

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ- 92-10177	89110000206	3/22/11

COMMENTS: COMMUN S (DECLASS)

DOES NOT CONTAIN CBI

334 119



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
RECEIVED
POST OFFICE

**Re: Declassification Activity-Health and Safety Filing
8EHQ-0892-10177 (EPA DCN 88920008479)**

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Any CBI substantiation which appears in the original submission is no longer applicable as the information which was originally claimed CBI is disclosed in this revised submission.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

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



Attachment 1
Public Display Version

<u>Chemical Identity</u>	<u>CAS RN</u>
Potassium hydroxide	
Potassium pyrophosphate	
Isopropanol	
Pine oil	
Benzenesulfonic acid, C10-16-alkyl derivatives	68584-22-5
Benzenesulfonic acid, (1-methylethyl)-, sodium salt	28348-53-0
Terpenes and Terpenoids, mixed sour and sweet orange-oil	68917-57-7
Cyclohexene, 1-methyl-4-(1-methylethylidene)-	586-62-9
Cyclohexene, 1-methyl-4-(1-methylethenyl)-	138-86-3
1-Naphthalenesulfonic acid, 3-[(2,4-dimethyl-5- sulfophenyl)azo]-4-hydroxy-, disodium salt	4548-53-2
Benzenesulfonic acid, 2,5-dichloro-4-[4,5-dihydro- 3-methyl-5-oxo-4-[(4-sulfophenyl)azo]-1H-pyrazol-1- yl]-, disodium salt	6359-98-4

Water

Fragrance

Procter & Gamble

8EHQ-0892-10177s
COMPANY SANITIZED

The Procter & Gamble Company
Ivorydale Technical Center
5299 Spring Grove Avenue, Cincinnati, Ohio 45217-1087

92 AUG 21 PM 1:14

Public Display Copy

August 20, 1992

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

8EHQ-92-10177 INIT
88920008479

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 B0447-01 is a confidential mixture. The composition of the mixture is appended as Attachment 1. The report is titled "Acute Oral Toxicity (LD50 Value in Rats)". Any correspondence relating to this submission should reference study # 1105-26489.

The attached study report indicates oral administration of the test material resulted in pharmacotoxic signs including ataxia, hypoactivity, piloerection, and high carriage following oral administration of 4800, 5760, 6912, and 8294 mg/kg of the test material. Tremors were observed in the 6912 and 8294 mg/kg groups. The acute oral LD₅₀ is calculated to be 6.8 g/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.

~~Procter & Gamble~~
~~CONFIDENTIAL~~

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) 627-9551.

Sincerely,

THE PROCTER AND GAMBLE COMPANY



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

Alkyl benzene sulfonic acid

Potassium hydroxide

Potassium pyrophosphate

Alkyl benzene sulfonic acid

Isopropanol

Pine oil

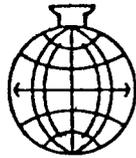
Mixed terpenes

Colorant

Water

Fragrance

1105-26489



International Research
and Development Corporation

MATTAWAN, MICHIGAN U.S.A. 49071 TELEPHONE (616) 668-3336

SPONSOR: The Procter and Gamble Company
SUBJECT: Acute Oral Toxicity (LD₅₀ Value in Rats)
DRD NO.: BSBTS 743
TSIN: B0447-01
REPORT NO.: 191-731
DATE OF SUBMISSION: March 22, 1982

RECEIVED BY
MAR 26 1982
OPERATIONS SECTION

191-731

"credence through research"

International Research & Development Corporation

STUDY SUMMARY

Study No: 191-731
 Sponsor Ref: BSBTS 743

Acute Oral Toxicity (LD₅₀ Value in Rats)
 Report of a biological test performed at:
 International Research and Development Corporation
 Mattawan, Michigan

Deviation from
 Protocol: None

During the period:
 January 21, 1982 to February 11, 1982
 According to the attached protocol
 (P & G No. C1)
 Issue Date: September 1, 1981

<u>Test Substance (TSIN)</u>	<u>Color</u>	<u>Physical Form</u>	<u>Storage Condition</u>
B0447-01	amber	liquid	room temperature

Sponsor's Divisional Toxicologist: James H. Benedict

Source and Strain of Animals Used: Charles River Laboratories, Inc.; Portage, MI
 Sprague-Dawley rats

Concentration and Amount
 of Test Substance Dosed: Administered undiluted as received at the following dosage levels
 and respective volumes: 4800 mg/kg--4.4 ml/kg; 5760 mg/kg--5.3
 ml/kg; 6912 mg/kg--6.4 ml/kg and 8294 mg/kg--7.7 ml/kg.

