

US EPA ARCHIVE DOCUMENT

11-30-77

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

003446

DATE: November 30, 1977

EPA Registration #1744-1

SUBJECT: Sunny Sol 5.25% Bleach
Caswell #776

FROM: William Dykstra, Ph.D.
Toxicology Branch

WDD 11/30/77

E 12/19/77

TO: A. E. Castillo, (34)

Action Type: Review DATA

Product Manager: A. E. Castillo, (34)

Recommendations:

The results of the primary eye irritation study show that this product is in toxicity Category I and requires a signal word of DANGER. It should not be available for domestic or unrestricted use.

The label currently in use is not correctly written to protect the user in patterns recommended by the registrant.

Not all the data are adequate to support the label statements at concentrations 1%-9% as requested by Jones Chemicals in their cover letter.

The oral and dermal LD₅₀ do not have to be repeated for the 2 X (9%) or the 1/5X (1%) solution. The eye and skin irritation studies for the higher concentration are not needed as well since we can conclude that the higher concentrations (up to 9%) would be just as corrosive (Category I). Skin and eye irritation studies on lower concentrations however, are required, in order to determine whether or not these formulations would fall in Category I or II.

Review:

Acute Toxicity Studies with Sunny Sol 5.25% Bleach (Industrial Bio-Test Labs, Inc, I.B.T.#8530-10145, 3/11/77; submitted by Jones Chemical Inc., 3/15/77).

1. Acute Oral Toxicity Study -Albino Rats.

40 Albino rats (20m + 20F), strain not reported, were used in this study and orally dosed with 4.556, 6.834, 10.250 and 15.380 gm/kg of Sunny Sol 5.25% Bleach. The animals were observed for 14 days.

Results:

Toxic Signs: Hypoactivity, muscular weakness, diarrhea, labored breathing, prostration, diuresis. Survivors revealed necrotic tissue in stomach lining.

153

-2-

Necropsy: red lungs, black spleen, gastro-intestinal hemorrhages in survivors.

LD₅₀ = 13.204 gm/kg

Classification: Core-Minimum DATA

TOX Category: IV Caution

2. Acute Dermal Toxicity Study - Albino Rabbits.

Six Albino Rabbits, strain not reported, (3M + 3F) were treated with 2000 mg/kg of Sunny Sol 5.25% Bleach on their skin (½ of the animals has abraded skin). The Rabbits were observed for 14 days.

Results:

No Deaths

LD₅₀ > 2,000 mg/kg

Toxic Signs: mild desquamation at 7 and 14 days.

Necropsy: Negative

Classification: Core-Minimum DATA

TOX Category: III Caution

Note: The toxic signs and pathology of the acute dermal test do not correspond to the primary skin irritation test.

3. Primary Eye Irritation Study

Test Material: Sunny Sol 5.25% Bleach

Six Albino Rabbits (3 washed eyes + 3 unwashed eyes) were used. 0.1 ml was instilled into the eyes of 3 rabbits and washed out after a 30 second exposure. 0.1 ml, undiluted, was instilled into the eyes of 3 other rabbits and left unwashed. Observations were made at 1, 24, 48, 72 hours and 7 and 14 days. Maximum score is 110.

Results:

a. <u>unwashed eyes</u>	35.7/110
b. <u>washed eyes</u>	44/110

Corrosive, irreversible corneal opacity, iritis and conjunctivitis at 14 days for washed and unwashed eyes.

Classification: Core-Minimum DATA

TOX Category: I, DANGER

2

003446

4. Primary Skin Irritation Test - Albino Rabbits

Six Albino Rabbits were used in the study. 0.5 ml undiluted Sunny Sol 5.25% Bleach was applied to intact (3 rabbits) and abraded skin (3 rabbits) for 24 hours and held by an inprevious plastic sheet. Rabbits were observed at 24 and 72 hours.

Results: Superficial-2nd degree

Chemical burns at 72-hours on both intact and abraded skin.

Classification: Core-Minimum DATA

TOX Category: II, WARNING

3