2-13-91

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

FEB 13 1991
1991

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 4822-GAE

OFF! Lotion Formula II

FROM: Mary L. Waller
Precautionary Review Section
Registration Support Branch
Registration Division (H75-05C)

2/13/91 (for Tom Ellwanger 2-13-91)

TO: Philip Hutton (PM 17)
Insecticide-Rodenticide Branch
Registration Division (H75-05C)

APPLICANT: S.C. Johnson & Sons, Inc.
1525 Howe Street
Racine, WI 53403

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
N,N-Diethyl-meta-Toluamide	7.125
Inert Ingredient(s):	92.5
Total	100.0%

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BACKGROUND: The registrant has submitted an acute oral, acute dermal, primary eye irritation, primary skin irritation, and dermal sensitization study. The registrant has stated that an acute inhalation toxicity study was not conducted because the product is not an airborne insecticide. The studies were conducted by Hill Top Biolabs., Inc. The MRID numbers are 415162-02 through -06.

RECOMMENDATIONS: RSB/PRS finds that the data is acceptable and classified as core guideline.

However, according to the Registration Standard for DEET, this product cannot be registered for its current intended use (domestic use) because of the primary eye irritation study results (Toxicity Category II Classification). In the Deet Registration Standard on page 10, under Acute Toxicity Limits, No. 2. Formulated Deet, it is stated that Deet products must not demonstrate eye irritation persisting for seven days or any corneal opacity in test animals.

The primary eye irritation study on this product not only exhibited corneal opacity, but also the corneal opacity did not clear until day 10.

NOTE TO PM:

The registration standard on Deet (page 46) states that two primary eye irritation studies on 15% formulated Deet products produced no corneal opacity and mild eye irritation which cleared by 72 hours. Speculating based on this fact, the registrants problem may not be with the Deet in his product (7.125%) but rather with some of the inerts contained in the formulation.

LABELING:

No labeling will be recommended at this time based on the fact that the current product is not registerable for its intended use.

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DATA REVIEW FOR ACUTE ORAL TOXICITY TESTING (§81-1)

Product Manager: (17)
MRID No.: 415162-02
Testing Facility: Hill Top Biolabs, Inc.
Author(s): James A. Kruezman, B
Species: Sprague-Dawley rats
Age: Young Adult
Weight: ♀: 206-249 g; ♂ = 251-283 g
Source: Harlan-Sprague Dawley, Inc.
Test Material: Lotion Repellent 5966D130 Batch #030790F (pale Green cream)
Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
Report Date: 4-3-90
Report No. 90-4043-21(A)
Observation Days (Post Exposure): (14); other ( )

Conclusion:

1. LD_{50} (mg/kg): Males = _____; Females = _____; Combined = _____
2. The estimated LD_{50} is > 5.0 g/kg
3. Tox. Category: IV. Classification: Guideline Data

Procedure (Deviations From §81-1): NONE

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
5.0 g/kg	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

Toxic symptoms observed were gasping breathing, piloerection, and fecal stains in males. No toxic symptoms were observed in the females.

No abnormalities were noted at necropsy.

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DATA REVIEW FOR ACUTE DERMAL TOXICITY TESTING (§81-2)

Product Manager: (17)
Reviewer: M. Waller
MRID No.: 415162-03
Report Date: 4/4/90
Testing Laboratory: Hill Top Biolabs, Inc.
Report No. 90-4043-2(B)
Author(s): James J. Kreuzmann
Species: New Zealand white rabbits
Sex: ♂ + ♀ Wt.: 2491-3388 g
Test Material: Lotion Repellent #5966D130 Batch #030790F1 (pale green cream)
Quality Assurance (40 CFR §160.12): Attached

Summary:

1. LD_{50} (mg/kg): Males = _____; Females = _____; Combined = _____;
2. The estimated LD_{50} is >2.0 g/Kg
3. Tox. Category: III. Classification: Guideline Data

Procedure (Deviations From §81-2): none

Results:

Reported Mortality

DOSAGE (/kg)	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
2.0 g/Kg	0/5	0/5	0/10

Symptomology & Gross Necropsy Findings:

Two animals exhibited nasal discharge. Animals exhibited erythema, edema, coriaceous ness and desquamation at test site.

