

ORIGINAL

**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ- 92 - 11203	<b>89110000208</b>	3/22/11

COMMENTS: COMMUN S (DECLASS)

**DOES NOT CONTAIN CBI**

334121



**The Procter & Gamble Company**  
NA Regulatory & Technical Relations  
One Procter & Gamble Plaza (C-6)  
Cincinnati, OH 45202  
www.pg.com

U.S. EPA  
Office of Pollution Prevention and Toxics  
Document Control Office (7407M)  
1200 Pennsylvania Ave., NW  
Washington, DC 20460  
Attn: TSCA Declassification Coordinator

11 MAR 22 AM 6:03  
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4591

**Re: Declassification Activity-Health and Safety Filing  
8EHQ-0892-11203 (EPA DCN 88920009486)**

Dear Sir/Madam:

The Procter & Gamble Company (P&G) provides this submission to amend the Public Display Version of our submission pursuant to the TSCA Section 8(e) Compliance Audit Program (CAP) under terms of CAP Agreement # 8ECAP-0003.

This amended submission is composed of the following:

- (a) new information provided in this cover letter and its attachment(s); and
- (b) the unaltered original submission which directly follows.

Any CBI substantiation which appears in the original submission is no longer applicable as the information which was originally claimed CBI is disclosed in this revised submission.

Should you have any questions concerning this amended submission, please contact me at (513) 983-2531 or [froelicher.jm@pg.com](mailto:froelicher.jm@pg.com).

Sincerely,

THE PROCTER & GAMBLE COMPANY

Julie Froelicher  
NA Regulatory & Technical Relations Manager  
The Procter & Gamble Company  
One Procter & Gamble Plaza  
Cincinnati, OH 45202  
(513) 983-2531  
[froelicher.jm@pg.com](mailto:froelicher.jm@pg.com)



**Attachment 1**  
**Public Display Version**

**Chemical Identity**

**CAS RN**

Water

Isopropanol

Fatty acids, C8-18 and C18-unsatd.

67701-05-7

Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.-  
hydroxy-, C10-16-alkyl ethers, sodium salts

68585-34-2

Glycine, N,N'-1,2-ethanediylbis[N-(carboxy-  
methyl)-, tetrasodium salt

64-02-8

Ammonium hydroxide

Potassium hydroxide

Pine oil

Fragrance

8EHQ-0892-11203c

COMPANY SANITIZED

**Procter & Gamble**

The Procter & Gamble Company  
Ivorydale Technical Center  
3299 Spring Grove Avenue, Cincinnati, Ohio 45217-1087

92 AUG 21 1992

**Public Display Copy**

August 19, 1992

Document Processing Center (TS-790)  
Office of Toxic Substances  
Environmental Protection Agency  
401 M St. S.W.  
Washington, D.C. 20460

8EHQ-92-11203 INT.  
88920009486s

Attn: Section 8(e) Coordinator (CAP Agreement)

This submission is being made pursuant to the TSCA Section 8(e) Compliance Audit Program and the terms of CAP Agreement # 8ECAP-0003. This report discharges our Company obligation to report the attached data under TSCA Section 8(e). The filing of these studies does not indicate that we agree that "substantial risk" exists. We are following the agency's guidance and the terms of the CAP agreement, but we expressly disclaim that the filings reflect a decision that these materials pose any significant human or environmental safety risks.

The material identified in the attached report as B7191 is a confidential mixture. The composition of the mixture is appended as Attachment 1. The report is titled "Acute Oral Toxicity (LD50) Study in Rats". Any correspondence relating to this submission should reference study # 944-21085.

The attached study report indicates oral administration of the test material resulted in pharmacotoxic signs including ataxia and decreased motor activity following oral administration of 2512, 3980, 6308, and 10000 mg/kg of the test material. Decreased respiratory rate and prostration were observed in all but the low dose group. The acute oral LD50 is calculated to be 4801 mg/kg.

We do not believe findings in this report reasonably support a conclusion of substantial risk to human health or the environment. Nevertheless, we are submitting this report to discharge any potential liability under TSCA Section 8(e).

To our knowledge, this report has not been the subject of a prior submission to EPA under the provisions of TSCA.

