ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ- 92-10079	89110000199	3/22/11

COMMENTS: COMMUN S (DECLASS)

DOES NOT CONTAIN CBI

334112

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

8EHQ-0311-10079B
DCN: 89110000199

RECEIVED
MAR 22 AM 6:03

Re: Declassification Activity-Health and Safety Filing 8EHQ-0892-10079 (EPA DCN 88920008380)

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Any CBI substantiation which appears in the original submission is no longer applicable as the information which was originally claimed CBI is disclosed in this revised submission.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

89110000199

Attachment 1

Public Display Version

Chemical Identity	CAS RN
Alcohols, C10-16, ethoxylated	68002-97-1
Benzenesulfonic acid, 4-methyl-, potassium salt	16106-44-8
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
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-,	64-02-8
2-Anthracenesulfonic acid, 4,4'-[(1-methyl-6471-01-8 ethylidene)bis(4,1-phenyleneimino)]bis[1-amino-9,10-dihydro-9,10-dioxo-, disodium salt	
Alkyl dimethyl amino 2-hydroxy propane sulfonate	
Sodium citrate	
Mono ethanol amine	
Water	

8EHQ-0892-10079
5

Procter & Gamble COMPANY SANITIZED

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

92 AUG 31 PM 1:27

Public Display Copy

August 25, 1992

8EHQ-92-10079S INIT
88920008380

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 P0924 is a confidential mixture. The composition of the mixture is appended as Attachment 1. The report is titled "Acute Percutaneous Toxicity of P0924". Any correspondence relating to this submission should reference study # 1052-24955.

The attached study report indicates dermal application of 2 ml/kg of the test material to intact and abraded skin resulted in dermal irritation including erythema, edema, fissuring, and eschar formation. Five of six animals did not eat or drink normally the day after dosing. Four animals lost weight during the study period. Three of six animals appeared to have enlarged hearts at necropsy. The acute oral LD_{50} is estimated to be >2 ml/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

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

Attachment I

Alkyl ethoxylate

Substituted amine

Sodium citrate

Substituted benzene

Mono ethanol amine

Substituted stilbene

Water

Substituted amine

Colorant

1052 - 24955

SPRINGBORN INSTITUTE
FOR BIORESEARCH, INC.

FINAL REPORT: ACUTE PERCUTANEOUS STUDY OF PC924 IN RABBITS

PROJECT NUMBER: 3029.633

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

SUBMITTED BY: SPRINGBORN INSTITUTE
FOR BIORESEARCH, INC.
553 North Broadway
Spencerville, Ohio 45887

INITIATION DATE: September 30, 1980

COMPLETION DATE: October 22, 1980

ST

CONTENTS

SHERMAN BORN INSTITUTE
FOR INDUSTRIAL HYGIENE, INC

1. OBJECTIVE — To determine the relative skin irritancy and systemic toxicity of a test substance when this substance is applied to the skin.

2. TEST ARTICLE

a)	I.D. Number	P0924
b)	Storage Conditions:	Room temperature
c)	Changes During Storage:	None noted
d)	Characteristics:	Clear blue liquid

3. METHODOLOGY

3.1 Animals

a)	Species:	Rabbit
b)	Pedigree:	New Zealand White
c)	Supplier:	Isaacs Lab Stock
d)	Acclimation Period:	Minimum of seven (7) days
e)	Required Body Weights:	2.0 - 3.5 kg
f)	Identification:	Numbered ear tags

3.2 Animal Maintenance — According to DHEW standards in a USDA registered, AAALAC accredited facility.

3.3 Group Size And Dose Levels — Group I - 1 male + 2 female - Intact skin - 2 ml/kg
Group II - 2 male + 1 female - Abraded skin - 2 ml/kg

3.4 Administration Of Test Article

a) Pre-administration Animal Preparation: The backs of all animals were clipped free of hair from the shoulders to the rumps using small animal clippers. The skin of animals in Group I were left intact and the skin of animals in Group II were abraded using the clipper head.

b) Methods Of Administration: The test article was applied to the prepared test site. The test site was then covered with a layer of 8-ply gauze, dental dam and several wrappings of Elastoplast tape. The animals were restrained in Newmann harnesses for 24 hours. After 24 hours exposure, all wrappings and the restrainers were removed and the excess test material was removed with wet wipings.

