

DP Barcode : D230159
PC Code No : 129121
EEB Out :

SEP 11 1997

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

From: Norman Cook, Acting 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 : EEB response to R-P rebuttal to Sec 3 for corn

Action Code : 101 Date Due : 1/25/97
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)			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

DP BARCODE: D230159

CASE: 016016
SUBMISSION: S511884

DATA PACKAGE RECORD
BEAN SHEET

DATE: 09/27/96
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 101 RESB NC-FOOD/FEED USE
RANKING : 0 POINTS ()
CHEMICALS: 129121 Fipronil 1.5000%

ID#: 000264-LLL REGENT 1.5G INSECTICIDE
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: 09/24/96 DUE OUT DATE: 04/02/97

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 230159 EXPEDITE: Y DATE SENT: 09/27/96 DATE RET.: / /
CHEMICAL: 129121 Fipronil
DP TYPE: 001 Submission Related Data Package
CSF: Y LABEL: Y

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 01/25/97
DIV : EFED	9/27/96	/ /	NEGOT DATE: / /
BRAN: EEB	9/30/96	/ /	PROJ DATE: / /
SECT: RS5		/ /	
REVR : FEDEROFF	10/2/96	/ /	
CONTR:	/ /	/ /	

* * * DATA REVIEW INSTRUCTIONS * * *

Note to Ann Stavola and Nick Federoff: Please review the attached response from Rhone Poulenc (no MRID) to the EEB review dated July 24, 1996. While Rhone Poulenc has offered to delete the T band method of application, they have not submitted new labels, so the attached label is an old one. Please call if you have questions or need anything else to complete your review. Ann Sibold 305-6502

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SEP 11 1997

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

SUBJECT: EEB Response to Rebuttal (D230159) by Rhone-Poulenc
Regarding Evaluation of the REGENT 1.5 G Section 3 for
use on corn (Chemical No. 129121) (D214762)

FROM: *for* Norman Cook, Acting Branch Chief *Arw Shuck* 1/28/97
Ecological Effects Branch
Environmental Fate and Effects Division (7507 C)

TO: Richard Keigwin, PM 10
Insecticide Branch
Registration Division (7505 C)

The EEB has reviewed the rebuttal by Rhone-Poulenc regarding the EPA evaluation (Section 3) of risks associated with the use of REGENT 1.5 G on corn. After review of the comments, EEB concludes that some changes will be made to the review.

Aquatic Risk Assessment

The Daphnia study and EC50 mentioned in the rebuttal (MRID# 429186-25) (EC50= 190 ppb) is, in fact, in error of the submitted data from Springborn Labs. However, after review of the entire study again and a meeting with the registrant, it was noted that in the written portion of the study the concentrations were listed as ug/L, while ng/L was listed in the data tables. The correct EC50 is in fact 190 ug/L (ppb) and all associated changes will be made to the review to reflect the correction.

In regards to the Mysid chronic study, the current NOEC to be used in any future risk assessments, as designated in the 8/2/96 memo, is 5 pptr. The review will be amended to reflect this and all other statements associated with the change. However, none of the above changes will affect the assessment endpoints or the conclusions of the assessment in relation to risks associated with estuarine invertebrates.

Avian Risk Assessment

EEB will delete the statement made on page 5 of the section 3 review concerning the use pattern in accordance with the label. In regards to the LD50 for quail used in the risk assessment, it is general policy to use data from studies using technical grade material. Nevertheless, both studies, as well as data from studies conducted with the red-legged partridge and the pheasant (LD50's of 34 and 31 mg/Kg, respectively), have an LD50 < 50 mg/Kg for a granular product. Therefore Fipronil meets the criteria for a Restricted Use classification (40 CFR 152.170 (c)(2)(i) as stated

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in the review.

It is evident that upland gamebird species are differentially more sensitive and susceptible to the acute and chronic effects of Fipronil than are waterfowl species. However, should Fipronil enter aquatic habitats, un-natural alterations in the food chain may occur, thus having impacts on ducklings. Fipronil is highly to very highly toxic to freshwater fish and highly toxic to freshwater invertebrates. Swanson et al. (1985) and Reinecke (1979) have indeed suggested that macroinvertebrates may represent a very high percentage of the diet of waterfowl species and especially their young. The importance of aquatic invertebrates for the young of several species of dabbling (Anatini) and diving (Aythyini) ducks has been established (Bartonek and Hickey, 1969; Sugden, 1973). Should Fipronil enter these habitats, invertebrate populations may decline, resulting in a decline in fish populations as a result of the toxicity of Fipronil itself to fish, and a decline of their food base. Also, if ducklings are present, competition for limited invertebrate food items may occur, thus reducing growth rates and increasing energy expenditures searching for food (Hunter et al., 1984; Hunter et al., 1986). While it has been suggested (Swanson et al., 1985) that waterfowl will adapt to natural limitations and variability in food resources, Fipronil entering an aquatic habitat would not be considered a natural phenomenon. Also, since it was stated that most waterfowl species have extended nesting strategies, which may involve moving overland to find other non-affected areas, higher predation rates on ducklings may be a result.

In response to the In-Furrow LD50 per sq.ft. issue, a 1 inch width is what EEB uses for the In-furrow equation. It is also standard practice to use LD50 data from a study using technical grade material for assessments, not data from studies using formulated product. With this in mind, the Restricted Use Classification would still be in effect (RQ= 0.2). The registrant stated that T-Band application will be taken off of the label, and if this is done, would help reduce risks associated with this method of application.

Mammalian Risk Assessment

EEB will delete the statement made on page 22 of the section 3 review regarding risk to mammalian species due to the fact that Fipronil should pose low risk to mammals from this use.

Citations

Bartonek, J.C. and J.J. Hickey. 1969. Food habits of Canvasbacks, Redheads, and Lesser Scaup in Manitoba. Condor 71:280-290.

Hunter Jr., M.L., J.W. Witham and H. Dow. 1984. Effects of a carbaryl-induced depression in invertebrate abundance on the growth and behavior of American black duck and mallard ducklings. Can. J. Zool. 62:452-456.

Hunter Jr., M.L., J.J. Jones, K.E. Gibbs and J.R. Moring. 1986. Duckling responses to lake acidification: do black ducks and fish compete? *Oikos* 47:26-32.

Reinecke, K.J. 1979. Feeding ecology and development of juvenile black ducks in Maine. *The Auk* 96:737-745.

Sugden, L.G. 1973. Feeding ecology of Pintail, Gadwall, American Widgeon, and Lesser Scaup ducklings. Canadian Wildlife Service Report Series No. 24.

Swanson, G.A., M.I. Meyer and V.A. Adomaitis. 1985. Foods consumed by breeding mallards on wetlands of south-central North Dakota. *J. Wildl. Management* 49(1):97-202.

If any questions should arise from this review please contact Nicholas Federoff of my staff at 703-305-5064.