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

AUG 3 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM:

SUBJECT: REVIEW FMC REQUEST FOR REMOVAL OF THE CLOSED SYSTEM MIXING/LOADING LABEL REQUIREMENT FOR FIVE BIFENTHRIN FORMULATIONS AND DISLODGEABLE RESIDUE ON COTTON LEAVES FOR CAPTURE 2.0 EC INSECTICIDE/MITICIDE

FROM: Bruce F. Kitchens, Chemist *Bruce F. Kitchens*

TO: George LaRocca, PM 13
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Registration Division (H7505C)

THRU: Mark I. Dow, Ph.D., Section Head *Mark I. Dow*
Special Review and Registration Section II

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Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Please find below, the OREB review of:

DP Barcode: 166181,166186,166190,166184,166175
Pesticide Chemical Code: 128825
EPA Reg. No.: 000279-03114,-03087,-03105,-03086,-03069
EPA MRID No.: None
Review Time: 3 DAYS
PHED: NO

Referred to Toxicology II (Byron Backus) for risk calculation.

1/5

I. INTRODUCTION:

The FMC Corporation is requesting removal of the closed system requirement for mixer/loaders from the labels of five formulated products which contain the active ingredient Bifenthrin. The registrant intends to replace the closed system mixing/loading requirement on the label with the following statement:

Mixers and loaders must wear long sleeve shirt, trousers, chemical resistant gloves and goggles, or face shield.

The following formulated products are included in this label amendment:

FORMULATIONS	A.I.	APPLICATION RATE
CAPTURE 2EC-CAL	25.1	0.02 - 0.1 lb ai/acre
CAPTURE 2 EC	25.1	0.02 - 0.1 lb ai/acre
TALSTAR 9.8 WSB	9.8	0.005 - 0.02 lb ai/10 gal ¹
TALSTAR 9.9 WSB	9.9	0.025 - 0.1 lb ai/50 gal ²
TALSTAR FLOWABLE	7.9	0.004 - 0.02 lb ai/10 gal ³

1. One bag of Talstar 9.8 WSB = 0.005 lb ai
2. One bag of Talstar 9.9 WSB = 0.025 lb ai
3. Talstar Flowable contains 2/3 lb ai/gal

A. Background:

The registrant's rationale for replacing the closed system mixing/loading requirement is based on a recent dermal penetration study which indicated that dermal penetration of bifenthrin is 17.83%. The Agency is currently using a dermal absorption value of 55.4% in estimating worker exposure. The registrant further states that the new dermal penetration value indicates the oncogenic risk for open pour mixing/loading, application, and reentry in fields treated with Capture 2EC does not exceed 1.75×10^{-8} . The registrant believes that this new information warrants the Agency's reconsideration of the mixing/loading closed system requirement for the previously mentioned products that contain the active ingredient bifenthrin.

Recently, bifenthrin was classified as a class C carcinogen without a Q_1 . Any exposure calculations will have to be compared to the reference dose 0.015 mg/kg/day.

Two recent actions from the Branch chemical file evaluated mixer/loader exposure. The first action, dated Feb. 6, 1990 (C. Lunchick) evaluated mixer/loader/applicator exposure for section 18 use of Bifenthrin on hops in Washington. Daily exposure for the m/l was estimated to be 0.0059 mg/kg/day. Annual exposure for the m/l was estimated to be 0.018 mg/kg/day.

The second action, dated Jan. 8, 1990 (C. Lunchick) evaluated an FMC request to remove the closed loading system restriction for mixer/loaders handling Capture 2EC. OREB concluded that the data submitted by FMC did not change the HED exposure estimate. OREB recommended that the mechanical transfer systems requirement for aerial applications of Capture 2EC be maintained on the label. OREB did not oppose the removal of the closed system restriction ground boom application for 5 - 10 gallon amounts of Capture 2EC and replacing it with the following personal protective equipment (PPE):

mixer/loaders are required to wear a full face shield, chemical resistant gloves, rubber apron, boots, and overalls.

B. Purpose:

The purpose of this memo is to evaluate the registrant's request to amend label to remove the closed system mixing/loading requirement from the labels of Capture 2EC, Capture 2EC-CAL, Talstar Flowable, Talstar 9.8 WSB, and Talstar 9.9 WSB insecticide/miticide.

II. DETAILED CONSIDERATIONS:

The registrant based their request for removal of the closed system mixer/loader on the fact that a recent dermal penetration study indicates that dermal penetration is 17.83%. The agency currently uses a 55.4% dermal absorption value to calculate worker exposure. The registrant submitted two dermal absorption studies to substantiate their claim. OREB defers to Tox Branch to make any adjustments to exposure estimates using current dermal absorption values.

A recent HED Peer Review reclassified of Bifenthrin as a class C carcinogen without a Q₁. OREB will compare exposure from the open pour mixer/loader to the closed system mixer/loader using the registrant's proposed PPE of:

long sleeve shirt, trousers, chemical resistant gloves and goggles, or face shield.

To evaluate the difference in exposure associated with open and closed loading systems, exposure from both open and closed m/l will be compared. The Capture 2 EC label for cotton represents the highest application rate and the highest lb. a.i./acre applied per season and thus presented the highest exposure situation possible for the mixer/loader. The following calculation is based on the unit exposure taken from the OREB surrogate data base for open pour mixer/loader and closed system mixing/loading. A memo from BEAD dated Dec. 9, 1987 addressing revised exposure parameters for the use of Monocrotophos (Azodrin) was consulted for a cotton use assessment which detailed the average acreage of a typical cotton farm. This exposure scenario assumed the PPE as outlined by the registrant is worn by the mixer/loader.

OPEN POUR M/L EXPOSURE PARAMETERS

Unit Exposure for Open Pour M/L = 0.93 mg/lb ai handled
Average Farm Size = 241 acres
Application Rate = 0.1 lb ai/acre

Calculations:

Total a.i. handled by Open pour m/l
241.0 acres/day x 0.1 lb ai/acre = 24.1 lbs ai/day

Exposure for Mixer/Loader who handles 24.1 lbs ai/day
0.93 mg/lb ai x 24.1 lb ai/day / 70kg = 0.320 mg/kg/day

CLOSED SYSTEM M/L EXPOSURE PARAMETERS

Unit Exposure for Closed System M/L = 0.015 mg/lb ai handled
Average Farm Size = 241 acres
Application Rate = 0.1 lb ai/acre

Calculations:

Total a.i. handled by Closed System m/l
241.0 acres/day x 0.1 lb ai/acre = 24.1 lbs ai/day

Exposure for Mix/Loader who handles 24.1 lbs ai/day
0.015 mg/lb ai x 24.1 lb ai/day / 70kg = 0.005 mg/kg/day

III. CONCLUSIONS:

OREB estimates that the open pour mixer/loader exposure is 0.320 mg/kg/day. The closed system mixer/loader exposure is 0.005 mg/kg/day. The closed system mixer/loader restriction can be replaced with the registrant's proposed PPE label statement if the open pour mixer/loader risk is acceptable to the Agency.

OREB defers to Chemical Coordination Branch for risk assessments.

cc: B. Kitchens
Chemical File: **BIFENTHRIN**
Circulation
Correspondence