



# Gibraltar Biological Laboratories, Inc.

122 FAIRFIELD ROAD, FAIRFIELD, NEW JERSEY

07008

TELEPHONE (201) 227-8882

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REPORT No.

GBL 45806

1 of 11

## LABORATORY REPORT

Assay Date: 4/23/88

Date Completed: 5/7/88

Sample No.: T-3320

Study No. (Reference): 1459-149-1459

Computer name: 45806 jd C:\RPT\

Sponsor: Simple Green

Attention: Mr. Bruce FaBrizio

Author: Daniel L. Prince, Ph.D.

REPORT ON THE ACUTE ORAL TOXICITY OF  
SIMPLE GREEN CONCENTRATED INDUSTRIAL  
STRENGTH CLEANER AND DEGREASER

Enclosed herewith is a report on the above compound.

### CONCLUSION

The formulation was non-toxic orally at 5g/kg.

GIBRALTAR BIOLOGICAL LABORATORIES, INC.  
122 FAIRFIELD ROAD, FAIRFIELD, NEW JERSEY 07006  
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GLP COMPLIANCE STATEMENT

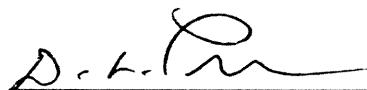
This study was conducted in accordance with the Principals of Good Laboratory Practices (GLP) as promulgated by the following regulatory agencies:

- U.S. Food and Drug Administration, as stated in the code of Federal Regulations, Title 21, Part 58, revised as of April 1, 1986.
- 40 CFR Ch.1 (7-1-85 edition) Part 160 Good Laboratory Practice Standards (EPA - FIFRA Pesticides).
- Organization for Economic Co-operation and Development Guidelines for Testing Chemicals, ISBN 92-64-12221-4, adopted by the council at its 535th meeting on 12th May, 1981.
- The Regulatory Agency, if any, to which this report will be submitted is not known by Gibraltar Biological Laboratories, Inc.

Study No.: 1459-149-1459

"To the best of my knowledge, the study was conducted in accordance with applicable Good Laboratory Practice regulations; there were no deviations from these regulations that significantly impacted on study conclusions".

Date Signed

  
Daniel L. Prince, Ph.D.  
Study Director

6/14/88





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## LABORATORY REPORT

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Results pertain to samples tested only and are not necessarily indicative of the qualities of apparently identical or similar samples or products from the same or different lots, batches, or sources.



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## LABORATORY REPORT

### Sponsor

Simple Green  
15922 Pacific Coast Highway  
Huntington Harbor, CA 92649

Sample: T-3320  
Description: One (1) gallon green  
sudsy pungent liquid in white plastic  
gallon size screw cap jug  
Your Ref: letter of 3/24/88  
PO#: none issued

Att: Mr. Bruce FaBrizio

Date Received: 4/12/88

### ACUTE ORAL TOXICITY IN RATS "MODIFIED LIMITS TEST"

A. Purpose: To determine the acute oral toxicity of the test article at the dose level of 5 grams per kilogram body weight.

#### Test System

B. Method: Oral limits test. Federal Hazardous Substances Act, CFR Title 16, Chap. 11, Part 1500.3 (2i), a 14 day determination of lethality from a single dose oral administration.

C. Species: Adult albino Sprague-Dawley rats, males and females, weights = 200-300 g.

D. Procedure: The rats were fasted for 24 hours and then individually marked. After the fast period, the animals were weighed and dosed according to this weight by use of a blunt oral dosage needle and syringe (gavage). 0.93 ml of the test article was administered per 200 grams of body weight. (Specific gravity = 1.07) Animals were observed for signs of illness and death to a total of 14 days. Dead animals were necropsied as well as those surviving 14 days. Animals were sacrificed by CO<sub>2</sub> asphyxiation. Other doses as noted.

### RESULTS

(See Tables 1-3)

LD<sub>50</sub> > 5g/kg

### SUMMARY

1. Simple Green Cleaner and Degreaser produced no death in rats at 5g/kg per os and therefore is considered to be non-toxic orally as per the guidelines of the CPSC.
2. All animals appeared healthy throughout the test period and displayed normal body weight gains.

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Date: 5/24/88

By: 

jd

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: Cleaner and Degreaser
  - 2) Sponsor: Simple Green
  - 3) Lot or Batch: none issued
  - 4) Species (strain, sex and weight): male and female  
Sprague-Dawley Albino rats, 200-300 grams
  - 5) Animal Supplier: Ace Animal Supply, Boyertown, PA
- B. Pre-test Conditions
- 6) Quarantine: 4 days
  - 7) Health: good
  - 8) Assignment to test: random
- C. Test Conditions
- 9) Animals per group or dose: 10
  - 10) Diet: Wayne Rodent Blox and water ad libitum
  - 11) Bedding: indirect
  - 12) Cages: USDA conforming
  - 13) Ambient temperature: 65-75° F
  - 14) Humidity: 40-60%
  - 15) Lighting: 12 hour diurnal cycle
  - 16) Animal Identification: Individual marked with electric tail tattoo machine (Spaulding & Rogers Mfg., Voorheesville, NY)
  - 17) SOP#: 13
  - 18) Protocol: 274
  - 19) 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 5 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 & 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
- I. Changes; No changes were made from the approved protocol.

