US EPA ARCHIVE DOCUMENT

3/9/94

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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 1.5G

Trade Name: FIPRONIL 1.5% Granular, Corn Soil Insecticide

100.0 Submission and Label Information

100.1 Nature and Scope of the Submission

Request ~~for an experimental use permit~~ (Section 5 of FIFRA) for use of Fipronil 1.5G on corn throughout the mid-western United States.

100.2 Treatment Area

Proposed label restricts use to the states of Indiana, Wisconsin, Iowa, Minnesota, Illinois, Ohio, Nebraska, and South Dakota.

Total Acreage: 1000; 50 tests

Total Quantity of Formulated Product: 8700 lbs

Total Quantity of Active Ingredient: 130 lbs

100.3 Target Organisms

Northern Corn Rootworm (*Diabrotica barberi*) larvae, Western Corn Rootworm (*Diabrotica vergifera vergifera*) larvae, and Wireworms (*Elateridae* (family)).

100.4 Formulation Information

Fipronil 1.5G in formulated as a granule and applied by either T-Band or In-Furrow methods.

*Active Ingredient:
5-amino-1-(2,6-dichloro-4-(trifluoromethyl)phenyl)-4-((1,R,S)-(trifluoromethyl)sulfinyl)-1-H-pyrazole-3-carbonitrile.....1.5%
InertIngredients.....98.5%

*Contains 0.015 pound of active ingredient per pound of product.

100.5 **Application Methods and Rates**

POUNDS OF FIPRONIL
1.5G PER 1000 ROW FEET

APPLICATION TIMING	PESTS CONTROLLED	T-BAND	IN-FURROW	APPLICATION DIRECTIONS
At planting	Northern and Western Corn Rootworm Larvae Wireworms	0.5 lbs. (8 oz.)for any row spacing. Do not apply more than 8.7 pounds of Fipronil 1.5G per acre.	0.5 lbs. (8 oz.)for any row spacing. Do not apply more than 8.7 pounds of Fipronil 1.5G per acre.	T-Band: Apply granules in a band 7 inches wide over an open seed furrow ahead of presswheel. In-Furrow: Apply the granules directly into the seed furrow behind planter shoe. In- furrow applications are recommended where wind or crop debris are likely to prevent proper placement of granules with a T-Band application.

USE RESTRICTIONS

Do not feed treated corn or fodder to livestock.

Do not allow livestock to graze in treated fields.

Do not harvest within 90 days of application.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift.

When treating agricultural crops, granules lying on the soil surface in turn areas at row ends must be incorporated to remove possible hazards to birds and other wildlife.

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Make application only during planting operation. Carefully calibrate granular application equipment to ensure accurate application.

For use on conventional or conservation tillage field corn systems.

100.6 Date and Duration

Duration is one year from the date of EPA approval.

100.7 Precautionary Labeling (excerpted from proposed product label)

Environmental Hazards

This pesticide is toxic to 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.

101.0 Hazard Assessment

101.1 Discussion

Rhone-Poulenc Ag Company has applied for an experimental use permit for FIPRONIL 1.5% Granular soil insecticide for corn. Fipronil 1.5G is a new soil insecticide with no currently registered uses.

Fipronil 1.5G is a soil insecticide formulated as a granule and applied with ground equipment at a rate of 8.7 pounds per acre. The pounds of active ingredient per acre are 0.13. It is applied by using one of two ground application methods either T-Band or In-Furrow at planting. There is only one application per season.

This EUP will be applied used in certain states (see below). Each test site will be up to 20 acres (maximum) in size. A maximum of fifty trials will each apply a maximum of 0.13 lb ai/A of Fipronil 1.5G once at planting. Corn is of the family Gramineae, and is a warm weather plant that requires a moderate amount of precipitation, but can be produced in semiarid regions. The growth period can be affected by photoperiod thereby affecting the time and the amount yield.

STATE	COUNTY	ACREAGE
Iowa	Grundy, Hardin, Jasper, Linn, Polk, Marion, Marshall, Tama	220
Illinois	Carroll, JoDavies, Ogle, Stephenson, Whiteside	200
Indiana	Tippecanoe, Porter, LaGrange, White	100
Minnesota	Blue Earth, Brown, Dakota, LaSeur, McLeod, Nicolette, Rice, Sibley, Waseca	120
Nebraska	Adams, Clay, Filmore, Hamilton, Johnson, Kearney, Lancaster, Saline, Seward, York	180
Ohio	Clark, Fayette, Madison, Tickaway, Wayne, Wood	60
South Dakota	Clay, Lincoln, Minnehala, Turner, Union	60
Wisconsin	Dane, Columbia, Rock	60

101.2 Likelihood of Adverse Effects on Non-Target Organisms

Terrestrial Organisms Toxicity

The following summarizes the acute data for birds for Fipronil 1.5G soil insecticide.

