

7-19-96

DP BARCODE: D214762

CASE: 016016
SUBMISSION: S486102

DATA PACKAGE RECORD
BEAN SHEET

DATE: 07/12/96
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 100 NC-FOOD/FEED USE
RANKING : 1 POINTS ()
CHEMICALS: 129121 Fipronil

1.5000%

ID#: 000264-LLL REGENT 1.5G INSECTICIDE
COMPANY: 000264 RHONE-POULENC AG COMPANY
PRODUCT MANAGER: 10 RICK KEIGWIN
PM TEAM REVIEWER: ANN SIBOLD
RECEIVED DATE: 04/28/95 DUE OUT DATE: 11/04/95

703-305-6788 ROOM: CM2 210
703-305-6502 ROOM: CM2 201

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 214762 EXPEDITE: Y DATE SENT: 04/28/95 DATE RET.: / /

CHEMICAL: 129121 Fipronil

DP TYPE: 001 Submission Related Data Package

CSF: Y

LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 08/26/95
DIV : EFED	05/01/95	/ /	NEGOT DATE: / /
BRAN: EEB	/ /	/ /	PROJ DATE: 07/20/96
SECT: RS5	/ /	/ /	
REVR : NFEDDERO	/ /	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

To: Ann Stavrola. Please put the data submitted on 1.5% granular fipronil in support of a Sec. 3 registration on corn into review. Related files include data submitted to support the section 3 registration on the technical (264-LLU), the permanent tolerance on corn (5F04426), and the 0.1% granular on turf (264-LLN). In addition, reams of data were submitted in support of the EUP and temporary tolerance on corn (3G4263 & 264-EUP-95). Please call if you have questions. 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
214763	EFGB/CRS1	04/28/95	08/26/95	Y	Y	Y
214766	RSB/PCRS	04/28/95	08/26/95	Y	Y	Y

7/19/96

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 1.5G, Corn soil insecticide

100.0 Submission and Label Information

Section 3 Registration

100.1 Nature and Scope of the Submission

Request for a Section 3 of FIFRA for use of Fipronil (REGENT 1.5G) on corn.

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 1.5G is considered a granular dispersible formulation and applied by either T-Band or In-Furrow application 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%

Inert Ingredients.....98.5%

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100.5 Application Methods and Rates

**OUNCES OF FIPRONIL
REGENT 1.5G PER 1000 ROW FEET**

APPLICATION SITES	PESTS CONTROLLED	T-BAND	IN- FURROW	Directions For Applying
At Planting	Northern and Western Corn Rootworm Larvae Wireworms	0.5 lbs (8 oz) REGENT 1.5G per1000 row feet. Do not apply more than 8.7 lbs REGENT 1.5G per acre.	0.5 lbs (8 oz) REGENT 1.5G per1000 row feet. Do not apply more than 8.7 lbs REGENT 1.5G per acre.	T-Band: Apply granules in a band 7 inches wide over or directly into an open seed bed furrow ahead of presswheel and lightly incorporate. In-Furrow: Apply the granules directly into the seed furrow behind planter shoe and ahead of presswheel. 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.

Make one application only during planting operation. Carefully calibrate granular application equipment to ensure accurate placement and rate.

Use In-Furrow method of application when possible.

For use on conventional or conservation tillage field corn systems.

Do not plant a cover crop for harvest, forage, or grazing following harvest of corn treated with REGENT 1.5G. Do not plant any crop other than field corn the year following REGENT 1.5G application.

When treating 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.

100.7 Precautionary Labeling (excerpted from proposed product label)

Environmental Hazards

This pesticide is toxic to 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.

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C. ENVIRONMENTAL ASSESSMENT

1. Ecological Toxicity Data

EFED has adequate data needed to assess the hazard of Fipronil (REGENT 1.5G) to nontarget terrestrial organisms.

a. Toxicity to Terrestrial Animals

(1) Birds, Acute and Subacute

In order to establish the toxicity of Fipronil to birds, the following tests are required using the technical grade material: one avian single-dose oral (LD_{50}) study on one species; two subacute dietary studies (LC_{50}) on one species of waterfowl and one species of upland game bird.

