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

JUL 21 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EVALUATION OF THE MITIGATION MEASURES PROPOSED BY MILES,INC. IN SUPPORT OF FENAMIPHOS (NEMACUR) REREGISTRATION DATA REQUIREMENTS

TO: Barry O'Keefe, Chemical Manager
Special Review and Reregistration Division (7508W)

FROM: Laura E. Morris, Environmental Scientist Laura E. Morris

THRU: Larry C. Dorsey, Chief
Occupational and Residential Exposure Branch
Health Effects Division (7509C)

This memorandum addresses the mitigation techniques proposed by the registrant in an effort to reduce potential worker exposure to fenamiphos. The proposed techniques were initiated by the registrant based on the results of the worker exposure assessment presented in the Reregistration Eligibility Decision document for Fenamiphos: Case #0333. SRRD has requested that OREB conduct an exposure assessment for the major use sites and provide Margins of Exposure based on this assessment.

Table 1. Summary Exposure Values Including the Proposed Mitigation Techniques presents exposure scenarios presented by the registrant in the mitigation proposal. Each scenario was defined by the types of potential mixing/loading and application equipment that could be employed based on the major use sites. An assessment was conducted for those sites which were determined to be the major use sites and representative of the use patterns.

Explanation of Some Table Descriptions:
"Proposed Application Rates" - Proposed application rates were provided by BEAD. According to the information presented these are the maximum application rates proposed by the registrant. It should be noted that these rates are not reflected on the current labels.

"Daily Maximum Acres Treated" - The estimated acres treated per day were based on the table provided from the registrant and the information on farm size provided by BEAD, with the exception of acres/day for chemigation which was estimated based on OREB's use information in conjunction with the registrant's information. [According to BEAD (conversation with R. Michell, 7/14/95), the figures presented by the registrant and the farm size information prepared by E. Mauer/BEAD (4/7/95) should be used to assess worker exposure. OREB recommends that BEAD verifies the use information used to conduct this exposure assessment to confirm that it is in accordance with usage and rate modifications.]

(1)

"Unit Dermal Exposure" and "Unit Inhalation Exposure" based on surrogate exposure data from PHED Version 1.1. There was high confidence in the data for all exposure scenarios except groundboom application for enclosed cabs for which there is medium confidence in the data.

[Note: It was discussed at the Fenamiphos Team meeting, that ornamentals were not a primary site of concern based on percent crop treated usage information, and that the decision to conduct an assessment on ornamentals would be based on poisoning incident data. According to discussion with J. Blondell/OREB (5/1/95) [summary of incidents forwarded electronically 5/1/95 to B. O'Keefe/SRRD and J. Smith/HED], from 1985 - 1991 there were a total of 7 cases reported from California: In 1990, 29 of the 2,396 fenamiphos applications were on ornamentals, and the number of reported incidents were low. In addition, from the 19 incidents reported from the poisoning center, it could not be determined if any of the incidents were based on ornamental use. Based on this information, an assessment was not conducted on ornamentals.]

Table 2. Summary of Exposure Values and Risk Calculations presents the daily dermal and inhalation exposure calculations. In addition, the margins of exposure are indicated based on both the estimated combined dermal and inhalation exposure and the NOEL of 0.5 mg/kg/day from Tox II/HED.

TABLE 1. SUMMARY EXPOSURE VALUES INCLUDING PROPOSED MITIGATION TECHNIQUES FOR FENAMIPHOS

Exposure Scenario	Formulation	Application Type	Crops	Proposed Application Rate (lb ai/acre)*	Daily Maximum Acres Treated	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (ug/lb ai)
Open Mixing Emulsifiable Concentrates	Nemacur 3 EC	Open mixing operations	citrus	7.5	200	0.04[1]	1.2
			cotton	3.0	50		
			fruit trees (peaches)	7.5	28	0.02[2]	
			grapes	6.0	40		
			tobacco	6.0	50		
			turf	10	10		
Closed Mixing Emulsifiable Concentrates	Nemacur 3 EC	Closed mixing operations	citrus	7.5	200	0.009[1]	0.08
			cotton	3.0	50		
			fruit trees (peach)	7.5	28		
			grapes	6.0	40		
			tobacco	6.0	50		
			turf	10	10		

