9-14-94

DP Barcode : D190975
PC Code No : 129086
EEB Out : / /

To: Robert Forrest
Product Manager 14
Registration Division (H7505C)

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

Attached, please find the EEB review of...

Reg./File # : 003125-EUP-202
Chemical Name : Phostebupirim & Cyfluthrin
Type Product : insecticide
Product Name : Aztec
Company Name : Miles
Purpose : Review avian field study.

Action Code: 719 Date Due: 7/24/93
Reviewer: ~~Regina Hirsch~~
R. FELTHOUSEN

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)	42752601	Y	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)						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: D190975

CASE: 031375 DATA PACKAGE RECORD DATE: 05/05/93
SUBMISSION: S440238 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: EUP (SECT 5) ACTION: 719 EUP NEW F/F FINAL REPORT
CHEMICALS: 129086 Phostebupirim 2.0000%
128831 Cyfluthrin 0.1000%

ID#: 003125-EUP-202
COMPANY: MILES INC
PRODUCT MANAGER: 14 ROBERT FORREST 703-305-6600 ROOM: CM2 219
PM TEAM REVIEWER: MARILYN MAUTZ 703-305-6785 ROOM: CM2 221
RECEIVED DATE: 04/29/93 DUE OUT DATE: 08/27/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 190975 EXPEDITE: N DATE SENT: 05/05/93 DATE RET.: / /
CHEMICAL: 129086 Phostebupirim
DP TYPE: 001 Submission Related Data Package
ADMIN DUE DATE: 07/24/93 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	05/04/93	/ /
BRAN: EEB	5/04/93	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Attached is the final report of the avian field study conducted under the subject EUP for your evaluation (MRID#42752601).
The sec. 3 application for registration of this EUP use is currently under evaluation in EEB (3125-URR and 3125-URE).

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

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL

2

ECOLOGICAL EFFECTS BRANCH

Chemical: AZTEC 2.1% Granular (Phostobupirim; Cyfluthrin)

100.0 Purpose of Submission

On October 25, 1991, the Registrant (Miles) applied for a Section 5 EUP to conduct an avian field study using AZTEC 2.1% Granular on corn. The Agency granted the EUP on May 5, 1992, which allowed for the conduct of an avian field study in the summer of 1992. This submission contains the final report for the study entitled, "AZTEC 2.1% Granular Insecticide: An Evaluation of Its Effects Upon Avian Species in and Around Corn Fields in Central Iowa" (MRID # 42752601).

101.0 Adequacy of Study

In general, the conduct and experimental design of the study was sufficient to determine if any ecological effects were occurring to non-target wildlife species. However, the following deficiencies should be noted:

1. No mention was made as to whether or not the target pest species was present at infestation levels at the initiation of the study? The EEB believes that the presence of the pest species is extremely important to the conduct of an acceptable study.

2. More effort should have been made searching adjacent habitats for dead, dying or otherwise affected non-target wildlife species. It is EEB's opinion that most species of wildlife die in adjacent habitats (as opposed to the actual treated fields) and that extensive searches of these areas are required. According to the report only 1/6 of the total time spent searching for carcasses was spent in these habitats.

102.0 SUMMARY

Although more effort should have been made to search adjacent habitats for dead, dying or otherwise affected wildlife species, the EEB believes that the carcass searching methods and effort was sufficient to satisfy the intent of the study.

In addition, although the EEB believes that the presence or absence of the pest species is an important aspect of the study, especially in the case of a flowable formulation, because this study involved the application of a granular formulation, this deficiency is not sufficient to invalidate the study (especially when considered in conjunction with the residue data).

103.0 CONCLUSIONS

The EEB has completed an abbreviated review of a terrestrial field study entitled, "AZTEC 2.1% Granular Insecticide: An Evaluation of its Effects Upon Avian Species In and Around Corn Fields in Central Iowa (MRID# 42752601).

Although it contains some minor design deficiencies, the EEB believes that the study is scientifically sound and done in accordance with good scientific practice and methodology. The EEB believes that the study authors have provided sufficient justification and rationale for the conduct and design of the study and that there are sufficient data and information (i.e., carcass searching results, residue analysis, and statistical evaluation) to conclude that mortality to non-target wildlife did not exceed "unacceptable levels" as put forth by Fite et al., (1988) in the Terrestrial Field Study Guidance Document.