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	*99.7 MB 46513	5	437766-01 (1993) Pedersen and Solatycki	Very Highly toxic	Supplemental
Mallard	*98.6 MB 46513	420	437766-02 (1994) Helsten and Solatycki	Moderate toxic	Supplemental

Northern Bobwhite	1.6 EXP- 60655A	1065 (formulation) 17 (active ingredient)	429186-19 (1993) Pedersen and DuCharme	Slightly toxic = Formul. Highly toxic = Active ingredient	Supplemental
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* Studies used metabolites/degradates of Fipronil

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 acute and subacute bases. The guideline requirements are fulfilled. (429186-16, 429186-17, 429186-20, 429186-21) Metabolite MB46513 is more toxic than parent Fipronil to birds (very highly toxic to upland gamebirds and moderately toxic to waterfowl on an acute oral basis).

(2) Birds, Chronic

Avian reproduction studies are required when birds may be exposed repeatedly or continuously through persistence, bioaccumulation, or multiple applications, or if mammalian reproduction tests indicate reproductive hazard. Present product labeling of Fipronil allows two applications of the end-use product per year.

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=1000ppm) and Bobwhite Quail (NOEC=10ppm). The NOEC of 10ppm for Bobwhite 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 quail NOEC is very conservative and no value of information is added by requiring a new study. Therefore the guideline requirements are fulfilled for this use. (429186-22 and 429186-23).

(3) Mammals

Wild mammal testing is required on a case-by-case basis, depending on the results of the lower tier studies such as acute and subacute testing, intended use pattern, and pertinent environmental fate characteristics. In most cases, however, an acute oral LD₅₀ from the Agency's Health Effects Division (HED) is used to determine toxicity to mammals (HED Tox Oneliners). These LD₅₀'s are reported below.

Mammalian Acute Oral Toxicity Findings			
Species	LD ₅₀ mg/kg	MRID #	Toxicity Category
Rat (small mammal surrogate)	97 mg/kg (MB 46030 93 % Technical)	429186-28	Mod. Toxic
Rat (small mammal surrogate)	218 mg/kg (MB 46136 98 % Technical) oxidation product	429186-75	Mod. Toxic
Rat (small mammal surrogate)	> 5000 (EXP 60655A 1.6 %)	429186-36	P.Non-Toxic
Rat (small mammal surrogate)	> 5000 (RM 1601c 0.25 %)	431211-04	P.Non-Toxic

The reported available mammalian data indicate that Fipronil (Technical) is moderately toxic to small mammals on an acute oral basis. (429186-28, 429186-75)

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b. Toxicity to Aquatic Animals

(1) Freshwater Fish

In order to establish the toxicity of a pesticide to freshwater fish, the minimum data required on the technical grade of the active ingredient are two freshwater fish toxicity studies. One study should use a coldwater species (preferably the rainbow trout), and the other should use a warmwater species (preferably the bluegill sunfish).

Freshwater Fish Acute Toxicity Findings					
Species	% A.I.	LC ₅₀ ppm a.i.	MRID No.	Toxicity Category	Fulfills Guideline Requirement
Bluegill sunfish	100 Technical	0.083	429186-24	Very highly toxic	Core
Rainbow trout	100 Technical	0.246	429779-02	Highly toxic	Core
*Rainbow trout	99.2 (MB46136)	0.039	429186-73	Very highly toxic	Supplemental
*Rainbow trout	94.7 RPA104615	> 100	432917-18	Pract. non-toxic	Supplemental
*Bluegill sunfish	99.2 (MB46136)	0.025	429186-74	Very highly toxic	Supplemental

* Studies used degradates/metabolites of Fipronil.

The results of the 96-hour acute toxicity studies indicate that Fipronil (Technical) is very highly toxic to Bluegill sunfish and highly toxic to Rainbow trout. The guideline requirements are fulfilled. (429779-02, 429186-73, 429186-24, 429186-74) The data also show that metabolite/degradate MB46136 is more toxic than parent Fipronil to freshwater fish (6.3 X for rainbow trout and 3.3 X for bluegill).

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Data from fish early life-stage tests are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; or if any acute LC_{50} or EC_{50} is less than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist: studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected; or physicochemical properties indicate cumulative effects; or the pesticide is persistent in water (e.g. half-life greater than 4 days). This study is required for Fipronil due to high acute toxicity and the probability that it will enter bodies of water from the proposed use on corn.

