ENVIROMENTAL FATE AND GROUND WATER BRANCH
Review Action

To: R. Kelgwin/A. Sibold
Registration Division (H7505)

From: Paul Mastradone, Section Chief
Chemistry Review Section 1
Environmental Fate & Ground Water Branch/EFED (H7507C)

Thru: Henry Jacoby, Chief
Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

<table>
<thead>
<tr>
<th>Common Name:</th>
<th>Fipronil</th>
<th>Trade name:</th>
<th>Chipco Gauntlet</th>
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</thead>
<tbody>
<tr>
<td>Company Name:</td>
<td>Rhone-Poulenc Ag. Company</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ID #:</td>
<td>000264-EUP-RNN</td>
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<tr>
<td>Purpose:</td>
<td>To review environmental fate studies (anaerobic aquatic metabolism, terrestrial field dissipation, and fish accumulation) submitted to support the new chemical registration of fipronil. In addition, a review of an EUP request for use of fipronil on turf in Southeastern United States</td>
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<table>
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<tr>
<th>Type Product:</th>
<th>Action Code:</th>
<th>EFGWB #(#):</th>
<th>Review Time:</th>
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<tr>
<td>Insecticide</td>
<td>010/100/700</td>
<td>12 day</td>
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STATUS OF STUDIES IN THIS PACKAGE: ADDRESSED IN THIS PACKAGE:

<table>
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<tr>
<td>162-3</td>
<td>43291704</td>
<td>A</td>
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<td>164-1</td>
<td>43291705</td>
<td>A</td>
</tr>
<tr>
<td>165-4</td>
<td>43291706</td>
<td>U</td>
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STATUS OF DATA REQUIREMENTS

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<td>164-1</td>
<td>S</td>
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<tr>
<td>165-4</td>
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</table>

1 Study Status Codes: A = Acceptable U = Upgradable C = Ancillary I = Invalid
2 Data Requirement Status Codes: S = Satisfied P = Partially satisfied N = Not satisfied R = Reserved W = Waived
1. **CHEMICAL:**
   
   **Chemical name:** 5-Amino-3-cyano-1-(2,6-dichloro-4-trifluoromethyl)phenyl)-4-[1R,S]-trifluoromethyl) sulfinyl]-1H-pyrazole-3-carbonitrile
   
   **CAS no.:** 120068-37-3
   
   **Common name:** Fipronil
   
   **Trade name:** Chipco Gauntlet
   
   **Chemical structure:**
   
   ![Chemical Structure Image]
   
   **Physical/Chemical properties of active ingredient fipronil:**
   
   **Physical characteristics:** White powder with mouldy smell
   
   **Molecular formula:** C_{12}H_{4}F_{5}N_{4}Cl_{2}OS
   
   **Molecular weight:** 437.14
   
   **Melting point:** 195.5-203°C
   
   **Vapor Pressure:** $1 \times 10^{-7}$ mm Hg
   
   **Solubility:** 2.4 mg/L at 20°C
   
   **Octanol/water partition coefficient:** 10,570

2. **TEST MATERIAL:**
   
   See individual DERs.

3. **STUDY/ACTION TYPE:**
   
   This study action is a review of environmental fate studies (anaerobic aquatic metabolism, terrestrial field dissipation, and fish accumulation) submitted to support the new chemical registration of fipronil on corn and turf. In addition, a review of an EUF application for use of Fipronil on turf in Southeastern United States is included.

4. **STUDY IDENTIFICATION:**
   
Chancey, E.L. and Norris, F.A. A TERRESTRIAL FIELD SOIL DISSIPATION STUDY WITH FIPRONIL (MR 46030) APPLIED INTO SLITS IN BARE SOIL AND SOIL WITH ESTABLISHED TURF. Sponsored and Submitted by Rhone-Poulenc Agriculture, Ongar, Essex, England; Performed by Rhone-Poulenc Ag. Company, Research Triangle Park NC under File No. 4424 and Study No. US93V02R; Study completed on 23 May 1994; Received by EPA 30 June 1994; MRID No. 43291705.