The specific chemical constituents and percentage composition of this mixture is claimed as confidential business information. A sanitized version of this submission containing generic chemical names has been included as part of this submission. Answers to the seven questions required to substantiate this claim of confidentiality are provided below:

1. Confidentiality of the chemical constituents and their percentages should be maintained indefinitely. There are no plans for this information to be otherwise disclosed, and this technology has significant commercial value.
2. To our knowledge, there have been no government confidentiality determinations made for this mixture.
3. The specific chemical identity and exact proportions of the constituents of this mixture have not been disclosed outside the Company. There are no plans to disclose publicly the exact composition of this mixture at any time in the future.

0 0 0 3

*Procter&Gamble*

4. Measures for protection of the compositional information include "need to know" internal restriction within the Company. An internal code is used to protect the identity of the material. Information is maintained in locked files. Employees leaving the Company are contractually bound not to disclose Company secrets.
  5. The exact composition of this mixture has not appeared in advertising or promotional literature, MSD sheets, any publications or any other media available to the general public or competitors.
  6. Disclosure of the information claimed as CBI would result in substantial harm to the Company's competitive position. This formula provides an important commercial opportunity for a competitor. Knowledge of the exact composition of this mixture could enable a competitor to duplicate the formula without R&D cost, thus providing an unfair competitive disadvantage to the Procter & Gamble Company. Development of this formula required many technically trained personnel, hundreds of hours of research and development, and significant capital investment valued in aggregate at . Any competitor would normally be required to make a similar investment to duplicate the formula. Disclosure of this information would allow a competitor to duplicate the formula without incurring significant R&D costs, thus doing substantial harm to our competitive position.
  7. The information we have identified as confidential is not health or safety data.
- Any questions concerning this submission, may be directed to me at (513) 627-5551.

Sincerely,

THE PROCTER AND GAMBLE COMPANY

Richard H. Hall, Ph.D.  
Manager  
Regulatory & Government Affairs  
The Procter & Gamble Company

**Water**

**Isopropanol**

**Fatty acid**

**Sodium alkyl ethoxy sulfate**

**Substituted amine**

**Ammonium hydroxide**

**Potassium hydroxide**

**Pine oil**

**Fragrance**

**Colorant**

**Substituted stilbene**

944-21085

Ⓞ

*International Research and Development Corporation*

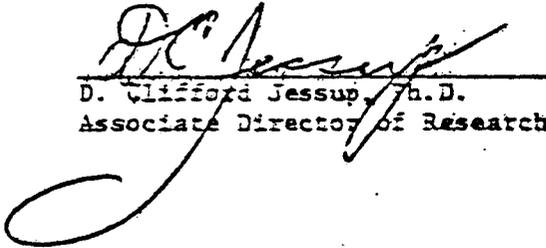
SPONSOR: The Procter and Gamble Company  
TEST MATERIAL: B7191  
SUBJECT: Acute Oral Toxicity (LD<sub>50</sub>)  
Study in Rats.

RECEIVED BY

JUN 29 1978

N. E. GILMAN

  
Wilson P. Dean, B.A.  
Director of Acute Toxicology  
and Special Studies  
(Study Director)

  
D. Clifford Jessup, Ph.D.  
Associate Director of Research

Collaborators:

Gary Thompson, B.S.  
Group Technical Supervisor  
Greg Ronig, B.S.  
Unit Technical Supervisor  
David Powell, B.A.  
Unit Supervisor,  
Report Preparation,  
Acute and Special Studies  
Department

Date: June 26, 1978

*International Research and Development Corporation*

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I. SYNOPSIS

The acute oral LD<sub>50</sub> and 95% confidence limits of B7191 in combined male and female rats were found to be: 4801 (3876 - 5933) mg/kg.

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II. TEST MATERIAL

The test material was received from The Procter and Gamble Company, Cincinnati, Ohio on October 3, 1977. It was identified as "Sample code B7191, Submitter code B7191, Request Ltr. #BSBTS 474" and was received as a yellow liquid.

