

US EPA ARCHIVE DOCUMENT

DP Barcode : D177464
 PC Code No : 106201
 EEB Out : JUN 24 1992

To: Dennis Edwards
 Product Manager 19
 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 # : 045639-RUA
 Chemical Name : Amitraz
 Type Product : Insecticide/miticide
 Product Name : Ovasyn
 Company Name : Nor-Am Chemical Company
 Purpose : Nor-Am's response to EEB's review of the proposed conditional registration on cotton

Action Code : 181 Date Due : 08/26/92
 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

DP BARCODE: D177464

CASE: 193369
SUBMISSION: S416830

DATA PACKAGE RECORD
BEAN SHEET

DATE: 04/28/92
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 181 RESB NW PRD-OC-NW F/F U
CHEMICALS: 106201 Dimethylphenyl)-N-((2,4-dimethylphenyl)imino)meth 19.8000%

ID#: 045639-RUA Ovasyn
COMPANY: 045639 NOR-AM CHEMICAL COMPANY
PRODUCT MANAGER: 19 DENNIS JR EDWARDS 703-305-6386 ROOM: CM2 207
PM TEAM REVIEWER: MEREDITH JOHNSON 703-305-7080 ROOM: CM2 201
RECEIVED DATE: 04/27/92 DUE OUT DATE: 11/03/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 177464 EXPEDITE: N DATE SENT: 04/28/92 DATE RET.: / /
CHEMICAL: 106201 Dimethylphenyl)-N-((2,4-dimethylphenyl)imino)methyl)-N-met
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 08/26/92 CSF: N LABEL: N

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

* * * DATA REVIEW INSTRUCTIONS * * *

NorAm is requesting clarification and further discussion on certain items contained in the EEB review of 3/27/92 for the pending registration of amitraz on cotton ("Ovasyn"). Please review the attached letter for their comments.

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

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 24 1992

MEMORANDUM

SUBJECT: Nor-Am's response to EEB's review of the proposed conditional registration on cotton (March 27, 1992).

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

TO: Dennis Edwards, PM 19
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Douglas Urban
6/23/92

Although many issues were raised in Nor-Am's response to EEB's review of the proposed conditional registration of Amitraz on cotton, only the points which are pertinent to EEB's risk assessment and which may drive future data requirements will be discussed in this response.

General Comments

Nor-Am stated in their response to EEB's review that EEB apparently did not communicate with EFGWB before writing the review. It was stated that "EEB comments are, in many instances, contrary to the conclusions reached by EFGWB." Although EEB did not have a copy of EFGWB's final review in hand, EEB did communicate with EFGWB prior to completing its review. Any apparent inconsistencies in the two reviews is due to the way in which environmental fate data is characterized and used by the two branches.

For example, it was observed that EEB considers the Amitraz degradate, BTS 27271, to be persistent while EFGWB stated that the same degradate should not persist under most environmental conditions. In interpreting these statements, one must realize that EEB and EFGWB have different criteria for characterizing a chemical as persistent or not. For example, if a chemical has a half-life of 14 days in water (such as the case with the above mentioned degradate) EEB would call it persistent (i.e. $t_{1/2} > 4$ days); EFGWB, on the other hand, would not as their classification

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system is based on different criteria.

Terrestrial Risk Assessment

Acute Effects

On April 27, 1992, EEB received clarification from the Toxicology Branch (HED) that the acute rat oral LD₅₀ of 200-400 mg/kg for technical Amitraz (93%) cited in the Tox. One-Liner (Acc. No. 112884 for DER 001123 and 005633) actually belongs to an azodrin study. Therefore, Amitraz is less toxic than previously indicated in EEB reviews (LD₅₀ = 400 mg/kg for the rat). Using an LD₅₀ of 400 mg/kg, a 1 lb application of Amitraz does not exceed the endangered species trigger for mammals.

Nor-Am stated that EEB's calculation of the number of single dose oral LD₅₀ per day for birds was incorrect because the molecular weight of Amitraz and its degradates was not taken into consideration. EEB concurs that when molecular weights and the metabolism of the compound are considered, a 1 lb application of Amitraz does not exceed the restricted use trigger (0.2 LD₅₀/day) for the degradate BTS 27271 (0.154 LD₅₀/day). However, the endangered species trigger (0.1 LD₅₀/day) is still exceeded.