RESULTS

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	
4800		1															0/5	1/5	1/10
5760				1													0/5	1/5	1/10
6912		1	5														1/5	5/5	6/10
8294		3	5														3/5	5/5	8/10

LD₅₀ (95% Confidence Limits) Combined Male and Female¹: 6.8(6.2-7.6) g/kg

REFERENCE

- Bliss, C. I., "The Determination of the Dosage Mortality Curve from Small Numbers",
 Quarterly Journal Pharm. Pharmacol, 11: p. 192-216, 1938.

International Research and Development Corporation

Results (Cont.)

Major Pharmacotoxic Signs (Appendix A):

The major pharmacotoxic signs observed in all dosage levels were: ataxia, hypoactivity and piloerection. High carriage was observed in the 5760, 6912 and 8294 mg/kg dosage levels.

Body Weights (Appendix B):

No remarkable changes or differences were observed in the body weights during the study period.

Pathology (Appendix C): There were no test article-related macroscopic changes observed during post-mortem examination of animals dying on study or sacrificed at the termination of the study.

Prepared By:

Daniel Rajasekaran
Daniel Rajasekaran, D.V.M., M.V.Sc. (Path),
F.R.V.C.S. (Path) Sweden
Staff Pathologist

3/18/82
Date

Reviewed By:

Ward R. Richter
Ward R. Richter, D.V.M., A.C.V.P.
Director, Pathology Division

3-19-82
Date

191-731

"credence through research"

International Research and Development Corporation

Technical Supervisory Staff,
Acute Toxicology and Special Studies:

Paul Moxon, B.S.
Unit Supervisor
Adalsteinn Olafsson, B.S.
Group Supervisor

Prepared By:

Julie L. Schmidt
Julie L. Schmidt, B.S.
Unit Supervisor
Acute Toxicology
and Special Studies

3-18-82
Date

Reviewed By:

Dale E. Johnson
Dale E. Johnson, Pharm.D., Ph.D.
Associate Director,
Toxicology Division

3/18/82
Date

STUDY DIRECTOR STATEMENT

The methods used in IRDC Study Number 191-731 followed the experimental criteria specified in the protocol.

To the best of my knowledge, there were no significant deviations from the Good Laboratory Practice Regulations which affected the quality or integrity of this study. This study was conducted in conformance with the Good Laboratory Practice Regulations. This report accurately reflects the raw data obtained during the performance of this study.

All data including the final study report are stored in the International Research and Development Corporation Archives.

James R. Myer
James R. Myer, B.S.
Study Director

3/22/82
Date

191-731

"credence through research"

APPENDIX A
Individual Pharmacotoxic Signs

191-731

80447-01

Individual Pharmacotoxic Signs
4800 mg/kg

Sex	Male				Female				Male	Female	Total Incidence	
	1690	1691	1693	1696	1740	1741	1742	1744				1745
Pharmacotoxic Sign	Day First Appeared	Day of Clearance										
Piloerection		d 2	d 2	c 2	c 2	1 4			1 3			3
High carriage			c 1					c 3	e 2			1
Afexia			c 3	d 2		c 4	1 4	1 4	d 3			2
Wet yellow stain, anogenital area				c 3	e 4	b 4	c 3					1
Dry yellow stain, anogenital area				3 10	4 7	4 1	3 12					3
Dry red material around both eyes						1 4						0
Hypoactivity						1 4	2 3	d 3				0
Possible respiratory congestion						2 7						0
Hair loss on abdomen						7 1	7 1	f 3				0
Clear discharge, both eyes							d 3					0
Wet clear stain around mouth								e 1				0
Day of Death									1			0

- a - 1/2 hour after dosing, Day 0
- b - 1 hour after dosing, Day 0
- c - 2 1/2 hours after dosing, Day 0
- d - 4 hours after dosing, Day 0
- e - Sign did not clear prior to death
- f - Sign did not clear prior to study termination
- g - Sign reappeared on Day 10 and did not clear prior to study termination

