DP Barcode : D171144
PC Code No : 106201
EEB Out : 4/30/92

To: Walter Waldrop
Product Manager 71
Special Review and Reregistration Division (H7508W)

From: Douglas J. Urban, Acting Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 106201
Chemical Name : Amitraz
Type Product : Insecticide
Product Name :
Company Name : NOR-AM Chemical Company
Purpose : Response to waiver request for 72-5 and 72-6

Action Code : 629 Date Due : 1/27/92
Reviewer : Tracy Perry

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed
S=Supplemental (Study provided useful information but Guideline was not satisfied)
N=Unacceptable (Study was rejected)/Nonconcur

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

APR 30 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Amitraz: status of waiver requests for guideline requirements 72-5 and 72-6.

FROM: Douglas Urban, Acting Branch Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C) 4/29/92

TO: Walter Waldrop, PM 71
Reregistration Branch
Special Review and Reregistration Division (H7508W)

On October 28, 1991, NOR-AM Chemical Company sent in a response to the September 30, 1991 Data Call-In, requesting a waiver/ clarification for two data requirements: 72-5 Fish Full-Life Cycle (with technical Amitraz) and 72-6 Aquatic Organism Accumulation (with parent Amitraz and Amitraz degradates BTS 27271 and BTS 27919).

In concurrence with EEB's March 25, 1992 review of the use of Amitraz on cotton, the following data requirements are in reserve for Amitraz degradates BTS 27271 and BTS 27919 pending the evaluation of environmental fate modeling data: 72-5 Fish Full-Life Cycle and 165-5 Aquatic Organism Accumulation.

The Fish Full-Life Cycle (72-5) and the Aquatic Organism Accumulation (72-6, 165-5) studies are neither required nor reserved for technical Amitraz.

If you have any questions, please contact Tracy Perry at 305-6451 or Henry Craven at 305-5320.

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DP BARCODE: D171144 REREG CASE #

CASE: 819393 DATA PACKAGE RECORD DATE: 11/13/91
SUBMISSION: S406785 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 629 GENERAL CORR - REREGIS
CHEMICALS: 106201 Amitraz (N'-(2,4-dimethylphenyl)-N-(((2,4-dimethyl 100.00 %

ID#: 106201
COMPANY:
PRODUCT MANAGER: 71 WALTER WALDROP 703-308-8062 ROOM: CS1 3B3
PM TEAM REVIEWER: WALTER WALDROP 703-308-8062 ROOM: CS1 3B3
RECEIVED DATE: 10/30/91 DUE OUT DATE: 01/28/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 171144 EXPEDITE: N DATE SENT: 11/13/91 DATE RET.: / /
CHEMICAL: 106201 Amitraz (N'-(2,4-dimethylphenyl)-N-(((2,4-dimethylphenyl)im
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 01/27/92 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	11/14/91	05/05/92
BRAN: EEB	11/18/91	4/30/92
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

PLEASE NOTE THAT REVIEWER IS NOT w waldrop but MARIO FIOL (308-8049).

I would appreciate it if you were to review and comment regarding the attached letter from NOR-AM regarding guidelines 72-5 and 72-6 in the DCI just mailed to them.

Please call me as soon as possible regarding setting a meeting or a response. NOR-AM must respond by Dec. 1991 to the DCI.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

3

DP BARCODE: D171144 REREG CASE #

CASE: 819393 DATA PACKAGE RECORD DATE: 11/13/91
SUBMISSION: S406785 BEAN SHEET Page 1 of 1

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ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	/ /	/ /
BRAN: EEB	/ /	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

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* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

22/April/92
Submission was lost in EEB. copy
of submission sent to them again.
Reply is attached note.
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22/April/1992

NOTE TO: Tracy Perry, EEB
CM#2, Room 1006-L

Tracy, as we discussed yesterday afternoon, I am attaching a complete copy of the documents (including bean sheet) originally submitted. In addition, and for your information, I have also attached a copy of the DCI and NOR-AM's response.

I would appreciate it if you would let me know as soon as possible as to the results of your review with regards to the two guidelines; 72-5 and 72-6. My telephone number is 308-8049.

Many thanks,

Mario Fiol
SEED/RB/Sect III

5

NOR-AM
A Schering Berlin Company

October 28, 1991

NOR-AM Chemical Company

3509 Silverside Road
P.O. Box 7495 • Wilmington, DE 19803
Telephone: (302) 575-2000
Telex: 835475
Telefax: (302) 575-2013

Document Processing Desk
Office of Pesticide Programs
(AMITRAZ DCI)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attention: Mario Fiol, Review Manager
Reregistration Branch
Crystal Station I

Subject: **Amitraz Data Call-In Dated September 30, 1991**
EPA Reg. No. 45638-51 (Technical)
Request for Clarification of Data Requirements

Dear Mr. Fiol:

We are in receipt of the amitraz Data Call-In and are preparing for the 90-day response, due on or before December 30, 1991. In reviewing the DCI, we noted some requirements which need clarification. Among these are the following EEB mandated requirements:

72-5	Fish Life Cycle (with technical amitraz)
72-6	Aquatic Organism Accumulation with parent amitraz and amitraz degradates BTS 27271 and BTS 27919)

Our questions are detailed below.

Fish Life Cycle - An EEB review dated September 18, 1989 indicated that four studies "are to be conducted" with BTS 27919 and the other listed studies, including a fish life cycle study with technical amitraz, are noted as "will be required" pending completion of EEC's by EFGWB.

Another EEB review, dated March 1, 1990, indicated the need for a fish full life cycle with technical amitraz (page 10 of the review). After NOR-AM received this review, a meeting was

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10-31-91

held with representatives of EEB and EFGWB on May 23, 1990. As a result of that meeting, it was NOR-AM's understanding that the requirements for chronic studies in fish with technical amitraz were waived/placed on RESERVED and that the focus would shift to the acute toxicity of the metabolites BTS 27271 and BTS 27919.