191-142

III. METHOD

Twenty male and 20 female rats of the Sprague-Dawley strain (obtained from Harlan Industries, Inc., Indianapolis, Indiana) weighing from 205 to 252 grams (pre-fasting body weight) were used for this study. The rats were housed by sex in groups of 5 rats per cage in hanging wire-mesh cages in temperature and humidity controlled quarters. They were maintained in accordance with the recommendations contained in H.E.W. Publication No. 74-23 (N.I.H.) entitled "Guide for the Care and Use of Laboratory Animals". The rats were conditioned for a minimum of 5 days prior to study initiation. Water and Purina Laboratory Chow were available ad libitum, except for an overnight period of 19½ to 20 hours immediately preceding oral administration during which food, but not water, was withheld.

The test material was administered orally by gavage, as received, undiluted, at the following dosage levels to male and female rats: 2512, 3980, 6308 and 10000 mg/kg.

Five rats of each sex were used at each dosage level. Volumes administered were as follows:

2512 mg/kg level - 2.59 ml/kg  
3980 mg/kg level - 4.10 ml/kg  
6308 mg/kg level - 6.50 ml/kg  
10000 mg/kg level - 10.31 ml/kg

Observations for pharmacotoxic signs and mortality were made at ½, ½, 1, 2, 4 and 24 hours and daily thereafter for a total of 14 days. Body weights were recorded immediately prior to fasting, immediately preceding dosing and at 7 and 14 days. All rats which died on study were subjected to gross necropsy examination as were all survivors at the end of the 14 day observation period.

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IV. RESULTS

A. MORTALITY AND LD<sub>50</sub> VALUES:

Dose - Mortality Data

Dosage Level mg/kg	Number of Deaths														Total Mortalities				
	Hrs		Days												Male	Female	Total		
	0-4	1	2	3	4	5	6	7-14	M	F	M	F	M	F				M	F
2512																	0/5	0/5	0/10
3980			1	2	1												0/5	4/5	4/10
6308	1	1	2	2	1												3/5	4/5	7/10
10000	1	1	4	4													5/5	5/5	10/10

Acute Oral LD<sub>50</sub> and 95% Confidence Limits

Combined Male and Female Rats: 4801 (3876 - 5933) mg/kg.

Statistical References

Computations were performed by Mr. R. Bruce, Statistician, The Procter and Gamble Company, using the computer program BLISS 17, written by D. J. Finney, University of Edinburgh, Scotland.

B. PHARMACOTOXIC SIGNS:

See attached Appendix 2.

C. BODY WEIGHTS:

All surviving rats exhibited normal body weight gains with the exception of one female at the 2512 mg/kg dosage level and one male and one female at the 6308 mg/kg dosage level which exhibited less than normal body weight gains. (See attached Appendix 1.)

D. NECROPSY FINDINGS:

Necropsy observations were noted as indicated on Table 1.

B7191: Acute Oral Toxicity (LD<sub>50</sub>) Study in Rats.

TABLE 1. Summary of Gross Necropsy Observations.

Site Lesion	3980 mg/kg		6200 mg/kg		10000 mg/kg		2512 mg/kg		3980 mg/kg		6200 mg/kg	
	F	M	F	M	F	M	F	M	F	M	F	M
Number necropsied	4	3	4	5	5	5	5	5	5	5	5	5
No gross lesions							1	1	3	3	2	2
External												
partially cannibalized	1											
moist white stain around mouth			1		1							
red stain around nose and mouth					2							
Stomach												
distension												
fluid filled	3	3	4	5	3							
mucosa, hyperemic	2	3	2	5	5							
mucosa, thickened	2	2	3	2	2							
plandular mucosa, dark red foci			3		1							1
plandular mucosa, white mucoid material adhering to mucosa					1							1
contains red fluid												
Intestines												
fluid filled			2	2	1							
small, contains watery ingesta	2											
cecum, contains watery ingesta	2											
Lungs												
congestion	2	2	3	4	2							
foci	1											
consolidation												
Liver												
dark red foci			2									
Kidneys												
mottled coloration											1	1
Uterus												
hydrometra												2

Appendix I

LD<sub>50</sub> - Record of Individual Dose Level

191-142

APPENDIX 1

IRDC = A-45.6

LD50 - RECORD OF INDIVIDUAL DOSE LEVEL

Dose level g/kg by 2.512 750 Code B 7191  
Number of animals dosed Male 5 Female 5

All data are based on sample as received.

