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DATA ACCESSION NO(S). 405508-01, 405508-02,

PRODUCT MANAGER NO. L. Rossi(21)

PRODUCT NAME(S) Rovral

COMPANY NAME Rhone-Poulenc

SUBMISSION PURPOSE Submission of further toxicity data to support
rice use

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
_____	<u>Rovral</u>	_____
_____	_____	_____
_____	_____	_____

ECOLOGICAL EFFECTS BRANCH REVIEW

Iprodione

100.0 Submission Purpose and Label Information

100.1 Submission Purpose and Pesticide Use

Rhone-Poulenc is requesting a section 3 registration for iprodione as a formulated product known as Rovral® for use on rice. This company applied earlier for a section 3 registration for rice but was required to submit additional data in order to complete an incremental risk assessment.

100.2 Formulation and Information

Active Ingredients:

Iprodione*	:	50%
Inert Ingredient:	:	50%
		<hr/>
		100%

*3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide.

100.3 Application Methods, Directions, Rates

Rovral may be applied by aerial equipment to all flooded rice areas except in California at a rate of 0.5 lb ai/A. This compound may be applied twice a year, the first application between joint movement and booting, the second 2 weeks later than heading (according to EEB Review, June 10, 1987, D. Rieder).

100.4 Target Organisms

Sheath Blight Rhizoctonia solani

100.5 Precautionary Labeling

Do not apply to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes.

101.0 Hazard Assessment

Discussion

In 1986 over 2,401,000 acres of rice were harvested in Arkansas, California, Louisiana, Mississippi, Missouri, and Texas. Arkansas harvested 44 percent of the U.S. crop production (Agricultural Statistics, 1987).

Rice is planted from mid-April until late May depending on the area and variety. Harvesting starts in early August and may extend until mid-November.

The rice plant is an annual which grows from 3- to 5-feet tall in Arkansas and is best adapted to an aquatic habitat and to moderately high temperatures and humidity. Rice has two periods of growth: 1) the vegetative stage, which includes germination, seedling establishment, and tillering, and 2) the reproductive stage which includes panicle (head) initiation, jointing, head development, booting, heading, flowering, pollination, grain development, and ripening. The vegetative stage accounts for most of the variation in length of growing season among varieties.

Rice should be grown on a 3-year rotation with soybeans and cotton/oats/grain sorghum to aid in seed bed preparation, unused fertilizer from the previous crop, etc.

Sheath blight, the target organism of Rovral, generally occurs when there is 100 percent humidity, temperature above 95 °F, dense canopy, high N content, and moderately warm temperatures (Rice Production in Arkansas, Circular 476 Rev., Cooperative Extension Service, University of Arkansas Division of Agriculture).

101.2 Likelihood of Adverse Effects to Nontarget Organisms

Terrestrial Organism Toxicity

The available avian toxicity data indicate iprodione is slightly toxic to upland game (bobwhite LD₅₀ = 930 mg/kg) on an acute oral basis and practically nontoxic to upland game and waterfowl (bobwhite LC₅₀ = 9200 ppm, mallard LC₅₀ = 20,000 ppm) on a dietary basis. The avian reproduction MATC was determined to be > 300 and < 1000 ppm.

Iprodione is practically nontoxic to the rat with an acute oral LD₅₀ > 3700 mg/kg.

Aquatic Organism Toxicity

Acute-Freshwater

Iprodione is moderately toxic to both coldwater and warmwater fish (rainbow trout LC₅₀ = 4.2 ppm and catfish LC₅₀ = 3.02 ppm). This chemical is highly toxic to Daphnia magna with a reported LC₅₀ = 0.43 ppm. Iprodione is moderately toxic to juvenile crayfish with a 7 day LC₅₀ > 4.1 ppm.

Acute- Marine

Iprodione technical is moderately toxic to the oyster with a reported 96 hour EC₅₀= 2.3 ppm, and highly toxic to mysid shrimp (LC₅₀= 0.68 ppm). This compound is moderately toxic to the sheepshead minnow with a reported LC₅₀= 7.7 ppm.

Chronic Toxicity- Freshwater

A Daphnia magna life cycle study indicates a MATC > 0.17 < 0.33 ppm. A fathead minnow early life stage toxicity study indicates the larval survival MATC to be > 0.26 mg/l and < 0.55 mg/l.

Chronic Toxicity- Marine

A supplemental mysid life cycle study indicated there was an effect on reproductive success at the lowest dose tested, 0.015 mg/l (15 ppb) mean measured concentration.

Formulated Data

Formulated testing indicates Rovral (50% ai) is moderately toxic to the warmwater fish and highly toxic to freshwater invertebrates (Bluegill LC₅₀= 8.6 ppm and Daphnia magna LC₅₀= 0.36 ppm).

Environmental Fate and Residues

Iprodione is stable to hydrolysis at a pH of 3, and the hydrolysis half-life is 20 days at a pH of 6 and 1 day at a pH of 9. The photolysis half-life is less than 1 week. Persistence of the parent compound in a field dissipation study ranged from 1 to 12 weeks. The water solubility is 13 ppm (EAB Review, December 17, 1987, H. Manning).