This was confirmed in an EEB review dated August 15, 1990 which presented "outstanding data requirements as established by the Ecological Effects Branch." The only mention of a fish full life cycle is that it is RESERVED for the degradates pending evaluation of acute studies with the degradates. NOR-AM agreed with the EEB review and set our work plan accordingly. This was communicated to the Agency in a letter dated September 26, 1990 which presented the list of requirements which we are working to fulfill.

Therefore, in light of the past reviews, NOR-AM requests that the requirement for a fish full life cycle with amitraz listed in the data call-in be deleted and, as we have already agreed, that the fish life cycle requirement be denoted as RESERVED for the amitraz degradates BTS 27919 and BTS 27271.

Aquatic Organism Accumulation - An EEB review dated March 1, 1990 noted that this study was required for technical amitraz (page 10) and was placed on RESERVED status for BTS 27271 (pages 11-12). Again, however, the recent EEB review dated August 15, 1990 indicates that this data requirement is RESERVED only for BTS 27271 and BTS 27919 pending evaluation of acute studies.

NOR-AM is, as mentioned above, in concurrence with this review and this was communicated to the Agency in a letter dated September 26, 1990.

Therefore, in light of these reviews, we request that the DCI requirement for an aquatic organism accumulation study with technical amitraz be deleted and that it be placed on RESERVED status for BTS 27271 and BTS 27919.

Note that the requirement for a bioaccumulation study in aquatic non-target organisms (Guideline Reference 165-5) with technical amitraz imposed by the registration standard in 1987 was placed on RESERVED status earlier this year.

Please note that I have included copies of the above-referenced reviews for your convenience. If you have any questions regarding

these requests, please call me at (302) 575-2048. Please keep in mind that our 90-day response is due soon so a timely reply to this letter would be appreciated. Best regards.

Sincerely,

Jacob J. Vukich

Jacob J. Vukich
Registration Project Manager

JJV:pmg
Enclosures
D:102891L1.JJV

cc: Mr. Dennis Edwards
Product Manager (19)
Registration Division
Crystal Mall 2

Sent via Airborne Express
Airbill Number 281-196-893

247524
RECORD NUMBER

COPY

PESTICIDE CHEMICAL CODE

REVIEW NUMBER

ECOLOGICAL EFFECTS REVIEW

DATE: IN 7/3/89 OUT 9/18/89

FILE OR REG. NO. 45639-49

PETITION OR EXP NO.

DATE OF SUBMISSION 6/19/89

DATE RECEIVED BY HED 6/30/89

RD REQUESTED COMPLETION DATE 9/19/89

EEB ESTIMATED COMPLETION DATE 9/19/89

RD ACTION CODE/TYPE OF REVIEW 331

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

DATA ACCESSION NO(S). 410931-01; 410931-01

PRODUCT MANAGER NO. D.Edwards (12)

PRODUCT NAME(S) Amitraz (Mitac)

COMPANY NAME Nor-Am Chemical Co.

SUBMISSION PURPOSE Review information provided to upgrade studies and reevaluate proposed uses on cotton and citrus

PESTICIDE CHEMICAL CODE	CHEMICAL AND FORMULATION	% A.I.

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

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

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
Sheepshead minnow 96-hour LC50	>2.4 mg/l	407805-07	Unchanged at Supplemental
Oyster 96-hour LC50	75 ug/l	407805-09	Supplemental to Core

The rainbow trout study 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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operating 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.

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.

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 12/22/88 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:

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

239936, 240811
RECORD #'s

106201
SHAUGHNESSY NO.

COPY

REVIEW NO.

EEB REVIEW

DATE: IN 2/27/89 DATE: OUT MAR 1 1990

FILE OR REG. NO. 45639-RUA

PETITION OR EXP. NO. 9F3770

DATE OF SUBMISSION 2-9-89

DATE RECEIVED BY EFED 2-27-89

RD REQUESTED COMPLETION DATE 4-27-89

EEB ESTIMATED COMPLETION DATE 4-27-89

RD ACTION CODE 160, 240

TYPE OF PRODUCT(S) : I,D,H,F,N,R,S INSECTICIDE/MITICIDE

DATA ACCESSION NO(S).

PRODUCT MANAGER (NO.) D. EDWARDS (12)

PRODUCT NAME(S) OVASYN (Amitraz)

COMPANY NAME NOR-AM Chemical Company

SUBMISSION PURPOSE Proposed registration for use on cotton

SHAUGHNESSY NO.	CHEMICAL & FORMULATION(S)	% A.I.
106201	Amitraz	19.8

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ECOLOGICAL EFFECTS BRANCH REVIEW
OVASYN (Amitraz)

100.0 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

The registrant, Nor-Am Chemical Company, proposes to register OVASYN (Amitraz) for use on cotton. OVASYN is an insecticide/miticide with ovicidal and synergistic activity on a variety of pests.

100.2 Formulation Information

Active Ingredient:
Amitraz (N'-(2,4-dimethylphenyl)-N-[[(2,4-dimethylphenyl) imino]methyl]-N-methylmethanimidamide).....19.8%

Inert Ingredients.....80.2%

100.3 Application Methods, Directions, and Rates

Directions For Use

It is a violation of federal law to use this product in any manner inconsistent with its labeling.
Do not apply this product in such a manner as to directly or through drift expose workers or other persons. The area being treated must be vacated by unprotected persons.

Application

Equipment: Apply by air or ground, using low drift nozzles. DO NOT use less than 1 gallon spray per acre by air and less than 10 gallons per acre by ground. Higher volumes will ensure better coverage for mite control in larger, more dense cotton.

Mite Control: Apply OVASYN as a single treatment of 2.66 to 5.33 pints per acre, or two sequential applications of 2.66 pints per acre. DO NOT exceed 5.33 pints per acre per season. Treatments should be applied when mite populations begin to build. OVASYN may be applied from the time cotton plants are 4-6 inches tall and up until 21 days before harvest.

