

US EPA ARCHIVE DOCUMENT

DP Barcode : D214746  
 PC Code No : 129121  
 EEB Out : JAN 16 1996

To: Richard 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 # : 264-LLN  
 Chemical Name : Fipronil  
 Type Product : Insecticide  
 Product Name : 0.1G CHIPCO-GAUNTLET  
 Company Name : Rhone-Polenc Ag Company  
 Purpose : Section 3-for use on turf

Action Code : 115 Date Due : 11/30/95  
 Reviewer : N.E. Federoff (Wildlife Biologist)

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)		
1-3			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(C)						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 not satisfied)  
 N = Unacceptable (Study was rejected)/Nonconcur

DP Barcode : D214840  
 PC Code No : 129121  
 EEB Out :

To: Richard 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 # : 264-LLU  
 Chemical Name : Fipronil  
 Type Product : Insecticide  
 Product Name : Fipronil Technical  
 Company Name : Rhone-Polenc Ag Company  
 Purpose : Section 3

Action Code : 100 Date Due : 12/1/95  
 Reviewer : N.E. Federoff

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(C)						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 not satisfied)

N=Unacceptable (Study was rejected)/Nonconcur

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DP BARCODE: D214840

CASE: 031271  
SUBMISSION: S486230

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 05/02/95  
Page 1 of 1

\*\*\* CASE/SUBMISSION INFORMATION \*\*\*

CASE TYPE: REGISTRATION ACTION: 100 NC-FOOD/FEED USE  
RANKING : 35 POINTS (KO)  
CHEMICALS: 129121 Fipronil 96.5000%

ID#: 000264-LLU FIPRONIL TECHNICAL  
COMPANY: 000264 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: 05/02/95 DUE OUT DATE: 11/08/95

\*\*\* DATA PACKAGE INFORMATION \*\*\*

DP BARCODE: 214840 EXPEDITE: Y DATE SENT: 05/02/95 DATE RET.: / /

CHEMICAL: 129121 Fipronil

DP TYPE: 001 Submission Related Data Package

CSF: Y LABEL: Y

ASSIGNED TO  
DIV : EFEB  
BRAN: EEB  
SECT: RS1  
REVR :  
CONTR:

DATE IN DATE OUT  
5/3/95 / /  
5/3/95 / /  
/ / / /  
/ / / /

ADMIN DUE DATE: 08/30/95  
NEGOT DATE: / /  
PROJ DATE: 12/1/95

\*\*\* DATA REVIEW INSTRUCTIONS \*\*\*

To: Ann Stavrola--Please put the data submitted on technical fipronil into review for a Sec. 3 registration. Data was submitted to support the temporary tolerance and EUP on corn (3G4263 & 264EUP95). Related files include the application for registration for a 1.5% granular on corn (264-LLL & 5F04426), and 0.1% granular on turf (264-LLN). 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  
214845

BRANCH/SECTION  
EFGB/CRS1

DATE OUT  
05/02/95

DUE BACK  
08/30/95

INS  
Y

CSF  
Y

LABEL  
Y

5

**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:** CHIPCO-GAUNTLET 0.1G, Turfgrass 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 (GAUNTLET 0.1G) on golf and commercial turfgrass (not for use on domestic turf or sod farms).

**100.3 Target Organisms**

Mole cricket (*Scapteriscus ssp.*)

**100.4 Formulation Information**

Gauntlet 0.1G is considered a granular dispersible formulation and applied by slit application methods.

\*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%

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100.5 Application Methods and Rates

**OUNCES OF FIPRONIL  
GAUNTLET 0.1G PER 1000 SQ FEET**

APPLICATION SITES	PESTS CONTROLLED	POUNDS PRODUCT/A	OZ PRODUCT/ 1000 SQ FT	Directions For Applying
Golf Turf and Commercial grounds	Mole cricket	12.5 to 25	4.6 to 9.2	Apply granules using slit -placement equipment only. Depth should be at thatch/soil interface. Apply at least 0.1 inch water right after application. A second application may be necessary in cases of heavy infestation but do not apply product within 4 months of first application. Do not make more than 2 applications per year and do not apply more than 25 pounds of product per acre (0.025 lb ai/A) per application.

**USE RESTRICTIONS**

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

Carefully calibrate granular application equipment to ensure accurate placement and rate.