Richard W. Felthousen, 8/17/94
Richard W. Felthousen, Wildlife Biologist
EFED/EEB

9-13-94
Les Touart, Head-Section 1
EFED/EEB

for Anthony F. Maciorowski, Chief 9/14/94
EFED/EEB

DATA EVALUATION RECORD

1. CHEMICAL: Cyfluthrin; Phostobupirim

2. TEST MATERIAL: AZTEC 2.1% Granular Insecticide

3. STUDY TYPE: Avian Field Study

4. CITATION AND MRID NO: Idema, P. F., et al., (1993). "AZTEC 2.1% Granular Insecticide: An Evaluation of its Effects Upon Avian Species In and Around Corn Fields in Central Iowa (MRID# 42752601).

5. AUTHORS, STUDY DATE, TEST LABORATORY :
Wildlife International Limited
8598 Commerce Drive
Easton, Maryland 21601

6. REVIEWED BY:

Richard W. Felthousen
Wildlife Biologist
EEB/EFED

Signature: R. W. Felthousen
Date: 8/17/94

7. APPROVED BY:

Les Touart
Head-Section 1
EEB/EFED

Signature: L Touart
Date: 9-13-94

8. CONCLUSIONS:

Although it contains some minor design deficiencies, the EEB believes that the study is scientifically sound and done in accordance with good scientific practice and methodology. The EEB believes that the study authors have provided sufficient justification and rationale for the conduct and design of the study and that there are sufficient data and information (i.e., carcass searching results, residue analysis, and statistical evaluation) to conclude that mortality to non-target wildlife did not exceed "unacceptable levels" as put forth by Fite et al., (1988) in the Terrestrial Field Study Guidance Document.

The EEB notes that this was an abbreviated Data Evaluation Report (DER) for the study and that a comprehensive DER should be completed prior to any regulatory action.

9. STUDY DESIGN AND METHODS:

Study Objectives: The main objective of the study was to measure indices of avian survival and mortality on paired

treatment and control sites. These data were then used to test the hypothesis that AZTEC applications cause "unacceptable" (as defined by Fite et al., 1988) reductions in avian survival.

Study Area- Boone County, Iowa

Test Sites- 8 paired test fields (16 sites). 8 control sites and 8 treated sites.

Application Rate: A 7 inch band on a 30-inch row spacing was used resulting in a average application rate of 6.6 lbs/acre. Two thousand five hundred and fifty pounds of AZTEC was used to treat 386 acres.

Blood Sampling for ChE Levels: A 44.7 ul sample of blood was drawn from the brachial vein.

Carcass Searches: Searches were conducted along 7200 meters of marked transects located in the field interior, adjacent habitat and on the field perimeter. Seven searches were conducted before application and five after application on all test replicates. Search area was concentrated along a 3 meter swath on each side of the transect. The entire perimeter of each test field was searched each day. Approximately 6 hours were spent searching each replicate on each day. One hour was spent in the adjacent habitat. The search effort resulted in approximately 10.7 acres per replicate per day. This resulted in approximately 1,198 acres being searched prior to application and 856 acres searched after application.

Carcass Detectability: Two carcass detectability trials were conducted on each replicate. Carcass detectabilty was calculated based on the total number of marked carcasses recovered during the study.

Samples: Residue sampling stations were randomly established on each replicate. Stations were placed approximately 10 to 100 m into the fields. Only soil and invertebrates samples were taken.

Soil Sampling: 6 sampling stations on each of the eight treated replicates. A scoop or trowel was used to collect approximately 300 g of soil. Samples were collected from he top one inch of soil.

Invertebrates: pitfall traps from three sampling stations. Approximately 10 g of invertebrates were collected per sample.

Application Methods: Band (7"), T-Band, In -Furrow

Calibration of Equipment- conducted by Wildlife International

Meteorological Conditions: Wind speed, direction, relative

humidity, temperature and rainfall were collected on each treatment replicate.

