



# Gibraltar Biological Laboratories, Inc.

122 FAIRFIELD ROAD, FAIRFIELD, NEW JERSEY  
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TELEPHONE (201) 227-8882  
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REPORT No.  
45802

GBL \_\_\_\_\_  
1 of 13

## LABORATORY REPORT

Assay Date: 4/25/88; 5/10/88  
Date Completed: 5/24/88  
GBL Sample No: T3320  
Study No: 077-188-097

Sponsor: Simple Green

Respondent: Mr. Bruce FaBrizio

Author: Daniel L. Prince, Ph. D.

REPORT ON THE ACUTE DERMAL TOXICITY OF  
SIMPLE GREEN CLEANER & DEGREASER

Enclosed herewith is a report on the above compound.

### CONCLUSION

The formulation was non-toxic in rabbits when administered at 2 g/kg.

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RESEARCH AND CONSULTING FOR THE PHARMACEUTICAL, COSMETIC, FOOD AND CHEMICAL INDUSTRIES



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## LABORATORY REPORT

### 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.

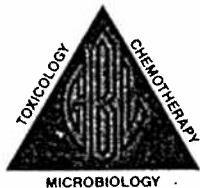
Study No.: 077-188-097

"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

D L Prince  
Daniel L. Prince, Ph.D.  
Study Director

7/1/88



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## LABORATORY REPORT

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## LABORATORY REPORT

Sponsor:	Reference: 077-188-097
Simple Green	Sample: T-3320
15922 Pacific Coast Highway	Description: Green sudsy pungent
Huntington Harbor, CA 92649	liquid in white screw cap gallon
	jug
Attn: Mr. Bruce FaBrizio	Assay Date: 4/25/88; 5/10/88
	Date Completed: 5/24/88
	Date Received: 4/12/88
	PO #: none issued
	Computer Name: 45802 jd c:\rpt

### ACUTE DERMAL TOXICITY IN RABBITS

A. Purpose: To determine the acute dermal toxicity of the formulation at the dose level of 2 grams per kilogram body weight.

#### Test System

B. Method: Federal Hazardous Substances Act, CFR Title 16, Chap. 11, Part 1500.40, Acute Dermal Toxicity, Part 1500 (2i) and Part 1500.41.

C. Species: Adult New Zealand albino rabbits, males and females, weighing at least 2-3 kg.

D. Conditions: (a) rabbit food and water ad libitum; (b) 12 hour diurnal lighting cycle; (c) relative humidity 40-60%; (d) temperature of animal room 65-75°F; (e) indirect bedding of absorbent liners over pine shavings; (f) stainless steel wire cages of USDA specifications; (g) animal quarantine and acclimatization prior to dosing.

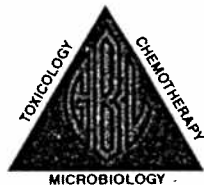
E. Procedure: Eighteen (18) test animals were clipped dorsa-laterally from the pectoral to the pelvic areas. The formulation was applied topically to the bare skin to cover the areas of the sacrospinalis and obloqus externus muscles. Approximately one half of the animals (4 males and 4 females) received longitudinal epidermal abrasions to the skin sites before treatment. The dose rate was 1.87 ml of test article per kilogram of body weight. (Specific gravity 1.09) The treated skin was covered for 24 hours under a gauze dressing and then plastic wrap. A cotton stockinette was additionally applied and secured with masking tape. After 24 hours of occlusive application, the animals were observed daily for signs of illness. The area was observed for erythema and edema at 24 hours after application and again at 72 hours. Necropsy was performed on all animals surviving at 14 days. Animals were sacrificed by CO<sub>2</sub> asphyxiation.

### RESULTS

(See Table 1-5)

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## LABORATORY REPORT

### MATERIALS AND TEST CONDITIONS

- A. Materials
- 1) Test Article: Simple Green Cleaner and Degeaser
  - 2) Sponsor: Simple Green
  - 3) Lot or Batch: none issued
  - 4) Species (strain, sex and weight): male and female  
New Zealand white rabbits, 2-3 Kg, approximately  
3 months of age
  - 5) Animal Supplier: Gingrich Farms
- B. Pre-test Conditions
- 6) Quarantine: one week
  - 7) Health: good
  - 8) Assignment to test: random
- C. Test Conditions
- 9) Animals per group or dose: 18
  - 10) Diet: Wayne Rabbit Chow (complete blend) 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 metal ear tags  
(National Band & Tag Co.) or marking pen.
  - 17) Protocol #: 275
  - 18) 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.
- Other Remarks:
- Ten (10) test animals were originally treated on 4/25/88 on intact skin only. In order to satisfy the requirements of the Consumer Product Safety Commission, eight (8) additional animals were treated on abraded skin on 5/10/88.
- 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: #08, #13