Although the potential for acute effects to endangered birds exists, EEB's major concern with the use of Amitraz is potential chronic effects to birds.

Chronic Effects

Chronic effects to birds may be expected due to the relative persistence of the degradates as compared with technical Amitraz. EEB will be better able to assess potential chronic hazard to birds once the ongoing avian reproduction studies are complete.

Nor-Am questioned whether a residue monitoring study was required or would be useful in EEB's risk assessment. A residue monitoring study is not required at this time; however, results from such a study, in conjunction with information from valid avian reproduction studies, would aid EEB in assessing chronic risk to birds.

Nor-Am also questioned the environmental fate values used in EEB's risk assessment. Nor-Am stated that it is more appropriate to use soil dissipation half-lives in a risk assessment than the aerobic soil metabolism half-lives used by EEB. Half-lives from aerobic soil metabolism studies were used in the risk assessment for the following reasons:

- * Aerobic soil metabolism studies are less subject to variation than field dissipation studies.

* EFGWB recommends that EEB use these values in its risk assessments.

Even if, at Nor-Am's suggestion, the soil dissipation half-lives ($T_{1/2}$ = 50 days (for BTS 27271, 41 days for BTS 27919) were used, they would still raise a chronic concern for birds due to the demonstrated persistence of the degradates (i.e. continued exposure over a period of several weeks).

Aquatic Risk Assessment

Acute Effects

Whether an aquatic EEC for technical Amitraz is calculated using both the runoff and drift components (10.4 ppb, EEB's assessment) or merely the drift component (3.1 ppb, Nor-Am's assessment), the results still exceed both the NOEL's and LOEL's found in the chronic daphnia (1.1 ppb, 2.2 ppb) and fish early-life stage (1.48 ppb, 2.7 ppb) studies.

As stated in EEB's review of March 27, 1992, a reduction in the maximum application rate from 1 lb to 0.25 lb would reduce the risk of adverse effects to aquatic organisms. A 0.25 lb application would result in an EEC of 2.6 ppb (EEB's assessment) or 0.76 ppb (Nor-Am's assessment).

Since technical Amitraz breaks down rapidly in water (hydrolysis = 22 hrs @ pH 7), the potential for chronic effects to nontarget aquatic organisms is expected to be minimal.

EEB's major concern with the use of Amitraz is potential chronic effects of the degradates as they are much more persistent in water than technical Amitraz (hydrolysis = 14 days @ pH 7 for BTS 27271 and 1.45×10^4 days @ pH 7 for BTS 27919).

Chronic Effects

EEB placed a number of chronic aquatic studies in reserve for the Amitraz degradates BTS 27271 and BTS 27919 pending the evaluation of environmental fate modeling data. Nor-Am feels that these studies should not be required for the degradates because they are less acutely toxic than parent Amitraz.

Based on calculations generated by Nor-Am, a 1 lb application of parent Amitraz would result in a maximum of 0.55 lb of BTS 27271 or a maximum of 1.02 lbs of BTS 27919. Therefore, the maximum EEC's resulting from a 1 lb un-incorporated ground application of Amitraz would be 16.8 ppb for BTS 27271 or 31.1 ppb for BTS 27919 (see Attachment A). Although neither of these EEC's surpass 1/100 of

any of the acute LC₅₀'s for the two degradates, the EEC for BTS 27271 is very close (1/100 EC₅₀ = 26 ppb for *Daphnia magna*).

According to the 40 CFR Part 158, data from fish early life-stage tests or life-cycle tests with aquatic invertebrates (or whichever species is most sensitive to the pesticide as determined from the results of acute toxicity tests) are required if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any EC₅₀ or LC₅₀ determined in acute toxicity testing and any of the following conditions exist:

- A) Studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected;
- B) Physiochemical properties indicate cumulative effects;
- C) The pesticide is persistent in water (e.g. half-life in water greater than 4 days).