3.5 Termination

a) Termination Schedule: On the 14th day, all surviving animals were weighed and terminated.

b) Methods: Barbiturate overdose

c) Extent Of Necropsy: Gross

4. RESULTS

4.1 Observations Table I

4.2 Necropsy Results Table II

5. DATA RETENTION

The raw data and the original of the final report will be on file at the testing facility for a period of not less than two years. The sponsor will be notified before final disposition of these items. Unused test articles will be destroyed unless requested otherwise by the sponsor. Exceptions to the above will be documented in the study file.

TABLE I

OBSERVATIONS

SKIN PREPARATION Intact DOSE 5.3 ml

Group I

Animal No. Rb-626-80	Sex M	1	2	3	4	5	6	DAY 7	8	9	10	11	12	13	14
Erythema		2	2	2	2	2	2	2	1	1	1	1	1	1	1
Edema		1	0	0	0	0	0	0	0	0	0	0	0	0	0
Atonia		0	0	1	1	2	2	1	1	1	0	0	1	1	1
Desquamation		0	0	0	0	1	0	0	0	0	0	0	1	1	1
Fissuring		0	0	0	0	0	2	2	2	2	2	2	1	1	1
Eschar		N	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y
Exfoliation		N	N	N	N	N	N	N	N	N	N	N	N	Y	Y

Weights (gm): Initial 2631 Final 2513

SKIN PREPARATION Intact DOSE 5.8 ml

Group I

Animal No. Rb-653-80	Sex F	1	2	3	4	5	6	DAY 7	8	9	10	11	12	13	14
Erythema		2	2	1	1	1	1	1	1	1	1	1	1	1	1
Edema		1	0	0	0	1	1	1	1	1	1	0	0	0	0
Atonia		0	0	0	0	0	0	0	0	0	0	0	0	0	0
Desquamation		0	0	0	0	0	0	0	0	0	0	0	0	0	1
Fissuring		0	0	0	0	2	2	2	3	3	2	2	1	1	1
Eschar		N	N	N	N	N	N	Y	Y	Y	Y	Y	Y	Y	Y
Exfoliation		N	N	N	N	N	N	N	N	N	N	N	Y	Y	Y

Weights (gm): Initial 2919 Final 3602

TABLE I

OBSERVATIONS

SKIN PREPARATION Intact DOSE 5.9 ml

Group I

Animal No. Rb-654-80	Sex F	1	2	3	4	5	6	DAY 7	8	9	10	11	12	13	14
Erythema		2	1	1	1	1	1	1	1	1	1	1	1	1	1
Edema		1	0	0	0	0	0	0	0	0	0	0	0	0	0
Atonia		0	0	0	0	0	1	1	0	0	0	0	0	0	0
Desquamation		0	0	0	0	0	0	0	0	0	0	0	0	0	1
Fissuring		0	0	0	0	0	1	1	1	1	1	1	1	1	1
Eschar		N	N	N	N	N	N	N	N	N	N	N	N	N	Y
Exfoliation		N	N	N	N	N	N	N	N	N	N	N	N	N	Y

Weights (gm): Initial 2966 Final 2574

SKIN PREPARATION Abraded DOSE 6.3 ml

Group II

Animal No. Rb-620-80	Sex M	1	2	3	4	5	6	DAY 7	8	9	10	11	12	13	14
Erythema		2	2	2	2	2	2	2	1	1	1	1	1	1	1
Edema		1	0	0	0	0	0	0	0	0	0	0	0	0	0
Atonia		0	0	0	0	1	1	1	0	0	0	0	0	0	0
Desquamation		0	0	0	0	0	0	0	0	0	0	0	1	1	1
Fissuring		0	0	1	1	1	1	1	1	1	1	1	1	1	1
Eschar		N	N	N	N	N	N	N	N	N	Y	Y	Y	Y	Y
Exfoliation		N	N	N	N	N	N	N	N	N	N	Y	Y	Y	Y