Fish Early Life-Stage Toxicity Findings							
Species	% A.I.	NOEC (ppm)	LOEC (ppm)	*MATC (ppm)	MRID No. Author/Year	Endpoints Affected	Fulfills Guideline Requirement
Freshwater: Rainbow trout	96.7 Technical	0.0066 ppm	0.015 ppm	0.0099 ppm	429186-27 (1992) Machado	Larval length	Core

* Geometric mean of NOEC and LOEC

The results indicate that Fipronil affects larval growth at concentrations greater than 0.0066 ppm in Rainbow Trout. The guideline requirement is fulfilled (429186-27).

(2) Freshwater Invertebrates

The minimum testing required to assess the hazard of a pesticide to freshwater invertebrates is a freshwater aquatic invertebrate toxicity test, preferably using first instar *Daphnia magna* or early instar amphipods, stoneflies, mayflies, or midges.

Freshwater Invertebrate Toxicity Findings					
Species	% A.I.	EC ₅₀ (48hr)	MRID NO. Author/Year	Toxicity Category	Fulfills Guideline Requirement
<i>Daphnia magna</i>	100 Technical	190 pptr	429186-25 (1990) McNamara	Very Highly toxic	Core
<i>Daphnia magna</i>	*94.7 RPA104615	100 ppm	432917-19 (1992) Collins	Prac.non- toxic	Supplemental
<i>Daphnia magna</i>	*100 (MB46136)	29 ppb	429186-71 (1990) McNamara	Very highly toxic	Supplemental
<i>Daphnia magna</i>	*100 (MB45950)	100 ppb	429186-69 (1990) McNamara	Highly toxic	Supplemental

* studies used different degradates/metabolites of Fipronil.

There is sufficient information to characterize parent Fipronil as very highly toxic to aquatic invertebrates. The guideline requirement is fulfilled. (429186-25, 429186-71, 429186-69).

Data from invertebrate life cycle tests are required if the product is applied directly to water or expected to be transported to water from the intended use site, and when the pesticide is intended for use such that its presence in water is likely to be continuous or recurrent regardless of toxicity; or if any acute LC_{50} or EC_{50} is less than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC_{50} or LC_{50} value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC_{50} or LC_{50} value and any of the following conditions exist: studies of other organisms indicate the reproductive physiology of fish and/or invertebrates may be affected; or physicochemical properties indicate cumulative effects; or the pesticide is persistent in water (e.g. half-life greater than 4 days). These studies are required for Fipronil due to high acute toxicity and the probability that the compound will enter bodies of water from the proposed use on corn.

Estuarine and Aquatic Invertebrate Life-Cycle Toxicity Findings							
Species	% A.I.	NOEC (ppb or ppt)	LOEC	*MATC	MRID No. Author/Yr	Endpo ints Affect ed	Fulfills Guideli ne Requir ement
Mysid Shrimp estuarine study	97.7 Tech	<5 pptr	5 pptr	<5 pptr	436812-01 (1995) Machado	Surviv Repro Dry wt Length	Supple mental
Daphnia magna freshwater study	100 Tech	9.8 ppb	20 ppb	14 ppb	429186-26 (1990) McNamara	Length	Supple mental

*Geometric mean of NOEC and LOEC

The reported 21 day EC_{50} for Daphnids was 39 ppb. The results indicate that Fipronil affects length in Daphnids at concentrations greater than 9.8 ppb (429186-26). The results also indicate that Fipronil affects reproduction, survival and growth in Mysids at concentrations less than 5 pptr (436812-01). The Mysid study does not meet guideline requirements because effects occurred at all test concentrations and an NOEC was not determined. The Daphnia study does not meet guideline requirements due to high mortality in the dilution water control and high variability in the analytical measurements. However, the requirement for a new Daphnia study is waived for this use (see

memo of Sept. 6, 1995 from A. Maciorowski).

(3) Estuarine and Marine Animals

Acute toxicity testing with estuarine and marine organisms is required when an end-use product is intended for direct application to the marine/estuarine environment or is expected to reach this environment in significant concentrations. The use of Fipronil on corn may result in exposure to the estuarine environment. The requirements under this category include a 96-hour LC_{50} for an estuarine fish, a 96-hour LC_{50} for shrimp, and either a 48-hour embryo-larvae study or a 96-hour shell deposition study with oysters.