Insect Control: In fields where bollworm pests have reached economic levels, apply at 0.66 to 1.33 pints per acre as needed or on an appropriate schedule. To control whitefly, apply 1.33 to 5.33 pints per acre in sufficient water to ensure complete coverage. DO NOT exceed 5.33

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pints per acre per season. DO NOT apply later than 21 days before harvest.

TABLE OF APPLICATION RATES

Desired Rate/Ac. (lbs. ai/ac)	Acres Treated Per Gallon	Pints Per Acre
0.125	12	0.66
0.17	9	0.89
0.25	6	1.33
0.50	3	2.66
0.75	2	4.00
1.0	1.5	5.33

100.4 Target Organisms

Target organisms include: bollworms, tobacco budworms, pink bollworms, whiteflies, and mites (two-spotted spider mite, strawberry mite, pacific mite, and carmine mite).

100.5 Precautionary Labeling

Environmental Hazards

This product is toxic to fish. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to fish in adjacent sites. Do not contaminate water by cleaning of equipment or disposal of wastes. Apply this pesticide only as specified on this label. Do not apply this product through any type of irrigation system.

Restrictions and Limitations

DO NOT apply more than 5.33 pints per acre OVASYN per growing season.
DO NOT apply OVASYN within 21 days of harvest.
DO NOT apply shortly before rainfall.
DO NOT allow prepared solutions to stand overnight.

101.0 Hazard Assessment

101.1 Discussion

Amitraz is currently registered (conditional, restricted) for outdoor use on pears. Several EUP's have been sought, including cotton, citrus, apples, and ornamental use. The estimated acreage of pear trees in 1987 was 115,476 acres (Agricultural Statistics Handbook, 1988). According to the same source, an estimated 10,407,200 acres were

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planted in cotton in 1987. Therefore, the proposed new use could potentially increase current acreage use by a factor of 90. The current maximum label rate for pears is 1.5 lb ai/Acre, whereas the proposed cotton rate is 1.0 lb ai/Acre. By using these label rates and the above acreage, the actual poundage of ai applied could potentially increase 60 fold with this proposed use on cotton.

OVASYN is an insecticide/miticide engaging ovicidal and synergistic activity on a variety of pests with the active ingredient Amitraz (19.8%). There is information available that suggests Amitraz is more toxic when used as a 20% EC formulation than a technical product. There is additional information that a degradate (BTS 27271; U-40481) is more toxic to mammals than is the parent compound. Several studies with the 20% EC formulation have been requested and many studies with the more toxic degradate (BTS 27271) have been reserved pending the acquisition of requested environmental fate data.

101.2 Likelihood of Adverse Effects to Nontarget Organisms

Terrestrial Organism Toxicity

Avian Toxicity

Technical Amitraz is slightly toxic to bobwhite quail on an acute oral basis (LD50=788 mg/kg), and practically non-toxic to mallards (LC50=7000 ppm) and bobwhite quail (LC50=3081 ppm) on a subacute dietary basis. Acceptable avian reproduction studies are lacking, but data suggest the NOEL is <40 ppm.

Mammalian Toxicity

Technical Amitraz is considered moderately toxic to rats (LD50=200-400mg/kg) on an acute oral basis. A 2-year rat feeding study established a NOEL=50 ppm, and a 3-generation rat reproductive study indicated the NOEL=15 ppm.
No LC50 data are available for wild mammals but the rat LD50 (200 mg/kg) can be used to estimate LC50's for representative herbivores and insectivores for which daily food consumption is known.

Weights and daily food consumption data from:
Davis, D. E., and F. B. Golley, 1963. Principles in Mammalogy. Reinhold Publ. Corp., 335 pp.

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SPECIES	PERCENT BODY WT. EATEN PER DAY	ESTIMATED* LC50
Herbivores		
Meadow vole	61.1	327 ppm
Hispid cotton rat	31.2	641 ppm
Eastern cottontail	71.8	278 ppm
Insectivores		
Least shrew	110	182 ppm
Water shrew	103	194 ppm
Common mole	61.7	324 ppm

*LC50 = LD50 x 100/Percent body wt. eaten per day.

The EEB chemical profile toxicity data (9/25/89; DJM) indicate that a degradate (U-40481; BTS 27271) is more toxic on an acute oral basis to mice, rats, guinea pigs, and dogs than is the parent compound (U-36059; BTS 27419). This degradate (BTS 27271) is considered moderately toxic to mice, rats, guinea pigs, and highly toxic to dogs. The other major degradate (U-36893; BTS 27919) has a limited toxicity data base, but indications are that it is similar in toxicity to that of the parent compound.

The following table shows estimated wild mammal LC50's as derived from the LD50 toxicity tests with the more toxic degradate (BTS 27271). The shrew, mole, and vole LC50's are based on the mouse LD50 = 100 mg/kg; the cotton rat LC50 on the rat LD50 = 200 mg/kg; the eastern cottontail LC50 on the rabbit LD50 = 100 mg/kg; and the beaver and deer LC50's on the dog LD50 = 20 mg/kg.

SPECIES	PERCENT BODY WT. EATEN PER DAY	ESTIMATED* LC50
Herbivores		
Meadow vole	61.1	164 ppm
Hispid cotton rat	31.2	641 ppm
Eastern cottontail	71.8	139 ppm
Beaver	3.0	667 ppm
Whitetailed deer	2.4	833 ppm
Insectivores		
Least shrew	110	91 ppm
Water shrew	103	97 ppm
Common mole	61.7	162 ppm

*LC50 = LD50 x 100/Percent body wt. eaten per day.

Beneficial Insect Toxicity

Technical Amitraz was found to be low in toxicity to honeybees (not toxic at 100 ug/bee). A 20% EC formulation test resulted in no mortality or repellency in a field test.
Two additional 20% EC formulated studies provided sufficient information to characterize Amitraz as low in toxicity to the predaceous ladybird beetle, Stethorus punctum.

Aquatic Organism Toxicity (Technical Amitraz)

Acute - Freshwater Organisms

Technical Amitraz is considered highly toxic to rainbow trout (LC50=0.74 ppm), and bluegill sunfish (LC50=0.34 ppm); and very highly toxic to Daphnia magna (LC50=0.035 ppm).

