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

8/17/95

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

To: Rick Keigwin PM 10
Registration Division (7505C)

From: for Anthony F. Maciorowski, Chief Ann Stavola 8/16/95
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

Subject: Fipronil 0.1G EUP on turf (D215537)

Rhom & Haas Company has applied for an Experimental Use Permit (EUP) to conduct field evaluation of insecticide Fipronil 0.1G for controlling mole crickets on turf. The Ecological Effects Branch has reviewed the request and completed an ecorisk assessment. The chemical is found to be very highly toxic and hazardous to non-target aquatic fish and invertebrate organisms. It is also highly toxic to very highly toxic to avian species tested (based on acute and subacute studies, respectively). However, EEB concludes that the proposed EUP provides for minimal acute hazards to nontarget organisms due to low application rate (0.025 lb./A.), minimal exposure (eg., 0.763 ppb for aquatic EEC), limited acreage (264 acres) and tonnage (10.1 lbs.) being proposed to be used on small test plots (ca. 3 A.) scattered over six states.

If you have any questions please contact Richard Lee (305-5577) or Ann Stavola (305-5354).

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6/20/95

DP BARCODE: D215537

CASE: 007276 DATA PACKAGE RECORD DATE: 05/19/95
SUBMISSION: S487075 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: EUP (SECT 5) ACTION: 700 EUP NC N-F/F USE
RANKING : 15 POINTS (J)
CHEMICALS: 129121 Fipronil 0.1000%

ID#: 000264-EUP-RNN
COMPANY: RHONE-POULENC AG COMPANY
PRODUCT MANAGER: 10 RICK KEIGWIN 703-305-6788 ROOM: CM2 210
PM TEAM REVIEWER: ANN SIBOLD 703-305-6502 ROOM: CM2 201
RECEIVED DATE: 05/10/95 DUE OUT DATE: 09/07/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 215537 EXPEDITE: Y DATE SENT: 05/18/95 DATE RET.: / /
CHEMICAL: 129121 Fipronil
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	5/22/95	/ /
BRAN: EEB	5/23/95	8/17/95
SECT: RS1	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

ADMIN DUE DATE: 08/06/95
NEGOT DATE: 8/16/95
PROJ DATE: / /

* * * DATA REVIEW INSTRUCTIONS * * *

To: Tony Maciorowski and Ann Stavrola, Please review the fipronil data already submitted in support of the proposed turf registration (264-LLN for turf and 264-LLU for the technical) which is being cited in support of this EUP. In addition to the CSF and the label, I've attached the description of the experimental program and the list of studies cited in support of this EUP. Please call if you have questions or need anything else to complete your review. Thanks, Ann Sibold 305-6502

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

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

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

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DP Barcode : D215537
PC Code No. : 129121
EEB Out : 8/17/95

To: Rick Keigwin
Product Manager 10
Registration Division (7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # : 000264-EUP-RNN
Chemical Name : Fipronil
Type Product : Insecticide
Product Name : Chipco Gaunlet 0.1G
Company Name : Rhone-Poulenc Ag Company
Purpose : Eup to control mole cricket on turf
^C
^C
Action Code : 510 Date Due : 8/6/95
Reviewer : Richard Lee

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

ECOLOGICAL EFFECTS BRANCH REVIEW

Chemical Name: Fipronil: 5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-((1,R,S)-(trifluoromethyl)sulfinyl)-1-H-pyrazole-3-carbonitrile

Common Name: FIPRONIL 0.1G

Trade Name: FIPRONIL (CHIPCO®, GAUNTLET™) 0.1% Granular, Turf Insecticide

100.0 Submission and Label Information

100.1 Nature and Scope of the Submission

Request for an experimental use permit (EUP) for use of Fipronil 0.1G to control mole cricket on turf. Objectives of the program are as follows:

1) To refine application methods and procedures with slit-application equipment.

2) To reaffirm performance under various environmental, geographic, and turf-grass cultural conditions.

3) To allow commercial applicators to obtain experience with a product which is applied at much lower volumes than they are accustomed to applying.

4) To allow key researchers and influencers the opportunity to evaluate this novel product.

100.2 Treatment Area

The product will be used in the states of Alabama, Georgia, Florida, Mississippi, North Carolina, and South Carolina.