Estuarine/Marine Acute Toxicity Findings					
Species	% A.I.	LC_{50}/EC_{50}	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Eastern oyster embryo larvae	96.1 Technical	$EC_{50}=0.77ppm$	432917-01 (1993) Dionne	Highly toxic	Core
Mysid Shrimp	96.1 Technical	$EC_{50}=140pptr$	432797-01 (1994) Machado	Very highly toxic	Upgraded to core
Sheepshead minnow	96.1 Technical	$LC_{50}=0.13ppm$	432917-02 (1993) Machado	Highly toxic	Core

There is sufficient information to characterize Fipronil as highly acutely toxic to oysters and sheepshead minnows, and very highly toxic to mysids. The guideline requirement is fulfilled. (432917-01, 432797-01, 432917-02)

c. Toxicity to Plants

(1) Aquatic

Currently, aquatic plant testing is not required for insecticides, although data has been submitted. The following species could be tested: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

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Tier 1 toxicity data on the technical/TEP material is listed below:

Nontarget Aquatic Plant Toxicity Findings					
Species	% A.I.	120hr EC50	MRID#	Author/Year	Fulfills guideline requirements
<i>Navicula pelliculosa</i> (Freshwater diatom)	96.1	>0.12 ppm	429186-58	Hoberg (1993)	Upgraded to core
<i>Lemna gibba</i> (Duckweed)	96.1	>0.10 ppm	429186-56	" (1993)	Supplemental
<i>Selenastrum capricornutum</i> (Freshwater green alga)	96.1	0.14 ppm	429186-60	" (1993)	Core
<i>Skeletonema costatum</i> (Marine Diatom)	96.1	>0.14 ppm	429186-59	" (1993)	Core
<i>Anabaena flos-aquae</i> (Freshwater Blue-green alga)	96.1	>0.17 ppm	429186-57	" (1993)	Core

3. Exposure and Risk Characterization

a. Ecological Exposure and Risk Characterization

Explanation of the Risk Quotient (RQ) and the Level of Concern (LOC): The Levels of Concern are criteria used to indicate potential risk to nontarget organisms. The criteria indicate that a chemical, when used as directed, has the potential to cause undesirable effects on nontarget organisms. There are two general categories of LOC (acute and chronic) for each of the four nontarget faunal groups and one category (acute) for each of two nontarget floral groups. In order to determine if an LOC has been exceeded, a risk quotient must be derived and compared to the LOC's. A risk quotient is calculated by dividing an appropriate exposure estimate, e.g. the estimated environmental concentration, (EEC) by an appropriate toxicity test effect level, e.g. the LC₅₀. The acute effect levels typically are:

- EC₂₅ (terrestrial plants),
- EC₅₀ (aquatic plants and invertebrates),
- LC₅₀ (fish and birds), and
- LD₅₀ (birds and mammals)

The chronic test results are the:

-NOEL (sometimes referred to as the NOEC) for avian and mammal reproduction studies, and either the NOEL for chronic aquatic studies, or the Maximum Allowable Toxicant Concentration (MATC), the geometric mean of the NOEL and the LOEL (sometimes referred to as the LOEC) for chronic aquatic studies.

When the risk quotient exceeds the LOC for a particular category, risk to that particular category is presumed to exist. Risk presumptions are presented along with the corresponding LOC's.

Levels of Concern (LOC) and associated Risk Presumption

Mammals, Birds

<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
acute RQ >	0.5	High acute risk
acute RQ >	0.2	Risk that may be mitigated through restricted use
acute RQ >	0.1	Endangered species may be affected acutely
chronic RQ >	1	Chronic risk, endangered species may be affected chronically,

Fish, Aquatic invertebrates

<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
acute RQ >	0.5	High acute risk
acute RQ >	0.1	Risk that may be mitigated through restricted use
acute RQ >	0.05	Endangered species may be affected acutely
chronic RQ >	1	Chronic risk, endangered species may be affected chronically

Plants

<u>IF THE</u>	<u>LOC</u>	<u>PRESUMPTION</u>
RQ >	1	High risk
RQ >	1	Endangered plants may be affected

Currently, no separate criteria for restricted use or chronic effects for plants exist.

(1) Exposure and Risk to Nontarget Terrestrial Animals

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. For granular pesticides the exposure is represented by the amount of active ingredient in a square foot area. This exposure value is then compared to the LD50 of the most sensitive test species to derive the risk quotient of an LD50 per square foot.

Avian Exposure - The LD₅₀ per square foot for Fipronil was based on T-Band and In-Furrow application rates (band width 7 inches for T-Band and 1 inch for In-Furrow) of 8 ounces REGENT 1.5G per 1000 row feet. This is equivalent to 8.7 lbs of product per acre (0.13 lbs ai/acre) based on a 30-inch row spacing. As indicated in EPA's Risk Analysis for Granular Pesticides, the T-Band and In-Furrow application techniques are likely to leave 8% and 1%, respectively, of the applied granules on the surface and available to birds and mammals. The efficiency index is included in the calculations. Maximum allowable amount applied per growing season is 8.7 pounds of product per acre (0.13 lbs ai/acre). The product is only applied at planting.

