

ORIGINAL

**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-92-10098	<b>89110000201</b>	3/22/11

COMMENTS: COMMUN S (DECLASS)

**DOES NOT CONTAIN CBI**

334114



**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

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11 MAR 22 AM 6:03

**Re: Declassification Activity-Health and Safety Filing  
8EHQ-0892-10098 (EPA DCN 88920008399)**

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Any CBI substantiation which appears in the original submission is no longer applicable as the information which was originally claimed CBI is disclosed in this revised submission.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

The mixture identified as P1906 is:

<u>Chemical Identity</u>	<u>CAS RN</u>
Benzenesulfonic acid, C10-16-alkyl derivatives	68584-22-5
Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.hydroxy-, C10-16-alkyl ethers, sodium salts	68585-34-2
Alcohols, C12-13, ethoxylated	66455-14-9
Fatty acids, C8-18 and C18-unsatd.	67701-05-7
1,2,3-Propanetricarboxylic acid, 2-hydroxy-	77-92-9
Glycine, N,N-bis[2-[bis(carboxymethyl)amino]ethyl]-, pentasodium salt	140-01-2
Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5[[4-[(2-hydroxyethyl)methylamino]-6-(phenylamino)1,3,5-triazin-2-yl]amino]-, disodium salt	13863-31-5
Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5[[1,4-dihydro-4-oxo-6-(phenylamino)-1,3,5-triazin-2-yl]-amino]-, disodium salt	1264-32-0
Formic acid, calcium salt	544-17-2
1,2-Ethanediamine, N-(2-aminoethyl)-N'-[2-[(2-aminoethyl)amino]ethyl]-, polymer with methyloxirane and oxirane	68815-65-6
Subtilisin	9014-01-1
Amylase	900-92-4

Fragrance Mixture

Boric acid

Ethanol, . 2-amino-

1,2-Propanediol

Ethanol

**Attachment 1 (continued)**

**Public Display Version**

*The mixture identified as P1907 is:*

**Chemical Identity**

**CAS RN**

Dodecanediperoxoic acid

66280-55-5

Benzenesulfonic acid, C10-16-alkyl derivatives

68584-22-5

2,6-Pyridinedicarboxylic acid

499-83-2

Sulfuric acid magnesium salt (1:1)

Sulfuric acid disodium salt

Water

Attachment 1 (continued)

Public Display Version

The mixture identified as P1472 is:

<u>Chemical Identity</u>	<u>CAS RN</u>
Benzenesulfonic acid, C10-16-alkyl derivatives	68584-22-5
Poly(oxy-1,2-ethanediyl), .alpha.-sulfo-.omega.hydroxy-, C10-16-alkyl ethers, sodium salts	68585-34-2
Alcohols, C12-13, ethoxylated	66455-14-9
Fatty acids, C12-18	67701-01-3
Glycine, N,N-bis[2-[bis(carboxymethyl)amino]ethyl]-, pentasodium salt	140-01-2
1-Dodecanaminium, N,N,N-trimethyl-, chloride	112-00-5
1,2-Ethanediamine, N-(2-aminoethyl)-N'-[2-[(2-aminoethyl)amino]ethyl]-, polymer with methyloxirane and oxirane	68815-65-6
Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[S[4- [(2-hydr'oxyethyl) methylamino] -6- (phenylamino)l, 3,5-triazin-2-yl]amino]-, disodium salt	13863-31-5
Benzenesulfonic acid~ 2,2'-(1,2-ethenediyl)bis[ S-[[1,4-dihydro-4-oxo-6-(phenylamino)-1,3,Striazin-2-yl]amino]-, disodium salt	1264-32-0
Formic acid, sodium salt	141-53-7
Calcium chloride	10043-52-4
2-Anthracenesulfonic acid, 4,4'-[(1-methylethylidene) bis(4,l-phenyleneimino)]bis[1-amino9,10-dihydro-9,10-dioxo-, disodium salt	6471-01-8

Attachment 1 (continued)

Public Display Version

P1472 (cont.):

**Chemical Identity**

**CAS RN**

1,2,3-Propanetricarboxylic acid, 2-hydroxy-

Ethanol

Water

1,2-Propanediol

Ethanol, 2-amino-

Ethanol, 2,2',2"-nitrilotris-

Sodium hydroxide

Potassium hydroxide

Fragrance Mixture

8EHO-092-10098

# Procter & Gamble COMPANY SANITIZED

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

## Public Display Copy

August 24, 1992

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

8EHO-92-10098, INIT  
88920008399

RECEIVED  
AUG 24 1992

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 materials identified in the attached report as P1906 and P1907 are confidential mixtures. The compositions of the mixtures are appended as Attachment 1. The report is titled "Acute Percutaneous Toxicity". Any correspondence relating to this submission should reference study # 1348-32390.

