

**Gibraltar Biological Laboratories, Inc.**

122 FAIRFIELD ROAD, FAIRFIELD, NEW JERSEY

07006

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52466

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LABORATORY REPORT

GBL Reference No.: 074-191-076

GBL Sample No.: T4856

Assay Date: 10/23/89

Date Completed: 11/6/89

SOP #: 17

Computer Name: X:\wp\rpt\G52466

Sponsor: Sunshine Makers, Inc.

Attention: Bruce Fabrizio

Author: Daniel L. Prince, Ph.D.

REPORT ON THE ACUTE INHALATION
TEST FOR
SIMPLE GREEN INDUSTRIAL STRENGTH
CLEANER AND DEGREASER

Enclosed herewith is a report on the above compound

CONCLUSION

The formulation was non-toxic by the inhalation route to rats at a nominal concentration of 202 mg/l.



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LABORATORY REPORT

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LABORATORY REPORT

Sponsor

Sunshine Makers, Inc.
15922 Pacific Coast Highway
Huntington Harbor, CA 92649

Att: Bruce Fabrizio

GBL Reference No.: 074-191-076

GBL Sample No.: T4856

Description: Dark green sudsy liquid
in a one (1) gallon white plastic screw
cap bottle.

Client Reference: none issued

P.O. No.: Letter of 10/6/89

Date Received: 10/10/89

Date Assayed: 10/23/89

Date Completed: 11/6/89

Computer Name: X:\wp\rpt\G52466

ACUTE INHALATION TOXICITY TEST

Test Article: Simple Green Industrial Strength Cleaner and Degreaser

Purpose: To determine the toxicity resulting from a single one hour
inhalation exposure of rats to the test article.

Test System

Method:

1. A group of ten (5 male and 5 female) Sprague-Dawley Albino rats (220-330 grams) were individually marked, put into a restraining cage, and placed into a 250 liter cylindrical glass chamber.
2. 50.51 grams of the test article was dispersed throughout the chamber as a mist directly from a laboratory pump spray bottle through a 4.5 cm in diameter chamber opening.

Chamber Observations

3. The animals were exposed for a total of one hour to the test article. Observations for general activity, respiration, or any signs of mucosal irritation were noted during the exposure period (See Table 1).

Cageside Observations

4. After exposure, the animals were returned to their individual cages and observed for signs of toxicity and/or death at one (1) hour post-exposure and then daily for 14 days (See Tables 2-3).

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5. Body weights were taken on days 0, 7, and 14 and body weight changes were recorded and calculated (See Table 4).
6. Animals dying during the study as well as those surviving at the end of 14 days were subjected to complete gross necropsy with particular attention given to the lungs (See Table 5).
7. The test article was considered to be toxic by inhalation route if a nominal exposure of 202 mg/liter* produced death in 50% or more of the animals during the 14 day observation period.

*The amount of the test article generated was a product of the total volume of the chamber and the desired concentration, as is shown below:

Administered Test Article (A) = VxC
 where V = Chamber Volume,
 and C = Desired Concentration (mg/l)
 A = 50.51 g (50,510 mg) to the chamber
 V = 250 liter chamber

$$C = \frac{A}{V} = \frac{50,510 \text{ mg}}{250 \text{ l}} = 202 \text{ mg/l}$$

Results

(See Tables 1-5)



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Summary

1. Simple Green Industrial Strength Cleaner and Degreaser produced no death in rats at a nominal concentration of 202 mg/l and therefore is considered non-toxic by the inhalation route as per the guidelines of the CPSC.
2. Six (6) of 10 animals displayed either eye irritation or discharge from the eyes or nares during the exposure period. All animals appeared healthy throughout the 14 day post-exposure period and displayed no abnormal clinical signs (Tables 1 and 2).
3. All animals displayed lower than normal body weight gains. However, it was not determined if this result was attributed to treatment (Table 4).
4. No toxicological abnormalities were observed at terminal necropsy (Table 5).

Date: 11/11/89
ji

Approved
By: *Daniel L. Prince*

Daniel L. Prince, Ph.D.
Richard N. Prince, Ph.D.





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LABORATORY REPORT

MATERIALS AND TEST CONDITIONS

A. Materials

- 1) Test Article: Simple Green Industrial Strength Cleaner and Degreaser
- 2) Sponsor: Sunshine Makers, Inc.
- 3) Client Reference: none issued
- 4) Species (strain, sex, weight, age and source): male and female Sprague-Dawley Albino rats, 220-330 grams, Ace Animal Supply, Boyertown, PA.

B. Pre-Test Conditions

- 5) Acclimatization: one week
- 6) Health: good
- 7) Assignment to test: random

C. Test Conditions

- 8) Animals per group or dose:
- 9) Diet: Wayne Rodent Blox and water ad libitum
- 10) Bedding: indirect
- 11) Cages: USDA conforming
- 12) Ambient temperature: 65-75°F
- 13) Humidity: 30-70%
- 14) Lighting: 12 hour day/night cycle
- 15) Animal Identification: Individually marked with metal ear tags (National Band and Tag Co.) or marking pen.
- 16) SOP #: 17
- 17) Archive Location: 122 Fairfield Road. Subfloor

D. Statistical Method: None.

E. **Records to be Maintained:** The test findings reflected in this experiment will be kept on file for a period of at least 2 years in the Gibraltar Biological Laboratories archives. Specific records to be maintained include a copy of this report, all raw data, sample information as provided by the sponsor and the findings of the QAU.