Table 1. Summary Exposure Values Including Proposed Mitigation Techniques for Fenamiphos (continued)

Exposure Scenario	Formulation	Application Type	Crops	Proposed Application Rate (lb ai/acre)	Daily Maximum Acres Treated	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (ug/lb ai)
Open Mixing for Chemigation	Nemacur 3EC	Low Pressure	citrus	3.0	800**	0.04[1]	1.2
			fruit trees		28	0.02[2]	
			grapes		40		
			turf	10.0	10		
Closed Mixing for Chemigation	Nemacur 3EC	Low Pressure	citrus	3.0	800**	0.009[1]	0.08
			fruit trees		28		
			grapes		40		
			turf	10.0	10		
Open Mixing Granulars	15G	All open mixing	cotton	3.0	50	0.006[1] 0.003[2]	1.7
	10G		turf	10.0	10		
Closed Mixing Granulars	15G		cotton	3.0	50	0.0001[1]	0.034
	10G		turf	10.0	10		

Table 1. Summary Exposure Values Including Proposed Mitigation Techniques for Fenamiphos (continued)

Exposure Scenario	Formulation	Application Type	Crops	Proposed Application Rate (lb ai/acre)	Daily Maximum Acres Treated	Unit Dermal Exposure (mg/lb ai)	Unit Inhalation Exposure (ug/lb ai)
			Applicator Exposure				
Groundboom Application open cab	Nemacur 3EC	Banding	citrus	7.5	200	0.01[1A]	0.7
			cotton	3.0	50		
			fruit trees	7.5	28		
			grapes	6.0	40		
			tobacco	6.0	50		
			turf	10	10		
	15G		cotton	3.0	50		
			turf	10	10		
Groundboom Application enclosed cab	Nemacur 3EC	Banding	citrus	7.5	200	0.007[1A]	0.04
			cotton	3.0	50		
			fruit trees	7.5	28		
			grapes	6.0	40		
			tobacco	6.0	50		
			turf	10	10		
	15G		cotton	3.0	50		
			turf	10	10		

[1] PHED Clothing Scenario - workers wearing long sleeved shirts, long pants, and chemical resistant gloves.
[1A] Workers wearing long sleeved shirts, long pants, and no gloves.
[2] PHED Clothing Scenario - workers wearing coveralls over long sleeved shirts, long pants, and chemical resistant gloves.

TABLE 2. SUMMARY OF EXPOSURE VALUES AND RISK CALCULATIONS

Exposure Scenario	Formulation	Application Type	Crops	Daily Dermal Exposure (mg/kg/day)	Daily Inhalation Exposure (mg/kg/day)	MOE (dermal and inhalation)
Open Mixing Emulsifiable Concentrates[3]	Nemacur 3 EC	Open mixing operations	citrus	0.5	0.03	$9.4*10^{-1}$
			cotton	0.05	$3.0*10^{-3}$	9.43
			fruit trees (peaches)	0.07	$4.2*10^{-3}$	6.74
			grapes	0.08	$4.8*10^{-3}$	5.9
			tobacco	0.1	$6.0*10^{-3}$	4.72
			turf	0.03	$2.0*10^{-3}$	94
Closed Mixing Emulsifiable Concentrates[4]	Nemacur 3 EC	Closed mixing operations	citrus	0.225	0.002	2.20
			cotton	0.022	$2.0*10^{-4}$	22
			fruit trees (peach)	0.032	$2.8*10^{-4}$	15.7
			grapes	0.036	$3.2*10^{-4}$	13.8
			tobacco	0.045	$4.0*10^{-4}$	11.1
			turf	0.015	$1.3*10^{-4}$	33.3

0.1

Table 2. Summary of Exposure Values and Risk Calculations (continued)

