

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

September 15, 2004

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 74771-1 / Benefect
Broad
Spectrum
Disinfectant

DP Barcode: D302850

To: Adam Heyward, PM 34 / Renae Whitaker
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist *Ian Blackwell*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader *Karen Hicks*
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C) 9/13/04

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Sensible Life Products, Division of Laid Back Designs, Ltd.

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Thymol	0.23
<u>Other Ingredient(s):</u>	<u>99.77</u>
Total:	100.00%

I **BACKGROUND:** Sensible Life Products, Inc., has submitted a set of three primary irritation studies. Two of these studies were conducted by Product Safety Laboratories. The dermal sensitization study was conducted by Toxcell LLC. The MRID Numbers are 462232-01, 462232-02 and 462663-01.

A 3/14/2004 cover letter from J. Michael Kelley, PhD states that the registrant has submitted these three studies based upon a directive from the California Department of Pesticide Regulation. No acute oral, acute dermal or acute inhalation toxicity studies were included in this submission.

MRID Number 462663-01 is not a report of a dermal sensitization study as is usually presented to CTT/PSB/AD. This volume is a collection of abstracts discussing dermal sensitization studies conducted on thyme, lemongrass oil, eucalyptus oil, and, clove leaf oil. Most of these ingredients have more than one study represented.

A 6/27/2002 CTT/PSB/AD review listed the acute toxicity profile of 74771-R as:

Study	Toxicity Category	Status
acute oral toxicity	IV	Cited
acute dermal toxicity	IV	Cited
acute inhalation toxicity	IV	Cited
primary eye irritation	IV	Cited
primary skin irritation	IV	Cited
dermal sensitization	Nonsensitizer	Cited

II **RECOMMENDATIONS:** PSB findings are:

- 1 The primary eye and skin irritation studies are acceptable.
- 2 The dermal sensitization study (MRID Number 462663-01) is not acceptable. The problems with this report are:
 - A A dermal sensitization study using Registration Number 74771-1 was not conducted.
 - B The report does not account a study conducted using EPA's guideline OPPTS 870.2600, Skin Sensitization, EPA 712-C-98-197.
 - C The report only includes abstracts of several study reports. Most of the reports do not include details such as the methods used.

D The abstracts and report in general do not state compliance with the 40 CFR §160.

The acute toxicity profile for Reg. No. 74771-1 is currently:

Study	MRID Number	Toxicity Category	Status
acute oral toxicity	456380-02	IV	Cited
acute dermal toxicity	456380-02	IV	Cited
acute inhalation toxicity	456380-02	IV	Cited
primary eye irritation	462232-02	IV	Acceptable
primary skin irritation	462232-01	IV	Acceptable
dermal sensitization	462663-01	Nonsensitizer	Cited

III LABELING:

- 1 The signal word is "CAUTION".
- 2 No Precautionary Statements are required.
- 3 No First Aid Statements are required.

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: 34
MRID No.: 462232-02

Reviewer: Ian Blackwell
Study Completion Date: 3/9/2004
Lab Study No.: 15038

Testing Laboratory: Product Safety Laboratories
Author(s): Daniel J. Merkel, B.S.

Quality Assurance (40 CFR §160.12): Compliance stated

Test Material: Benefect Disinfectant, Reg. No. 74771-1, "light tan liquid"
Dosage: 0.1 mL

Species: New Zealand albino rabbit
Sex: 2 males + 1 female

Weight: not reported
Age: young adult
Source: Robinson Services, Inc.

Summary:

1. **Toxicity Category:** IV
2. **Classification:** Acceptable

Procedure (Deviations From §81-4): (none)

Results:

Observations	(number "positive"/number tested)							
	Hour	Days						
	1	1	2	3	4	7	14	21
Corneal Opacity	0/3	0/3	0/3	0/3	—	—	—	---
Iritis	0/3	0/3	0/3	0/3	—	—	—	—
Conjunctivae								
Redness	3/3	0/3	0/3	0/3	—	—	—	—
Chemosis	0/3	0/3	0/3	0/3	—	—	—	—
Discharge	3/3	0/3	0/3	0/3	—	—	—	---

--- = no observations at this point

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DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: 34
MRID No.: 462232-01

Reviewer: Ian Blackwell
Study Completion Date: 2/23/04
Lab Study No.: 14957

Testing Laboratory: Product Safety Laboratories
Author: Daniel J. Merkel

Quality Assurance (40 CFR §160.12): Compliance stated

Test Material: Benefect Disinfectant, Reg. No. 74771-1, "light tan liquid"

Dosage: 0.5 mL

Species: New Zealand albino rabbit

Age: young adult

Sex: 3 females

Weight: not reported

Source: Robinson Services, Inc.

Summary:

- 1. Toxicity Category:** IV
- 2. Classification:** Acceptable

Procedure (Deviations From §81-5): None

Results: One hour after treatment, very slight erythema was observed in 3/3 animals. Twenty-four, forty-eight and seventy-two hours after exposure, no dermal irritation was present. No edema was noted at any treatment site during the study.

Special Comments: None

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DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: 34
MRID No.: 462663-01

Reviewer: I. Blackwell
Study Completion Date: 3/12/2004
Lab Study No.: none

Testing Laboratory: none
Author: none

Quality Assurance (40 CFR §160.12): Non-compliant

Test Material: various plant oils
Positive Control Material: none

Species: guinea pigs
Weight: not reported
Source: not reported

Age: not reported

Method: Magnusson-Kilgman

Summary:

- 1. This Product is / is not a dermal sensitizer.**
- 2. Classification:** Unacceptable

Procedure (Deviation From §81-6):

~~13~~ This study was not conducted using the test material, nor was it conducted according to EPA guidelines.

Procedure: None reported

Results: specifics are not reported

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