

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-92-6342	89110000195	3/22/11

COMMENTS: COMMUN S (DECLASS)

DOES NOT CONTAIN CBI

334108



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-0311-06342B
DCN: 89110000195

11 MAR 22 AM 6:02
RECEIVED
DPT/CTIC

**Re: Declassification Activity-Health and Safety Filing
8EHQ-0892-6342 (EPA DCN 88920004988)**

Dear Sir/Madam:

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

This amended submission is composed of the following:

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

Any CBI substantiation which appears in the original submission is no longer applicable as the information which was originally claimed CBI is disclosed in this revised submission.

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

Sincerely,

THE PROCTER & GAMBLE COMPANY

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



Attachment 1
Public Display Version

Chemical Identity

CAS RN

Isopropanol

Propanol, 1(or 2)-butoxy-

29387-86-8

Sulfuric acid monododecyl ester sodium salt

151-21-3

Sulfuric acid, mono-C10-16-alkyl esters, sodium salts

68585-47-7

Ammonia

Fragrance

Sodium hydroxide

Water

Procter & Gamble COMPANY SANITIZED

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

92 AUG 17 PM 1:51

8EHO-0892-6342₂ Int Public Display Copy

August 5, 1992

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

88920804988₂

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 B1462.01 is a confidential mixture. The composition of the mixture is appended as Attachment 1. The report is titled "Acute Oral Toxicity". Any correspondence relating to this submission should reference study # 1458-35507.

The attached study report indicates oral administration of the test material resulted in pharmacotoxic signs including ataxia and hyperactivity following oral administration of 5 ml/kg and 10 ml/kg of the test material. An additional dose level of 3 ml/kg included in the study did not produce any significant pharmacotoxic signs. The acute oral LD₅₀ was not determined in this study.

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.

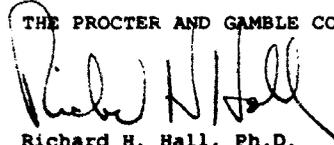
0003

Procter & Gamble

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

Sincerely,

THE PROCTER AND GAMBLE COMPANY



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

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Attachment I

Public Display Copy

Isopropanol

Substituted aliphatic alcohol

Sodium alkyl sulfate

Ammonia

Fragrance

Sodium hydroxide

Water

0 0 0 5

1458-35607

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

Acute Oral Toxicity In The Dog

B89-6043

BSBTS 1138

B1462.01

September 12, 1989



THE PROCTER & GAMBLE COMPANY

MIAMI VALLEY LABORATORIES
P O BOX 39677, CINCINNATI, OHIO 45239-8777

The following study was audited by the Quality Assurance Unit:

TEST FACILITY:	The Procter & Gamble Company Miami Valley Laboratories Cincinnati, Ohio 45247		
STUDY NUMBER:	B89-6043		
NOTEBOOK NUMBER:	YE-1237		
DIVISIONAL REQUEST DOCUMENT:	BSBTS 1138		
TSIN:	E1462.01		
TYPE OF STUDY:	Acute Oral Toxicity (Modified)		
PORTION(S) OF STUDY AUDITED:	AUDITOR:	DATE AUDITED:	DATE REPORTED TO STUDY DIRECTOR:
Test System	L. K. Klahm	9/12/89	9/12/89

The protocol was audited for compliance to the GLP regulations.

The final study report was audited. The results presented in this report accurately reflect the raw data of the study.

Marjorie Gauer 9/12/89
Quality Assurance Unit Date

Procter & Gamble Company, Research and Development
Department Memorandum, H&ES Division

Acute Oral Toxicity In The Dog

Study #: B89-6043
Notebook #: YE 1237

Divisional Request Document :
Test Substance Identification Number
Divisional Toxicologist
Performed At :
During The Period
According To The Attached Protocol
Deviations From The Protocol
Strain And Source Of Animals :
Test Substance Concentration

BSBTS 1138
B1462.01-07/27/89
J.H.Saylor
Miami Valley Laboratories
07/27/89 Thru 07/30/89
C6
See Page 16
Beagles, MVL Colony
Sample As Received

Test Results and Summary

Dose Level: 3ml/kg

4 Hour Observation Summary
Onset, Duration (minutes)

Dog #	Sex		<u>Onset</u>	<u>Duration</u>	<u>Episodes</u>
3195	M	Emesis	24	25	2
3110	F	Emesis	0	0	0

Remarks: No response.

D. E. Stitzel

D.E. Stitzel

D. K. Hysell

D.K. Hysell

Procter & Gamble Company, Research and Development
Department Memorandum, H&ES Division

Acute Oral Toxicity In The Dog

Study #: B89-6043
Notebook #: YE 1237

Divisional Request Document :
Test Substance Identification Number
Divisional Toxicologist
Performed At :
During The Period
According To The Attached Protocol
Deviations From The Protocol
Strain And Source Of Animals :
Test Substance Concentration

BSBTS 1138
B1462.01-07/28/89
J.H.Saylor
Miami Valley Laboratories
07/28/89 Thru 07/31/89
C6
See Page 16
Beagles, MVL Colony
Sample As Received

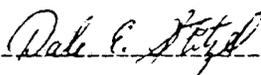
Test Results and Summary

Dose Level: 5ml/kg

4 Hour Observation Summary
Onset, Duration (minutes)

Dog #	Sex		Onset	Duration	Episodes
3341	M	Emesis	15	51	2
3228	F	Emesis	0	0	0

Remarks: No response.