Exposure Scenario	Formulation	Application Type	Crops	Daily Dermal Exposure (mg/kg/day)	Daily Inhalation Exposure (mg/kg/day)	MOE (dermal and inhalation)
Open Mixing for Chemigation[3]	Nemacur 3EC	Low Pressure	citrus	0.8	0.048	$5.89*10^{1}$
			fruit trees	0.028	0.0017	16.7
			grapes	0.04	0.0024	11.8
			turf	0.033	0.002	14.2
Closed Mixing for Chemigation[4]	Nemacur 3EC	Low Pressure	citrus	0.36	0.0032	1.38
			fruit trees	0.0126	$1.1*10^{-4}$	39.4
			grapes	0.018	$1.6*10^{-4}$	27.5
			turf	0.015	$1.3*10^{-4}$	33
Open Mixing Granulars[3]	15G	All open mixing	cotton	0.0075	$4.25*10^{3}$	42.5
			turf	0.005	$2.83*10^{-3}$	63.9
Closed Mixing Granulars[4]			cotton	0.00025	0.00085	1,515
			turf	$1.67*10^{-4}$	$5.67*10^{-5}$	2,232

0.1

5.0

(2)

Table 2. Summary of Exposure Values and Risk Calculations (continued)

Exposure Scenario	Formulation	Application Type	Crops	Daily Dermal Exposure (mg/kg/day)	Daily Inhalation Exposure (mg/kg/day)	MOE (dermal and inhalation)
Applicator Exposure						
Groundboom Application open cab[5]	Nemacur 3EC	Banding	citrus	0.25	0.0175	1.87
			cotton	0.025	$1.75*10^{-3}$	18.7
			fruit trees	0.035	$2.45*10^{-3}$	13.4
			grapes	0.04	0.0028	11.7
			tobacco	0.05	0.0035	9.34
			turf	0.0167	$1.17*10^{-3}$	27.9
	15G		cotton	0.025	$1.75*10^{-3}$	18.7
			turf	0.0167	$1.17*10^{-3}$	27.9
Groundboom Application enclosed cab[5]	Nemacur 3EC	Banding	citrus	0.175	0.001	2.84
			cotton	0.0175	0.0001	28.4
			fruit trees	0.0245	0.00014	20
			grapes	0.028	0.00016	17.7
			tobacco	0.035	0.0002	14.2
			turf	0.0117	$6.67*10^{-5}$	29.2
	15G		cotton	0.175	0.001	2.84
			turf	0.012	$6.67*10^{-5}$	29.2

Footnotes for Table 2. Summary of Exposure Values and Risk Calculations

[3] Daily dermal expsosure values based on workers wearing coveralls over long sleeved shirts and long pants, and chemical resistant gloves.

[4] Daily dermal exposure values based on workers wearing long sleeved shirts, long pants, and chemical resistant gloves.

[5] Daily dermal exposure values based on workers wearing long sleeved shirts, long pants and no gloves.

Daily exposure (mg/kg/day) = [(Exposure (mg/lb ai) * Max. Application Rate (lb ai/acre) * Max. Treated)/60 kg (body weight)]

MOE = NOEL/Exposure, NOEL = 0.50 mg/kg/day based on 21 day maternal toxicity study on rabbits.

CONCLUSIONS/RECOMMENDATIONS

Margins of Exposure were less than 100 for all exposure scenarios which the exception of closed mixing/loading for granular formulations. The registrant has reduced the application rates, the number of acres treated per day, and in some cases cancelled the use of the granular formulation on some crops. Therefore, it is not probable that additional mitigation techniques would result in acceptable MOEs. The registrant may want to consider providing dermal absorption data if the data would demonstrate that absorption was significantly less than 100%.