B0447-01

Individual Pharmacotoxic Signs
6912 mg/kg

Sex	Animal Number	Male						Female						Total Incidence	
		1647	1653	1657	1660	1661	1704	1700	1715	1714	1716	1716			
		Day First Appeared	Day of Clearance												
	Pharmacotoxic Sign														
	Ataxia	c	b	a	a	c	c	d	c	d	d	d	d	d	e
	Wet yellow stain, enogenital area	d		3	1	e									e
	Dry yellow stain, ventral surface	2	b												e
	Clear wet stain around mouth			b	1	b									e
	Hypoactivity														e
	Body hypothermic to touch														e
	High carriage														e
	Clear discharge, both eyes														e
	Piloerection														e
	Body Tremors														e
	Proxals														e
	Day of Death														e

- a - 1/2 hour after dosing, Day 0
- b - 1 hour after dosing, Day 0
- c - 2 1/2 hours after dosing, Day 0
- d - 4 hours after dosing, Day 0
- e - Sign did not clear prior to death

191-731

B0447-01

Individual Pharmacotoxic Signs
6294 mg/kg

Sex	Animal Number	Male				Female				Total Incidence			
		1648	1650	1651	1654	1658	1700	1701	1703		1707	1715	
	Pharmacotoxic Sign	Day First Appeared	Day of Clearance	Day of Clearance	Day of Clearance								
	Ataxia	d	c	d	d	d	e	d	d	d	d	d	d
	High carriage	d	d	c	d	d	d	d	d	d	d	d	d
	Wet yellow stained anogenital area	c	1	d	d	c	d	d	b	d	d	c	d
	Body tremors	1	1	3	d	d	d	d	d	d	d	d	d
	Hyporeactivity	1	1	3	d	d	d	d	d	d	d	d	d
	Piloerection	1	4	5	d	d	d	d	d	d	d	d	d
	Dry red material around both eyes		2	7									
	Dry yellow material, anogenital area		3	10									
	Clear wet stain around mouth				e								
	Possible respiratory congestion					d	s						
	Clear discharge, both eyes												
	Ptosis												
	Day of Death	1 (P.M.)											

- a - 1/2 hour after dosing, Day 0
- b - 1 hour after dosing, Day 0
- c - 2 1/2 hours after dosing, Day 0
- d - 4 hours after dosing, Day 0
- e - Sign did not clear prior to death

APPENDIX B
Body Weights

191-731

ACUTE TOXICITY (LD₅₀) RECORD

TEST COMPOUND 60447-01 STUDY NO. 191-731
 IRDC NO. 7511
 DOSE VOLUME ml/kg: see dose volume calculation sheet SPECIES RAT SEX m JF
 ROUTE OF ADMINISTRATION Oral DATE ANIMALS RECEIVED 11/14/82 SOURCE CHARLES RIVER
 TIME OF FASTING* 1620 FASTING TECHNICIAN JP DATE 1/27/82
 TIME OF DOSING 1155 DOSING TECHNICIAN KS DATE 1/28/82

DOSAGE 490 mg/kg	ANIMAL NUMBER	1690	1691	1693	1695	1696	TECHNICIAN ^B	1/5	DATE	1/82
		PREFASTED WEIGHT (g)	263	240	277	265	270	*		
	INITIAL BODY WEIGHT (g)	239	219	247	262	249	*			
	ACTUAL DOSE (ml)	1.1	0.96	1.1	1.2	1.1	KS	1/28		
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓	KS	1/28		
	DAY 14 BODY WEIGHT (g)	340	282	328	359	336	JP	2/11		
	DAY BODY WEIGHT (g)									
	DAY BODY WEIGHT (g)									
	DAY BODY WEIGHT (g)									
DOSAGE 490 mg/kg	ANIMAL NUMBER	1740	1741	1742	1744	1745	KS	1/5		
	PREFASTED WEIGHT (g)	217	245	227	205	206	*			
	INITIAL BODY WEIGHT (g)	204	226	206	192	192	*			
	ACTUAL DOSE (ml)	0.90	0.99	0.91	0.84	0.84	KS	1/28		
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓	KS	1/28		
	DAY 14 BODY WEIGHT (g)	237	285	239	277	217	JP	2/11		
	DAY BODY WEIGHT (g)									
	DAY BODY WEIGHT (g)									
	DAY BODY WEIGHT (g)									
DOSAGE 490 mg/kg	ANIMAL NUMBER									
	PREFASTED BODY WEIGHT (g)									
	INITIAL BODY WEIGHT (g)									
	ACTUAL DOSE (ml)									
	DOSE ADMINISTRATION									
	DAY BODY WEIGHT (g)									
	DAY BODY WEIGHT (g)									
	DAY BODY WEIGHT (g)									
	DAY BODY WEIGHT (g)									