Calculation for Number of LD50 per Square Foot T-Banded with incorporation Application

$$\frac{\text{Product (oz)/1000row ft} \times \% \text{ A.I.} \times 28349\text{mg/oz}}{1000 \text{ ft} \times \text{bandwidth (ft)}} = \frac{8 \times 0.015 \times 28349}{1000 \times 0.583} = 5.84 \text{ A.I. (mg)/sq.ft.}$$

$$\begin{array}{rcl} \text{A.I. (mg)/sq.ft.} & \times & \% \text{ unincorporated} \\ 5.84 & \times & 8\% \end{array} = \begin{array}{rcl} \text{Exposed A.I. mg/sq.ft.} \\ = 0.47 \text{ (T-Band)} \end{array}$$

$$\frac{\text{Exposed A.I. mg/Ft}^2}{\text{LD}_{50} \times \text{Wgt. of Bird (Kg)}} = \frac{0.47}{11.3 \times .178 \text{ kg}} = 0.23 \text{ LD}_{50} / \text{Ft}^2$$

Calculation for Number of LD50 per Square Foot In-Furrow with incorporation Application

$$\frac{\text{Product (oz)/1000row ft} \times \% \text{ A.I.} \times 28349\text{mg/oz}}{1000 \text{ ft} \times \text{bandwidth (ft)}} = \frac{8 \times 0.015 \times 28349}{1000 \times 0.083} = 40.99 \text{ A.I. (mg)/sq.ft.}$$

$$\begin{array}{rcl} \text{A.I. (mg)/sq.ft.} & \times & \% \text{ unincorporated} = \text{Exposed A.I. mg/sq.ft.} \\ 40.99 & \times & 1\% = 0.41 \text{ (T-Band)} \end{array}$$

$$\frac{\text{Exposed A.I. mg/Ft}^2}{\text{LD}_{50} \times \text{Wgt. of Bird (Kg)}} = \frac{0.41}{11.3 \times .178 \text{ kg}} = 0.20 \text{ LD}_{50} / \text{Ft}^2$$

Avian Risk

The proposed use of Fipronil on corn does not exceed the criteria for high risk ($\text{LD}_{50}/\text{Ft}^2 \geq 0.5$) for T-Band and In-furrow application methods. However, the ($\text{LD}_{50}/\text{sq.ft.}$ for both methods does meet the criteria for Restricted Use Classification ($\text{LD}_{50}/\text{sq.ft.} \geq 0.2$). These results are based on the bobwhite quail, the most sensitive species tested. The toxicity data indicate that degradate MB46513 is also very highly toxic to birds with an LD_{50} value of 5 mg/Kg. Substituting this value in the above equations gives $\text{LD}_{50}/\text{sq.ft.}$ values of 0.53 (T-Band) and 0.46 (In-Furrow). The $\text{LD}_{50}/\text{sq.ft.}$ value of 0.53 exceeds our criteria of high acute risk. The Environmental Fate Assessment of 9/25/95 does not indicate how prevalent or persistent MB46513 is in the terrestrial environment. Therefore the likelihood of this degradate presenting a high risk to birds in the field is unknown.

There currently is no methodology for assessing reproductive risks to birds from exposure to granular pesticides.

Mammalian Risk

The registrant reported a rat acute oral $\text{LD}_{50} > 5000$ mg/kg using RM1601C (Fipronil 0.25%), a rat acute oral $\text{LD}_{50} = 97$ mg/kg using MB 46030 Technical (Fipronil 93%), a rabbit acute dermal $\text{LD}_{50} > 2000$ mg/kg, and a rat acute dermal inhalation $\text{LD}_{50} > 5.11$ mg/L. Mammalian (Rat) $\text{LD}_{50}/\text{sq.ft.} = 0.01$ for both T-Band and In-Furrow calculated from an LD_{50} of 97 mg/kg and a body weight of 0.4 Kg. Fipronil's proposed use on corn does not present a risk to small mammals that would be similar in size and sensitivity to the rat.

There currently is no methodology for assessing reproductive risks to mammals from exposure to granular pesticides.

