

Shaughnessy #: 009001

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Product Manager #15
Registration Division (TS-767C)

From: David A. Jaquith, Acting Chief
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Attached please find the EAB review of...

Reg./File No.: 6830-18, -37

Chemical: Lindane

Type Product: Insecticide

Product Name: 1% Lindane Dust, Military Specification MIL-I-11490

Company Name: N/A

Submission Purpose: Applicator exposure study review

ZBB Code: _____ ACTION CODE: 655

Date In: 10/26/86 EAB # 70060

Date Completed: 4/23/87 TAIS (level II) _____ Days

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Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

_____ Benefits and Use Division

Monitoring study requested by EAB: / /

1.0 INTRODUCTION

The US Army Environmental Hygiene Agency (USAEHA), in response to the lindane Registration Standard (RS-85-027, September, 1985), has submitted a study measuring applicator and recipient exposure during delousing treatments with 1% lindane dust, the standard military pediculicide.

There has been no need for peacetime delousing of US forces, and 1% lindane dust is restricted to use under wartime conditions only. It is proposed that this delousing use of lindane be restricted as follows:

1. Labeling the product for use against body lice only, therefore making it inappropriate for use in peacetime. Individual cases of pediculosis (head or crab lice) in peacetime are treated with FDA-approved pediculicides issued by prescription only through Service pharmacies.
2. Restricting the issue and use of mass delousing equipment and bulk quantities of 1% lindane dust to military medical and quartermaster units whose personnel are trained to use it.
3. Restricting the troop issue and use of personal 2-oz bottles of 1% lindane dust to "emergencies only, when authorized by medical authorities." The same restrictions apply to the issue of 25-lb cans to combat units for use in unit delousing with manual dusters.
4. Making the use of 1% lindane dust a medical decision and not a tactical decision.

Usage information for 1% lindane dust, supplied by the Department of Defense, indicates that an individual would receive a maximum of two delousing treatments in a lifetime. For applicators, it is reasonable to assume that 35 soldiers would be treated in a day.

2.0 MATERIALS AND METHODS

A simulated delousing operation, using mannequins as recipients of the dusting, was conducted in July 1986 at Ft. Detrick, MD, in conjunction with the US Army Medical Bio-Engineering Research and Development Laboratory. Five mannequins dressed in military fatigues were placed approximately four feet apart in a standing position facing the wind. Three military certified pesticide applicators performed eight standard delousing procedures, each consisting of delousing the five mannequins twice. Details of the delousing procedure are described in Appendix A. In addition to standard military fatigues, consisting of hat, long sleeved shirt, and long pants, applicators also wore underwear,

high top combat boots, neoprene chemical protective gloves, and respirators.

Application of lindane was accomplished using a standard military mass delousing insecticide duster and insecticide dusting powder spray gun. The treatment rate was 60 g of 1% lindane dust per subject (6.0 g ai/operation), and the total application time averaged 14 minutes.

Dermal exposure to applicators was measured using 32-ply gauze pads with an exposed surface area of 40.32 cm². Pads were located under the applicator's clothing on the chest, the back of the neck, the left and right shoulders, the left and right forearms, the left and right thighs, and the left and right shins. Additional pads were placed outside applicator clothing adjacent to the inside pads on the chest, back, and left and right shoulders. Two hand rinses in 200 ml of isopropanol were performed to determine hand exposure.

Respiratory exposure of the applicators and recipients was measured using personal air samplers; applicators had respiratory monitors both inside and outside their masks. Air samplers were equipped with a Millipore two piece closed face cassette with a 37 mm glass fiber filter, and a 30 ml glass midget impinger containing 15 ml of isooctane as the absorbent. Sampling pumps were operated at 1.5 l/min.

3.0: ANALYTICAL METHODS AND QUALITY ASSURANCE PROCEDURES

All samples were frozen until analysis. Dermal pads and respirator filters were extracted with isooctane. Lindane was quantified using GC with electron-capture detection. The detection limits were 0.01 ug/cm² (dermal pads), 0.10 ug/cm² (hand rinse), 0.05 ug/sample (respirator filters), and 0.1 or 0.3 ug/sample (impinger samples). Recovery of lindane from fortified samples is shown in Tables 1-3.