Use only slit-placement method of application.

When treating turf, granules spilled from loading or lying on the soil surface must be covered, incorporated or removed to prevent possible hazards to birds and other wildlife.

**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. Do not contaminate water when disposing of equipment washwater.



## C. ENVIRONMENTAL ASSESSMENT

### 1. Ecological Toxicity Data

EFED has adequate data needed to assess the hazard of Fipronil (GAUNTLET 0.1G) 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 <sub>50</sub> 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. The NOEC=10ppm for Bobwhite, which was the highest level tested, and 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 LD<sub>50</sub> from the Agency's Health Effects Division (HED) is used to determine toxicity to mammals (HED Tox Oneliners). These LD<sub>50</sub>'s are reported below.

Mammalian Acute Oral Toxicity Findings			
Species	LD <sub>50</sub> 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)

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 <sub>50</sub> 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<sub>50</sub> or EC<sub>50</sub> is less than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC<sub>50</sub> or LC<sub>50</sub> value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC<sub>50</sub> or LC<sub>50</sub> 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 turf.

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- Techni- cal	0.0066 ppm	0.015 ppm	0.0099 ppm	429186-27 (1992) Machado	Larval length	Core

The results indicate that Fipronil affects larval growth at a 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 <sub>50</sub> (48hr)	MRID NO. Author/Year	Toxicity Category	Fulfills Guideline Requirement
<i>Daphnia magna</i>	100 Technical	190 ppb	429186-25 (1990) McNamara	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 Fipronil as highly toxic to aquatic invertebrates. The guideline requirement is fulfilled. (429186-25, 429186-71, 429186-69). Degradate/Metabolite MB46136 is 6.6X more toxic than parent Fipronil and degradate/metabolite MB45950 is 1.9X more toxic than parent Fipronil to freshwater invertebrates.

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<sub>50</sub> or EC<sub>50</sub> is less than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC<sub>50</sub> or LC<sub>50</sub> value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC<sub>50</sub> or LC<sub>50</sub> 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 turf.

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

The reported 21 day EC50 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 ppb (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 turf may result in exposure to the estuarine environment. The requirements under this category include a 96-hour LC<sub>50</sub> for an estuarine fish, a 96-hour LC<sub>50</sub> 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 <sub>50</sub> /EC <sub>50</sub>	MRID No. Author/Year	Toxicity Category	Fulfills Guideline Requirement
Eastern oyster embryo larvae	96.1 Technical	EC50=0.77ppm	432917-01 (1993) Dionne	Highly toxic	Core
Mysid Shrimp	96.1 Technical	EC50=140ppb	432797-01 (1994) Machado	Very highly toxic	Upgraded to core
Sheepshead minnow	96.1 Technical	LC50=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 is supplemental and can be used in a risk assessment. The following species could be tested: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

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 LC<sub>50</sub>. The acute effect levels typically are:

- EC<sub>25</sub> (terrestrial plants),
- EC<sub>50</sub> (aquatic plants and invertebrates),
- LC<sub>50</sub> (fish and birds), and
- LD<sub>50</sub> (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 LD<sub>50</sub> per square foot for Fipronil was based on slit-placement application rates of 9.2 ounces (max rate) of GAUNTLET 0.1G per 1000 row feet. Maximum allowable amount applied per year is 50 pounds of product per acre (25 pounds per application with a maximum of 2 applications yearly). A single application rate is 0.025 lb ai/A. With slit-placement application the granules are placed in the ground at the thatch/soil interface to contact the target pest. As indicated in EPA's Risk Analysis for Granular Pesticides, this application technique is likely to leave from 1% to 8% of the granules on the surface and available to birds and mammals. This efficiency index is included in the calculation.

