

US EPA ARCHIVE DOCUMENT



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

008644

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No./File Symbol 121-31

Cutter Evergreen Scent Insect Repellent Spray
Formula MIMI

FROM: William S. Woodrow USC 3-12-90
Precautionary Review Section
Registration Support Branch E 3/13/90
Registration Division (H7505C)

TO: Hutton/Tavano (PM 17)
Insecticide - Rodenticide Branch
Registration Division (H7505C)

APPLICANT: Miles, Inc.
Consumer Household Products Division
7123 West 65th St.
Chicago, IL 60638

FORMULATION FROM LABEL:

	Active Ingredient(s):	% by wt.
346	<u>Permethrin (N,N-Diethyl-3-(2-toluylamido)-2-propylpiperonyl ether)</u>	<u>20.5</u>
	<u>Other Ingredients</u>	<u>1.1</u>
613	<u>N-DEET (N-DEETYL DIETHYLPHENYLACETAMIDE)</u>	<u>3.5</u>
084	<u>2,3,4,5-DI-(BENZYL)TETRAHYDRO-2H-PYRIDIN-2-ONE</u>	<u>1.0</u>
	<u>Inert Ingredient(s):</u>	<u>74.9</u>
	Total	100.0%

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BACKGROUND

Miles, Inc. in a letter (Jan. 16, 1989) to Phil Hutton applied for an amended registration for Cutter Evergreen Scent Repellent Spray Formula #121-31. The amendment included:

- a. [REDACTED]
- b. inclusion of a new ocular irritation study, presumably to reflect any increases in eye irritation due to [REDACTED] which had been requested by PM Team 17. (MIRID NO. was 409300-01)

RECOMMENDATION

- 1) The acute eye irritation study submitted by Miles is acceptable to RSB/DRS, and was designated Toxicity Category II.
- 2) The current toxicity (acute) profile for 121-31 is not based on data performed using 121-31, but based on "similar" Miles products 121-21 and 121-E1, under the site all method of support:
3-12-90 Tox profile for 121-31:

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INERT INGREDIENT INFORMATION IS NOT INCLUDED

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	<u>Tox. Category</u>
Acute oral	III
Acute dermal	III
Acute inhalation	III
Primary eye irritation	II
Primary skin irritation	IV
Dermal Sensitization - not a contact sensitizer	

3) A Nov. 1, 1939 letter from Phil Nutton to Miles, Inc. accepted the proposal to substitute [REDACTED] in the product formulation.

4) No additional acute toxicity data is required at the present time; however Miles, Inc. should explain why the latest Confidential Statement of formula shows a list [REDACTED] active and inert ingredients (dated Feb. 16, 1990) while the previous CSF (Jan. 16, 1959) shows [REDACTED] ingredients. Apparently, [REDACTED] by weight was removed in the latest formulation. What effect(s) on acute toxicity of 121-31 will the removal of [REDACTED] have?
WE BELIEVE THIS CONSTITUTES A FORMULATION CHANGE. E 3/13/90

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LABELING

- 1) The WARNING signal word is appropriate
- 2) Under Precautionary Statements, add
" ... not absorbed through skin", to
Harmful if swallowed".
Add "Wash thoroughly with soap and
water after handling. Remove contaminated
clothing and wash before reuse." "Wear
goggles, face shield, or safety glasses."
- 3) The Statement of Practical Treatment is
appropriate.

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

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Product Manager: (17)
 MRID No.: 409800-01
 Testing Laboratory: Tox. Dept., Miles Inc.
 Author(s): R. L. Kowalsky, R. E. Kartmull
 Species: Rabbit, N2 white
 Sex: 9 males Weight: 1.7-2.1 Kg.
 Source: Hazleton Res., PA
 Dosage: 0.1 ml
 Test Material: Gutter Evertan Scent
 Quality Assurance (40 CFR §160.12): Odorless

Reviewer: H. Waller
 Report Date: 3-8-90
 Report No. WTD0089

Summary:

Tox. Category: II Classification: Guidelines

Procedure (~~Deviation from §81-4~~): Animal eyes were anesthetized prior to instilling 0.1 ml into 1 eye of each of 9 m rabbits (conjugated eye).
Upper & lower lids held together 1 sec. Treated eyes of 3 animals irrigated w/ saline, beginning 20-30 sec. after instillation, for 1 minute, remainder not washed. Treated eyes examined and scored for irritation according to

Results: Drain @ 1 hr, 2, 3, 7, 10 & 12 days.
 Observations

	(number "positive"/number tested)								
	Hour	Days							
	1	1	2	3	*	7	10	12	
Cornea Opacity	9/9	9/9	9/9	8/9		3/9	1/9	0/9	1.0 scores
Iris	0/9	0/9	0/9	0/9		0/9	0/9	0/9	
Conjunctivae Redness	6/9	9/9	9/9	9/9		1/9	0/9	0/9	1.0 scores
Chemosis	9/9	9/9	9/9	9/9		4/9	0/9	0/9	3/2/1 scores
Discharge	9/9	9/9	9/9	9/9		1/9	0/9	0/9	3/2/1 scores

Comments: Corneal op-ict present in 1/9 animals - through day 10; conjunctival irritation present in 4/9 animals through day 7. Conducted in alternate of animals containing

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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