ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ- 92-6341	89110000194	3/22/11

COMMENTS: COMMUN S (DECLASS)

DOES NOT CONTAIN CBI

334107

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

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

Re: Declassification Activity-Health and Safety Filing
8EHQ-0892-6341 (EPA DCN 88920004987)

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Any CBI substantiation which appears in the original submission is no longer applicable as the information which was originally claimed CBI is disclosed in this revised submission.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

8 9 1 1 0 0 0 0 1 9 4

Attachment 1

Public Display Version

Chemical Identity	CAS RN
Sodium nitrilotriacetate	
Sodium carbonate	
Sodium hydroxide	
Hydrogen peroxide	
Sodium toluene sulfonate	
Ethanol	
C10-16 Alkyl Polyglycoside	P82-319
1-Dodecanamine, N,N-dimethyl-, N-oxide	1643-20-5
9-Octadecenoic acid	112-80-1
Amides, coco, N,N-bis(hydroxyethyl)	68603-42-9
Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)-bis [5-[[4-[(2-hydroxyethyl)methylamino]-6-(phenyl-amino)-1,3,5-triazin-2-yl]amino]-, disodium salt	13863-31-5
Fragrance	
Colorant	

COMPANY SANITIZED

Procter&Gamble

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

92 AUG 10 PM 2:20

Public Display Copy

8EHQ-0892-6341(S) Inst

August 4, 1992

88920004987 S

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

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 P1082 is a confidential mixture. The composition of the mixture is appended as Attachment 1. The report is titled "Acute Oral Toxicity (LD_{50} Value in Rats)". Any correspondence relating to this submission should reference study # 1205-28071.

The attached study report indicates oral administration of the test material resulted in pharmacotoxic signs including ataxia, hypoactivity, decreased limb tone, and tremors following oral administration of 8000, 8800, 9680, 10648, and 11713 mg/kg of the test material. Impaired righting reflex was also observed in the 9680, 10648, and 11713 mg/kg groups. The acute oral LD_{50} is calculated to be 9680 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.

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

Attachment I

Public Display Copy

Chemical
Sodium nitrilotriacetate
Sodium carbonate
Sodium hydroxide
Hydrogen peroxide
Sodium toluene sulfonate
Ethanol
Alkyl Polyglycoside
Alkylamine oxide
Fatty acid
Substituted amine
Fragrance
Colorant
Substituted stilbene

1205-28071

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 (LD_{50} Value in Rats)

DRD NO.: BTS 2721

TSIN: P1082

REPORT NO.: 191-668

DATE OF SUBMISSION: November 25, 1981

RECEIVED BY
DEC 2 1981
OPERATIONS SECTION

191-668

"credence through research"

STUDY SUMMARY

Study No: 191-668
Sponsor Ref: BTS 2721

Acute Oral Toxicity (LD_{50} Value in Rats)
Report of a biological test performed at:
International Research and
Development Corporation
Mattawan, Michigan

Deviation from
Protocol: None

During the period:
August 27, 1981 to September 29, 1981

According to the attached protocol
(P & G No. C1)
Issue Date: September 15, 1980

Test Substance (TSIN)	Description	Storage Condition
P1082	blue-green liquid	room temperature

Sponsor's Divisional Toxicologist: Robert L. Campbell

Source and Strain of Animals Used: Charles River Laboratories, Inc., Portage, Michigan
Sprague-Dawley Rats

Concentration and Amount of
Test Substance Dosed: Administered undiluted as received at the following dosage levels and respective volumes: 8000 mg/kg - - 7.4 ml/kg; 8800 mg/kg - - 8.2 ml/kg; 9680 mg/kg - - 9.0 ml/kg; 10648 mg/kg - - 9.9 ml/kg and 11713 mg/kg - - 10.9 ml/kg

RESULTS

Dose - Mortality Data:

Dosage Level (mg/kg)	Number of Deaths: Hrs 0-4 M	F	Days 1 M	F	2 M	F	3 M	F	4 M	F	5 M	F	6 M	F	7-14 M	F	Total Mortalities: Male	Female	Total
8000		1				1											0/5	2/5	2/10
8800	1	4															1/5	4/5	5/10
9680	2	4															2/5	4/5	6/10
10648		4															0/5	4/5	4/10
11713	4	4															4/5	4/5	8/10

LD_{50} (95% Confidence Limits) Combined Male and Female[1,2,3]: 9680 (7927-11821) mg/kg

191-668

Results
(Continued)

Major Pharmacotoxic Signs:

The major pharmacotoxic signs observed in all dosage levels were; piloerection, ataxia and hypoactivity. Ptosis of both eyes were observed in the 8000, 8800, 9680, 10648 and 11713 mg/kg dosage levels. High carriage was observed in a few rats in all dosage levels. Most surviving rats appeared normal by Day 4.

Body Weights: No major changes or differences in body weights were observed during the study period.

Pathology: There were no test article-related changes observed during postmortem examination of animals dying during the study or sacrificed at the termination of the study. Macroscopic changes recorded were considered to be agonal or nonspecific.