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Calculation for acute mammalian risk (LD50/sq. ft.)

RQ = Exposed A.I. mg. per sq. ft. / LD50 x body wt. of rat

RQ = 0.41-0.47 / 97 x 0.4 kg

RQ = 0.01

Fipronil (mammalian acute RQ=0.01) does not exceed any acute mammalian LOC.

Aquatic Risk Assessment

Expected Aquatic Concentrations: Fipronil displays high toxicity to most aquatic organisms tested to date. EFED calculated generic EEC levels based on runoff from a 10 hectare field to a 1 hectare x 2 meter deep water body. These generic EEC's (GEEC's) take into account degradation in the field prior to a rain event. The available environmental fate inputs typically used in GENEED and the input values used for Fipronil are as follows:

Water solubility 2.4ppm
 Koc (Organic Carbon Adsorption coefficient) 2671.0-7818.0
 Hydrolysis half-life stable (pH 7)
 Aqueous photolysis half-life 0.15 days
 Aerobic soil metabolism 122-128 days
 Aerobic aquatic metabolism half-life N/A
 Incorporation depth 1.0 inches
 % spray drift 0

ESTIMATED ENVIRONMENTAL CONCENTRATIONS (GEECs)						
Crop	Application Method	Application Rate in lbs a.i./A	Peak GEEC (pptr)	4-day GEEC (pptr)	21-day GEEC (pptr)	56-day GEEC (pptr)
Corn	In-Furrow	0.13	773.61	708.60	470.85	277.50
Corn	T-Band	0.13	515.74	472.40	313.90	185.00

AQUATIC RISK QUOTIENTS FOR FIPRONIL FOR T-BAND AND IN-FURROW METHOD APPLICATIONS

The acute risk quotients (RQ) for freshwater and estuarine organisms are:

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 429186-24	83,000	515.74 peak	773.61 peak	0.01	0.01
Mysid Shrimp 432797-01	140	515.74 peak	773.61 peak	*3.68	*5.53
Oyster 432917-01	770,000	515.74 peak	773.61 peak	0.001	0.001
Sheepshead Minnow 432917-02	130,000	515.74 peak	773.61 peak	0.004	0.006
Daphnia 429186-25	190	515.74 peak	773.61 peak	*2.71	*4.07

* Exceeds the LOC

Based on the acute risk quotient (RQ) values ($RQ = EEC/LC50$ or $EC50$) for regulatory action outlined by the new paradigm, Fipronil does not exceed the LOC values for high acute risk or risk that may be mitigated through Restricted Use for freshwater fish or estuarine mollusks and fish. However, the proposed use of Fipronil on corn does present a high risk to freshwater and estuarine invertebrate species as indicated by the RQs for mysids and daphnids. Therefore if Fipronil enters a nearby body of water following an application to corn, these invertebrates are likely to be adversely impacted even with an incorporated method of application.

Based on data from the degradate MB46136 and its toxicity in Bluegill (25,000 pptr), the T-Band $RQ = 0.02$ and the In-Furrow $RQ = 0.03$. Also, using MB46136 data and the toxicity to Daphnids (29,000 pptr), the T-Band $RQ = 0.02$ and the In-Furrow $RQ = 0.03$. The EFED Fipronil team decided to assume that degradate MB46136 is as available to aquatic organisms as is the parent compound. Therefore, these quotients are based on the assumption that the degradate is present in the water column at the levels determined by GENECC for parent Fipronil. These RQs indicate that risks to freshwater fish and invertebrates from this degradate are minimal.

The chronic RQ's ($RQ = EEC/MATC$) for freshwater and estuarine organisms are:

ORGANISMS/MRID	MATC (pptr)	GENEEC EEC/T-BAND	GENEEC EEC/IN- FURROW	RISK QUOTIENTS T-BAND	RISK QUOTIENTS IN-FURROW
Rainbow trout 429186-27	9900	185 (56 day)	277.5 (56 day)	0.02	0.03
Daphnia magna 429186-26	14,000	313.9 (21 day)	470.85 (21 day)	0.02	0.03
Mysid shrimp 436812-01	<5	313.9 (21 day)	470.85 (21 day)	> *62.8.	> *94.2

* Exceeds LOC

These results indicate that there is a high chronic risk to estuarine invertebrates exposed to Fipronil in their environment. Based on the results of the Mysid life cycle study, estuarine invertebrates are likely to show significant reductions in survival, growth and reproduction from chronic, low level exposure to Fipronil. However, the final determination for Mysids is preliminary since the study did not give an NOEC, the risk is expected to be greater based on a lower NOEC. The risk assessment for estuarine invertebrates will be refined upon a recalculation of a new toxicity endpoint estimate by EEB to be used in future risk assessments.