As all three of these conditions are true for BTS 27271, the following study is now required for the degradate BTS 27271:

72-4 (b) Life-cycle aquatic invertebrate (*Daphnia magna*)

Although the above conditions hold true for BTS 27919, the maximum EEC (31.1 ppb) for BTS 27919 is far enough below 1/100 of the lowest LC₅₀ (252 ppb for the mysid shrimp) for this degradate that chronic concerns are not triggered at this time.

Based on the results of the above required study, the degradate studies reserved in Section 101.4 of the March 27, 1992 review may be required.

Repetition of Individual Studies

In EEB's Amitraz review of March 27, 1992, it was stated that three of the estuarine studies conducted with the degradates (MRID Nos. 421246-13, 421246-10, 421246-11) did not meet the guideline requirements and need to be repeated. EEB has determined that the existing data base is sufficient to characterize the toxicity of Amitraz and its degradates. Therefore, these studies do not need to be repeated.

It should be noted that the test diet analyses are still outstanding for the two avian dietary studies (MRID Nos. 421246-04, 421246-06). These studies may be upgraded to core upon receipt of this information.

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

ATTACHMENT A

apparent application rates for BTS 27271 and BTS 27919 based on assumptions (a) and (b) above are:

1) **BTS 27271:** 1 mole amitraz (M. Wt. 293) → 1 mole BTS 27271 (M. Wt. 162)

$$\text{Therefore 1 lb/A amitraz} \rightarrow \frac{1 \text{ (lb)} \times 1 \text{ (mole)} \times 162 \text{ (M. Wt. BTS 27271)}}{293 \text{ (M. Wt. amitraz)}}$$

$$= 0.55 \text{ lb/A BTS 27271}$$

2) **BTS 27919:** 1 mole amitraz (M. Wt. 293) → 2 moles BTS 27919 (M. Wt. 149)

$$\text{Therefore 1 lb/A amitraz} \rightarrow \frac{1 \text{ (lb)} \times 2 \text{ (moles)} \times 149 \text{ (M. Wt. BTS 27919)}}{293 \text{ (M. Wt. amitraz)}}$$

$$= 1.02 \text{ lb/A BTS 27919}$$

Thus the theoretical maximum yields from a 1.0 lb ai/A amitraz application are 0.55 lb/A and 1.02 lb/A for BTS 27271 and BTS 27919, respectively. The effective application rate for BTS 27919 is slightly higher than for amitraz due to the addition of water.

From these figures, "worst case" values of the EECs for amitraz, BTS 27271 and BTS 27919 were calculated as summarized in the table below for ground and aerial application. Calculations are detailed in Appendix IV. Note that due to its extremely short half-life, amitraz will not contribute to an EEC via run-off.

EEC Values for Amitraz and its Degradates Following Ground and Aerial Application

Compound	Ground Application	Aerial Application
	Theoretical Max (ppm)	Theoretical Max (ppm)
Amitraz	-	0.003
BTS 27271	0.017	0.012
BTS 27919	0.031	0.022

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BTS 27919 EEC CALCULATION SHEET

Theoretical Maximum Scenario

I. For un-incorporated ground application

A. Runoff

$$\underline{1.02} \text{ lb(s)} \times \begin{matrix} 0.05 \\ (5\% \text{ runoff}) \end{matrix} \times \begin{matrix} 10 \text{ (A)} \\ (\text{from } 10 \text{ A.} \\ \text{drainage basin}) \end{matrix} = \underline{0.51} \text{ lb(s)} \quad (\text{tot. runoff})$$

EEC of 1 lb a.i. direct application to 1 A. pond 6-foot deep = 61 ppb

$$\text{Therefore, EEC} = 61 \text{ ppb} \times \underline{0.51} \text{ (lb)} = \underline{31.1} \text{ ppb}$$

