1-8-90

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

JAN 8 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: REEVALUATION OF CLOSED SYSTEM LABEL RESTRICTION FOR CAPTURE 2EC (BIFENTHRIN) (HED PROJECT #0-0201)

TO: G. LaRocca, PM 15
Insecticide and Rodenticide Branch
Registration Division (H7505C)

FROM: Curt Lunchick
Environmental Chemistry Review Section
Non-Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Michael Firestone, Ph.D., Section Head
Environmental Chemistry Review Section
Non-Dietary Exposure Branch
Health Effects Division (H7509C)

THRU: Charles L. Trichilo, Ph.D., Chief
Non-Dietary Exposure Branch
Health Effects Division (H7509C)

Please find below the NDEB review of ....

HED Project #: 0-0201

RD or SRRD Record #: 254971

Caswell #: 463F

Date Received: 11/22/89 Review Time: 5 days

Date Returned: 01/04/90

Deferral to: _____ Biological Analysis Branch/BEAD

_____ Science Analysis & Coordination Branch

_____ TB - Insecticide/Rodenticide Support Section

_____ TB - Herbicide/Fungicide/Antimicrobial Support Section

1

1.0 INTRODUCTION

On 30 October 1989, FMC Corporation submitted a request to remove the closed loading system restriction for mixer/loaders handling Capture 2EC. Capture 2EC contains bifenthrin as the active ingredient. FMC proposes that the Capture 2EC label be amended to include the protective clothing statement currently on Ammo 2.5EC and Cymbush 3E labels. Both products contain cypermethrin as the active ingredient. The labels require the mixer/loader to wear "full face shield, impermeable gloves, a rubber apron, boots, and protective clothing. Mixer/loaders, in addition, wear a chemical resistant apron." The protective clothing is defined by the labels as one piece overalls which have long sleeves and long pants. The redundancy in the protective clothing language, such as mentioning aprons twice, should be eliminated. FMC submitted a cypermethrin worker exposure study to support its request to remove the closed system requirement.

2.0 CONCLUSIONS

NDEB has evaluated FMC's request to remove the closed loading system requirement from Capture 2EC labels. Based on the FMC submission, NDEB concludes that the Chester et al. data do not substantially change the HED exposure estimates based on Kutney (14 March 1989). Because the exposure remains unchanged, the HED risk estimates also remain unchanged. Based on the risk estimates, the potentially large quantities of Capture 2EC handled, and the practicality of mechanical transfer systems, NDEB recommends requiring mechanical transfer systems for aerial applications of Capture 2EC. Based on the small quantities of Capture 2EC handled for ground boom application and the impracticality of requiring mechanical transfer systems for 5 to 10 gallons of formulation, NDEB would not oppose the removal of the closed system restriction for ground boom applications of Capture 2EC and replacing it with the FMC proposed protective equipment language. The protective clothing label language should be clarified to eliminate redundancies such as requiring aprons twice in the same paragraph. This will make understanding of the protective clothing requirements easier for the user.

3.0 HED ASSESSMENT OF BIFENTHRIN RISK

The Health Effects Division's risk assessment for bifenthrin was presented in a 28 June 1989 memorandum from D. Beckus (Handler Exposure Assessments for

Bifenthrin Use on Cotton and Associated Risk) and a 8 August 1989 memorandum from B. Backus (Margins of Safety Associated with Applicator Exposure to Bifenthrin).

The 28 June risk estimates for mixer/loaders were as follows:

	GROUND APPLICATION	AERIAL APPLICATION
Open Pour	8×10^{-5}	9×10^{-4}
Closed Loading	8×10^{-7}	9×10^{-6}

The risk estimates were based on the exposure assessment conducted on 14 March 1989 by L. Kutney (Handler Exposure Assessment for Bifenthrin Use on Cotton, HED Project #9-0130).