Prepared By: Linda C. Uraih, D.V.M., M.S. — Date: 11-17-81
Staff Pathologist

Reviewed By: Ward R. Richter, D.V.M., A.C.V.P. — Date: 11-18-81
Director, Pathology Division

191-668

References

1. Weil, C.S., "Tables for Convenient Calculation of Median Effective Dose and Instruction in their Use," Biometrics, 8:249-263, 1952.

2. Thompson, W.R., and Weil, C.S., "On the Construction Tables for Moving Average Interpolation'" Biometrics, 8:51-54, 1952.

3. Eby, R., "Statistical Tables for Dose Evaluation, Report No. 5711", Miles-Ames Research Laboratory, Elkhart, Indiana, 1957.

Technical Supervisory Staff,

Acute Toxicology and Special Studies:

Paul Moxon, B.S.
Unit Supervisor

Adalsteinn Olafsson, B.S.
Group Supervisor

Prepared By: _____ 11-5-81
Julie L. Schmidt, B.S. — Date
Unit Supervisor
Acute Toxicology
and Special Studies

Reviewed By: _____ 11/5/81
Dale E. Johnson, Pharm.D., Ph.D. — Date
Associate Director,
Toxicology Division

STUDY DIRECTOR STATEMENT

The methods used in IRDC Study Number 191-668 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.

_____ 11/24/81
James R. Myer, B.S. — Date
Study Director

191-668

APPENDIX I

Test Article Preparation

191-68

The test article, IRDC 7382 (container #1), was prepared for dosing in the same manner as on 8/27/81. Refer to Test Article Preparation for specific procedures.

RD 9/15/81
P– 9/15/81

Specific Gravity

The specific gravity of IRDC 7382 (container #1) will be the same as the one calculated on ~~August~~ since. Specific gravity of IRDC 7382 (container #1) is 1.074 g/ml. Refer to dose range section of study for specific procedure.

RD 9/15/81
P– 9/15/81

Dose Volume Calculations

The dose volumes of IRDC 7382 (container #1) were calculated using the following formula:

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

8000 mg/kg $\quad \frac{8000 \text{ mg/kg}}{1.074 \text{ g/ml}} = 7.4$ ml/kg

11713 mg/kg $\quad \frac{11713 \text{ mg/kg}}{1.074 \text{ g/ml}} = 10.9$ ml/kg

RD 9/15/81
P– 9/15/81

ACUTE TOXICITY (LD_{50}) RECORD

TEST COMPOUND P 1082 STUDY NO. 191-669

IRDC NO. 7352 (Weinhaimer #1)

DOSE VOLUME ml/kg: see dose volume calculation, SPECIES Rats SEX M

ROUTE OF ADMINISTRATION Oral DATE ANIMALS RECEIVED 8/10/81 SOURCE Charles River

TIME OF FASTING[a] 1600 FASTING TECHNICIAN NA DATE 8/26/81

TIME OF DOSING 1143 DOSING TECHNICIAN P— DATE 8/27/81

DOSAGE 6800 mg/kg	ANIMAL NUMBER	91395	91433	91443	91451	91490	TECHNICIAN P—	DATE 8/27/81
	PREFASTED WEIGHT (g)	295	286	276	268	295	⊗	
	INITIAL BODY WEIGHT (g)	267	263	248	246	266	⊗	
	ACTUAL DOSE (ml)	2.2	2.2	2.0	2.0	2.2	P—	8/27/81
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓	P—	8/27/81
	DAY 7 BODY WEIGHT (g)	318	[illegible]	306	284	313	JK	9/3/81
	DAY 14 BODY WEIGHT (g)	363	[illegible] 8/27/81	346	327	363	JP	9/10/81
	DAY BODY WEIGHT (g)							
	DAY BODY WEIGHT (g)							
DOSAGE 0680 mg/kg	ANIMAL NUMBER	91407	91440	91446	91504	91513	P—	8/27/81
	PREFASTED WEIGHT (g)	264	284	267	290	298	⊗	
	INITIAL BODY WEIGHT (g)	237	257	246	263	280	⊗	
	ACTUAL DOSE (ml)	2.2	2.3	2.2	2.4	2.5	P—	8/27/81
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓	P—	8/27/81
	DAY 7 BODY WEIGHT (g)	272	[illegible]	259	303	[illegible]	JK	9/3/81
	DAY 14 BODY WEIGHT (g)	312	[illegible] 8/27/81	315	339	[illegible] 8/27/81	JP	9/10/81
	DAY BODY WEIGHT (g)							
	DAY BODY WEIGHT (g)							
DOSAGE 10649 mg/kg	ANIMAL NUMBER	91387	91417	91461	91466	91502	P—	8/27/81
	PREFASTED BODY WEIGHT (g)	283	277	275	267	286	⊗	
	INITIAL BODY WEIGHT (g)	255	272	253	241	256	⊗	
	ACTUAL DOSE (ml)	2.5	2.7	2.5	2.4	2.5	P—	8/27/81
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓		
	DAY 7 BODY WEIGHT (g)	290	279	303	277	291	JK	9/3/81
	DAY 14 BODY WEIGHT (g)	338	344	351	316	330	JP	9/10/81
	DAY BODY WEIGHT (g)							
	DAY BODY WEIGHT (g)							