Chapleo, S. and Hall, B.E. (14C)M & B 46030: BIOACCUMULATION TEST IN BLUEGILL SUNFISH. Sponsored and Submitted by Rhone-Poulenc Agriculture, Ongar, Essex, England; Performed by Inveresk Research International, Tranent, Scotland under IRI Project No. 381457; Study completed on 21 October 1992; Received by EPA 30 June 1994; MRID No. 43291706.


5. REVIEWED BY:

Gail Maske
Chemist, Review section #1
OPP/EFED/EFGWB

6. APPROVED BY:

Paul Mastradone, Chief
Review section #1
OPP/EFED/EFGWB

7. CONCLUSIONS:

This action is a request to review three environmental fate studies (anaerobic aquatic metabolism, terrestrial field dissipation, and fish accumulation) submitted by Rhone-Poulenc to support an Experimental Use Permit (EUP) and Section 3 registration of fipronil for terrestrial non-food and terrestrial food and feed uses. A review of the EUP application for use of Fipronil on turf in Southeastern United States (Alabama; Florida, Georgia, Mississippi, North Carolina, South Carolina) is included, as well. Other environmental fate studies (not reviewed in this action) needed to support the EUP and Section 3 registrations were submitted with an EUP application for use of fipronil on corn. Those studies were reviewed in June 1994 (WCM;06/13/94). In addition, the environmental fate of fipronil in aquatic and soil environments is assessed.

ENVIRONMENTAL FATE ASSESSMENT SUMMARY

Based on acceptable laboratory and terrestrial field data submitted to support registration and EUP, fipronil appears to dissipates below the soil surface by soil binding (Kds=26.2-148.6 for ads; Kocs=2671 to 7818) followed by slower biotic mediated processes (aerobic soil half-life=128 days; anaerobic aquatic half-lives=116-130 days). However, on the soil surface (or
turf foliage) the major route of degradation may be photolysis (aquatic photolysis half-life=3.63 hours, soil photolysis half-life=34 days) and/or soil binding followed by slower biotic mediated processes. In addition, laboratory data indicate that fipronil is not mobile in soils tested and degrades slowly under alkaline hydrolytic conditions (hydrolysis half-life at pH 9-28 days). Fipronil does appear to be stable to hydrolysis at pH 5 and pH 7 (half-life-stable). The field data appears to support the laboratory data. Half-lives of 1.1 to 1.5 months for bare soil and 0.4 to 0.5 months for turfed soil are reported in field data. In bare soil plots fipronil residues were discernible only in the 0-6 inch soil depth. Therefore, since fipronil appears to bind to soil matter, movement off-target would appear to be associated with sediment contained in surface water and runoff water. In addition, potential for ground water contamination is considered low.

Review of EUP Application for use of Fipronil on Turf:

Based on the EFGWB files, there is sufficient data to support the EUP for use of fipronil on turf in the Southeastern United States. Except for the fish accumulation data requirement which is conditionally required, all the environmental fate data requirements for Section 3 registration of fipronil for terrestrial food and feed crop and terrestrial non-food crop uses (corn and turf field) are fulfilled for applications rates of ≤0.05 lb a.i./A. Even though the accumulation in fish (storage stability data needed) these data are not expected to significantly change the environmental fate assessment of fipronil.

Review of Section 3 Registration for Terrestrial Non-Food Crop Uses:

There is sufficient data to support Section 3 registration of terrestrial non-food crop uses of fipronil. The environmental fate data requirements (laboratory and field) for terrestrial non-food crop uses are fulfilled for application rates of ≤0.05 lb a.i./A.