Sample Preparation: \_\_\_\_\_ g of sample was mixed with \_\_\_\_\_ (g) (ml) solvent \_\_\_\_\_ to make a dosing solution of \_\_\_\_\_ (v/v) \_\_\_\_\_ (v/v).

Specific Gravity: 10 ml of sample weighed 9.70 g at 22 °C.  
S.G. = 0.970 g/ml.

Individual Animal Data

Date	Animal #	1					2				
		7905	7916	7927	7949	7967	7980	7991	7993	7993	7984
	Sex	♂	♂	♂	♂	♂	♀	♀	♀	♀	♀
1/24/78	Prefasted Wt. g	205	233	220	232	250	211	221	217	230	225
1/25/78	Fasted Wt. g	192	222	208	221	237	201	211	205	218	212
1/25/78	Dose/24z ml	0.50	0.57	0.54	0.57	0.61	0.52	0.55	0.53	0.56	0.55
	Time of Death										
	14 Day Wt. g	250	309	298	345	361	229	250	248	230	238

GH  
1/25/78

7 Day Wt. 253 274 276 312 327 232 246 247 233 240  
 Avg. prefasted weight 224.4 OP 3/26/78  
 Avg. prefasted weight of survivors 224.4  
 Avg. 14 day weight of survivors 275.8 OP 3/26/78  
 Total Dead: Male 0 Female 0  
 Animals Received: 1120178 Harlan

$\frac{2.512 \text{ g/kg}}{0.970 \text{ g/ml}} = 2.59 \text{ ml/kg}$

Worker's Signature M. Harris Date 1/25/78  
 Corroborating Witness W. J. J. Date 1/25/78  
 Worker's Signature G. R. O. Date 3/31/78  
 Corroborating Witness M. J. J. Date 3/31/78

191-142

APPENDIX 1

ERDC = A 456

LD50 - RECORD OF INDIVIDUAL DOSE LEVEL

Dose level g/kg by 3.980 PSC Code R 7191
Number of animals dosed Male 5 Female 5

All data are based on sample as received.

Sample Preparation: g of sample was mixed with (g) (ml)
solvent to make a dosing solution of
(v/v) (v/v).

Specific Gravity: 10 ml of sample weighed 9.70 g at 22 °C,
S.G. = 0.970 g/ml.

Individual Animal Data

Table with columns for Date, Animal #, Sex, Prefasted Wt. g, Fasted Wt. g, Dose/Eac ml, Time of Death, 14 Day Wt. g. Rows include dates 1/24/78, 1/25/78, 1/25/78 and animal numbers 1-10.

Avg. prefasted weight 221.1
Avg. prefasted weight of survivors 220.7
Avg. 14 day weight of survivors 314.3
Total Dead: Male 0 Female 4
Animals Received: HARLAN 1/20/78

Worker's Signature [Signature] Date 1/25/78
Corroborating Witness [Signature] Date 1/25/78
Worker's Signature [Signature] Date 3/31/78
Corroborating Witness [Signature] Date 3/31/78

191-142

APPENDIX 1

IRDC = A456.

LD50 - RECORD OF INDIVIDUAL DOSE LEVEL

Dose level g/kg by 6.308 P&G Code B7191  
Number of animals dosed Male 5 Female 5

All data are based on sample as received.

Sample Preparation: \_\_\_\_\_ g of sample was mixed with \_\_\_\_\_ (g) (ml) solvent \_\_\_\_\_ to make a dosing solution of \_\_\_\_\_ (v/v) \_\_\_\_\_ (v/v).

