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211299
RECORD NO.

SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 1-11-88 OUT 3/15/89

FILE OR REG. NO. 3125-269

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 12-17-87

DATE RECEIVED BY HED 1-7-88

RD REQUESTED COMPLETION DATE 3-4-88

EEB ESTIMATED COMPLETION DATE 3-4-88

RD ACTION CODE/TYPE OF REVIEW 660

TYPE PRODUCT(S) : I, D, H, F, N, R, S Insecticide/nematicide

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. L. Rossi(21)

PRODUCT NAME(S) Fenamiphos

COMPANY NAME Mobay

SUBMISSION PURPOSE Registrant follow-up to Reg. Standard

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
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7 pages with Attachment (2 pages)

ECOLOGICAL EFFECTS BRANCH

Chemical: Fenamiphos

100.0 Submission Purpose

On December 17, 1987, the Registrant (Mobay Corporation) submitted a letter requesting clarification of Registration Standard Data Requirements relative to required label changes and field testing on birds and mammals. In two subsequent letters (10/19/88 and 11/28/88) the Registrant has requested meetings with the EEB to discuss both the aquatic and terrestrial data requirements set forth in the Standard. However, due to various work load priorities and scheduling problems, these meetings were not held.

On January 6, 1989, the Registrant again requested that the EEB meet with them to discuss and review the study plan for work in 1989 for the terrestrial field studies (EPA Guideline No. 71-5). Specifically the Registrant wanted to cover the following points:

1. Description of study sites
2. Species at risk and routes of exposure
3. Citrus study plan
4. Golf course study plan
5. Tobacco study plan

In addition, the Registrant also wanted to get some clarification of requirements for tests on aquatic organisms. Specifically, the registrant wanted clarification on:

- 72-1 - Acute Toxicity to freshwater fish
- 72-2 - " " " " invertebrates
- 72-3 - " " " estuarine/marine organisms
- 72-4 - Fish early life stage and aquatic invertebrate life cycle
- 72-5 - Fish life cycle
- 72-6 - Aquatic organism accumulation
- 72-7 - Simulated/Actual field test-aquatic organisms

On February 14, 1989, the EEB, in two separate sessions met with representatives of Mobay Corporation to discuss these issues. As a result of this meeting, the EEB has prepared the following review to clarify the data requirements specified in the Standard.

101.0 Data Requirements

101.1 Terrestrial Field Study Discussion

The meeting centered around three main issues: (1) Which formulation should be used in the tobacco study?, (2) Which formulation should be used in the turf study? and (3) Should the level II study in citrus still be required since broadcast applications on citrus are no longer allowed by the Nemacur 15% Granular label?

Tobacco Issue

The registrant mentioned that, in a previous letter to the Agency (dated 10/21/88), due to a lack of sales, tobacco was removed from the Nemacur 15% granular label. The EEB informed the registrant that it was unaware the 15G formulation was removed from the label and that until such time as the EEB was formally notified by the Registration Division, the data requirement was still in effect. The EEB informed the registrant that even if the label has been changed, a similar type study, using the broadcast application of the 15G formulation on soybeans, would still be required to satisfy the data requirement.

Turf Issue

The Generic Data Requirements as specified in the Reregistration Standard call for testing the 15% G formulation for the sod and turf uses (primarily golf courses). The registrant claims that most golf courses use Nemacur 10% Turf and Ornamental Nematicide on the tees and greens only and use Nemacur 3 Turf Nematicide on the fairways due to its ease of application. As such they would like to conduct a field test accordingly. The EEB responded by saying that such a study would be acceptable provided the 15% G formulation, currently registered for such use, was removed from the label.

Citrus Issue

Because of the numerous avian and mammalian species that extensively utilize citrus orchards for feeding, nesting, loafing and cover habitat, the EEB decided this would be a good use pattern for conducting an extensive field study (Level II) for acute and subacute effects from either the 15% granular or the 3 lb./gal. EC formulations. Apparently, the Registrant has voluntarily removed citrus from the Nemacur 15% granular label. The EEB believes that, in order to satisfy the outstanding data requirement for citrus that a Level II study using the 3 lb./gal EC formulation as a broadcast application is now required.

Additional Field Studies

The EEB reminds the Registrant that the footnotes to the

Generic Data Requirements Table also stated that a field study using the band application of the 15% granular formulation in fruit trees (peaches, apples or cherries), at 20 lbs. ai/acre, is required.