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

PREFASTED BODY WEIGHTS BALANCE NO. 00624 K

DAY 7 BODY WEIGHT BALANCE NO. 00400 JK 9/3/81

DAY NA BODY WEIGHT BALANCE NO. NA

INITIAL BODY WEIGHTS BALANCE NO. 00400 K

DAY 14 BODY WEIGHT BALANCE NO. 00624 JP 9/10/81

DAY NA BODY WEIGHT BALANCE NO. NA

IR36-61-4

⊗ - Data transferred from body weight record P— 8/27/81

Calculations verified by AC 8/27/81

Doses administered verified by AC 8/27/81

ACUTE TOXICITY (LD_{50}) RECORD

TEST COMPOUND P 1082 STUDY NO. 191-668

IRDC NO. 7332 (container #1)

DOSE VOLUME ml/kg: see dose volume calculations SPECIES Rats SEX F

ROUTE OF ADMINISTRATION Oral DATE ANIMALS RECEIVED 8/10/81 SOURCE Charles River

TIME OF FASTING[a] * FASTING TECHNICIAN * DATE *

TIME OF DOSING * DOSING TECHNICIAN * DATE *

DOSAGE 8800 mg/kg	ANIMAL NUMBER	91588	91591	91593	91655	91657	TECHNICIAN P—	DATE 8/27
	PREFASTED WEIGHT (g)	231	211	222	216	217	⊗	
	INITIAL BODY WEIGHT (g)	211	192	204	202	204	⊗	
	ACTUAL DOSE (ml)	1.7	1.6	1.7	1.7	1.7	P—	8/27/81
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓	P—	8/27/81
	DAY 7 BODY WEIGHT (g)	231	[illegible]	[illegible]	[illegible]	[illegible]	JK	9/3/81
	DAY 14 BODY WEIGHT (g)	252	[illegible]	[illegible]	[illegible]	[illegible]	JP	9/10/81
	DAY BODY WEIGHT (g)							
	DAY BODY WEIGHT (g)							
DOSAGE 9680 mg/kg	ANIMAL NUMBER	91519	91572	91587	91633	91656	P—	8/27/81
	PREFASTED WEIGHT (g)	219	232	224	214	227	⊗	
	INITIAL BODY WEIGHT (g)	195	214	210	205	215	⊗	
	ACTUAL DOSE (ml)	1.8	1.9	1.9	1.8	1.9	P—	8/27/81
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓		
	DAY 7 BODY WEIGHT (g)	[illegible]	[illegible]	[illegible]	[illegible]	228	JK	9/3/81
	DAY 14 BODY WEIGHT (g)	[illegible]	[illegible]	[illegible]	[illegible]	240	JP	9/10/81
	DAY BODY WEIGHT (g)							
	DAY BODY WEIGHT (g)							
DOSAGE 10648 mg/kg	ANIMAL NUMBER	91529	91568	91582	91577	91600	P—	8/27/81
	PREFASTED BODY WEIGHT (g)	215	232	212	210	216	⊗	
	INITIAL BODY WEIGHT (g)	197	214	200	192	199	⊗	
	ACTUAL DOSE (ml)	2.0	2.1	2.0	1.7	2.0	P—	8/27/81
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓		
	DAY 7 BODY WEIGHT (g)	[illegible]	235	[illegible]	[illegible]	[illegible]	JK	9/3/81
	DAY 14 BODY WEIGHT (g)	[illegible]	249	[illegible]	[illegible]	[illegible]	JP	9/10/81
	DAY BODY WEIGHT (g)	[illegible]		[illegible]	[illegible]	[illegible]		
	DAY BODY WEIGHT (g)							

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

PREFASTED BODY WEIGHTS BALANCE NO. 00624 ⊗ DAY 7 BODY WEIGHT BALANCE NO. 00520 9/3/81 DAY NA BODY WEIGHT BALANCE NO. NA

INITIAL BODY WEIGHTS BALANCE NO. 00400 ⊗ DAY 14 BODY WEIGHT BALANCE NO. 00624 9/10/81 DAY NA BODY WEIGHT BALANCE NO. NA

IRDC-61-4 * See first sheet AO 9/26/81

⊗ - Data Transferred from Body Weight Record P 8/27/81

Calculations verified by AO 8/27/81. Doses administered verified by AO 8/27/81

Specific Gravity

The Specific Gravity of IRDC 7382 (Container #1) was determined to be 1.074 g/ml. Refer to Dose Range Section of Study for Specific Procedure.