A aquatic field dissipation study indicated that the initial concentration of parent iprodione ranged from 0.02 to 0.70 ppm, and the degradate RP-30228 comprised up to 50 percent of the total residues immediately posttreatment (EAB Review, July 30, 1987, H. Manning).

The half-life of ¹⁴C iprodione ranged from 20 to 70 days for soil under aerobic conditions and from 20 to 50 days for soil under anerobic conditions.

An incomplete study indicated residues in rice grain from 1.0 lb/A treatment gave 1.1 to 2.5 ppm at

32 to 36 days posttreatment in LA; in MS, 0.8 to 0.7 ppm 32 to 58 days posttreatment; and in AR, 0.5 to 0.2 ppm 38 to 43 days posttreatment. Residues in straw were generally slightly higher (EAB Review, May 5, 1986, H. Manning).

Iprodione residues accumulated in crayfish with maximum bioconcentration factors of 10X in edible tissue and 20X in whole organisms during 28 days exposure (EAB Review, July 30, 1987, H. Manning).

A bluegill sunfish accumulation study indicated a maximum bioaccumulation in edible tissue of 103X in 7 days, in viscera it was 555X in 7 days, and in whole fish it was 177X in 7 days. By day 28, it was 65X (edible), 155X in viscera, and 52X (whole fish) (EAB Review, May 6, 1986, H. Manning).

Terrestrial Residues

The following residues are expected immediately following a single application of 0.5 lb a.i./A (based on EEB's nomograph, Urban, D.J.; Cook, N.J. (1986); Hazard Evaluation Division, Standard Evaluation Procedure, Ecological Risk Assessment:

<u>Substrate</u>	<u>Residues (ppm)</u>
Short rangegrass	120
Long grasses	55
Leaves and leafy crops	63
Forage (alfalfa and clover, exposed seeds, small insects)	29
Pods containing seeds (large insects)	6
Fruit	4
Soil (top 0.1 inch after direct application)	11

Aquatic Residues

The following aquatic estimated environmental concentration (EEC) was calculated based on the specific use on rice. Based on an earlier EEB Review (Dan Reider, iprodione on rice, June 10, 1987), the following assumptions were made:

0.5 lb ai/A into 3" water=734 ppb;
2 " of rain dilutes concentrations to 440 ppb;
Discharge water is 440 ppb which is diluted by 50%
in the receiving water to 220 ppb.

Therefore, the EEC is 220 ppb.

It should be noted that an incomplete field dissipation study submitted to support this use pattern indicates the residues to be as high as 700 ppb for the parent compound following initial application to the flooded rice fields. Concentrations of the degradates RP-30228 and RP-32490 ranged from <10 to 700 ppb and <10 to 170 ppb, respectively.

Since, EEB estimated the residue of the parent compound to be 734 ppb after direct application to the rice field, and the actual measured residues were as high as 700 ppb, the concern for significant residues (EEC=220 ppb) in the receiving water are supported.

101.3 Risk Assessment

A. Effects on Terrestrial Organisms

Avian Wildlife

Iprodione is slightly toxic to upland game on an acute oral basis, and practically nontoxic to both upland game and waterfowl on a dietary basis.

Based on the maximum estimated residues in short rangegrass, 120 ppm is well below both the triggers for restricted use classification and the endangered species classification (1/5 LC₅₀ = 1840 ppm and 1/10 LC₅₀ = 920 ppm, respectively). The residue of 120 ppm is also well below the avian reproductive NOEL \leq 300 ppm.

Mammals

Iprodione is not expected to pose a hazard to mammals based on the acute oral rat LD₅₀ = 3700 mg/kg which is converted to 3700 ppm. The short rangegrass residue of 120 ppm is well below both the restricted use and endangered species classification triggers (740 and 370 ppm, respectively).

B. Effects on Aquatic Organisms

Iprodione technical is moderately toxic to both freshwater and marine fish with reported LC₅₀ values ranging from 3.02 to 7.7 ppm. Iprodione technical is highly toxic to freshwater invertebrates and moderately toxic to highly toxic to marine invertebrates. The Daphnia magna life cycle MATC was reported to be >0.17 <0.33 ppm. The MATC for fathead minnow early life stage toxicity study was >0.26 mg/l and <0.55 mg/l.

The NOEL was less than 0.015 mg/l for a supplemental mysid life cycle study.

The special review trigger of 215 ppb for aquatic invertebrates (using 1/2 LC₅₀ as the criteria) is exceeded by an EEC of 220 ppb. In addition, the EEC exceeds the lowest effect level of 15 ppb for the mysid, and the NOEL for the Daphnia magna of 170 ppb. Therefore, there is a potential risk to aquatic non-target invertebrates (both freshwater and marine) from the use of this compound.

Endangered Species Considerations

There are no concerns for endangered terrestrial wildlife, based on the estimated residues and the available toxicity data.

There were concerns for both endangered fish and aquatic invertebrates. EEB has consulted with the U.S. Fish and Wildlife Service and has determined that only endangered aquatic invertebrates are at risk from the use of this compound on rice, due to the location of where rice is grown.