NA - Not Applicable * - food removed J - Dose indicated was administered

PREFASTED BODY WEIGHTS DAY 14 BODY WEIGHT DAY BODY WEIGHT
 BALANCE NO. * BALANCE NO. 02400 JP 2/11/82 BALANCE NO. NA
 INITIAL BODY WEIGHTS DAY BODY WEIGHT DAY BODY WEIGHT
 BALANCE NO. * BALANCE NO. NA BALANCE NO. NA

IR36-61-4 * Refer to body weight record 11/14/82
 @m...

Test Article Preparation

191-731

Specific Gravity Determination

Refer to determination in dose range conducted on 1/1/02
Specific Gravity = 1.080 g/ml at 25°C

Dose Volume Calculation

The dose volume was calculated as follows:

$$\frac{\text{Dose Level (}\mu\text{g)}}{\text{Specific Gravity (g/ml)}} = \text{Dose Volume (ml/kg)}$$

$$4800 \mu\text{g} \quad \frac{4800 \mu\text{g}}{1.080 \text{ g/ml}} = 4.4 \text{ ml/kg}$$

The test article was prepared in the same manner as on 1/21/02

KS 1/23/02
P- 1/25/02

Dosing Procedure

The test article was dosed in the same manner as on 1/21/02

KS 1/23/02
P- 1/25/02

- ⊙ recording error
- ⊙ derivation 1/24/02

ACUTE TOXICITY (LD₅₀) RECORD

TEST COMPOUND B0447-01 STUDY NO. 191-731
 IRDC NO. 7511 (CONTAINER NO. 1)
 DOSE VOLUME ml/kg: REFER TO DOSE VOLUME CALCULATION SHEET SPECIES RAT SEX M
 ROUTE OF ADMINISTRATION ORAL DATE ANIMALS RECEIVED 1/14/82 SOURCE CHARLES RIVER
 TIME OF FASTING* 1600 FASTING TECHNICIAN ML DATE 1/20/82
 TIME OF DOSING 1200 DOSING TECHNICIAN KJ DATE 1/21/82

5760 mg/kg DOSAGE	ANIMAL NUMBER	1646	1645	1655	1656	1659	TECHNICIAN	1/21/82
	PREFASTED WEIGHT (g)	209	199	213	194	210	*	
	INITIAL BODY WEIGHT (g)	176	177	184	167	190	*	
	ACTUAL DOSE (ml)	0.93	0.94	0.98	0.97	0.95	KJ	1/21
	DOSE ADMINISTRATION	/	-	/	0.95 ml	-	KJ	1/21
	DAY 14 BODY WEIGHT (g)	302	297	288	250	286	KD	2/4
	DAY BODY WEIGHT (g)							
6912 mg/kg DOSAGE	ANIMAL NUMBER	1647	1653	1657	1660	1661	KJ	1/21
	PREFASTED WEIGHT (g)	210	213	201	207	231	*	
	INITIAL BODY WEIGHT (g)	156	185	171	186	205	*	
	ACTUAL DOSE (ml)	1.2	1.2	1.1	1.2	1.3	KJ	1/21
	DOSE ADMINISTRATION	/	/	/	/	/	KJ	1/21
	DAY 14 BODY WEIGHT (g)	377	317	285	Food removed 1/20/82	318	KD	2/4
	DAY BODY WEIGHT (g)							
8294 mg/kg DOSAGE	ANIMAL NUMBER	1648	1650	1651	1654	1658	KJ	1/21
	PREFASTED BODY WEIGHT (g)	232	205	206	203	196	*	
	INITIAL BODY WEIGHT (g)	202	178	179	174	167	*	
	ACTUAL DOSE (ml)	1.6	1.4	1.4	1.3	1.3	KJ	1/21
	DOSE ADMINISTRATION	-	/	/	/	/	KJ	1/21
	DAY 14 BODY WEIGHT (g)	Food removed 1/20/82	276	Food removed 1/20/82	Food removed 1/20/82	261	KD	2/4
	DAY BODY WEIGHT (g)							