10. REPORTED RESULTS

Avian Abundance and diversity: A total of 143 species of birds were observed in the study area (Appendix VII). A total of 1,386 captures were recorded on the treatment replicates while 1,687 captures occurred on the control replicates. There was no statistical difference in the mean number of captures between treatment and control. The five most commonly captured species were the robin,brown thrasher,blue jay, gray catbird and brown-headed cowbird.

Blood Cholinesterase: 1,281 blood samples were collected; 572 on treatment replicates and 709 on control replicates. on treatment fields, 6.6% of the birds had blood ChE levels which were less than or equal to the diagnostic threshold level while 1.6% of the blood ChE levels for birds on the control fields were less than or equal to the diagnostic threshold level. This resulted in a mean survival index of 0. 97 pre-treatment and 0.92 post-treatment on treatment replicates and 0.98 pre-treatment and 0.99 post-treatment on control replicates. There were no statistically significant differences between the survival index of birds on treatment and control sites prior to application or after application.

Brain Cholinesterase Activity: A total of 37 brains were removed from intact avian carcasses representing 16 species of birds and one white-footed mouse. No statistical differences were found in brain cholinesterase activity between treatment and control levels.

Casualty searches: A total of 89 casualties were found during the study; 48 were found on the treatment plots. These consisted of 24 birds, 20 mammals 3 reptiles and one amphibian. Forty-one vertebrates were found on control plots; 14 birds; 26 mammals and one reptile. There was no statistically significant differences in casualties between treatment and control fields.

Carcass Detectability: Recovery rates averaged 26% for both treatment and control fields.

Residue Analysis: Post-application phostebupirim residues in soil over the course of the study ranged from <0.1 ppm to 3.59 ppm with the highest mean value for a given day (0.69 ppm) occurring seven days after application. The half-life of phostebupirim in soil was estimated to be 27.7 days. Residues of phostebupirim in invertebrates during the study ranged from <0.1 ppm to 2.24 ppm, with the highest mean value for a given day (0.20 ppm) occurring the day following application. Residues levels in both soil and invertebrates were much less than dietary concentrations known to cause mortality in

laboratory tests.

11. STUDY AUTHORS CONCLUSIONS AND SUMMARY

(See attached sheets)

12. REVIEWER'S DISCUSSION:

Study Area and Agricultural practice

The study area represents a major corn growing region of the country and the agricultural practices employed are typical of how corn is planted and cultivated in Iowa.

Application Rates, Methods and Equipment

Application was made at the maximum label rate allowed using equipment and methods typically used in Iowa. The number of applications and intervals between applications are in accordance with label directions.

Test Sites

Test sites were appropriately selected and were sufficient in size and number.

Experimental Design

In general, the conduct and experimental design of the study was sufficient to determine if any ecological effects were occurring to non-target wildlife species. However, the following deficiencies should be noted:

1. No mention was made as to whether or not the target pest species was present at infestation levels at the initiation of the study? The EEB believes that the presence of the pest species is extremely important to the conduct of an acceptable study.

2. More effort should have been made searching adjacent habitats for dead, dying or otherwise affected non-target wildlife species. It is EEB's opinion that most species of wildlife die in adjacent habitats (as opposed to the actual treated fields) and that extensive searches of these areas are required. According to the report only 1/6 of the total time spent searching for carcasses was spent in these habitats.

Sample Collection

Sample collection was adequate to determine potential exposure levels.

Analytical Procedures

Proper collection, handling, shipping and residue analysis of samples was conducted.

Carcass Searching

The EEB would have liked to seen more effort searching adjacent habitats for dead, dying or otherwise affected species. Only one hour was spent searching such habitat as opposed to six hours of searching the treated field.

13. ADEQUACY OF STUDY

(1) Classification: Acceptable

(2) Rationale: Although more effort should have been made to search adjacent habitats for dead, dying or otherwise affected wildlife species, the EEB believes that the carcass searching methods and effort was sufficient to satisfy the intent of the study (especially when considered in conjunction with the residue data). In addition, although the EEB believes that the presence or absence of the pest species is an important aspect of the study, especially in the case of a flowable formulation, because this study involved the application of a granular formulation, this deficiency is not sufficient to invalidate the study.

(3) Repairability: N/A