

EFFICACY REVIEW

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FILE OR REG. NO. 50404-L

PETITION OR EXP. PERMIT NO. _____

DATE DIV. RECEIVED May 23, 1989

DATE OF SUBMISSION May 22, 1989

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TYPE PRODUCT(S): (I, D, H, F, N, R, S) Repellent

DATA ACCESSION NO(S). 411135-01; 411135-02; Record Number: 246155; Action Code: 166

PRODUCT MGR. NO. 15-LaRocca

PRODUCT NAME(S) Permethrin Arthropod Repellent

COMPANY NAME Coulston International Corporation

SUBMISSION PURPOSE Provide performance data in support of use against
Aedes taeniorynchus mosquitoes and Amblyomma ameri-
cana, Ixodes dammini and Dermacentor variabilis ticks,

CHEMICAL & FORMULATION Permethrin 0.50%
(aerosol spray, 6 ounces)

CONCLUSIONS & RECOMMENDATIONS See attached.

50404-L, submission of May 22, 1989

200.0 Introduction

200.1 Use(s) (see label)

200.2 Background information

Coulston International Corporation, in cooperation with the United States Army Environmental Hygiene Agency, is developing a permethrin arthropod repellent for application to battle dress uniforms (BDU's) for the purpose of protecting military personnel from attack by mosquitoes, chiggers and ticks, as well as other arthropod pests. This is the aerosol formulation designed to be applied by the wearer to the uniform and associated netting prior to exposure to arthropod-infested habitats. A previous submission received August 22, 1988 was reviewed by Phillip O. Hutton on February 9, 1989.

200.2.1 Factors affecting amount/type of data required

Conclusions from the aforementioned previous review:

- A. It was pointed out that no data had been submitted regarding the use of aerosols for chiggers, mosquitoes or other pests.
- B. While the data indicated excellent protection against lone star tick, Amblyomma americana and deer tick, Ixodes dammini, a limitation of label claims to those 2 species would require revised label wording instructing the user to apply the product for a minimum of 30 seconds to each shirt or pair of pants treated.
- C. Other label claims were not acceptable pending the submission of data indicating the ability of the application system to deliver the target dose of 0.125 mg per cm².
- D. Mention was made of the need to establish a drying time following application of the product which the user could rely on to prevent violation of the warning to not allow contact with the treated surface until the spray had dried. Recommendation was made for submission of information indicating a drying time (assuming humid conditions) prior to wearing.

201.0 Data Summary

201.1 Abstract of test reports

- A. EPA Accession (MRID) Number 411135-01, entitled "Evaluation of Everglades Testing of Permethrin Aerosol Treated Battle Dress Uniforms", contains 11 pp.; author is Travis B. Griffin, Ph.D., D.A.B.T.; performing laboratory is Coulston International Corporation, Easton, PA 18044; study completed May 2, 1989.
- B. EPA Accession (MRID) Number 411135-02, entitled "Field Evaluation of a Permethrin-Impregnated Battle Dress Uniform (BDU) versus a Permethrin-Sprayed BDU for Prevention of Tick Bite", contains 54 pp.; author is Sandra R. Evans; performing laboratory is the United States Army Environmental Hygiene Agency, Aberdeen Proving Ground, MD 21010; study completed August 17, 1988.

201.1.1 Brief description of tests

- A. "The repellent activity of Battle Dress Uniforms (BDU's) sprayed with Permanone" brand of 0.5% permethrin was studied in the Everglades National Park. The test included groups of volunteers who wore BDU's which had been sprayed with the aerosol. The uniforms were worn with and without additional application of deet insect repellent to exposed skin (arms, face and neck) and, during walks along the park trails, tallies of mosquito bites through the BDU's and on the skin were recorded. Some sets of BDU's had been washed 2 or 5 times. The number of bites was compared with those obtained when the volunteers wore BDU's which had no repellent treatment.

"Treatment of BDU's with Permanone" brand of 0.5% permethrin aerosol spray provided excellent protection against mosquito bites. Furthermore, the efficacy of the repellent activity of the treated BDU's was not decreased by 2 or 5 washings as the concentration of permethrin decreased from 0.024 mg/cm² (0 washings) to 0.011 mg/cm² (5 washings). Protection from mosquito bites was improved when additional repellent [in the form of deet lotion] was applied to the exposed skin and, mosquitoes are repelled even in the vicinity of permethrin sprayed BDU's."

- B. "To conduct a field evaluation of a permethrin-impregnated battle dress uniform (BDU) versus a permethrin-sprayed BDU for the prevention of tick bite. The effectiveness of an extended-duration deet repellent formulation in preventing tick bites, when applied to uniforms only, was compared to the permethrin treatments..."

