



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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: REVIEW OF REPEAT EXPOSURE STUDY FOR PROPOXUR AEROSOL
SPRAY (HED Project No. 1-1208)

TO: David Chen
Special Review Branch
Special Review and Reregistration Division (H7508C)

FROM: David Jaquith
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Please find below the OREB review of

HED Project #: 1-1208

RD or SRRD Record #: 164120

Caswell #: 508

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Deferral to: Biological Analysis Branch/BEAD

 Science Analysis & Coordination Branch

 TB -I

 TB -II

1.0 INTRODUCTION

In December 1987 the Agency issued a Data Call In Notice (DCI) requiring exposure data for several uses of propoxur. Propoxur is a carbamate insecticide with a number of indoor and outdoor uses around occupied structures. One of the scenarios included in the DCI was the use of pressurized aerosols by homeowners. Mobay Corporation responded to this requirement with a protocol for an exposure study addressing the use of aerosol products containing this compound. The protocol was approved by OREB/NDEB in 1988 (1).

The resulting study was reviewed by OREB/NDEB in February 1990 (2). The participants wore protective nitrile gloves during the application of the aerosol product. Such protection was NOT specified in the study protocol nor are such items specified on the product label. It was OREB's opinion that the use of protective gloves on a homeowner aerosol product was a clear violation of the study protocol and that the study did not accurately reflect the potential exposures of individuals using this product. The portion of the review that addressed homeowner aerosol exposure have been excerpted and are included with this report as Appendix A. The study was therefore rejected as an appropriate response to the DCI. The registrant has repeated the study and submitted a report that is the subject of this review.

2.0 CONCLUSIONS

OREB has completed a review of an exposure study measuring the potential exposures of individuals to propoxur (BAYGON) when applied as a 1 percent aerosol spray. The study was submitted by Mobay Corporation as a replacement for an earlier study that was rejected by the Agency because of protocol violations, specifically the use of protective gloves on homeowners. The current submission does not suffer from that deficiency and has been found to be an acceptable response to the DCI issued in 1987. OREB has provided exposure estimates for 4 clothing scenarios ranging from minimal clothing (shorts and shoes only) to long sleeved shirt and long pants. The calculated dermal exposures of individuals spraying the entire contents of the product for each of these clothing situations are briefly summarized in Table 1. Estimated annual dermal exposures, using an assumption of 12 applications per year, are presented in Table 2. Respiratory exposures are summarized in Table 3.

The previous study did not adequately measure the exposure of the hands. OREB notes that the current submission indicates that the hands receive much higher exposures than the other areas of the body, averaging as much as 59 percent of the total when long sleeves and long trousers are worn. OREB also notes that the applications in this study were conducted indoors. OREB does not expect that the application of pressurized aerosol products

outside, such as for wasp control, would result in higher exposures than those recorded in the current submission. The current study can therefore serve as an adequate surrogate for outdoor applications of propoxur when an aerosol product is used.

3.0 DESCRIPTION OF STUDY

A typical homeowner aerosol product (Raid Ant and Roach Killer, EPA Reg. No. 4822-84) containing 1 percent propoxur as the active ingredient was sprayed into cracks, crevices, baseboards, under sinks, and in other places where insects commonly hide. Each replicate included the spraying of an entire can of the product which contains 16 ounces of formulation. All applications were conducted at residences in Vero Beach, Florida. A total of 15 replicates were performed.

The applicators wore long-sleeved work shirts, cotton trousers, and baseball caps over normal clothing which consisted of denim or cotton trousers, long-sleeved shirts and shoes. Dermal exposure was monitored by gauze patches (3 in x 3 in) enclosed in an aluminized paperboard holder. A 5.6 cm circular opening was cut in each holder, yielding an exposed surface area of 24.63 cm². Ten such dosimeters were attached to the outside of the clothing on the upper arms, forearms, right chest, left back, front of thighs, and shins. An additional dosimeter was attached to the bill of the applicator's cap. Another set of dosimeters was attached inside of the outer clothing on both upper arms, forearms, left chest, right back, front of thighs, and shins. Care was taken to avoid overlap of the inner and outer dosimeters. Dosimeters were removed with tweezers, placed in 1 ounce glass bottles, and stored on dry ice.