Chronic - Freshwater Organisms

Two supplemental, non-repairable studies are the only information available concerning chronic risks to freshwater organisms. A 21-day renewal (life cycle) chronic test with Daphnia magna found the MATC <0.02 mg/L, but the precise MATC could not be determined. Additionally, a fathead minnow early life stage test found the MATC <3.53 ug/L, but a precise MATC value was lacking.

Acute - Estuarine Organisms

Technical Amitraz is classified as highly toxic to Atlantic oyster larvae (48-hour LC50=0.85 ppm), slightly toxic to grass shrimp (96-hour LC50=65.1 ppm), and practically non-toxic to fiddler crabs (96-hour LC50 >1000 ppm).

Aquatic Organism Toxicity (20% EC Formulation)

In the past, there has been a question as to the toxicity of technical Amitraz when in a 20% EC formulation, particularly to aquatic organisms. The Registration

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Standard of 1984 stated that 2 studies suggested technical Amitraz may be more toxic when in a 20% EC formulation than by itself. Since 4 submitted studies with a 20% EC formulation (MRID #'s 00030444, 00030445, 00030447, 00030448) did not fulfill guideline requirements, the Registration Standard suggested repeating the coldwater fish acute study and also required the following studies with a 20% EC formulation: Aquatic Invertebrate LC50, Estuarine Fish LC50, Shrimp LC50, and Acute Mollusc testing. EEB has recently accepted 5 studies conducted with a 20% EC formulation as core.

Acute - Freshwater Organisms

Amitraz as a 20% EC formulation is considered moderately toxic to rainbow trout (LC50=2.2 mg/L) and bluegill sunfish (LC50=3.14 mg/L). There is a supplemental study classifying the 20% EC as highly toxic to rainbow trout (LC50=0.2-0.4 mg/L). A Daphnia magna acute LC50 of 3.38 mg/L classifies 20% EC Amitraz as moderately toxic.

Acute - Estuarine Organisms

Amitraz as a 20% EC formulation is considered moderately toxic to the sheepshead minnow (LC50=7.9 mg/L); highly toxic to Mysid shrimp (LC50=0.48 mg/L); and very highly toxic to eastern oysters under flow through conditions (LC50=85 ug/L).

Chronic - Freshwater or Estuarine Organisms

No studies submitted with the 20% EC formulation.

Environmental Fate and Residue Data

Physical and Chemical Properties

Solubility
Water 1 ppm (room temperature); >300 g/L acetone; Toluene at room temperature; soluble in common organic solvents; only slightly soluble in water.

Soil Adsorption Coefficient (Estimation)
Kd value of 75 in soil with 1.5% organic content.

Vapor Pressure
2.6×10^{-4} mmHg at 25° C

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Behavior in the Environment

See Attachment A for details. In summary, Amitraz degrades rapidly in water (half-life < 1 day) and soil (half-life < 1 to 5 days). Degradates of Amitraz are very persistent in the environment (BTS27271 half-life 110 days, BTS27919 half-life 150 days, Total residues half-life 450 days).

Terrestrial Residue

The maximum proposed rate of application is 5.33 pints/acre or 1.0 lb ai/acre per season. By using EEB's nomograph (Urban and Cook, Ecological Risk Assessment; EPA-540/9-85-001), the following terrestrial residues are expected based on a single application at this rate.

SUBSTRATE	RESIDUES (ppm)
Short Rangegrass	240
Long Grass	110
Leafy Crops	125
Forage	58
Pod Containing Seeds	12
Fruit	7

Aquatic Residue

Nontarget aquatic organisms may be exposed to OVASYN via drift and/or runoff from treated cotton fields. Attachment B shows the expected EEC's at the proposed application rate in a 1 acre pond from a 10 acre drainage basin. The highest EEC is 80.7 ppb resulting from aerial application.

Risk Assessment

A. Effects on Terrestrial Organism

Avian

Amitraz is considered slightly toxic to bobwhite quail and practically non-toxic to waterfowl on a dietary basis. Since the LC50 values of avian species are well in excess of the maximum EEC of 240 ppm, acute effects to non-target birds appear unlikely. However, since most of the EEC's on various substrates exceed the maximum NOEL for avian reproduction (40 ppm), chronic

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reproductive effects may occur at this application rate. Two factors indicate that the scenario used in this risk assessment probably underestimates the potential hazards to non-target birds:

1) An avian reproductive NOEL of 40 ppm was used for risk assessment although EEB is certain it is < 40 ppm (Registration Standard by D. Reider, 11-27-84).

2) Since the degradate BTS 27271 is more toxic to mammals than is the parent compound, it is likely more toxic to other organisms, including birds. This degradate is also very persistent in the environment (soil half-life = 110 days), thus increasing risk of chronic effects.

Many avian species including bobwhite quail, wild turkey, ring-necked pheasants, doves, greater prairie chickens, sandhill cranes, ducks, geese, and various songbirds have been observed utilizing cotton fields for various reasons. Additionally, because the primary region for cotton growth is the south-eastern part of the country, including the gulf states, many shorebirds may also be exposed (Gusey, W. F., and Z. D. Maturgo, 1973. Wildlife Utilization of Croplands. Environmental Affairs, Shell Oil Co., Houston, Texas. 278 pp.)
Because the estimated residue on avian foodstuffs (forage, leaves, grasses) exceeds the chronic NOEL, special review criteria as per 40 CFR Part 154.7 has been exceeded for non-target avian species.

Mammalian (Technical Amitraz)
Since the estimated LC50's for herbivores are in excess of the maximum EEC on short range grass, and the estimated LC50's for insectivores are in excess of the maximum EEC on forage (insects), acute effects are unlikely. However, since the maximum EEC of 240 ppm is 5-16 times greater than the feeding and reproductive NOEL's, chronic mammalian effects appear likely. Special review criteria as per 40 CFR Part 154.7 has been exceeded for non-target mammals. Furthermore, all estimated LC50's exceed the restricted use (EEC $\geq$ 1/5 LC50) and endangered mammal (EEC $\geq$ 1/10 LC50) classifications.