REFINED EEC's (PRZM2 MODEL, VERSION 2.3)

Based upon the high aquatic toxicity and the LOC exceedences for estuarine invertebrates predicted from GENEEC exposure values, the EFED Fipronil team determined that higher tier surface water modeling was needed. Below are the refined EEC's from the PRZM2 model, version 2.3, and the new risk quotients based on these EEC's.

ESTIMATED ENVIRONMENTAL CONCENTRATIONS (PRZM2)							
Crop	Application Method	Application Rate in lbs a.i./A	Peak EEC (pptr)	4-day EEC (pptr)	21-day EEC (pptr)	60-day EEC (pptr)	90-day EEC (pptr)
CORN	In-Furrow	0.13	248	147	65	32	21

These EEC's are based on application to corn in Mississippi. The results indicate a total annual loss of 0.65% of the amount of Fipronil applied of which 64.7% was lost in the dissolved runoff and 35.3% was lost bound to eroding soil. The EECs in the table are dissolved concentrations.

AQUATIC RISK QUOTIENTS FOR USE CLASSIFICATION FOR FIPRONIL FOR IN-FURROW METHOD OF APPLICATION

The acute risk quotients (RQ) for freshwater and estuarine organisms are:

Organism/ MRID No.	LC50/EC 50 (pptr)	PRZM2 EEC's (pptr) (PEAK)	RISK QUOTIENTS
Bluegill 429186-24	83,000	248	0.003
Mysid Shrimp 432797-01	140	248	*1.77
Oyster 432917-01	770,000	248	0.0003
Sheepshead Minnow 432917-02	130,000	248	0.002
Daphnia 429186-25	190	248	*1.31
Daphnia 429186-71 (MB46136) Degradate	29,000	248	0.01
Bluegill 429186-74 (MB46136) Degradate	25,000	248	0.01

*Exceeds the LOC

Based on PRZM2 model derived EEC's, Fipronil presents a high acute risk and also exceeds the LOC values for risk that may be mitigated through restricted use for freshwater and estuarine invertebrates from the use on corn by In-Furrow application methods. Potential risks from exposure to degradates was also evaluated. The RQ's for the degradates are based on the assumption that, at worst, the concentration of MB46136 will be as great as that of parent Fipronil. Even with this worst case assumption, the results indicate that acute risks to freshwater organisms from exposure to MB46136 are not likely.

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The chronic RQ's ($RQ = EEC/MATC$) for freshwater and estuarine organisms are:

ORGANISMS/MRID	MATC (pptr)	PRZM2 EEC VALUES	RISK QUOTIENTS
Rainbow trout 429186-27	9900	32 pptr (60 day)	0.003
Daphnia magna 429186-26	14,000	65 pptr (21 day)	0.005
Mysid shrimp 436812-01	<5	65 pptr (21 day)	>*13

*Exceeds the LOC

Based on PRZM2 model derived EEC's, Fipronil presents a chronic risk to estuarine organisms (mysid shrimp) from the proposed use on corn by In-Furrow application methods. However, the risk determination for mysids is only preliminary since the chronic study did not give an NOEC which is needed to calculate the MATC, the concentration used to determine risk. This preliminary risk quotient of 13 indicates that Fipronil does present a potential risk to non-molluscan estuarine invertebrates. The risk assessment for estuarine invertebrates will be refined upon a recalculation of a new toxicity endpoint estimate by EEB to be used in future risk assessments.

AQUATIC PLANT RISK

The EC_{50} for the freshwater green algae, *Selenastrum capricornutum*, is 140,000 pptr. Based on the RQ values ($RQ=0.001$), Fipronil does not exceed the LOC, therefore, Fipronil has a low risk to aquatic plants.

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101.3 Endangered Species Concern

Endangered freshwater and estuarine aquatic invertebrates are likely to be jeopardized by the proposed use of Fipronil on corn. Acute RQ's (mysid = 1.8 and daphnid = 1.31) exceed the LOC (0.05) for acute risks to Endangered aquatic invertebrates. Chronic RQ's (mysid = 13.0) exceed the LOC (1.0) for chronic risks to Endangered aquatic invertebrates. However, there are currently no estuarine organisms on the endangered/threatened species list.