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## LABORATORY REPORT Sample No: T-3320

TABLE 1  
LETHALITY OF TEST ARTICLE  
Rabbits treated with Simple Green Cleaner and Degreaser  
Dose: 2 g/kg

### BODY WEIGHT DATA

Animal	Sex	Dose	Weight (kg) at day			Wt. (kg)	Day Dead	Behavioral Signs
			0	7	14			
1439	M	3.9	2.11	2.27	2.19	+0.08	survived	normal
1444	M	4.4	2.37	2.41	2.45	+0.08	survived	normal
1440	M	4.1	2.21	2.22	2.22	+0.01	survived	normal
1455	M	4.3	2.30	2.36	2.66	+0.36	survived	normal
1443	M	4.1	2.20	2.11	2.19	-0.01	survived	normal
1511	M	4.0	2.13	2.32	2.34	+0.21	survived	normal
1512	M	4.1	2.21	2.43	2.59	+0.38	survived	normal
1513	M	4.0	2.12	1.82	2.16	+0.04	survived	normal
1514	M	4.0	2.14	2.29	2.38	+0.24	survived	normal
1483	F	4.1	2.22	2.41	2.32	+0.10	survived	normal
1472	F	4.0	2.16	2.29	2.19	+0.03	survived	normal
1480	F	3.8	2.04	2.16	2.11	+0.07	survived	normal
1481	F	3.8	2.02	2.16	2.27	+0.25	survived	normal
1482	F	3.9	2.10	2.20	1.97	-0.13	survived	normal
1527	F	4.1	2.20	1.88	2.09	+0.11	survived	normal
1528	F	3.9	2.10	2.02	2.07	-0.03	survived	normal
1529	F	4.1	2.19	2.20	2.25	+0.06	survived	normal
1530	F	4.3	2.32	1.86	----	-----	10	depressed

Average weight change males: +0.15 kg = +150 grams  
 Average weight change females: +0.05 kg = +51 grams  
 Average weight change (males and females): +0.102 kg = +102 grams

Remarks: Animals #1511 - 1514 (males) and #1527-1530 (females) received longitudinal epidermal abrasions, to the treated sites before application of the test article.

Remarks: Animal #1530 (female) developed severe diarrhea on day 8 and was found dead on day 10. The cause of death is not considered to be attributed to treatment. All surviving animals appeared healthy throughout the test period.



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## LABORATORY REPORT

Sample No. T-3320

TABLE 2

### Necropsy Summary of Animals in This Experiment

Dose Level: 2 g/kg

<u>Animal No.</u>	<u>Died</u>	<u>Survived</u>	<u>Clinical Observations</u>	<u>Date</u>
1439		Day 14	A	5/9/88
1444		Day 14	A	5/9/88
1440		Day 14	A	5/9/88
1455		Day 14	A	5/9/88
1443 (males)		Day 14	A	5/9/88
1511		Day 14	A	5/24/88
1512		Day 14	A	5/24/88
1513		Day 14	A	5/24/88
1514		Day 14	A	5/24/88
1483		Day 14	A	5/9/88
1472		Day 14	A	5/9/88
1480		Day 14	A	5/9/88
1481		Day 14	A	5/9/88
1482		Day 14	A	5/9/88
1527		Day 14	A	5/24/88
1528		Day 14	A	5/24/88
1529		Day 14	A	5/24/88
1530		Day 10	B, C and D	5/20/88

A = All findings negative  
B = Splenomegaly  
C = Gall Bladder enlarged  
D = Heart enlarged

Conclusion: All surviving animals displayed no toxicological abnormalities at terminal necropsy.



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## LABORATORY REPORT

Sample No: T3320

TABLE 3

### DERMAL FHSA (CPSC) PRIMARY SKIN IRRITATION RESULTS

Assay Date: 4/25/88; 5/10/88  
Expt. #: 077-188-097

#### MALES

Animal No.	24 hour Erythema & Eschar		24 hour Edema		72 hour Erythema & Eschar		72 hour Edema		Individual Primary Irritation Score
	Int	Abr	Int	Abr	Int	Abr	Int	Abr	
1439	0		0		0		0		0.0
1444	0		0		0		0		0.0
1440	0		0		0		0		0.0
1455	0		0		0		0		0.0
1443	0		0		0		0		0.0
1511		0		0		0		0	0.0
1512		0		0		0		0	0.0
1513		1		0		0		0	0.5
1514		0		0		0		0	0.0

Primary Irritation Score = 0.06

#### Erythema and Eschar

- 0 - No erythema
- 1 - very slight erythema (barely perceptible)
- 2 - Well defined erythema
- 3 - Moderate to severe erythema
- 4 - Severe erythema (best redness) eschar formation (injuries in depth)

#### Edema

- 0 - no edema
- 1 - very slight edema (barely perceptible)
- 2 - Slight edema (edges of area well defined by definite raising)
- 3 - Moderate edema (raised approximately 1mm)
- 4 - Severe edema (raised more than 1 mm and extending beyond the area of exposure)

Note: A score of >5 is taken to indicate that the article is a primary skin irritant.