Dermal exposure of the hands was measured by handwash with ethanol. A 200 ml portion of ethanol was placed in a plastic bag which was then held tightly around the applicator's wrist. The hand and bag were then shaken 50 times. Each rinse was conducted twice for each hand. The samples were then pooled in a 1 liter container. After shaking, a portion of the rinsate was poured into a 1 ounce bottle for analysis and the remainder discarded. The sample bottles were stored on dry ice.

Respiratory exposure was determined by drawing air, at a known rate of approximately 1 liter per minute, through a quartz microfilter contained in a cassette attached to the lapel of the applicator. After sampling, the cassettes were capped, bagged, and stored on dry ice.

All samples were stored on dry ice until field collection was completed. The samples were then stored in a freezer at -7 degrees C until shipped to the analytical laboratory. The handwashes and quartz filters were analyzed by a laboratory certified by the American Industrial Hygiene Association in Kansas City and the gauze patches by a similar laboratory in Pittsburgh.

Table 1. Total Dermal Exposure of Individuals Applying a 1 Percent Aerosol Container of Propoxur. Values are expressed as μg per kg per application of a 16 ounce container.

Replicate	Long Sleeves, Long Pants, Shoes	Short Sleeves, Long Pants, Shoes	Short Sleeves, Shorts, Shoes	Minimal Clothing (Shorts & Shoes Only)
1	28	67	67	299
2	26	33	35	61
3	38	48	81	107
4	38	55	59	114
5	32	46	48	88
6	30	38	40	75
7	21	32	33	57
8	26	44	57	143
9	19	29	31	74
10	58	58	60	63
11	27	30	32	49
12	24	26	26	52
13	68	83	141	197
14	17	17	17	26
15	20	32	38	49
MEAN	31	43	51	97
S.D.	14	17	29	68
MAX	68	83	141	299
Geo. Mean	29	39	45	80

Table 2. Annual Dermal Exposures of Homeowners Applying a 1 Percent Propoxur Aerosol Product 12 Times Per Year. Values are expressed as μg per kg per year.

Replicate	Long Sleeves, Long Pants, Shoes	Short Sleeves, Long Pants, Shoes	Short Sleeves, Shorts, Shoes	Minimal Clothing (Shorts and Shoes only)
1	336	804	804	3588
2	312	396	420	732
3	456	576	972	1284
4	456	660	708	1368
5	384	552	576	1056
6	360	456	480	900
7	252	384	396	684
8	312	528	684	1716
9	228	348	372	888
10	696	696	720	756
11	324	360	384	588
12	288	312	312	624
13	816	996	1692	2364
14	204	204	204	312
15	240	384	456	588
MEAN	378	510	612	1163
S.D.	166	203	351	821
MAX	816	996	1692	3588

Table 3. Estimated Respiratory Exposures of Individuals Applying Propoxur as a 1 Percent Aerosol Spray.

Replicate	Exposure per Single Application			Annual µg/kg/yr	
	µg Found	µg/kg/hr	µg/kg/oz. ai		
1	0.67	0.00031	0.00066	0.00195	0.00374
2	0.43	0.00021	0.00047	0.00131	0.00252
3	0.68	0.00028	0.00053	0.00174	0.00334
4	1.60	0.00081	0.00189	0.00508	0.00976
5	1.36	0.00057	0.00110	0.00357	0.00685
6	0.89	0.00033	0.00060	0.00205	0.00392
7	0.48	0.00030	0.00094	0.00188	0.00360
8	1.44	0.00065	0.00144	0.00404	0.00775
9	0.88	0.00033	0.00063	0.00208	0.00401
10	0.34	0.00015	0.00031	0.00091	0.00175
11	0.26	0.00015	0.00039	0.00091	0.00175
12	0.47	0.00016	0.00027	0.00102	0.00197
13	0.83	0.00033	0.00062	0.00205	0.00395
14	0.28	0.00019	0.00065	0.00121	0.00233
15	0.51	0.00021	0.00040	0.00128	0.00246
MEAN		0.00033	0.00073	0.00207	0.00398
STD. DEV.		0.00020	0.00045	0.00123	0.00235
MAXIMUM		0.00081	0.00189	0.00508	0.00976

Propoxur in the gauze pads was desorbed by rotating the sample for 30 minutes in a sealed bottle with 15 ml of ethanol. The solution was then filtered with a LID/X filter, and analyzed by HPLC equipped with a post-column derivatization unit and a fluorescence detector. The level of detection was approximately 0.75 μg per sample. Recoveries from gauze pads spiked with 1.0 μg of the aerosol spray formulation and analyzed up to 100 days later ranged from 94 to 107 percent. No correction for recovery was used on the calculations. Desorption efficiency samples for the aerosol spray (100 μg) averaged 91.4 percent. Hand rinses were filtered and the propoxur quantified as described above. The level of detection was approximately 10 μg per sample. Storage stability samples indicated that propoxur was stable in this medium for up to 125 days. Glass filters were also desorbed with ethanol and analyzed in a similar manner. The level of detection was 0.1 μg per sample. Spiked samples were stable up to 217 days.

4.0 CALCULATION OF EXPOSURES

4.1 Assumptions

The dermal and respiratory exposures were presented by the registrant in terms of mg per hour, mg per replicate, and mg per ounce of active ingredient applied. OREB has also calculated exposures in these terms. In order to calculate exposures of individuals to propoxur a number of assumptions were required:

- 1) An average applicator was assumed to have a body weight of 70 kg and have standard surface areas as presented in the Agency's Pesticide Assessment Guidelines - Subdivision U.
- 2) The respiratory volume of an individual applying propoxur aerosol spray is 1.7 m^3 per hour.
- 3) The entire contents of the aerosol can is applied at each spray interval and the material is applied 12 times per year.
- 4) Residues below the level of detection were assumed to be present at amounts equal to one half of the level of detection.

5) OREB has provided exposure estimates for 4 different clothing scenarios:

- a) Long-sleeved shirt, long pants, and shoes
- b) Short-sleeved shirt, long pants, and shoes
- c) Short-sleeved shirt, shorts, and shoes
- d) Minimal clothing, shorts only

It was further assumed that hats or gloves are not normally worn during homeowner applications. The dosimeters used for calculation of dermal exposures for each of these scenarios are presented in Table 4.

4.2 Exposure Calculations

Dermal exposure of a specific body area, except for hands, was calculated by multiplying the residues detected on a gauze pad by the standard surface area and dividing by the patch surface area, 24.63 cm².

$$\text{Dermal Exposure} = \frac{\text{Residues } (\mu\text{g/patch}) \times \text{Surface Area } (\text{cm}^2)}{24.63 \text{ cm}^2/\text{patch}}$$

($\mu\text{g}/\text{body part}$)

The surfaces of the hands were sampled in their entirety and no corrections for surface areas were necessary. Respiratory exposures were calculated by determining the concentration of propoxur in the air and multiplying by the respiratory volume during the application period:

$$\text{Respiratory Exposure} = \frac{\mu\text{g found} \times 1.7 \text{ m}^3/\text{hr} \times \text{exposure time (hrs)}}{(\text{flow rate in m}^3/\text{hr} \times \text{sample time in hrs})}$$

(μg)

Exposure values are often normalized by the application time and amount of active ingredient handled to allow comparison with other application scenarios. All applications in this study dispensed 0.16 ounces (0.01 lbs ai). However, it is OREBs opinion that the most useful exposure values for homeowner applications of this product are those for application an entire container rather than values normalized by time or ai handled. Dermal exposure estimates for each clothing scenario, for a single application and for 12 applications per year, are presented in Tables 1 and 2. Respiratory exposure values are presented in Table 3.

REFERENCES

- 1) Memorandum from M. Firestone (NDEB) to D. Edwards (RD) dated April 29, 1988.
- 2) Memorandum from D. Jaquith (NDEB) to D. Edwards (RD) titled "Review of propoxur exposure studies submitted by Mobay Corporation in response to Data-Call-in Notice (Hed Project nos. 9-1935, 9-1936, 9-1937, 9-1938, 9-1939) and current estimates of exposure for other scenarios", dated February 7, 1990.

Table 4. Dosimeters Used to Calculate Dermal Exposure to Propoxur Aerosol Under Four Different Clothing Scenarios

Body Area	Dosimeter/Patch Used for Calculations			
	Long Sleeves, Long Pants, Shoes	Short Sleeves, Long Pants, Shoes	Short Sleeves Shorts & Shoes Shoes	Minimal (Shorts, Shoes only)
Head	Hat Patch	Hat Patch	Hat Patch	Hat Patch
Back of Neck	Outside Back	Outside Back	Outside Back	Outside Back
Front of Neck	Outside Chest	Outside Chest	Outside Chest	Outside Chest
Chest	Inside Chest	Inside Chest	Inside Chest	Outside Chest
Back	Inside Back	Inside Back	Inside Back	Outside Back
Upper Arms	Inside Upper Arms	Inside Upper Arms	Inside Upper Arms	Outside Upper Arms
Forearms	Inside Lower Arms	Outside Lower Arms	Outside Lower Arms	Outside Lower Arms
Thighs	Inside Upper Legs	Inside Upper Legs	Inside Upper Legs	Outside Upper Legs
Calves	Inside Lower Legs	Inside Lower Legs	Outside Lower Legs	Outside Lower Legs
Hand	Handwash	Handwash	Handwash	Handwash

Appendix A. Excerpted from NDEB Review of February 7, 1990

3.3 EXPOSURE DURING AEROSOL SPRAY APPLICATION - HOMEOWNER

CITATION: Exposure of Applicators to Propoxur During Residential Application of an Aerosol Spray Containing 1% Propoxur. Mobay Corporation Report 99132. MRID No. 410547-05.

Reviewed by: Contractor

Description of Study and Results:

Dermal and respiratory exposures were measured during the application of a 1 percent aerosol product, Laser Ant and Roach Killer II. The product was packaged in a 15 ounce can and contained 0.0094 pounds of propoxur as the active ingredient. The entire container was emptied in each of the 15 replicates monitored. The insecticide was sprayed into cracks, around baseboards, and around sinks and appliances. The treatments averaged 0.41 hours (0.22-0.55 hrs). The applicators wore cotton/polyester coveralls and nitrile gloves. THE LABEL FOR THIS PRODUCT DOES NOT REQUIRE THE USE OF PROTECTIVE CLOTHING AND PROTECTIVE GLOVES WERE NOT INCLUDED IN THE PROTOCOL REVIEWED BY NDEB (10). Dermal exposure of the body was measured using gauze pads attached to the clothing at locations defined in the Agency's Pesticide Assessment Guidelines - Subdivision U. Duplicate sets of patches were used, one located outside of the clothing and the other beneath the coveralls. The geometric mean dermal exposure was calculated by the contractor to be 0.49 mg per replicate (53 mg per lb ai). and exposure , measured inside of protective gloves, was 0.01 mg per replicate (0.96 mg per lb ai). The corresponding geometric mean respiratory exposure was calculated to be 39 mg per replicate (4.1×10^3 ug per lb ai). It is unlikely that a typical homeowner applying this product would wear protective gloves during treatment. It is NDEB's opinion that, although the study was scientifically valid, the exposure scenario addressed was not in compliance with the label or the approved protocol and does not represent typical homeowner exposures. Therefore, the study was not considered to be valid for the purposes of estimating the exposures of homeowners to aerosol products.

Exposure Estimates:

The previous assessment (1) estimated exposures from aerosol application using a surrogate study from the literature in which the herbicide paraquat was applied using a hand held compressed-air sprayer. The current submission, which was intended to be used to revise this estimate, has been judged to be unacceptable because protective gloves were worn. In lieu of adequate updated information, NDEB must continue to use the exposure values from its previous assessment. However, it is NDEB's opinion that any exposure estimate for aerosol spray application derived from

treatment using compressed air apparatus may not accurately reflect actual exposures and must be interpreted carefully.

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