Arlington Suncell
Room 272
2-4-94
430662-01

UNITED STATES ENVIRONMENTAL PROTECTI
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

Subject: EPA Reg. #: 675-39; Spor-O-syl

TO: John Lee, PM 31 Attn: Velma Noble
Antimicrobial Program
Registration Division (7505C)

FROM: David L. Ritter, Toxicologist DLR 2-4-94
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

THRU:: Thomas C. Ellwanger, Jr., Section Head
Precautionary Review Section
Registration Support Branch
Registration Division (7505W)

Mary Waller for T.E 2/4/94

308 8811

Registrant: L & F Products
225 Summit Ave.
Monvale NJ 07645-1575

FORMULATION FROM LABEL:

Active Ingredient(s):	% by Wt.
Hydrogen Peroxide	6.00%
Phosphoric Acid	0.85%
Inert Ingredient(s):	93.15%
Total	100.00%

Action Requested:

1. Review 6(a)(2) data consisting of a dermal irritation study in rabbits and an eye irritation study in rabbits.

2. Review precautionary labeling to reflect new acute toxicity profile.

PRS Response:

1. The data have been reviewed and the DERs are attached. The eye irritation study was rated TOX category I because of irritation beyond 21 days; the dermal irritation study was rated TOX category II based on moderate irritation at through day 14. Both studies are classified CORE Guideline.

000595

Acute Toxicity Data Requirements (40 CFR §158.340).
Pesticide Assessment Guidelines, Subdivision F. Hazard Evaluation: Human and Domestic Animals. (1982; revised 1984).

Data Required	MRID #	Toxicity Category	Classification
Eye Irr. (§81-4)	430662-02	I	G
Dermal Irr. (§81-5)	" -01	II	G

Precautionary Labeling Review:

Signal Word: Danger

Precautionary Statement(s):

Replace the proposed Statement with the following:

"Corrosive. Causes irreversible eye damage. Due to corrosive nature, may be harmful or fatal if swallowed. Do not get in eyes, on skin or on clothing. Wear face shield or safety glasses. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse."

Statement of Practical Treatment:

The proposed Statement should be replaced with the following:

IF IN EYES: Flush with water for 15 minutes. Call a physician.

IF SWALLOWED: Drink promptly a large quantity of milk, egg whites or gelatin solution, or, if these are not available, drink large quantities of water. Avoid alcohol.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage.

Note to PM:

Criterion for Toxicity Category I:

The finding of eye irritation beyond day 21 places this product in Toxicity Category I.

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PM-31
Marshall Swindell
Room 272

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Criterion for Restricted Use Classification:

The finding of eye irritation into the 21st day of the eye irritation study meets the criterion for a "Restricted Use" classification (certified applicators only). PM Team must decide if alternative labeling is sufficient to offset the hazard and the requirement for Restricted Use Classification.

Criterion for Child-Resistant Packaging:

The finding of eye irritation into the 21st day of the eye irritation study meets the criterion for child resistant packaging ~~pursuant to~~. If classified for Restricted Use only, CRP is not required.

nw

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DATA EVALUATION RECORD FOR PRIMARY DERMAL IRRITATION TESTING §81-5

Product Manager : 31 EPA Reg. No.: 675-39

Reviewer: David L. Ritter, Toxicologist DLR 2-4-94

MRID No.: 430662-01

Testing Laboratory: Springborn Laboratories, Inc.
640 North Elizabeth Street
Spencerville OH 45887

Title of Report: A Primary Skin Irritation Study in Rabbits with J-0791-3B.

Date of Report: 10/29/93

Laboratory Identification No.: 3157.97

Author(s): Deborah A. Douds, MS

Species: New Zealand white rabbits

Sex: 2M + 4F Wt.: 2.648 kg - 2.818 kg

Source: Myrtle's Rabbitry, Thompson Station, TN.

Test Material: J-0791-3B

Dosage: 0.5 ml undiluted Test Article applied topically.

Quality Assurance (40 CFR, Section 160.12): Acceptable

Summary:

This product is TOX Category II for dermal irritation based on NW continued irritation through days 7, 14.

The study is rated CORE Guideline

Procedure (note any serious deviation from §81-5):

Standard laboratory animal husbandry and GLP was observed.

Animals were weighed initially.

Animals were clipped free of dorsal hair 24 hours prior to application. 0.5 ml undiluted Test Article was applied topically under a gauze patch to an area of approximately 1 in^2. The test sites were then secured with semi-occlusive dressings.

After 24 hours the dressings were removed and the test sites cleansed with water.

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Test sites were evaluated for irritation after the method of Draize at 1, 24, 48 and 72 hours and on days 7, 10 and 14 following removal of dressings.

Results:

Irritation was reported at all examination periods up to and including that of day 14.

DERMAL IRRITATION SCOREBOARD

#Rab	Eschar/Erythema					Edema						Score
	Observation times in hours											
	1.0	24	48	72	DAY 14	1.0	24	48	72	DAY 14		
98M	2	2	2	2	1	3	2	2	2	1		4.25
47F	2	2	1	1	0	2	1	1	1	0		2.75
56F	2	1	1	0	0	1	1	0	0	0		1.50
32F	2	2	2	2	0	3	2	1	1	0		3.75
37F	2	2	2	2	0	3	2	1	1	0		3.75
22M	2	2	1	1	0	3	2	1	1	0		3.25

MW

Score = sum of numerical grades/no. observation periods at 1, 24, 48 and 72 hours.

PII = Sum of scores/No. animals = 3.21

Slight < 2.0; Moderate 2 - 5; Severe > 5

Conclusions:

MW

This product is TOX Category II for dermal irritation based on continued irritation through days 7, 10 and 14.

The study is rated CORE Guideline.

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ACUTE TOX ONE-LINER

1. PC CODE: 000595; Hydrogen peroxide
076001; Phosphoric acid

2. CURRENT DATE: 2/4/94

3. TEST MATERIAL: Spor-O-Syl

4. EPA Reg. #: 675-39

Study/Species/Lab/ Study#/Date	MRID No.	Results	Tox. Cat.	Core Grade
Eye Irr./Rabbit/ SLI/3157-96/8-11-93	430662-02	Irritation persisting thru day 21	I	G
Skin Irr./Rabbit/ SLI/3157-97/ 10-29-93	" -01	Irritation at 72 hours, and on days, 7, 14.	II	G

DLR 2-4-94

Core Grade Key:

G = Guideline
M = Minimum
S = Supplementary