

US EPA ARCHIVE DOCUMENT

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DP Barcode : D219266
PC Code No : 129121
EEB Out :

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

From: Doug Urban
Screening and Greybeard Panel/EFED (7507C)

Attached, please find the EEB review of...

Reg./File # :264-EUP-RNR
Chemical Name :Fipronil
Type Product :Insecticide
Product Name :REGENT 80WG
Company Name :Rhone-Polenc Ag Company
Purpose :Section 5 (EUP)-for use on cotton
Action Code :710 Date: 7/11/97
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) | 437766-01 | C | 72-2(A) | | | 72-7(A) | | |
| 71-1(B) | 437766-02 | C | 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

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 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 cotton throughout selected areas in the United States.

100.2 Treatment Area

Proposed label restricts use to the states of Alabama, Arkansas, Arizona, California, Florida, Georgia, Louisiana, Mississippi, Missouri, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, and Texas.

Total Acreage: 1996: 3,360 (84 locations)
1997: 4,720 (118 locations)

Total Quantity of Formulated Product: 1996: 1,260 lbs
1997: 1,770 lbs

Total Quantity of Active Ingredient: 1996: 1,008 lbs
1997: 1,416 lbs

100.3 Target Organisms

Thrips, Plant bugs (*Lygus*), and Boll weevil.

100.4 Formulation Information

REGENT 80 WG is considered a dry powder flowable water dispersible formulation and applied by either foliar spray 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.

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100.5 Application Methods and RatesPOUNDS OF FIPRONIL
REGENT 80 WG

| APPLICATION METHOD | PESTS CONTROLLED | OUNCES PER ACRE | DIRECTIONS | USE RESTRICTIONS |
|-----------------------|------------------|--|---|---|
| In-furrow at planting | Thrips | 2.0-3.0 oz. in a minimum of 3 gallons of water | Straight-stream or flat-fan nozzles aligned with the row. | Do not exceed 0.3 lbs ai/acre (6 oz 80 WG) |
| Foliar spray | Thrips | 0.5 to 0.75 | Apply a minimum 1 gallon of water mixture by air per acre. Apply minimum of 3 gallons of spray per acre by ground. Repeat as necessary to maintain control. | Do not apply less than 45 days before harvest. Only make one In-furrow application |
| Foliar spray | Plant bugs | 0.75 to 1.0 | Apply ounces of product in a minimum of 1 gallon of water/A by air. 3 gallon minimum spray/A by ground. | Begin application when insects reach recognized economic threshold. Apply at 3-10 day interval to maintain control. |
| Foliar spray | Boll Weevil | 1.0 to 1.36 | Apply ounces of product in a minimum of 1 gallon of water/A by air. 3 gallon minimum spray/A by ground. | |

100.6 Date and Duration

Duration is two years 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) insecticide for cotton for the 1996 and 1997 growing seasons. 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 by air or with ground equipment. It is applied by using one of two application methods; either one In-Furrow application at planting or by foliar spray.

This EUP will be applied/used in certain states (see below). Each test site will range from 20 to 65 acres (maximum) in size with an average plot size of 40 acres. A maximum of 0.3 lb ai/A of REGENT 80 WG will be applied per acre per season.

| STATE | COUNTY | ACREAGE | |
|------------|--|---------|------|
| | | 1996 | 1997 |
| California | Kern, Tulare, Fresno, Madera, Merced, Imperial, Riverside | 360 | 480 |
| Arizona | Maricopa, Yuma, LaPaz, Pinal, Pima | 200 | 400 |

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| | | | |
|------------|---|-----|-----|
| New Mexico | Dona Ana, Luna, Curry, Roosevelt, Lea | 40 | 80 |
| Texas | Dawson, Gaines, Hale, Hockley, Lamb, Lynn, Cochran, Bailey, Floyd, Crosby, Lubbock, Parmer, Castro, Swisher, Martin, Midland, Glasscock, Knox, Scurry, Haskell, Hall, Collinsworth, Childress, Hardman, Reeves, Pecos, Tom Green, Runnels, Williamson, Hidalgo, Harlington, Kennedy, Nueces, San Patricio, Uvalde, Cameron, Willacy, Fort Bend, Refugio, Matagorda, Wharton, Starr, Kleberg, Brazos, Robertson, Burleson, Caldwell, Milam, Ellis, Navarro, Hunt, Hill, Fannin, Falls, Denton, Collin, Bowie | 600 | 880 |
| Oklahoma | Jackson, Tillman, Harmon, Washita, Kiowa, Caddo, Greer, Beckham, Custer, Grady, Cotton, Coal, Garvin, Commanche, Canadian, Blain | 80 | 120 |
| Missouri | Dunklin, Peniscot, New Madrid, Stoddard | 80 | 160 |