Total Acreage: 95 sites/264 acres

Total Quantity of Formulated Product: 10,900 lbs. (100 lbs. of product is needed to charge equipment, but will be collected and retained.)

Total Quantity of Active Ingredient: 10.1 lbs.

100.3 **Target Organisms**

Mole cricket (Scapteriscus spp.)

100.4 **Formulation Information**

Fipronil 0.1G is formulated as a granule and applied using slit-placement equipment.

*Active Ingredient:
5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-((1,R,S)-(trifluoromethyl)sulfinyl)-1-H-pyrazole-3-carbonitrile.....0.1%
Inert Ingredients.....99.9%

*Contains 0.001 pound of active ingredient per pound of product.

100.5 **Application Methods and Rates**

Application rate will be 0.0125 lb. a.i. per acre of a 0.1% granular product (12.5 to 25.0 lbs. of formulated product per acre).

Apply using slit-placement equipment only. Depth of the slit should be targeted at the thatch/soil interface. Apply at least 0.1 inch of water immediately after application.

Make application timed to control overwintering adult mole crickets or at peak egg hatch to control young nymphs.

Use higher rate against heavy insect infestations or older insect life stages.

In case of heavy insect infestations, a second application may be necessary; however, do not apply the product within 4 months of the first application.

Do not make more than 2 applications per year. Do not apply more than 25 pounds of product per acre (0.025 lb. a.i./A) per application.

100.6 **Date and Duration**

A two year permit is being requested - one year for 1995, and one year for 1996.

100.7 **Precautionary Labeling**

Environmental Hazards

This pesticide is toxic to birds and aquatic organisms (fish and invertebrates). Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Cover, incorporate or clean up granules that are spilled during loading or visible on soil surface in turn areas. Do not contaminate water when disposing of equipment wash water or rinsate.

101.0 **Hazard Assessment**

101.1 **Discussion**

Rhone-Poulenc Ag Company has applied for an experimental use permit to use FIPRONIL 0.1% Granular soil insecticide on turf (golf courses and commercial grounds). Fipronil 0.1G is a new soil insecticide with no currently registered uses.

The details of the proposed EUP program is as follows:

1) Studies will be season-long evaluations conducted on warm-season turfgrass cultivars for control of mole cricket (Scapteriscus spp.).
2) Application rates will be 0.0125 to 0.025 lb. a.i. per acre of 0.1% granular product(12.5 to 25.0 pounds of formulated product per acre). There are one to two applications per season with a maximum of 25 pounds of product per acre.

3) Application will be made using slit-placement application equipment to ensure accurate delivery and maximize efficacy. This method of application will also minimize potential run-off and exposure to non-target organisms.
4) Studies wil be limited to the six southeastern United States where mole cricket populations are highest (see the table below).
5) If re-treatment is necessary, spot re-treatment rather than broadcast application will be employed.

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STATE	COUNTY	No. of TESTS	ACREAGE	POUNDAGE APPLIED (A.I.)*
Alabama	Baldwin, Barbour, Elmore, Lee, Mobile, Montgomery	15	42	1.6
Georgia	Bibb, Chatham, Crisp, Dougherty, Glynn, Tift	20	55	2.1
Florida	Alachua, Brevard, Broward, Charlotte, Collier, Dade, Duval, Escambia, Highlands, Hillsborough, Indian River, Lake, Lee, Manatee, Martin, Okaloosa, Orange, Osceola, Palm Beach, Polk, St. Lucie, St. Johns, Sarasota, Seminole	30	83	3.1
Mississippi	Hancock, Harrison, Jackson, Lauderdale, Lowndes, Newton, Oktibbeha, Rankin	10	28	1.1
North Carolina	Pender, Onslow, Carteret	10	28	1.1
South Carolina	Horry, Georgetown, Barkley, Charleston, Beaufort	10	28	1.1
Totals		95	264	10.1

* 1 treatment at 0.0125 lb ai/a plus 1 treatment at 0.025 lb ai/a.

101.2 Likelihood of Adverse Effects on Non-Target Organisms

Terrestrial Organisms Toxicity

The following summarizes the acute bird toxicity data for Fipronil 0.1G soil insecticide. Based on these data, there is sufficient information to characterize fipronil as highly /very highly toxic to avian species tested (on acute/subacute basis, respectively).

