MEMORANDUM:

SUBJECT: EVALUATION OF FOLIAR DISLODGEABLE RESIDUE STUDY ON CHRYSANTHEMUMS AND ROSES WITH TALSTAR®WSB INSECTICIDE/MITICIDE (a.i. bifenthrin)

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THRU: Mark I. Dow, Ph.D., Section Head
Special Review and Registration Section II
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Occupational and Residential Exposure Branch
Health Effects Division (7509C)

Please find below, the OREB review of:

DP Barcode: D172866, D172868, D172870
Pesticide Chemical Code: 128825
EPA Reg. No.: 279-3057, 279-3086, 279-3087
EPA MRID No.: 421422-00, 421422-01
Review Time: 4-days
PHED: N/A
I. INTRODUCTION:

FMC Corporation submitted a foliar dislodgeable residue study with Talstar® WSB insecticide/miticide to determine levels of the active ingredient bifenthrin which dislodge from chrysanthemums and roses. The California Department of Food and Agriculture requested this study which was then submitted to the Agency for information purposes. The Agency does not require this study to satisfy any data requirements.

A. Background:

Bifenthrin is the active ingredient in the product Talstar® WSB. Talstar® WSB is used as a broad spectrum insecticide/miticide formulated as an emulsifiable concentrate and as a wettable powder.

Bifenthrin is a Group C carcinogen with a Qₜ₁₀ of 5.4 x 10⁻². The maternal NOEL is 1 mg/kg/day. Bifenthrin is a tox category 3 compound for acute dermal toxicity (personal communication with J. Rowland of Tox Branch II).

B. Purpose:

This review evaluates the previously mentioned study to determine whether it meets Subdivision K guidelines for post-application reentry exposure. A reentry interval will also be calculated from the data presented in the study.

II. DETAILED CONSIDERATIONS:

First, a brief summary of the study is presented followed by the registrant’s results and conclusions. Then, a calculation of the reentry interval is presented using data from the study.

Study Summary:

This study determined the levels of bifenthrin residues dislodged from the leaf surfaces after foliar applications of Talstar® WSB/Talstar 10WP. Chrysanthemums and roses were selected to represent fine, short haired and smooth leaf surfaces, respectively. Two individual greenhouses were used to conduct the study. One greenhouse housed the treated samples while the other greenhouse housed control samples only. Three applications of Talstar® WSB were made to chrysanthemums and roses at a rate of 0.2 lbs/100 gallons. A CO₂ backpack sprayer equipped with a drop boom was used to apply the test material to the three treated replicates (50 plants per replicate). Twenty-two sampling events were performed. Samples were collected using a Birkestrand 0.5-inch
Reentry Interval Calculations:

The calculation of the reentry follows this outline.

1) Allowable Exposure Level (AEL)

\[
AEL \text{ (mg/hr)} = \frac{\text{tox endpoint of concern (NOEL mg/kg/day)}}{8 \text{ hours}} \times 60 \text{kg}
\]

assumptions: average greenhouse worker weighs 60 kg
average work day is 8 hours
100% dermal absorption

Example: assuming 10% dermal absorption (with supporting dermal data) the AEL would then be:

\[
AEL \text{ (mg/kg/day)} \times 60 \text{ kg} / 8 \text{ hours} = 0.1
\]

2) Reentry Level

the "safe" level of pesticide allowed on the leaf surface in \( \mu g/cm^2 \) at the time of reentry

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

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

3) Use safety factor (S.F.) if necessary, i.e., 10 for ChE inhibition, the Reentry Level then becomes:

\[
\text{Reentry Level (ug/cm2)} \times 0.1
\]
punch (which produced a total sample surface area of 127 cm$^2$) and were transferred to the lab, dislodged, and extracted on the day of collection.

Prior to the first application, a method validation was conducted using leaf tissue extract. Fortification levels ranged from 0.00315 μg/cm$^2$ to 7.87 μg/cm$^2$ (based on a sample size of 127 cm$^2$) and yielded an average recovery of 87.7% ± 8.3%.

Recovery of fortification samples analyzed during study sample analysis average 88.2% ± 15.3%. Average residues ranged from 0.266 to 0.758 μg/cm$^2$ on chrysanthemums and 0.209 to 0.550 μg/cm$^2$ on roses.

Decline curves were plotted for each application interval. In chrysanthemums, bifenthrin residues were observed to decline slowly over the time-frame of the study. In roses, no appreciable decline was evident after the first application. Subsequent applications also showed a slow decline in residues for the remainder of the study. Table 1. provides a summary of the foliar dislodgeable residues in roses and chrysanthemums after the final (3) application of Talstar® WSB at 0.2 lb. ai/100 gal water.

| TABLE 1. Mean bifenthrin DFR from roses and chrysanthemums foliage following the application of Talstar® WSB at 0.2 lb ai/100 gal of water (μg/cm$^2$) |
|---|---|---|
| Time (days) | Roses | Chrysanthemums |
| 0 | 0.386 | 0.758 |
| 1 | 0.329 | 0.623 |
| 3 | 0.314 | 0.422 |
| 5 | 0.350 | 0.564 |
| 7 | 0.287 | 0.375 |
| 14 | 0.297 | 0.360 |
| 21 | 0.272 | 0.407 |
| 28 | 0.319 | 0.271 |
| 35 | 0.305 | 0.276 |
4) Compare this Reentry Level with the foliar dislodgeable residue data which is also in µg/cm² to determine the Reentry Interval (days post-treatment)

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Using maternal toxicity as an endpoint with a NOEL of 1 mg/kg/day we have the following:

1.) AEL

\[
1 \text{ mg/kg/day} \times 60 \text{ kg} \div 8 \text{ hr/day} = 7.5 \text{ mg/hr}
\]

2.) REENTRY LEVEL

\[
7.5 \text{ mg/hr} \times 1,000 \mu g/mg = 7500 \mu g/hr
\]

Reentry Level

\[
7500 \mu g/hr \div 10,000 \text{ cm}^2/hr = 0.75 \mu g/cm^2
\]

3.) Safety factor not used.

4.) Reentry Interval for roses and chrysanthemums is: when sprays have dried and dusts have settled.

III. CONCLUSIONS:

OREB concludes that the study Dislodgeable Foliar Residues of Bifenthrin from Application to Chrysanthemum and Roses does meet most of the Subdivision K guidelines for postapplication reentry exposure. However, this study adequately addresses the issue of reentry exposure and is acceptable for regulatory purposes. Several points of discussion follow below. The registrant need not respond to these comments unless they deem a response necessary.
1. OREB was unable to confirm that the study application rate was in fact the label recommended maximum application rate. Therefore, any regulatory decisions would apply only to the study application rate.

2. No tank mix analysis was submitted in the study.

3. Reagent blanks were not analyzed as stated in the protocol.

CC: B. Kitchens  
Chemical File: BIFENTHRIN (128825)  
Circulation  
Correspondence