Shaughnessy #: 009001

EAB Log-Out Date: MAR 10 1986

Init: SM

To: Carol Langley
Product Manager #73
Registration Division (TS-767C)

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

Attached please find the EAB review of...

Reg./File No.: _____

Chemical: Lindane

Type Product: Insecticide

Product Name: _____

Company Name: CIEL

Submission Purpose: Rebuttal to Exposure Assessment

Date In: 11/04/85

ACTION CODE: 860

Date Completed: 11/13/85

EAB # 6128

Days

5

Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

_____ Benefits and Use Division

Monitoring study requested by EAB /_/

Monitoring study voluntarily conducted by registrant: /_/

Note to: Carol Langley
Special Review Branch

This note is to clean up the paperwork associated with the lindane rebuttal submitted by CIEL in November 1985. As you know this rebuttal was answered on 13 November 1985. Somehow the paper trail was sidetracked. I've attached a copy of the November reply in case you need it.

Dave

Dave Jaquith

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

NOV 13 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: Carol Langley
Special Review Branch

THRU: Joseph C. Reinert, Chief
Special Review Section
Exposure Assessment Branch
Hazard Evaluation Division

JCR

SUBJECT: Registrant's Comments on Lindane PD 4 Reassessment

On August 22, 1985 EAB completed a reassessment of the exposure estimates of the Lindane PD 4 (1). The reassessment indicated that additional use data was necessary in order to conduct an exposure assessment for forestry and some other uses. The required information was provided by BUD (2). The reassessment was conducted according to current EAB standards and used some surrogate data not available or not used in the original PD 4. The reassessment also indicated that substantial changes should be made in the exposure estimates for forestry application and for application to uninhabited buildings and storage bins. Partially as a result of this reassessment, the forestry and uninhabited building uses of lindane were placed into Special Review. The registrants have submitted a rebuttal to the reassessment. The rebuttal, written by the registrant's consultant on exposure, Dr. Clive Edwards, claims that inappropriate surrogate studies were selected for the reassessment. EAB disagrees and will present it's responses to these claims in the order they were presented by the registrant.

1) Forestry Use - Applicator

The original PD 4 estimated that dermal exposure to workers applying a 0.5 percent (w/w) solution of lindane to trees was 1.4 mg/hr. This estimate was based on a study by Lavy et al. (3) and assumed that protective clothing offered 80 percent protection. The PD 4 also assumed that a worker treats 16 trees per day, 5 minutes per tree, 30 days per year. The annual dermal exposure was 56 mg/yr. Respiratory exposures were 0.0071 mg/hr or 0.28 mg/yr. The reassessment used 3 additional surrogate studies. The exposure estimates

from Wolfe (4), Copplestone et al. (5) and BAAL (6) were combined with the Lavy study to form a small database. The decision to estimate lindane exposure using this database was based on 2 considerations:

a) The variation of exposure tends to be high, both within and between studies. It is EAB's policy to try to increase the reliability of exposure estimates by combining studies whenever possible in order to increase replicates and minimize bias that could result from the selection of a single surrogate.

b) The Lavy study in the PD 4 has a number of weaknesses and is only marginally acceptable by EAB standards. The height of application was not specified. Presumably the material was applied to brush when backpack equipment was used. The Copplestone study involved the application of pesticide to plants that averaged 70 cm (28 inches), similar to the height of brush. Hand exposure, often an appreciable part of total dermal exposure, was not measured during the Lavy study. This study also failed to measure the exposure of the legs due to destruction of the pads while walking through the brush. Exposure of the legs was 90 and 58 percent of the total dermal exposure in the Copplestone and BAAL studies, respectively. The Lavy study, when used by itself, may appreciably underestimate exposure.

For these reasons, EAB believes that a more reliable estimate of exposure results from a combination of all of these surrogate studies. At any rate the PD 4 dermal exposure estiamte of 1.4 mg/hr is in good agreement with the reassessment value of 5.3 mg/hr, given the degree of variability inherent in exposure studies. It is also in excellent agreement with a recent study in which carbaryl was applied to the bark of forest trees using a high pressure ground sprayer (7).

