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106201
SHAUGHNESSEY NO

REVIEW NO.

EEB REVIEW

AUG 15 1990

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TYPE PRODUCT(S) INSECTICIDE

DATA ACCESSION NO(S) 410931-01, 02 411120-01

PRODUCT MANAGER, NO. 12

PRODUCT NAME(S) OVASYN

COMPANY NAME NOR-AM

SUBMISSION PURPOSE REVIEW SUPPLEMENTAL DATA FOR UPGRADING PREVIOUS STUDIES

SHAUGHNESSEY NO.	CHEMICAL	% A.I.
106201	AMITRAZ	

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of Supplemental Data

FROM: James Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division

TO: Dennis Edwards
Product Manager (12)
Insecticide-Rodenticide Branch
Registration Division

COPY

Nor-Am Chemical Company has sent additional information (accession No.'s 410931-01, 410931-02, 411120-01) to be used for upgrading 3 supplemental studies. This information was previously reviewed by EEB on 8/31/89, and a copy of that memorandum is attached. The degradate testing requirements outlined in this 8/31/89 memorandum are outdated as since that time we have requested additional studies. Because of the likelihood that the hazard of this pesticide to nontarget organisms actually resides with either 1 or 2 of Amitraz's degradation products, we have required testing with both degradates. However, testing requirements with either degradate may be waived pending the review of acceptable environmental fate data by EFGWB.
The following list is the outstanding data requirements as established by the Ecological Effects Branch:

A. Technical Grade Amitraz

The following data requirements with technical grade Amitraz are not fulfilled:

71-4 - Avian reproduction with bobwhite and mallard.
72-3 - Estuarine fish acute LC50.

In addition, other studies reserved pending the acceptance of the above and environmental fate data are:

71-5 - Simulated and actual field testing - mammals and birds.
72-7 - Simulated and actual field testing - aquatic organisms.

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B. Degradates BTS 27271 and BTS 27919

According to the 1984 Registration Standard, the following studies using U-40481 (BTS 27271) were reserved pending environmental fate data:

72-1 - Freshwater fish 96-hour LC50.
72-2 - Aquatic invertebrate 48-hour LC50.
71-2 - Avian 8 day dietary with upland game bird.
72-3 - Estuarine acute toxicity tests (fish, shrimp, mollusc).

Because of their toxicity and persistence in the environment, the following studies have been requested with each degradate (BTS 27271 and BTS 27919). Species in parentheses are preferred:

71-2 Avian dietary LC50 with an upland game bird (bobwhite quail) and a waterfowl species (mallard).

72-1 Freshwater fish 96-hour LC50 with a warm water fish (bluegill) and a coldwater species (rainbow trout).

72-2 Freshwater invertebrate 48-hour LC50 with Daphnia magna.

72-3 Estuarine and marine acute LC50 with fish (sheepshead minnow), shrimp (Mysid shrimp), and mollusks (eastern oyster).

The following studies, with these degradates, are reserved pending the evaluation of the above acute studies and environmental fate data:

72-4 Avian reproduction with an upland game bird (bobwhite quail) and a waterfowl species (mallard).

72-4 Freshwater fish early life-stage (rainbow trout) and freshwater invertebrate life-cycle with Daphnia magna.

72-4 Estuarine fish early life stage (sheepshead minnow) and estuarine invertebrate life-cycle (Mysid shrimp)

72-5 Fish full life-cycle.

72-6 Aquatic organism accumulation.

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

8/31/89

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Amitraz Registration Standard; Nor-Am Chemical Company's Submission Dated 6/19/89.

COPY

TO: Dennis Edwards, PM 12
Insecticide-Rodenticide Branch
Registration Division (H7505C)

FROM: Jim Akerman, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

The registrant has submitted additional information, accessioned under Nos. 410931-01 and 411120-01, in response to previous study reviews (12/22/88) by the Ecological Effects Branch (EEB). The reevaluation results are as follows:

Study Type	Test results	EPA Acc.No.	Status
Rainbow trout 96-hour LC50	2.2 mg/l	407805-05	Supplemental to Core (by 41093102)
Sheepshead minnow 96-hour LC50	>2.4 mg/l	407805-07	Unchanged at Supplemental (by 41093101)
Oyster 96-hour LC50	75 ug/l	407805-09	Supplemental to Core (41112001)

The rainbow trout study (407805-05) was previously rated as supplemental because of concerns for slightly contaminated controls, presumably the result of laboratory contamination error in sample analysis or false positive chromatographic readings . Contamination in the controls could not be confirmed because the suspected levels were below the limits of analytical detection. Further, the submission of chromatogram printouts suggest the possibility of false positives which indicate that it is difficult to differentiate a faintly detectable peak from the baseline readings generated from UV detection of solvent elucidation from the chromatographic column. False positives may indicate electronic instrumentation.

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cperating conditions or indicate the presence of other chemicals (e.g., unprecipitated proteins) which can mask the readings or have the same elucidation time of a known chemical. Such false positive readings are recognized and accepted by various laboratories as a reflection of the imperfections of the state-of-the-art chromatographic methodologies. In light of such incidences, the measured concentrations in the treatment groups and lack of mortalities in the controls provides EEB minimum justification to upgrade the study to Core.

40780507

The supplemental sheepshead minnow study with the technical grade remains nonrepairable, primarily because the solubility limits do not permit an LC50 value to be computed. However, the guideline requirements can be fulfilled with the citations of all technical and formulation studies combined togather.

40780509

The oyster study has been upgraded to Core on the basis of the resubmitted information. EEB's statistical analysis agrees with the reported results although the EC50 value was computed to be 75 ug/l, as opposed to the reported 85 ug/l. This does not change the "highly toxic" classification.

The PM and registrant is advised to take note and correct a typographical error in EEB's 12/22/89 memorandum summarizing the results of the reviewed aquatic invertebrate life cycle study. The reported results should correctly read < 0.02 mg/l instead of > 0.2 mg/l.

The review results of the available toxicity and environmental fate studies indicate a need to require additional studies in order to continue the hazard assessments of the proposed citrus and cotton use patterns. The review results indicate that amitraz is expected to impact aquatic organisms through initial acute exposure to the parent compound, followed by exposure to the more persistant degradation products. The degradation toxicity studies outlined below are to be conducted with the primary degradation product of amitraz, earlier identified as U-40481 by the Registration Standard and presently identified as BTS 27919 in recently submitted studies.

While the registrant conducts the studies, EEB defers the establishment of aquatic and terrestrial estimated environmental concentrations (EEC) of amitraz and its degradation products to the Environmental Fate and Ground Water Branch (EFGWB). The EECs are needed to advance the hazard assessment of amitraz. The required studies, EECs, and the hazard assessments will allow the determination for field studies to be made, in addition to providing EEB with an adequate database to initiate a consultation with the Office of Endangered Species to determine if there is any potential for jeopardy to endangered species.

The following studies will be required:

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Technical Amitraz

72-4	Aquatic Invertebrate Life Cycle (repeat)
72-4	Freshwater Fish Full Life Cycle (repeat)
72-4	Mysid Shrimp Life Cycle
72-5	Estuarine Fish Full Life Cycle

Degradation Testing (U-40481 or BTS-27919)

71-1	Upland Game Bird Acute Dietary LC50
72-1	Freshwater Fish 96-hour LC50
72-2	Aquatic Invertebrate 48-hour LC50
72-3	Estuarine Organisms Acute Tests

John Noles, Biologist
Ecological Effects Branch

John Noles
8/31/89