



Gibraltar Biological Laboratories, Inc.

122 FAIRFIELD ROAD, FAIRFIELD, NEW JERSEY
07006
TELEPHONE (201) 227-8882
FAX: (201) 227-9029

REPORT No.

45650

GBL

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LABORATORY REPORT

Assay Date: 4/22/88
Date Completed: 5/25/88
Sample No.: T-3320
Study No. (Reference): 039-194-049
Computer name: G45650 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 & DEGREASER
(EYE IRRITATION)

Enclosed herewith is a report on the above compound.

CONCLUSION

1. The formulation produced irreversible corneal opacity in 1/6 animals at 21 days when tested at full strength without rinsing.
2. The formulation produced irreversible corneal opacity in 1/3 animals at 21 days when tested at full strength with rinsing performed 30 seconds after treatment.

GIBRALTAR BIOLOGICAL LABORATORIES, INC.
122 FAIRFIELD ROAD, FAIRFIELD, NEW JERSEY 07006
(201) 227-6882

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.: 039-194-049

"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

6/13/88



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Sponsor

Simple Green
15922 Pacific Coast Highway
Huntington Harbor, CA 92649

Att: Mr. Bruce Fabrizio

LABORATORY REPORT

Sample: T-3320
Description: Green sudsy pungent liquid
in white plastic screw cap gallon jug.
Your Ref: none issued
PO#: none issued
Date Received: 4/12/88

DRAIZE EYE IRRITATION TEST

Attached hereto are the results of the acute toxicity test performed as per the methods of the Federal Hazardous Substances Act, CFR Title 16, Chap. 11, Parts 1500.3 (2i) and 1500.42. Details on methods and scoring appear on the results sheet attached to this report.

Purpose: To determine the ocular irritation potential of the test article in the washed and unwashed eyes of rabbits.

Test System

Method: 0.1 ml of the formulation was instilled into one eye of each of 6 albino rabbits weighing 2-3 kg with no subsequent rinsing. An additional three (3) animals were treated with 0.1 ml of the formulation with subsequent rinsing performed 30 seconds after treatment. Gross observations were performed daily under white light and under longwave ultra violet light subsequent to fluorescein staining.

RESULTS


(See Tables 1 & 1A, 2 and 2A)

SUMMARY

1. Simple Green Cleaner and Degreaser produced a 24 hour primary eye irritation score of 15.0 (Table 1) with 5/6 animals positive (Table 1A) as per the scoring system of the CPSC. Corneal opacity was observed in 4/6 animals at day 3 and in 1/6 animals at day 21.
2. The formulation produced a 24 hour primary eye irritation score of 14.0 (Table 2) with 3/3 animals positive when eyes were rinsed 30 seconds after treatment. Corneal opacity was observed in 1/3 animals at day 21.

GIBRALTAR BIOLOGICAL LABORATORIES, INC.

Date: 5/25/88
jd

By: 
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: 9 (6 no rinse, 3 rinse)
- 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#: 8
- 18) Protocol: #272
- 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

For use of client only. Neither the name of this laboratory nor any member of its staff to be used for sales or advertising without written authorization.

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.

Table 1
PRIMARY RABBIT EYE IRRITATION SCREEN

Sponsor lot no.:Simple Green Cleaner & Degreaser Assay Date: 4/22/88
GBL Lab No. T-3320
Concentration:neat Vehicle:none Rinse:no rinse

1 hour

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	1	1	1	2	13
2	0	0	1	1	1	2	13
3	1	1	1	2	2	2	22
4	2	1	1	2	2	3	29
5	0	0	1	1	1	2	13
6	0	0	1	1	1	2	13
Average							17.2

Day 1

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	1	1	1	1	11
2	0	0	1	1	1	2	13
3	1	1	1	1	1	1	16
4	2	1	1	1	1	2	23
5	2	1	1	1	1	2	23
6	0	0	0	1	0	1	4
Average							15

Day 2

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	1	1	1	0	9
2	0	0	1	1	1	0	9
3	0	0	1	1	1	0	9
4	1	1	1	1	1	1	16
5	1	1	1	1	1	1	16
6	1	1	0	1	0	0	7
Average							11