Mammalian (Degradate; BTS 27271)
Based on estimated LC50's for BTS 27271, it is shown that the EEC of 240 ppm on short range grass exceeds the estimated LC50 for 2 grazing herbivores (meadow

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vole LC50 = 164 ppm; eastern cottontail LC50 = 139 ppm). Furthermore, this degradate is very persistent in the soil (half-life = 110 days) thus increasing potential chronic risks. Therefore acute, subacute, and probably adverse reproductive effects can be anticipated when mammals are exposed to this degradate.

Beneficial Insects
Technical Amitraz and the 20% EC formulation are essentially non-toxic to beneficial insects. The effects of the degradate BTS 27271 are unknown and needs to be addressed.

B. Effects on Aquatic Organisms

Technical Amitraz
The preliminary aquatic EEC of 81 ppb is more than double the LC50 for Daphnia magna (LC50 = 0.035 ppm), and more than 4 times the maximum MATC for the same species (MATC < 0.02 mg/L). Furthermore, this EEC exceeds the maximum MATC in a fathead minnow early life stage test by nearly 23 times (MATC < 3.53 ug/L). Special review criteria as per 40 CFR Part 154.7 has been exceeded for non-target aquatic organisms. Restricted use (EEC $\geq$ 1/10 LC50) and the endangered species triggers (EEC $\geq$ 1/20 LC50) are exceeded in all freshwater toxicity tests.

20% EC Formulation
The preliminary aquatic EEC of 81 ppb is nearly equal the LC50 of 85 ug/L for the eastern oyster shell deposition study, therefore exceeding special review criteria. The LC50 for rainbow trout (0.2-0.4 mg/L) also exceeds the restricted use, endangered species, and special review classifications for the 20% EC formulation. With new data supporting, and in contrast to previous reviews, it appears that Technical Amitraz is more toxic than the 20% EC formulation, at least to rainbow trout, bluegill sunfish, and Daphnia magna. Therefore, no further 20% EC formulated testing is needed for assessing risk at this time, but EEB may require additional formulated testing for additional uses or when requested environmental fate and toxicity data is received.

Degradate; BTS 27271
Since hydrolysis and photolysis of the parent compound occurs quickly, additional data on the toxicity and environmental fate of the toxic degradate is needed.

This information is essential to complete a full risk assessment, including computer modeling to better estimate aquatic residues.

Endangered Species Considerations

The maximum terrestrial EEC of 240 ppm is well above 1/10 LC50 for all mammals reviewed. The preliminary aquatic EEC of 81 ppb is also in excess of 1/20 LC50 for all aquatic organisms tested with technical Amitraz except fiddler crabs and grass shrimp. A request for formal consultation with USFWS OES will be submitted to address hazards posed to endangered species when degradate data requirements are fulfilled. If use of this pesticide is permitted, attachment C provides a list of counties that should be banned from use due to risk to endangered species.

101.4 Adequacy of Toxicity Data

A. Technical Amitraz

Although data were sufficient for a preliminary hazard assessment, several data gaps are still evident. The following data requirements (as requested by the 1984 Registration Standard) with technical grade Amitraz are not fulfilled:

71-4 - Avian reproduction with upland game bird.
72-3 - Estuarine fish acute LC50.
72-4 - Fish early life stage.
72-4 - Freshwater invertebrate life cycle.

Additional data requirements with technical Amitraz needed to adequately ensure the safety of non-target organisms for this proposed use include:

72-4 - Estuarine invertebrate life cycle.
72-4 - Estuarine fish early life stage.
72-5 - Fish full life cycle.
72-6 - Aquatic organism accumulation.

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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As of 26 December, 1989 the following environmental fate data on the parent compound has not been adequate to satisfy guideline requirements for the Registration Standard:

- Photodegradation (soil).
- Leaching - Adsorption/Desorption (batch equilibrium).
- Accumulation in Laboratory Fish.
- Accumulation in Aquatic Organisms.
- Laboratory / Field Volatility (field data).

B. Degradate (U40481; BTS 27271)

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

~~71-2~~ - 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 the increased toxicity and persistence in the environment, the following studies are being requested with the degradate BTS 27271. Species in parentheses are preferred:

~~71-1~~ 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 the degradate, 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).

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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.

In addition, a complete compliment of environmental fate data on the degradate BTS 27271 is needed to fully address hazards to non-target organisms. Studies include:

161-1 Hydrolysis
161-3 Photodegradation - soil
161-4 Photodegradation - water
162-1 Aerobic soil metabolism
162-2 Anaerobic soil metabolism
163-1 Leaching - Adsorption/Desorption
163-2 Laboratory / Field volatility
164-1 Field dissipation
165-4 Accumulation in laboratory fish
165-5 Accumulation in aquatic non-target organisms

NOT TO BE TRANSMITTED PER CONSERV. DIV. Jim Akerman DATE 3/27/90

101.5 Adequacy of Labeling

The environmental hazards label statement is adequate. However, if use of this pesticide is permitted, a label regarding county restrictions must be included (See Attachment C).

102 Classification

Based on the current risk assessment, Amitraz qualifies for Restricted Use Classification (EEC $\geq$ 1/10 LC50 for aquatic species and EEC $\geq$ 1/5 for mammalian species) and Special Review (as per 40 CFR Part 154.7).

103 Conclusions

Despite existing data gaps, EEB has been able to complete a preliminary risk assessment of the proposed use of OVASYN (Amitraz) on cotton. The use of this pesticide as proposed can cause mortality to mammalian and aquatic organisms since

the terrestrial and aquatic EEC's exceed LC50 values. Additionally, adverse reproductive effects to birds and mammals can be anticipated. Furthermore, since the data base on the potentially more toxic degradate (BTS 27271) is very limited, and it is very persistent in the environment, risks to non-target organisms are likely greater than this review suggests.

Special review criteria as per 40 CFR Part 154.7 have been exceeded for birds, mammals, and aquatic organisms.

