1-10-95

DP Barcode : D205183
PC Code No : 129121
EEB Out :

To: Robert Brennis
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-EUP-OL
Chemical Name :Fipronil
Type Product :Insecticide
Product Name :Photlysis product (MB46513) & Active Ingrd. MB46030
Company Name :Rhone-Polenc Ag Company
Purpose :6(a)(2) - Data - Review Studies

Action Code :405 Date Due :12/31/95
Reviewer : A. Bryceland

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)	432797-04	NR	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)	432797-01	S	122-2	432797-05	NR
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	432797-05	NR
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)	432797-02	NR	72-5			141-1		
72-1(C)			72-6			141-2		
72-1(C)	432797-03	NR				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
***Rebuttals submitted 8/94

NR = not reviewed

JAN 10 1995

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

FILE COPY

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

To: Marion Johnson, PM10
Registration Division (7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C)

1/6/95

Subject: Response to 6(a)(2) data for Fipronil

ITEM 1:

The following studies that have been submitted will not be reviewed due to the fact that all of them have been done with a photolysis product and not the technical grade material:

- MB46513-Acute Toxicity to Bluegill Sunfish (*Lepomis macrochirus*) Under Static Renewal Conditions. MRID No. 432797-02.
- MB46513-Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Static Renewal Conditions. MRID No. 432797-03.
- (MB 46513)-Chronic Toxicity to Daphnids (*Daphnia magna*) Under Static Renewal Conditions. MRID No. 432797-04.
- MB46513-Toxicity To The Freshwater Green Alga, *Selenastrum capricornutum*. MRID No. 432797-05.

However, it should be noted, according to an earlier screen document, "that the photodegradate is more toxic, in some cases, than the parent, this degradate warrants close consideration. It is not automatically assumed that just because it is more toxic, it represents a greater risk than the parent. The exposure could, hypothetically, also be correspondingly lower .. or negligible, depending on how and when it forms, and how much forms. There is insufficient information to determine this at this time" (see Attachment I).

ITEM 2:

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One study, MB46030 - Acute Toxicity To Mysid (*Mysidopsis bahia*) Under Static Conditions (MRID 432797-01), is with the technical grade material. This was the only study that was reviewed (see Attachment II).

72-3(c) - Acute Toxicity Test for Estuarine and Marine Organisms (Shrimp 96-Hour Acute Toxicity Test. Species Tested: *Mysidopsis bahia*

CITATION: Machado, M. 1994. MB 46030 - Acute Toxicity To Mysids (*Mysidopsis bahia*) Under Static Conditions. SLI Report No. 94-4-5224. Prepared by Springborn Laboratories, Inc. Wareham, MA. Submitted by Rhone-Poulenc Ag Company. EPA MRID No. 432979-01

CONCLUSION: This study is scientifically sound but does not fulfill the guideline requirements for an acute toxicity test on mysid shrimp. The reasons for this conclusion are the following; negative control contamination, test temperature was too high (25 to 26°C), and the study chambers were too small with an insufficient amount of test solution (1 liter glass beakers with 1 liter test solution). The 96-hour EC_{50} was 140 ng ai/L (95% c.i.; 120 to 160 ng ai/L), which classifies Fipronil (MB 46030) as being very highly toxic to mysid shrimp. The NOEC is less than 62 ng ai/L.

If there are any questions contact Andrew Bryceland of my staff at 305-7347.

Attachment I

SCREEN

FIPRONIL AND ITS' PHOTOMETABOLITE: MB 46513
129121
432797-00,01,02,03,04,05,06

00=cover letter

SPECIES	UNITS	FIPRONIL	MB 46513
BLUEGILL	LC50	85 PPB	20 PPB
RAINBOW TROUT	LC50	248 PPB	31 PPB
DAPHNIA MAGNA	NOEL, LOEL, GEO MEAN	9.8, 20, 14 PPB	41, 100, 64 PPB
BOBWHITE QUAIL	LD50	11.3 MG/KG	5.41 MG/KG
MALLARD DUCK	LD50	>2150 MG/KG	437 MG/KG
SELENASTRUM CAPR	EC50	≥0.14 PPM	0.065 PPM