101.4 Adequacy of Toxicity Data

The following studies were reviewed to support registration of iprodione on rice:

Suprenant, D.C. 1988. Chronic Toxicity of Iprodione Technical to Mysid Shrimp (Mysidopsis bahia). Prepared by Springborn Life Sciences, Inc., Wareham, MA. Submitted by Rhone-Poulenc AG Company, Research Triangle park, North Carolina. Report No. 88-2-2640. Accession No. 405508-02.

This study is scientifically sound, however, does not satisfy guideline data requirements for invertebrate life cycle test because the MATC could not be accurately determined. Based on the most sensitive indicator (i.e. reproductive success), the MATC of Iprodione Technical

for Mysidopsis bahia was below the lowest concentration tested, 15 ng/l (ppb).

Suprenant, D.C. 1988. The Toxicity of Iprodione Technical to Fathead Minnow (Pimephales promelas) Embryos and Larvae. Prepared by Springborn Life Sciences, Inc., Wareham, MA. Submitted by Rhone-Poulenc AG Company, North Carolina. Report No. 88-2-2639. Accession No. 405508-01.

This study is sound and meets the guideline requirements for a fish early life stage study. Based on significant adverse effects on larval survival., the MATC of Iprodione Technical for Pimephales promelas was estimated to be >0.26 mg/l and <0.55 mg/l. The testing laboratory should be informed that in the future, the study design should include four replicate embryo cups per test concentration.

Based on these data and the previously submitted data, the following studies are required:

- An acceptable marine invertebrate life cycle study to satisfy guideline data requirement reference no. 72-4.
- A residue monitoring study to determine actual residues.

Since an aquatic field dissipation study supports the estimated environmental concentration for the receiving water, a residue monitoring study is required on at least 5 sites measuring the following:

- residue bound to the sediment in the rice fields; and
- residue that will transport to adjacent aquatic habitat during periods of flooded discharge or overflow.

The residue monitoring study protocol should be submitted for approval prior to study initiation to ensure that the study addresses all of the concerns.

In addition, since this is a fungicide that will be applied directly to water, the effect on the growth and reproduction of aquatic plants (Tiers 1) with the following five species must be evaluated:

- Lemna gibba
- Skeletonema costatum
- Anabaena flos-aquae
- Selenastrum capricornutum
- Unspecified species- Freshwater diatoms

101.5 Adequacy of Labeling

The following labeling is required:

" This pesticide(or product) is toxic to aquatic invertebrates. Do not contaminate water when disposing of equipment washwaters."

Endangered Species Restrictions

As a result of a formal consultation with U.S. Fish and Wildlife Service (March 28, 1988), the following labeling is required to protect the endangered aquatic invertebrate, fat pocketbook pearly mussel:

" The use of Iprodione(Rovral) on rice is restricted to protect the endangered fat pocketbook pearly mussel (Potamilus capax) and its habitat. Use is prohibited in the following areas of Arkansas:

Mississippi County- Within the basin that drains directly into the Right Hand Chute of Little River, south of Big Lake National Wildlife Refuge.

Poinsett County- Between Crowley's Ridge and the levee east of the Right Hand Chute of Little River and the St. Francis Floodway. Use is also prohibited west of Rt. 140 and north of Rt. 63 at the siphon near Marked Tree. Except that the prohibited area does not include the area bounded by Arkansas highway 373 on the west, highway 63 on the east and highway 14 on the south.

Cross, St. Francis and Lee Counties- Between Crowley's Ridge and the levee east of the Right Hand Chute of Little River and the St. Francis Floodway as far south as the confluence of L'Anquille River(Lee County)".

102.0 Classification

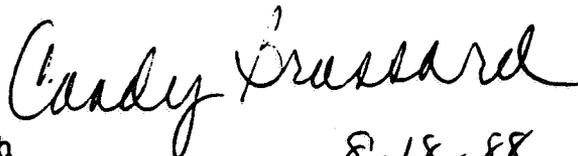
Based on the aquatic toxicity data and the proposed use pattern, this pesticide is required to be classified as a "Restricted Use Pesticide".

103.0 Conclusion

Based on the available data, the EEC (which is supported by the submitted fate data) exceeds the endangered species, restricted use and the special review triggers for aquatic invertebrates. There are no currently registered use patterns where iprodione is applied directly to water. Therefore, the use of this compound on rice may pose a significant increase in exposure and hazard to both nonendangered and endangered aquatic invertebrates.

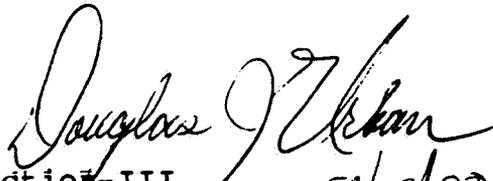
EEB has reviewed the proposed registration of iprodione for use on rice. EEB is unable to complete an incremental risk assessment for this use because pertinent data are lacking. In order to assess the risks associated with this use, EEB requires the data listed in section 101.4.

Candy Brassard
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)



8-18-88

Douglas J. Urban, Head Section-III
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)



8/18/88

James W. Akerman, Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769C)