NA - Not Applicable a - food removed J - Dose indicated was administered

PREFASTED BODY WEIGHTS DAY 14 BODY WEIGHT DAY 14 BODY WEIGHT
 BALANCE NO. X BALANCE NO. 00-24 2/1/82 BALANCE NO. NA
 INITIAL BODY WEIGHTS DAY 14 BODY WEIGHT DAY 14 BODY WEIGHT
 BALANCE NO. X BALANCE NO. NA BALANCE NO. NA

IR36-61-4 x Ref. to Body weight Record 1/21/82

Continued

ACUTE TOXICITY (LD₅₀) RECORD

TEST COMPOUND RO447-01 STUDY NO. 191-131
 IRDC NO. 7511 (CONTAINER NO. 1)
 DOSE VOLUME ml/kg: REFER TO BOX VOLUME SPECIES RAT SEX F
CONCENTRATED STOCK
 ROUTE OF ADMINISTRATION ORAL DATE ANIMALS RECEIVED 1/4/62 SOURCE CHARLES RIVET
 TIME OF FASTING* 0 FASTING TECHNICIAN 0 DATE 0
 TIME OF DOSING 0 DOSING TECHNICIAN 0 DATE 0

DOSAGE	mg/kg	ANIMAL NUMBER					TECHNICIAN	DATE	
		1702	1705	1710	1711	1712			
5760	mg/kg	PREFASTED WEIGHT (g)	205	211	219	216	219	*	
		INITIAL BODY WEIGHT (g)	188	190	197	199	205	*	
		ACTUAL DOSE (ml)	1.0	1.0	1.0	1.1	1.1	KJ	1/21
		DOSE ADMINISTRATION	✓	✓	✓	✓	✓	KJ	1/21
		DAY 14 BODY WEIGHT (g)	211	235	226	235	200	KJ	2/4
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
6912	mg/kg	PREFASTED WEIGHT (g)	205	206	212	225	208	*	
		INITIAL BODY WEIGHT (g)	185	186	200	205	197	*	
		ACTUAL DOSE (ml)	1.2	1.2	1.3	1.3	1.3	KJ	1/21
		DOSE ADMINISTRATION	✓	✓	✓	✓	✓	KJ	1/21
		DAY 14 BODY WEIGHT (g)	200	200	200	200	200		
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
8292	mg/kg	PREFASTED BODY WEIGHT (g)	193	199	205	200	207	*	
		INITIAL BODY WEIGHT (g)	173	183	187	181	195	*	
		ACTUAL DOSE (ml)	1.3	1.4	1.4	1.4	1.5	KJ	1/21
		DOSE ADMINISTRATION	✓	✓	✓	✓	✓	KJ	1/21
		DAY 14 BODY WEIGHT (g)	190	190	190	190	190		
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							
		DAY BODY WEIGHT (g)							

NA - Not Applicable a - food removed J - Dose indicated was administered

PREFASTED BODY WEIGHTS DAY 14 BODY WEIGHT DAY 14 BODY WEIGHT
 BALANCE NO. * BALANCE NO. 0 BALANCE NO. NA
 INITIAL BODY WEIGHTS DAY 14 BODY WEIGHT DAY 14 BODY WEIGHT
 BALANCE NO. * BALANCE NO. NA BALANCE NO. NA

IR36-61-6 ① See first sheet X5 1/21/62

* Refer to body weight record X5 1/21/62

Dose Calculations See sheet C-1/21/62
 Dose Administration See sheet C-1/21/62

Test Article Preparation

151-731

Specific Gravity Determination -

Refer to determination in Ouse Range of this study, conducted on 11/1/82

Specific Gravity = 1.080 g/ml at 25°C

Dose Volume Calculation

The dose volume was calculated as follows:

$$\frac{\text{Dose Level (g/kg)}}{\text{Specific Gravity (g/ml)}} = \text{Dose Volume (ml)}$$

$$5760 \text{ mg/kg} - \frac{5760 \text{ g/kg}}{1.080 \text{ g/ml}} = 5.3 \text{ ml/kg}$$

$$6912 \text{ mg/kg} - \frac{6912 \text{ g/kg}}{1.080 \text{ g/ml}} = 6.4 \text{ ml/kg}$$

$$8294 \text{ mg/kg} - \frac{8294 \text{ g/kg}}{1.080 \text{ g/ml}} = 7.7 \text{ ml/kg}$$

The test article was checked undiluted as received. Enough of I 206 7511 (container #1) to dose all animals was poured into a clean labeled beaker. Any unused test article was returned to storage.