Attachments (4)

cc: Laura Morris/OREB (w/Attachments)
Paula Deschamp/HED/7509C
Jane Smith/HED/7509C
Rich Michell/BEAD/7503W (w/Attachments)
Chemical File
Correspondence File

Attachment 1

Table 1. PROPOSED FENAMIPHOS RISK REDUCTION USE PROFILE[1/] (6/5/95 Draft)

CROP	FORMULATION	PESTS	PROPOSED APPLICATION RATE (LBS. AI/A)[2/]	METHOD OF APPLICATION (TIMING)	COMMMENTS[3/]
CITRUS	3EC [Granular proposed to be cancel-led]	Nematodes, suppression of Citrus root weevil complex (including Fuller rose beetle)	2.5-5.0 (FL); 5.0-7.5 (other states)	Band & Inc., band width = 50% of row spacing (postplant)	PHI = 30 days; In CA, do not apply to Kumquat, Tangelo or Citrus hybrids; see also Florida limitations[4/]; <u>Band:</u> maximum seasonal rate = the maximum application rate; maximum of 2 applications per season <u>Chemigation:</u> seasonal limit = 3-6 lbs ai/acre (FL= 3-4.5 lbs); maximum of 4 applications/ season; RAI = 30 days;
			1.5-3.0 (all states)	Chemigation [low pressure irrigation] (postplant)	

CROP	FORMULATION	PESTS	PROPOSED APPLICATION RATE (LBS. AI/A)[2/]	METHOD OF APPLICATION (TIMING)	COMMMENTS[3/]
COTTON	3EC	Nematodes, Thrips	1.5-3.0 (40" rows)	18" Band Soil Inject. (preplant)	CA only; maximum rate of 3 lbs ai/A (any row spacing)
			0.75-2.2 (40" rows)	IF or covered Band, or 6-12" Band & Inc. (at planting)	EC label also recommends an at planting tank mix with Treflan applied as a 12-18" band
	15G		1.0-1.5 (40" rows)	IF (at planting)	
FRUIT TREES (PEACH)	3EC	Nematodes	5.0-7.5	Band & Inc., band width equal to 50% of row spacing (postplant); incorporate mechanically or with irrigation	PHI = 45 days; Band: 7.5 lbs ai/A/year; Chemigation: 1-4 applications per season; 3-6 lbs ai/A/season; RAI = 30 days
			1.5-3.0	Chemigation [low pressure irrigation] (postplant)	

CROP	FORMULATION	PESTS	PROPOSED APPLICATION RATE (LBS. AI/A)[2/]	METHOD OF APPLICATION (TIMING)	COMMMENTS[3/]
GRAPES	3EC	Nematodes	1.5-3.0	Chemigation [low pressure irrigation] (postplant)	PHI = 2 days; maximum of 6 lbs ai/A/season; Chemigation: 1-4 applications/ season; 3-6 lbs ai/A/season; RAI = 30 days
			3.0-6.0	Band & Inc., band width = 50% of row spacing (postplant)	
TOBACCO (excludes shade tobacco)	3EC	Nematodes, suppression of Aphids	4.0-6.0	Broadcast & Inc. (preplant)	label also recommends two tank mixes with insecticides (chlorpyrifos, ethoprop)
TURF (Sod farms, Golf courses, Cemeteries, Industrial grounds)	10G	Nematodes	10	Broadcast & Inc. w/irri-gation (post-plant)	1-2 applications per year; EC formulation is not recommended for use on tees and greens; Many restrictions on both formulat-ions[5/]
TURF (Golf courses, Sod farms)	3EC	Nematodes	10	Broadcast (coarse spray) & Inc. w/irri-gation (post-plant)	

Abbreviations: Inc. = Incorporate; IF = In-furrow; RAI = repeat application interval; PHI = preharvest interval

1/ Reflects risk reduction proposals submitted by Miles, Inc. on 10/26/94 and amended by their 1/6/95 letter.

2/ Where specific row spacings are listed for specific rates, these rates will vary inversely with changes in the row spacing utilized. The row spacings listed were obtained from the labels and documents published by one or more major production states and are presumed to reflect commonly used row spacings. Preliminary estimates of overall seasonal rates, calculated from national usage data (i.e., total pounds applied ÷ total acres treated, for each crop), are: Citrus = 6.2 lbs/A; Cotton = 0.75 lbs/A; Peaches = 11.5 lbs/A; Grapes = 1.3 lbs/A; Tobacco = 3.4 lbs/A; no information available on turf usage.