Review of Section 3 Registration for Terrestrial Food and Feed Crop Uses:

All environmental fate laboratory data requirements for Section 3 registration of fipronil for terrestrial food and feed crop uses are fulfilled. However, additional field data are needed for Section 3 registration of terrestrial food and feed crop uses at application rates ≥0.05 lb a.i./A. The label for the corn use suggests an application rate of 0.13 lb a.i./A. Therefore, additional terrestrial field dissipation data are needed to support the higher application rate for corn. However, these field dissipation data for higher application rate are not expected to significantly change the environmental fate assessment of fipronil.

Review of Submitted Environmental Fate Studies to Support Registration:

a. Anaerobic Aquatic Metabolism (162-3):

This anaerobic aquatic metabolism study is scientifically valid and can be used to fulfill data requirement (162-3). No further anaerobic metabolism data for fipronil are needed at this time.

Fipronil was reported to degrade with half-lives of 116 days (by HPLC analyses) and 130 days (by TLC analyses) under anaerobic conditions. Two major degradates, MB 45,950 (5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-3,4-dichloro-4-trifluoromethylthio-pyrazole) and RPA 200766, the amide (5-amino-3-carbamoyl-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-trifluoromethanesulfanylpyrazole), were discernible at maximum...
concentrations of ≈47% and ≈18% of applied radioactivity, respectively, at 365 days posttreatment. MB 45,950 was predominately detected in the soil extracts. However, RPA 200766 was detected in both water and soil extracts. One other major component, unextractable soil residue, reached a maximum concentration of ≈18% of applied radioactivity during the testing period. There were ten unidentified minor degradates ≤6% of applied radioactivity) discernible in soil and water extracts by TLC analyses. However, there were four and three minor unidentified minor degradates ≤7% of applied radioactivity) discernible in soil and water extracts, respectively, by HPLC analyses.

See DER for details.

b. Terrestrial field dissipation (164-1):
MRID No. 43291705

This terrestrial field dissipation study is scientifically valid and can be used to fulfill the data requirement (164-1). No further terrestrial field dissipation data for fipronil are needed for applications of ≤0.044 ppm at this time.

Fipronil was reported to dissipate with half-lives of 1.1, 0.4, 1.5, and 0.5 months when applied to Florida bare sand soil, Florida turfed sand soil, North Carolina bare loamy sand soil, and North Carolina turfed sandy loam soil, respectively. Of the six degradation products identified in soil metabolism and photolysis studies, two were discernible in field soil samples at >2 μg/kg (limit of detection). These were the oxidation product, MB 46136 (5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-3-cyano-4-trifluoromethyl-sulphonyl-pyrazole, and the carbonitrile hydrolysis product, RPA 200766, the amide (5-amino-3-carbamoyl-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-trifluoromethanesulfinylpyrazole). MB 46136 was detected in both bare soil and turfed soil samples at maximum concentrations ranging from 5.6 to 8.9 μg/kg at 2-3 months postapplication during the 4 month testing period. RPA 200766 was detected in the bare soil test samples at both test sites reaching a maximum concentration of 3.7 μg/kg at 3 months postapplication for each test site. Despite excess rainfall/irrigation levels, the fipronil residues remained in the upper 6 inch soil segment (no residue detected in the 0.15-0.30 meter soil depth) at each location during the 4 month testing period. Therefore, fipronil appears to demonstrate a low potential for leaching to ground-water.

See DER for details.

c. Fish Accumulation (165-4):
MRID No. 43291706 & 43291707

This fish accumulation study is scientifically valid and can be used as supplemental data. However, it cannot be used to fulfill the data requirement (165-4) at this time. Storage stability data for tissue samples and the length of storage of tissue samples were not reported. These data are needed to validate the tissue characterization data.