Day 3

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	1	1	0	1	1	0	9
4	1	1	0	1	1	1	11
5	1	1	0	0	1	1	9
6	1	1	0	0	0	0	5
Average							5.7

Day 4

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	0	0	0	1	1	0	4
4	1	2	1	1	2	2	25
5	1	1	0	0	1	0	7
6	1	1	0	0	0	0	5
Average							6.8

Day 7

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	0	0	0	0	1	0	2
4	1	2	0	1	1	0	14
5	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0
Average							2.7
AVERAGE OF ALL PRIMARY SCORES							9.7

Day 14

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0
4	1	2	0	0	0	0	10
5	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0
Average							1.7

Day 21

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0
4	1	2	0	0	0	0	10
5	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0
Average							1.7

AVERAGE OF ALL PRIMARY SCORES 7.6

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Table 1

PRIMARY RABBIT EYE IRRITATION SCREEN

Sponsor lot no.:Simple Green Cleaner & Degreaser Assay Date: 5/4/88

GBL Lab No. T-3320

Concentration:neat

Vehicle:none Rinse:30 seconds

1 hour

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	1	2	2	3	19
2	0	0	1	2	2	2	17
3	0	0	1	2	2	3	19
Average							18.3

Day 1

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	2	2	2	12
2	0	0	0	2	1	1	8
3	1	1	1	2	2	2	22
Average							14

Day 2

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	1	1	1	6
2	0	0	0	1	0	0	2
3	1	1	1	1	2	2	20
Average							9.3

Day 3

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	1	1	1	1	2	2	20
Average							6.7

Day 4

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	1	1	1	1	2	2	20
Average							6.7

Day 7

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	1	2	0	1	1	2	18
Average							6

Day 14

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	1	3	0	1	1	2	23
Average							7.7

Day 21

Rabbit	Cornea		Iris	Conjunctivitis			Primary Score
	Area	Severity		Redness	Chemosis	Discharge	
1	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0
3	1	2	0	0	1	2	16
Average							5.3
AVERAGE OF ALL PRIMARY SCORES							9.3

DRAIZE EYE IRRITATION STUDY

Sample: T3320
 Experiment: 039-94-050
 Concentration: NEAT
 Vehicle: WATER SOP#: 9

Assay Date: 5/14/88 pH:
 5/18/88

Client: SIMPLER OILFIELD
 Test Article: SIMPLER GELPERAL Cleaners - Degreaser
 Rack #: Vojabom 5/14/88 GLP

PART A. DAILY TREATMENT SCHEDULE

Instructions: Circle operation when performed on Part A.

Date	5/14	5/15	5/16	5/17	5/18	5/19	5/20	5/21	5/22	5/23	5/24	5/25	5/26	5/27	5/28	5/29	5/30	5/31
Day																		
Treatment																		
Observations																		
Body Weight:																		
Dose: 0.1 ml																		
100 mg by vol																		
One Section Spray																		
Rinse:																		
None																		
2 Sec.																		
4 Sec.																		
30 Sec.																		

Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
Animal #	14359	14360	14361	14362	14363	14364	14365	14366	14367	14368	14369	14370	14371	14372	14373	14374	14375	14376	14377	14378	14379	14380	14381	14382	14383	14384	14385	14386	14387	14388	14389	14390
Cornea																																
Iris																																
Fluorescein																																
Redness																																
Chemosis																																
Discharge																																

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ADDENDUM A
RANKING OF TOXICITY

CPSC 1500.42 Rabbit Eye Irritation Screen**

Fraction Positive - 6 rabbit screen

- 1. 0/6
 >----- non-irritating > --FHSA
- 2. 1/6
- 3. 2/6 ----- borderline
- 4. 3/6, 4/6, 5/6, 6/6 ----- eye irritant

Numerical Scale Classification of Relative Eye Irritancy
(Kay and Calandra, 1962, J. Soc. Cosmetic Chemists 13: 281)