3/ The following general use restrictions apply to all labeled crops, except turf and ornamentals: "When used on erodible soils, best management practices for minimizing runoff should be employed. Consult your local Soil Conservation Service for recommendations in your use area."; "Do not apply within 100 feet of the following aquatic areas: lakes, resevoirs, rivers, permanent streams, marshes, natural ponds and estuaries."; "Do not cultivate within 10 feet of an aquatic area to allow growth of a vegetative filter strip."

4/ Florida Use Restrictions: a] "Apply between October 15 and April 30"; b] "Do not apply within 300 ft. of a drinking water well. If soils have a permeability rate greater than 20 inches per hour, do not apply within 1,000 ft of a drinking water well unless it is known or reasonably believed based on authorative sources that such wells are either cased to 100 ft below ground level or a minimum of 30 ft below the water table."

5/ Only for use on golf courses and sod farms in CA; Do not apply more than 20 lbs ai/A/year; Do not treat more than 10 acres at a time on any golf course, with a 3-day minimum interval before an additional 10 acres (or less) can be treated; Do not apply w/in 10' of any surface body of water or fairway surface drains; Do not apply between noon and sunset during the heavy thunderstorm season (June thru September); On sod farms, treated turf should not be cut for sod or sod handled for 30 days after treatment; Do not apply product after soil has become saturated with water (reached field capacity); apply irrigation only so that puddling or runoff does not occur; Irrigation must be completed within 6 hours after treatment;

Attachment 2

[R. Michell 4/18/95]

SUMMARY OF PROPOSED USE-RELATED RISK MITIGATION LABELING CHANGES FOR FENAMIPHOS (10/20/94 LABELING DRAFTS & 1/6/95 Letter)

ALL CROPS (Excluding Turf & Ornamentals) -

EC & 10G Formulations:

- imposed the restriction "When used on erodible soils, best management practices for minimizing runoff should be employed. Consult your local Soil Conservation Service for recommendations in your use area.";
- imposed the restriction "Do not apply within 100 feet of the following aquatic areas: lakes, resevoirs, rivers, permanent streams, marshes, natural ponds and estuaries.";
- imposed the restriction "Do not cultivate within 10 feet of an aquatic area to allow growth of a vegetative filter strip."

CITRUS -

EC Formulation:

band treatment

- lowered maximum application rate, in states other than FL, from 10 to 7.5 lbs ai/A;
- lowered the dosage range in FL from 5 to 10 to 2.5 to 5 lbs ai/A
- lowered maximum seasonal rate, in states other than FL, from 10 to 7.5 lbs ai/A/season;
- imposed a restriction in FL prohibiting applications within 300 to 1,000 ft of a drinking water well (see label for precise language);
- lowered the maximum seasonal rate, in FL, from 10 to 5 lbs ai/A/season.

chemigation

- lowered the maximum application rate, in all states, from 4.5 to 3 lbs ai/A;
- lowered the maximum number of applications, in all states, from 6 to 4 per season;
- increased the repeat application interval, in all states, from 14 to 30 days;
- lowered the seasonal dosage range, in states other than FL, from 4.5 to 9 to 3 to 6 lbs ai/A/season;
- lowered the seasonal dosage range, in FL, from 4.5 to 10 to 3 to 4.5 lbs ai/A/season;
- imposed a restriction in FL prohibiting applications within 300 to 1,000 ft of a drinking water well (see label for precise language);
- imposed a limitation in FL that applications must be made between October 15 and April 30.

15G Formulation:

- proposed to cancel (band treatment).

COTTON -

EC Formulation:
- no changes proposed (in-furrow, covered or incorporated band, and soil injection [band] treatments).

15G Formulation:
- no changes proposed (in-furrow treatment).

TOBACCO (excluding shade tobacco) -

EC Formulation:
- no changes proposed (preplant broadcast treatment).

Granular Formulations:
- not registered.

