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11-30-84

Shaughnessy #: 109702

Due Date: 1 December, 1984

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To: T. Gardner
Product Manager # 17
Registration Division (TS-767)

From: Joseph C. Reinert
Chief, Special Review Section # 2
Exposure Assessment Branch
Hazard Evaluation Division (TS-769-C)

JCR

Attached please find the EAB review of:

Reg./File No.: 279-3046

Chemical: Cypermethrin

Type Product: Insecticide

Product Name: Cymbush 3E

Company Name: ICI Americas, Inc

Submission Purpose: Applicator Exposure Monitoring Field Study

ZBB Code: _____

ACTION CODE: 435

Date In: 11/15/84

EAB #: 5089

Date Completed: 11/30/84

TAIS (level II)

Days

62

4

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

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Data Evaluation Record

1. Chemical: Cypermethrin
2. Citation: Cypermethrin: Dermal Exposure and Absorption in Workers During Ultra Low Volume Aerial Application of Cymbush 3E Formulation in Oil to Cotton. (11/13/84) Submitted by ICI Americas Inc. Agricultural Chemicals Division.
(Accession no. 255601) 200 (hrs)
3. Type of Application: Aerial spraying of cotton
4. Type of Formulation: Emulsifiable concentrate diluted in oil.
5. Reviewed/Prepared by:

Anne R. Keller
Chemist
Exposure Assessment Branch, HED

Signature Anne R. Keller
Date 11-30-84
6. Approved by:

Joseph C. Reinert
Chief, Review Section #2
Exposure Assessment Branch
Hazard Evaluation Division

Signature Joseph C. Reinert
Date 11/30/84
7. Topic: Exposure to Cymbush 3E formulation in oil during application to cotton.
8. Conclusion: This document presents a valid monitoring study of exposure to cypermethrin during aerial application of an Ultra Low Volume (ULV) formulation in oil. The study is a combined report of exposure and dermal absorption; only the exposure part of the document is reviewed here. The study was carried out according to WHO guidelines for monitoring studies. The results indicate that the oil formulation results in the same order of magnitude of exposure as was calculated from surrogate data for an aqueous formulation aurally applied to cotton.
9. Materials and Methods: This study was jointly sponsored and conducted by ICI PLC, Plant Protection Division, FMC, and ICI Americas Inc.

The product was applied as an insecticide in 12 replicate operations to cotton during an eight hour day. A formulation containing 3 lb cypermethrin per gallon (US) was diluted with refined soybean oil to give an application rate of 2 pints per acre at a concentration of 0.06 lb per acre, or 2.9% (29 g/l). Each replicate application was applied to 200 acres.

Two pilots each performed 6 replicate applications on one of two commercial farms near Greenwood, Mississippi, using different kinds of equipment and mixing/loading procedures.

Two professional mixer-loaders who regularly worked with the pilots each performed three mixing/loading operations (two per hour), and they alternated this task with two volunteer mixer-loaders who each performed three mixing/loading operations. The two pilots and the two professional mixer-loaders were monitored for dermal exposure while the volunteer mixer-loaders were being monitored for dermal absorption. In addition, one other volunteer mixer-loader performed a simulated mixing and loading at Site 1 in order to provide measurement of absorption of cypermethrin following 'worst case' mixing and loading (12 times over a 6 hour period).

The dermal exposure sampling medium was a clean 'Tyvek' overall with hood, worn over the label recommended protective clothing consisting of long-sleeved shirt, long pants, socks and shoes. Pilots also wore brown cotton gloves and nylon/acrylic socks which were part of the sampling material. The overalls, gloves and socks were removed by a supervisor after each replicate operation, and the overalls were sectioned into ten parts representing different parts of the body.

A field recovery was run using twenty 5 x 5 cm² squares cut from each of the three sampling materials. Ten and 100 ul aliquots of the spray dilution were applied to the squares, and half the samples were exposed to sunlight for periods of 30 to 50 minutes to assess photodegradation. The other half of the samples were stored immediately.

10. Results: Two kinds of exposure were calculated for each set of samples:

'Total potential' dermal exposure - The amount of cypermethrin collected on all the sampling materials.

'Actual' dermal exposure - The amount of cypermethrin collected on the hood of the overall and the gloves, which represents the uncovered areas of skin of workers wearing the recommended protective clothing.

The three mixer-loaders who were monitored for absorption wore short-sleeved shirts, long trousers, socks and shoes with no hat or gloves.

In addition, all the mixer/loaders were required to wear protective equipment consisting of calf length rubber boots, coated rubber gauntlets, ankle length rubber apron and face visor over the sampling materials (or over protective clothing in the case of the workers monitored for absorption).

Thus the dermal exposure samples used for calculation (hood of overall and gloves) should show the extent of contamination beneath these items.

The following table is adapted from the Summary Table in the report being reviewed here: 'Cypermethrin: Dermal Exposure and Absorption in Workers During Ultra Low Volume Aerial Application of Cymbush 3E Formulation in Oil in Cotton' by G. Chester & T. B. Hart.

	Average 'total potential' dermal exposure*		Average 'actual potential' exposure**	
	mg/8 hr.***	mg/kg of cypermethrin applied	mg/8 hr.***	mg/kg of cypermethrin applied
Pilots	1.1	0.014	0.66	0.008
Mixer-loaders	10	0.12	2.4	0.028

* potential cypermethrin contamination of clothing and uncovered skin.

** cypermethrin contamination of uncovered areas of skin, i.e. head and hands for pilots, or under protective equipment for the mixer-loaders.

*** pilots exposure time corrected for actual number of minutes of exposure for the six runs; mixer-loaders calculated for the average value of the replicate samples multiplied by the number of replicates (16) in an eight hour day.

The following are also summarized from the report cited above:
Limits of Detection: 0.2 ug. (0.01 ug/ml in final extract, or 0.5-1.0 ug/sample)

Lab Recovery: 10 ug, 5 samples: 102% + 9.7
100 ug, 5 samples: 104% + 5.0

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Field Recovery: suit: 91 + 4.9% to 94 + 2.3%
glove: 95 + 1.5% to 119 + 11%
sock: 87 + 2.3% to 106 + 4.4%

Comparable results from previous exposure analysis: (Excerpted from Table 1, Cypermethrin Applicator Exposure Estimate, of March 2, 1984 and May 17, 1984 memoranda by Robert K. Hitch, EAB, HED)

Daily Dermal Exposure (based on application rate of 0.08# ai/A, mixer/loader handling 100#/day)

	<u>Conditions</u>	<u>Typical Case</u>	<u>Range</u>
Mixing/load Cymbush/Water/ Aerial	No Special Protective Clothing Assumed	240 mg/day	5.0-1200 mg/day
"	Assuming Mixer/loaders Wear Gloves	24 mg/day	0.5-120 mg/day
Pilot/Cymbush/ Water	No Special Protective Clothing Assumed	0.37 mg/day	0.26-0.51

10. Results and Discussion:

This study is a valuable contribution to our data base, since we had no other studies involving Ultra Low Volume application of pesticides aerially applied in oil. It is particularly interesting for the data on distribution of residues on the pilots and mixer-loaders, the amount of pesticide detected on parts of the body which were covered with protective equipment and for the comparison with values calculated from surrogate data on the same chemical. It appears that the exposures calculated from surrogate data are in the same range as the actual exposure values determined for the ULV oil formulation. In addition, the use of protective equipment is important in significantly reducing exposure, as predicted in the previous analysis.

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