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

MAR 25 1993

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: REVIEW DISLodgeABLE FOLIAR RESIDUE DATA FOR THE USE OF
BIFENTHRIN ON COTTON

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THRU: Mark I. Dow, Ph.D., Section Head *Mark I. Dow*
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Please find below, the OREB review of:

DP Barcode: D181079

Pesticide Chemical Code: 128825

EPA Reg. No.: 000279-03114

EPA MRID No.: 419175-04, 419175-05

Review Time: 3 DAYS

PHED: N/A



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I. INTRODUCTION:

A. Background:

The FMC Corporation has submitted a study to determine the dislodgeable foliar residues on cotton treated with the formulation CAPTURE® 2.0 EC. Bifenthrin, a synthetic pyrethroid, is the active ingredient in CAPTURE® 2.0 EC. This study is entitled Reentry Protection Study of CAPTURE® 2.0 EC (Bifenthrin) Treated Cotton: Dislodgeable Residue on Cotton Leaves (MRID # 419175-04). The registrant also submitted an additional field report entitled Capture 2 EC Insecticide/Miticide: Cotton Field Trials for Determining Dislodgeable Foliar Residues (MRID # 419175-05). Capture® 2.0 EC is currently being developed by the FMC Corporation for use in the control of several foliar pests on a variety of crops, including cotton.

The field study trial was conducted at three trial locations in California. CAPTURE® 2.0 EC was applied to cotton plants at 0.1 lb ai/A for five individual applications.

The tox endpoint of concern is acute mammalian toxicity to the technical material (Category II, by the ingestion route with an LD₅₀ of about 70 mg/kg in male rats and 54 mg/kg in female rats). The RfD (0.015 mg/kg/day) is based on a NOEL of 1.5 mg/kg/day from a 1 yr. dog feeding study.

B. Purpose:

This review intends to evaluate the registrant's dislodgeable foliar residue study and calculate a reentry interval based on the dislodgeable foliar residues.

II. DETAILED CONSIDERATIONS:

A. Study Description

The study, Reentry Protection Study of CAPTURE® 2.0 EC (Bifenthrin) Treated Cotton: Dislodgeable Residue on Cotton Leaves was intended to satisfy the Subdivision K Guidelines 132-2. The study was conducted in three different sites in California. Site one was located in Holtville, CA.; site two was located in Reedly, CA.; and site three was located in Visalia, CA. Temperature and humidity were reported for Site

¹ Tice, John, OREB Memorandum Section 18 Washington State Request to Use Bifenthrin on Hops, March 3, 1993.

1 only, and were measured at the Imperial Valley Agricultural Center.

Dislodgeable foliar residues were measured after 5 separate applications at 0.1 lb ai/A to cotton. A ground sprayer was used to apply bifenthrin. Foliar samples were taken with a leaf punch, and consisted of fifty 1.0 inch diameter leaf punches per replicate, for a total of 200 leaf discs per treated and untreated plot at each sampling interval. Samples were collected in quadruplicate. Samples were collected randomly from upper, lower, and bottom leaves in each replicate. Reagent blanks were generated, as were field and method blanks by the use of controls (untreated samples). Samples were stored in glass jars on blue ice, and shipped overnight to the laboratory for dislodging. Leaf samples were taken at the following time intervals after the fifth pesticide application: 1 hour, 1, 3, 8, 14, 21, and 35 days.

Leaf discs were dislodged via a reciprocating platform shaker with a 210 $\mu\text{g/L}$ aqueous surfactant solution of sodium dioctylsulfosuccinate. Residue calculations are based on two-sided leaves.

B. Study Results

Bifenthrin dislodgeable foliar residues ranged from 0.007 - 0.184 $\mu\text{g/cm}^2$ for Site 1, 0.004 - 0.272 $\mu\text{g/cm}^2$ for Site 2, and 0.005 - 0.270 $\mu\text{g/cm}^2$ for Site 3. Reentry intervals were not calculated by the registrant.

C. Discussion

Evaluation of the study based on Subdivision K Guidelines reveals that most of the criteria for study acceptance were met. A discussion of the criteria in question follows.

1. **The study must include meteorological data obtained at or near the location of the test site.**

Weather data were reported from Site 1 only, located near Holtville, California. There were no meteorological data reported for site 2 near Reedly, California and Site 3 near Visalia, California. Table 1 from the field report gave the site descriptions. This table reported temperature range in degrees Fahrenheit, total rainfall, and irrigation for each site. Weather data from the study report (Site 1) and the field report do not match. Dissipation curves showed similar residue decline at all three sites. Climatic conditions appear not to have affected the study outcome; however, the discrepancy between the study report and the field report must be clarified.

2. **Application of test material at the maximum recommended application rate.**

OREB could not confirm that the test material was applied at the label recommended maximum application rate.

3. **Review of QA/QC procedures**

Reagent blanks were generated, as were field and method blanks by the use of controls. Ten out of the ninety-nine controls had detectable levels of bifenthrin. Twenty-one out of the ninety-nine controls had detectable but unquantifiable levels of bifenthrin. Sampling technique seems to be questionable after these results.