Weights (gm): Initial 3125 Final 3022

TABLE I

OBSERVATIONS

SKIN PREPARATION Abraded DOSE 6.6 ml

Group II

Animal No. Rb-597-80	Sex M	1	2	3	4	5	6	DAY 7	8	9	10	11	12	13	14
Erythema		2	2	2	2	2	2	1	1	1	1	1	1	1	1
Edema		1	1	1	0	0	0	0	0	0	0	0	0	0	0
Atonia		0	0	0	0	2	2	1	1	0	0	0	0	0	0
Desquamation		0	0	0	0	0	0	1	1	1	1	1	1	1	1
Fissuring		0	0	0	0	1	1	1	1	1	1	0	0	0	0
Eschar		N	N	N	N	N	N	N	N	N	N	N	N	N	N
Exfoliation		N	N	N	N	N	N	N	N	N	N	N	N	N	N

Weights (gm): Initial 3317 Final 3224

SKIN PREPARATION Abraded DOSE 6.6 ml

Group II

Animal No. Rb-621-80	Sex F	1	2	3	4	5	6	DAY 7	8	9	10	11	12	13	14
Erythema		2	2	2	2	2	2	2	1	1	1	1	1	1	1
Edema		1	0	0	0	0	0	0	0	0	0	0	0	0	0
Atonia		0	0	0	0	1	0	0	0	0	0	0	0	0	0
Desquamation		0	0	0	0	0	0	0	0	0	1	1	1	1	1
Fissuring		0	0	0	0	1	2	2	1	2	2	1	1	0	0
Eschar		N	N	N	N	N	N	N	N	N	N	Y	Y	Y	N
Exfoliation		N	N	N	N	N	N	N	N	N	N	Y	Y	Y	N

Weights (gm): Initial 3310 Final 3475

TABLE II

NECROPSY RESULTS

Group I- Intact	
Rb-626-80 (M)	Not Remarkable
Rb-653-80 (F)	Heart appears enlarged; uterine horns appear irritated.
Rb-654-80 (F)	Uterine horns appear irritated
Group II- Abraded	
Rb-620-80 (M)	Not Remarkable
Rb-597-80 (M)	Heart appears enlarged
Rb-621-80 (F)	Heart mildly enlarged with dilated ventricles, pitting of renal cortex and renal subcapsular hemorrhage, mild spleenomegaly, and uterine congestion.

6. CONCLUSIONS:

The acute percutaneous toxicity of test article P0924 was determined in rabbits according to P&G protocol C10 (5-1-80). No animals died; the LD_{50} is greater than 2 ml/kg. Skin reactions included erythema, edema, atonia, desquamation, fissuring, eschar and exfoliation. Five of six animals did not eat or drink normal amounts the day after dosing. Four of six animals lost weight during the study period. Three of six animals had what appeared to be enlarged hearts at the necropsy.

SUPERVISED AND CONDUCTED BY

Barbara Foraker

Barbara Foraker, B.S.
Laboratory Technician

Richard A. Hiles 10/21/80

Richard A. Hiles, Ph.D.
Vice President and Director
of Acute and Subchronic Toxicology
(Study Director)

Jon C. Fulfs

Jon C. Fulfs, Ph.D.
Executive Vice President and
Director of Toxicology

EVALUATION OF SKIN REACTIONS (CODE)

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 (slight impairment of elasticity)
2 - Moderate (slow return to normal)
3 - Marked (no elasticity)