4.0 EXPOSURE CALCULATIONS

Lindane levels on gauze pads and in hand rinse and air samples are shown in Table 4. Lindane was detected (>0.01 ug/cm²) on only six of 80 dermal pad samples placed under applicator clothing; all external pad samples were found to contain lindane (0.57-79.83 ug/pad). Lindane was not detected (<0.1 ug/cm²) in any hand rinse samples.

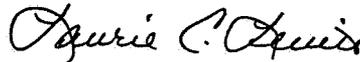
Dermal exposure values were calculated by dividing the mean amount of lindane on gauze pads (ug) by the surface area of the pad (40 cm²), and then multiplying the result by the surface area (cm²) of the body region which each pad represented. This result (ug/body part) was then adjusted by the application time, applicator body weight, and the amount of lindane handled (Table 5).

All exposures determined to be below analytical detection were considered as positive at the detection limit for calculation purposes. This deviation from standard practice (use of half the detection limit) was considered by EAB to be appropriate in this case because the analytical limit of detection was unusually high.

5.0 SUMMARY AND CONCLUSIONS

Exposure of military personnel performing standard delousing treatments with 1% lindane dust was measured using passive dosimetry. Exposure values are not corrected for dermal absorption. Total exposure to applicators is estimated to be 2.2×10^3 ug/kg/lb ai. Daily applicator exposure, if 35 individuals are treated, is estimated to be 1.1×10^2 ug/kg/day. Respiratory exposure was minimal, accounting for <2% of the total applicator exposure.

The dose to the recipient is assumed to be the total amount of lindane applied (1.2 g ai). Respiratory exposure was negligible compared to dermal exposure (2.25 ug).



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Table 1. Recovery (%) of lindane from fortified dermal pad samples.

Fortification level (mg)	Number of replicates	Recoveries		
		Mean	SD	Co. of var.
<u>Laboratory spiked dermal pads</u>				
4.00	7	111.7	7.44	6.66
20.0	7	93.0	6.31	6.78
202.0	7	94.1	3.38	3.58
<u>Storage stability on dermal pads (one week)</u>				
4.00	3	106.6	7.60	7.13
20.0	3	89.9	1.47	1.64
202.0	3	100.9	3.31	3.28
<u>Storage stability on dermal pad extracts (one week)</u>				
4.00	3	123.3	11.48	9.31
20.0	3	89.3	4.60	5.15
202.0	3	100.9	1.99	1.98
<u>Storage stability on dermal pad extracts (two weeks)</u>				
4.00	3	122.5	7.02	5.73
20.0	3	93.4	2.26	2.42
202.0	3	95.6	1.95	2.04
<u>Storage stability on dermal pad extracts (four weeks)</u>				
4.00	3	123.7	9.00	7.28
20.0	3	87.4	0.61	0.70
202.0	2	92.8	4.81	5.18

Table 2. Recovery (%) of lindane from fortified hand rinse samples.

Fortification level (mg)	Number of replicates	Recoveries		
		Mean	SD	Co. of var.
<u>Laboratory spiked hand rinse</u>				
130.0	3	93.7	3.80	4.06
650.0	3	94.6	2.73	2.89
<u>Storage stability in hand rinse (one week)</u>				
130.0	3	99.0	5.11	5.16
650.0	3	94.9	2.21	2.33

Table 3. Recovery (%) of lindane from fortified respiratory media.a

Fortification level (mg)	Number of replicates	Sampling time(min.)	Recoveries		
			Filters	Impingers	Total
<u>Laboratory spiked samples</u>					
1000	1	15	89	2	91
1000	1	30	96	2	98
1000	1	60	88	3	91
1000	1	90	90	5	95
<u>Field spiked samples</u>					
--b	5	10	90.6	6.8	97.4
--	7	20	85.4	8.7	94.1

a Desorption efficiency of lindane averaged 108% (range of 103 to 112%).

b Not reported.