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DATA REVIEW FOR ACUTE EYE IRRITATION TESTING (§81-4)

Product Manager: (17)
MRID No.: 415162-04
Testing Laboratory: Hill Top Biolabs, Inc.
Author(s): James J. Krauzemann
Species: New Zealand White rabbit
Sex: 3♂ + 3♀ Weight: Not specified
Source: Hasenpfeffer Hill Experimental Rabitry
Dosage: 0.1 ml
Test Material: Lotion Repellent 5966D130 (Pale green cream) Batch # 030790F2
Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
Report Date: 6/1/90
Report No. 90-4043-21D

Summary:

Tox. Category: II Classification: Core Guideline Data

Procedure (Deviation From §81-4): —

Results:

	Observations (number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	10 7	10 14	21
Cornea Opacity	2/6	6/6	4/6	3/6	3/6	2/6	0/6	
Iris	3/6	3/6	3/6	1/6	0/6	0/6	0/6	
Conjunctivae Redness	0/6	4/6	5/6	2/6	1/6	0/6	0/6	
Chemosis	6/6	5/6	4/6	2/6	1/6	0/6	0/6	
Discharge	6/6	1/6	0/6	0/6	0/6	0/6	0/6	
Blistered appearance of conjunctiva	6/6	5/6	0/6	1/6	0/6	0/6	0/6	
Conjunctiva appears thickened			6/6	6/6	3/6	0/6	0/6	

Comments: —

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DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5)

Product Manager: (17)
MRID No.: 415162-05
Testing Laboratory: Hill Top Biolabs, Inc.
Author(s): James J. Krauzmann
Species: New Zealand white rabbits
Age: Young adult
Sex: 3♂, 3♀
Weight: not specified
Dosage: 0.5 ml
Test Material: Lotion Repellent 5966D130
Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
Report Date: 6-1-90
Report No. 90-4025-21(c)

Summary:

The Primary Irritation Index = _____

Toxicity Category: IV

Classification: Guideline Data

Procedure (Deviations From §81-5): —

Results:

At 24 hours, 4/6 animals exhibited very slight erythema and 1/6 animals exhibited very slight edema. At 48 and 72 hours, all irritation had subsided.

Special Comments:

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

Product Manager: (17)
MRID No.: 415162-06
Testing Laboratory: Hill Top Biolabs, Inc.
Author(s): James J. Kreuzmann
Species: Hartley Albino Guinea Pig
Sex: ♂ + ♀ (10 each) Weight: 398-519 g
Source: Murphy Breeding Laboratories, Inc.
Test Material: Lotion Repellent 5966D Induced - 100% conc.; challenged - 50% in H2O
Positive Control Material: DNCB tested 2-9-90
Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
Report Date: 6-1-90
Report No. 90-4043-2(E)

Method: Buehler

Summary:
1. This product is / is not a dermal sensitizer.
2. Classification: Guideline Data

Procedure (Deviation From §81-6): —

Results: At challenge, (24 hrs.) 8/20 test animals exhibited slight patchy erythema. At 48 hrs. after challenge, 7/20 test animals exhibited slight patchy erythema.

At challenge, the naive control group exhibited the following: at 24 hours, 4/10 animals exhibited slight patchy erythema and 3/10 animals exhibited slight patchy erythema at 48 hours.

The average mean score for both groups was 0.2.

At challenge, 10/10 positive control animals exhibited slight confluent to severe erythema, and 2/10 animals exhibited edema and blanching. The 5 naive control animals exhibited slight patchy erythema.