This submission provides data on the acute percutaneous toxicity of a mixture of P1906 and P1907 mixed in a 5.5 to 1 ratio and dosed at 2 ml/kg. This mixture resulted in severe skin irritation, the death of 3/6 rabbits treated, and the occurrence of slightly fatty livers in the three animals which died on test. Surviving animals had no significant findings other than skin effects at necropsy.

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:

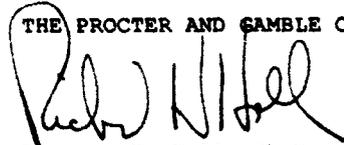
1. Confidentiality of the chemical constituents and their percentages should be maintained indefinitely. There are no plans for this information to be otherwise disclosed, and this technology has significant commercial value.
2. To our knowledge, there have been no government confidentiality determinations made for this mixture.

~~CONFIDENTIAL~~

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

The mixture identified as P1906 is:

Alkyl benzene sulfonic acid

Sodium alkyl ethoxy sulfate

Alkyl ethoxylate

Fatty acid

Citric acid

Substituted amine

Mono ethanol amine

Propylene glycol

Ethanol

Substituted stilbene

Fragrance

Boric Acid

Calcium salt

Substituted amine

Enzyme

***Procter & Gamble***

Attachment I (cont.)

**Public Display Copy**

The mixture identified as P1907 is:

Derivatized organic acid

Magnesium sulfate

Sodium sulfate

Alkyl benzene sulfonic acid

Organic acid

Water

1348-32390

THE PROCTER & GAMBLE COMPANY  
Miami Valley Laboratories  
P.O. Box 39175  
Cincinnati, Ohio 45247

ACUTE PERCUTANEOUS TOXICITY

B85-0007

BTS 3201

P1906  
P1907

April 4, 1985

B85-0007

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# THE PROCTER & GAMBLE COMPANY

MIAMI VALLEY LABORATORIES

P. O. BOX 39175  
CINCINNATI, OHIO 45247

The following study was reviewed by the Quality Assurance Units:

LABORATORY: The Procter & Gamble Company  
BIF - Miami Valley Laboratories  
P.O. Box 39175  
Cincinnati, Ohio 45247

STUDY NUMBER: B85-0007

DIVISIONAL REQUEST DOCUMENT: BHS 3201

TSIN: P1906, P1907

TYPE OF STUDY: Acute Percutaneous Toxicity

PORTION(S) OF STUDY REVIEWED:	REVIEWED BY:	DATE(S) OF REVIEW:	DATE(S) FINDINGS REPORTED TO STUDY DIRECTOR:
Test Substance Handling	L. K. Klahn	1/14/85	1/14/85

The protocol was reviewed for compliance to the GLP regulations.

Significant audit findings (if any) were reported to the Study Director and Facility Management immediately. All audit findings are reported to Management on a periodic basis.

The final study report was reviewed for inaccuracies and procedural compliance. The results reflect the raw data of the study.

T. E. Gulman / JER 4/4/85  
Quality Assurance Unit Coordinator

SUMMARY AND CONCLUSIONS

The acute dermal LD50 of a combination of P1907 and P1906 (1:5.5 ratio) was found to be 2.0 ml/kg. This test substance mixture resulted in the death of 3 of 6 animals. Relatively severe dermal responses were noted on all animals which resulted in the development of eschar on the surviving animals. The extent of dermal irritation was not considered to be the direct cause of death.

Postmortem examination of 3 animals that died prematurely revealed severe dorsal treatment area skin erythema and evidence of fatty livers, but no evidence to suggest a probable cause of death. Remaining animals were necropsied according to schedule, and although dorsal treatment area skin alterations consistent with the final in-life observation were present, no evidence of any other alterations was observed. The significance of the fatty alteration in livers of animals that died prematurely could not be determined within the confines of the present study.

OBJECTIVES AND BACKGROUND

The purpose of this study was to evaluate and characterize the gross dermal and systemic effect produced by P1907 and P1906 (1:5.5 ratio) when applied to the backs of rabbits at a dose level of 2 ml/kg.