| | | | |
|-------------|---|-----|-----|
| Tennessee | Haywood, Crockett, Dyer, Tipton, Fayette, Gibson, Lauderdale, Madison | 120 | 160 |
| Arkansas | Mississippi, Craighead, Crittenden, Lee, Phillips, Lonoke, Miller, Lincoln, Lafayette, Ashley, Drew, Chicot, Desha, Jefferson | 320 | 440 |
| Mississippi | Calhoun, Panola, Le Flore, Tallahatchie, Sunflower, Boliver, Washington, Lee, Marshall, Tunica, Quitman, Sharkey, Adams, Yazoo, Isaquena, Humphreys, Claiborn, Warren, Hinds, Jefferson, Rankin, Copiah, Carroll, Madison, Attala, Leake, Oktibbeha, | 480 | 560 |
| Louisiana | Morehouse, East Carrol, West Carrol, Richaland, Ouachita, Catahoulla, Franklin, Concordia, Madison, Tensas, Caddo, Red River, Natchitoches, Point Coupee, Avoyeles, Rapides, Bossier, DeSoto, Webster | 480 | 560 |

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| | | | |
|---------|---|-----|-----|
| Georgia | Thomas, Baker, Cook, Tift, Jeff Davis, Turner, Wilcox, Macon, Siminole, Brooks, Mitchell, Berrien, Irwin, Appling, Sumter, Dooly, Bleckley, Decatur, Early, Colquitt, Worth, Coffee, Lee, Crisp, Pulaski, Burke, Emanuel, Ware, Grady, Lowndes, Clay, Ben Hill, Dodge, Houston, Bulloch, Screven, Pierce | 160 | 240 |
| Florida | Madison, Gadsen, Levy, Suwanee, Gilchrist, Alachua, Lafayette, Jackson, Houston, Russell, Barbour, Covington, Pike, Mobile, Conecuh, Washington, Baldwin, Escambia, Monroe, Wilcox, Santa Rosa | 40 | 40 |

| | | | |
|----------------|--|-----|-----|
| Alabama | Cobert, Lawrence, Madison, Blount, Lee, Cherokee, Chambers, Shelby, Tallapoosa, Calhoun, Autauga, Hale, Elmore, Macon, Henry, Montgomery, Lauderdale, Limestone, Morgan, Cullman, Etowah, Fayette, Pickens, Talladega, Chilton, Dallas, Greene, Lowndes, Tuscaloosa, Dale, Coffee, Marengo, Crenshaw, Geneva | 160 | 240 |
| North Carolina | Halifax, Scotland, Sampson, Johnston, Union, North Hampton | 80 | 120 |
| South Carolina | Calhoun, Florence, Clarendon, Lee, Orangeburg, Marlboro, Dillon, Sumter, Hampton, Williamsburg | 160 | 240 |

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 | 99.7 MB46513 | 5 | 437766-01 (1993) Pedersen and Solatycki | Very Highly Toxic | Supplemental |
| Mallard | 98.6 MB46513 | 420 | 437766-02 (1994) Helsten and Solatycki | Moderately 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 quail NOEC is very conservative and no value of information is added by requiring a new study. Therefore the guideline requirements are fulfilled. (429186-22 and 429186-23)

Mammalian Toxicity**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)

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)

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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 cotton.

| 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 |

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

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

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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 LC₅₀ or EC₅₀ is less than 1 mg/L; or if the EEC in water is equal to or greater than 0.01 of any acute EC₅₀ or LC₅₀ value; or if the actual or estimated environmental concentration in water resulting from use is less than 0.01 of any acute EC₅₀ or LC₅₀ 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 cotton.

| 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 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).

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 LC₅₀ for an estuarine fish, a 96-hour LC₅₀ 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 | EC50=0.77ppm | 432917-01 (1993) Dionne | Highly toxic | Core |
| Mysid Shrimp | 96.1 Technical | EC50=140ppm | 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)

Toxicity to Plants

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 |

Environmental Fate and Residues

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

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.

Exposure and Risk to Nontarget Terrestrial Animals

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 and Mammalian Exposure : Mammalian and Avian risk for aerial and ground spray application.

| SPECIES | TOXICITY (ppm) | EXPECTED CONCENTRATIONS (Fletcher 1994) (ppm for 1 lb ai/A) | EEC (ppm) 0.068 lb ai/A rate X Fletcher | RISK QUOTIENT |
|-------------------------------|------------------------------------|---|---|-----------------------------------|
| Bobwhite Acute | LC50= 48 | shortgrass= 240 broadleaf= 135 long grass= 110 fruit= 15 | 16.32 9.18 7.48 1.02 | 0.34* 0.19** 0.16** 0.02 |
| Bobwhite ¹ Chronic | NOEC= 10 | " | 64 36 29 - | 6.4*** 3.6*** 2.9*** - |
| Rat | LD50= 97 Converted to mg/Kg/day | " | " | 0.008 0.005 0.004 0.001 |

* Risk may be mitigated through restricted use

** Exceeds LOC for endangered species

*** Exceeds LOC for Chronic risk, endangered species may be affected chronically

Rat LD50 / % body wt consumed = 1940

EEC/1940 = Rat RQ

¹ Based on aerobic soil metabolism

Based on the risk quotients above, Fipronil exceeds the acute LOC values for Restricted Use Classification and risks to endangered bird species. Also, all chronic LOCs were exceeded (RQ > 1) for avian species. There are no risks to mammals from acute dietary exposure. Risk may be mitigated through restricted use.