PM 8/27/81
AO 8/27/81

Dose Volume Calculations

The Dose Volumes of IRDC 7382 (Container #1) were calculated using the following formula

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

8800 mg/kg $\quad \frac{8800 \text{ mg/kg}}{1.074 \text{ g/ml}} = 8.2 \text{ ml/kg}$

9680 mg/kg $\quad \frac{9680 \text{ mg/kg}}{1.074 \text{ g/ml}} = 9.0 \text{ ml/kg}$

10648 mg/kg $\quad \frac{10648 \text{ mg/kg}}{1.074 \text{ g/ml}} = 9.4 \text{ ml/kg}$

PM 8/27/81
AO 8/27/81

ACUTE TOXICITY (LD_{50}) RECORD

TEST COMPOUND P1082 STUDY NO. 191-668

IRDC NO. 7382 (continued #1)

DOSE VOLUME ml/kg: See dose volume calculations SPECIES Rat SEX M/F

ROUTE OF ADMINISTRATION Oral DATE ANIMALS RECEIVED 9/2/81 SOURCE Charles F [illegible]

TIME OF FASTING[a] 1620 FASTING TECHNICIAN KD DATE 9/14/81

TIME OF DOSING 1145 DOSING TECHNICIAN KD DATE 9/15/81

DOSAGE M 8000 mg/kg	ANIMAL NUMBER	93700	93709	93710	93711	93718	TECHNICIAN KD	DATE 1981 9/15
	PREFASTED WEIGHT (g)	242	239	240	248	274	(W)	
	INITIAL BODY WEIGHT (g)	224	221	219	225	253	(W)	
	ACTUAL DOSE (ml)	17	16	1.6	1.7	19	KD	9/15
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓	KD	9/15
	DAY 7 BODY WEIGHT (g)	275	264	269	287	307	ME	9/22
	DAY 14 BODY WEIGHT (g)	304	251	309	331	343	ME	9/29
	DAY BODY WEIGHT (g)							
	DAY BODY WEIGHT (g)							
DOSAGE F 8000 mg/kg	ANIMAL NUMBER	93733	93744	93747	93750	93751	KD	9/15
	PREFASTED WEIGHT (g)	224	244	214	225	220	(W)	
	INITIAL BODY WEIGHT (g)	203	230	200	204	209	(W)	
	ACTUAL DOSE (ml)	15	17	15	15	15	KD	9/15
	DOSE ADMINISTRATION	✓	✓	✓	✓	✓	KD	9/15
	DAY 7 BODY WEIGHT (g)	[illegible]	260	[illegible]	222	234	ME	9/22
	DAY 14 BODY WEIGHT (g)	[illegible]	273	[illegible]	235	250	ME	9/29
	DAY BODY WEIGHT (g)	KD 9/15		9/22				
	DAY BODY WEIGHT (g)							
DOSAGE mg/kg	ANIMAL NUMBER						DOSE CALCULATIONS VERIFIED: [illegible] 9/15/81	
	PREFASTED BODY WEIGHT (g)						Dose administration [illegible]	
	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 a - food removed ✓ - Dose indicated was administered

PREFASTED BODY WEIGHTS BALANCE NO. (W) DAY 7 BODY WEIGHT BALANCE NO. [illegible] DAY NA BODY WEIGHT BALANCE NO. NA

INITIAL BODY WEIGHTS BALANCE NO. (W) DAY 14 BODY WEIGHT BALANCE NO. [illegible] DAY NA BODY WEIGHT BALANCE NO. NA

IR36-61-4 (W) Refer to Body Weight Record KD 9/15/81

ACUTE TOXICITY (LD_{50}) RECORD

TEST COMPOUND P1152 STUDY NO. 191-166

IRDC NO. 7347 (container #1)

DOSE VOLUME ml/kg: [illegible] SPECIES Rat SEX M/F

ROUTE OF ADMINISTRATION Oral DATE ANIMALS RECEIVED 9/2/81 SOURCE Charles River

TIME OF FASTING[a] * FASTING TECHNICIAN * DATE *

TIME OF DOSING * DOSING TECHNICIAN * DATE *

DOSAGE 1113 mg/kg							TECHNICIAN RL	DATE 9/15
ANIMAL NUMBER	93695	93712	93715	93716	93721			
PREFASTED WEIGHT (g)	264	264	244	264	261		(W)	
INITIAL BODY WEIGHT (g)	234	248	224	236	242		(W)	
ACTUAL DOSE (ml)	2.6	2.7	2.4	2.6	2.6		RL	9/15
DOSE ADMINISTRATION	✓	✓	✓	✓	✓		RL	9/15
DAY 7 BODY WEIGHT (g)	Force fed	272	Force fed	Force fed	Force fed		ME	9/22
DAY 14 BODY WEIGHT (g)	Day 0 [illegible]	318	Day 0 [illegible]	Day 0 [illegible]	Day 0 [illegible]		ME	9/29
DAY BODY WEIGHT (g)	RL [illegible]		RL [illegible]	RL [illegible]	RL [illegible]			
DAY BODY WEIGHT (g)								

DOSAGE 1113 mg/kg								
ANIMAL NUMBER	93727	93729	93745	93749	93752		RL	9/15
PREFASTED WEIGHT (g)	233	251	228	234	197		(W)	
INITIAL BODY WEIGHT (g)	217	232	213	217	181		(W)	
ACTUAL DOSE (ml)	2.4	2.5	2.3	2.4	2.0		RL	9/15
DOSE ADMINISTRATION	✓	✓	✓	✓	✓		RL	9/15
DAY 7 BODY WEIGHT (g)	Force fed	Force fed	Force fed	238	Force fed		ME	9/22
DAY 14 BODY WEIGHT (g)	Day 0 [illegible]	Day 0 [illegible]	Day 0 [illegible]	236	Day 0 [illegible]		ME	9/29
DAY BODY WEIGHT (g)	RL [illegible]	RL [illegible]	RL [illegible]		RL [illegible]			
DAY BODY WEIGHT (g)								