The 8 August 1989 risk estimates were for bifenthrin use on corn. This risk assessment assumed that corn and cotton use would be similar enough to permit the use of cotton risk estimates for corn. However, the exposure estimates for corn were based on an earlier exposure assessment by L. Lewis (Bifenthrin Exposure Assessment, 28 May 1987). L. Kutney's exposure estimates, which are an update and revision of the 1987 assessment, should have been used for corn as it was for cotton. The 1989 exposure assessment was revised to incorporate the label requirement that mixer/loaders wear chemical resitant gloves which was not required at the time of the 1987 assessment. All exposure and risk estimates assume 100% dermal absorption.

4.0 EXPOSURE TO BIFENTHRIN BASED ON CYPERMETHRIN DATA

FMC submitted a published study by Chester et al. (Worker Exposure to, and Absorption of, Cypermethrin During Aerial Application of an "Ultra Low Volume" Formulation to Cotton, Arch. Environ. Contam. Toxicol., 16:69-78, 1987) to support its request to remove the closed loading restriction from Capture 2EC labels. FMC believes the cypermethrin study is a more appropriate surrogate for bifenthrin than is NDEB's surrogate data base because both bifenthrin and cypermethrin are synthetic pyrethroids applied at similar application rates (0.02 to 0.1 lb ai/acre) by ULV techniques. The FMC arguement contains merit and NDEB reevaluated the bifenthrin exposure estimates by using Chester et al. The Chester data were originally

evaluated and found acceptable when submitted in support of the registration of Cymbush 3E (A. Keller, EAB# 5089, 30 November 1984).

In assessing exposure, the mixer/loaders and pilots wore Tyvek coveralls with hood and cotton gloves as the monitoring dosimeters. These items were placed over the mixer/loaders and pilots long sleeve shirts and long pants. The mixer/loaders then placed calf-length rubber boots, coated rubber gloves, ankle-length rubber apron, and a full-face shield over the whole body dosimeters. Based on the cypermethrin residues on the dosimeter, Chester calculated "Total Potential" and "Actual" dermal exposure. Total potential exposure was defined as exposure representative of cypermethrin contamination of clothing and uncovered skin areas. Actual exposure estimates were derived from residues on the hood and from the cotton glove dosimeters only.

Actual exposure, therefore, assumes no exposure to any body area other than the head and hands. Tables 1 and 2 in Chester et al. clearly demonstrate that cypermethrin residues were present on the torso and limbs. Total potential exposure assumes that the shirt and pants would afford no protection. NDEB has reviewed data pertaining to the protective value of clothing and the data indicate that cloth fabric clothing provides an average protection of 90 to 97%; however, the protective value of any one data point is extremely variable and can range from complete protection to no protection. Because the toxicity endpoint with bifenthrin is carcinogenicity, NDEB has assumed that the overalls proposed for the bifenthrin label will provide an average 90% protection to the torso and limbs.

NDEB has estimated mixer/loader and pilot exposure based on the data provided by Chester et al. As previously stated, the cypermethrin residues found on the torso and limb dosimeters were reduced by 90% to estimate the protective value of cloth overalls. Adjustments for the protective value of rubber boots, rubber gloves, apron, and face shield worn by the mixer/loaders were not necessary since the dosimeters were placed under this equipment. Tables 1 and 2 present mixer/loader and pilot exposure, respectively. Since each replication involved the treatment of 200 acres with 4 gallons of Cymbush 3E and Cymbush 3E contains 3 lbs ai/gallon; a total of 12 lbs ai were handled per replication. The average mixer/loader exposure was 19 ug/lb ai and the average pilot exposure was 4.6 ug/lb ai. The Chester et al. description of the mixing and loading equipment and procedures for the two professional mixer/loaders indicates that the spray

mix was pumped into the spray tank. It is unclear whether the 4 gallons of Cymbush 3E were poured or pumped in with the soybean oil prior to mixing. Assuming the 4 gallons were poured, the exposure would be representative of a combination of open pouring and mechanical transfer.