STUDY IDENTIFICATION

STUDY DIRECTOR: G. A. Nixon

DIVISIONAL TOXICOLOGIST: K. W. Miller

SPONSORING DIVISION: Packaged Soap & Detergent Division

TESTING FACILITY: The Procter & Gamble Company  
Miami Valley Laboratories  
Biological Testing Facility

DIVISIONAL REQUEST DOCUMENT

NUMBERS: BIS 3201

STUDY NUMBER: B85-0007

STUDY NOTEBOOK: YE-7371

DATES: 1/10/85 - 1/24/85

MATERIALS AND METHODS (PROTOCOL ATTACHED)

TEST SUBSTANCE

TEST SUBSTANCE

IDENTIFICATION: P1906, P1907

CONCENTRATION OF TEST

SUBSTANCE TESTED: One (1) part P1907 and 5.5 parts P1906 (Undilute)

**TEST SUBSTANCE STORAGE**

CONDITION: Room Temperature and Humidity

CONTROL SUBSTANCE: None

**ANALYSIS OF TEST**

SUBSTANCE/CARRIER

MIXTURE: Not required, see Protocol Page 3

TEST SYSTEM**SPECIES, STRAIN AND SOURCE**

OF ANIMALS: Rabbit, New Zealand Albino, Hazleton Research Animals

INITIAL ANIMAL WEIGHT RANGE: 2807-3403g

ANIMAL RESTRAINT: Harness

**GROUP AND TREATMENT:**

GROUP	NUMBER OF ANIMALS		TREATMENT
	MALE	FEMALE	
1	4626, 4633, 4646	4595, 4597, 4617	1 part P1907 + 5.5 parts 1906, undilute, 2 ml/kg (Intact skin)

IN-LIFE

The study was conducted according to the attached protocol. There were no known deviations.

ANATOMIC PATHOLOGY

Three animals were found dead on January 13, 1985 and postmortem examinations were performed on these animals on January 14, 1985 (4646, 4597, 4617). P. H. Long, D.V.M., of the Pathology Section performed these necropsies.

Scheduled postmortem examinations were performed on the three remaining animals (4626, 4633, 4595) on January 24, 1985. The following pathology personnel were in attendance:

R. L. Kanerva - Pathologist Designate  
W. E. Wyder - Necropsy Coordinator  
D. M. Barnett - Prosector

No tissues were taken at either sacrifice for histologic processing.

RESULTS AND DISCUSSIONIN-LIFE

The acute dermal LD<sub>50</sub> of a mixture of P1906 and P1907 was found to be approximately 2.0 ml/kg. The test substance mixture produced severe erythema (6 animals) and slight edema (4 of 6 animals) on the test sites following the 24 hour exposure period.

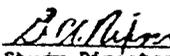
The abdominal area of all animals was moist when the wrappings were removed. This eventually led to denuded (all survivors) and raw (1 survivor) skin in this area. Atonia developed on 5 of 6 animals within 3-4 days. Three animals died on days 4-5. Signs of anorexia were observed for all animals that died plus one survivor. General signs of morbidity and depression were also observed for 4 of 6 animals. Test site skin eschar leading to exfoliation was noted on all survivors. Except for skin, all gross signs of toxicity subsided by day 7 although one animal showed a significant body weight loss over the course of the study (In-Life Table 1).

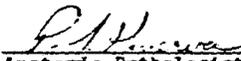
Individual animal skin and health data sheets are attached as In-Life Appendices 1 and 2, respectively.

Anatomic Pathology

Postmortem examinations of 3 animals that died prematurely were conducted on 1/14/25. Examination of each animal revealed severe dorsal treatment area skin erythema, evidence of a fatty liver (generally mild), little or no food in the stomach, and evidence of postmortem change. In addition, one animal had pulmonary congestion. The probable cause of the premature death of these animals could not be determined.

The remaining animals were necropsied according to schedule. Gross examination of these animals revealed dorsal treatment area skin alterations that were consistent in degree and nature with the final in-life observations. There was, however, no evidence of any other alterations. The significance of the fatty alteration in livers of animals that died prematurely could not be determined within the confines of the present study.