432797-01 MYSID ACUTE
432797-02 BLUEGILL ACUTE
432797-03 RAINBOW TROUT ACUTE
432797-04 DAPHNIA MAGNA CHRONIC
432797-05 GREEN ALGAE (SELENASTRUM CAPRICORNUTUM) GROWTH
432797-06 RAT ACUTE

bobwhite quail LD50=5.41 mg/kg
bobwhite LD50 for parent=11.3 mg/kg
mallard duck LD50=437 mg/kg
mallard LD50 for parent>2150 mg/kg

Koc for fipronil reported to be from 2671-7818
Use rate in EUP: 0.13 lb ai/acre soil incorporated
It was unclear from the documentation provided for screening exactly what studies went with what results. It is assumed, the fish study MRID's go with the fish test results, however, no MRID's were provided for the bird studies, and no shrimp or mammal study results were provided. This lack of connection between study MRID and results does not preclude screening the reported results for potential risk.

Avian Acute Risk:

Based on the overall use rate of 0.13 lb ai/acre, the rate would be 0.65 lb ai/acre on a sq ft basis in the bands to which the granules would be applied.
0.65 lb ai/acre = 6.7 mg ai/sq foot
assuming soil incorporation, only 15% is available to birds:
6.7 X 0.15 = 1 mg ai/sq foot is exposure to birds for acute risk

Assuming a quail weighs 162 g, the LD50 for an individual bird would be 1.84 mg ai (based on an LD50 of 11.4 mg/kg)
A risk quotient is calculated:
RQ = 1/1.84 = 0.54

RQ exceeds [by a narrow margin] current LOC (0.5) for acute risk to birds. This conclusion is not significantly different from the conclusion of the EUP, in which restricted use was recommended because of acute risk to birds. This suggests the possibility of acute risk...i.e. bird mortality. However, since the only current useage is under EUP's the extent of ecological damage, if any, would be relatively limited on a regional/national environmental scale, occurring only in the local areas around the experimental use plots.

Risk from the photodegradate:

Since it is more toxic, in some cases, than the parent, this degradate warrants close consideration. It is not automatically assumed that just because it is more toxic, it represents a greater risk than the parent. The exposure could, hypothetically, also be correspondingly lower...or negligible, depending on how

and when it forms, and how much forms. There is insufficient information to determine this at this time. Presumably, when all fate data have been submitted and reviewed, EFED will be able to estimate, roughly, potential exposure of the degradate to birds.

No "urgent" regulatory action would be warranted; the risk suggested by this 6a2 data, and all available data should be considered in future regulatory decisions.

Aquatic Risk:

Exposure from runoff would be relatively low because of the relatively high binding potential (see Koc). Based on preliminary exposure estimates (see attached eec printout), concentrations in surface water are unlikely to represent a high risk to aquatic organisms; based on this 6a2 data, and previously submitted toxicity data. It is possible that some endangered species may be affected; this was addressed in the EUP review. No immediate regulatory action is warranted.

Conclusion of Screen:

These data indicate possible risk to birds, however, no "new" risks are identified based on this screen. All risk suggested by these 6a2 data were previously identified in a recent EUP review.

It is recommended that this data be routed to EFED for standard, nonexpedited review with an estimated completion date of 18 months. It is acknowledged that RD or SRRD may have a reason for expediting review of these data beyond that due to high risk potential. In that case, it is assumed that the importance of reviewing this data would be balanced against the importance of other high priority actions.

As stated earlier, no "urgent" regulatory action, or new data requirements are triggerred based on this screen. **However, review of proposed uses under Section 3 registrations may discover need for risk reduction or new data requirements.** Note that there have been several avian acute and dietary studies conducted to characterize acute hazard to birds.

Dan Rieder

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Attachment II

DATA EVALUATION RECORD

1. CHEMICAL: MB46030 Fipronil

2. TEST MATERIAL: MB 46030 (Fipronil): 5-amino-1-(2,6-dichloro-α,α,α-trifluoro-p-tolyl)-4-trifluoromethylsulfinylpyrazole-3-carbonitrile; 96.1% TGAI, grey powder, Batch Number 6ADM93.

