

DP BARCODE: D218701

CASE: 039679
SUBMISSION: S491313

DATA PACKAGE RECORD
BEAN SHEET

DATE: 03/22/96
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: EUP (SECT 5) ACTION: 710 EUP-NC-F/F USE
RANKING : 0 POINTS ()
CHEMICALS: 129121 Fipronil

80.0000%

ID#: 000264-EUP-RNR

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: 07/27/95

DUE OUT DATE: 11/24/95

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 218701 EXPEDITE: Y DATE SENT: 08/25/95 DATE RET.: 12/07/95

CHEMICAL: 129121 Fipronil

DP TYPE: 001 Submission Related Data Package

CSF: Y

LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 11/13/95
DIV : EFED	08/29/95	12/07/95	NEGOT DATE: / /
BRAN: EEB	08/29/95	11/27/95	PROJ DATE: / /
SECT: RS5	08/29/95	11/27/95	
REVR : JEISEMAN	08/29/95	11/27/95	
CONTR: N. FEDEROFF	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Note to Ann Stavola, Attached are the CSF and label submitted by Rhone-Poulenc in support of their EUP for a liquid formulation of 80% fipronil for use on corn. They did not submit any new data, nor did they propose how to bridge from existing data. Please review fipronil data already on file to determine if this EUP should be granted. Related files include the technical (264-LLU), the 1.5% granular (264-LLL), and the 1.5% granular corn EUP (264EUP-95). Please let me know if you have questions or need additional information 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
218692	RSB/PCRS	08/25/95	11/13/95	Y	Y	Y
218696	RSB/PRS	08/25/95	11/13/95	Y	Y	Y
218697	RCAB/RS	08/25/95	11/13/95	Y	Y	Y
218891	TSCB/TS-1	09/01/95	/ /	Y	Y	Y
218897	OREB/RS-2	09/01/95	/ /	Y	Y	Y

DP BARCODE: D218700

CASE: 039679
SUBMISSION: S491313

DATA PACKAGE RECORD (CONTINUED)
BEAN SHEET

DATE: 03/22/96
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* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
218700	IRB/PMT-10	08/25/95	11/13/95	Y	Y	Y
218703	EFGB/CRS1	08/25/95	11/13/95	Y	Y	Y

11/27/95

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

Trade Name: REGENT 80 WG, 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 (REGENT 80 WG) on corn throughout the mid-western and eastern United States.

100.2 Treatment Area

Proposed label restricts use to the states of Maine, Vermont, New York, New Jersey, Pennsylvania, Michigan, Indiana, Wisconsin, Iowa, Minnesota, Illinois, Ohio, Nebraska, Kansas, Missouri, South Dakota, Colorado, Maryland, and Kentucky.

Total Acreage: 4,210 (243 locations/sites)

Total Quantity of Formulated Product: 684.125 lbs

Total Quantity of Active Ingredient: 547.3 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

REGENT 80 WG is considered a dry powder flowable water dispersible formulation 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.....80%

Inert Ingredients.....20%

*Contains 0.833 pounds of active ingredient per pound of product.

100.5 Application Methods and RatesPOUNDS OF FIPRONIL
REGENT 80 WG PER 1000 ROW FEET

APPLICATION TIMING	PESTS CONTROLLED	T-BAND	IN-FURROW	APPLICATION DIRECTIONS
At planting	Northern and Western Corn Rootworm-Larvae Wireworms	0.13lbs. (2.6 oz.) for any row spacing. Do not apply more than 8.7 pounds of REGENT 80 WG per acre.	0.13lbs. (2.6 oz.) for any row spacing. Do not apply more than 8.7 pounds of REGENT 80 WG per acre.	T-Band: Apply spray in a band 7 inches wide over or directly into an open seed furrow ahead of presswheel. In-Furrow: Apply the spray 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 spray 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.

Do not apply to sweet corn or pop corn.

Make one application only during planting operation.

Use in-furrow method of application when possible.

For use on conventional or conservation tillage field corn systems.

Do not plant any rotational crops except corn in treated fields within one year of REGENT 80 WG application.

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 birds and aquatic and estuarine 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 (REGENT 80 WG) soil insecticide for corn. REGENT 80 WG is a new soil insecticide with no currently registered uses.