Ann -

found some errors after checking DER's - what to do?

- NICK

AVIAN TEST RESULTS

TABLE 1.

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.		
71-1A	Mallard, Acute Oral LD_{50}	429186-16	1/5/94	Core, Practically Non-Toxic	96.8	1990	ai/kg
71-1A	Quail, Acute Oral LD_{50}	428186-17 429186-17	1/4/94	Core, Highly Toxic	96	1993	LD_{50} = 11.3 mg ai/kg
71-1A	Quail, Acute Oral LD_{50}	429186-19	1/13/94	Supp., Highly Toxic	1.6	1993	LD_{50} = 17.0 mg ai/kg
71-2B SUB	Mallard, Acute Dietary LC_{50}	429186-21	1/14/94	Core, Slightly Toxic (oral - non-toxic)	>95	1993	LC_{50} = 4480 ppm ai
71-2A SUB	Quail, Acute Dietary LC_{50}	429186-20	1/12/94	Core, Very Highly Toxic	>95	1993	LC_{50} = 48.0 ppm ai
71-2A	Pheasant, Acute Dietary LC_{50} (oral LD_{50})	428186-15 429186-15	1/6/94	Core, Suppl. Very Highly Toxic (Highly toxic)	95.4	1991	LC_{50} = 31 mg/kg (nom.)
71-2A	House Sparrow, Acute Dietary LC_{50} (oral LD_{50})	429186-18	1/6/94	Supp., Moder. Toxic (Slightly toxic)	96.7	1991	LC_{50} = 1000 mg ai/kg
71-2A	Red-Legged Partridge, Acute Dietary LC_{50} (oral LD_{50})	428186-14 429186-14	1/10/94	Supp., Very Highly Toxic (Highly toxic)	95.4	1991 1992	LC_{50} = 34 mg ai/kg

71-2A	Pigeon, Acute Dietary LC_{50}	428186 -13	1/5/94	Supp., Moder. Toxic	97.7	1991	LC_{50} = >500 mg/kg (nom.)

Mammalian Toxicity

The registrant reported a rat acute oral LD_{50} >5000 mg/kg, a rabbit acute dermal LD_{50} >2000 mg/kg, and a rat acute dermal inhalation LD_{50} >5.11 mg/L. However these studies have not yet been validated by HED.

Aquatic Plant Toxicity

Five aquatic plant studies were conducted with Fipronil 0.1G. Two studies were evaluated as supplemental because the highest test concentration was lower than the maximum label rate calculated for a direct application to the surface of a 15cm or 6-inch water column. The results of these studies are presented below.

Table 2.

GLN#	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% AI	TEST DATE	RESULT
122-2	Freshwater Green Alga[1], Aquatic Plant-Tier 1	429186 -60	1/6/94	Core	96.1	1993	EC_{50} = 0.14 mg/l
122-2	Freshwater Blue-Green[2] Alga, Aquatic Plant-Tier 1	429186 -57	1/6/94	Core	96.1	1993	EC_{50} = >0.17 mg/l

[1] *Selenastrum capricornutum*

[2] *Anabaena flos-aquae*

122-2	Marine Diatom[3], Aquatic Plant-Tier 1	429186 -59	1/7/94	Core	96.1	1993	EC_{50} = >0.14 mg/l
122-2	Duckweed[4], Aquatic Plant-Tier 1	429186 -56	1/7/94	Supp	96.1	1993	EC_{50} = >0.10 mg/l
122-2	Freshwater Green Alga[5], Aquatic Plant-Tier 1	429186 -58	1/7/94	Supp	96.1	1993	EC_{50} = >0.12 mg/l

Toxicity to Freshwater Organisms

The following summarizes fipronil acute toxicity data for freshwater organisms. Based on these data, there is sufficient information to characterize fipronil as very highly toxic to freshwater organisms.

TABLE 3.