"In general, the mean number of ticks found on uniforms from each treatment category decreased in the following order: untreated, deet-treated, permethrin-impregnated (PI), and permethrin-sprayed (PS) uniforms.

"Significant differences were observed among the treatment means ($p < 0.05$). The two permethrin-treated categories did not differ significantly from each other, but were significantly different from the other treatments. The number of ticks found on deet-treated uniforms also differed significantly from that found on untreated uniforms.

"Only two ticks (one impaired and one dead) were found on the skin or undergarments of subjects wearing either of the permethrin treatments. No skin-attached ticks were found on subjects from either category. In contrast, low numbers of ticks were frequently found on subjects who wore untreated or deet-treated uniforms. All of these ticks were alive, and a number were attached to the skin.

"Both PI- and PS-treated BDU's provided excellent protection from tick bites.

"Permethrin, whether applied as an aerosol spray or as an impregnant was more effective than deet, applied to uniforms only, in protecting individuals from tick bite.

"The slightly higher, but statistically insignificant, protection provided by the PS uniform over the PI uniform was most likely due to the frequent application procedures used in this study.

201.1.1, B. (continued)

"Deet was less consistent in its protection of individuals from tick bite than either of the permethrin treatments.

"A system combining one of the permethrin treatment methods with a dermal application of the deet formulation should provide the soldier with nearly 100% protection from a variety of biting arthropods, including ticks.

"The ease, convenience and persistence of a one-time IDA [individual dynamic absorption] treatment makes permethrin-impregnation very practicable for long-term field use. The use of deet lotion, solely as a uniform treatment, is not an acceptable alternative to the permethrin treatments."

201.1.2 Data summaries (attached to reviewer's copy only)

A. Tables I and II from pages 10 and 11, respectively, of MRID No. 411135-01

1. Mosquito Bites Through Battle Dress Uniforms (BDU's)
2. Mosquito Bites on Skin (Arm/Head)

B. Tables 1 and 5 from pages 22 and 30, respectively, of MRID No. 411135-02

1. Total number of ticks collected from BDU's, tabulated by species and life stage.
2. Percent protection provided by deet, PI and PS against I. dammini, D. variabilis and A. americana.

202.0 Conclusions

202.1 Claims supported by the data submitted

- A. The data presented in EPA MRID No. 411135-01, having been obtained from field testing conducted according to a protocol incorporating the essential features of § 95-9(a) on p. 263 and meeting the standards of § 95-9(b)(1)(iv) on p. 264 of the Product Performance Guidelines, are adequate to support the claims "kills/repels mosquitoes [of genus Aedes]" and "for protection against mosquitoes [of genus Aedes]" when the subject product is applied according to the directions as to rate and frequency to battle dress uniforms of 100% cotton or of 50% nylon/50% cotton.
- B. The data presented in EPA MRID No. 411135-02, having been obtained from field testing conducted according to a protocol incorporating the essential features of § 95-9(a) on p. 263 and meeting the standards of § 95-9(b)(1)(iii) on p. 264 of the Product Performance Guidelines, are adequate to support the claims "kills/repels ticks" and "for protection against ticks" when the subject product is applied according to directions to battle dress uniforms of 100% cotton or of 50% nylon/50% cotton.

202.2 Claims not supported by the data submitted

202.2.1 Insufficient data

There is not enough data in MRID 411135-01 to establish a general claim for kill/repellency of mosquitoes since only one species was tested.

202.3 Additional data required to support claims and achieve registration

A minimum of either laboratory or field testing using mosquitoes of the genera Anopheles, Culex, Culiseta, Mansonia and/or Psorophora, with special emphasis on the first 2 listed, and using a rate equivalent to approximately 0.025 mg/cm² on treated clothing, is needed to establish the general claim for kill/repellency of mosquitoes when the subject product is applied according to label directions.

202.3.1 P. M. Note

The data presented in MRID Nos. 411135-01 and 411135-02 are adequate to establish that it is not required to achieve a deposit of 0.125 mg/cm² on treated clothing in order to achieve satisfactory protection against mosquitoes and ticks; that the aerosol formulation is equally effective in comparison to the clothing impregnation with a solution made from the wettable powder; and to establish that a drying time of 2 hours generally to 4 hours under humid conditions is satisfactory to ensure that the wearer will not come into contact through the skin with permethrin based on the fact that permethrin-impregnated battle dress uniforms were allowed to dry for at least 5 hours, and the volume of liquid applied at one time in an aerosol spray is much less.

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July 11, 1989

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