REGENT 80 WG is a soil insecticide formulated as a fine flowable powder mixable in water 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 0.13 lb ai/A of REGENT 80 WG will be applied 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
Maine	Penobscot	5
Vermont	Addison, Franklin	10
New York	Clinton, Columbia, Cayuga, Livingston, Ontario, Wyoming	50
New Jersey	Salem, Warren	20
Pennsylvania	Crawford, Center, Columbia, York, Huntington, Lancaster	60
Michigan	Clinton, Hillsdale, Lenawee, Sainaw, Tuscola, Cass, Kalamazoo, Ottawa, St. Joe, Eaton, Ionia, Kent	220
Indiana	Adams, Kosciusko, LaPorte, Madison, Marshall, Pulaski, Tipton, Bartholomew, Decatur, Harrison, Jackson, Jay, Johnson Randolph, Scott, Shelby, Wayne, Benton Boone, Carrol, Clinton, Montgomery, Jasper, Newton, Porter, Tippecanoe, Warren, White, Dubois Gibson, Knox, Posey	640
Wisconsin	LaCrosse, Pierce, Green, Dodge, Grant, Chippewa	140

Iowa	Mitchell, Winnebago, Floyd, Cerro Gordo Clay, Plymouth, Sioux Calhoun, Webster, Delaware, Winneshiek Fayette, Clayton, Hardin, Marshall, Buena Vista, Pottawattamie, Cass, Union, Mills, Audubon Dallas, Carroll, Shelby, Jones, Jackson, Jasper, Marion, Warren, Poweshiek, Crawford, Ida, Monona, Woodbury	700
Minnesota	Blue Earth, Steele, Chippewa, Lyon, Good Hue, Wabasha, Carver, Sterns, Wright, Rock, Sherburne, Pipestone	240
Illinois	Bureau, Henry, Mercer Henderson, Knox, Warren, Stark, Carrol JoDavies, Lee, Ogle, Rock Island, Stephenson, Whiteside, Winnebago Boone, DeKale, Putnam Marshall, Logan, Mason, Menard, Peoria Tazewell, Woodford, Sangamon, DuPage, Grundy, Kane, Kendall Lake, LaSalle, McHenry, Will, Kankakee, Adams, Brown, Fulton, Hancock, McDonough, Schuyler, Cass, Pike, Morgan, Scott, DeWitt McLean, Macon, Platt, Champaign, Ford, Iroquois, Livingston Virmillion, Douglas, Edgok	1120

Ohio	Fulton, Henry, Mercer Putnam, Van Wert, Williams, Huron, Knox Wayne, Champaign, Clinton, Dark, Fayette, Madison, Clarke, Hancock, Delaware, Pickway	345
Nebraska	Filmore, Thayer, Dawson, Red Willow Seward, Saline, Madison, Cuming, Scottsbluff	180
Kansas	Shawnee, Brown, Republic, Finney, Haskel.	100
Missouri	Saline, Scottland, Platte	60
South Dakota	Lincoln, Union, Huges Potter, Spink, Brown	80
Colorado	Phillips, Yuma, Weld, Kit Carson, Morgan, Washington	120
Maryland	Carrol, Frederick	80
Kentucky	Fayette, Caldwell, Davis, Hancock	40

101.2 Likelihood of Adverse Effects on Non-Target Organisms

Terrestrial Organisms Toxicity

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

AVIAN TEST RESULTS TABLE 1.

Avian Acute Oral Toxicity Findings					
Species	% A.I.	LD ₅₀ mg/kg	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	96 Technical	11.3	429186-17 (1990) Pedersen	Highly toxic	Core
Mallard	96.8 Technical	> 2150	429186-16 (1990) Pedersen	Practically non-toxic	Core
Pigeon	97.7 Technical	> 500	429186-13 (1991) Hakin and Rodgers	Slightly toxic	Supplemental
Red-legged Partridge	95.4 Technical	34	429186-14 (1992) Hakin and Rodgers	Highly toxic	Supplemental
Pheasant	95.4 Technical	31	429186-15 (1992) Hakin and Rodgers	Highly toxic	Supplemental
House Sparrow	96.7 Technical	1000	429186-18 (1991) Pedersen and Helsten	Slightly toxic	Supplemental
Northern Bobwhite	1.6 EXP-60655 A	1065 (formulation) 17 (active ingredient)	429186-19 (1993) Pedersen and DuCharme	Slightly toxic = Formul. Highly toxic = Active ingredient	Supplemental

Avian Subacute Dietary Toxicity Findings					
Species	% A.I.	LC ₅₀ ppm	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Northern Bobwhite	> 95 Technical	48.0	429186-20 (1993) Pedersen	Very highly toxic	Core
Mallard	> 95 Technical	> 5000	429186-21 (1993) Pedersen	Practically non-toxic	Core