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-1C	Rainbow Trout LC_{50}	429779 -02	1/10/94	Core, Highly Toxic	100	1991	LC_{50} = 246 µg/L
72-1C	Rainbow Trout LC_{50}	429186 -73	1/11/94	Core, Very Highly Toxic	99.2	1993	LC_{50} = 39 µg/L
72-1A	Bluegill, LC_{50}	429186 -24	1/10/94	Core, Very Highly Toxic	100	1991	LC_{50} = 83 µg/L

[3] *Skeletonema costatum*

[4] *Lemna gibba*

[5] *Navicula pelliculosa*

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72-1A	Bluegill, LC_{50}	429186-74	1/12/94	Core, Very Highly Toxic	99.2	1992	LC_{50} = 25 µg/L
72-2A	Daphnia magna, EC_{50}	429186-25	1/12/94	Invalid	100	1990	NA
72-2A	Daphnia magna, EC_{50}	429186-69	1/13/94	Core, ~~Very Highly Toxic~~	100	1990	EC_{50} = 92.6 µg/L
72-2A	Daphnia magna, EC_{50}	429186-71	1/13/94	Core, Very Highly Toxic	100	1990	EC_{50} = 29 µg/L

Environmental Fate and Residues

Environmental fate data were submitted by the registr have not been fully reviewed by EFGWB.

Terrestrial Risk Assessment

The principles of ecological risk assessment used to regulate pesticides under the Federal Insecticide, Fungici Rodenticide Act (FIFRA) are explained in the EPA Standard Evaluation Procedures (SEP). These procedures define risk hazard in the form of a hazard ratio comparing the potent estimated exposure to the greatest experimental toxicity obtained.

The potential estimated exposure is represented by t calculation of an Estimated Environmental Concentration (based application rates, intervals, frequencies, and othe quantitative information found on the label. The greatest toxicity level comes from the results of the studies which are required for registration.

Avian Exposure - The LD_{50} per square foot for Fipronil 0.1G was based on the application rate of 25 lbs. (0.025 lb. a.i. per acre) with the slit-placement application at the thatch/soil interface. This application method incorporates the pesticide into the soil at root level where the pest resides. The equipment opens a slit in the soil, drops the granules, then seals the slit with soil to close it. Based upon the efficiency rates for different methods of granule incorporation taken from the Granular Risk Assessment Document, approximately 1% to 8% of the granules are likely to be unincorporated from the slit application (Laura Dye, EEB, pers. comm.).

Calculation for Number of Single Dose Oral LD50 per Square foot - Slit Placement Application

$$\text{Milligram per Square Foot} = \frac{\text{Product Appl. Rate (lbs/acre)} * \% \text{ A.I.} * 453{,}590 \text{ Mg/lb}}{43{,}560 \text{ Square Feet / Acre}}$$

$$\text{or Milligram per Square Foot} = \frac{25 \text{ (lbs/acre)} * 0.001 \text{ (\% a.i.)} * 453.590 \text{ (Mg/lb)}}{43{,}560 \text{ (Square Feet / Acre)}} = 0.26 \text{ Mg/ft}^2$$

$11{,}339.75 / 43{,}560 \downarrow .0026$

Assuming 1% to 8% granules left on surface:

$0.01 * 0.26 = 0.0026 \text{ Mg/ft}^2$

$0.08 * 0.26 = 0.0208 \text{ Mg/ft}^2$

$$\text{Single Dose LD50 per Square Foot} = \frac{\text{Mg / ft}^2}{\text{(LD50 Mgs / Kg) * Weight of birds (kg)}}$$

$$\text{or \# of LD50 per ft}^2 = \frac{0.0026 \text{ Mg/ft}_2}{\text{(11.3 Mg /kg) * 0.178 (kg)}}$$

= 0.00129 (for 1% unincorporated)

$$= \frac{0.0208 \text{ Mg/ft}_2}{\text{(11.3 Mg /kg) * 0.178 (kg)}}$$

= 0.0103 (for 8% unincorporated)

The values of 0.00129 and 0.0103 for the number of single dose LD50 per ft^2 is less than the criteria for the risk to endangered sp. ($LD_{50}/Ft^2 > 0.1$) and the criteria for high risk to nontarget avian species ($LD_{50}/Ft^2 > 0.5$). The assessment is based on the toxicity data of bobwhite quail the most sensitive species tested. Therefore, terrestrial wildlife is not expected to be at risk from the proposed use of fipronil on turf using the slit application method.