AVIAN TEST RESULTS

TABLE 1.

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
71-1A	Mallard, Acute Oral LD_{50}	429186-16	1/5/94	Core, Practically Non-Toxic	96.8	1993	LD_{50} = 2150 mg ai/kg
71-1A	Quail, Acute Oral LD_{50}	428186-17	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	Mallard, Acute Dietary LC_{50}	429186-21	1/14/94	Core, Slightly Toxic	>95	1993	LC_{50} = 4480 ppm ai
71-2A	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}	428186-15	1/6/94	Core, Very Highly Toxic	95.4	1991	LC_{50} = 31 mg/kg (nom.)
71-2A	House Sparrow, Acute Dietary LC_{50}	429186-18	1/6/94	Supp., Moder. Toxic	96.7	1991	LC_{50} = 1000 mg ai/kg
71-2A	Red-Legged Partridge, Acute Dietary LC_{50}	428186-14	1/10/94	Supp., Very Highly Toxic	95.4	1991	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 1.5G. Two studies were graded 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 the acute data for freshwater organisms for Fipronil 1.5G soil insecticide.

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*

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 was submitted by the registrant but has not been fully reviewed by EFGWB.

Terrestrial Risk Assessment

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

The potential estimated exposure is represented by the calculation of an Estimated Environmental Concentration (EEC) based application rates, intervals, frequencies, and other 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 1.5G was based on T-Band and In-Furrow application rates (band width 7 inches for T-Band) of 8 ounces (0.12 oz ai) per 1000 row feet. Maximum amount applied per growing season is 8.7 pounds of product per acre (0.1275 lbs ai/acre). The product is only applied at planting.

Calculation for Number of LD50 per Square Foot Banded or In-Furrow with Incorporation Application

$$\frac{\text{Product (oz)/1000ft of row X \% A.I. X 28349mg/oz}}{\text{1000 Ft X bandwidth (Ft)}} = \text{A.I.mg/Ft}^2$$

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A.I. (mg)/Ft^2 X Percent Unincorporated = Exposed A.I. mg/Ft^2

$$\frac{\text{Exposed A.I. mg/Ft}^2}{\text{LD}_{50}\text{ X Wgt. of Bird (Kg)}} = \text{LD}_{50}\text{ /Ft}^2$$

Fipronil 1.5G (bobwhite, T-Band = 0.41 LD_{50}/Ft^2; bobwhite, In-Furrow = 0.16 LD_{50}/Ft^2) does not exceed the criteria for high risk (LD_{50}/Ft^2>0.5), but it does exceed the criteria for restricted use (LD_{50}/Ft^2>0.2) for the T-Band application. Additionally the LD_{50} of 11.3 mg/kg also exceeds the criteria for restricted use (LD_{50}≤50mg/kg) (see Appendix I for calculations). Both data are based on the bobwhite quail the most sensitive species tested. Therefore Fipronil 1.5G meets the criteria, and may be considered a candidate for Restricted Use Classification.

Aquatic Risk Assessment

EEC calculations for In-Furrow and T-Band ground applications are based on an application rate of 8.7 lbs/A (0.13 lbs ai/A). The final EEC value is determined by the hypothetical runoff from a 10 acre drainage basin to a 1 acre pond which is 6 feet deep. The EECs for transport to in a pond 6 feet deep are 3.14ppb and 1.04ppb for T-Band (see Appendix I for T-Band EEC calculation) and In-Furrow respectively.