Endangered birds are likely to be jeopardized by this proposed use. There may be risks associated with the degradates/metabolites of Fipronil but the availability of these compounds to endangered birds and mammals is unknown. For aquatic plants there are no endangered species concerns.

The Endangered Species Protection Program is expected to become final sometime in the near future. Limitations in the use of Fipronil may 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. Modifications would most likely consist of the generic label statement referring pesticide users to use limitations contained in county Bulletins.

101.4 Adequacy of Data

One outstanding study is a fish early life stage study (72-4a) conducted with an estuarine fish species. The data requirement is waived for this submission due to the similarities in acute toxicities and acute risk quotients for freshwater and estuarine fish. As the acute and chronic risks to freshwater fish are low, the chronic data for freshwater fish are adequate to assess chronic risks to estuarine fish. Therefore, no additional information would be gained by requiring this study for the corn use. Another outstanding data requirement is another estuarine invertebrate life cycle study conducted with Mysid shrimp (72-4b). Although the submitted study (MRID#436812-01) was deemed deficient as the test concentrations selected did not provide for calculation of an NOEC, the requirement for a new study is waved based on the results of a meeting held with the registrant (6/18/96). A recalculation of a toxicity endpoint estimate by EEB will be used in future risk assessments (see memo from A. Maciorowski, 6/25/96). Also, due to the binding properties of Fipronil to soil and sediment, this chemical meets the criteria for requirement of a sediment toxicity test. Once the revised 158 guidelines are finalized, this study will be required.

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101.5 Adequacy of Labeling

The environmental hazards label statement for REGENT 1.5G for use on corn needs to be amended as follows:

This pesticide is toxic to birds, fish, and aquatic 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. Do not contaminate water when disposing of equipment washwater or rinsate.

This pesticide also meets the criteria for classification as a **Restricted Use Pesticide** with regard to risks to freshwater and estuarine invertebrates and birds (40 CFR 152.170 (c)(1)(iii)), and with regard to an avian acute oral toxicity value less than 50mg/kg for a granular product (LD50 for Bobwhite Quail = 11.3mg/kg) (40 CFR 152.170 (c)(2)(i)).

101.6 Conclusions

According to Agricultural Statistics, 1994 (USDA) over 73 million acres of corn were planted in 1993 in 47 states (Alaska, Hawaii, Rhode Island excluded). Much of the corn belt includes ecologically sensitive ecosystems. A significant portion of the corn acreage occurs in such wildlife rich areas as the Prairie Pothole region, the Sandhills lake region of Nebraska and the playa lakes areas in the southwest. These areas are used by waterfowl and shorebirds as breeding, feeding and migratory resting grounds, and they support a significant proportion of the total population of these birds. Corn is also grown in many coastal counties. Off-site movement of chemicals applied to cornfields in these counties can enter estuarine areas which support not only abundant aquatic communities but also wildlife communities.

Based on the current toxicity data and the proposed use of Fipronil (REGENT 1.5G) on corn, EEB concludes that Fipronil may present a direct risk to nontarget avian and mammalian species. Although Fipronil is highly toxic to terrestrial organisms, the method of application significantly reduces exposure of these animals feeding on the treated areas such that the risk can be mitigated by **Restricted Use Classification**. One of the degradates of Fipronil (MB46513) may present a high risk to birds, but there is insufficient information to determine the likelihood of this occurring under actual use conditions.

However, freshwater invertebrates are at high acute risk and estuarine invertebrates are at high acute and chronic risk from entry of Fipronil into freshwater ecosystems and estuaries adjacent to treated areas, even with incorporation of the product into the soil. Invertebrate species are fundamental food items not only for fish but also birds. Invertebrates are the primary food source for the young of many waterfowl and shorebirds species, therefore, the attraction of the areas mentioned above as prime avian habitats. Mesocosm studies and field

studies conducted with insecticides have shown that depletion of invertebrates populations causes reduced growth in fish and high mortality in juvenile waterfowl, respectively. So although fipronil may not directly affect fish, the use of this chemical in the corn regions can have detrimental effects on fish populations located in these areas. Fipronil has the potential to result in both direct and indirect adverse effects on bird populations in areas where it is used.

The registrant must consider methods to reduce exposure in freshwater and estuarine areas. Options include reduction of application rate and buffer zones between the treated field and adjacent bodies of water.

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