  
Study Director

  
Anatomic Pathologist  
Designate

  
Anatomic Pathologist

In-Life Table 1  
B85-0007

INDIVIDUAL ANIMAL BODY WEIGHTS

<u>ANIMAL #/ SEX</u>	<u>INITIAL (g)</u>	<u>FINAL (g)</u>	<u>CHANGE (g)</u>
4595 F	2807	2945	138
4626 M	3214	3331	117
4633 M	3069	2765	-304
4597 F	3403	+	+
4646 M	2958	+	+
4617 F	3283	+	+

+ Premature death

ACUTE PERCUTANEOUS TOXICITY

Study #: 885-0007 CID #: 812 320 / TRIN #: \*  
 Animal #: 4595 Sex: (M) / (F) (F)  
 Dose Level: 500 mg/kg by gavage / (i.p.)  
 Concentration: 100 mg/ml / (i.v.)  
 Animal Source/Supplier: Harlan Winkelmann  
 Date(s) shipped: 1-10-85  
 \* 1 part P1907 to 5.5 parts P1906 mixed for 2 minutes  
 Initial Body Wt. (g.): 2807 Balance # N.Y.: 23152  
 Total Dosed (Took Substance and Vehicle): 5  
 Time Protocol: 1:15 PM Abraded (A): None (I): IF  
 Signature: [Signature] Date: 1-10-85  
 Date/Time Wrapping Material: 1:15 PM 1-11-85  
 Final Body Wt. (g.): 2945 Balance # N.Y.: 23152  
 Initial Body Wt. (g.): 2807 Balance # N.Y.: 23152  
 Study Date: 1-20-85  
 Study Room #: 217  
 Retriever: [Signature]

NOTE: OBSERVATIONS - One for evaluating skin reactions is found in protocol

DATE	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
IRTHNA	0	3	3	3	3	3	3	3	3	3	3	3	3	3	3
FOOD	0	0	0	1	1	1	1	1	1	1	1	1	1	1	1
WTR	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1
RESQUAMTION	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PISSING	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SCHEAS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
EXPIRATION	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
WORKER'S INITIALS	RF														

Comments: \* Unable to evaluate symptoms due to sickness.  
RF 1/21/85

ACUTE PERCUTANEOUS TOXICITY

Study #: 885-0007 and #: ATA 320/1018 #1 \*  
 Animal #: 41026 Sex: V (M) (F)  
 Group Label: Control No. Mice/Animals: 3 Dilutions: \_\_\_\_\_  
 Concentration: 100000  
 Animal Source/Species: Hyphessobrycon equidens (Peters)  
 Date(s) Clipped: 1-10-83 all the belly  
 \* 1 part P1907 to 5.5 parts P1906 mixed for 2 months

Initial Body Wt. (g.): 3.214 Balance # N.Y.: 23/52  
 Total Food (Feed Substance and Vehicle): C.F. and  
 Time Fed: 1:37 PM Abated (A): None (H): \_\_\_\_\_  
 Signature: Richard Pearce Date: 1-10-83  
 Time/Date Weighing Animals: 1:37 PM 1-11-83  
 Final Body Wt. (g.): 3.331 Balance # N.Y.: 23/52 Date: 1-24-83  
 Study Date: 1-17  
 Pathologist: Herman

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in Protocol

DATE	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
EMERSON	0	3	3	3	3	3	3	2	2	2	2	**	**	**	**
EDNA	0	1	1	1	1	1	1	1	1	1	1	**	**	**	**
ATONTA	0	0	1	1	1	1	1	1	1	1	1	**	**	**	**
DESQUAMATION	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
FISSURING	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
ESCHAR	N	N	N	N	N	N	N	N	N	N	N	**	**	**	**
EXFOLIATION	N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y
VOICES'S INITIALS	RF														

\*\* Eschar - unable to evaluate.

ACUTE PERCUTANEOUS TOXICITY

Study #: 885-0007 Sub #: ATA 3201 Test #: \* Initial Body Wt. (g.): 3069 Balance / N.Y.: 23/52  
 Subject #: 4633 Sex: ✓ (M) — (F) Total Dose (Total Doses and Volume): 6.1/0.1  
 Dose Level: 2mg/kg In Solution: \* Dilution: — Time Points: 1, 3, 8, 24 hrs Absorbed (All Intake): —  
 Genotoxicity: Not Done Signature: Shawna B. Smith Date: 1-10-85  
 Subject Name/Species: Hydromys chrysomelas / mouse Time/Date Weighing Interval: 4, 8, 24, 48 hrs Date: 1-11-85  
 Date(s) Clipped: 1-10-85 Initial Body Wt. (g.): 2762 Balance / N.Y.: 23/52 Date: 1-24-85  
 \* 1 part P1907 to 5.5 parts P1906 mixed for 2 minutes Study Room #: 8.17  
 Retriever: Yannick