Several basic data requirements with the parent compound remain unfulfilled. Several other studies with the degradate BTS 27271 are being requested because of the increased toxicity and persistence in the environment (See Section 101.4). These data are needed to complete a full risk assessment.

The use of this pesticide would pose serious risk to endangered and non-endangered non-target aquatic organisms. Risks to endangered and non-endangered mammalian and avian species are also of concern. A request of formal consultation with OES concerning risk to endangered species will be submitted when the above studies are received.

Mark R. Roberts
Wildlife Biologist
Ecological Effects Branch

Mark R. Roberts 1/31/90

Ann Stavola
Acting Head, Review Section III
Ecological Effects Branch

Ann Stavola 2/9/90

James Akerman, Chief
Ecological Effects Branch

James Akerman 2/26/90

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ATTACHMENT H

103 Behavior in the Environment

103.1 Soil

Source	Comment
EAB; 11/5/82	Under the conditions of the study, Amitraz was rapidly degraded in sandy loam soil (T 1/2 < 1 day) and silt loam soil (T 1/2 = 5 days.)
" "	Amitraz and its degradate BTS 27919, were shown to have intermediate mobility in four test soils.
" "	Aged, treated (with Amitraz) sandy loam soil constituted the top layer of a soil column, Amitraz and its metabolites were not observed to leach readily.
EAB; 7/10/81	A Kd value of 75 and low solubility indicates that Amitraz is reltively immobile in the soil environment.
EAB; 8/23/82	Summary fro previous EAB review (2/25/77): Under most adverse conditions of temperature and pH, the half-life of Amitraz was found to be less than 24 hours. An aged leaching study in Florida sandy soil found a retention of >46% of the applied in the top .5", and >66% in top 12".
EAB; 6/20/80 (see 3/9/79 EEB review)	- Amitraz dissipates in the field from soil with a halflife of 1-3 months. Evidence of leaching not seen.
	- Dissipation of Amitraz from soil is evident to 1/2 2.3 months.
	- There is an indication of soil residue buildings between the dripline and trunks of treated trees from multiple treatments.
EAB; 2/25/77	(3.2.2) Photodegradation of Amitraz on soil surface expected to be minimal.
	(4.0) Aerobic soil metabolism: Halflife of BTS-27419 in Lenton soil is approximately 3 days.
	Approximately 95% of ^{14}C-Amitraz was bound to soil after 24 weeks. Amitraz bound residues are persistent. Parent and all metabolites were detectable at 24 weeks. (unacceptable study)
	Major metabolites: BTS 27919 t 1/2 48 days
	Mobility: Aged leaching - In Florida sandy soil and in Lenton sand, Amitraz leached 11.8" and 12.7" respectively.
	Anaerobic soil Metabolism: Degradation under anaerobic conditions appears similar to degradation under aerobic conditions. Amitraz bi[illegible] rapidly to soil.
EFGWB review	Photodegredation on Soil (Brehm, 00407805)
RS date	The study is acceptable.
6-28-89	[^{14}C] Amitraz (ring-labeled, purity >98%0 at ca.0.89 lb/A (ca.1 kg/ha) on sandy loam soil -TLC plate was continuously irradiated for 30 minutes with an Xenon arc lamp at <30 C. Amitraz degraded with a half-life of 20 minutes. The intensity of the light source was calculated at 8.0 mW/cm^2 as compared to 3.0 mW/cm^2 for theoretical value for sunlight at 40 C N latitude. The degradates were BTS 27919 and BTS 27271. There were no significant amounts of volatile products in the trapping solutions. Material balances ranged from 96.4 to 99.9%

(same)

Aerobic Soil Metabolism (Somerville, 40798003)

The study is acceptable.

[^{14}C] Amitraz (radiolabeled position unspecified, purity 96% at 6 ug/g was incubated 364 days in silt loam and sandy loam soils at 25 C and 50% moisture capacity. Degradation occurred with a half-life of <1 day. Nonvolatile degradates were BTS 27271 (12.9%). At the end of the study, $^{14}CO_2$ was 24.8 - 34.5% of applied in the two soils; unextractable residues were 52.9 - 64.5%. Material balances ranged from 89.1 to 107.9%.

(same)

Anaerobic Soil Metabolism (Somerville, 40798003)

The study is scientifically sound and provides supplemental information on the soil metabolism of Amitraz under anaerobic conditions. The major deficiency of the study was the 30-day aging period, the duration of which appeared excessive in light of the short half-life (< one day) of Amitraz.

Amitraz degraded under 60 days of anaerobic conditions at 25 C in silt loam and sandy loam soils. The treated soils (6 ppm) had been previously aged for 30 days under aerobic conditions before being flooded with water and purged with N_2 to establish anaerobic conditions. While no half-life was calculated, 50% less CO_2 evolved from the soils than from the aerobic study, indicating slower metabolism is occurring. In addition, three degradates were produced: BTS 27919 (12.9% of applied), BTS 24868 (5.5), and BTS 27271 (1.3%). Even though the study is supplemental, the study does not have to be repeated because no additional, useful data is likely to be obtained.

(Same)

Mobility - Leaching and Adsorption/Desorption (Arnold and Barrett, 40780505)

This batch equilibrium study is unacceptable because the soils were sieved too finely (1 mm), rather than 2 mm, which would increase the clay content and favor adsorption. Also, desorption was not studied and the CECs were not typical of U.S. soils.

Aged [$_{14}C$] Amitraz residues were mobile in soil columns (30-cm length, 4.6-cm diameter) of sand, sandy loam, and clay loam soils that were treated with 1.38 lb ai/A (1.55 kg ai/ha, maximum field rate) [^{14}C]-ring-labeled Amitraz. Radiochemical purity was 96.5% The columns were leached with 844 ml of 0.01 M $CaCl_2$ solution (50.8 x cross sectional area of column). While the majority of the [^{14}C] residues (82.7-74.8%) were in the upper 10 cm of the column, the residues were distributed throughout the columns, with 5.2-1.55% of applied being found in the leachate. These residues were polar products and not identifiable with known degradates. Material balance ranged from 94.9 to 87.1% of applied for all the soil columns. Amitraz degraded with a half-life of <2 days. Amitraz was aged aerobically for 3 days at 25 C and 40% moisture capacity. Degradates identified were . . .