- 5. 0.0 ----- non-irritating
- 6. 0.1 - 10.0 ----- practically non-irritating
- 7. 10.1 - 25.0 ----- mildly irritating
- 8. 25.1 - 50.0 ----- moderately irritating
- 9. 50.1 - 110.0 ----- extremely irritating

[EYE SCORES]	Positive Score	Negative	Possible range
**Tissue	for FHSA	Score	of scores
Conjunctivae			
Redness.....	2+3+	0,1+	0-3
Chemosis.....	2+3+4+	0,1+	0-4
Iritis.....	1+2+	0	-2
Corneal Opacity.....	1+2+3+4+	0	-4

ADDENDUM BCONSUMER PRODUCT SAFETY COMMISSION

Classification of Eye Irritation

CLASSIFICATION OF SEVERITY OF EYE IRRITATION

- NEGATIVE (N): No opacity, iritis, or conjunctivitis
(negative 1-7 days)
- MARGINAL (MA): Generally redness or chemosis:
no positive responses in 3/6 or more
test animals
- SLIGHT (SL): Primarily conjunctivitis (redness and chemosis);
scores of grade 2 and above. (Positive at 24 hours;
eyes returning to normal at 72 hours).
- MODERATE (M): Corneal opacity and/or iritis, and conjunctivitis.
(Positive at 24-72 hours; no opacity or iritis at
seventh day).
- SEVERE (S): Corneal opacity, iritis and conjunctivitis; positive
at 24 hours. One or more eyes still positive for
opacity or iritis at seventh day. Conjunctivitis
still observed at the seventh day.

ADDENDUM C
GIBRALTAR BIOLOGICAL LABORATORIES, INC.
EYE IRRITATION (FDA & FHSA)

I. Cornea

- A. Opacity--Degree of Density (area which is most dense is taken for reading)
 - Scattered or diffuse area--details of iris clearly visible _____ 1* _____
 - Easily discernible translucent areas, details of iris slightly obscured _____ 2* _____
 - Opalescent areas, no details of iris visible, size of pupil barely discernible _____ 3* _____
 - Opaque, iris invisible _____ 4* _____

 - B. Area of Cornea Involved
 - One quarter (or less) but not zero _____ 1 _____
 - Greater than one quarter - less than one-half _____ 2 _____
 - Greater than one-half less than three quarters _____ 3 _____
 - Greater than three-quarters up to whole area _____ 4 _____
- Score equals A x B x 5
Total maximum = 80

II. Iris

- A. Values
 - Folds above normal, congestion, swelling circumcorneal injection (any one or all these or combination of any thereof), iris still reacting to light (sluggish reaction if positive) _____ 1* _____
 - No reaction to light, hemorrhage; gross destruction (any one or all of these) _____ 2* _____

III. Conjunctivae

A. Redness (refers to palpebral conjunctivae only)
 Vessels definitely injected above normal _____ 1 _____

More diffuse, deeper crimson red, individual vessels not easily discernible _____ 2* _____

B. Chemosis
 Any swelling above normal (includes nictitating membrane) _____ 1 _____

Obvious swelling with partial eversion of the lids _____ 2* _____

Swelling with lids about half closed _____ 3* _____

Swelling with lids about half closed to completely closed _____ 4* _____

C. Discharge
 Any amount different from normal (does not include small amounts observed in inner canthus of normal animals) _____ 1 _____

Discharge with moistening of the lids and hairs just adjacent to the lids _____ 2 _____

Discharge with moistening of the lids and considerable area around the eye _____ 3 _____

Score (A + B + C) X 2
 Total maximum = 20

*Positive Score - Federal Hazardous Substances Act (CFR 191, Title 21).

GIBRALTAR BIOLOGICAL LABORATORIES, INC.
122 FAIRFIELD ROAD, FAIRFIELD, NEW JERSEY 07006
(201) 227-6882

GBL Lab No.: T-3320
Sponsor Lot/ID#: none issued
Reference #: 039-194-049

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

Audits were conducted on the following date(s):

5/25/88

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

6/8/88
Daniel L. Prince, Ph.D.
Study Director

6/8/88
Robert G. Prince
Management

Christopher Perino
Christopher Perino, B.S.
Auditor

Date: 6/13/88