Specific Gravity: 10 ml of sample weighed 9.70 g at 22 °C  
S.G. = 0.970 g/ml

Individual Animal Data

		1	2	3	4	5	1	2	3	4	5
Date	Animal #	79695	79696	79697	79698	79699	79700	79701	79702	79703	79704
Sex	Sex	♂	♂	♂	♂	♂	♀	♀	♀	♀	♀
1/24/78	Prefasted Wt. g	232	221	233	252	233	230	233	243	235	215
1/25/78	Fasted Wt. g	221	210	222	241	222	219	222	233	224	204
1/25/78	Dose/Eat ml	1.4	1.4	1.4	1.6	1.4	1.4	1.4	1.5	1.5	1.3
	Time of Death	1/26/78	1/27/78	SG 2.0 285	1/27/78	SG 2.0 250	1/27/78	SG 2.0 235	1/27/78	1/27/78	1/27/78
SG 2.8-78	14 Day Wt. g			285		250		235			

GH  
1/25/78

RECORD NO. 378 DRY WT. 268 223 225 \* MARKED IN  
 Avg. Prefasted weight 232.7 OP 3/24/78  
 Avg. Prefasted weight of survivors 233.0 OP 3/26/78  
 Avg. 14 day weight of survivors 256.7 OP 3/26/78  
 Total Dead: Male 3 Female 4  
 Animals Received: 11/20/78

$$\frac{6.308 \text{ g/kg}}{0.970 \text{ g/ml}} = 6.50 \text{ ml/kg}$$

Worker's Signature Gene Harris Date 1/25/78  
 Corroborating Witness [Signature] Date 1/25/78  
 Worker's Signature [Signature] Date 3/31/78  
 Corroborating Witness [Signature] Date 3/31/78

91-142

APPENDIX 1

IRDC = A456

250 - RECORD OF INDIVIDUAL DOSE LEVEL

Dose level g/kg by 10.000 PSG Code - B7191
Number of animals dosed Male 5 Female 5

All data are based on sample as received.

Sample Preparation: g of sample was mixed with (g) (ml) solvent to make a dosing solution of (v/v) (v/v).

Specific Gravity: 10 ml of sample weighed 9.70 g at 22 °C, S.G. = 0.970 g/ml

Individual Animal Data

Table with columns for Date, Animal #, Sex, Prefasted Wt. g, Fasted Wt. g, Dose/Day ml, Time of Death, and 14 Day Wt. g. Rows include data for animals 1-5 in two groups.

Avg. prefasted weight 224.2 DP3/24/78
Avg. prefasted weight of survivors
Avg. 14 day weight of survivors
Total Dead: Male 5 Female 5
Animals Received: HARHAN 1/20/78

10.000 g/kg / 0.970 g/ml = 10.31 mg/kg

Worker's Signature Gene Harris

Date 1/25/78

Corroborating Witness

Date

Worker's Signature

Date 3/31/78

Corroborating Witness

Date 3/5/78

Appendix 2

Acute Oral Toxicity Observation Data

APPENDIX 2

ACUTE ORAL TOXICITY OBSERVATION DATA

No. of Males/Females Affected - Blank Square = Normal

P&G Code B7191 Dose Level g/kg 2.512 Dose Time 1:00 pm Dose Date 1/25/78

SYMPTOM	Hours				Days											
	1/4	1/2	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Prior activity increase																
Prior activity decrease																
Respiratory rate increase																
Respiratory rate decrease																
Fine body tremors																
Coarse body tremors																
Blanching																
Cyanosis																
Gaspings																
Abnormal Griping																
Diarrhea																
Pilo Erection																
Others ATAXIA																
Worker's Initials																

NORMAL  
DEATH  
Worker's Initials

Special Notes: (Including Necropsy Observations)

APPENDIX 2

ACUTE ORAL TOXICITY OBSERVATION DATA

No. of Males/Females Affected - Blank Square = Normal

P&G Code B7191 Dose Level g/kg 3.980 Dose Time 1:10 pm Dose Date 1/25/78

Symptoms	Hours		Days														
	1/1	1/2	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Prior activity increase																	
Prior activity decrease																	
Respiratory rate increase		5/5	5/5	5/4	1/1												
Respiratory rate decrease			0/3	0/3	0/1												
Tine body tremors																	
Coarse body tremors																	
Bleaching																	
Cyanosis																	
Gaspings																	
Abnormal griping																	
Diarrhea																	
Pilo erection																	
Other: ATAXIA		2/2	5/5	5/5	0/3	2/1											
PROSTATION		0/3	0/3	0/1	0/1												
HYPOTHERMIA				0/3	0/1												
Worker's Initials	GH	GH	GH	GH	GH	GH	GH	GH	GH	GH	GH	GH	GH	GH	GH	GH	GH