BTS 27271 (N-methyl-N'-(2,4-xylyl)formamidine);

BTS 27919 (form-2', 4'-xylidide);and

BTS 24868 (2,4-dimethylaniline).

(same)

Mobility - Leaching and Adsorption/Desorption (Fortsch, 40780516)

The study is scientifically sound and provides supplemental information on the soil column mobility of a degradate (BTS 27919) of Amitraz. A major deficiency of the study was the leaching of the columns with only 20 cm of water instead of 50.8 cm.

[^{14}C]BTS 27919 residues were mobile in sand and loamy sand soil columns

(30-cm length, 50-mm diameter) that were treated with 2-methyl-labeled BTS 27919 (purity >99% at 0.82 kg/ha (0.73 lb/A) and leached with 20 cm (ca. 8 inches) of water. The residues were distributed throughout the columns with the upper 10 cm containing 33-43.4% of applied in the sand, 29.2-42.2% in one loamy sand, and 68.4-86.2% in the loamy sand soil. Activity in the leachate was <3.1% of applied for all three soils. Material balances were 85.9-90.4% for all columns.

(Same)

Mobility - Leaching and Adsorption/Desorption (Fortsch, 40780516)

This study is scientifically sound and provides supplemental information on the soil column mobility of a degradate (BTS 27271) of Amitraz. A major deficiency of the study was the leaching of the columns with only 20 cm of water instead of 50.8 cm.

[^{14}C]BTS 27271 residues were relatively immobile in sand and loamy sand soil columns (30-cm length, 50-mm diameter) that were treated with 2-methyl-labeled BTS 27271(purity 95%) at 0.82 kg/ha (0.73 lb/A) and methyl-labeled BTS 27271 (purity 95%) at 0.82 gk/ha (0.73 lb/A) and leached with 20 cm (ca. 8 inches) of water. The radioactivity remained in the upper 4-5 cm of the columns (73.6-91.3%), with <0.3% being leached from the columns. Identified in the extracts of the soil were BTS 27271 abd BTS 27919, Material balances were 80.6-92.1% in all soil columns.

(Same)

Mobility - Laboratory Volatility (Leake, 40780518)

The study is acceptable and meets EPA data requirements for laboratory volatility of [^{14}C] Amitraz (formulated as a 20% EC) from sand soil.

Sand soil treated with ca.1.38 lb ai/A (ca.1.55 kg ai/ha) phenyl-labeled [^{14}X] Amitraz (formulated as a 20% EC) was minimally volatile when incubated in the dark at 15 or 30 C for 17-18 days at 15-60% soil moisture capacity. At the end of 17-18 days, 0.1% of applied Amitraz had evolved at 15 C and <0.9% at 30C. Volatilization of total [^{14}C] residues (at 15 C) was <1.9%, regardless of moisture content (15 or 60%) or air flow (100 mL, or 1 L/minute). The major volatile degradate was BTS 24868, with $^{14}CO_2$ also being detected. The major nonvolatile degradates were BTS-27919 and BTS 27271. Material balances ranged from 86.1 to 101.7% of the applied. The vapor pressure of Amitraz was reported as 2.6 x 10^{-6} mm Hg (25 C); for BTS 27919, it was 2.6 x 10^{-5}; for BTS 27271, it was 9.0 x 10^{-4}; and for BTS 24868 (volatile degradate), it was 0.2 mm Hg.

(Same)

Field Dissipation - Terrestrial (Manley and Snowdon, 40798004)

The study is scientifically sound and provides supplemental information on the field dissipation of Amitraz. The study does not fulfill EPA data requirements because the method of analysis for residues of Amitraz were not available for review, storage stability data were not provided, and characterization of soils was incomplete, as were field test data.

The study indicated a half-life for parent of s/residues half-lives were 110 days (BTS 27271), 150 days BTS 27919), and 450 days (total residues). The degradate BTS 27271 was </=0.04 ppm in 8-12 inch core up to 364 days; BTS 27919 declined to <0.02 ppm in 4-8 inch core by 0-14 days. Although the study is supplemental, it does not have to be repeated since no additional, useful data is likely to be obtained.

103.2 Water

Source

EAB;6/20/80 (see 3/9/79 EEB review)

Comment

Amitraz will hydrolyze as follows:

pH Halflife hours

5.1	1.26
7.1	15.00
9.2	35.00

Compound 27271 is a major product at pH's 5 and 7 and minor at pH 9. Compound 27919 is major at all pH's. Compound 24868 does not exceed 9% at any pH. Two minor unidentified compounds are found at all pH's. (See page 13 of this reference for hydrolytic metabolite structures.)

EAB; 2/25/77 Hydrolysis of BTS-27419 is pH dependent. It hydrolyzes faster in acid than in base. Study was categorized:

pH	t 1/2 minutes
0.79	0.28
1.12	0.63
1.42	1.32
1.8	2.68
2.17	5.67
3.06	6.40
4.13	15.3
6.18	172
7.3	433
8.3	1200

EAB; 2/25/77 Rate of Hydrolysis of BTS 27419 with water

Parts by weight of water:	0.1	1	10	100
Time (weeks) to hydrolyze:	2	6	12	12

The more the chemical is dispersed, the slower it breaks down.

EFGWB review RS data 6-28-89 Hydrolysis Campbell, 40780512)

This study is acceptable and meets EPA's data requirements for the hydrolysis of Amitraz in buffered solutions at pH 5, 7, and 9.