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
SITTINDA	0	3	3	3	3	3	2	**	**	**	**	**	**	**	**
EDOMA	0	1	1	2	2	2	1	1	1	1	1	1	1	1	1
STONIA	0	0	0	1	2	2	2	2	3	3	3	**	**	**	**
INCORPORATION	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
PISSURING	0	0	0	0	0	0	0	0	0	0	0	**	**	**	**
SCALD	N	N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y
EVOLUTION	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
VOUCHER'S INITIALS	RF	RF	DS	DS	RF										

Comments: \*\* 1/24/85 to evaluate symptoms due to eczema 1/11/85



ACUTE PERCUTANEOUS TOXICITY

Study #: 085-0007 and #1 BTS 320/1918 \*  
 Animal #1: 11696 Sex: M (M) (F)  
 Design Level: 2000/10 As Noted: \* Dilution: \_\_\_\_\_  
 Concentration: 1000/100  
 Animal Source/Species: Highway 17100 Zeebird  
 \_\_\_\_\_ Alison Kelly  
 Date(s) elapsed: 1-10-85  
 \* 1 part P1907 to 5.5 parts P1906 mixed for 2 minutes

Initial Body Wt. (g.): 2958 Balance I.N.T.: 23152  
 Total Dose (Total Substances and Vehicles): 5.9 ml  
 Time Wounded: 1:42 PM Absorbed (All) Initial (1): I  
 Signature: Alison Kelly Date: 1-10-85  
 Time/Date Wounding Reported: 1:42 PM Date: 1-11-85  
 Final Body Wt. (g.): \_\_\_\_\_ Date: \_\_\_\_\_  
 Balance I.N.T.: \_\_\_\_\_ Study No. #1: 11697  
 Restrictor: Hammes

SKIN OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	10	11	12	13																	
ERYTHEMA	0	3	2	-																	
EDOMA	0	0	0	-																	
VIOMA	0	0	0	-																	
REGONNATION	0	0	0	-																	
FISSURING	0	0	0	-																	
ESCHAR	N	N	N	-																	
EXFOLIATION	N	N	N	-																	
WOUNDS/INITIALS	RF	RF	RF	RF																	

found dead 1/15/85

ACUTE RESPIRATORY TOXICITY

Study #: 885-007 MD #: 578 320 Date: 11/10/85 \*  
 Animal #: 4617 Sex: M Age: 17  
 Dose Level: 5.5 mg/kg No. Inoculated: 3 Division: 1  
 Concentration: Handwritten  
 Subject Source/Species: Respiration System / mice  
 Inoculum: Handwritten  
 Inoculation Site: Handwritten  
 Initial Body Wt. (g.): 2283 Balance of N.Y.: 23/85  
 Total Blood (Total Substrate and Vehicle): 6.6 ml  
 Time Protocol: 184 PM Interval (h): 1800 (11)  
 Signature: Handwritten Date: 1-10-85  
 Time/Date Shipping Material: Handwritten Date: 1-11-85  
 Final Body Wt. (g.): \_\_\_\_\_ Date: \_\_\_\_\_  
 Balance of N.Y.: \_\_\_\_\_ Study Room #: 11/17  
 Restriction: Handwritten

\* 1 part P1907 to 5.5 parts P1906 mixed for 2 minutes

SEX OBSERVATIONS - Code for evaluating skin reactions is found in protocol

DATE	1/10	1/11	1/12	1/13															
SEX OBSERVATIONS	0	3	3	3															
EDDIA	0	1	1	2															
ATONIA	0	0	1	1															
DERMATITIS	0	0	0	0															
TISSUE	0	0	0	0															
TECHN	N	N	N	N															
EMOLLITION	N	N	N	N															
VORTEX'S INITIALS	RE	RF	RF	RF															

Continued

HEALTH OBSERVATION  
(BARKING DAIK)

Study # 1085-0007  
TRIN # R1906 + 1907

Pathology # \_\_\_\_\_  
Pre-Study Health Record: YE-575  
Husband Health Check: \_\_\_\_\_

