



Gibraltar Biological Laboratories, Inc.

122 FAIRFIELD ROAD, FAIRFIELD, NEW JERSEY

07006

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REPORT No.

45652

GBL _____

1 of 7

LABORATORY REPORT

Assay Date: 5/9/88

Date Completed: 5/12/88

Sample No.: T-3320

Study No. (Reference): 941-192-1001

Computer name: G45652 jd C:\RPT\

Sponsor: Simple Green

Attention: Mr. Bruce FaBrizio

Author: Daniel L. Prince, Ph.D.

REPORT ON THE ACUTE TOXICITY OF
SIMPLE GREEN CLEANER AND DEGREASER
(SKIN IRRITATION)

Enclosed herewith is a report on the above compound.

CONCLUSION

The formulation produced a skin irritation score of 0.2

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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.

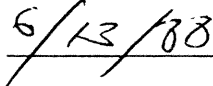
Study No.: 941-192-1001

"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".



Daniel L. Prince, Ph.D.
Study Director

Date Signed



6/13/88



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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: Green sudsy pungent
liquid in 1 gallon white plastic
screw cap jug.
Your Ref: none issued
PO#: none issued
Date Received: 4/12/88

Att: Bruce FaBrizio

RABBIT PRIMARY SKIN IRRITATION TEST REPORT

Attached hereto are the results of the acute toxicity test performed as per the method of Federal Hazardous Substances Act, CFR Title 16, Chap. 11, Parts 1500.3 (2i) and 1500.41.

Purpose: To determine the level of skin irritation of the test article using a single semi-occlusive patch test procedure.

Test System

Method: 0.5 ml of the test article applied to the clipped intact and abraded skin of each of 6 adult 2.0-3.0 Kg male & female albino rabbits for a period of 24 hours. Observations for erythema and edema were performed at 24 and 72 hours after application. Score of 5 or more is considered a primary irritant.

Method of Application

Liquid: Applied to a 1 x 1 inch gauze patch taped to torso with one inch wide non-irritating tape.

RESULTS

(See Table 1)

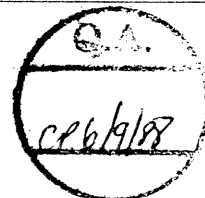
SUMMARY

1. Simple Green Cleaner and Degreaser, produced a skin irritation score of 0.2 (Table 1) and therefore is not considered to be a primary skin irritant as per the guidelines of the Consumer Product Safety Commission.
2. The formulation produced minimal transient erythema in 3/6 animals. No irritation was observed at 72 hours.

GIBRALTAR BIOLOGICAL LABORATORIES, INC.

Date: 5/24/88
jd

By: *D. 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 Cleaner and Degreaser
- 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: 3-7 days
- 7) Health: good
- 8) Assignment to test: random

C. Test Conditions

- 9) Animals per group or dose: 6
- 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) SOP#: 10
- 18) Protocol#: #273
- 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: #08, #13

I. Changes: No changes were made from the approved protocol.

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Table 1
FHSA (CPSC) PRIMARY SKIN IRRITATION SCORE

Sponsor Lot No.Simple Green Cleaner & Degreaser Assay Date: 5/9/88
GBL Lab No. T-3320

24 Hour Erythema & Eschar		24 Hour Edema		72 Hour Erythema & Eschar		72 Hour Edema		Individual Primary Irritation Score	Initial Body Weight (Kg)
Int	Abr	Int	Abr	Int	Abr	Int	Abr		
0	0	0	0	0	0	0	0	0	2.41
0	1	0	0	0	1	0	0	.5	2
1	1	0	0	0	0	0	0	.5	2.17
0	0	0	0	0	0	0	0	0	2
0	0	0	0	0	0	0	0	0	2.28
0	*1	0	0	0	0	0	0	.25	2.09

Primary Irritation Score = .2

REMARKS: * Animal bit through wrapping.

Erythema and Eschar

0=No erythema

1=Very slight erythema (barely perceptible)

2=Well defined erythema

3=Moderate to severe erythema

4=Severe erythema (beet redness) to slight eschar formation (injuries in depth)

Int=Intact; Abr=Abraded

Edema

0=No edema

Very slight (barely perceptible)

2=Slight (edges of area well defined by definite raising)

3=Moderate (raised approx. 1 mm)

4=Severe (raised more than 1 mm and extending beyond the area of exposure)

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QUALITY ASSURANCE STATEMENT

GBL Lab No.: T-3320
Sponsor Lot/ID#: none issued
Reference #: 941-191-1001

Sponsor: Simple Green
Study Director: Daniel L. Prince, Ph.D.
Type of Study: Skin Irritation

Audits were conducted on the following date(s):

6/9/88

The findings of the Quality Assurance Unit during the audit are as follow

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
 Daniel L. Prince, Ph.D.
 Study Director

6/10/88
 Robert G. Prince
 Management

Christopher Perino
 Christopher Perino
 Auditor

Date: 6/13/88