3. STUDY TYPE: §72-3 Acute Toxicity Test for Estuarine and Marine Organisms (Shrimp 96-Hour Acute Toxicity Test). Species Tested: *Mysidopsis bahia*

4. CITATION:

Author:	Mark W. Machado
Title:	MB 46030 - Acute Toxicity To Mysids (*Mysidopsis bahia*) Under Static Conditions
Date:	29 March 1994
Laboratory Report #:	94-4-5224
Any Other Study #:	10566.0394.6340.510
Sponsor:	Rhone-Poulenc Ag Company
Laboratory:	Springborn Laboratories, Inc. Wareham, MA
MRID No.:	432979-01

5. REVIEWED BY:

Andrew C. Bryceland, Fishery Biologist Signature: [signature] 1/4/95
Ecological Effects Branch
Environmental Fate and Effects Division (7507C) Date:

6. APPROVED BY:

fy Ann Stavola, Chief, Section 5 Signature: Allen W. Vaughan 1.4.95
Ecological Effects Branch
Environmental Fate and Effects Division (7507C) Date:

7. CONCLUSION

This study is scientifically sound but does not fulfill the guideline requirements for an acute toxicity test on mysid shrimp. The reasons for this conclusion are the following; negative control contamination, test temperature was too high (25 to 26°C), and the study chambers were too small with an insufficient amount of test solution (1 liter glass beakers with 1 liter test solution). The 96-hour EC_{50} was 140 ng ai/L (95% c.i.; 120 to 160 ng ai/L), which classifies Fipronil (MB 46030) as being very highly toxic to mysid shrimp. The NOEC is less than 62 ng ai/L.

8. RECOMMENDATIONS

9. BACKGROUND

10. MATERIALS AND METHODS

A. Test Organisms: Mysid Shrimp

Guideline Criteria	Reported Information
Species (Scientific Name)	*Mysidopsis bahia*
Mean Weight (> 0.5 grams)	≤ 24 hours old
Supplier	Aquatic Biosystems, Ft. Collins, Colorado
All shrimp from same source (yes or no)	yes
All shrimp from the same year class (yes or no)	yes
Other Comments	

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period (minimum 10 days)	14 days
Wild caught 7 day quarantine (yes or no)	no
Check for signs of disease or injury (yes or no, if yes describe)	Information not available
If diseased it can be treated in 48-hr pretest no sign of the disease remains (Report hours prior to test in which no sign of disease or N/A)	
No feeding during the study (When last fed)	Fed once daily throughout the study
<3% mortality 48 hours prior to testing (% mortality, if any)	Information not available

C. Test System:

Guideline Criteria	Reported Information
Describe source of dilution water	Seawater collected from Cape Cod Canal, Bourne, MA
Does water support test animals without observable signs of stress?	yes
What was the salinity of the water used? (30-34% ppt for marine (stenohaline) shrimp and 10-17% ppt for estuarine (euryhaline) shrimp.	30-32%
Water Temperature (22°C)	25 ± 1°C Waterbath 25 - 26°C Daily test chamber
pH 8.0-8.3 marine (stenohaline) shrimp 7.7-8.0 estuarine (euryhaline) shrimp	7.7-7.8
Dissolved Oxygen (Static 1st 48 hrs 40%; 2nd 48 hrs 60%; Flow-through 60%) (% of lowest conc. & hour)	78-100% saturation
Total Organic Carbon	<2.0 mg/l
Test Aquaria 1. Material (glass or stainless steel) 2. a. Static volume (18.9 L (5 gal or 19000 cc) with 15 L solution) b. Static or flow-through volume (300x600x300 = 54000 cc.)	1 liter glass beakers with 1 liter of test solution. 2.7 cm depth.
Type of Dilution System (Reproducible supply of toxicant)	yes
Flow rate Consistent flow rate-meter systems calibrated before study and checked 2*24 hours - 5 to 10 vol/24 hours	N/A Study under static conditions.

