Nemacur 3	Low Pressure	Variable	Pome/Stone/Citrus Fruits, Grapes, Kiwi, Pineapple, Tree Nuts, Leather Leaf Fern, Deciduous Fruit Trees	9.0 lb/acre	200			4.5	12.0	0.1
		Solid Set (on LUIS report)	Variable	Ornamental Non-Flowering Plants	12.0 lb/acre	20			0.6	1.6	0.8
Applicator Exposure Levels											
Groundboom Application (IV)	Nemacur 3	In-Furrow	At/Pre-Plant	Cotton, Ornamental Herbaceous Plants	12.0 lb/acre	80	0.01	1.3	0.16	20.8	3.1
			Post-Plant	Ornamental Herbaceous Plants	12.0 lb/acre				0.16	20.8	3.1
		Banding	At/Pre-Plant	Beets, Cotton, Asparagus, Peanuts	2.7 lb/acre				0.04	4.68	12.5
			Pre-Transplant	Strawberry, Asparagus	2.7 lb/acre				0.04	4.68	12.5
			At/Post-Transplant	Eggplant	2.0 lb/acre				0.03	3.47	16.7
				Apple, Cherry, Citrus, Deciduous Fruit Trees, Grapes, Nectarine, Peaches, Tree Nuts	10.0 lb/acre				0.13	17.33	3.8
			Bearing/Foliar	Grapes[H], Citrus[I]	10.0 lb/acre				0.13	17.33	3.8

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (ug/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (µg/kg/day)	MOE Dermal[H,m]
Groundboom Application (cont.) (IV)	Nemacur 3	Banding (cont.)	Fall	Ornamental Herbaceous Plants	12.0 lb/acre				0.16	20.8	3.1
			Nonbearing Nursery-stock	Tree Nuts, Unspecified Deciduous Fruit Trees	9.0 lb/acre				0.12	15.6	4.2
			No Timing Specified	Citrus, Cotton	10.0 lb/acre				0.13	17.3	3.8
			Dormant, Post-Harvest	Asparagus, Raspberry	6.0 lb/acre				0.08	10.4	6.3
			Post-Plant, Pre-Emergent	Asparagus	2.0 lb/acre				0.03	3.5	16.7
		Soil Injection	At/Pre-Plant	Cotton	3.0 lb/acre				0.04	5.2	12.5
		Broadcast/ Spray	At/Pre-Plant	Tobacco, Pineapple	20.0 lb/acre				0.27	34.7	1.9
			Non-Bearing	Grapes, Kiwi, Unspecified Orchards	9.0 lb/acre				0.12	15.6	4.2
			Post-Harvest (Ratoon)	Pineapple	10.0 lb/acre				0.13	17.3	3.8
			Post-Plant, Pre-Emergent	Pineapple	3.0 lb/acre				0.04	5.2	12.5
			Foliar	Sod Farm Turf[I], Ornamental Woody Shrubs and Vines, Ornamental Lawns and Turf, Golf Course Turf[K], Pineapple[L]	10.0 lb/acre				0.13	17.3	3.8

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (ug/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (µg/kg/day)	MOE Dermal[H,**]
Granular Application (V)	Nemacur 10G & 15G	Broadcast	Foliage on Plant[I]	Ornamental Herbaceous Plants, Commercial and Industrial Turf, Golf Course Turf, Ornamental Lawns and Turf, Ornamental Non-Flowering Plants	10.0 lb/acre	50	3.59	678	29.91	5,650	0.02
			At/Pre-Plant	Pineapple	20.0 lb/acre	50	3.59	678.0	59.8	11,300	< 0.1
			Post-Plant	Ornamental Herbaceous Plants (Protea), Ornamental Woody Shrubs and Vines	9.75 lb/acre	10			5.8	1101.8	< 0.1
			Nursery Stock	Ornamental Shade Trees, Ornamental Herbaceous Plants, Ornamental Woody Shrubs and Vines	10.0 lb/acre	10			6.0	1130	< 0.1
	Nemacur 10G & 15G	Banding	At/Pre-Plant	Iris, Lily, Narcissus,	10.0 lb/acre	5	0.001	0.0001	0.0008	0.00008	625
				Cotton, Cabbage, Pepper, Chinese Cabbage, Okra, Peanuts	0.17 lb/1000 row (3.0 lb/acre on 30" rows)	69			0.003	0.0003	167
			1 Year Stock	Iris, Lily, Narcissus	10.0 lb/acre	5			0.0008	0.00008	625
			Pre-Emergent, Post-Plant	Cabbage, Brussel Sprouts	0.17 lb/1000 row (3.0 lb/acre on 30" rows)	69			0.003	0.0003	167