Special Notes: (Including Necropsy Observations)

APPENDIX 2

ACUTE ORAL TOXICITY OBSERVATION DATA

No. of Males/Females Affected - Blank Square = Normal

P&G Code B 7191 Dose Level g/kg 6.30X Dose Time 1:15 pm Dose Date 1/25/78

SYMPTOM	Hours										Days									
	1/4	1/2	1	2	4	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Motor activity increase																				
Motor activity decrease																				
Respiratory rate increase																				
Respiratory rate decrease																				
Fine body tremors																				
Coarse body tremors																				
Blepharospasm																				
Cyanosis																				
Gaspings																				
Abnormal Griping																				
Diarrhea																				
Pilo Erection																				
Others: ATAXIA																				
PROSTRICTION																				
HYPOTHERMIA TO TAIL																				
URINE STAINED ABDOMEN																				
Worker's Initials																				

Special Notes: (Including Necropsy Observations)

APPENDIX 2

ACUTE ORAL TOXICITY OBSERVATION DATA

No. of Males/Females Affected - Blank Square = Normal

P&G Code B 7191 Dose Level g/kg 0.000 Dose Time 1:22 pm Dose Date 1/25/78

SYNDROME	Hours				Days															
	1/4	1/2	1	2	4	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Motor activity increase																				
Motor activity decrease																				
Respiratory rate increase	3/4	5/5	5/5	4/4	4/4															
Respiratory rate decrease																				
Fine body tremors																				
Coarse body tremors																				
Bleaching																				
Cyanosis																				
Gasping																				
Abnormal Gripping																				
Stertor																				
Pilo Erection																				
Others																				
		5/5	5/5	4/4	4/4															
		0/1	5/5	4/4	4/4															
Worker's Initials	GH	GH	GH	GH	GH	YI	GH													

DEAD

1/25/78 1/25/78

Special Notes: (Including Necropsy Observations)

INTERNATIONAL RESEARCH AND DEVELOPMENT CORPORATION

Lab Project No. 191-142 Sheet 1 Date 10/3/77 Authorized by   
 W. Dean

DISTRIBUTION

Dr. Wazeter	<u>    </u>	Mr. Cain	<u>X</u>	Mrs. Finlay	<u>    </u>	Dr. Cookson	<u>    </u>
Dr. Goldenthal	<u>    </u>	Mr. Vollmar	<u>    </u>	Dr. Leong	<u>    </u>	Miss Lohrberg	<u>    </u>
Dr. Geil	<u>X</u>	Miss Emmons	<u>    </u>	Mr. Benson	<u>X</u>	Mr. Vrbancic	<u>    </u>
Dr. Jessup	<u>X</u>	Ms. French	<u>    </u>	Mr. Rodwell	<u>    </u>	Mr. Dean	<u>X</u>
Dr. Griffith	<u>X</u>	Mr. Pangburn	<u>    </u>	Mrs. Schwartz	<u>    </u>	<u>Mr. Thompson</u>	<u>X</u>
				Miss Morseh	<u>    </u>	Dr. Thorstenson	<u>    </u>

<u>Compound</u>	<u>Identification Number</u>	<u>IRDC No.</u>
B7191		A-456

TITLE: ACUTE ORAL TOXICITY STUDY IN RATS

Conduct in accordance with the attached protocol with the following special instructions:

- 1) Administer test material undiluted.
- 2) Initially conduct a dose range study at the following dosage levels:  
 1,000; 5,000; 10,000; 20,000 mg/kg. Use 2 rats/dosage level.
- 3) Return all unused samples at the conclusion of the study to Helen Hiltz.

