207564
RECORD NO.

SHAUGHNESSEY NO. REVIEW NO.

EEB REVIEW

DATE: IN 11-13-87 OUT 3/15/89

FILE OR REG. NO 3125-269

PETITION OR EXP. NO.

DATE OF SUBMISSION 10-30-87

DATE RECEIVED BY HED 11-13-87

RD REQUESTED COMPLETION DATE 11-20-87

EEB ESTIMATED COMPLETION DATE 11-20-87

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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3 pages w/2 Attachments

ECOLOGICAL EFFECTS BRANCH

CHEMICAL: Fenamiphos

100.0 Submission Purpose

The Registrant submitted a letter, dated September 17, 1987, relative to the fish and wildlife data requirements set forth in the Fenamiphos Reregistration Standard. The Registrant requested that the Agency address the following issues:

1. The use of the TEP for conducting an aquatic organism accumulation study;

2. Clarification as to why the Agency listed data requirements 72-4, 72-5, 72-6, and 72-7 as "Reserved".

101.0 Discussion

Issue 1: The Science Chapter, showing that the aquatic accumulation study should be conducted using the TEP, is in error. According to 40 CFR Part 158 and Subdivision Guidelines, the TGAI or purest available form of the principle degradation product(s) should be used in the study.

Issue 2:

(72-4) - Aquatic Invert. Life Cycle Study
This study is listed as "reserved" pending the submission of an acceptable acute 48-hour EC50 for an aquatic invertebrate. If the EC50 value derived from the study is less that 1 mg/l the aquatic invertebrate life cycle study will be required.

(72-5) - Fish Life Cycle Study

This study was listed as "reserved" pending results of the Fish Early Life Stage Test. If, based upon the results of the early life stage test, the EECs are equal to or greater than 1/10 of the no-effect level, the life cycle test will be required.

(72-6) - Aquatic Organism Accumulation Studies

These studies are required by the EFGWB and were so foot-noted in the Science Chapter. Testing should be done using the TGAI.

(72-7) - Simulated/Actual Field Tests

These tests were listed as "reserved" pending results of the fish early life stage and/or aquatic

invertebrate life cycle tests. The results of these tests will determine whether or not simulated/actual field testing of the material will be required.

Issue 3:

(71-1) Acute Oral Avian LD50 Study

The study in question was identified in the Standard as not fulfilling the requirement because an inappropriate species (Japanese Quail) was tested. However, the study was classified as Supplemental and could be used in a hazard assessment. The other two studies reviewed both satisfied the data requirement.

3/15/89
Richard W. Felthousen, Wildlife Biologist
EFED/EEB

3.15.89
Norm Cook, Head, Section 2
EFED/EEB

3/15/89
J. Akerman, Chief
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# Mobay

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CERTIFIED MAIL 651 345 359

Ms. Lois A. Rossi
Product Manager (21)
Environmental Protection Agency
Registration Division (TS-767C)
401 M Street, S.W.
Waterside Mall
Washington, D.C. 20460

September 17, 1987

Subject: Reregistration of NEMACUR® Fenamiphos Insecticide-Nematicide Products
Request for Clarification of Ecological Effects Data Requirements

Dear Ms. Rossi:

We have examined the Guidance Document for the reregistration of pesticide products containing fenamiphos and wish at this time to bring to your attention several items which require prompt clarification by EPA in order for Mobay to be able to respond in an appropriate and timely manner to the deadlines which the Agency has imposed for ecological effects data.

Table A, page 101, indicates that the accumulation studies on aquatic organisms (Guideline No. 72-6) are to be conducted with a typical end use product (TEP) and submitted within 12 months after issuance of the registration standard. However, 40 CFR 158 and Subdivision E of the Pesticide Assessment Guidelines state that such studies should be conducted using the technical grade of the active ingredient or the purest available form of the principal degradation product(s). The Agency must clarify this discrepancy promptly.

Table A, pages 100 and 101, indicates that the Agency is requiring (1) an aquatic invertebrate life cycle study (Guideline No. 72-4), (2) a fish life cycle study (Guideline No. 72-5), (3) aquatic organism accumulation studies on crustacea, fish, insect nymphs and mollusks (Guideline No. 72-6), and (4) simulated/actual field testing on aquatic organisms (Guideline No. 72-7), yet all of these studies are listed in the Ecological Effects Science Chapter as "Reserved". Obviously, the Agency will need to clarify these discrepancies as soon as possible in order for Mobay to schedule the appropriate tests if, in fact they are to be required.

Yours very truly,

MOBAY CORPORATION
AGRICULTURAL CHEMICALS DIVISION

John S. Thornton/brh

John S. Thornton, Manager
Registrations
Research and Development

JST:RPH:brh

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August 24, 1987

TO V

3125-209

Ms. Lois A. Rossi
Product Manager (21)
Environmental Protection Agency
Registration Division (TS-767C)
401 M Street, S.W.
Waterside Mall
Washington, D.C. 20460

Subject: NEMACUR® Fenamiphos Insecticide Nematicide
Mutagenicity and Avian Toxicity Studies

Dear Ms. Rossi:

With your letter dated May 18, 1987 you provided a copy of the Toxicology Branch's review of two mutagenicity studies (Mobay Reports No. 89087 and 90100; EPA Accession No. 262617 and 263729) on fenamiphos and a copy of the Ecological Effects Branch's review of a summary report (Mobay Report No. 89021; EPA Accession No. 262616) on avian toxicity. We note that these studies were reviewed in connection with preparation of the registration standard for fenamiphos.

We are enclosing supplementary data for the two mutagenicity studies as follows:

Mobay Report No. 89087 - Salmonella/Microsome Test to Evaluate for Potential Point Mutation.

The Agency's review notes that this study is not acceptable but that it could be upgraded upon submission of the bacteriological procedures used to standardize the bacterial cell suspension to the desired density of viable cells per milliliter. The enclosed Mobay Report No. 89087-2 contains the information on standardization procedures needed to upgrade this study.

Mobay Report No. 90100 - CHO/HGPRT Mutation Assay in the Presence and Absence of Exogenous Metabolic Activation.

The Agency's review states that this study is acceptable but that the purity of the test material must be submitted. This information is included in the enclosed Mobay Report No. 90100-1 to supplement the original study report.

Mobay Report No. 89021 - Acute Oral Toxicity on Birds. EEB

The Agency's review states that the data in this report are considered only as supplemental since (1) complete raw data and description of each individual study were not provided and (2) the test species are not indigenous to the United States. This report was never intended to fill any data requirements for fenamiphos and was submitted only to fulfill our legal responsibility to submit toxicity data of the sort to EPA. Numerous other studies have been submitted by Mobay to fill the requirement for avian acute oral toxicity data. Since the experiments summarized in the report were conducted in Japan, it is highly unlikely that the complete raw data and test descriptions are available. Also, since the test species are not indigenous to the United States, it would be pointless to seek the additional information.

We trust that the additional data in the enclosed Mobay Reports No. 89087-2 and 90100-1 will adequately address the Agency's comments with respect to the two mutagenicity studies on fenamiphos.

Yours very truly,

MOBAY CORPORATION
AGRICULTURAL CHEMICALS DIVISION

John S. Thornton

John S. Thornton, Manager
Registrations
Research and Development

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Enclosures: Mobay Reports No. 89087-2 and 90100-1 (3 copies)

cc: Mr. Philip Anderson, California Department of Food and Agriculture
(with 1 copy of reports)