No tank mix analysis was performed, consequently the amount of test material applied during the study cannot be verified.

Field spikes were not prepared for the study. The study report states that samples were collected and stored in glass jars on blue ice and shipped overnight to the laboratory for dislodging. This was purported to have been accomplished within 24 hours of sample collection. It is the responsibility of the registrant to demonstrate that transportation conditions do not adversely affect residues. Field spikes would seem to best accomplish this task.

Storage stability of dislodgeable extracts were not conducted for this study. There were insufficient data submitted to determine the lapsed time between sample shipment and the time the samples were dislodged. Also, the lapsed time between sample extraction and sample analysis could not be determined. Technically storage stability could have been checked via field spikes; however, in this instance lack of storage stability does not appear to affect the outcome of the study.

D. Calculation of Reentry Intervals

The calculation of the reentry follows this outline.

1) Allowable Exposure Level (AEL)

$$\text{AEL (mg/hr)} = \frac{\text{subchronic dermal NOEL (mg/kg/day)} \times 70\text{kg}}{8 \text{ hours}}$$

Calculation of Reentry Intervals (con't)

assumptions: average fieldworker weighs 70 kg
average work day is 8 hours
100% dermal absorption

If dermal absorption data are known the AEL would then be adjusted by the appropriate factor.

2) Reentry Level

the "safe" level of pesticide allowed on the leaf surface in $\mu\text{g}/\text{cm}^2$ at the time of reentry

$$\text{AEL (mg/hr)} \times 1,000 = \text{AEL } (\mu\text{g/hr})$$

$$\text{Reentry Level } (\mu\text{g}/\text{cm}^2) = \frac{\text{AEL } (\mu\text{g/hr})}{10,000 \text{ cm}^2/\text{hr} \text{ (dermal transfer coefficient from Zweig, 1985)}}$$

- 3) A safety factor of 10 is applied for ChE inhibition; in this case bifenthrin is not a ChE inhibitor.
- 4) Compare this Reentry Level with the foliar dislodgeable residue data which is also in $\mu\text{g}/\text{cm}^2$ to determine the Reentry Interval (days post-treatment)

From the 1-yr. dog feeding study using bifenthrin, the NOEL was 1.5 mg/kg/day

1.) AEL

$$1.5 \text{ mg/kg/day} \times 70 \text{ kg} \div 8 \text{ hr/day} = 13.1 \text{ mg/hr}$$

2.) REENTRY LEVEL

$$13.1 \text{ mg/hr} \times 1,000 \mu\text{g}/\text{mg} = 13125 \mu\text{g/hr}$$

$$13125 \mu\text{g/hr} / 10,000 \text{ cm}^2/\text{hr} = 1.31 \mu\text{g}/\text{cm}^2$$

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Calculation of Reentry Intervals (con't)

3.) Bifenthrin is not a cholinesterase inhibitor ∴
reentry level is:

1.31 $\mu\text{g}/\text{cm}^2$

4.) Reentry Interval = 1 hour post-treatment *

* See Appendix I for dislodgeable foliar residue curves.

III. CONCLUSIONS:

OREB concludes that the study, Reentry Protection Study of CAPTURE® 2.0 EC (Bifenthrin) Treated Cotton: Dislodgeable Residue on Cotton Leaves is supplemental at this time. The study does provide useful information for exposure assessment purposes. The study can be upgraded to acceptable status upon satisfactory and acceptable response from the registrant to the comments in section C under Detailed Considerations.

In the interim, OREB will set a 24 hour reentry interval until such time that the registrant responds to OREB's previously stated concerns. This reentry interval is set as prescribed by the Worker Protection Standards for a tox category II compound.

IV. REFERENCES: N/A

cc: B. Kitchens
Chemical File: BIFENTHRIN
Circulation
Correspondence

APPENDIX I

TABLE I
DISSIPATION OF BIFENTHRIN FOLIAR DISLODGEABLE RESIDUES FROM
COTTON FOLIAGE AT THREE SITES FOLLOWING THE APPLICATION OF CAPTURE®
2EC AT 0.1 lb ai/A

Time (days)	Site 1 Mean Residue ($\mu\text{g}/\text{cm}^2$)	Site 2 Mean Residue ($\mu\text{g}/\text{cm}^2$)	Site 3 Mean Residue ($\mu\text{g}/\text{cm}^2$)
1 hour	0.184	0.272	0.270
1	0.147	0.209	0.227
3	0.143	0.194	0.157
7	0.056	0.100	0.079
14	0.015	0.072	0.056
21	0.012	0.019	0.013
28	0.011	0.011	0.006
35	0.007	0.004	0.005

BIFENTHIN

Page _____ is not included in this copy.

Pages 9 through 11 are not included.

The material not included contains the following type of information:

- Identity of product inert ingredients.
 - Identity of product impurities.
 - Description of the product manufacturing process.
 - Description of quality control procedures.
 - Identity of the source of product ingredients.
 - Sales or other commercial/financial information.
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 - The product confidential statement of formula.
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