Fipronil appears to bioaccumulate in Bluegill Sunfish when exposed to treated water at a concentration of ≈900 ng equiv.1 for 35 days. Bioconcentration factors (BCFs) of 321, 164, and 575 were reported for whole fish, edible tissue, and non-edible tissue, respectively. These BCFs were determined for the apparent steady-state phase, days 14 and 35 post-exposure, of the testing period. The depuration phase indicates that accumulated fipronil residues are almost completely eliminated (>96%) after 14 days depuration. By day 7 of the depuration period
90% of the accumulate fipronil residues were eliminated. These results are considered by the study authors to be in agreement with the octanol/water coefficient (K<sub>ow</sub>=10,570). Residues for both the uptake and depuration phase were characterized. The major metabolites identified in fish tissues were MB 46136 (5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-3-cyano-4-trifluoromethyl-sulphonyl-pyrazole) with reported concentrations of 54.90%, 59.07%, and 27.98% of accumulated residue in pooled uptake edible, inedible, and whole fish tissue fractions, respectively, and MB 45897 (5-amino-3-cyano-1-(2,6-dichloro-4-trifluoromethylphenyl)pyrazole) with reported concentrations of 14.16%, 22.92%, and 24.28% of accumulated residue in pooled uptake edible, inedible, and whole fish tissues fractions, respectively, and MB 45950 (5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-3-cyano-4-trifluoromethylthio-pyrazole) with reported concentrations of 9.04%, 9.03%, and 8.55% of accumulated residue in pooled uptake edible, inedible, and whole fish tissues fractions, respectively. The study authors stated that another metabolite, RPA 200766 (the amide), was discernible in test samples at much smaller quantities (amount not reported).

See DER for details.

**ENVIRONMENTAL FATE ASSESSMENT**

Available laboratory data indicate that below the soil surface fipronil dissipates by soil binding (k<sub>ds</sub>=26.2-148.6 for ads; K<sub>ocw</sub>=2671 to 7818) followed by slower biotic mediated processes (aerobic soil half-life=128 days; anaerobic aquatic half-lives=116-130 days). However, on the soil surface (or turf foliage) the major route of degradation may be photolysis (aerobic photolysis half-life=3.63 hours, soil photolysis half-life=34 days) and/or soil binding followed by slower biotic mediated processes. In addition, laboratory data indicate that fipronil is not mobile in soils tested and degrades slowly under alkaline hydrolytic conditions (hydrolysis half-life at pH 9-28 days). Fipronil does appear to be stable to hydrolysis at pH 5 and pH 7 (half-life-stable). The field data appears to support the laboratory data. Half-lives of 1.1 to 1.5 months for bare soil and 0.4 to 0.5 months for tilled soil are reported in field data. In bare soil plots fipronil residues were discernible only in the 0-6 inch soil depth. Therefore, since fipronil appears to bind to soil matter, movement off-target would appear to be associated with sediment contained in surface water and run-off water. In addition, potential for ground water contamination is considered low.

There is limited data on the persistence and mobility of degradates. However, limited data does indicate that the metabolites are not mobile in soil. There were two major degradates, RPA 200766 (the amide) and MB 46136 (5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-3-cyano-4-trifluoromethyl-sulphonyl-pyrazole), identified in the aerobic metabolism study at maximum concentrations of 27-38% and 14-24% of applied radioactivity, respectively. In the anaerobic aquatic study, the major degradates were MB 45950 (5-amino-1-(2,6-dichloro-4-trifluoromethylphenyl)-3-cyano-4-trifluoromethylthio-pyrazole) and RPA 200766 which were discernible at maximum concentrations of =47% and =18% of applied radioactivity, respectively. In addition to the metabolites identified in the metabolism studies, degradation products MB 46515 (5-amino-3-cyano-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-trifluoromethylpyrazole), MB 45350, and RPA 104615 (5-amino-3-cyano-1-(2,6-dichloro-4-trifluoromethylphenyl)pyrazole-4-sulfonic acid (potassium salt)) were identified in the photolysis studies. Other minor metabolites were identified in laboratory studies at concentrations of <6% each.
Supplemental fish accumulation indicate that fipronil does absorb in fish tissues. Bioconcentration factors (BCFs) of 321, 164, and 575 for whole fish, edible tissues, and non-edible tissues, respectively, are reported for the steady-state phase. However, the depuration data indicate that these fipronil residues are almost completely eliminated (>96%) after 14 days of non-exposure. These data appear to be in agreement with the octanol/water coefficient (10,570). Storage stability data on tissue samples are needed to validate the analytical data for the fish accumulation study to be upgraded to acceptable.

