

4-12-93

DP Barcode : 235236
PC Code No : 103301
EEB Out :

To: Rob Forrest
Product Manager 16
Reregistration Division (H7505C)

From: Anthony F. Maciorowski, Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 239-2471
Chemical Name : Orthene Technical
Type Product : Insecticide
Product Name : Acephate
Company Name : Valent USA Corporation
Purpose : Submission of terrestrial residue monitoring data for tobacco and cotton in response to Registration Standard.

Action Code : 660 Date Due : 02/22/89
Reviewer : R. Felthousen Date In : 11/23/88

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(D)			70-1	408741-04 408741-05	N N	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

①

235236
RECORD NO.

SHAUGHNESSEY NO.

REVIEW NO.

EEB REVIEW

DATE: IN 11-29-88 OUT _____

FILE OR REG. NO. 239-2471

PETITION OR EXP. NO. _____

DATE OF SUBMISSION 10-31-88

DATE RECEIVED BY EFED 11-23-88

RD REQUESTED COMPLETION DATE 2-22-89

EEB ESTIMATED COMPLETION DATE 2-22-89

RD ACTION CODE/TYPE OF REVIEW 160

TYPE PRODUCT(S) : I, D, H, F, N, R, S INSECTICIDE

DATA ACCESSION NO(S). 408741-04, -05

PRODUCT MANAGER NO. Dr. MILLER (16)

PRODUCT NAME(S) ACEPHATE

COMPANY NAME VALENT (CHEVRON)

SUBMISSION PURPOSE Submission of Terrestrial Residue
Monitoring Data for Tobacco and Cotton
in Response to RS

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION 8 A.I.

ECOLOGICAL EFFECTS BRANCH

Chemical: Acephate

100.0 Purpose of Submission

The Registrant (Chevron) has submitted results of terrestrial monitoring studies for tobacco and cotton. The studies are entitled: "A Residue Monitoring Study in Tobacco to Assess Exposure to Avian Species Under Standard Agricultural Use Condition in North Carolina" (MRID# 41023505) and "A residue Monitoring Study in Cotton to Assess Exposure to Avian Species Under Standard Agricultural Use Conditions in Alabama." The studies were required in order to satisfy the Subdivision E 158.145 data requirements for wildlife as per the Acephate Reregistration Standard issued September 22, 1987.

101.0 Background

In a June 20, 1988 review, the EEB identified 10 issues, relative to either the design or conduct of the tobacco study, that made the study "Invalid" to satisfy the data requirement. Subsequently, the Registrant provided an extensive rebuttal to this review. In response to the Registrant's rebuttal comments, the EEB prepared a review that addressed every major issue rebutted by the Registrant. The following is a summary of that review:

" The EEB has completed a review of the Registrant's rebuttal arguments to our initial review of a field monitoring study designed to collect field residue data on the use of Orthene in tobacco. In conducting this review the EEB has contacted various "experts" on tobacco agricultural practices as well as some noted ecotoxicologists for their opinions and comments relative to the design and conduct of the study. In addition, the EEB has spent considerable time revisiting the Acephate Reregistration Standard and EEB file, rereading the terrestrial field study Guidance Document, and internally discussing the issues with the terrestrial field study team.

Based upon these discussions and review of the entire study, the EEB must again conclude that the study was poorly designed and that the Registrant has failed to adequately rebut the EEB's original comments (See Section 101.0 for discussion).

Therefore, the EEB maintains that the study is "Invalid" and that it cannot be used to satisfy the data requirement as specified in the Standard."

102.0 Discussion

The EEB has now completed its' review of the cotton study and has determined that many of the problem issues identified in the tobacco study are also relevant to the cotton study (See attached previous reviews and rebuttal comments by R. Felthousen for a complete discussion). The EEB specifically noted that the cotton study failed to conduct formal carcass searches and that ChE data were collected from live birds that were flying around the study area. The EEB does note, however, that the spectrum of residues collected compares to those that are predicted from the Kenega nomograph. As such, the data presented supports the presumption that environmental concentrations of acephate and methamidaphos are likely to exceed EEB concern levels when used according to label directions for tobacco and cotton.

103.0 Summary

The field study data presented herein were collected by the Registrant in order to rebut the Agency's presumption that environmental exposure from the use of acephate on cotton and tobacco would exceed EEB concern levels. Based upon the reported results, the EEB must conclude that the studies are inadequate to support the guideline data requirement.

In accordance with the Agency's new paradigm for risk assessment, the EEB must conclude that before any further regulatory action can be taken, risk mitigation measures must be developed by the Registrant and submitted to the Agency for review.

Richard W. Felthousen 4/2/93
Richard W. Felthousen, Wildlife Biologist
EFED/EEB

Norm Cook 4.12.93
Norm Cook, Head-Section 2
EFED/EEB

Anthony F. Maciorowski, Chief
EFED/EEB

Anthony F. Maciorowski