Aquatic Risk Assessment (Rough-cut Estimate With 1-Inch Soil Incorporation)

EEC calculations for the soil incorporated (slit replacement) application is based on an application rate of 25 lbs./A (0.025 lbs a.i./A). The rough-cut procedure is used for calculation due to lack of the chemical fate data. The final EEC value is determined by the hypothetical runoff from a 10 acre drainage basin with 1-inch soil incorporation to a 1 acre pond which is 6 feet deep. The EEC for transport into a pond 6 feet deep is 0.305 ppb (see the calculation below).

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Calculation of runoff for soil incorp. application

Application Rate X 5% ÷ Depth (cm) x 10A = Total
(lbs a.i./A) (% runoff) (Soil (10 Acre Runoff
(Incorp.) basin)

or 0.025 (lbs.) x 0.05 ÷ 2.5 (cm) x 10(A) = 0.005 (Lbs.)

EEC = 61 ppb for 6' deep x Total Runoff = _____ ppb
or = 61 ppb x 0.005 (lbs.) = 0.305 ppb

Table 5 AQUATIC HAZARD RATIOS FOR FIPRONIL 0.1G

Organism/ MRID No.	Depth	Appl. Rate (lb ai/A)	1/2 LC_{50} (ppb)	1/20 LC_{50} (ppb)	EEC (ppb)
Bluegill/ 429186-74	6 ft.	0.025	12.5	1.25	0.305
Daphnia/ 429186-71	6 ft.	0.025	14.5	1.45	0.305

Based on the criteria for regulatory action outlined by the new paradigm the aquatic EEC of 0.305 ppb does not exceed both 1/2 the LC_{50} (1/2 the LC_{50} for Bluegill = 12.5ppb) and 1/20 the LC_{50} (1/20 the LC_{50} for Bluegill = 1.25ppb). The LC_{50} for the Bluegill sunfish (*Lepomis macrochirus*) which was the most sensitive species tested was used for the comparison to the EEC (Table 5).

The criteria for freshwater invertebrates is the same as that of fish. The EEC (0.305 ppb) does not exceed both 1/2 the LC_{50} (1/2 the LC_{50} for Daphnia = 14.5ppb) and 1/20 the LC_{50} (1/20 the LC_{50} for Daphnia = 1.45ppb). The LC_{50} for *Daphnia magna* was used for the comparison to the EEC (Table 5). Therefore, Fipronil 0.1G poses no acute risk to both non-target and endangered aquatic species.

The EC_{50} for the freshwater green algae, *Selenastrum capricornutum*, is 140ppb (Table 2). Therefore, Fipronil 1.5G also has a low acute risk to aquatic plants.

101.3 Endangered Species Concern

Based on the available information, the proposed experimental use of Fipronil 0.1G on the turf using the slit-placement application method is unlikely to jeopardize both nontarget terrestrial and aquatic species.

The registrant must ensure that experimental plots are not in the vicinity of any of these listed species. The Endangered Species Protection Program is expected to become final sometime in the future. Limitations in the use of products containing Fipronil will be required to protect endangered and threatened species, but these limitations have not been defined and may be formulation specific. EPA anticipates that a consultation with the Fish and Wildlife Service will be conducted in accordance with the species-based priority approach described in the Program. After completion of consultation, registrants will be informed if any required label modifications are necessary. Such modifications would more likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

101.4 Adequacy of Toxicity Data

Listed below are the data requirements that have been satisfied. Additional test have been submitted and are currently pending review. They are 72-4 freshwater fish early life-stage test (*O. mykiss*) and 72-4 freshwater invertebrate life-cycle test (*D. magna*).

Guideline #	Study	Rating
71-1	Acute Avian Oral	Core
72-2	Acute Avian Dietary	Core
122-2	Aquatic Plant Growth, Tier 1	Core
72-1	Acute Freshwater Fish Toxicity	Core
72-2	Acute Aquatic Freshwater Invertebrate Toxicity	Core

101.5 Adequacy of Labeling

Precautionary labeling should read as stated in section 100.7.

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101.6 Conclusions

Based on the available toxicity data and exposure information, EEB concluded that the proposed experimental use of Fipronil 0.1G on turf is unlikely to jeopardize both nontarget and federally listed endangered/threatened terrestrial and aquatic organisms excepts endangered avian species.

Richard M. Lee, Entomologist
Ecological Effects Branch, Section 5
Environmental Fate and Effects Division

Ann Stavola, Supervisory Biologist
Ecological Effects Branch, Section 5
Environmental Fate and Effects Division

Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division