12-9-91

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MEMORANDUM:

Subject: EPA File Symbol/EPA Reg. No.: 4822-204 6017 Formula 7 Insect Repellent

From: Mark Perry, Biologist
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

MDP 12-4-91

To: Richard Mountfort, PM 10
Insecticide-Rodenticide Branch
Registration Division (H7505C)

Thru: Thomas C. Ellwanger, Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (H7505C)

12/9/91

Applicant: S.C. Johnson & Son, Inc.
1525 Howe Street
Racine, WI 53403

FORMULATION FROM LABEL:

		% by wt.
Active Ingredient(s):	N,N-diethyl-meta-toluamide (DEET)	28.50
	Other DEET isomers	1.50
Inert Ingredient(s):		70.00
Total:		100%

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BACKGROUND

S.C. Johnson & Son submitted a dermal sensitization study as requested in the Agency letter dated 9-13-90. The product is 6017 Formula 7 Insect repellent and the active ingredients are N,N-diethyl-meta-toluamide (DEET) (28.50%) and other DEET isomers (1.50%). The study was performed by Hill Top Biolabs and the MRID number is 419919-01.

RECOMMENDATION

Since the sensitization study was performed with Deep Woods OFF and not the subject product, 6017 Formula 7 Insect Repellent, the study has been graded core supplementary. The registrant must submit a sensitization study performed with the subject product. In addition, a review of acute toxicity data supporting this product revealed only an eye irritation study. Since a complete battery of acute studies is required, the Registrant must also submit or cite acute oral, acute dermal, acute inhalation, and dermal irritation studies or acceptable waiver requests to support the registration of the subject product.

LABELING

The following label revisions are based on the category two eye irritation study. Further label revisions may be required upon submission of outstanding acute study data.

(1) The first three sentences of the precautionary statements should read as follows:

"Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or safety glasses."

The following should also appear under precautionary statements:

"Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

(2) The statements of practical treatment should read as follows:

IF IN EYES: Flush with plenty of water. Call a physician.
IF SWALLOWED: Call a physician or Poison Control Center. Drink promptly a large quantity of milk, egg whites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol.

NOTE TO PM: Some of the precautionary statements appropriate for eye irritation category two (2) materials may not be practical for this product. The PM should decide how to resolve this situation.

ACUTE TOXICITY PROFILE

Acute Oral	Requested
Acute Dermal	Requested
Acute Inhalation	Requested
Eye Irritation*	Category 2/Guideline
Dermal Irritation	Requested
Dermal Sensitization	Supplementary

* See memo (4-6-?) from D. Williams to A. Castillo

NOTE TO PM: Due to eye irritation, this product meets the criteria for restricted use classification. The PM should decide if the label contains sufficient alternative labeling language to offset the need for this classification.

DATA REVIEW FOR SKIN SENSITIZATION TESTING (§81-6)

Product Manager: 10
MRID No.: 419919-01
Testing Laboratory: Hill Top
Author(s): T. Morris
Species: Guinea pig
Weight: --
Source: Murphy Breeding Labs
Test Material: Deep Woods OFF
Positive Control Material: DNCB
Quality Assurance (40 CFR §160.12): Present

Reviewer: M. Perry
Report Date: 11-30-90
Report No.: 90424921

Method: Buehler

Summary:

1. **According to the results of this study, the test material is not a dermal sensitizer.**

2. **Classification:** Supplementary

Procedure: Twenty test animals were exposed (for 6 hrs) to the test material once per week for three weeks. The appropriate dose level was determined from a range-finding study prior to the main study. Following a two week rest period, the test animals and a group of naive controls were exposed, at naive sites, for a period of six hours. The exposure sites were evaluated at twenty-four and forty-eight hours.

Results: Six of twenty test animals exhibited +/- scores at twenty-four and forty-eight hours. Two of ten naive animals at twenty-four and four of ten at forty-eight hours exhibited +/- grades.

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