In summary, the EEB has determined that because certain uses of the 15% granular formulation have been removed from the current label, the following field tests are now required to satisfy the outstanding data requirements:

1. Soybean field study using the 15% granular applied as broadcast application;
2. Golf course field study using the 10% granular on the tees and greens and the Nemacur 3 formulation on the fairways;
3. Fruit tree (apple, peach or cherry) study using the 15% granular formulation (band application); and
4. A citrus study (Level II) using the 3 lb./gal. EC formulation as a broadcast treatment.

101.2 Aquatic Testing Discussion

In a letter dated October 19, 1988, the Registrant informed the Agency that it had submitted, on August 18, 1988, studies to satisfy the following data requirements:

1. 72-1 - Acute toxicity to freshwater fish
2. 72-2 - " " " " invertebrates
3. 72-3 - " " " estuarine/marine organisms

The registrant also informed the EEB that the following studies were in progress and will be available upon completion:

1. 72-4 - Invertebrate Life Cycle
2. 72-4 - Fish Early Life Stage

In the separate session on aquatic testing, the discussion mainly concerned the need to conduct tests to satisfy the aquatic generic data requirements 72-5, 72-6, and 72-7.

72-5 -Fish Life Cycle

It was decided that this data requirement will be reserved pending results of the fish early life stage and daphnia chronic tests.

72-6- Aquatic Organism Accumulation

The registrant has completed a bluegill accumulation study which showed the chemical to have a BCF of 110X. The Registrant believes that this study shows that the chemical does not pose any bioaccumulation problems and that the data requirement has been satisfied. The EEB will reserve comment until such time as the EFGWB has reviewed the study and commented as to its adequacy to satisfy the data requirement.

72-7- Simulated/Actual Field Test-Aquatic Organisms

Before undertaking an actual field study, the Registrant wants to conduct an exposure study to determine actual residues from runoff and drift. There was considerable discussion as to a monitoring study protocol. It is EEBs' opinion that until such time as the Registrant clearly shows that EECs are not representative of "actual residues", that a mesocosm study is required.

102.0

Summary Discussion

To date, the EEB has not reviewed any of the submitted aquatic studies for data adequacy. As such, the EEB will withhold any comment relative to these studies until such time as they have been evaluated.

The fish life cycle study will remain "reserved" pending the results of the fish early life stage and daphnia chronic tests.

Relative to the aquatic organism accumulation study, the EEB will withhold comment until such time as the EFGWB has had time to review and comment on the adequacy of the bluegill accumulation study.

Until such time as the Registrant clearly shows (i.e. actual field monitoring of residues) that EECs are not representative of "actual" field residues, the mesocosm study is required.

The EEB believes, given the proposed label changes, that the following terrestrial field studies are required to meet the Generic Data Requirements for Fenamiphos:

1. Soybean field study using the 15% granular applied as broadcast application;
2. Golf course field study using the 10% granular on the tees and greens and the Nemacur 3 formulation on the fairways;
3. Fruit tree (apple, peach or cherry) field study

using the 15% granular formulation (band application); and

4. A citrus study (Level II) using the 3 lb./gal. EC formulation as a broadcast treatment.

103.0 ADDENDUM TO REVIEW.

As a result of the Registrant (Mobay) removing various use patterns from the registered labels and because the EEB was never fully apprised of these changes, the EEB (R. Felthousen and E. Fite) and a representative from the Registration Division (S. Jackson) met on Wednesday, March 1, 1989 to again discuss what field studies needed to be conducted to satisfy the Reregistration data requirement. The EEB met with Mr. John Thornton and Mr. Dave Fisher. As a result of this meeting the following field studies are required to support the registration of fenamiphos:

<u>Use Pattern</u>	<u>Incorporation Formulation</u>	<u>Technique</u>	<u>Level</u>
Golf Course ¹	EC	Irrigated	I
Golf Course ²	10 G	Irrigated	I
Citrus ³	15 G	Mechanical	I
Citrus ⁴	EC	Irrigated	II
Tobacco ⁵	EC	Mechanical	I

¹ Reports from golf course superintendents suggest that this use pattern impacts birds feeding on the target pest (i.e. mole crickets). The EC formulation is typically used on fairways.

² The 10 G can be used on golf courses and is typically used on greens.

³ This study will satisfy data requirements for the peanut and cotton use patterns.

⁴ This study will satisfy data requirements for many use patterns requiring irrigation

⁵ This study will satisfy use patterns for crops requiring mechanical incorporation for the EC.