L. Kutney in the March 1989 exposure assessment received use information indicating bifenthrin may be aerially applied to up to 1400 acres of cotton in one day by a pilot. The average application rate is 1.23 oz ai/acre or 0.078 lbs ai/acre. It was assumed that a pilot would spray bifenthrin five days annually. therefore a pilot would spray 110 lbs ai/day. A mixer/loader was assumed to mix for two pilots and therefore would handle 220 lbs ai/day.

The annual exposure to the pilot using the same use data and pilot exposure based on Chester et al. is (4.6 ug/lb ai x 110 lbs ai/day x 5 days/year x 1/70 kg) 36.1 ug/kg/yr. The mixer/loader exposure is estimated to be (19 ug/lb ai x 220 lbs ai/day x 5 days/year x 1/70 kg) 299 ug/kg/yr. The Kutney assessment amortized the annual exposure estimates over 365 days/yr. When the Chester et al. based estimates are also amortized over 365 day/yr the comparisons are as follows:

	DERMAL EXPOSURE (mg/kg/day)	
	Kutney	Chester
M/L-open pour	4.0×10^{-2}	
M/L-closed loading	3.9×10^{-4}	
M/L-open and mech. trans.		8.1×10^{-4}
Pilot	3.3×10^{-5}	9.9×10^{-5}

A comparison indicates that refining the exposure/risk estimates based on the Chester, et al. data would not significantly alter the estimates previously based on Kutney's evaluation.

5.0 CLOSED SYSTEM REQUIREMENT

As previously stated in Section 3.0, the carcinogenic risk to open pour mixer/loaders handling Capture 2EC is 8×10^{-5} for ground boom application and 9×10^{-4} for aerial application. Both risk estimates [illegible] dermal absorption. At a label maximum rate

of 0.1 lb ai/acre, the ground applicator treating 100 to 200 acres/day would mix and load 10 to 20 lbs ai or 5 to 10 gallons of Capture 2EC formulation. The availability of closed transfer systems, outside the state of California, that can handle quantities as small as 5 to 10 gallons is questionable. FMC has proposed the requirement that mixer/loaders be required to wear a full face shield, chemical resistant gloves, rubber apron, boots, and overalls. In light of the small quantity of Capture 2EC handled for ground boom application, NDEB would not oppose removing the closed system restriction for ground boom applications and replacing it with FMC's proposed protective equipment requirements.

The aerial mixer/loader handles substantially more Capture 2EC than the ground boom mixer/loader. Application to 1400 acres would require 70 gallons of Capture 2EC at the label maximum rate of 0.1 lb ai/acre. The use of mechanical transfer systems in aerial applications is practical and relatively common. Based on the risk to aerial mixer/loaders, the large quantity of formulation handled, and the practicality of mechanical transfer systems, NDEB recommends requiring mechanical transfer systems for aerial uses of Capture 2EC. Closed loading is often interpreted to mean hard coupling of the hose/pump system to both the container of formulation and the spray/mix tank. This degree of sophistication does not appear warrented for Capture 2EC.

cc: B. Backus, Fungicide/Herbicide/Antimicrobial
Toxicology Branch
SACB
Circulation
Bifenthrin File
Correspondence File

