

UNDATED



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

To: Marion Johnson
Registration Division (7505C)

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

A handwritten signature in black ink, appearing to read "A. F. Maciorowski".

Subject: New Chemical Screen-Expedited Review for Fipronil Insecticide [Regent 1.5G] - (Fipronil Technical: sulfoxide 5-amino-1-[2,6-dichloro-4-trifluoromethyl]phenyl]-4-[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile

Ecological Effects Branch (EEB) has reviewed aquatic plant, fish, and wildlife toxicity data submitted by Rhone-Poulenc Ag Company to support registration of Fipronil insecticide. The registrant has submitted ten avian, ten aquatic invertebrate, nine fish, and six aquatic plant studies to support the proposed use on **corn (terrestrial/food use)**. A number of these studies were conducted with the degradates of Fipronil (ie; RPA104615). The acceptance of these studies has not been addressed in this new chemical screen memo.

The LD₅₀ values for mallards and bobwhite are 2150 ppm a.i. (active ingredient) (practically non-toxic) and 11.3 ppm a.i. (very highly toxic), respectively. The LC₅₀ values for mallards and bobwhite are >4480 ppm a.i. (practically non-toxic) and 48 ppm a.i. (very highly toxic), respectively.

In the mallard duck reproduction study the NOEC (no observable effect concentration) was 1000 ppm a.i. The bobwhite quail reproduction study does not fulfill guideline requirements because a Low Observable Effect Concentration (LOEC) could not be determined from the range of test concentrations. The NOEC for the bobwhite study was 10 ppm a.i. All of the avian studies above have been fully reviewed by EEB (Table 1; excerpted from the Fipronil EUP for use on cotton).



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AVIAN TEST RESULTS

TABLE 1.

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
71-1A	Mallard, Acute Oral LD ₅₀	429186-16	1/5/94	Core, Practically Non-Toxic	96.8	1993	LD ₅₀ = 2150 mg ai/kg
71-1A	Quail, Acute Oral LD ₅₀	428186-17	1/4/94	Core, Highly Toxic	96	1993	LD ₅₀ = 11.3 mg ai/kg
71-1A	Quail, Acute Oral LD ₅₀	429186-19	1/13/94	Supp., Highly Toxic	1.6	1993	LD ₅₀ = 17.0 mg ai/kg
71-2B	Mallard, Acute Dietary LC ₅₀	429186-21	1/14/94	Core, Slightly Toxic	>95	1993	LC ₅₀ = 4480 ppm ai
71-2A	Quail, Acute Dietary LC ₅₀	429186-20	1/12/94	Core, Very Highly Toxic	>95	1993	LC ₅₀ = 48.0 ppm ai
71-4B	Mallard Avian Repro.	429186-23	4/8/94	Core	96.7	1993	NOEC= 1000 ppm ai
71-4A	Quail, Avian Repro.	429186-22	5/16/94	Supp.	96.7	1993	NOEC > 10 ppm ai

The acute LC₅₀ freshwater values for rainbow trout, bluegill sunfish, and *Daphnia magna* are 39 µg a.i./l (very highly toxic), 25 µg a.i./l (very highly toxic), and 29 µg a.i./l (very highly toxic), respectively (Table 2; excerpted from the Fipronil EUP for use on cotton). Additional aquatic studies have been submitted by the registrant but their acceptance has not been determined on the technical grade or it's degradate.

Aquatic Invertebrates and Fish Results

TABLE 2.

GLN #	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% A.I.	TEST DATE	RESULT
72-1C	Rainbow Trout LC ₅₀	429779-02	1/10/94	Core, Highly Toxic	100	1991	LC ₅₀ = 246 µg/L
72-1C	Rainbow Trout LC ₅₀	429186-73	1/11/94	Core, Very Highly Toxic	99.2	1993	LC ₅₀ = 39 µg/L

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72-4A	Rainbow Trout, Fish Early Life-Stage	429186-27	3/9/94	Core	96.7	1992	MATC= 9.9 $\mu\text{g/L}$
72-1A	Bluegill, LC ₅₀	429186-24	1/10/94	Core, Very Highly Toxic	100	1991	LC ₅₀ = 83 $\mu\text{g/L}$
72-1A	Bluegill, LC ₅₀	429186-74	1/12/94	Core, Very Highly Toxic	99.2	1992	LC ₅₀ = 25 $\mu\text{g/L}$
72-4B	Life-Cycle Aquatic Invertebrate (<i>D. magna</i>)	429186-26	3/10/94	Invalid	100	1990	N/A
72-4B	Life-Cycle Aquatic Invertebrate (<i>D. magna</i>)	429186-70	3/3/94	Invalid	100	1990	N/A
72-4B	Life-Cycle Aquatic Invertebrate (<i>D. magna</i>)	429186-72	3/4/94	Invalid	99.2	1992	N/A
72-2A	Daphnia magna, EC ₅₀	429186-25	1/12/94	Invalid	100	1990	NA
72-2A	Daphnia magna, EC ₅₀	429186-69	1/13/94	Core, Very Highly Toxic	100	1990	EC ₅₀ = 92.6 $\mu\text{g/L}$
72-2A	Daphnia magna, EC ₅₀	429186-71	1/13/94	Core, Very Highly Toxic	100	1990	EC ₅₀ = 29 $\mu\text{g/L}$

Additional freshwater studies that have been submitted by the registrant are chronic daphnid (72-4b), acute bluegill sunfish (72-1a), and acute rainbow trout (72-1c). These recent submissions have not been fully reviewed. Upon cursory examination of these studies the endpoints, as reported by the registrant, are 41 μg a.i./L (very highly toxic), 20 μg a.i./L (very highly toxic) and 31 μg a.i./L (very highly toxic), respectively.