II. For incorporated ground application

A. Runoff

$$\underline{\quad} \text{ lb(s)} \div \begin{matrix} \underline{\quad} \text{ (cm)} \\ (\text{depth of} \\ \text{incorporation}) \end{matrix} \times \begin{matrix} 0.0 _ \\ (_ \% \text{ runoff}) \end{matrix} \times \begin{matrix} 10 \text{ (A)} \\ (10 \text{ A.} \\ \text{d. basin}) \end{matrix} = \underline{\quad} \text{ lb(s)} \quad (\text{tot. runoff})$$

$$\text{Therefore, EEC} = 61 \text{ ppb} \times \underline{\quad} \text{ (lbs)} = \underline{\quad} \text{ ppb}$$

III. For aerial application (or mist blower)

A. Runoff

$$\underline{1.02} \text{ lb(s)} \times \begin{matrix} 0.6 \\ (\text{appl.} \\ \text{efficiency}) \end{matrix} \times \begin{matrix} \underline{0.05} \\ (5\% \text{ runoff}) \end{matrix} \times \begin{matrix} 10 \text{ (A)} \\ (10 \text{ A.} \\ \text{d. basin}) \end{matrix} = \underline{0.306} \text{ lb(s)} \quad (\text{tot. runoff})$$

B. Drift

$$\underline{1.02} \text{ lb(s)} \times \begin{matrix} 0.05 \\ (5 \% \text{ drift}) \end{matrix} = \underline{0.051} \text{ lb(s)} \quad (\text{tot. drift})$$

$$\text{Tot. loading} = \begin{matrix} \underline{0.306} \text{ lb(s)} \\ (\text{tot. runoff}) \end{matrix} + \begin{matrix} \underline{0.051} \text{ lb(s)} \\ (\text{tot. drift}) \end{matrix} = \underline{0.357} \text{ lb(s)}$$

$$\text{Therefore, EEC} = 61 \text{ ppb} \times \underline{0.357} \text{ (lbs)} = \underline{21.8} \text{ ppb}$$

BTS 27271 EEC CALCULATION SHEET

Theoretical Maximum Scenario

I. For un-incorporated ground application

A. Runoff

$$0.55 \text{ lb(s)} \times \frac{0.05}{(5\% \text{ runoff})} \times \frac{10 \text{ (A)}}{\text{(from 10 A. drainage basin)}} = \frac{0.275}{\text{(tot. runoff)}}$$

EEC of 1 lb a.i. direct application to 1 A. pond 6-foot deep = 61 ppb

$$\text{Therefore, EEC} = 61 \text{ ppb} \times 0.275 \text{ (lb)} = \underline{16.8} \text{ ppb}$$

II. For incorporated ground application

A. Runoff

$$\underline{\quad} \text{ lb(s)} \div \frac{\underline{\quad} \text{ (cm)}}{\text{(depth of incorporation)}} \times \frac{0.0 \text{ (A)}}{(\% \text{ runoff})} \times \frac{10 \text{ (A)}}{\text{(10 A. d. basin)}} = \underline{\quad} \text{ lb(s)} \text{ (tot. runoff)}$$

$$\text{Therefore, EEC} = 61 \text{ ppb} \times \underline{\quad} \text{ (lbs)} = \underline{\quad} \text{ ppb}$$

III. For aerial application (or mist blower)

A. Runoff

$$0.55 \text{ lb(s)} \times \frac{0.6}{\text{(appl. efficiency)}} \times \frac{0.05}{(5\% \text{ runoff})} \times \frac{10 \text{ (A)}}{\text{(10 A. d. basin)}} = \frac{0.165}{\text{(tot. runoff)}} \text{ lb(s)}$$

B. Drift

$$0.55 \text{ lb(s)} \times \frac{0.05}{(5\% \text{ drift})} = \frac{0.0275}{\text{(tot. drift)}} \text{ lb(s)}$$

$$\text{Tot. loading} = \frac{0.165}{\text{(tot. runoff)}} \text{ lb(s)} + \frac{0.0275}{\text{(tot. drift)}} \text{ lb(s)} = \frac{0.1925}{\text{(tot. runoff)}} \text{ lb(s)}$$

$$\text{Therefore, EEC} = 61 \text{ ppb} \times 0.1925 \text{ (lbs)} = \underline{11.7} \text{ ppb}$$

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