Descuamation (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

APPENDIX II

SUMMARY QUALITY ASSURANCE LOG SHEET

Study No. 3029.633 Compound No. P0924

Phase of study reviewed.	Date	Q.A. Reviewer
In-life Q.A. of dosing and dose level calculations	9/30/80	P.J. Delap
Q.A. of study notebook	10/16/80	P.J. Delap
Q.A. of final typed report	10/21/80	C. S. Davis

Internal Quality Assurance — Date 10-21-80

RESULTS REPORTED TO:

Study Director — Date 10/21/80

Management — Date 10/21/80

PROTOCOL NO. C10

Acute Percutaneous Toxicity

Issue Date: May 1, 1980
Supersedes Issue Dated: January 1, 1980

Test Substance Indentification Number (TSIN) # P0924

Divisional Request Document Number (DRD) # BTS 2634

Sponsor: The Procter & Gamble Company
Cincinnati, Ohio

Testing Facility: (To be filled in by Operations Section)
Springborn Institute for Bioresearch, Inc.
Spencerville, Ohio 45887

Study # 3[illegible] 633 (To be filled in by Testing Facility)

Purpose: To determine the relative skin irritancy and systemic toxicity of a test substance when this substance is applied to the skin.

Justification for Selection of Test System: Historically, the New Zealand White 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 intact and abraded 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.

PROTOCOL NO. C10 (cont'd)

Acute Percutaneous Toxicity

Issue Date: May 1, 1980

Test Substance(s)

TSIN #	DRD Number	Description: Color	Description: Physical Form	Expiration Date
P0924	BTS-634	Clear Blue	Liquid	9/1/81

S 80.130.3029

Storage Conditions: (Check one)

[X] Room temp. (60-80°F) [ ] Refrigerator (about 40°F) [ ] Freezer (<30°F)
[ ] Other

Hazards: (Check one)

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

Special Instructions: (Check one)

[X] None
[ ] As follows:

Dose Preparation: (Check appropriate box)

[X] Dose undiluted
[ ] Dose as a _____% (w/w) solution/suspension
[ ] Dose as a _____% (w/v) solution/suspension
[ ] Dose per special instructions

Vehicle: _____* Dissolve or suspend the test substance in the vehicle at the required concentrations and record the quantities mixed.

*A vehicle control should be [ ], should not be [ ], included in this study. If included, the vehicle control should be tested concurrently with the test substance.

Dosing Instructions:

Weigh animals just prior to dosing to determine the total volume and/or weight of test substance to be applied.

[ ] Dose at 2 gm/kg of the test substance as received
[ ] Dose at 2 gm/kg of the required solution/ suspension
[X] Dose at 2 ml/kg of the test substance as received
[ ] Dose at 2 ml/kg of the required solution/ suspension
[ ] Other

Animals:

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

Animal Care:

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.

Procedure:

Clip the back of each animal from shoulder to rump with a small animal clipper. The skin of three animals is left intact and the skin of the other three is abraded with an electric clipper blade or other appropriate device so as to penetrate the horny layer of the epidermis without causing bleeding. Each abraded and intact skin group shall have at least one (1) animal of each sex.

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 in appropriate harness or collar 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 spread over 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.

After 24 hours, remove the harness or collar, uncover the test site, remove the test substance with wet disposable gauze, paper towel, or equivalent. Observe

Procedure (cont'd): daily for next 14 days for signs of skin irritation using the attached scale (Appendix 1). Observe twice daily for morbidity, and mortality. On the 14th day, count, weigh, and sacrifice the surviving animals. Weighing animals at 7 days is optional.

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

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 Principal Investigator. This document is then attached to the protocol as an addendum.

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_{50} 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_{50} value. If additional dose levels are not requested, the LD_{50} value will not be reported.

Sponsor: Jack Mann
Principal Investigator

Date Approved by Principal Investigator 9/12/80

Proposed Starting Date: 10/7/80

Proposed Completion Date: 11/19/80
(Final Report Available)

Study Director: C A Hile

Date: 9/24/80

Study Cost: 725

(To be completed by the Test Facility)

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

049J82034979

$ 19.05

03/15/2011

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