## ACUTE AVIAN RISK

Calculation for Number of LD50 per Square Foot with incorporation Application

$$\begin{array}{rcl} \text{A.I. (mg)/Ft}^2 & \times & \text{Percent Unincorporated} & = & \text{Exposed A.I. mg/Ft}^2 \\ 0.26 & \times & 8\% & = & 0.02 \end{array}$$

0.0092 oz product/sq. ft  
 0.0000005 lb ai/sq.ft  
 0.26 mg ai/sq. ft

$$\begin{array}{rcl} \text{Exposed A.I. mg/Ft}^2 & & 0.02 \\ \hline \text{LD}_{50} \times \text{Wgt. of Bird (Kg)} & & 11.3 \times .178 \text{ kg} \end{array} = 0.01 \text{ LD}_{50} / \text{Ft}^2$$

Fipronil (bobwhite acute RQ= 0.01) does not exceed the criteria for high risk ( $\text{LD}_{50}/\text{Ft}^2 \geq 0.5$ ) and does not exceed the criteria for restricted use ( $\text{LD}_{50}/\text{sq.ft.} \geq 0.1$ ) However, the  $\text{LD}_{50}$  of 11.3 mg/kg does exceed the criteria for Restricted Use Classification ( $\text{LD}_{50} \leq 50\text{mg/kg}$ ). Both data are based on the bobwhite quail, the most sensitive species tested.

Mammalian Toxicity

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. However these studies have not yet been validated by HED. Mammalian (Rat)  $\text{LD}_{50}/\text{sq.ft.} = 0.00052$  calculated from an  $\text{LD}_{50}$  of 97 mg/kg.

Calculation for acute mammalian risk ( $\text{LD}_{50}/\text{sq.ft.}$ )

RQ = Exposed A.I. mg. per sq.ft. /  $\text{LD}_{50}$  x body wt. of rat

RQ = 0.02 / 97 x 0.4 kg

RQ = 0.00052

Fipronil (mammalian acute RQ=0.00052) does not exceed the mammalian LOC (0.5) for high acute risk or the mammalian LOC (0.2) for restricted use.

**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 GENEEC 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 ..... 0.33 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)	Chemical Product
Turf	Slit	0.025	150.39	137.75	91.53	53.95	Gauntlet 0.1G

**AQUATIC RISK QUOTIENTS FOR USE CLASSIFICATION  
FOR FIPRONIL FOR SLIT-PLACEMENT METHOD  
APPLICATIONS**

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

Organism/ MRID No.	LC50/EC 50 (pptr)	GENEEC EEC's (pptr)	RISK QUOTIENTS
Bluegill 429186-24	83,000	150.39 peak	0.002
Mysid Shrimp 432797-01	140	150.39 peak	*1.074
Oyster 432917-01	770,000	150.39 peak	0.0002
Sheepshead Minnow 432917-02	130,000	150.39 peak	0.001
Daphnia 429186-25	190,000	150.39 peak	0.001

\* 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 species or estuarine mollusks and fish. However, the proposed use of Fipronil on turf does present a high risk to other estuarine invertebrate species as indicated by the RQ for mysids.

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

ORGANISMS/MRID	MATC (pptr)	GENEEC EEC VALUES	RISK QUOTIENTS
Rainbow trout 429186-27	9900	53.95 (56 day)	0.005
Daphnia magna 429186-26	14,000	91.53 (21 day)	0.007
Mysid shrimp 436812-01	<5	91.53 (21 day)	* > 18.31

\* 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 risk determination for Mysids is only preliminary since the study did not give an NOEC which is needed to calculate an MATC, the concentration used to determine risk. The risk assessment for estuarine invertebrates will be refined upon submission of a new Mysid chronic study.

#### REFINED EEC's (PRZM2 MODEL, VERSION 2.3)

Based upon the high aquatic toxicity and the LOC exceedences for estuarine invertebrates predicted from GENECC 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)
Turf	Slit-placement	0.025	5.6	3.9	1.7	0.89	0.68

**AQUATIC RISK QUOTIENTS FOR USE CLASSIFICATION FOR FIPRONIL FOR SLIT-PLACEMENT METHOD OF APPLICATION**

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

<b>Organism/ MRID No.</b>	<b>LC50/EC 50 (pptr)</b>	<b>PRZM2 EEC's (pptr) (PEAK)</b>	<b>RISK QUOTIENTS</b>
Bluegill 429186-24	83,000	5.6	0.00007
Mysid Shrimp 432797-01	140	5.6	0.04
Oyster 432917-01	770,000	5.6	0.00001
Sheepshead Minnow 432917-02	130,000	5.6	0.00004
Daphnia 429186-25	190,000	5.6	0.00003
Daphnia 429186-71 (MB46136) Degradate	29,000	5.6	0.00003
Bluegill 429186-74 (MB46136) Degradate	25,000	5.6	0.0002

Based on PRZM2 model derived EEC's, Fipronil does not present an acute risk to freshwater organisms from the use on turf by slit-placement application methods. Potential risks from exposure to degradates was also evaluated as the toxicity data indicate that one of the degradates, MB46136, is more toxic than parent Fipronil. 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 minimal.



