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FILE COPY

DP BARCODE: D220094

CASE: 031271
SUBMISSION: S494805

DATA PACKAGE RECORD
BEAN SHEET

DATE: 07/22/96
Page 1 of 1

*** CASE/SUBMISSION INFORMATION ***

CASE TYPE: REGISTRATION ACTION: 101 RESB NC-FOOD/FEED USE
RANKING : 1 POINTS ()
CHEMICALS: 129121 Fipronil 96.5000%

ID#: 000264-00554 FIPRONIL TECHNICAL
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: 10/02/95 DUE OUT DATE: 04/09/96

*** DATA PACKAGE INFORMATION ***

DP BARCODE: 220094 EXPEDITE: Y DATE SENT: 10/16/95 DATE RET.: / /
CHEMICAL: 129121 Fipronil
DP TYPE: 001 Submission Related Data Package
CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT	ADMIN DUE DATE: 02/13/96
DIV : EFED	10/18/95	/ /	NEGOT DATE: 02/13/96
BRAN: EEB	10/18/95	/ /	PROJ DATE: / /
SECT: RS5	10/18/95	/ /	
REVR : ASTAVOLA	10/18/95	/ /	
CONTR:	/ /	/ /	

*** DATA REVIEW INSTRUCTIONS ***

Note to Ann Stavola,
Attached are two letters from Rhone-Poulenc regarding two fipronil studies, the daphnia study and the bobwhite study. If Gulf Breeze completed a review document exists for the daphnia study, please send me a copy and I'll forward it. Regarding the bobwhite study, my notes of the April meeting say that the study did not need to be repeated but they are not clear on whether the study was acceptable. I've attached my notes of the April meeting. Please call if you have questions or need anything else to respond to these letters. Thanks, Ann 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

JUL 31 1996

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to Rhone-Poulenc Ag Company Regarding the Evaluations of the Bobwhite Reproduction Study (MRID 429186-22) and the Daphnia Magna Life cycle Study (MRID 429186-26) (D220094)

FROM: *fa* Anthony F. Maciorowski, Chief *Amw Staveland*
Ecological Effects Branch
Environmental Fate and Effects Division (7507c) *7/31/96*

TO: Richard Keigwin, PM - 10
Insecticides - Rodenticides Branch
Registration Division (7505c)

Attached to this memo are copies of EEB's memo to you dated September 6, 1995 and the memo to EEB from Michael Lewis, Chief of the Gulf Coastal Ecology Branch, at the U.S. EPA Environmental Research Laboratory at Gulf Breeze, Florida regarding the evaluation and the peer review of the *Daphnia magna* life cycle study (MRID 429186-26).

As stated in EEB's memo, Dr. Lewis concluded that the deficiencies noted by EEB do not invalidate the study. Based on his conclusions, EEB classified the study as supplemental; it is scientifically sound but does not meet Agency requirements for a freshwater invertebrate life cycle study. Therefore, the need for a new *Daphnia* life cycle study is waived for the turf and corn uses (the only section 3 submissions EEB has reviewed to date). The requirement for submission of a new study to support the registration(s) of future uses will be dependent on the proposed use site and if the uses indicate that EECs may exceed the NOEC from this supplemental study.

As EEB stated in the April 4, 1995 meeting with the registrant, the NOEC of 10 ppm from the bobwhite reproduction study (MRID 429186-22) 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 for two avian reproduction studies are fulfilled.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ENVIRONMENTAL RESEARCH LABORATORY

1 SABINE ISLAND DRIVE

GULF BREEZE, FLORIDA 32541-5298

July 3, 1995

MEMORANDUM

SUBJECT: Chronic Study of M&B 46030 to Daphnia magna Under Flow-Through Conditions (MRID No. 429186-26)

FROM: Michael A. Lewis *ML*
Branch Chief-Gulf Coastal Ecology

TO: Anthony F. Maciorowski
Ecological Effects Branch (7507C)

I have reviewed, at your request, the technical details of the chronic study of M&B 46030 to Daphnia magna under flow-through conditions (MRID No. 429186-26). The scientific validity of the study has been uncertain due to high control mortality, some analytical variation and questions on detection limits.

It is my opinion after a thorough review of the study and the previous correspondence that the study is scientifically valid. The study certainly had some "irregularities" but none of these impact the effect and no-effect concentrations. Comparison of the effects in the various test concentrations to those in the solvent control where there was high survival is standard practice. The analytical inconsistency at one concentration does not invalidate the study in my opinion.

If you have any questions or need any clarification, please call me at 904-934-9382. Attached are all materials that were sent to me.

Attachment



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

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

SEP - 6 1995

MEMORANDUM

SUBJECT: Peer Review by the EPA Gulf Breeze Laboratory of the Chronic Study of M&B 46030 (Fipronil) to Daphnia magna (MRID 429186-26)

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

TO: Richard Keigwin, PM-10
Insecticides Branch
Registration Division (7505c)

The Ecological Effects Branch received the peer review of the Daphnia chronic toxicity study [Guideline 72-4(b)] for the chemical fipronil. The reviewer, Dr. Michael Lewis, concluded that the deficiencies noted by EEB -- the high mortality in the dilution water control and the analytical inconsistency in some of the test concentrations -- are not severe enough to invalidate the results of the study.

Based on his review, the EEB is classifying the study as supplemental; it is scientifically sound but does not meet Agency requirements for a freshwater invertebrate lifecycle study.

EEB is waiving the requirement for a new Daphnia chronic study to support the proposed uses of fipronil on corn, based on the proposed label rates. Preliminary estimated environmental concentrations (EECs) in water from the corn uses are 4 ug/l or less, which is less than the NOEC in the study. However, if additional proposed uses of fipronil indicate that the EECs may exceed the NOEC from this study, EEB will require that a new Daphnia lifecycle study be submitted to support those uses.

If there are any further questions regarding this issue, please contact Ann Stavola, Supervisory Biologist, EEB at 703 - 305 - 5354.

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