Biomass Loading Rate (Static no > 0.8 g/L ≤ 17°C; >17°C 0.5 g/L; Flow-through 1 g/L/24	0.0033 g biomass/L
Photoperiod (16 L & 8 D)	16 light and 8 dark
Solvents 1. (Do not exceed 0.5 ml/L for static tests) 2. (Do not exceed 0.1 ml/L for flow-through)	0.10 ml/L
Other Comments	

D. Test Design:

Guideline Criteria	Reported Information
Range Finding Test (LC_{50} >100 mg/L with 30 shrimp, no definitive test required.)	13, 22, 36, 60, 100 ng ai/L 15% mortality 100 @ ng ai/L
Definitive Test	
Nominal Concentrations (control+5 treatment levels; dosage should be 60% of the next highest concentration; concentrations should be geometric series)	61, 100, 170, 280, 470 ng ai/L
Controls (Minimum control mortality; static 10%; flow-through 5%	0% in negative control 5% in solvent control
Number of Test Organisms; (Minimum 20/level can be divided among containers)	20 /test concentration and controls
All organisms must be randomly assigned to test vessels. (yes or no, describe if no)	yes
Biological Observations (yes or no)	yes

Water Parameter Measurements 1. Temperature - record every 6 hrs;>1°C. 2. D.O. beginning,48 hrs,end for control high, medium, and low dose. 3. pH beginning,48 hrs, end for control, high, medium, and low dose.	Temp. continuously measured in the surrounding waterbath. Temp. measured in all other test and control vessels daily. For DO and pH see Table 1
Chemical Analysis (needed if aeration, volatile, insoluble, precipitate, not steel or glass, known to adsorb, and flow-through) (yes or no)	No visible signs of undissolved test material
Other Comments	

11. REPORTED RESULTS:

Guideline Criteria	Reported Information
Mean Measured Concentrations (report conc.)	62, 97, 140, 240, 390 ng ai/L
Recovery of Chemical (% recovery)	
Mortality & Observations (Describe observations & attach mortality tables)	See Table 4
Author's Comments	Repl. A of the solvent control showed 10% mortality. Negative control showed 16 ng ai/l of test substance.

12. STUDY AUTHOR'S CONCLUSIONS / QUALITY ASSURANCE MEASURES:

No conclusions were made.

Quality assurance and good laboratory practice statements were included in the report, indicating that the study was conducted in accordance with U.S. EPA Good Laboratory Practices Regulations set forth in FIFRA 40 CFR Part 160 except for the following:

Routine water and food contaminant screening analyses for pesticides, PCBs, and metals were conducted using standard U.S. EPA procedures by Lancaster Laboratories, Lancaster, PA. These data were not collected in accordance with GLP procedures (i.e., no distinct protocol, Study director,

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etc.). Stability, characterization, and verification are the responsibility of the Study Sponsor. Total organic carbon analyses for filtered seawater conducted by Galbraith Laboratories, Knoxville, Tennessee, utilized standard U.S. EPA procedures, but were not conducted in accordance GLP procedures.

13. REVIEWER'S DISCUSSION AND INTERPRETATION

A. Test Procedure:

The following items did not meet the guideline criteria:

1. Negative control contamination.

2. No notation of acclimation observations prior to testing for disease or mortality.

3. Test temperature was too high (25 to 26°C). SEP states a test temperature of 22°± 1°C.

4. Study chambers were 1 liter glass beakers with 1 liter test solution. Smaller than SEP recommendation. SEP states; "For static tests larger organisms (0.5 g each or larger) should be exposed in 19.6 liter containers with 15 liters of solution. Smaller organisms may be exposed in 3.9 liter containers with two or three liters of solution."

B. Statistical Analysis

Guideline Criteria	Reported Information
Binomial (yes, no, or not reported)	
Moving Average Angle (yes, no, or not reported)	
Probit (yes, no, or not reported)	yes, 140 ng a.i./L 95% CI 120 to 160 ng a.i./L
Other Comments -- study used nonlinear interpolation	

C. Discussion/Results:

This study is scientifically sound but does not fulfill the guideline requirements for an acute toxicity test on mysid shrimp. The 96-hour EC_{50} was 140 ng ai/L (95% c.i.; 120 to 160 ng ai/L), which classifies Fipronil (MB 46030) as being very highly toxic to mysid shrimp. The NOEC is less than 62

ng ai/L.

D. Adequacy of the Study:

1. Classification: Supplemental

2. Rational: Negative control contamination. Test temperature was too high (25 to 26°C). Study chambers too small, 1 liter glass beakers with 1 liter test solution.

3. Reparability: Irreparable.

14. COMPLETION DATE OF ONE-LINER FOR STUDY: