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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Permanone (Permethrin) Tick Repellent Dermal Absorption Data

Tox. Chem. No.: 652BB
HED Project No.: 0-0489
EPA ID No.: 4816-AUA

TO: George LaRocca, PM #15
Registration Division (H7505C)

FROM: Roger Gardner, Acting Section Head
Review Section I *Rog Gardner 6-20-90*
Toxicology Branch I (Insecticide/Rodenticide Support)
Health Effects Division (H7509C)

THRU: Karl Baetcke, Ph. D., Chief *Karl Baetcke 6/20/90*
Toxicology Branch I (Insecticide/Rodenticide Support)
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Conclusions

1. Using the Registrant's assumptions, which are unverified by the Nondietary Exposure Branch (NDEB), and adjusting the Registrant's exposure estimate for dermal absorption predicted by an animal study, the carcinogenic risk ranges from 9×10^{-7} to 2.1×10^{-6} .
2. Comparison of the daily exposure estimate (0.000036 mg/kg/day) reported by the Registrant with the NOEL from a chronic feeding study in rats (5 mg/kg/day) indicated a Margin of Exposure (MOE) of 138,889. An estimate of maximum daily exposure which is unverified by NDEB indicated that the MOE's may range from 455 to 1250.

Recommendations

The Nondietary Exposure Branch should be asked:

1. to verify assumptions made in the Army's assessment of the dermal exposure to permethrin impregnated Battle Dress Uniforms (BDU) and
2. to verify or provide estimates of the maximum single daily exposure to applicators and individuals.

- 2 -

I. Background Information

The characterization of risks described below is supplementary to the memorandum prepared by Dr. John Doherty of Toxicology Branch I (Subject: EPA Id #63120-R, -E, and -G. Permethrin: Request from the military for registration of three products for use on battle dress uniforms and clothing and bed netting and other fabrics. [HED Project No. 0-0601]). That memorandum contains background information on instructions for use of the three products and comments on the reports submitted by the Registrant (the U. S. Army).

Assumptions made in the risk characterization below are described in greater detail by Lunchick (1989 and 1990), Zendzian (1990a and b), and Schiefer (1990).

A. Previous Carcinogenic Risk Estimates

A previous risk characterization for another permethrin product used to treat battle dress uniforms (BDU) was conducted by Zendzian (1990a). That assessment was based on a maximum permethrin concentration of 0.027 mg/cm² of fabric (Lunchick, 1989). The daily dermal exposure was estimated to be 0.0056 mg permethrin/kg body weight/day or 2.0 mg/kg/year for a 70 kg individual. These values were not corrected for dermal absorption, but absorption data in rabbits indicated that 30.1 to 71.1% of the available permethrin would be absorbed. Estimates of the carcinogenic risk were determined by multiplying the exposure estimate by a Q^{1*} of 1.84 X 10⁻² (mg/kg/day)⁻¹, and risk estimates were presented as follows:

Risk for the low absorption rate = 1.3 X 10⁻⁵

Risk for the high absorption rate = 3.2 X 10⁻⁵

These risks were considered overestimations, and they were corrected by a factor of 0.011 based on corrections for

1. more likely duration for wearing of BDU's and
2. rabbit skin is approximately 10 to 15 times more permeable to chemicals than human skin.

The corrected risk estimates for the previous use were:

Risk for the low absorption rate = 1.4 X 10⁻⁷

Risk for the high absorption rate = 3.5 X 10⁻⁷

- 3 -

B. U. S. Army Risk Characterization

The Army's risk characterization for its permethrin products used in treating BDU's was conducted by Schiefer (1990). That assessment was based on a target permethrin concentration of 0.125 mg/cm^2 of fabric. The chronic daily dermal exposure was estimated to be $3.6 \times 10^{-5} \text{ mg permethrin/kg body weight/day}$, and the risk was estimated using a Q_1^* of $1.6 \times 10^{-2} (\text{mg/kg/day})^{-1}$. The estimated risk was 6×10^{-7} .

II. Discussion

A. U. S. Army Exposure Assessment

There were several assumptions made in the Army's assessment of the dermal exposure to permethrin impregnated BDU's upon which the Non-Dietary Exposure Branch should comment.

The Army's assessment also cited data from a summary article on the dermal absorption of pyrethroids as the source for the 2% dermal absorption factor used in the estimation of exposure. These pesticides were formulated as skin creams, lotions or shampoos for use in treatment of scabies, and dermal absorption would not be comparable to the exposure from impregnated fabric (see Zendzian, 1990b). Therefore, the Army risk estimate should be corrected by the 30.1 to 71.1% used in the previous calculations described above (approximately a 15- to 35-fold increase in the risk).

Without verification by the NDEB of the assumptions used in the Army's exposure assessment and adjusting for dermal absorption of available permethrin from treated BDU's, the risk estimates are as follows:

Risk for the low absorption rate = $(6 \times 10^{-7}) \times 15 = 9 \times 10^{-6}$

Risk for the high absorption rate = $(6 \times 10^{-7}) \times 35 = 2.1 \times 10^{-5}$

These estimates are further corrected for the 10-fold greater permeability of rabbit skin in comparison to human skin and the resulting carcinogenic risk may range from 9×10^{-7} to 2.1×10^{-6} .

B. Characterization of Non-Carcinogenic Risks

The Agency's Reference Dose (RfD, formerly known as Acceptable Daily Intake) is based on a no-observed-effect level (NOEL) of 5 mg/kg/day established in a 2-year chronic feeding study in rats. An uncertainty factor of 100 was applied to the NOEL to obtain an RfD of 0.05 mg/kg/day .

Comparison of the daily exposure estimate reported by the Registrant ($0.000036 \text{ mg/kg/day}$) with the NOEL indicates a Margin of Exposure of 5 mg/kg/day divided by $0.000036 \text{ mg/kg/day}$ or 138,889.

- 4 -

This exposure represents a lifetime daily average rather than a maximum estimate of a daily exposure.

If the Registrant's assumptions that 0.49% of the permethrin migrates from treated fabric₂ per day and that there is an initial concentration of 0.125 mg/cm² are appropriate, then there would be 0.0006 mg/cm² available for dermal absorption. Lunchick (1989) stated that an area of 17,420 cm² of skin would be in contact with treated fabric of a BDU, and therefore, 0.0006 mg/cm² X 17,420 cm² = 10.5 mg permethrin would be available for dermal absorption. Using the 30.1 to 71.1% dermal absorption factor suggested by the rabbit study described above, the estimated dermal dose for a 70 kg individual would be 3.1 to 7.5 mg. Correcting for the 10-fold greater permeability of rabbit skin in comparison to human skin, the estimated dermal dose for humans would range from 0.31 to 0.75 mg. The maximum single day exposure could range from 0.31 mg/70 kg body weight = 0.004 mg/kg to 0.75 mg/70 kg body weight = 0.011 mg/kg. Comparing these values to the 5 mg/kg NOEL as above provides MOE's ranging from 1250 to 455.

III. References

Lunchick, C. Memorandum dated July 31, 1989. Subject: Registration of Permethrin for Military Use (HED Project #9-1356). To: G. LaRocca, PM #15, Registration Division, H7505C. 3 pages.

Lunchick, C. Memorandum dated June 13, 1990. Subject: Dermal Exposure Assessment for Permethrin Used as a Tick Repellent (HED Project #0-1177). To: G. LaRocca, PM #15, Registration Division, H7505C. 4 pages.

Schiefer, B. January 5, 1990. Insect/Arthropod Repellent Protective Treatment for Military Battle Dress Uniform. Vol. 3, Permethrin Quantitative Risk Assessment, Registration Supplement. Submitted by U. S. Army Medical Materiel Development Activity, Fort Detrick, Frederick, MD. 21701-3009. MRID 413657-03.

Zendzian, R. Memorandum dated September 1, 1989. Subject: Permethrin Oncogenic Risk Assessment for Military Use on Fabric. To: K. Baetcke, Chief, Toxicology Branch I, Health Effects Division H7509C.

Zendzian, R. Memorandum dated April 17, 1990. Subject: Permanone (Permethrin) Tick Repellent, Dermal Absorption Data. To: R. Gardner, Acting Section Head, Section I, Toxicology Branch I, Health Effects Division H7509C.



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MEMORANDUM

SUBJECT: EPA Id # 63120-R, -E, and -G. Permethrin:
Request from the military for the registration of
three products for use on battle dress uniforms
and clothing and bed netting and other fabrics.

TOX CHEM No.: 652BB
TOX PROJECT No.: 0-0601
Record No.: 258343

FROM: John Doherty *John Doherty* 6/12/90
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Background

The Department of the Army is applying for registration for three products containing permethrin (refer to letter dated January 16, 1990 from Col. Bernard A. Schiefer, Project Manager, Applied Medical Sciences) for use on battle dress uniforms (BDU), bed netting and other fabrics which may come into contact with military personnel. These products are listed below together with their application instructions. The application instructions are included to demonstrate the need for information on applicator and user/wearer exposure.

1. Insect/Arthropod Repellent Protective Treatment for Military Battle Dress Uniform (Company Product Number: 63120-G).

This product contains 9 ml of formulation and is for individual treatment of BDUs. The application procedure as it appears on the label is as follows:

"Place 3/4 canteen cup of clear water into bag. Pour contents of 1 bottle of Permethrin into bag. Ziplock bag and shake 2 times to mix. Unzip bag, place rolled and tied coat or trousers in bag. Ziplock, shake 2 times and let stand 2 1/2 hours or more. Unzip bag, remove garment and hang for 3 hours or until dry. When dry, garment is ready to wear. Mark uniform with date of treatment. DO NOT RETREAT UNIFORMS; one treatment is effective for the life of the uniform. DO NOT TREAT UNDERWEAR OR CAP".

2. Insect/Arthropod Repellent Fabric Treatment (Company Product Number: 63120-R).

This product contains 151 ml of formulation and is for use by certified or trained personnel for treating BDUs or bed nets using a two gallon sprayer. The application procedure as it appears on the label is as follows:

"TO AVOID INHALATION, APPLICATOR MUST WEAR RESPIRATOR. Thoroughly clean 2-gallon field sprayer by triple rinsing with clean water. Place entire contents of permethrin container to two gallons of clean water in a 2-gallon field sprayer. Agitate and bring to a pressure of 55 psi. For clothing: Place each article of Battle Dress Uniform (jacket and trousers) on the ground and spray each side for 50 seconds at 55 psi. Hang the uniform for 3 hours or until dry. When dry, garment is ready to wear. Mark uniform with date of treatment. DO NOT RE-TREAT UNIFORM: one treatment is effective for life of the uniform. DO NOT TREAT UNDERWEAR OR CAP. For bednet: Spread netting on the ground and spray at a distance of 12-18 inches using a fan nozzle at 55 psi. Spray with a slow sweeping motion to completely cover the netting fabric without runoff."

- 3 . Insect/Arthropod Repellent Treatment for Military Battle Dress Uniform Fabric (Company Product Number: 63120-E).

This product is a 30 gallon container for industrial treatment of camouflage fabrics prior to manufacturer of BDU which may be specified in times of mobilization (not during peacetime). The application

procedure as it appears on the label is as follows:

"Pass Battle Dress Uniform fabric through a 40% permethrin/water emulsion bath of a Proctor Schwartz padder (or equivalent) and then through a set of squeeze rolls at a constant pressure resulting in a treatment level of 0.125mg/cm²."

All three products contain 40% permethrin and are stated as being identical to Fairfield American Corporation's Permanone 40 MFG Concentrate (EPA Reg. #4816-552).

No new toxicity data were submitted with this application. A document entitled "Volume 2 Permethrin Toxicology Summary Registration Supplement" was provided. This document was perused by Toxicology Branch I (TB-I) and it is noted that the data were previously reviewed by the Agency.

The registrant also submitted a document entitled "Volume 3 Permethrin Quantitative Risk Assessment Registration Supplement" (copy attached). This document contains the registrants approach to a quantitative carcinogenic risk assessment for the proposed usage of these products in/on military fabrics. TB-I has perused this document. The Agency, however, will do its own quantitative carcinogenic risk assessment pending finalization of the exposure assessment by Non-Dietary Exposure Branch and determination of the dermal penetration factor (refer to points 1, 2 and 3 below). HED will utilize a Q_1^* of 1.82×10^{-2} which is slightly different from the Q_1^* of 1.6×10^{-2} when the ^{Agency} does the risk assessment. The Agency also expects to do a MOE evaluation utilizing the systemic NOEL of 5 mg/kg/day based on the NOEL of the rat chronic feeding study.

Before the quantitative carcinogenic risk assessment and MOE evaluation will be done by TB-I, the product manager and/or registrant is advised of the following:

1. Each product will have to be reviewed by Non-Dietary Exposure Branch to determine the extent of exposure to military personnel and applicators. Considerations in the exposure assessment should include the possibility that some personnel may be exposed to permethrin resulting from all three of the products.
2. The migration of permethrin from the fabrics to the skin resulting from the treatment of different types of fabric should be demonstrated and related to each of the three products.

NOTE: The labels of these products may have to be modified to clearly define the fabric material to which these products may be applied.

3. There is still no study which TB-I considers acceptable which defines the dermal penetration of permethrin. Such a study should be conducted and submitted to the Agency to support the use of these products.

[Note 1: The reference which states that dermal penetration of permethrin is 2%/day (Taplin and Meinking, 1987, see page 5 of the registrant's risk assessment document) has not been reviewed by HED and based on the title of the paper the product tested is probably a cream designed for topical application to skin. If so the data from this study would not be acceptable for demonstrating dermal penetration for the proposed use on military fabric.]

Note 2: In supporting an earlier registration of a permethrin containing product for military use, TB-I considered the data from the studies by Snodgrass on the migration of radiolabelled permethrin from fabric to skin to be acceptable for that particular registration. TB-I still considers that a study designed to assess the dermal penetration of permethrin is necessary to support additional registrations for fabric treatment with this insecticide.]

4. NDEB is also requested to review all assumptions and quantitative data related to the exposure to permethrin as it is presented in the risk assessment provided by the registrant (refer to Volume 3 "Permethrin Quantitative Risk Assessment Registration Supplement" submitted by Col. Bernard Schiefer, January 5, 1990).

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**INSECT/ARTHROPOD REPELLENT
PROTECTIVE TREATMENT FOR MILITARY
BATTLE DRESS UNIFORM
EPA REG. NO.
BASIC FORMULATION (FE C75)**

**VOLUME 3
PERMETHRIN QUANTITATIVE RISK ASSESSMENT
REGISTRATION SUPPLEMENT**

SUBMITTED BY COL BERNARD SCHIEFER

**U.S. ARMY MEDICAL MATERIEL DEVELOPMENT ACTIVITY
FORT DETRICK, FREDERICK, MARYLAND 21701-5009**

JANUARY 5, 1990

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

Company: U. S. Army Medical Materiel Development Activity

Company Agent: COL Bernard Schiefer

Date: 1/5/90

Project Manager
(Title)

Bernard G. Schiefer
(Signature)

QUANTITATIVE RISK ASSESSMENT
PERMETHRIN-IMPREGNATED BATTLE DRESS UNIFORM
OCTOBER 1989

1. REFERENCES. See Appendix for a list of references cited in this assessment.

2. BACKGROUND AND INTRODUCTION. The following describes the procedures used to quantify the potential carcinogenic risks from wearing the permethrin-impregnated Battle Dress Uniform (BDU). A risk assessment is an attempt to describe potential health risks resulting from specific exposure scenario to a given contaminant. For the present assessment, we proceeded in stages as recommended in reference 1.

a. Hazard Evaluation. This is the process of gathering and evaluating all data that may reveal the type of adverse effects produced by a substance. This can include animal as well as human toxicity data.

b. Dose Response Evaluation. In this step, the dose response relationships are described for each biological response. This step also includes extrapolation of animal data to humans, if required.

c. Human Exposure Evaluation. Qualitative and quantitative descriptions of each potential exposure route are detailed. Populations at risk and sensitive subgroups should also be identified.

d. Risk Characterization. This involves combining the analyses in the above steps to provide a measure of the potential risks.

3. PERMETHRIN RISK ASSESSMENT.

a. Hazard Evaluation. Several recent reviews have summarized the toxicity of permethrin (references 2 and 3) and these should be consulted for more complete information. In this assessment, we will focus on potential carcinogenic risks. Seven long term carcinogen bioassays have been performed with permethrin. Of these, only one (FMC Mouse II) showed a statistically significant dose-related increase in cancer. In this study, female mice exhibited an increased incidence of alveolar cell adenomas and carcinomas. These animals also tended to have a dose-related increase in liver adenomas and carcinomas. This study was used by the Environmental Protection Agency (EPA) as the basis for classifying permethrin as a Category C compound (possible human carcinogen).

b. Dose Response Extrapolation. A key toxicity value in quantifying potential carcinogenic risk is the carcinogen potency factor. This value represents the slope of the upper 95% confidence interval of the extrapolated dose response curve. A published potency factor was not available for permethrin, so we derived a value based on the positive female mouse data. This process involved extrapolation of the bioassay data from high doses to low doses and then to humans. We used the Linearized Multistage Model for dose extrapolation. This model is relatively conservative and results in a plausible upper bound estimate of risk (reference 4). This is also the model

Permethrin Risk Assessment—2

used by the EPA for most of their published potency factors. As recommended in reference 5, alveolar cell adenomas were combined with carcinomas for use in the dose response extrapolation. Animal doses were converted to human dose levels using a surface area correction as described in reference 4. Table 1 summarizes the data and results of the dose response extrapolation.

TABLE 1. DATA SUMMARY AND DOSE RESPONSE EXTRAPOLATION

Concentration in Food (ppm)	Daily Dose * (mg/kg/day)	Human Equivalent ** Dose (mg/kg/day)	Tumor Incidence
0	0	0	15/74
20	2.7	0.2	24/74
2500	333	25	35/75
5000	667	50	44/75

Oral Potency Factor: $0.016 \text{ (mg/kg/day)}^{-1}$

* Based on animal weight of 30 grams and 4 grams food per day.

** Human equivalent Dose = Animal Dose / $(70 \text{ kg} / 0.03 \text{ kg})^{1/3}$

c. Exposure Assessment. The current exposure assessment addresses potential human exposures resulting from wearing a permethrin-impregnated BDU. It is anticipated that this treatment process will be utilized by military personnel, deployed to areas posing a recognized threat from insect-borne diseases. Two potential exposure routes should be addressed: inhalation of vapor volatilizing from the fabric and dermal exposures.

(1) Inhalation. Since permethrin is a solid at room temperature and has a relatively low vapor pressure (10 torr at 50°C), the inhalation route is probably insignificant and will not be considered further.

(2) Dermal. A preliminary exposure assessment was previously published (reference 6). The predicted exposure of approximately 0.005 mg/kg/day was based on continuous wear of a uniform impregnated with permethrin at a target concentration of 0.125 mg/cm^2 . Skin area exposed to contaminant was assumed to be 2.2 m^2 with a dermal penetration of 2%. Although field operations may require soldiers to wear the BDU on a continual basis, this seems an unlikely scenario for more than a few days. Similarly, estimates of carcinogenic risk are typically based on a lifetime exposure,

Permethrin Risk Assessment—3

however, no one will spend an entire lifetime in the military. Finally, laundering of the BDUs removes a portion of the impregnant with each wash as does migration of the compound out of the fabric during wear. We therefore have adjusted the predicted exposure factors to account for these differences:

(a) Initial Treatment Level - 0.125 mg/cm^2

(b) Adjustment Factor - 26 %

Time-weighted average of permethrin remaining in impregnated 100% cotton and NYCO BDU fabrics through 50 washings (reference 7).

(c) Body Contact area - 1.5 m^2

EPA has established that the average body surface area for a 70 kg man is 1.9 m^2 . This value is adjusted to 1.5 m^2 when the area for hands, feet, head and neck (not contacted by the impregnated cloth) is subtracted (reference 8).

(d) Dermal Absorption - 2 % / day

Value is reported for man (reference 9).

(e) Migration - 0.49 % / day

Permethrin migrating from treated fabrics to the skin surface. Collective experimental data for 7-day exposures in animals (references 6 and 10).

(f) Body Weight - 70 kg.

The EPA uses 60 kg (132 lbs.) as the average body weight. Seventy kg (154 lbs.) is more realistic for military combat personnel.

(g) Daily Wear - 16 hrs / day

While soldiers may sleep in clothing, 16 hours per day is the maximum predicted contact time when averaged over a 6-year exposure period.

(h) Time Worn (Exposed) - 6 yrs

Initial assignment of 3 years is typically followed by a 3-year reenlistment.

(i) Lifetime - 75 years

From EPA guidelines (reference 8).

13

Permethrin Risk Assessment—4

The Exposure Dose (ED) is derived by multiplying the values (a) through (f); the value for (f) being 1/70.

$$\text{Exposure Dose} = 6.8 \times 10^{-4} \text{ mg/kg/day.}$$

The Chronic Daily Intake (CDI) is derived by modifying the ED by the predicted exposure period:

$$\begin{aligned} \text{Chronic Daily Intake} &= 6.8 \times 10^{-4} \text{ mg/kg/day} \times (16/24) \times (6/75) \\ &= 3.6 \times 10^{-5} \text{ mg/kg/day} \end{aligned}$$

d. Risk Characterization. An estimate of carcinogenic risk can be calculated using the potency factor and CDI values derived above. This calculation is shown in the following expression:

$$\begin{aligned} \text{RISK} &= (\text{CDI}) \times (\text{Potency Factor}) \\ &= (3.6 \times 10^{-5} \text{ mg/kg/day}) \times (1.6 \times 10^{-2} \text{ mg/kg/day}) \\ &= 6 \times 10^{-7} \end{aligned}$$

This value represents an upper bound estimate of carcinogenic risk under the exposure conditions outlined above. Under the assumed conditions, an individual faces a probability of less than 1 chance in 1,000,000 of developing cancer as a result of permethrin exposure. In terms of populations, we would expect 1 excess cancer to develop in 2,000,000 exposed individuals as a result of permethrin. These calculations are based upon very conservative assumptions, and in all likelihood, actual risks will be less than this value.

e. Uncertainties.

(1) Toxicological Assessment/Dose Extrapolation. As discussed in reference 4, there are many uncertainties in the low dose extrapolation and animal to human extrapolation which could affect the actual risk to exposed humans. There are important species differences in contaminant uptake, distribution and metabolism as well as target organ susceptibility for which we have no information. Our potency factor derivation is also based on summaries of animal data and not the original literature. We were forced to estimate animal dose levels based on estimated body weights and food consumption rates.

(2) Human Exposure. In the exposure dose assessment, the 6.8×10^{-4} mg/kg/day estimated dose was based in part on a daily migration rate from fabric to skin of 0.49%. This value was determined experimentally in animal studies and represents the maximum rate measured over the first seven days of continuous wear. Subsequent weeks showed a much smaller transfer of contaminant (reference 11). Laundering of these garments would

Permethrin Risk Assessment—5

be expected to reduce the migration rate even further. The dermal penetration rate is a second critical value which could dramatically affect estimated risks. The 2% penetration value was taken from a literature summary (reference 9) and represents the maximum absorption seen in human volunteers. Average values were approximately half this value. Finally, the effects of weathering on the permethrin content of treated BDUs were not considered. It is likely that these factors, particularly photodynamic, may significantly accelerate degradation of the substance.

Permethrin Risk Assessment—6

APPENDIX

REFERENCES

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