The only estuarine studies that have been submitted to date by the registrant are for acute flow-through sheepshead minnow (72-3a), acute flow-through oyster (72-3b), and acute mysid shrimp (72-3c). These recent submissions have not been fully reviewed. Upon cursory examination of these study the LC₅₀s, reported by the registrant, are 130 μg a.i./l (highly toxic), greater than 0.77 mg a.i./l (highly toxic), and 140 ng a.i./L (very highly toxic), respectively.

The acute aquatic plant LC₅₀s (Table 3; excerpted from the EUP on Fipronil for use on cotton) are as follows:

Aquatic Plants

Table 3.

GLN#	TEST TYPE	MRID	EVALUATION DATE	CLASSIF.	% AI	TEST DATE	RESULT
122-2	Freshwater Green Alga ¹ , Aquatic Plant-Tier 1	429186-60	1/6/94	Core	96.1	1993	EC ₅₀ = 0.14 mg/l
122-2	Freshwater Blue-Green ² Alga, Aquatic Plant-Tier 1	429186-57	1/6/94	Core	96.1	1993	EC ₅₀ = >0.17 mg/l
122-2	Marine Diatom ³ , Aquatic Plant-Tier 1	429186-59	1/7/94	Core	96.1	1993	EC ₅₀ = >0.14 mg/l
122-2	Duckweed ⁴ , Aquatic Plant-Tier 1	429186-56	1/7/94	Supp	96.1	1993	EC ₅₀ = >0.10 mg/l
122-2	Freshwater Green Alga ⁵ , Aquatic Plant-Tier 1	429186-58	1/7/94	Supp	96.1	1993	EC ₅₀ = >0.12 mg/l

An additional freshwater aquatic plant study has been submitted by the registrant for the freshwater algae *S. capricornutum* with an EC₅₀, as reported by the registrant, of 0.065 mg a.i./L. This study has not been fully reviewed by EEB.

Listed below in Table 4 are the guideline requirements that have been fulfilled and what may be required.

¹*Selenastrum capricornutum*

²*Anabaena flos-aquae*

³*Skeletonema costatum*

⁴*Lemna gibba*

⁵*Navicula pelliculosa*

Table 4.

Required Studies	Requirement Fulfilled (Y or N)				
	Fipronil Technical MB 46030	MB 45950	MB 46136	MB 46513	RPA1046 15 K salt
Avian Oral LD ₅₀ (Bobwhite or Mallard) 71-1	Y ¹ (Bobwhite and Mallard)				
Avian Dietary LC ₅₀ (Bobwhite and Mallard) 71-2	Y ¹ (Bobwhite and Mallard)				
Avian Reproduction (Bobwhite and Mallard) 71-4	Y ¹ (Mallard) and [suppl. ³] (Bobwhite)				
Acute Freshwater Fish LC ₅₀ (Bluegill and Rainbow) 72-1	Y ¹ (Bluegill and Rainbow)	Y ¹ (Bluegill)		Y ² (Rainbow and Bluegill)	Y ² (Rainbow)
Acute Freshwater Invertebrate LC ₅₀ (<i>D. magna</i>) 72-2	Y ¹ (<i>D. magna</i>)	Y ¹ (<i>D. magna</i>)	Y ¹ (<i>D. magna</i>)		Y ² (<i>D. magna</i>)
Acute LC ₅₀ Marine/Estuarine Fish 72-3	Y ² (Sheepshead)				
Acute LC ₅₀ Marine/Estuarine Mollusk/Shrimp 72-3	Y ² (Mollusk) Y ² (Shrimp)				
Fish Early Life Stage (Freshwater) 72-4	Y ¹ (Rainbow)				
Aquatic Invertebrate Life-Cycle (Freshwater) 72-4	N ⁴ (<i>D. magna</i>)	N ⁴ (<i>D. magna</i>)	N ⁴ (<i>D. magna</i>)	Y ² (<i>D. magna</i>)	

Fish Early Life Stage (Marine) 72- 4	N ⁵				
Aquatic Invertebrate Life-Cycle (Marine) 72- 4	N ⁵				

¹Studies have been reviewed and have met guideline requirements. ²Studies have not been reviewed but have been submitted. ³Suppl. = Supplemental; Study has been reviewed but has not met guideline requirements. ⁴Study was reviewed and did not fulfill the guideline requirement. ⁵Request for data pending results from acute mar./est. studies and environmental fate data.

Fipronil fails the new chemical screen. The avian reproduction and aquatic invertebrate life-cycle studies are to be repeated. These studies are required in order to support the proposed use of Fipronil on corn.

If you have any questions about this review contact Andrew Bryceland at (703) 305-7347.

DP Barcode : D208905
 PC Code No : 129121
 EEB Out :

To: Marion Johnson
 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-LLL
 Chemical Name : Fipronil
 Type Product : Insecticide
 Product Name : Regent 1.5G
 Company Name : Rhone-Polenc Ag Company
 Purpose : New Chemical Screen use on Corn

Action Code : 015 Date Due : 11/22/94
 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)			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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