These results indicate that Fipronil is highly toxic to upland game bird species on an acute oral basis, is very highly toxic on a subacute dietary basis, and is practically non-toxic to waterfowl on an acute and subacute basis. The guideline requirements are fulfilled. (429186-16, 429186-17, 429186-20, 429186-21)

Avian Reproduction Findings						
Species	% A.I.	NOEC ppm	LOEC ppm	Endpoints affected	MRID No. Author/Year	Fulfills Guideline Requirement
Northern Bobwhite	96.7 Technical	10	Not reported	None	429186-22 (1993) Pedersen and DuCharme	Supplemental
Mallard Duck	96.7 Technical	1000	Not reported	None	429186-23 (1993) Pedersen and Lesar	Core

The avian reproductive studies indicate that Fipronil had no effects at the highest levels that were tested in Mallard (NOEC=1000) and Bobwhite Quail. The NOEC=10 for Bobwhite, which was the highest level tested, will be used as the regulatory endpoint. Although the quail study does not fulfill guideline requirements, the need for a new study is waived. The NOEC is very conservative and no value of information is added by requiring a new study. Risk Quotients for avian reproduction ($RQ = ai \text{ mg/kg} \times \text{bodyweight}/\text{NOEC}$) are as follows: T-Band application $RQ=0.16$ and In-Furrow application $RQ=0.0098$. Therefore the guideline requirements are fulfilled. (429186-22 and 429186-23)

Mammalian Toxicity

The registrant reported a rat acute oral LD₅₀ > 5000 mg/kg using RM1601C (Fipronil 0.25 %), a rat acute oral LD₅₀ = 97 mg/kg using MB 46030 Technical (Fipronil 93 %), a rabbit acute dermal LD₅₀ > 2000 mg/kg, and a rat acute dermal inhalation LD₅₀ > 5.11 mg/L. However these studies have not yet been validated by HED. Mammalian (Rat) LD₅₀/sq.ft. = 0.021 (T-Band) and 0.0014 (In-Furrow).

Subchronic dietary RQ = ai mg/sq.ft. x bodyweight/NOEC (mg/kg/day). T-Band application RQ = 0.98 and In-Furrow RQ = 0.06. The T-Band application RQ approaches the high risk level (RQ > 1) for chronic effects but does not exceed the LOC.

Aquatic Plant Toxicity

Five aquatic plant studies were conducted with Fipronil. The results of these studies are presented below.

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
122-2	Marine Diatom ³ , Aquatic Plant-Tier 1	429186-59	1/7/94	Core	96.1	1993	EC ₅₀ = > 0.14 mg/l

¹*Selenastrum capricornutum*

²*Anabaena flos-aquae*

³*Skeletonema costatum*

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 soil insecticide.

GLN #	TEST TYPE	MRID	EVALUATION DATE CLASSIF.		% A.I.	TEST DAT	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
72-1A	Bluegill, LC ₅₀	429186-74	1/12/94	Core, Very Highly Toxic	*99.2	1992	LC ₅₀ = 25 µg/L

⁴*Lemna gibba*

⁵*Navicula pelliculosa*

72-2A	Daphnia magna, EC ₅₀	429186-25	1/12/94	Upgraded to core, Highly toxic	100	1990	EC ₅₀ = 190 ng/L pptr
72-2A	Daphnia magna, EC ₅₀	429186-69	1/13/94	Core, Highly Toxic	**100	1990	EC ₅₀ = 100 µg/L
72-2A	Daphnia magna, EC ₅₀	429186-71	1/13/94	Core, Very Highly Toxic	*100	1990	EC ₅₀ = 29 µg/L

NF
5/24/96

*(MB46136)

**(MB45950)

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 on application rates, intervals, frequencies, and other quantitative information found on the label. The greatest toxicity level comes from the results of studies which are required for registration.

