3-27-79 20

EEE BRANCH REVIEW

DATE: IN 2/1/79 OUT 2/8/79 IN _____ OUT _____ IN _____ OUT _____
3/27/79

FISH & WILDLIFE ENVIRONMENTAL CHEMISTRY EFFICACY

FILE OR REG. NO. 100 ANR

PETITION OR EXP. PERMIT NO. 8G2121

DATE DIV. RECEIVED

DATE OF SUBMISSION

DATE SUBMISSION ACCEPTED

TYPE PRODUCTS(S): I, D, H, (F) N, P, S Fungicide

DATA ACCESSION NO(S). 236854, 234439

PRODUCT MGR. NO. 21, Jacoby

PRODUCT NAME(S) Ridomil

COMPANY NAME Ciba Geigy Corp.

SUBMISSION PURPOSE Registration of Technical Product

CHEMICAL & FORMULATION N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine
methyl ester 90%
Inert Ingredients.....10%

100.0 Pesticide Use

Technical Ridomil is to be used for the formulation of fungicides.

100.1 Application Methods/Directions

CGA 48988 (Ridomil) is for formulation use only.

100.3 Precautionary Labeling

Keep Out of Reach of Children.

Keep out of lakes, streams, or ponds. Do not contaminate water by cleaning of equipment or disposal of wastes.

101.0 Chemical and Physical Properties

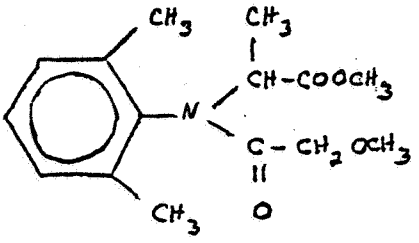
101.1 Chemical Name

N-(2,6-dimethylphenyl)-N-(methoxyacetyl) alanine methyl ester.

101.2 Common Name

Ridomil - No generic name given.

101.3 Structural Formula



101.4 Molecular Weight

279.34

101.5 Physical State

The description of the technical material used in the toxicity tests appeared to be a tan powder to a brown solid material. No other information is available.

101.6 Solubility

Unknown for the technical material, formulated product (Ridomil 2E - 25% a.i.) are as follows:

water	0.7%
Methanol	65%
Benzene	55%
Hexane	0.9%
Isopropanol	27%

Solubility information and material sample has been requested.

102.0 Behavior in the Environment

Information from the review of Sam Creeger dated 3/5/79:

1) at pH 5.7 and 9 and at 20 - 20°C the halflife of CGA - 48988 is not reached before 4 weeks.

2) CGA - 48988 is stable to hydrolytic conditions normally found in the environment.

No other information is available.

103.0 Toxicological Properties

All toxicological information for the technical material is listed in table 1.

104.0 Hazard Assessment

A hazard assessment will not be performed on the technical material since a use pattern has not been identified.

104.1 Discussion

The technical material appears relatively innocuous.

CGA-48988 is the technical material with which systemic fungicides are to be made. According to the report by Environmental Fate the expected halflife/breakdown of the product in normal use can be expected to be greater than four weeks.

Due to the difficulty of disolving the chemical in water for the aquatic toxicity test and due to the results of the test (LC50>100 ppm) it is anticipated that CGA 48988 is not going to be a problem in the aquatic environment. Neither is it anticipated to be a problem with mammals or birds.

104.1.1 and 104.1.2 Non-target and Endangered Species Considerations

Since a specific use pattern has not been identified, the hazards to non-target and endangered species were not considered.

104.1.3 Adequacy of Toxicity Data

The basic study requirements for the registration of the technical material have been fulfilled, however, due to the problems observed with aquatic studies further testing may be necessary for specific use patterns and formulated products.

The first aquatic tests submitted (accession #234439) were all validated as supplemental because of the following reasons:

1) studies were conducted at temperatures lower than recommended. (carp & bluegill)

2) species were not native (carp, guppy)

3) test temperatures varied $\pm$ 2°C (all)

4) test was aerated (trout)

Table 1. Studies Validated in a 9/1/78 Review for Ridomil 2E. (except where noted.)

	Organism	Test	Results(95% CI)	5 Active	Data Review #	Validation Category
Mammal	rats	acute oral LD50	669 mg/kg	Tech.	-	-
	mice	"	788 mg/kg	"	-	-
	rabbits	"	697 mg/kg	"	-	-
	rat	acute dermal LC50	6000 mg/kg	"	-	-
	rabbit	"	3100 mg/kg	"	-	-
Bird	mallard duck	acute oral LD50	1,466(1128-1906)mg/kg	Tech.	ES-C-1	Core
	Japanese quail	"	923(798-1069)mg/kg	"	ES-C-2	Invalid
	Bobwhite quail	8-day dietary LC50	10,000 ppm	"	ES-D-1	Core
	Japanese quail	"	"	"	ES-D-2	Supp
	mallard duck	"	"	"	ES-E-1	Core
Fish	Rainbow trout	96-hr LC50	100 ppm	Tech.	ES-G-1	Supp
	Bluegill	"	100 ppm	"	ES-F-1	Supp
	Catfish	"	100 ppm	"	"	Supp
	Carp	"	100 ppm	"	"	Supp
	Guppy	"	100 ppm	"	"	Supp
	Rainbow trout	"	130 ppm	"	ES-G-1*	Core**
	Bluegill	"	150 ppm	Tech.	ES-F-1*	Core**
Invertebrates	Daphnia magna	48-hr. LC50	29.3(21.6-38.9)ppm	Tech.	ES-H-1	Supp
	"	"	28(21-37) mg/l	"	ES-H-1	Core**