DOSAGE mg/kg						
ANIMAL NUMBER						DOSE CONFIRMATION VERIFIED [illegible]
PREFASTED BODY WEIGHT (g)						[illegible]
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 a - food removed ✓ - Dose indicated was administered

PREFASTED BODY WEIGHTS BALANCE NO. (W)

DAY 7 BODY WEIGHT BALANCE NO. [illegible]

DAY 14 BODY WEIGHT BALANCE NO. NE

INITIAL BODY WEIGHTS BALANCE NO. (W)

DAY 14 BODY WEIGHT BALANCE NO. [illegible]

DAY 14 BODY WEIGHT BALANCE NO. NE

IR36-61-4 (W) Refer to Body Weight Record RL 9/15/81

* Refer to first sheet RL 9/15/81

P1082.

APPENDIX II
Individual Pharmacotoxic Signs
8000 mg/kg

Sex	Male										Female										Male	Female
Animal Number	93700		93709		93710		93711		93718		93733		93744		93747		93750		93751		Total Incidence	
Pharmacotoxic Sign	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance		
Piloerection	c	2	d	3			c	3							d	e					3	1
Ataxia	d	1					b	1			a	e			a	e	c	2	a	2	2	4
Dry yellow stained anogenital area	1	2																			1	0
Hypersensitive to touch			b	3							a	b	a	2			b	1			1	3
Hypoactivity					d	1	b	3			b	e	c	1	b	e			d	1	2	4
Wet yellow stained anogenital area					1	2			1	2							1	3			2	1
Red material on face					1	2															1	0
Ptosis - both eyes											a	e			a	e					0	2
High carriage											a	b			a	e					0	2
Decreased limb tone											b	e			b	d					0	2
Low carriage											b	e									0	1
Wet clear stain on face															a	1					0	1
Clear discharge - both eyes															1	e					0	1
Body tremors															1	a					0	1
Day of Death											c				2						0	2

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

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APPENDIX II
Individual Pharmacotoxic Signs
8800 mg/kg

Sex	Male										Female										Male	Female
Animal Number	91395		91431		91441		91451		91490		91588		91591		91593		91655		91657		Total Incidence	
Pharmacotoxic Sign	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance		
Wet clear stain on face			a	e																	1	0
Hypoactivity			a	e																	1	0
Ataxia			b	e									a	e	a	e	a	e			1	3
Ptosis - both eyes			b	e									a	e	a	e	a	e			1	3
Wet yellow stained anogenital area							1	2													1	0
Decreased limb tone													a	e	a	e	a	e			0	3
High carriage													a	e							0	1
Low carriage																	a	e			0	1
Body Tremors																	a	e			0	1
Day of Death			c										c		c		c		e		1	4

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

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APPENDIX 11

Individual Pharmacotoxic Signs

9680 mg/kg

Sex	Male										Female										Male	Female
Animal Number	91407		91440		91446		91504		91513		91519		91572		91587		91633		91656		Total Incidence	
Pharmacotoxic Sign	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance		
Hypoactivity	a	1	a	e					a	e			a	e	b	e					3	2
Ataxia	a	2	a	e	c	1			a	e			a	e	b	e			a	2	4	3
Wet red stained anogenital area	1	2			2	4															2	0
Low carriage			b	e																	1	0
Ptosis - both eyes			b	e					a	e			a	e	a	e	a	e			2	3
Body tremors			c	e													b	e			1	1
Wet tan stain on face					a	1					a	a									1	1
Wet yellow stained anogenital area					1	4															1	0
Red crusty material on nose					2	4															1	0
Prostration											a	e									0	1
Gasping											a	e					b	e			0	2
Feet appear flushed											b	e									0	1
High carriage													a	e							0	1
Impaired righting reflex															a	b	a	e			0	2
Decreased limb tone															b	e					0	1
Wet clear stain on face																	b	e			0	1
Wet reddish yellow stained anogenital area																			1	2	0	1
Day of Death			d						c		c		c		e		c				2	4

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

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APPENDIX II
Individual Pharmacotoxic Signs
10648 mg/kg

Sex	Male										Female										Male	Female
Animal Number	91384		91447		91461		91466		91502		91529		91568		91582		91597		91600		Total Incidence	
Pharmacotoxic Sign	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance		
Wet clear stain on face	e	1							a	1											2	0
Wet yellow stained anogenital area	1	2	1	4	1	2			1	4											4	0
Ataxia	1	2	c	3	b	2	b	2	a	3	b	e					a	e	b	e	5	3
Hypoactivity	1	2	a	3	c	1	b	2	a	4	b	e					a	e			5	2
Low carriage			c	1																	1	0
High carriage			1	2			1	2					a	d,f					a	e	2	2
Decreased limb tone							b	1			b	e					a	e			1	2
Wet reddish-yellow stained anogenital area							1	2					1	2							1	1
Possible respiratory congestion									1	6											1	0
Impaired righting reflex											a	b									0	1
Ptosis - both eyes											a	e					a	e			0	2
Hypersensitive to touch													a	2							0	1
Body tremors																	a	e			0	1
Day of Death											c				a		b		c		0	4