Standard Procedure #1 for Toxicological Evaluation

Acute Oral Toxicity - Rats

Date: March 31, 1977

Issue #2

- Purpose:** To measure the acute oral toxicity of a substance in order that it might be compared to more familiar materials.
- Animals:** Rats, Sprague-Dawley derived (caesarean-derived), 190-270 g, conditioned to the environment for a minimum of 4 days. Obtain animals from Charles River, Laboratory Supply or Harlan. Maintain the animals according to standards outlined in the Guide For the Care and Use of Laboratory Animals, DHEW # (OSHA-74-23), 1974.
- Procedure:** Place 10 animals in each group, divided equally by sex. Determine prefasted and fasted body weights. Fast the animals for 18-20 hours before administering the test material.
- Dissolve or suspend the test material in an appropriate vehicle at the required concentrations and record quantities mixed. Deliver the test material into the stomach of the animal from a syringe fitted with a size 8 catheter as a stomach tube or from a syringe fitted with a 13-gauge animal-feeding needle.
- Choose 4 dosage levels, with the lowest being approximately the highest no-death dosage level observed in range-finding studies, or being estimated from prior results with similar compounds. Unless otherwise specified, choose higher dosage levels according to a geometric progression of 1.4 (i.e. the second dose equals the first dose x 1.4, the third dose equals the first dose x  $[1.4]^2$ , etc.). Administer each dosage level to one group of 10 animals. Adjust the dose for each animal according to fasted weight to give the specified quantities of material per unit of body weight. Administer additional dose levels, as needed, so that the total number of dead is sufficient to calculate an LD<sub>50</sub> value. Immediately after dosing, return the animal to ad libitum feeding. Record all of the above information on the "LD<sub>50</sub> Record of Individual Dose Level" sheet (Appendix I).
- Observations:** Observe the animals and their behavior at intervals of 15, 30, 60, 120 and 240 minutes after dosing and daily thereafter for 14 days. Use the "Toxicity Observation Data" sheet (Appendix 2) to record symptoms and number of animals involved. Unusual observations or symptoms not listed on the "Toxicity Observation Data" sheet should be noted where appropriate (under "Symptoms" or "Special Notes"). Necropsy all animals that die during the course of the study. At 14 days, weigh all surviving animals and record weight. Necropsy surviving animals and examine them grossly for abnormalities.

Acute Oral Toxicity - Rats (P&G Procedure) (cont'd)

**Report:**

Report all data recorded on the Record of Individual Dose Level and the Acute Oral Toxicity Observation Data sheets. Report the  $LD_{50}$  and 95% confidence limits of the test material, preferably calculated by the Probit Method\*. If necessary, other calculation methods may be used to fit the death/dose response. The method used should be specified. File the final report within 3 weeks after completion of the experiment.

PRINCIPAL INVESTIGATOR: J. H. Benedict

DATE: 9/22/77

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\* D. J. Finney, Statistical Method in Biological Assay, Third Edition, 1971.

APPENDIX 1

LD<sub>50</sub> - RECORD OF INDIVIDUAL DOSE LEVEL

Dose level g/kg by \_\_\_\_\_ P&C Code \_\_\_\_\_  
Number of animals dosed Male \_\_\_\_\_ Female \_\_\_\_\_

All data are based on sample as received.

Sample Preparation: \_\_\_\_\_ g of sample was mixed with \_\_\_\_\_ (g) (ml)  
solvent \_\_\_\_\_ to make a dosing solution of  
\_\_\_\_\_ % \_\_\_\_\_ (w/v) \_\_\_\_\_ (v/v).

Specific Gravity: \_\_\_\_\_ ml of sample weighed \_\_\_\_\_ g at \_\_\_\_\_ °C,  
S.G. = \_\_\_\_\_ g/ml.

Individual Animal Data

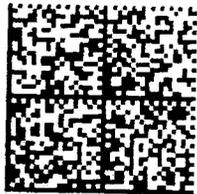
Date	Animal #										
	Sex										
	Prefasted Wt. g										
	Fasted Wt. g										
	Dose/Rat ml										
	Time of Death										
	14 Day Wt. g										

Avg. prefasted weight \_\_\_\_\_ g  
Avg. prefasted weight of survivors \_\_\_\_\_ g  
Avg. 14 day weight of survivors \_\_\_\_\_ g  
Total Dead: Male \_\_\_\_\_ Female \_\_\_\_\_

Worker's Signature \_\_\_\_\_ Date \_\_\_\_\_

Corroborating Witness \_\_\_\_\_ Date \_\_\_\_\_





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