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## LABORATORY REPORT

Sample No. T-3320

TABLE 1

### LETHALITY OF BOTH SEXES

<u>Dose Level</u>	<u>Dose</u>	<u>Specific Gravity</u>	<u>Vehicle</u>	<u>Concentration</u>
5 g/kg	0.93 ml/200g rat	1.07	none	neat

Animals: Number 10 Species: rat Sex: mixed

Route: Per os

#### #Dead/treated at Day

<u>Dose (g/kg)</u>	<u>Sex</u>	<u>1</u>	<u>3</u>	<u>6</u>	<u>10</u>	<u>14</u>	<u>% dead</u>
5	Male	0/5	0/5	0/5	0/5	0/5	0
	Female	0/5	0/5	0/5	0/5	0/5	0
	Total	0/10	0/10	0/10	0/10	0/10	0

**Conclusion:** All animals appeared unaffected by the oral administration of the test article throughout the test period.

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Table 2

Oral Limits Test-Weight Changes of Both Sexes

Sponsor Lot No.Simple Green Cleaner & Degreaser GBL Lab No. T-3320

Dose: 5g/kg  
Weight (g)

Animal Number	Sex	Initial Weight	Day 7 Weight	Day 14 Weight	Weight Change
333	Male	218	240	290	72
334	Male	222	326	400	178
335	Male	226	302	382	156
336	Male	226	298	370	144
337	Male	222	310	382	160
364	Female	220	230	244	24
365	Female	218	250	262	44
366	Female	200	224	250	50
367	Female	216	246	274	58
368	Female	210	238	244	34

	Average Female Weight Change	Average Male Weight Change	Average Weight Change of Both Sexes
Day 7	24.8 g	72.4 g	48.6 g
Day 14	42 g	142 g	92 g



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## LABORATORY REPORT

Sample No. T-3320

TABLE 3

Necropsy Summary of Animals in This Experiment

Dose Level: 5g/kg (0% dead)

<u>Animal No.</u>	<u>Died</u>	<u>Survived</u>	<u>Clinical Observations</u>	<u>Date</u>
333		Day 14	A	5/7/88
334		Day 14	A	5/7/88
335 (males)		Day 14	A	5/7/88
336		Day 14	A	5/7/88
337		Day 14	A	5/7/88
364		Day 14	A	5/7/88
365		Day 14	A	5/7/88
366 (females)		Day 14	A	5/7/88
367		Day 14	A	5/7/88
368		Day 14	A	5/7/88

A = All findings negative

## ADDENDUM A

## RANKING OF TOXICITY

Probable oral Lethal Dose Gleason et. al., Clin. Toxicol. Comm. Prod.  
1976,

(Williams & Wilkins)

Toxicity Rating	Dose	Probable Oral Lethal Dose (Humans) Person (150 lbs)
6 Super toxic	< 5 mg/kg	a taste (7 drops)
5 Extremely toxic	5-50 mg/kg	Between 7 drops and 1 teaspoonful
4 Very toxic	50-500 mg/kg	Between 1 teaspoon and ounce
3 Moderately toxic	0.5-5 g/kg*	Between 1 oz and 1 pint (or lb)
2 Slightly toxic	5-15 g/kg	Between 1 pint and 1 quart
1 Practically nontoxic	> 15 g/kg	More than 1 quart (2.2 lb)

\* LD<sub>50</sub> < 5g/kg = toxic orally as per FHSA (CPSC)

ADDENDA B  
LIMITS TEST (95% confidence)

Basic Limit Tables

1) <u>No. of Animals Tested</u>	<u>No. Dead</u>	<u>Estimated LD<sub>50</sub></u> (with 95% confidence)
5 to 7	0	
8 to 10	1	
11 to 12	2	LD <sub>50</sub> = > the dose given
13 to 15	3	
16 to 17	4	
18 to 20	5	

Note: Observed conditions of the animals at 1 hour, 4 hours, and 24 hours, as well as daily for 14 days.

2) If the number of animals dying exceeds the table number, but is <50% of the number tested, report that

"Estimated" LD<sub>50</sub> is > the dose given

3) If exactly 1/2 of the animals die, report that

"Estimated" LD<sub>50</sub> = the dose given

4) If more than 50% of the animals die, report that

"Estimated" LD<sub>50</sub> is < the dose given

Summary for 10 animals (e.g., 5g/kg)

<u>Dead</u>	<u>LD<sub>50</sub> (g/kg)</u>
0	>5
1	
2	
3	"estimated" >5
4	
5	"estimated" = 5
6	
7	
8	"estimated" <5
9	
10	

To convert from an "estimated" LD<sub>50</sub> to a "firm" LD<sub>50</sub>, requires a full dose-response titration with more animals. It is the purpose of the Limits Test to avoid this.

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GBL Lab No.: T-3320  
Sponsor Lot/ID#: none issued  
Reference #: 1459-149-1459

Sponsor: Simple Green  
Study Director: Daniel L. Prince, Ph.D.  
Type of Study: Oral Toxicity

Audits were conducted on the following date(s):

5/4/88

The findings of the Quality Assurance Unit during the audit are as follows:

NO DEVIATIONS

The findings were communicated to the individuals listed below and to the appropriate personnel involved with the study in a timely fashion. It is our belief that any such deviations did not significantly alter the outcome of the experiment.

Date Reported to

6/10/88	6/9/88
Daniel L. Prince, Ph.D.	Robert G. Prince
Study Director	Management

Albert Jablonski  
 Albert Jablonski, B.S.  
 Auditor

Date: 6/14/88