



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  
**Source:** Robinson Services, Inc.  
**Age:** young adult

**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	—	—	—	—
<b>Conjunctivae</b>								
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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