Exposure Scenario (Scen. #)	Formulation[B]	Application Type[C]	Application Timing	Application Targets[D]	Maximum Rate (lb ai/acre)[D]	Daily Maximum Treated[E] (Acres)	Unit Dermal Exposure (mg/lb ai)[F]	Unit Inhalation Exposure (ug/lb ai)[F]	Daily Dermal Exposure[G] (mg/kg/day)	Daily Inhalation Exposure[G] (µg/kg/day)	MOE Dermal[H,**]
Granular Application (V)	Nemacur 10G & 15G	Banding (cont.)	At/Post-Transplant	Strawberries (Production and Nonbearing Nursery Stock), Cabbage, Brussel Sprouts, Eggplant, Citrus Fruit[j], Ornamental Herbaceous Plants	10.05 lb/acre	69			0.01	0.001	50.0
			Pre-Transplant	Strawberries (Production and Nonbearing Nursery Stock)	2.0 lb/acre	69			0.002	0.0002	250
			Any Time[i]	Citrus Fruits	10.05 lb/acre	69			0.01	0.001	50.0
	Nemacur 15 G	In-Furrow	At/Pre-Plant	Cotton, Garlic	4.5 lb/acre	69			0.005	0.0005	100
			Post-Plant	Ornamental Herbaceous Plants	12.0 lb/acre	10			0.002	0.0002	250

A The EPA Reg. Nos. for the fenamiphos formulations considered in this table include: (1) Nemacur 3: 3125-283; (2) Nemacur 10G: 3125-237; and (3) Nemacur 15G: 3125-236. For post application exposure considerations, any crop with a pre-harvest interval of $\leq$ 30 days is noted on an individual basis.

B Denotes fenamiphos formulation for which this exposure scenario is applicable.

C Application type refers to the category as referred to in the LUIS system nomenclature (e.g, banding or broadcast).

D Values are defined based on the maximum application rate for the corresponding application target(s).

E Values represent the maximum number of acres which can be treated on a daily basis. [These assumptions should be validated/refined by BEAD.]

F See Table 2. Exposure Scenario Descriptions For Fenamiphos below for information concerning the source of the data points used in this exposure assessment.

G Daily Exposure (mg/kg/day) = [(Exposure (mg/lb ai) * Max. Appl. Rate (lb ai/acre) * Max. Treated)/60 kg]

H MOE values calculated using the following equation: MOE = NOEL/Exposure, NOEL = 0.50 mg/kg/day based on 21 day maternal toxicity study on rabbits (MRID #s 154497 and 403476-02).

i LUIS reported application time as "foliar" which was interpreted to mean treatments anytime foliage was available on the target of interest. No applications of fenamiphos are directly to foliar surfaces for any target/treatment scenario.

j 2 day Pre-Harvest Interval established by Residue Chemistry Branch for this use.

k 30 day Pre-Harvest Interval established by Residue Chemistry Branch for this use.

* For use on pineapples it is assumed that a maximum of 50 acres may be treated at the maximum rate of 20 lb ai/acre.

** MOEs for Inhalation Exposure were not calculated due to the absence of an inhalation toxicity endpoint.

[Note: Based on label statements, discrepancy exists for the maximum application rate using the banding technique. Also, there is an issue concerning the dermal absorption of granular formulations (data are not documented to support the fact that granulars may not be as readily absorbed dermally as liquid formulations).]

Table 2. Exposure Scenario Descriptions For Fenamiphos[a]

Exposure Scenario (Scen. #)	Data Source	Clothing Scenario	Equipment	Formulation	Standard Assumptions[a] (8 hour workday)	Comments
Mixer/Loader Exposure Levels						
Open Mixing Granulars (I)	PHED	Coveralls, gloves	PHED Open Mixing Category	Granular	Based on various broadcast applications for which up to 1000 lb ai/day can be used.	Dermal data: All grade data/0-14 replicates Inhalation: All grade data/14 replicates
Open Mixing Emulsifiable Concentrates (II)	PHED	Long Sleeves, Long Pants, No Gloves	PHED Open Mixing Category	All Liquids	Based on broadcast preplant treatment of pineapples	50% protection factor applied to unit exposure data as no data were available for the WPS clothing scenario (coveralls over normal work clothing)
Open Mixing For Chemigation (III) [Only ECs are used]	PHED	Long Sleeves, Long Pants, No Gloves	PHED Open Mixing Category	All Liquids	See chemigation for Nemacur 3	Dermal: Grades A&B/14+ replicates for each body part. Inhalation: Grades A&B/40 replicates.
Applicator Exposure Levels						
Groundboom Application (IV)	PHED	Long Sleeves, Long Pants, No Gloves	PHED Groundboom Category/Open Cab	All Formulations		Dermal: Grades A, B, C/6+ replicates Inhalation: Grades A, B, C/56 replicates 50% protection factor applied to unit exposure data as no data were available for the WPS clothing scenario (coveralls over normal work clothing)
Granular Application (V) Broadcast	PHED	Coveralls, gloves	PHED Granular Category	Granular		Data based on combined mixer/loader/applicator activities. However, no adjustments to exposure data were completed based on the nominal exposures noted for the open mixing of granules (Scenario 1) – these values were nominal in comparison. Dermal: Grades C&E/5+ replicates. Inhalation: Grades C&E/19 replicates.
Granular Application (V) Banding and In-Furrow	PHED	Total Deposition	PHED Granular Category	Granular		Dermal and Inhalation: Grades A & B/2 replicates 50% protection factor applied to unit exposure data as no data were available for the WPS clothing scenario (coverall over normal work clothing)

a Standard Assumptions are all based on an 8 hour workday as estimated by OREB. BEAD data were not available to justify many scenarios. Additionally, all standard assumptions were based on the maximum application rate allowable by each end-use product label.

objective for completing this table was to define a series of standard exposure values for OREB use during the RED process. All values were defined using high quality data and a large number of replicates to calculate exposures if the data were available. However, if not available, rangefinder exposure values were calculated using all data available in PHED.

Based on the toxicological endpoints and the significant potential for exposure, fenamiphos meets EPA's criteria for the requirement of mixer/loader/applicator exposure data. See the **Data Requirements** section below for more specific information.

In addition, fenamiphos has been implicated in a handler exposure poisoning incident which resulted in hospitalizing the worker (per conversation 2/94 with J. Blondell/OREB). The Agency is expecting additional human incident data concerning possible worker exposure poisoning. Due to the lack of sufficient data at the time, OREB can not adequately evaluate the potential hazards associated with the use of this chemical which may result in human poisoning.

Post Application/Re-Entry Exposure:

[TO BE INCLUDED AT A LATER DATE]

Restricted Entry Interval (REI):

[TO BE INCLUDED AT A LATER DATE]

Data Requirements:

Based on the results of the MOE calculations (see **Table 1. Summary Exposure Values for Fenamiphos**), the following confirmatory mixer/loader/applicator requirements were identified. The following data are required to support the reregistration of fenamiphos:

Guideline Series	Study Category (Title)	Required Scenarios
231	Estimation of Dermal Exposure at Outdoor Sites	(1) Mixing/Loading with Granulars and Emulsifiable Concentrates (2) Broadcast and Banding Application of Granulars (3) Groundboom Application of Emulsifiable Concentrates
232	Estimation of Inhalation Exposure at Outdoor Sites	(1) Mixing/Loading with Granulars and Emulsifiable Concentrates (2) Broadcast and Banding Application of Granulars (3) Groundboom Application of Emulsifiable Concentrates

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Conclusions:

Fenamiphos is an organophosphate insecticide/acaricide used to control groundborne pests such as nematodes on a variety of agricultural and ornamental crops/targets. Significant potential for exposure to fenamiphos exists via several pathways based on the use patterns of this chemical. Mixer/loader/applicator exposure is of concern as several application scenarios and configurations of application equipment can be typical for the use of fenamiphos. As a result, additional mixer/loader/applicator exposure data are required to adequately evaluate the risks associated with the use of fenamiphos.

Personal Protective Equipment (PPE) Requirements:

PPE selection for mixer/loader/applicators and other handlers will be based on the end-use product. The following statements to be included on the fenamiphos labels are located on the attached Pesticide Worksheets -- Parts One and Two: **Reduce PPE When Engineering Controls Used; User Safety Requirements; Application Restrictions; Entry Restrictions; Early Entry PPE; and Notification Statements.**

The Agency is requiring PPE for applicators, mixer/loaders and other handlers as well as early entry workers consistent with the PPE level required for pesticides classified as Toxicity Category I for acute dermal toxicity. It should be noted that PR Notices 93-7 and 93-11 indicated that fenamiphos is classified as Toxicity Category II, and that existing data indicates fenamiphos should be classified as a Toxicity Category I pesticide (for acute dermal toxicity). OREB recommends that the criteria as specified in the Worker Protection Standards for Toxicity Category I pesticides be adhered to unless data are evaluated which would initiate the need for an amendment.

REFERENCES

1. U.S. EPA, 1992. Label Use Information System Report For Fenamiphos Dated 6/8/93 (Cover Memo Dated 7/15/93); Agency Approved Labels 3125-236 dated 12/10/91; 3125-237 dated 5/8/92; 3125-283 dated 7/20/93.

2. U.S. EPA, 1987. Registration Standard For Products Containing Fenamiphos: Issued .

3. PHED, 1992. The Pesticide Handlers Exposure Database. Developed by Versar, Inc., under contract by the U.S. Environmental Protection Agency (Contract No. 68-D9-0166), Health and Welfare Canada, and the National Agricultural Chemicals Association.

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