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

JAN 10 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: Status of data requirement 72-3 with technical Amitraz.

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 Co. has submitted a request for a waiver of data requirement 72-3(a); (Estuarine Fish LC₅₀ with technical Amitraz). An earlier EEB memorandum (9-18-89) stated that an estuarine fish LC₅₀ study (MRID #40780507) was supplemental and non-repairable because the solubility limits did not permit an LC₅₀ to be computed. This study resulted in an LC₅₀ value of >2.4 mg/L and a NOEC of 0.09 mg/L. However, it was also stated that the guideline requirement can be fulfilled with the citations of all technical and formulation studies combined together.

Since the hazard of this pesticide is likely due to the degradation products, EEB has previously advised Nor-Am that degradate testing must be conducted. Nor-Am has agreed to conduct all acute tests with 2 major metabolites (See attachment). Therefore, as much acute data has been generated for amitraz, and all acute studies will be conducted with 2 major metabolites, the estuarine fish LC₅₀ study with technical Amitraz (MRID #40780507), in addition to other acceptable estuarine toxicity tests, can be used to fulfill data requirement 72-3. A new estuarine fish LC₅₀ study with technical Amitraz is not required.

If you have any questions regarding this matter please contact Mark Roberts (557-2438).



September 26, 1990

Office of Pesticide Programs
Document Processing Desk
Room 266A, Crystal Mall #2
1921 Jefferson Davis Hwy
Arlington, VA 22202
Attn: Dennis Edwards, PM12

NOR-AM Chemical Company

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

Dear Mr. Edwards:

Subject: OVASYN (EPA FILE SYMBOL 45639-RUA)
EEB REVIEW OF AUGUST 15, 1990

Thank you for your letter of August 27, 1990 which included the above referenced review (copy attached). I discussed this review with Mark Roberts who asked that I submit this letter to:

- 1) Request a waiver of the requirement for an estuarine fish acute LC₅₀ study (Guideline Reference 72-3(a)) conducted with technical amitraz;
- 2) Agree to conduct studies listed in the EEB review.

To that end, we are hereby requesting a waiver of the requirement to conduct an estuarine fish acute LC₅₀ study with technical amitraz. An earlier EEB review dated September 18, 1989 (copy also enclosed) indicated that "the supplemental sheepshead minnow study with the technical grade (MRID No. 40780507) 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 together." A waiver of the requirement to repeat this study is appropriate in light of the fact that we are now focusing attention on the degradates BTS 27271 and BTS 27919 and will be conducting estuarine fish acute LC₅₀ studies on these metabolites.

NOR-AM Chemical Company also agrees to conduct the following studies, as proposed in the August 15, 1990 EEB review, to support the registration of OVASYN:

A Schering Berlin Company

Mr. Dennis Edwards
September 26, 1990
Page 2

<u>Guideline Reference</u>	<u>Title</u>	<u>TestSubstance</u>
71-4(a)	Avian reproduction (quail)	amitraz technical
71-4(b)	Avian reproduction (duck)	amitraz technical
71-2(a)	Avian LC ₅₀ (quail)	BTS 27271
71-2(a)	Avian LC ₅₀ (quail)	BTS 27919
71-2(b)	Avian LC ₅₀ (duck)	BTS 27271
71-2(b)	Avian LC ₅₀ (duck)	BTS 27919
72-1(a)	Fish acute LC ₅₀ (bluegill)	BTS 27271
72-1(a)	Fish acute LC ₅₀ (bluegill)	BTS 27919
72-1(c)	Fish acute LC ₅₀ (trout)	BTS 27271
72-1(c)	Fish acute LC ₅₀ (trout)	BTS 27919
72-2(a)	Invertebrate LC ₅₀	BTS 27271
72-2(a)	Invertebrate LC ₅₀	BTS 27919
72-3(a)	Estuarine fish LC ₅₀	BTS 27271
72-3(a)	Estuarine fish LC ₅₀	BTS 27919
72-3(b)	Mollusk LC ₅₀	BTS 27271
72-3(b)	Mollusk LC ₅₀	BTS 27919
72-3(c)	Shrimp LC ₅₀	BTS 27271
72-3(c)	Shrimp LC ₅₀	BTS 27919

We note that the other studies listed in the August 15th EEB review are RESERVED pending review of the above listed acute studies.

Thank you for your continued attention to the registration efforts for OVASYN. If you have any questions, or wish to discuss this matter any further, please feel free to contact me at 302/575-2048.

Best regards.

Sincerely,


Jacob J. Vukich
Registration Project Manager

JV11opp/dm