8. RECOMMENDATIONS:

The registrant should be informed of the following:

a. There is sufficient environmental fate data to support the EUP and Section 3 registration of fipronil on Turf at application rates of ≤0.05 lb a.i./A.

b. There is insufficient environmental fate data to support Section 3 registration for use of fipronil on corn at an application rate of 0.13 lb a.i./A due to lack of field dissipation data at this higher application rate.

c. Anaerobic aquatic metabolism and terrestrial field dissipation (for application rates ≤0.05 lb a.i./A) studies are acceptable to fulfill the respective data requirements.

d. The fish accumulation study is not acceptable at this time to fulfill the data requirement. Storage stability data for tissue samples are needed to validate the tissue characterization data.

e. The current status of environmental fate data requirements to support the registration of fipronil on terrestrial food and feed and terrestrial non-food crops (including turf) is as follows:

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<th>Environmental Fate Data Requirements</th>
<th>Status of Data Requirement</th>
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<td>161-1 Photodegradation in air¹</td>
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<td>Mobility Studies</td>
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Environmental Fate
Data Requirements

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</table>

1. Based on the low vapor pressure (=1 x 10⁻⁷ mm Hg), volatility data is not needed at this time.

2. An acceptable anaerobic aquatic metabolism study will fulfill the anaerobic metabolism data requirement.

3. The terrestrial field dissipation data requirement is fulfilled for applications rates of ≤0.05 lb a.i./A. The suggested application rate of fipronil on corn is 0.13 lb a.i./A. Additional terrestrial field dissipation data are needed to support the higher application rate and to make a complete environmental fate assessment of the higher application rate.

4. Additional storage stability data are needed for tissue samples.

9. BACKGROUND:

Fipronil is a phenylpyrazole insecticide at present used to control rootworms and/or wireworms in corn and to control mole crickets in turf. According to the manufacturer's data, fipronil affects the gamma-aminobutyric acid neurotransmission system by interfering with the passage of chloride. In addition, research data indicate that fipronil displays a higher potency in insect GABA chloride channel than in vertebrate GABA chloride channel which may indicate selective toxicity.

The application rate for fipronil is 0.13 lb a.i./A for control of rootworms and wireworms in corn and 0.0125 lb a.i./A to 0.025 lb a.i./A for control of mole crickets in turf. For corn fields fipronil is applied by ground equipment directly into the seed furrow behind the planter shoe. Slit-placement equipment is used for application of fipronil on infected turf. The application rate for fipronil is approximately one-tenth of that of previous used insecticides, terbufos, and chlorpyrifos.

10. DISCUSSION:

See individual DERS for details of reviewed studies.

11. COMPLETION OF ONE-LINER:

See attached one-liners.
GRI APPENDIX:

N/A
Common Name: FIPRONIL
Smiles Code:
PC Code #: 129121       CAS #: 120068-37-3
Chem. Name: 5-amino-3-cyano-1-(2,6-dichloro-4-trifluoromethylphenyl-4-trifluoromethylsulphinyl pyrazole
Action Type: insecticide

Trade Names:
(Formul'tn): 1.5% granular
Physical State: white powder

Use: control of rootworm and wireworm in corn
Patterns: terrestrial food and feed
(% Usage): approximately 0.13 lb a.i./A

Empirical Form: C₁₂H₄Cl₂F₆N₄S
Molecular Wgt.: 439.14       Vapor Pressure: E⁻⁷ Torr
Melting Point: 195-203.8°C       Boiling Point: °C
Log Kow : 4
Henry's : E       Atm. M₃/Mol (Measured)