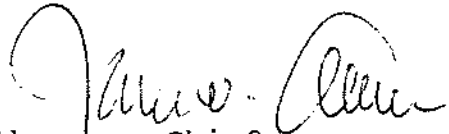
 3/10/89

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3.15.89

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December 17, 1987

Subject: NEMACUR® Fenamiphos Insecticide-Nematicide
Clarification of Registration Standard Data Requirements

Dear Ms. Rossi:

In addition to the items noted in our previous letters, there are several data requirements in the registration standard guidance document for fenamiphos that require further clarification by the Agency. We ask that the Agency review the following matters immediately and provide Mobay with written clarification as soon as possible.

A. Clarification of Required Label Changes and Requirement for Field Testing on Birds and Mammals (Guideline No. 71-5)

Section IV "Regulatory Position and Rationale" (Paragraph 4 on page 49) of the guidance document states that all labels are required to be revised as follows: "(1) Directions for broadcast spray will be deleted for sites which currently have directions for both band and broadcast spray; (2) All labels will prohibit the use of mist sprayers and will direct applicators to use only coarse sprays directed at the soil to reduce the possibility of spray drift; (3) All labels will specifically prohibit aerial application."

Table A, "Generic Data Requirements for Fenamiphos", page 102, footnote 2, states, in part, "Actual field testing with birds and mammals is required as per 40 CFR 158.145 with a typical granular formulation. Initial sites to be tested, based on application rates and wildlife usage information, include tobacco, citrus, sod and turf (broadcast applications)."

With respect to these requirements in the registration standard guidance document we hereby request that the Agency provide Mobay with written clarification as to the following points:

1. The guidance document does not address label claims for broadcast application of granular formulations of fenamiphos to sites for which band application claims are also registered. The "Regulatory Position and Rationale" section refers only to "broadcast spray" applications which means that only the label for NEMACUR 3 Emulsifiable, EPA Reg. No. 3125-283 must be changed in order to comply with this requirement. The question we pose is what is the Agency's intention with respect to label claims for broadcast applications of NEMACUR 15% Granular, EPA Reg. No. 3125-236, to sites for which band applications are also registered?

2. If the Agency's response to Point 1 is that we are required to delete label claims for broadcast application of NEMACUR 15% Granular to sites for which band applications are also registered, then the requirement in Table A (page 102, footnote 2) for field testing on birds and mammals using broadcast applications of a typical granular formulation of fenamiphos to citrus is clearly not appropriate and such field testing, if required, should be conducted using band applications on citrus. Since only broadcast applications are claimed for tobacco and turf on labeling for products containing fenamiphos, any required avian/mammalian field testing on these sites should be conducted with broadcast applications.
3. Although, as we have noted above, Section IV "Regulatory Position and Rationale" of the guidance document states that claims for broadcast spray application must be deleted for sites which also have band application claims, this is not specified in the "Labeling" requirements on pages 54 through 59. Therefore, to be sure we know what is actually being required in the way of label changes, we request that the Agency clarify whether or not the labeling for NEMACUR 3 Emulsifiable must be revised to delete claims for broadcast spray application on crops for which band application claims are also registered.

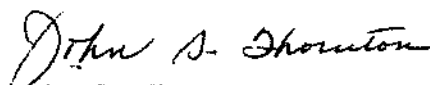
B. Clarification of Requirements for Tests on Aquatic Organisms

Section IV "Regulatory Position and Rationale" (first paragraph on page 48) of the guidance document and the "Pesticide Fact Sheet" for fenamiphos (last paragraph on page 5) state that estimated environmental concentrations (EEC's) for water contaminated by aerial application to crops and runoff exceed the LC₅₀ values for bluegill sunfish, and therefore, would cause significant adverse effects. On this basis the Agency is requiring (Table A, pages 99 through 101) data on freshwater fish toxicity (Guideline No. 72-1), freshwater invertebrate toxicity (Guideline No. 72-2), estuarine and marine acute toxicity (Guideline No. 72-3), fish early life stage testing (Guideline No. 72-4), fish life cycle testing (Guideline No. 72-5), aquatic invertebrate life cycle (Guideline No. 72-4), aquatic organism accumulation (Guideline No. 72-6), and simulated and actual field testing of aquatic organisms (Guideline No. 72-7).

We do not believe these studies on aquatic organisms should be required for fenamiphos because (1) there are no claims for aerial application on the labels of any granular or liquid end use products containing fenamiphos, and (2) even if there were label claims for aerial application they would have to be deleted in accordance with Section IV.D.2 (page 56) of the guidance document which requires specific label prohibitions against aerial application of formulations other than granular.

Yours very truly,

MOBAY CORPORATION
AGRICULTURAL CHEMICALS DIVISION


John S. Thornton, Manager
Registrations
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JST:RPH:brh