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 reappeared on Day 1 and cleared on Day 2

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APPENDIX II

Individual Pharmacotoxic Signs

11713 mg/kg

Sex	Male										Female										Male	Female
Animal Number	93695		93712		93715		93716		93721		93727		93729		93745		93749		93752		Total Incidence	
Pharmacotoxic Sign	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance	Day First Appeared	Day of Clearance		
Wet clear stain on face	a	e			a	e	a	e													3	0
Ataxia	a	e	a	2	a	e	a	e	a	e	a	e	a	e	a	e	a	2			5	4
Hypoactivity	a	e	c	2	a	e	b	e	a	e	a	e			a	e	a	2	c	e	5	4
Ptosis - both eyes	a	e			b	e			a	e	a	e	b	e	a	e	c	1	c	e	3	5
Impaired righting reflex	b	e			b	e	b	e	b	e			b	e	c	e			c	e	4	3
Possible respiratory congestion			a	3																	1	0
Piloerection			c	11							a	e									1	1
High carriage			1	3					a	b							c	3	b	c	2	2
Body tremors					b	e					a	e									1	1
Hypersensitive to touch							a	b													1	0
Decreased limb tone											a	e	b	e							0	2
Prostration													c	e							0	1
Body hypothermic to touch													c	e							0	1
Reddish yellow stained anogenital area																	1	2			0	1
Dry brown stain - abdomen and anogenital area																	2	11			0	1
Day of Death	c				c		c		c		c		d		d				d		4	4

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

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APPENDIX III
INDIVIDUAL MACROSCOPIC OBSERVATIONS
Deaths and Unscheduled Sacrifices, Males

SITE - OBSERVATION	8800 mg/kg	9680 mg/kg	11713 mg/kg
ANIMALS EXAMINED	91433	91440, 91513	93695, 93715, 93716, 93721
ANIMALS WITHIN NORMAL LIMITS			93715
BRAIN			
- Sub-dural hemorrhage, diffuse, moderate			93695, 93716, 93721
LUNGS			
- Left lobe, congestion, focal, moderate			93716
STOMACH			
- Glandular mucosa hyperemic, diffuse, moderate	91433	91440, 91513	93695, 93716, 93721
SMALL INTESTINE			
- Mucosa hyperemic diffuse, moderate	91433		

APPENDIX III
INDIVIDUAL MACROSCOPIC OBSERVATIONS
Deaths and Unscheduled Sacrifices, Females

SITE - OBSERVATION	8000 mg/kg	8800 mg/kg	9680 mg/kg	10648 mg/kg	11713 mg/kg
ANIMALS EXAMINED	93747, 93733,	91591, 91593, 91655, 91657	91519, 91572, 91587, 91633	91529, 91582, 91597, 91600	93727, 93729, 93745, 93752
ANIMALS WITHIN NORMAL LIMITS			91519		
BRAIN					
- Vessels injected mild	93747				
- Sub-dural hemorrhage, focal/diffuse, mild/moderate	93733				93729, 93745
STOMACH					
- Glandular mucosa hyperemic, diffuse, mild/moderate/severe	93733	91591, 91593, 91655, 91657	91633, 91572, 91587	91529, 91582, 91597, 91600	93727, 93729, 93745, 93752

APPENDIX III
INDIVIDUAL MACROSCOPIC OBSERVATIONS
Terminal Sacrifice, Males

SITE - OBSERVATION	8000 mg/kg	8800 mg/kg	9680 mg/kg	10648 mg/kg	11713 mg/kg
ANIMALS EXAMINED	93700, 93709, 93710, 93711. 93718	91443, 91490, 91451, 91395	91440, 91407, 91446, 91504	91384, 91466, 91502, 91447, 91461*	93712
ANIMALS WITHIN NORMAL LIMITS	93700, 93709, 93710, 93711, 93718	91443, 91490, 91451, 91395	91407, 91446, 91504	91384, 91466, 91502, 91447	
KIDNEYS - mottled					93712
STOMACH - Glandular mucosa hyperemic, diffuse, moderate			91440		

*Observations inadvertently not recorded for this animal

APPENDIX III
INDIVIDUAL MACROSCOPIC OBSERVATIONS
Terminal Sacrifice, Females

SITE - OBSERVATION	8000 mg/kg	8800 mg/kg	9680 mg/kg	10648 mg/kg	11713 mg/kg
ANIMALS EXAMINED	93744, 93750, 93751	91588	91656	91568	93749
ANIMALS WITHIN NORMAL LIMITS	93744, 93750, 93751	91588	91656	91568	93749

QUALITY ASSURANCE STATEMENT

Study Title: Acute Oral Toxicity (LD_{50} Value in Rats)

Test Article: P1082

An inspection of the protocol for this study was conducted on August 26, 1981. A randomly sampled phase of the conduct of this study was inspected on August 27, 1981. Findings were reported to management and the Study Director on October 30, 1981.