Calculation for Unincorporated Ground Application

Runoff

Application Rate (lbs a.i./A)	X	5.0% (% runoff based on solubility)	X	10A (10 Acre drainage basin)	=	Total Runoff

Calculation for Incorporated Ground Application

Application Rate (lbs a.i./A)	/	Depth of incorporation	X	5.0% (% runoff based on solubility)	X	10A (10 Acre drainage basin)	=	Total Runoff

EEC = 61ppb for 6' deep x Total Runoff = ppb

Table 5 AQUATIC HAZARD RATIOS FOR USE CLASSIFICATION FOR FIPRONIL 1.5G FOR T-BAND AND IN-FURROW APPLICATIONS

Organism/ MRID No.	Depth	Appl. Rate (lb ai/A)	1/2 LC_{50} (ppb)	1/10 LC_{50} (ppb)	T-band EEC (ppb)	In-Furrow EEC (ppb)

Bluegill/ 429186-74	6 ft.	0.13	12.5	2.5	3.14	1.04
Daphnia/ 429186-71	6 ft.	0.13	14.5	2.9	3.14	1.04

Based on the criteria for regulatory action outlined by the new paradigm the EEC (T-Band EEC = 3.14ppb) exceeds 1/10 the LC_{50} (1/10 the LC_{50} for Bluegill = 2.5ppb) but is less than 1/2 the LC_{50} (1/2 the LC_{50} for Bluegill = 12.5ppb) for T-Band application and may be considered for Restricted Use Classification due to the acute aquatic risk ($1/10LC_{50} \leq EEC \leq 1/2LC_{50}$). The second type of application is In-Furrow. The EEC (In-Furrow EEC = 1.04ppb) for In-Furrow is less than 1/10 the LC_{50} ($EEC < 1/10LC_{50}$) and has a low acute aquatic risk. 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 (T-Band EEC = 3.14ppb) exceeds 1/10 the LC_{50} (1/10 the LC_{50} for Daphnia = 2.9ppb) but is less than 1/2 the LC_{50} (1/2 the LC_{50} for Daphnia = 14.5ppb) for T-Band application and may be considered for Restricted Use Classification due to the acute aquatic risk to invertebrates ($1/10LC_{50} \leq EEC \leq 1/2LC_{50}$). The EEC (In-Furrow EEC = 1.04ppb) for In-Furrow is less than 1/10 the LC_{50} ($EEC < 1/10LC_{50}$) and has a low acute aquatic risk.The LC_{50} for *Daphnia magna* was used for the comparison to the EEC (Table 5).

The EC_{50} for the freshwater green algae, *Selenastrum capricornutum*, is 140ppb (Table 2). The aquatic EECs for both T-Band and In-Furrow applications are 3.14ppb and 1.04ppb respectively. Therefore, Fipronil 1.5G has a low acute risk to aquatic plants.

101.3 Endangered Species Concern

For aquatic organisms the proposed use of Fipronil 1.5G in the T-Band application method does exceed endangered species criteria (EEC > 1/20 LC_{50}; 1/20 LC_{50} for bluegill = 1.25ppb; 1/20 LC_{50} for daphnia = 1.45ppb; T-Band EEC = 3.14). Therefore Fipronil 1.5G is likely to jeopardize federally listed endangered/threatened aquatic organisms and insects. However the In-Furrow method of application does not exceed the endangered species criteria for aquatic organisms. For terrestrial species and aquatic plants there are no endangered species concerns.

The registrant is advised not to have test sites where endangered species may be present and if endangered species are present they should contact the state fish and game agencies (Appendix II).

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
71-2	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

Based on the current avian and aquatic toxicity data and the EEC's this pesticide (Fipronil 1.5G) is a candidate as a **Restricted Use Pesticide.**

101.6 Conclusions

Based on the current toxicity data and the proposed registered use of Fipronil 1.5G on corn, EEB concludes that Fipronil 1.5G exceeds Restricted Use Classification criteria for birds and fish. Use on corn is likely to jeopardize federally listed endangered/threatened aquatic organisms and insects (see section 101.3) for details on endangered or threatened species.

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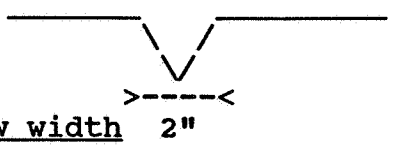
APPENDIX I

Aquatic EEC Calculation for T-Band Application

Surface band 2.5" 2.5"



Furrow width 2"

Total Band Width = 7 inches
Furrow width = 2 inches
Furrow depth = 1.5 inches (for corn)
Surface band width = 5 inches

Percent unincorporated = Total surface band/Total Band Width
Percent incorporated = Furrow width/Total Band Width

Calculation for Unincorporated Ground Application

Runoff

Application Rate (lbs a.i./A)	X	5.0% (% runoff based on solubility)	X	10A (10 Acre drainage basin)	=	Total Runoff

EEC = 61ppb for 6' deep x Total Runoff = ppb

Unincorporated EEC = EEC X Percent Unincorporated

Calculation for Incorporated Ground Application

Application Rate (lbs a.i./A)	/ Depth of incorporation	X	5.0% (% runoff based on solubility)	X	10A (10 Acre drainage basin)	= Total Runoff