Amitraz, [^{14}C]-labeled in the phenyl ring (radiochemical purity >95%), was tested at 0.04 or 0.05 ppm in sterile buffer solutions at pH 5, 7, and 9. Degradation occurred in the dark with half-lives at 2.1 hours at pH 5, 22.1 hours at pH 7, and 25.5 hours at pH 9. The degradates were:

2,4-dimethylformanilide (BTS 27919),
2,4-dimethylaniline (BTS 24868), and
N-2,4-dimethylphenyl-N'methylformamidine (BTS27271).

The material balance was 82.6-109.4% in the pH 5 solution, 76.6-101.8% in the pH 7 solution, and 78.0-123.4% in the pH 9 solution.

(same) Photodegradation in Water (Brehm, 40780513)

This study is scientifically sound and provides supplemental information on the aqueous photolysis of Amitraz. The primary deficiency of the study was that the light source did not simulate sunlight.

Amitraz photodegraded in a buffered, aqueous solution (pH 7, 28 C) with a $t_{1/2}$ = 11.8 hours; the degradates were BTS 27919 and BTS 27271. Although the study is supplemental, it does not have to be repeated since no additional useful data is likely to be obtained.

103.4 Animal

Source Comment

6/16/81

Amitraz will accumulate in bluegill when exposed to a constant concentration of 0.01 ppm. Residues chiefly accumulate in the viscera (2000x) and carcass (1467 x) with less accumulation occurring in the muscle (200 x). About 80% of the residues in the whole fish are released after 2 weeks depuration.

EAB: 2/25/77

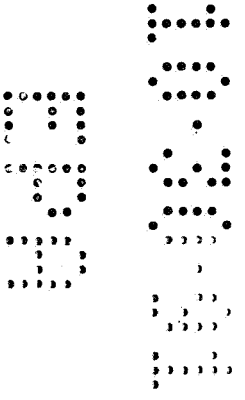
In contrast (and unreconciled) to the above information the data of this review show Amitraz not to bioaccumulate in channel catfish.

EFGWB Review
RSdata
6-28-89

Laboratory Accumulation - Fish (00072503)

The study may be acceptable if the information on the source of the degradates (specific fish tissue) is provided. It could not be determined if the data from the degradate analysis were for a single tissue (muscle, viscera, or carcass), or were averaged from all tissues. In addition, residues in the water were not identified.

Using a flow-through system that exposed bluegill sunfish to ca. 0.01 ppm of [^{14}C] Amitraz (purity 99.7% for 30 days, residues were observed to accumulate with maximum bioconcentration factors of ca. 280x for muscle, 2118x for viscera, 1467x for carcass tissues, and 933x for whole fish. At the end of the 14-day depuration period, residues were 0.5 ppm in muscle, 4.2 ppm in viscera, 3.8 ppm in carcass tissues, and 1.9 ppm in whole fish. Analysis of the 21-day sample (tissue type unspecified) indicated the presence of the degradates BTS 27919 (18% of total activity). BTS 27271 7.4, polar products (8.5%), and unidentified compounds (12.6%).



ATTACHMENT B

EEC CALCULATION SHEET

I. Foliar Application

Runoff:

1.0 lb. (ai/A) X 0.01 (1% runoff) X 10 A (from 10 A drainage basin) = 0.1 lb. (total runoff)

EEC in 6 inches of water = 734 ppb X 0.1 lb = 73.4 ppb

EEC in 6 feet of water = 61 ppb X 0.1 lb = 6.1 ppb

II. Aerial Application

A. Runoff:

1.0 lb (ai/A) X 0.6 (application efficiency) X 0.01 (1% runoff) X 10 A (10 A drainage basin) = 0.06 lb (total runoff)

B. Drift:

1.0 lb (ai/A) X 0.05 (5% drift) = 0.05 lb (total drift)

Total Loading = 0.06 lb (runoff) + 0.05 lb (drift) = 0.11 lb

EEC in 6 inches of water = 734 ppb X 0.11 lb = 80.7 ppb

EEC in 6 feet of water = 61 ppb X 0.11 lb = 6.7 ppb

EEC of 1.0 lb ai direct application to 1 A pond 6 inches deep = 734 ppb.

EEC of 1.0 lb ai direct application to 1 A pond 6 feet deep = 61 ppb.

ATTACHMENT C

COUNTIES OF COTTON PRODUCTION THAT NEED BE RESTRICTED FROM PESTICIDE USE.

Information from:

Gianessi, L. P. 1989. Estimation of Cotton Acreage Affected by Insecticide Usage Restrictions Pursuant to the Endangered species Program (final draft). Quality of the Environment Division. Wash. D.C.

ALABAMA

Colbert, Greene, Lamar, Lauderdale, Limestone, Madison, Marshall, Morgan, Pickens.

ARIZONA

Graham, Maricopa, Mohave, Pima, Pinal.

ARKANSAS

Clay, Cross, Lawrence, Lee, Poinsett, St. Francis.

CALIFORNIA

Fresno, Imperial, Kern, Kings, Madera, Merced, Riverside, San Bernadino, Tulare.

GEORGIA

Bulloch, Burke, Candler, Emanuel, Jefferson, Johnson, Washington.

MISSISSIPPI

Copiah, Hinds, Itawamba, Lowndes, Monroe.

NEW MEXICO

Chaves, Eddy.

NORTH CAROLINA

Edgecombe, Nash.

SOUTH CAROLINA

Aiken, Barnwell, Marion.

TENNESSEE

Franklin, Hardin, Lincoln.

TEXAS

Austin, Bastrop, Burleson, Cameron, Fort Bend, Hays, Pecos, Reeves, Refugio.

265301
RECORD NO.

106201
SHAUGHNESSEY NO

COPY

REVIEW NO.

EEB REVIEW

AUG 15 1990

DATE: IN 6-8-90 OUT 15 Aug 90

FILE OR REG. NO. 45639-RUH

PETITION OR EXP. NO.

DATE OF SUBMISSION 5-25-90

DATE RECEIVED BY EFED 6-5-90

RD REQUESTED COMPLETION DATE 10-5-90

EEB ESTIMATED COMPLETION DATE 10-5-90

RD ACTION CODE/TYPE OF REVIEW 181

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	

37

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

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.