* Studies Validated in this review

** Studies Core for the technical material only.

107.1 Environmental Fate and Toxicology

The Environmental Fate review dated 3/5/79 by S.M. Seeger was in this review however no other reviews by Environmental Chemistry or Toxicology were consulted.

107.2 Classification

The technical material was not classified.

107.3 Labeling

The labeling as presented is adequate.

107.4 Data Adequacy

The fish and wildlife toxicity studies, as submitted, have satisfied the basic requirements for technical CGA-48988. The acceptable studies are as follows:

1) Acute Oral LD50 - mallard duck - CGA-48988 technical, Final Report. Project No. 108-149 dated Nov. 3, 1977. Acc ssion No. 234439.

2) Eight day dietary LC50 - Bobwhite quail - CGA-48988 Technical, Final Report. Project No. 108-147 dated Nov. 10, 1977. Accession No. 234439.

3) Eight day dietary LC50 - mallard duck - CGA-48988 Technical, Final Report. Project No. 108-148 dated Nov. 3, 1977. Accession No. 234439.

4) Acute Toxicity of CGA-48988 Technical to Bluegill (Lepomis macrochirus). Report # BW-78-12-381. dated Dec. 18, 1978. Accession No. 236854.

5) Acute Toxicity of CGA-48988 Technical to Rainbow trout (Salmo gairdneri). Report # BW-78-12-376. dated Dec. 21, 1978. Accession No. 236854.

6) Acute Toxicity of CGA-48988 to the water flea (Daphnia magna). Report No. BW-78-12-364. dated Dec. 8, 1977. Accession No. 236854.

All other studies (with the exception of the Japanese Quail acute toxicity study) submitted in the above mentioned assession number are not adequate to support registration of the product however they do contain useful information. The Japanese quail study is not acceptable because the bird is not an acceptable test species.

5) loading factor excessive (all)

6) an LC50 was not established >100 ppm (all fish)

7) numbers of fish tested/number of concentrations not adequate (carp, catfish, bluegill).

The Daphnia study submitted had statistical problems (data hetergenious). When they were submitted the first aquatic tests were validated supplemental and it was recommended that the three basic studies be resubmitted.

These studies were submitted and analyzed in this review. They were validated as core even though the researchers experienced difficulty in, 1) keeping the DO at an acceptable level (i.e., 40% saturation or above), and 2) getting the chemical into solution which was ultimately accomplished. The studies were also plagued with a surface film which also may have added to the DO problem.

The studies were validated core despite the problems, because of two main factors:

1) the problems experienced placed an added stress on the animals.

2) all aquatic test results indicate a fish LC50 of >100 ppm.

104.1.4 Additional Data Required

Because the aquatic tests submitted did experience problems, and because the test temperatures, water chemistry and other physical conditions were unique (yet acceptable), further aquatic test will be necessary. The additional tests will be required for the registration of specific products formulated with the technical material and will be conducted using the formulated product.

105.0 Classification

This chemical is not classified because the use is the Technical Product Registration.

107.0 Conclusions

The Ecological Effects Branch has no objections to the registration of technical CGA-48988. It is understood that CGA-48988 technical will be used in the formulation of systemic fungicides, however, specific use patterns have not been supplied as yet.

Upon analyzing, the aquatic tests, it was noticed that the testing facility reported problems related to the dissolution of the chemical into the water. Because of this, the studies were accepted to support the registration of the technical material only. Until such time as the Agency is satisfied that the studies are good indicators of the affects of CGA-48988 Technical to aquatic organisms, aquatic tests of the formulated products will be necessary for the products registration.

It is requested that a 10 gram sample of CGA-48988 Technical be sent to our EPA testing facility so that further experimentation can be conducted by the Agency. A sample, along with water solubility information and laboratory methods used to determine aquatic concentrations would enable the Agency to gain further knowledge of the chemical's actions in the aquatic environment. The information should be forwarded to:

John McCann
Environmental Protection Agency, Bldg. 402
Agricultural Research Center East
Beltsville, MD 20705

It is hoped that this information will clear up the questions about the aquatic tests so that future product registrations can be processed without further testing.

John Tice 3/28/79
Ecological Effects Branch

Jim Akerman
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Clayton Bushong 4/18/79
Branch Chief
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