Attachment

TABLE 1. MIXER/LOADER DERMAL EXPOSURE TO CYPERMETHRIN

Summary: @SUM Field: dermal exposure
Rows: replicate Columns: sample

	Back Trunk	Front Trun	Head	Lft Front	Lft Forear	Lft Hand	Lft Shin	Lft Thigh	Lft Uppera	Rt Front	Rt Forearm	Rt Hand	Rt Shin	Rt Thigh	Rt Upper A	ALL
2	2.	8.66	20.9	11.8	2.18	106	1.47	15.9	0.579	14.8	6.27	168	1.24	2.76	1.89	364.779
4	27	8.02	23.2	32.4	0.964	46	0.798	2.49	0.396	43.1	2.94	57	0.568	0.804	0.53	246.6
6	1.[illegible]	67.4	60.3	12.4	1.16	36.9	0.816	1.81	0.162	9.29	31.8	232	0.502	1.47	2.14	459.98
8	8.[illegible]	3.16	16.6	7.27	18.7	28.8	2.21	1.24	4.56	7.5	1.33	63.9	1.72	0.897	0.473	167.12
10	0.5[illegible]	0.732	3.69	2.71	1.4	11.9	0.589	0.728	3.53	7.66	15.6	21.5	3.64	5.4	0.908	80.494
12	0.6[illegible]	0.399	2.21	4.2	7.74	4.22	0.548	0.306	2.8	3.94	0.462	7.26	0.138	0.175	0.2	35.297
All	41.[illegible]	88.171	126.9	70.78	32.144	232.82	6.431	22.474	12.017	86.29	58.402	549.66	7.808	11.506	6.141	1353.27

AVERAGE TOTAL EXPOSURE = 1353 µg/6
= 225.5 µg

EACH MIXER/LOADER HANDLED 12 lbs ai

AVERAGE MIXER/LOADER EXPOSURE = 225.5 µg/12 lbs ai
= 19 µg/lb a.i.

Pilots

Summary: @SUM : Id: dermal exposure
Rows: replicate : Columns: sample

	Back Tru	Front Trun	Hood	Lft Foot	Lft Forea	Lft Hand	Lft Shin	Lft Thigh	Lft Uppera	Rt Foot	Rt Forearm	Rt Hand	Rt Shin	Rt Thigh	Rt Upper A	ALL
1	0.5	0.273	1.12	1.94	0.184	58.5	0.58	0.393	0.1	4.76	0.376	26.2	0.134	0.344	0.071	95.483
2	0.2	0.184	0.68	16.9	0.107	33.2	0.1	0.28	0.062	5.67	0.089	101	0.1	0.272	0.062	159.035
3	0.7	0.1	0.5	3.85	0.05	17.3	0.1	0.1	0.05	4.05	0.05	67.5	0.1	0.243	0.05	94.387
4	0	0.1	1	14.4	0.05	15.4	0.1	0.1	0.05	10.7	0.05	82.4	0.1	0.1	0.05	124.7
5	0	0.1	0.5	3.37	0.05	20.3	0.1	0.156	0.05	4.6	0.05	5.14	0.1	0.1	0.05	34.766
6	0.1	0.163	0.5	14.3	0.05	17.5	0.1	0.63	0.05	4.99	0.05	11.1	0.1	0.215	0.05	49.909
7	0	0.122	0.5	0.5	0.05	11.2	0.1	0.291	0.055	0.5	0.091	7.37	0.1	0.1	0.058	21.337
8	0.4	0.274	0.5	0.93	0.05	8.46	0.1	0.1	0.05	1.08	0.05	2.11	0.1	0.1	0.05	14.421
9	0	0.225	0.5	0.82	0.05	9.95	0.1	0.1	0.05	0.68	0.05	1.88	0.1	0.1	0.05	14.755
10	0.1	0.1	0.5	1	0.346	11.5	0.1	0.1	0.05	1.04	0.05	1.81	0.1	0.1	0.05	16.978
11	0.8	0.146	0.5	1.12	0.067	13.4	0.1	0.1	0.05	0.5	0.05	1	0.1	0.1	0.05	18.557
12	12	0.2	0.76	0.96	2.24	5.07	0.1	0.1	0.05	0.5	0.584	1	0.1	0.1	1.36	25.224
All	15.2	2.186	7.56	60.09	3.294	221.78	1.68	2.46	0.667	39.51	1.54	308.51	1.234	1.874	1.951	669.582

AVERAGE TOTAL EXPOSURE = 669.6 µg/12
= 55.8 µg

EACH PILOT SPRAYED 12 lbs ai

AVERAGE PILOT EXPOSURE = 55.8 µg/12 lbs ai
= 4.6 µg/lb ai

TABLE 2. PILOT DERMAL EXPOSURE DURING ULV APPLICATION OF CYPERMETHRIN