EEC = 61ppb for 6' deep x Total Runoff = ppb

Incorporated EEC = EEC X Percent Incorporated

Final EEC Calculation for T-Band Application

T-Band EEC = Incorporated EEC + Unincorporated EEC

Aquatic EEC Calculation for T-Band Application

Percent unincorporated = 5"/7" = 71.4%
Percent incorporated = 2"/7" = 28.6%

Calculation for Unincorporated Ground Application

Runoff

0.1305 lbs ai/A	X	0.05 (% runoff based on solubility)	X	10A (10 Acre drainage basin)	=	0.652

EEC = 61ppb for 6' deep x 0.0652 = 3.98ppb

Unincorporated EEC = 3.98ppb X 0.714 = 2.84ppb

Calculation for Incorporated Ground Application

0.1305 lbs ai/A	/ 3.81cm	X	0.05 (% runoff based on solubility)	X	10A (10 Acre drainage basin)	= 0.017 Runoff

EEC = 61ppb for 6' deep x 0.017 = 1.04ppb

Incorporated EEC = 1.04ppb X 0.286 = 0.299ppb

Final EEC Calculation for T-Band Application

T-Band EEC = 0.299ppb + 2.84ppb = 3.14ppb

EEC Calculation for Incorporated Ground Application
In-Furrow Application

0.1305 lbs ai/A	/ 3.81cm	X	0.05 X (% runoff based on solubility)	10A = (10 Acre drainage basin)	0.017 Runoff

EEC = 61ppb for 6' deep x 0.017 = 1.04ppb

Number of LD50 per Square Foot Banded or In-Furrow with Incorporation
T-Band Application

$$A.I.mg/ft^2 = \frac{(8 \text{ oz per } 1000ft/row)\ (0.015)\ (28349 \text{ mg/oz})}{(1000 \text{ ft})\ (0.6ft)} = 5.66$$

Exposed
$A.I.mg/ft^2$ = 5.66 X 0.15 = 0.8505

Bobwhite Quail

$$LD_{50}/ft^2 = \frac{0.8505}{(11.5 \text{ mg/kg})\ (0.18kg)} = 0.41$$

Mallard Duck

$$LD_{50}/ft^2 = \frac{0.8505}{(2150 \text{ mg/kg})\ (1.0 \text{ kg})} = 0.41$$

Number of LD50 per Square Foot Banded or In-Furrow with Incorporation
In-Furrow Application

$$A.I.mg/ft^2 = \frac{(8 \text{ oz per } 1000ft/row)\ (0.015)\ (28349 \text{ mg/oz})}{(1000 \text{ ft})\ (0.1ft)} = 34.018$$

Exposed
$A.I.mg/ft^2$ = 34.018 X 0.1 = 0.3402

Bobwhite Quail

$$LD_{50}/ft^2 = \frac{0.3402}{(11.5 \text{ mg/kg})\ (0.18kg)} = 0.16$$

Mallard Duck

$$LD_{50}/ft^2 = \frac{0.3402}{(2150 \text{ mg/kg})\ (1.0 \text{ kg})} = 0.0002$$

APPENDIX II

STATE: Illinois

COUNTY: Carroll
- Pearly Mussel, Higgins Eye

COUNTY: Jo Davies
- Pearly Mussel, Higgins Eye
- Snail, Iowa Pleistocene

COUNTY: Whiteside
- Pearly Mussel, Higgins Eye

STATE: Indiana

COUNTY: Lagrange
- Satyr, Mitchell's

COUNTY: Porter
- Butterfly, Karner Blue

COUNTY: Tippecanoe
- Fanshell
- Mussel, Clubshell
- Mussel, Fat Pocketbook
- Mussel, Ring Pink (= Golf Stick Pear)
- Pearly Mussel, Rough Pigtoe
- Pearly Mussel, Tubercled-Blossom
- Pearly Mussel, White Wartyback

STATE: Indiana

COUNTY: White
- Fanshell
- Mussel, Clubshell

STATE: Ohio

COUNTY: Madison
- Madtom, Scioto
- Mussel, Clubshell
- Riffle Shell, Nothern

STATE: South Dakota

COUNTY: Clay
- Sturgeon, Pallid

COUNTY: Union
- Beetle, American Burying

STATE: Wisconsin

COUNTY: Dane

Pearly Mussle, Higgin's Eye