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	0.89 pptr (60 day)	0.0001
Daphnia magna 429186-26	14,000	1.7 pptr (21 day)	0.0001
Mysid shrimp 436812-01	<5	1.7 pptr (21 day)	>0.34

Based on PRZM2 model derived EEC's, Fipronil does not present a chronic risk to freshwater organisms from the proposed use on turf by slit-placement 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  $> 0.34$  indicates that Fipronil does present a potential risk to non-molluscan estuarine invertebrates, but it is presently uncertain if this risk is high. This risk assessment will be refined upon submission of a new mysid chronic study.

#### 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.

### **101.3 Endangered Species Concern**

There are no acute risks to endangered species as the risk quotients are below the levels of concern (LOC) for terrestrial and aquatic organisms (0.1 and 0.05 respectively). Once an acceptable mysid chronic study with a valid NOEC is submitted, there is a possibility that the chronic risk quotient based on this study will equal the LOC for chronic risks to endangered species (1.0). However, there currently are no estuarine organisms on the endangered/threatened species list. There are no acute avian risks associated with the proposed use of Fipronil. Fipronil is unlikely to jeopardize federally listed endangered/threatened freshwater aquatic organisms. 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. This data requirement is waived for this submission, based on the similarities between the acute toxicities and risk quotients of estuarine and freshwater fish and the comparative chronic toxicities and RQ's of the two invertebrate test species and freshwater fish. No additional information would be gained by requiring this study for the turf use. Another outstanding data requirement is another estuarine invertebrate life cycle study conducted with Mysid shrimp (72-4b). The submitted study (MRID#436812-01) was deficient as the test concentrations selected did not provide for calculation of an NOEC. A new study conducted with a lower range of concentrations is needed to provide both an LOEC and an NOEC. There is a high value of information associated with the need for a new Mysid chronic study since the risks to estuarine invertebrates are high.

**101.5 Adequacy of Labeling**

The environmental hazards label statement for Chipco Gauntlet 0.1G for use on golf and commercial turfgrass needs to be amended as follows:

This pesticide is toxic to birds, mammals, 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 estuarine invertebrates (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**

Based on the current toxicity data and the proposed use of Fipronil (GAUNTLET 0.1G) on commercial turfgrasses and golfcourses, EEB concludes that Fipronil will not present a risk to nontarget avian and mammalian species. Although Fipronil is highly toxic to terrestrial organisms, the slit-placement method of application significantly reduces exposure of these animals feeding on the treated areas. EEB also concludes that the proposed use will not affect freshwater organism from acute and chronic exposures. There is a possibility that the proposed use may cause high chronic risks to non-molluscan estuarine invertebrates. However this latter assessment is uncertain until a valid mysid chronic study as described in section 101.4, above, is accepted.

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Fipronil

RUN No. 1 FOR FIPRONIL INPUT VALUES

RATE (#/AC) ONE (MULT)	APPLICATIONS NO. - INTERVAL	SOIL KOC	SOLUBILITY (PPM)	% SPRAY DRIFT	INCRP DEPTH (IN)
.025 ( .025)	1 1	2671.0	2.4	.0	1.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
128.00	0	N/A	.33- 40.49	.00	40.49

GENERIC EECs (IN PPT)

PEAK GEEC	AVERAGE 4 DAY GEEC	AVERAGE 21 DAY GEEC	AVERAGE 56 DAY GEEC
150.39	137.75	91.53	53.95

0 day Hydrolysis

pH 7 = stable

TO: David

FROM: Ann

Here is the revised EEB review for the use of fipronil on turf. The aquatic risk assessment section plus the sections on Endangered Species and the conclusion were changed to reflect the analysis with the PRZM2 numbers.

In addition, pages 5, 7, and 9 (addition of description of degradate data); 6 and 8 (typos at top and bottom of pages, respectively); 21--- Adequacy of data and 22-- labeling.