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: 4-23-81

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

191-668

INTERNATIONAL RESEARCH AND DEVELOPMENT CORPORATION

PROTOCOL REVISION OR CLARIFICATION

Protocol Sheet No. 1 Study No. 191-668

Title: ACUTE ORAL TOXICITY (LD_{50} 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 will not be submitted to a regulatory agency

Approved by:

Sponsor's Representative Date 8/25/81

Study Director James R. Myer, B.S.

Signature Date 8/17/81

IR90-49-5

THE PROCTER & GAMBLE COMPANY

PROTOCOL NO. C1

Acute Oral Toxicity (LD_{50} Value in Rats)

Issue Date: September 15, 1980
Supersedes Issue Dated: January 1, 1980

Test Substance Identification Number (TSIN) # P1082

Divisional Request Document Number (DRD) 2721

Sponsor: The Procter & Gamble Company
Cincinnati, Ohio

Testing Facility: (To be filled in by Operations Section)
International Research and Development Corporation
Mattawan, Michigan 49071

Study # 191-668
(To be filled in by Testing Facility)

Purpose: To establish the LD_{50} value of a test substance in the rat so that it may be compared with more familiar substances.

Justification for Selection of Test System: The rat is the animal classically used due to its small size, ready availability, and the large amount of background data.

Route of Administration of Test Substance and Reason for Choice: By gavage. This is a method for administering a known quantity of test substance and has been the route of choice historically.

Diet and/or Water Analyses Required: None (no known contaminants expected which would interfere with this study)

Records to be Maintained: All records that would be required to reconstruct the study and demonstrate adherence to protocol.

Acute Oral Toxicity (LD_{50} Value in Rats)

Issue Date: September 15, 1980

Test Substance(s)

TSXN #	DRD Number	Description: Color	Description: Physical Form	Expiration Date
P1082	BTS 2721	Blue green	liquid	9/1/82

Storage Conditions: (Check one)

[✓] Room temperature [ ] Refrigerator [ ] Freezer
[ ] Other

Hazards: (Check one)

[✓] None known. Take ordinary precautions in handling.
[ ] As follows:

Special Instructions: (Check one)

[ ] None
[✓] As follows: AVOID SKIN and EYE contact

Animals: Forty (40) rats, Sprague-Dawley (cesarean-dervied), 20 males and 20 females, 190-300 grams prefasted weight. Additional animals will be required if more than four groups are requested. (See pp. 3 and 4.) Fewer animals will be required if only a single group is requested. (See p. 3.)

Animal Care: Follow the approved Standard Operating Procedures of the Test Facility.

Environmental Conditions: Follow the approved Standard Operating Procedures of the Test Facility.

Animal Identification: Follow the approved Standard Operating Procedures of the Test Facility.

Acute Oral Toxicity (LD_{50} Value in Rats)

Issue Date: September 15, 1980

Estimated LD_{50} value of the undiluted test substance: 8-10 g/kg
(If unknown, conduct a range-finding experiment following the Standard Operating Procedures of the Test Facility.)

Group Assignment: Determine prefasted body weights and select animals weighing 190-300 grams for study.

If the range finding experiment or Sponsor's estimate indicates the Acute Oral Toxicity/LD_{50} value to be >20 g/kg of test substance, administer a single dose of 20 g/kg to ten (10) animals (5 males and 5 females). If the dose volume required to administer 20 g/kg exceeds 25 ml/kg, contact the Sponsor's Divisional Toxicologist for further instructions. If the mortality of these animals indicates that the LD_{50} value would be >20 g/kg, report an estimated LD_{50} value of >20 g/kg.

If the range finding experiment or Sponsor's estimate indicates an LD_{50} value of less than 20 g/kg, choose four (4) dosage levels, based upon the estimated LD_{50} value and/or range finding experiment. When feasible, choose dosage levels following a geometric progression of 1.4. If high dose levels require dose volumes which exceed 25 ml/kg, contact Sponsor's Divisional Toxicologist for further instructions. Place ten (10) animals in each group, divided by sex (5 males, 5 females). Assign animals to groups following the Standard Operating Procedures of the Test Facility.

Dose Preparation: Test Group(s): (Check appropriate box)

[✓] Dose test substance undiluted
[ ] Dose as a _____% (w/w) solution/suspension of test substance in _____.
[ ] Dose as a _____% (w/v) solution/suspension of test substance in _____.
[ ] Dose per Special Instructions (see page 2)

Control Group

A control group should be [ ]; should not be [✓] included in this study. If included, the control substance _____ should be tested concurrently with the test substance at a dosage level of _____.

Dose Preparation (Cont'd):

Test Group(s) (Cont'd)

Note

A concentration analysis of the test substance - vehicle mixture(s) will [ ]; will not [✓] be required.

If a concentration analysis is required:

[ ] Prepare a sufficient quantity of the test substance - vehicle mixture(s) so that a portion can be returned to the Sponsor's Divisional Toxicologist.

Shipping Instructions

Send approximately _____ml. Send [ ] frozen; [ ] under ambient conditions; [ ] other_____ _____

[ ] Analyze the test substance - vehicle mixture(s) for test substance concentration using the analytical method in Appendix _____.