DATE	11/08/85	11/09/85	11/10/85	11/11/85	11/12/85	11/13/85	11/14/85	11/15/85	11/16/85	11/17/85	11/18/85	11/19/85	11/20/85	11/21/85	11/22/85	11/23/85
TIME	06:00	07:30	07:50	08:30	09:00	09:15	09:30	09:45	10:00	10:15	10:30	10:45	11:00	11:15	11:30	11:45
INITIALS	AF	BE	RE	RS	SS	TS	VS	WS	XS	YS	ZS	AA	BB	CC	DD	EE
4595E	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4626M	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4633M	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4597E	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4646M	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
4617E	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

N = no abnormalities present  
A = abnormalities noted, see detailed observation below  
\* = time recorded to the time the first animal was observed

N\* NOT EATING BUT APPEARS NORMAL  
A\* NOT EATING  
A Seem severely depressed  
A2 Moribund  
4646 dead 1/13  
4597 dead 1/13  
4617 Dead 1/14

THE PROCTER & GAMBLE COMPANY

PROTOCOL NO. C10

Acute Percutaneous Toxicity

Issue Date: May 1, 1984  
Supersedes Issue Dated: June 15, 1983

Test Substance Identification Number (TSIN) # P1906 and P1907

Divisional Request Document Number (DRD) # BTS-3201

Sponsor: The Procter & Gamble Company  
Cincinnati, Ohio

Testing Facility: The Procter & Gamble Company  
(To be filled in by Miami Valley Laboratories - BIR  
Operations Section) Cincinnati, OH 45247

Study # B85-0007  
(To be filled in by  
Testing Facility)

*Study # 4E 737 I*

Purpose: To determine the skin irritancy of a test substance and its potential gross systemic and lethal effects when applied to the skin.

Justification for Selection of Test System: Historically, the New Zealand albino rabbit has been the animal of choice due to the large amount of background information on this species.

Route of Administration of Test Substance and Reason for Choice: Place on clipped area of skin under occlusive dressing. Historical. Based on Draize procedure.

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 Percutaneous Toxicity

Issue Date: May 1, 1984

Test Substance(s)

<u>TSIN #</u>	<u>DDI Number</u>	<u>Description</u>		<u>Expiration Date</u>
		<u>Color</u>	<u>Physical Form</u>	
P1906	315-3201	yellow	liquid	Indefinite
P1907	315-3201	white, opaque	liquid with suspended solids	3/1/85

Storage Conditions: (Check one)

Room temperature       Refrigerator       Freezer  
 Other

Hazards: (Check one)

None known. Take ordinary precautions in handling.  
 As follows: P1906 - possible skin and eye irritant  
P1907 - possible severe skin and eye irritant

Special Instructions: (Check one)

None  
 As follows: Add one (1) volume of test substance P1907 to 5.5  
volumes of test substance P1906 and mix for 2 minutes.  
Dose the animals with this mixture at 2 ml/kg.

Animals:

Each test group will consist of six (6) New Zealand albino rabbits (3 males and 3 females) weighing 2.0-3.5 kg.

Animal Care  
and Diet:

Follow the approved Standard Operating Procedures of the Test Facility. (Acclimation period must be a minimum of seven (7) days.)

Environmental  
Conditions:

Follow the approved Standard Operating Procedures of the Test Facility.

Animal  
Identification:

Follow the approved Standard Operating Procedures of the Test Facility.

PROTOCOL NO. C10 (Cont'd)

Acute Percutaneous Toxicity

Issue Date: May 1, 1984

Site Preparation:

Clip an area on the back of each animal from shoulder to rump, approximately 15 cm wide, with a small animal clipper. The skin of all animals is left intact.

Dose Preparation:

Test Group(s) (Check appropriate boxes)

Dose undiluted as follows:  2 ml/kg,  2 g/kg

Dose as a freshly prepared \_\_\_\_\_ % (w/v) solution/suspension as follows:  2 ml/kg,  2 g/kg  
Vehicle: \_\_\_\_\_

Dose as a freshly prepared \_\_\_\_\_ % (w/v) solution/suspension as follows:  2 ml/kg,  2 g/kg  
Vehicle: \_\_\_\_\_

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 \_\_\_\_\_.

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. Store solution/mixture at  room temperature;  refrigerator;  freezer;  other \_\_\_\_\_

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 \_\_\_\_\_.