Int = Intact; Abr = Abraded

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## LABORATORY REPORT

Sample No: T3320

TABLE 4

### DERMAL FHSA (CPSC) PRIMARY SKIN IRRITATION RESULTS

Assay Date: 4/25/88; 5/10/88

Expt. #: 077-188-097

#### FEMALES

Animal No.	24 hour Erythema & Eschar		24 hour Edema		72 hour Erythema & Eschar		72 hour Edema		Individual Primary Irritation Score
	Int	Abr	Int	Abr	Int	Abr	Int	Abr	
1483	0		0		0		0		0.0
1472	0		0		0		0		0.0
1480	0		0		0		0		0.0
1481	0		0		0		0		0.0
1482	0		0		0		0		0.0
1527		0		0		0		0	0.0
1528		0		0		0		0	0.0
1529		1		0		0		0	0.5
1530		0		0		0		0	0.0

Primary Irritation Score = 0.06

#### Erythema and Eschar

- 0 - No erythema
- 1 - very slight erythema (barely perceptible)
- 2 - Well defined erythema
- 3 - Moderate to severe erythema
- 4 - Severe erythema (best redness) eschar formation (injuries in depth)

#### Edema

- 0 - no edema
- 1 - very slight edema (barely perceptible)
- 2 - Slight edema (edges of area well defined by definite raising)
- 3 - Moderate edema (raised approximately 1mm)
- 4 - Severe edema (raised more than 1 mm and extending beyond the area of exposure)

Note: A score of >5 is taken to indicate that the article is a primary skin irritant.

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## LABORATORY REPORT

Sample No: T3320

TABLE 5

### Summary of Results of Rabbits

	No. dead/No. treated on Day		
	Day 1	Day 7	Day 14
Males	0/9	0/9	0/9
Females	0/9	0/9	1/9
Total	0/18	0/18	1/18

Conclusion: Dermal LD<sub>50</sub> is considered to be >2.0 g/kg (see Addendum A).

### SUMMARY

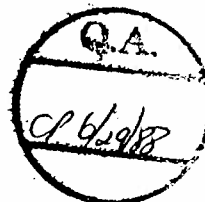
1. Simple Green Cleaner and Degreaser is considered to have an LD<sub>50</sub> of greater than 2 g/kg upon topical application wherein death was observed in only 1/18 test animals.
2. No treatment related abnormalities were observed for surviving animals at terminal necropsy (Table 2).

GIBRALTAR BIOLOGICAL LABORATORIES, INC.

Date: 6/30/88  
jd

By: *DLP*

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



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## ADDENDA A

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 dos 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> =  $\geq$  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> =  $\leq$  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.

Chapter I—Environmental Protection Agency

§ 162.10

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may

appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD <sub>50</sub>	Up to and including 50 mg/kg.	From 50 thru 500 mg/kg.	From 500 thru 5000 mg/kg.	Greater than 5000 mg/kg.
Inhalation LC <sub>50</sub>	Up to and including .2 mg/liter.	From .2 thru 2 mg/liter.	From 2 thru 20 mg/liter.	Greater than 20 mg/liter.
Dermal LD <sub>50</sub>	Up to and including 200 mg/kg.	From 200 thru 2000	From 2,000 thru 20,000.	Greater than 20,000.
Eye effects	<del>Corrosive, irritant</del> <del>opacity not reversible</del> <del>within 7 days</del>	<del>General opacity</del> <del>reversible within 7</del> <del>days; irritation</del> <del>persisting for 7 days.</del>	<del>No corneal opacity,</del> <del>which is non-reversible</del> <del>within 7 days.</del>	<del>No irritation</del>
Skin effects	Corrosive	Severe irritation at 72 hours.	Moderate irritation at 72 hours.	Mild or slight irritation at 72 hours.

\* See PR 81-3

(1) *Human hazard signal word—(A) Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher

Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment—(A) Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the

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GBL Lab No.: T-3320  
Sponsor Lot/ID#: none issued  
Reference #: 077-188-097

Sponsor: Simple Green  
Study Director: Daniel L. Prince, Ph.D.  
Type of Study: Acute Dermal

Audits were conducted on the following date(s):

4/25/88

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.  
Study Director

Robert G. Prince  
Management

  
Christopher Perino, B.S.  
Auditor

Date: 6/9/88