Dosing Instructions: Deprive the animals of food for 18-20 hours before administering the test substance. Determine fasted body weights. Calculate the dose for each animal according to fasted body weight to give the specified quantities of test substance per unit of body weight.*

More than four dosage levels may be required to establish a death-to-dose response that will allow the LD_{50} value to be calculated. (Note: If the data generated from four dosage levels do not lend themselves to statistical analysis by the Test Facility's Standard Operating Procedures, the Sponsor should be contacted prior to further experimental work.)

*Determine specific gravity values, if required, to calculate dose levels for all test substances dosed undiluted or solutions prepared for dosing on a weight to weight (w/w) basis.

PROTOCOL NO. C1 (Cont'd)

Acute Oral Toxicity (LD_{50} Value in Rats)

Issue Date: September 15, 1980

Dosing Instructions (Cont'd):

The test substance, at the concentration specified under "Dose Preparation", will be gavaged into the stomach of the animal following the Test Facility's Standard Operating Procedures. Record all information necessary to document animal weights and volume of test substance administered to each animal.

Immediately after dosing, return the animal to *ad libitum* feeding.

Observations:

Option A [ ] Observe all animals for mortality at frequent intervals during the first 4 hours after dosing (at least once during the first 30 minutes) and daily thereafter for the next 14 days. Record time of death. On day 14 weigh and discard survivors following the Test Facility's Standard Operating Procedures.

Option B [ ] Observe all animals for mortality and pharmacotoxic symptoms at frequent intervals during the first 4 hours after dosing (at least once during the first 30 minutes) and daily thereafter for the next 14 days. Record all pharmacotoxic symptoms and time of death. On day 14 weigh and discard survivors following the Test Facility's Standard Operating Procedures.

Option C [✓] Observe all animals for mortality and pharmacotoxic symptoms at frequent intervals during the first 4 hours after dosing (at least once during the first 30 minutes) and daily thereafter for the next 14 days. Record all pharmacotoxic symptoms and time of death. Perform a gross necropsy on all animals that die following the Test Facility's Standard Operating Procedures. On day 14 weigh and perform a gross necropsy on the surviving animals. Record all findings. Discard animals following the Test Facility's Standard Operating Procedures.

Protocol Changes:

If it becomes necessary to change the approved protocol, verbal agreement to make this change should be made between the Study Director and the Sponsor. As soon as practical, this change and the reasons for it should be put in writing and signed by both the Study Director and the Sponsor's Divisional Toxicologist. This document is then attached to the protocol as an addendum.

PROTOCOL NO. C1 (Cont'd)

Acute Oral Toxicity (LD_{50} Value in Rats)

Issue Date: September 15, 1980

Report: Report dates of study initiation and termination. Report all data regarding dose preparation, individual dose level, body weights, mortality, pharmacotoxic signs, gross necropsy results, etc., where appropriate. Report the LD_{50} value and 95% confidence limits of the test substance preferably calculated by the Probit Method* by the use of the computer program BLISS17**. Other calculation methods may be used. The method used should be specified in the final report. This report shall conform to all requirements outlined in Section 58.185, Subpart J, Good Laboratory Practices Regulations.

Sponsor: Robert L. Campbell
Divisional Toxicologist

Date Approved by Sponsor's Divisional Toxicologist 7/31/81

Proposed Starting Date: Week of 8/24/81

Proposed Completion Date: November 4, 1981
(Final Report Available)

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

Date: August 17, 1981

Study Cost:

(To be completed by the Test Facility)

*D. J. Finney, Probit Analysis, 3rd Ed., Cambridge Univ. Press 1971, pp. 50-90.

**Fortran version of BLISS17 program, written by D. J. Finney.

International Research
and Development Corporation
MATTAWAN, MICHIGAN U.S.A. 49071 TELEPHONE (616) 668-3336

Amendment
to the
Final Report

SPONSOR:	The Procter and Gamble Company
SUBJECT:	Acute Oral Toxicity (LD_{50} Value in Rats)
DRD NO.:	BTS 2721
TSIN:	P1082
REPORT NO.:	191-668
DATE OF SUBMISSION:	January 4, 1982

191-668

"credence through research"

The following correction is made in this report originally issued November 25, 1981:

Appendix III, Terminal Sacrifice, Males

Delete

Stomach

- Glandular mucosa hyperemic, diffuse, moderate

Delete animal number 91440 from table

James R. Myer, B.S.
Study Director

12/29/81
Date

191-668

APPENDIX III
INDIVIDUAL MACROSCOPIC OBSERVATIONS
Terminal Sacrifice, Males

SITE - OBSERVATION	8000 mg/kg	8800 mg/kg	9680 mg/kg	10648 mg/kg	11713 mg/kg
ANIMALS EXAMINED	93700, 93709, 93710, 93711, 93718	91443, 91490, 91451, 91395	91407, 91446, 91504	91384, 91466, 91502, 91447, 91461*	93712
ANIMALS WITHIN NORMAL LIMITS	93700, 93709, 93710, 93711, 93718	91443, 91490, 91451, 91395	91407, 91446, 91504	91384, 91466, 91502, 91447	
KIDNEYS - mottled					93712

*Observations inadvertently not recorded for this animal

James R. Myer, B.S.
Study Director

12/29/01
Date

Revised Page

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