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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) | Ave=803 |
| 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 inch for In-furrow |
| % spray drift | 5% Aerial and 1% Ground |

LOCs were exceeded using the GENEEC model. Thus, tier 2 assessment models (PRZM2/EXAMII) were then needed to calculate refined EECs. The Pesticide Root Zone Model (PRZM2) simulates pesticides in field runoff on daily time steps incorporating runoff, infiltration, erosion, and evapotranspiration. The model calculates foliar dissipation and runoff, pesticide uptake by plants, microbial transformation, volatilization, and soil dispersion and retardation. The Exposure Analysis Modeling System (EXAMII) simulates pesticide fate and transport in an aquatic environment. Refined EECs are tabulated below:

REFINED EEC's (PRZM2 MODEL, VERSION 2.3)

| 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) |
| Cotton | Foliar spray (Aerial) | 0.068 x 4 applications | 2459 | 2391 | 2205 | 1946 | 1845 |

AQUATIC RISK QUOTIENTS FOR USE CLASSIFICATION FOR FIPRONIL FOR AERIAL SPRAY METHODS 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 | 753 Aerial | 0.03 |
| Mysid Shrimp 432797-01 | 140 | 753 Aerial | ***17.6 |
| Oyster 432917-01 | 770,000 | 753 Aerial | 0.003 |
| Sheepshead Minnow 432917-02 | 130,000 | 753 Aerial | 0.02 |
| Daphnia 429186-25 | 190 | 753 Aerial | ***13.0 |
| Daphnia 429186-71 (MB46136) Degradate | 29,000 | 753 Aerial | *0.08 |
| Bluegill 429186-74 (MB46136) Degradate | 25,000 | 753 Aerial | *0.1 |

* Endangered species may be affected acutely

** Exceeds the LOC, risk may be mitigated through restricted use

*** Exceeds the LOC for high acute risk

Based on the PRZM2/EXAMII model derived acute risk quotient (RQ) values ($RQ = EEC/LC50$ or $EC50$) for regulatory action outlined by the new paradigm, Fipronil exceeds the LOC values for high acute risk, risk that may be mitigated through restricted use and endangered species LOCs for freshwater and estuarine invertebrates (daphnids and mysids) for aerial application methods. Therefore, if Fipronil enters nearby bodies of water following application to cotton, these invertebrates are likely to be adversely impacted.

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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 | 1946 pptr (60 day) | 0.02 Aerial |
| Daphnia magna 429186-26 | 14,000 | 2205 pptr (21 day) | 0.16 Aerial |
| Mysid shrimp 436812-01 | 5 | 2205 pptr (21 day) | *441.0 Aerial |

* Exceeds chronic LOC ($RQ > 1$)

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 reproductive effects from chronic, low level exposure to Fipronil.

AQUATIC PLANT RISK

The EC_{50} for the freshwater green algae, *Selenastrum capricornutum*, is 140,000 pptr. Based on the RQ value ($RQ = 0.02$ aerial spray), Fipronil does not exceed the LOC ($RQ > 1$), therefore, Fipronil has a low risk to aquatic plants.

101.3 Endangered Species Concern

The only group of endangered/threatened organisms likely to be jeopardized by the proposed use of Fipronil on cotton are freshwater and estuarine invertebrates. Invertebrates living in vernal pools in California (California Lideriella, Conservancy shrimp, Longhorn Fairy shrimp, Riverside Fairy shrimp, Vernal pool fairy shrimp, and the Vernal pool tadpole shrimp) may be affected from runoff or direct drift. Contact CA Dept. of Pesticide Regulation (DPR). There are no acute avian risks associated with the proposed use of Fipronil. 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

Only 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 both invertebrate test species and freshwater fish.

101.5 Adequacy of Labeling

The environmental hazards label statement for REGENT 80 WG for use on cotton 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 and drift from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not contaminate water when disposing of equipment washwater or rinsate.

This pesticide also meets the criteria for classification as a **Restricted Use Pesticide** (40 CFR 152.170 (c) (iii) with regard to risks to estuarine invertebrates.

101.6 Conclusions

Based on the current toxicity data and proposed use of Fipronil (Regent 80 WG) on cotton, EEB concludes that Fipronil may present an acute risk to nontarget avian species which may be mitigated through restricted use. There may also be chronic risk to avian species at all trophic levels. Although Fipronil is highly toxic to terrestrial organisms, the method of application may significantly reduce exposure of these animals feeding on the treated areas. However, freshwater and estuarine invertebrates are at high acute and chronic risks from the entry of Fipronil into estuaries adjacent to treated areas, especially from aerial (based on PRZM2/EXAMSII model values) and ground spray application methods (GENEEC values). The registrant needs to consider methods to reduce exposure in freshwater and estuarine areas.

Use on cotton may jeopardize federally listed endangered/threatened aquatic organisms and other endangered or threatened avian and mammalian species.

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