Solubility in ...
Water  2.40E² ppm @20.0°C
Acetone  E ppm @ °C
Acetonitrile  E ppm @ °C
Benzene  E ppm @ °C
Chloroform  E ppm @ °C
Ethanol  E ppm @ °C
Ethanol  E ppm @ °C
Toluene  E ppm @ °C
Xylene  E ppm @ °C

Hydrolysis (161-1)
[V] pH  5.0: STABLE
[V] pH  7.0: STABLE
[V] pH  9.0: 28 DAYS
[ ] pH :
[ ] pH :
[ ] pH :
Photolysis (161-2, -3, -4)
[V] Water: 3.63 HOURS OR 0.33 DAYS FLORIDA SUNLIGHT

[V] Soil: 34 DAYS
[ ] Air:

Aerobic Soil Metabolism (162-1)
[V] 122-128 DAYS
[ ]

Anaerobic Soil Metabolism (162-2)
[ ]

Anaerobic Aquatic Metabolism (162-3)
[V] tl=116 days by HPLC
[ ] tl=130 days by TLC

Aerobic Aquatic Metabolism (162-4)
[ ]
Soil Partition Coefficient (Kd) (163-1)
[V] 26.2 - 35 FOR MANNINGTREE UK LOAMY SAND SOIL
[V] 58-128 FOR FRENCH SANDY-CLAY-LOAM SOIL
[V] 89.6-253 FOR GERMAN LOAMY SAND SOIL
[V] 148.6-222 FOR MANNINGTREE UK LOAM SOIL
[V] Koc FOR SAME SOILS = 2671 TO 7818

Soil Rf Factors (163-1)

Laboratory Volatility (163-2)

Field Volatility (163-3)

Terrestrial Field Dissipation (164-1)
[V] t½=1.1 to 1.5 months for bare soil
[ ] t½=0.4 to 0.5 months for turfed soil

Aquatic Dissipation (164-2)

Forestry Dissipation (164-3)
Environental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FIPRONIL
Last Update on October 24, 1994
[V] = Validated Study  [S] = Supplemental Study  [U] = USDA Data

Long-Term Soil Dissipation (164-5)

Accumulation in Rotational Crops, Confined (165-1)

Accumulation in Rotational Crops, Field (165-2)

Accumulation in Irrigated Crops (165-3)

Bioaccumulation in Fish (165-4)
[S] BCF = 321, 164, 575 for whole fish, edible tissue, and non-edible tissue, respectively.

Bioaccumulation in Non-Target Organisms (165-5)

Ground Water Monitoring, Prospective (166-1)

Ground Water Monitoring, Small Scale Retrospective (166-2)

Ground Water Monitoring, Large Scale Retrospective (166-3)

Ground Water Monitoring, Miscellaneous Data (158.75)
Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FIFRONIL
Last Update on October 24, 1994
[V] = Validated Study   [S] = Supplemental Study   [U] = USDA Data

Field Runoff (167-1)
[ ]
[ ]
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Surface Water Monitoring (167-2)
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Spray Drift, Droplet Spectrum (201-1)
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Spray Drift, Field Evaluation (202-1)
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[ ]

Degradation Products

FIFRONIL AMIDE FOR HYDROLYSIS
MB 46513 FOR PHOTOLYSIS
MB 45897, RPA 200766, RPA 105048, MB 46136, RPA 104615, MB45950,
MB 46058 FOR AEROBIC METABOLISM

SEE ATTACHED FOR CONFIGURATIONS
Environmental Fate & Effects Division
PESTICIDE ENVIRONMENTAL FATE ONE LINE SUMMARY
FIPRONIL
Last Update on October 24, 1994
[V] = Validated Study  [S] = Supplemental Study  [U] = USDA Data

Comments

References: ENVIRONMENTAL FATE STUDIES, FARM CHEMICAL HANDBOOK
Writer: GML