Avian Exposure - The LD₅₀ per square foot for Fipronil (REGENT 80 WG) was based on T-Band and In-Furrow application rates (band width 7 inches for T-Band) of 0.138 ounces REGENT 80 WG per 1000 row feet. Maximum amount applied per growing season is 2.6 ounces of product per acre (0.13 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

$$\frac{\text{Product (oz)/1000row ft X \% A.I. X 28349mg/oz}}{1000 \text{ Ft X bandwidth (Ft)}} = \frac{.138 \times .8 \times 28349}{1000 \times .583} = 5.386 \text{ A.I.mg/Ft}^2$$

$$\begin{array}{rclcl} \text{A.I. (mg)/Ft}^2 & \times & \text{Percent Unincorporated} & = & \text{Exposed A.I. mg/Ft}^2 \\ 5.368 & \times & .15 & = & 0.8053 \text{ (T-Band)} \\ 5.368 & \times & .01 & = & 0.05368 \text{ (In-Furrow)} \end{array}$$

$$\frac{\text{Exposed A.I. mg/Ft}^2}{\text{LD}_{50} \text{ X Wgt. of Bird (Kg)}} = \frac{(.8052 \text{ T-Band) and (.05368 In-Furrow)}}{11.3 \times .178 \text{ kg}} = \frac{(0.4 \text{ T-Band})}{(0.03 \text{ In-Furrow})} \text{ LD}_{50} / \text{Ft}^2$$

REGENT 80 WG (bobwhite, T-Band = 0.40 LD₅₀/Ft²; bobwhite, In-Furrow = 0.03 LD₅₀/Ft²) does not exceed the criteria for high risk (LD₅₀/Ft² > 0.5), but it does exceed the criteria for restricted use (LD₅₀/Ft² > 0.2) for the T-Band application. Additionally the LD₅₀ of 11.3 mg/kg also exceeds the criteria for restricted use (LD₅₀ ≤ 50mg/kg). Both data are based on the bobwhite quail, the most sensitive species tested. Therefore REGENT 80 WG meets the criteria, and may be considered a candidate for Restricted Use Classification.

Aquatic Risk Assessment

AQUATIC HAZARD RISK QUOTIENTS FOR USE CLASSIFICATION FOR FIPRONIL REGENT 80 WG FOR T-BAND AND IN-FURROW APPLICATIONS

Organism/ MRID No.	LC50/ EC50 (pptr)	GENEEC EEC's (pptr) T-Band	GENEEC EEC's (pptr) In- Furrow	RISK QUOTIENTS T-Band	RISK QUOTIENTS In-Furrow
Bluegill/ 429186-74	25,000	59.6-203.8	85.0- 295.8	.002-.008	.003-.012
Daphnia/ 429186-71	29,000	112.7-347.6	160.0- 503.0	.004-.012	.006-.017

Soil KOC's and Aerobic Soil Metabolism Half-lives had a range of values thereby giving ranges for the GENEEC values. Based on the risk quotient (RQ) values ($RQ = EEC/LC50$ or $EC50$) for regulatory action outlined by the new paradigm, REGENT 80 WG does not exceed the LOC for freshwater invertebrates or fish and may be considered for Restricted Use Classification.

The EC_{50} for the freshwater green algae, *Selenastrum capricornutum*, is 140,000 pptr. Based on the RQ values for T-Band and In-Furrow applications, REGENT 80 WG does not exceed the LOC, therefore, REGENT 80 WG has a low acute risk to aquatic plants and may be considered for Restricted Use Classification.

101.3 Endangered Species Concern

For aquatic organisms, the proposed use of REGENT 80 WG in the T-Band or In-Furrow application method does not exceed the LOC for endangered species ($RQ > .05$). There are, however, acute avian risks associated with T-Band application. The RQ (LD50/sq.ft.) for T-Band application ($RQ = 0.4$) exceeds the LOC for endangered avian species ($RQ > 0.1$). REGENT 80 WG is unlikely to jeopardize federally listed endangered/threatened aquatic organisms. For 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. (see Endangered Species list)

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
72-4	Avian Reproduction	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 is a candidate as a **Restricted Use Pesticide**.

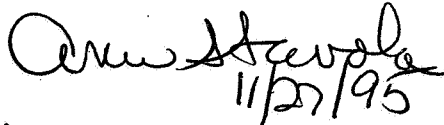
101.6 Conclusions

Based on the current toxicity data and the proposed experimental use of REGENT 80 WG on corn, EEB concludes that REGENT 80 WG exceeds Restricted Use Classification criteria for birds when the chemical is applied using T-Band application methods ($RQ=0.4$). The risk quotient for T-Band application ($RQ=0.98$) approaches the high risk level for chronic effects in mammals (based on data from rat studies) but does not exceed the level of concern. Use on corn is likely to jeopardize federally listed endangered/threatened avian species.

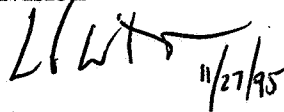
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