2) Forestry Use - Mixer/loader

The exposure of mixer/loaders to lindane during forestry use was not addressed in the original PD 4. It is EAB policy to provide separate estimates of mixer/loader and applicator exposure whenever possible. An assessment of mixer/loader exposure, based on use data provided by BUD (2) and on the BAAL study, was completed on 9/11/85 (8). The dermal exposure was estimated to be 53 mg/day. Respiratory exposure was negligible. The dermal exposure value was based on the assumption that 1 mixer/loader prepares material for 1 applicator and that an applicator treats 32 trees per day, with 2 gallons of 0.5 percent solution being required for each tree. EAB did not correct the exposure values for dermal penetration or protective clothing. These corrections were provided by the Science Integr-

ation Staff (SIS). The registrant claims that 4.5 liters are used for each tree and that 16 trees are treated per day. No documentation to support this claim was provided by the registrant. In lieu of such documentation, EAB believes that the exposure estimate for mixer/loaders is reasonable and appropriate.

3) Uninhabited Buildings and Storage Bins

The estimate of applicator exposure from the original PD 4 for lindane use in uninhabited buildings and storage bins was 1.3 mg/hr. The annual dermal exposure was 0.53 mg/yr, based on the assumption that 0.4 hours per year were spent applying a 1 percent mixture of lindane. The surrogate study used for this estimate was by Culver et al. (9). The study measured worker exposure during the treatment of pasture land with malathion and chlorthion for mosquito control. The equipment used was a Jeep drawn aerosol gererator. EAB believes that this type of outdoor exposure scenario is not an appropriate surrogate for an indoor application, such as to storage bins or uninhabited buildings. For the reassessment, an indoor scenario, spraying of houses with DDT for insect control was selected as a surrogate (10). When this surrogate was used the dermal exposure to lindane was estimated to be 351 mg/hr or 140 mg/yr. The registrant claims that this is an inappropriate surrogate because a fan type sprayer was used and that the droplet size is larger with this equipment, resulting in appreciable droplet rebound from the walls. The registrant proposes that a more relevant study would be one in which resmethrin was sprayed with an aerosol can and that the aerosol produced by this method is similar to that produced by the spraying of lindane. EAB realizes that the aerosol characteristics are partially dependent on the type of equipment used. However, the registrant has produced no evidence that a very fine spray is used for storage bin application. EAB has found that the label for at least one registered product (EPA Reg. NO. 40831-80) instructs the user to apply the material as a <u>coarse</u> spray, not a fine aerosol as claimed by the registrant.

After careful consideration of the registrant's coments, EAB believes that the exposure estimates of the PD 4 reassessment, and the surrogates used to derive these estimates, are both reasonable and appropriate for these uses. If the registrants wish to conduct exposure studies to support their position,

protocols must be submitted to EAB and approved prior to the conduct of the studies. EAB would be willing to reassess it's position should acceptable data indicate that such a change is appropriate.

David Jaquith
Special Review Branch
Exposure Assessment Branch
Hazard Evaluation Division

cc: K. Barbehenn
J. Moyer

REFERENCES

(1) Memo from D. Jaquith (EAB) to A. Barton (HED) dated 8/22/85.

(2) Memo from M. Dow (BUD) to J. Reinert (EAB) titled "Use Information for Lindane", dated 9/10/85.

(3) Lavy, T.L., Shepard, J.S. and Mattice, J.D. (1980) Exposure Measurements of Applicators Spraying (2,4,5-Trichlorophenoxy) acetic Acid in the Forest. J. Agric. Food Chem., 28:3 pp 626-630.

(4) Wolfe, H.R., Armstrong, J.F. and Durham, W.F. (1974) Exposure of Mosquito Control Workers to Fenthion. Mosquito News, 34:3 pp 263-267.

(5) Copplestone, J.F., Fakhri, Z.I., Miles, J.W., Mitchell, C.A., Osman, Y. and Wolfe, H.R. (1976) Exposure to pesticides in agriculture: a survey of spraymen using dimethoate in the Sudan. Bull. World Health Organ., Vol 54, pp 217-223.

(6) British Agrochemicals Association Limited (1984) Spray Operator Safety Study. British Agrochemicals Association Limited, London.

(7) Haverty, M.I., Page, M., Shea, P.J., Hoy, J.B. and Hall, R.W. (1983) Drift and Worker Exposure Resulting from Two Methods of Applying Insecticides to Pine Bark. Bull. Environm. Contam. Toxicol., Vol. 30, pp 223-228.

(8) Memo from D. Jaquith (EAB) to A. Barton (HED) dated 9/11/85.

(9) Culver, D., Caplan, P., and Batchelor, G.S. (1956) Studies of Human Exposure During Aerosol Application of Malathion and Chlorthion. A.M.A. Archives of Industrial Health, Vol 13, pp 37-50.

(10) Wolfe, H.R., Walker, K.C., Elliott, J.W. and Durham, W.F. (1959) Evaluation of the Health Hazards Involved in House-Spraying with DDT. Bull. World Health Org., Vol 20, pp 1-14.