Table 4. Concentration of lindane (ug/patch) found in dermal field samples.

Patch location	Replicate No.								Mean
	1	2	3	4	5	6	7	8	
				<u>Inside clothing</u>					
Shoulder	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	0.40
Back	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	0.40
Chest	0.52	<0.40	<0.40	0.64	0.69	0.69	<0.40	1.29	0.63
Forearm	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	0.40
Thigh	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	0.44	<0.40	0.41
Shin	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	<0.40	0.40
				<u>Outside clothing</u>					
Back	1.73	1.09	0.57	1.53	2.34	3.59	0.91	5.69	2.18
Chest	16.24	3.02	1.84	6.61	6.01	10.48	6.46	8.71	7.42
Upper arm	--	--	--	11.31	8.55	12.89	4.69	43.06	32.19
Hand	<82.00	<82.00	<82.00	<82.00	<82.00	<82.00	<82.00	<82.00	82.00

Table 5. Exposure of applicators to lindane from delousing treatments.

Body part	Amt/patch (ug/40 cm ²) ^a	ug/cm ²	Surface Area (cm ²)	ug/body part	ug/body ^b part/hr	ug/kg/hr ^c	ug/kg/lb ai ^d
Face/front of neck ^e	7.42	0.19	800	152.0	651.4	9.31	1.6 x 10 ²
Back of neck	2.18	0.05	110	5.5	23.6	0.34	6.0
Shoulders	0.40	0.01	2910	29.1	124.7	1.78	31
Back	0.40	0.01	3550	35.5	152.1	2.17	38
Chest	0.63	0.02	3550	71.0	304.3	4.35	77
Forearms	0.40	0.01	1210	12.1	51.9	0.74	13
Thighs	0.41	0.01	3820	38.2	163.7	2.34	41
Shins	0.40	0.01	2380	23.8	102.0	1.46	26
Hands	82	2.05	820	1681.0	7204.3	102.92	1.8 x 10 ³
Total Dermal						125.41	2.2 x 10 ³
Respiratory ^{g,h}				1.64	135.9	1.94	34
Respiratory ⁱ				0.27	22.4	0.32	5.7
Total Applicator Exposure							2.2 x 10 ³

^a Average of replicate samples. All exposures determined to be below analytical detection were considered as positive at the detection limit² for calculation purposes (i.e., for dermal pads, the detection limit is 0.01 ug/cm² x 40 cm² = 0.4 ug/patch).

^b Application time averaged 14 minutes (0.23 hr).

^c Assuming a 70 kg worker.

^d Adjusted exposure per lb ai handled (ug/kg/lb ai) = ug/kg/hr x 0.013 lb ai/application

^e External pad value for chest used (See Table 4).

^f External pad value for back used (See Table 4).

^g Sample calculation: 1.64 ug/21 L x 1740 L/hr = 135.9 ug/hr

^h Samples taken at collar.

ⁱ Samples taken at mask.

APPENDIX A. Delousing procedure.

1. The gasoline powered generator was readied for use.
2. Personal air monitors on the mannequins and applicator were started and the time documented.
3. First, the applicator removed the mannequins hat and dusted the head, simulating whitening of the hair.
4. Secondly, the inside of the hat was dusted.
5. Next, the nozzle was inserted up the right sleeve toward the armpit and the trigger pulled. Repetition of this procedure was followed the the left sleeve.
6. The upper torso was then dusted by inserting the nozzle in the front of the shirt at the collar directing the powder toward the right armpit, the stomach, and finally the left armpit.
7. The nozzle was then inserted in the front leg of the trousers directing the powder toward the left leg, the pubic region, and finally the right leg.
8. Next, the back was dusted by inserting the nozzle at the collar. The right shoulder, the small of the back, and the left shoulder were dusted. The collar itself was then turned up and powdered.
9. Finally, the gun was inserted in the back of the trousers, directing the powder toward the right leg, the buttocks, and toward the left leg.
10. The personal air monitors were immediately stopped and the time documented.