PEACHES -

EC Formulation:

band treatment -

- changed dosage range from 5 to 10 to 5 to 7.5lbs ai/A;
- reduced maximum amount applied/year from 10 to 7.5 lbs ai/A/year;

chemigation treatment -

- changed dosage range from 1.5 to 4.5 to 1.5 to 3 lbs ai/A;
reduced the maximum no. of applications per season from 6 to 4;
- increased the repeat application interval from 14 to 30 days;
- lowered the minimum and maximum amounts applied per season from 4.5 to 9 to 3 to 6 lbs ai/A/season.

Granular Formulations
- not registered.

GRAPES -

EC Formulation:

band treatment -

- lowered the dosage rate from 3 gal/A to 1 to 2 gal/A;
- lowered the maximum amount/season from 3 to 2 gal/A.

chemigation treatment -

- changed the dosage range from 1 qt to 1 gal to 2 qt to 1 gal/A;
- changed the total no. applications from one or more to 1 to 4 applications;
- added a 30 day minimum interval between repeat applications.

Granular Formulations

- not registered.

TURF -

EC & 10G Formulations:

broadcast treatment -

- imposed a 10 acre maximum treatment area on any golf course with a 3-day minimum interval before an additional 10 acres (or less) can be treated;
- imposed a prohibition against applications within 10 ft. of any surface body of water or fairway surface drain;
- imposed a prohibition against applications being made between noon and sunset during the heavy thunderstorm season (June thru September);
- delete claim for control of mole crickets.**

** Note: stated in their letter, but not reflected on labeling.

(16)

Attachment 3

The following list reflects the average farm size by state and site. The numbers in parentheses are estimates of the relative percentage of total US fenamiphos usage for each site. (E. Maurer 4/7/95)

CITRUS:
- CA - 35 acres (27)
- FL - 108 acres (73)

COTTON:
- CA - 453 acres (5)
- NC - 176 acres (4)
- SC - 223 acres (20)
- TX - 322 acres (71)

GRAPEVINES:
- CA - 73 (99)
- MI - 15 (1)

PEACHES:
- CA - 28 acres (34)
- MI - 9 acres (33)
- NC - 7 acres (33)

TOBACCO:
- FL - 30 acres (1)
- GA - 24 acres (19)
- NC - 16 acres (58)
- SC - 26 acres (19)
- VA - 7 acres (3)

GOLF COURSES:
- CA - 125 acres (5.9)
- FL - 128 acres (8.0)
- MI - 134 acres (6.1)
- NY - 138 acres (6.5)
- OH - 136 acres (6.0)

Attachment 4

NEMACUR

MIXER/LOADER/APPLICATOR INFORMATION

CROP	UNIT SIZE	HR/DAY		HR/YR		NO. OF MLA	APPL TYPE (%)			ACRES/DAY		
		ML	A	ML	A		LPI	BAND	BCST	LPI	BAND	BCST
TOBACCO/NC	<25 A		6		12	2	0	0	100	0	0	12
NC	>100 A		8		24	1	0	0	100	0	0	35
NC	Custom		10		400	1	0	0	100	0	0	55
GA	100 A	1.3	10	2.6	20	2	0	35	65	0	50	50
CITRUS/FL-EC			1		2	1	80	0	0	200	0	0
FL-G			8		8	1	0	20	0	0	200	0
CA-EC			2-4		210-420	1(80%)	50	50	0	6	6	
COTTON		0.7	6	2.2	18	1-2	0	100	0	0	40-50	0
PEANUT		0.7	6	2.2	18	1-2	0	100	0	0	40-50	0
GRAPE 1			8		24	1	85	15	0	80	40	0
2			1-3		13-39	1(80%)	95	5	0	20	1	0
3		/1	1/4	/112	332/414	1(90%)	85	15	0	34	18	0
CABBAGE			1-4		24-96	1(95%)	0	100	0	0	7	0
BROCCOLI			1-6		10-60	1(95%)	0	100	0	0	10	0
PINEAPPLE/HI			2-4		78-156	1(75%)	75	0	25	10	0	3
TURF			6		12-36	1(20%) 2(60%)	0	0	100	0	0	3-8 EC 25-40 G