

US EPA ARCHIVE DOCUMENT

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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 ^{mw}
Precautionary Review Section ^{2/13/91}
Registration Support Branch ^{OMS (for Tom Ellinger)}
Registration Division (H75-G5C) ²⁻¹³⁻⁹¹

TO: Philip Hutton (PM 17)
Insecticide-Rodenticide Branch
Registration Division (H75-G5C)

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

FORMULATION FROM LABEL:

Active Ingredient(s):	g by wt.
<u>N,N-Diethyl-meta-Toluamide</u>	<u>7.125</u>
_____	_____
_____	_____
Inert Ingredient(s):	<u>92.5</u>
Total	100.0g

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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 FM:

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) Reviewer: M. Waller
 MRID No.: 415162-02 Report Date: 4-3-90
 Testing Facility: Hill Top Biolabs, Inc. Report No. 90-4043-21(A)
 Author(s): James A. Kruczman, MS
 Species: Sprague-Dawley rats
 Age: Young Adult Observation Days (Post
 Weight: ♀=206-249g; ♂=251-283g Exposure): (14); other ()
 Source: Harlan-Sprague Dawley, Inc.
 Test Material: Lotion Replent 5966D130 Batch #030790F (pale green cream)
 Quality Assurance (40 CFR §160.12): Attached

Conclusion:

- LD50 (mg/kg): Males = _____; Females = _____; Combined = _____
- The estimated LD50 is > 5.0 g/kg
- Tox. Category: IV. Classification: Guideline Data

Procedure (Deviations From §81-1): NONE

Results:

DOSAGE (/kg)	Reported Mortality		
	(NUMBER KILLED/NUMBER TESTED)		
	Males	Females	Combined
<u>5.0 g/kg</u>	<u>0/5</u>	<u>0/5</u>	<u>0/10</u>

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)
 MRID No.: 415162-03
 Testing Laboratory: Hill Top Biolabs, Inc.
 Author(s): James J. Kreuzmann
 Species: New Zealand white rabbits
 Sex: ♂ + ♀ Wt.: 2491-3388 g
 Test Material: Lotion Repellent #5966D130 Batch #030790F1 (pak green cream)
 Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
 Report Date: 4/4/90
 Report No. 90-9043-1(B)

Summary:

- LD50 (mg/kg): Males = _____; Females = _____; Combined = _____;
- The estimated LD50 is >2.0 g/Kg
- 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, coriaceousness and desquamation at test site.

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

Product Manager: (17) Reviewer: M. Waller
 MRID No.: 415162-04 Report Date: 6/1/90
 Testing Laboratory: Hill Top Biolabs, Inc. Report No. 90-4043-21D
 Author(s): James J. Krausemann
 Species: New Zealand white rabbit
 Sex: 3 ♂ + 3 ♀ Weight: Not specified
 Source: Hasenpfeffer Hill Experimental Rabbits
 Dosage: 0.1 ml
 Test Material: Lotion Repellent 5966 D130 (Pale green cream) Batch # 030790FZ
 Quality Assurance (40 CFR §160.12): Attached

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	7	10
Cornea Opacity	2/6	6/6	4/6	3/6	3/6	2/6	0/6	
Iris	3/6	3/6	3/6	4/6	0/6	0/6	0/6	
Conjunctivae Redness	0/6	4/6	5/6	2/6	1/6	0/6	0/6	
Chemosis	0/6	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. Kreuzmann
 Species: New Zealand white rabbits
 Age: Young adult
 Sex: 3 ♂, 3 ♀
 Weight: not specified
 Dosage: 0.5 ml
 Test Material: Lotion Repellent 5966 D130
 Quality Assurance (40 CFR §160.12): Attached

Reviewer: M. Waller
 Report Date: 6-1-90
 Report No. 90-4023-21(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%
 Positive Control Material: DNCB tested 2-9-90 IN 172
 Quality Assurance (40 CFR §160.12): Attached

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 bleaching. The 5 naive control animals exhibited slight patchy erythema.