D.E. Stitzel



D.K. Hysell

Procter & Gamble Company, Research and Development
Department Memorandum, H&ES Division

Acute Oral Toxicity In The Dog

Study #: 889-6043
Notebook #: YE 1237

Divisional Request Document :
Test Substance Identification Number
Divisional Toxicologist
Performed At :
During The Period
According To The Attached Protocol
Deviations From The Protocol
Strain And Source Of Animals
Test Substance Concentration

BSBTS 1138
B1462.01-07/31/89
J.H.Saylor
Miami Valley Laboratories
07/31/89 Thru 08/03/89
C6
See Page 16
Beagles, MVL Colony
Sample As Received

Test Results and Summary

Dose Level: 10ml/kg

4 Hour Observation Summary
Onset, Duration (minutes)

Dog #	Sex		<u>Onset Duration Episodes</u>		
			Onset	Duration	Episodes
3193	M	Emesis	19	1	1
3324	F	Emesis	12	31	3
3342	M	Emesis	1	15	2

Remarks:

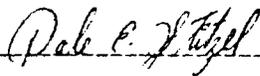
Dog #3342 showed ataxia 34 minutes after dosing for a duration of 113 minutes. The dog showed intermittent hyperactivity 57 minutes after dosing for a duration of 105 minutes.

The first emetic episode occurred at dosing time as the dosing tube was withdrawn.

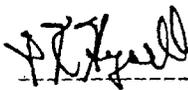
3378	F	Emesis	71	1	1
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Remarks:

Dog #3378 showed ataxia 24 minutes after dosing for a duration of 177 minutes. The dog showed intermittent hyperactivity 51 minutes after dosing for a duration of 80 minutes.



D.E. Stitzel



D.K. Hysell

Procter & Gamble Company, Research and Development
Department Memorandum, H&ES Division

Acute Oral Toxicity In The Dog

Study #: 889-6043
Notebook #: YE 1237

Divisional Request Document :	BSBTS 1138
Test Substance Identification Number	B1462.01-08/04/89
Divisional Toxicologist	J.H. Saylor
Performed At :	Miami Valley Laboratories
During The Period	08/04/89 Thru 08/07/89
According To The Attached Protocol	C6
Deviations From The Protocol	See Page 16
Strain And Source Of Animals :	Beagles, MVL Colony
Test Substance Concentration	Sample As Received

Test Results and Summary

Dose Level: 3ml/kg

4 Hour Observation Summary
Onset, Duration (minutes)

Dog #	Sex		<u>Onset</u>	<u>Duration</u>	<u>Episodes</u>
3327	M	Emesis	4	4	5
3303	F	Emesis	2	1	1

D.E. Stitzel

D.E. Stitzel

D.K. Hysell

D.K. Hysell

Procter & Gamble Company, Research and Development
Department Memorandum, H&ES Division

Acute Oral Toxicity In The Dog

Study #: 889-6043
Notebook #: YE 1237

Divisional Request Document :
Test Substance Identification Number
Divisional Toxicologist
Performed At :
During The Period
According To The Attached Protocol
Deviations From The Protocol
Strain And Source Of Animals :
Test Substance Concentration

BSBTS 1138
B1462.01-08/04 (5 ml/kg)
J.H.Saylor
Miami Valley Laboratories
08/04/89 Thru 08/07/89
C6
See Page 16
Beagles, MVL Colony
Sample As Received

Test Results and Summary

Dose Level: 5ml/kg

4 Hour Observation Summary
Onset, Duration (minutes)

Dog #	Sex		Onset	Duration	Episod
3200	M	Emesis	50	1	2
Remarks: Dog #3200 showed ataxia at 39 minutes after dosing for a duration of 22 minutes.					
3222	F	Emesis	7	1	8
Remarks: Dog #3222 was wheezing and coughing 11 minutes after dosing for 6 minutes.					