Acute Percutaneous Toxicity

Issue Date: May 1, 1964

Dosing Instructions:

Spread the test substance over the clipped area. Cover with a layer of 8-ply gauze, rubber dam and several wrappings of 3-inch Elastoplast tape or equivalent wrapping material. Restrain the animal to prevent it from removing the wrappings. Dry or powdered substances are placed directly onto the gauze. The gauze containing the dry test material is placed upon a layer of rubber dam and wrapping tape. Place the animal on his back over the test substance and secure the wrapping tape around the trunk. Repeat this procedure for the remaining animals.

[ ] See Options on page 4

Observations:

After 24 hours, remove the animal from restrainers. Uncover the test sites, remove the test substance with wet disposable gauze, paper towel, or equivalent. Observe daily for next 14 days for signs of skin irritation using the attached scale (Appendix 1). Observe twice daily for mortality following the Test Facility's Standard Operating Procedures. There should be at least 4 hours between observations, or the maximum possible elapsed time on weekends or holidays. On the 14th day, count, weigh, and sacrifice the surviving animals.

Necropsy:

Necropsy animals that died or were sacrificed during study and examine grossly for any abnormalities. Perform the necropsy following the Test Facility's Standard Operating Procedures. Record all gross necropsy findings.

[X] See Options on page 5

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.

Options:

[ ] Abrade the skin of \_\_\_\_\_ males and \_\_\_\_\_ females to make a total of \_\_\_\_\_ animals/group (including abraded and intact skin). Abrade according to the Test Facility's Standard Operating Procedure so as to penetrate the horny layer of the epidermis without causing bleeding.

Acute Percutaneous Toxicity

Issue Date: May 1, 1984

Options (Cont'd):

Perform a gross necropsy on all animals surviving at the conclusion of the 14-day observation period according to the Test Facility's Standard Operating Procedures. Record all gross necropsy findings.

Report:

Report should include how study was conducted, dates of study initiation and termination, and the individual animal observations including deaths, if any, degree of skin irritation as a function of time, body weights, signs of gross systemic effects and necropsy observations. If no deaths are observed at the 2 ml/kg or 2 gm/kg dose level, the LD<sub>50</sub> value is reported as greater than 2 ml (liquids) or 2 gm (solids or semi-solids) per kg of body weight. If deaths were observed at the 2 ml/kg or 2 gm/kg dose level, additional dose levels may be requested to produce a sufficient number of deaths to calculate an LD<sub>50</sub> value. If additional dose levels are not requested, the LD<sub>50</sub> value will not be reported. This report shall conform to all requirements outlined in Section 58.185, Subpart J, Good Laboratory Practices Regulations.

Sponsor: Kenneth W. Miller  
Divisional Toxicologist

Date Approved by Sponsor's Divisional Toxicologist 12/17/84

Proposed Starting Date 1-10-85 )

Defined as Treatment Date )

Proposed Completion Date: 1-24-85 )

Defined as Gross Necropsy Date ) To be completed  
by the Test  
Facility

Study Director: D. A. Nelson )

Date: 1/2/85 )

Study Cost: \$950 )

PROTOCOL - APPENDIX 1

SCALE FOR EVALUATING SKIN REACTIONS

**Erythema**

- 0 - None
- 1 - Slight (barely perceptible)
- 2 - Moderate (well defined)
- 3 - Severe (beet red)

**Edema**

- 0 - None
- 1 - Slight (barely perceptible to well defined by definite raising)
- 2 - Moderate (raised approximately 1 mm)
- 3 - Severe (raised more than 1 mm)

**Atonia (not including eschar area)**

- 0 - Normal
- 1 - Slight (impairment of elasticity)
- 2 - Moderate (slow return to normal)
- 3 - Marked (no elasticity)

**Desquamation (not including eschar area)**

- 0 - None
- 1 - Slight (slight scaling)
- 2 - Moderate (scabs and flakes)
- 3 - Marked (pronounced flaking with denuded areas)

**Fissuring**

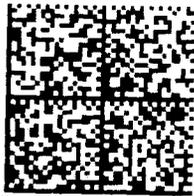
- 0 - None
- 1 - Slight (definite cracks in epidermis)
- 2 - Moderate (cracks in dermis)
- 3 - Marked (cracks with bleeding)

**Eschar**

- N - No
- Y - Yes

**Exfoliation (sloughing of the eschar tissue)**

- N - No
- Y - Yes



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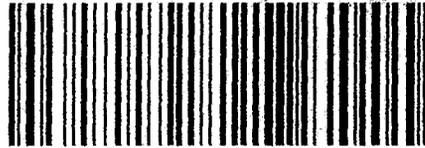
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