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

001743

AUG 3 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Eye Irritation Studies on N,N-diethyl Toluamide (DEET) and Ethanol

TO: Mr. Tim Gardner (PM-17)
Registration Division (TS-767)

FROM: Byron T. Backus B.T. Backus 7-30-84
Toxicology Branch
HED (TS-769)

THROUGH: William Butler, Head William Butler 8-1-84
Review Section III
and
William Burnam, Chief
Toxicology Branch

Registration # 4822-7

Tox. Chem. 346

Registrant: S.C. Johnson & Son, Inc.

Action:

This is a review of eye irritation studies on Deet, Deet/ethanol and ethanol formulations. According to the information received, these studies utilized the standard Draize method of scoring as well as measurements of corneal thickness, area of corneal epithelial damage, and corneal "reepithelialization" to assess irritation potential.

Conclusions:

1. This study has been classified as invalid.

2. There is extremely poor presentation of the raw data, and a considerable amount is missing. There is no breakdown, in most cases, of the relative contributions of conjunctival and iridial irritation, or degree of corneal opacity (and area affected) to the Draize scores.

3. The data which are presented are sometimes confusing. There appear to have been two animals numbered 44, two numbered 47, and two numbered 52.

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4. An additional problem is that there are some inconsistencies in the data. As examples, on one page animals #53, #52, #55, and #54 (in eyes treated with 100 ul Deet) are reported as having had Draize scores of 19, 4, 19 and 5 respectively at 24 hours. On another sheet (the following page) the same animals and same eyes are reported as having Draize scores of 29, 24, 19 and 25 respectively at 24 hrs.

5. It is disturbing that at 168 hours there remained a corneal "cloudiness" in eyes which had been treated with 80% EtOH-20% Deet or 100% Deet, but that Draize scores for these eyes were zero.

6. No Draize scores (either as averages or for individual eyes) are presented for the testing involving 50% Deet-50% EtOH or 80% Deet-20% EtOH.

7. Although the affiliation of ~~one~~ some of the investigators is given as the Medical College of Wisconsin there is no indication as to where or when these studies were actually conducted.

Discussion:

While the report text is well written (and has been accepted for publication) the presentation of the raw data on which the report is based is both unsatisfactory and disquieting.

A major problem is the poor presentation of Draize scores, with an almost complete lack of individual Draize scores, and a breakdown for conjunctival and iridial irritation, as well as degree and extent of corneal involvement.

It is extremely disturbing that there are a number of occasions for which a corneal score of 1.0 or 1.5 is given, but that simultaneously the Draize score is reported as zero.

However, beyond this there are problems of inconsistencies in the data as presented. On one page animals #53, #52, #55 and #54 (in eyes treated with 100 ul Deet) are reported as having had Draize scores of 19, 4, 19 and 5 respectively. On another page these values are reported as 29, 24, 19 and 25 respectively. Animal #55, treated in its left eye with 80% EtOH-20% Deet, is reported as having had a Draize score of 15 for this eye at 1 week; however, the average for the group is reported as 0! Animal B125 (also reported as 6125) is reported as having a Draize score of 2 at 72 hours on one sheet and 32 at 72 hours on another sheet.

From these considerations, the study is classified as Invalid.

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Data Evaluation Report

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Compound:

N,N-diethyl-m-toluamide (DEET)

Citation:

S.M. Mac Rae, M.D., B.A. Brown, M.D., J.L. Ubels, Ph.D., H.F. Edelhauser, Ph.D., and C.L. Dickerson, Ph.D. The Ocular Toxicity of Diethyltoluamide (Deet). The affiliation of most of the investigators is given as the Medical College of Wisconsin, 8701 Watertown Plank Rd, Milwaukee, WI 53226; however, there is no confirmatory statement that this was where the study was conducted. There is no information as to when the study was conducted. The write-up was submitted to the Journal of Toxicology, Cutaneous and Ocular Toxicology on November 28, 1983. The data were received at EPA 1-26-84, and are in Acc. 252568.

Reviewed by:

Byron T. Backus B.T. Backus
Toxicologist 7-30-84

Core Classification: INVALID

Conclusion:

The reporting of individual eye irritation scores is inadequate. What information is present is group averages, and the data is presented in graph form. It is impossible to reconstruct the study from the copies of raw data which are provided, particularly as a considerable amount of information is missing.

The most serious problem involves inconsistencies in the data. The most glaring example is found on comparing the first and second "large" pages of raw data. On the first page animals #53, 52, 55 and 54 are reported as having Draize scores of 19, 4, 19 and 5 respectively at 24 hours. On the second page the Draize scores of three animals appear to have been changed so that they are 29, 24, 19 and 25 respectively.

There are additional problems with this study. However, it is pointless to attempt to list them when the discrepancies force a core classification of invalid.