KJ 1/21/82
f- 1/21/82

APPENDIX C
Individual Macroscopic Observations

191-731

INDIVIDUAL MACROSCOPIC OBSERVATIONS
Died on Study, Males

B0447-01

<u>SITE</u>	<u>- OBSERVATION</u>	<u>6912 mg/kg</u>	<u>8294 mg/kg</u>
ANIMALS EXAMINED	1660	1648, 1651 1654	
ANIMALS WITHIN NORMAL LIMITS	1660	1648, 1651 1654	

B0447-01
 INDIVIDUAL MACROSCOPIC OBSERVATIONS
 Died on Study, Females

SITE	4800 mg/kg	5760 mg/kg	6912 mg/kg	8294 mg/kg
- OBSERVATION				
ANIMALS EXAMINED	1744	1712	1704, 1708, 1713 1714, 1716	1700, 1701, 1703 1707, 1715
ANIMALS WITHIN NORMAL LIMITS	1744	1712	1704, 1708, 1713, 1714, 1716	1700, 1707, 1715

STOMACH

- Nonglandular mucosa
 hyperemic, focal, mild
 , diffuse, mild

1701
 1703

INDIVIDUAL MACROSCOPIC OBSERVATIONS
Terminal Sacrifice, Males

B0447-01

SITE	4800 mg/kg	5760 mg/kg	6912 mg/kg	8294 mg/kg
- OBSERVATION				
ANIMALS EXAMINED	1690, 1691, 1693, 1695, 1696	1646, 1649, 1655 1656, 1659	1647, 1653, 1657, 1661	1650, 1658
ANIMALS WITHIN NORMAL LIMITS	1690, 1691, 1693, 1695, 1696	1646, 1649, 1655, 1656	1647, 1653, 1657, 1661	1650, 1658

LIVER

- Foci, tan, 2 x 6 mm linear,
focal, mild

1659

INDIVIDUAL MACROSCOPIC OBSERVATIONS
Terminal Sacrifice, Females

B0447-01

SITE	OBSERVATION	4800 mg/kg	5760 mg/kg
ANIMALS EXAMINED	1740, 1741, 1742, 1745	1702, 1705, 1710, 1711	
ANIMALS WITHIN NORMAL LIMITS	1740, 1741, 1742, 1745	1702, 1705, 1710, 1711	

International Research and Development Corporation

QUALITY ASSURANCE STATEMENT

Study Title: Acute Oral Toxicity (LD₅₀ Value in Rats)

Test Article: B0447-01

An inspection of the protocol for this study was conducted on January 20, 1982. A randomly sampled phase of the conduct of this study was inspected on January 21, 1982. Findings were reported to management and the Study Director on January 26, 1982.

This report has been reviewed by the International Research and Development Corporation Quality Assurance Department in accordance with the United States Food and Drug Administration's Good Laboratory Practice Regulations of June 20, 1979.

Approved And
Submitted By:


Barry W. Benson, B.S.
Director of Quality Assurance

3/19/82
Date

191-731

"credence through research"

INTERNATIONAL RESEARCH AND DEVELOPMENT CORPORATION
PROTOCOL REVISION OR CLARIFICATION

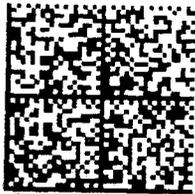
Protocol Sheet No. 1 Study No. 191-731

Title: ACUTE ORAL TOXICITY (LD₅₀ VALUE IN RATS)

ITEM	JUSTIFICATION
1	Study initiation
2	Clarification of IRDC Quality Assurance procedures
3	Clarification of submission to regulatory agency

ITEM	PROTOCOL REVISION OR CLARIFICATION
1	Conduct study in accordance with the attached protocol
2	This study is subject to IRDC Quality Assurance procedures
3	This study is intended to support the registration of products regulated by the Environmental Protection Agency

Study Director James R. Myer, B.S.
James R. Myer . 1/6/82
Signature Date



neopost

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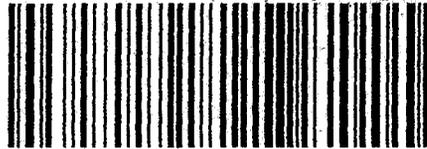
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