F. **Stability and Purity Information:** Not known by Gibraltar Biological Laboratories, Inc.

G. **Circumstances:** No circumstances arose during the course of this study which compromised the quality or integrity of the data reported herein.

H. **Analyst:** #04 and #45



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LABORATORY REPORT

Sample No.: T4856

Acute Inhalation Test
Concentration: neat
Product Application: Pump Spray (mist)
Table 1
Chamber Observations

Animal No.	Sex	Sign	Onset	Duration*
769	Male	E DIS.E	15 minutes 1 hour	45 minutes <1 hour
770	Male	NR		
771	Male	DIS.N	45 minutes	<75 minutes
772	Male	NR		
773	Male	DIS.N	15 minutes	<30 minutes

DIS.E = dried brownish discharge from eyes

E = eyes red and inflamed

DIS.N = dried reddish-brown nasal discharge

NR = nothing remarkable

*relative to the initial onset of chamber observation



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LABORATORY REPORT

Sample No.: T4856

Acute Inhalation Test
Concentration: neat
Product Application: Pump Spray (mist)
Table 1, Continued
Chamber Observations

Animal No.	Sex	Sign	Onset	Duration*
777	Female	DIS.N	30 minutes	<2 hours
778	Female	NR		
780	Female	NR		
755	Female	DIS.N	15 minutes	<1 hour, 45 minutes
756	Female	DIS.N	30 minutes	<1 hour, 30 minutes

E = eyes red and inflamed

DIS.N = dried reddish-brown nasal discharge

NR = nothing remarkable

*relative to the initial onset of chamber observation



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LABORATORY REPORT

Sample No.: T4856

Table 2

Daily Behavioral signs at day

<u>Animal #</u>	0	1	2	3	4	5	7	8	9	10	11	12	14
769	1	1	1	1	1	1	1	1	1	1	1	1	1
770	1	1	1	1	1	1	1	1	1	1	1	1	1
771	1	1	1	1	1	1	1	1	1	1	1	1	1
772	1	1	1	1	1	1	1	1	1	1	1	1	1
773	1	1	1	1	1	1	1	1	1	1	1	1	1
777	1	1	1	1	1	1	1	1	1	1	1	1	1
778	1	1	1	1	1	1	1	1	1	1	1	1	1
780	1	1	1	1	1	1	1	1	1	1	1	1	1
755	1	1	1	1	1	1	1	1	1	1	1	1	1
756	1	1	1	1	1	1	1	1	1	1	1	1	1

Remarks: All animals appeared healthy throughout the fourteen (14) day post-exposure period. No observations were performed on Sunday (days 6 and 13).



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LABORATORY REPORT

Sample No.: T4856

Table 3

Extended Observations (Post Exposure)

<u>Sex</u>	No. Dead/NO. Treated at:								<u>Percent Dead</u>
	<u>1 hr</u>	<u>6 hr</u>	<u>Day 1</u>	<u>3</u>	<u>5</u>	<u>7</u>	<u>10</u>	<u>14</u>	
Male	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0
Female	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0/5	0
Total	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0/10	0

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Table 4

CPSC Inhalation Limits Test

Sponsor Lot No. Industrial Cleaner and Degreaser

GBL Lab No.

T4856

Dose: 202mg/l

Weight (g)

Animal Number	Sex	Initial Weight	Day 7 Weight	Day 14 Weight	Weight Change
769	Male	332	392	416	84
770	Male	316	346	368	52
771	Male	330	356	390	60
772	Male	320	350	376	56
773	Male	326	354	376	50
777	Female	236	252	244	8
778	Female	238	244	244	6
780	Female	232	240	250	18
755	Female	234	250	258	24
756	Female	220	224	230	10

	Average Female Weight Change	Average Male Weight Change	Average Weight Change of Both Sexes
Day 7	10 g	34.8 g	22.4 g
Day 14	13.2 g	60.4 g	36.8 g



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Sample No.: T4856

Table 5

Necropsy Summary of Animals in This Experiment

Dose Level: 202 mg/l (0% Dead)

<u>Animal No.</u>	<u>Dead</u>	<u>Survived</u>	<u>Clinical Observation</u>	<u>Date</u>
769		Day 14	A	11/6/89
770		Day 14	A	11/6/89
771		Day 14	A	11/6/89
772		Day 14	A	11/6/89
773		Day 14	A	11/6/89
777		Day 14	A	11/6/89
778		Day 14	A	11/6/89
780		Day 14	A	11/6/89
755		Day 14	A	11/6/89
756		Day 14	A	11/6/89

A = all findings negative