Dale E. Stitzel

D.E. Stitzel

D.K. Hysell

D.K. Hysell

Procter & Gamble Company, Research and Development
Department Memorandum, H&ES Division

Acute Oral Toxicity In The Dog

Study #: B89-6043
Notebook #: YE 1237

Divisional Request Document :	BSBTS 1138
Test Substance Identification Number	B1462.01-08/07/89
Divisional Toxicologist	J.H.Saylor
Performed At :	Miami Valley Laboratory
During The Period	08/07/89 Thru 08/10/89
According To The Attached Protocol	C6
Deviations From The Protocol	See Page 16
Strain And Source Of Animals :	Beagles, MVL Colony
Test Substance Concentration	Sample As Received

Test Results and Summary

Dose Level: 3ml/kg 4 Hour Observation Summary

Dog #	Sex		Onset, Duration (minutes)		Ep
			Onset	Duration	
3025	M	Emesis	0	0	
Remarks: No response.					
3063	F	Emesis	0	0	
Remarks: Dog #3063 was wheezing and coughing 13 minutes after dosing for 6 minutes					

D.E. Stitzel

D.E. Stitzel

D.K. Hysell

D.K. Hysell

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INTERDEPARTMENTAL CORRESPONDENCE

FROM:

DATE: 7-7-89

TO: Operations Section

R/L:

B826013

SUBJECT: NONCLINICAL STUDY REGULATORY STATUS

Notification pertaining to:

DRD # BSTBS 1138

TSIM TS 1462-01

1. The study described in the above protocol is to be considered:

- Safety
- Regulated Safety
- Investigational

2. The data is expected to be submitted to the following regulatory agency:

- FDA
- EPA
- Other _____

The data is not expected to be submitted to a regulatory agency. (Boxes #4 and #5 below need not be checked)

3. The test substance has been characterized and results are shown on the test substance characterization report (TSCR).

4. The method of synthesis, fabrication, or derivation of the test related substances has been documented (required for regulated studies).

5. Stability testing has been done or will be done on the test substance (required for regulated studies).

Sponsor's Divisional Toxicologist

J.H. Saylor

Date:

7-7-89

bg: REGSTAT
10/23/86

PROTOCOL NO. CSA

ACUTE ORAL TOXICITY IN THE DOG

Issue Date: January 19, 1988
Supersedes Issue Dated: October 1, 1986

Test Substance Identification Number (TSIN) B 1462.01

Divisional Request Document Number (DRD) BSBTS 1138

Sponsor: The Procter & Gamble Company
Cincinnati, Ohio

Testing Facility: The Procter & Gamble Company Study # B9-6043
Miami Valley Laboratories - BTF (To be filled in by
Cincinnati, OH 45247 Testing Facility)

Purpose: To determine the acute toxic effects in the dog of a
single exposure to a test substance at a p.e.-selected
level.

Justification for
Selection of Test
System: The Beagle dog is the animal of choice because
experience has shown that this species is a good model
in predicting the acute toxicity of a substance.

Route of Administration
of Test Substance: Administer substance by stomach tube.

Reason for Choice: This provides an accurate method of delivering the
desired dose to the animals' stomach.

Diet and/or Water
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 the protocol.

PROTOCOL NO. C5A (cont'd)

ACUTE ORAL TOXICITY IN THE DOG

Issue Date: January 19, 1988

Test Substance(s):

TSIN #	DRD Number	Description		Expiration Date
		Color	Physical Form	
B1462-01	ISRTS 1138	clear	liquid	12/89 7/90 <i>PH</i> 1/24/89

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: *Dose 2 dogs at 3 ml/kg. If no effects as described on Pg 3 are observed dose 4 additional animals and observe. If no effects, terminate study. If effects are observed reduce dose level to 1 ml/kg and repeat procedure. If questions since call toxicologist.*

Dose Preparation: (Check one)

- Dose test substance as received
 Dose test substance as a ___% solution/suspension w/v in _____

Notes:

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 _____

Dosage Levels:

Dose level (not to exceed 10 g/kg or 10 ml/kg of the undiluted test substance):

___ ml/kg of test substance as received (liquid)
___ ml/kg of the required solution/suspension

PROTOCOL NO. C5A (cont'd)

ACUTE ORAL TOXICITY IN THE DOG

Issue Date: January 19, 1988

Animals: Beagles, healthy, pure bred, 6 months to 5 years of age, 1 male and 1 female that have not been used on other studies for a minimum of 14 days are selected from the stock colony. Two to 4 days prior to scheduled dosing, perform an endoscopic examination of the upper digestive tract of the dogs. Select only dogs that appear normal.

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

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

Procedure: Fast the dogs for a minimum of 18-20 hours and deprive them of water for approximately 3 hours before dosing. Determine fasted body weights. Calculate the dose for each animal to give the specified quantities of the test substance. Dose one animal at a time by gavage following the Standard Operating Procedure of the Test Facility.

Observe the animals continuously for ^{two (2) hours} ~~one (1) hour~~. Record the onset and type of toxic symptom. The toxic symptoms include, but may not be limited to, diarrhea, bloody diarrhea, emesis, hematemesis and death. ^{two (2) hours} Observe the animals occasionally for the next ~~three (3) hours~~, withholding food and water. Observe the animals daily for the next ~~thirteen (13) days~~ ^{or until endoscopic examination shows the dog is normal (see Option)}.

Option: [] Perform endoscopic examination of the upper digestive tract of the dogs one day after dosing and if needed, weekly thereafter until the dog returns to normal. Discontinue daily observations at this time.

At the termination of the study, return the animals to the stock colony of the Facility.

* *observe dosed animals especially for signs of neurotoxic effects as ataxia, depression, and loss of limb tone. also note time of recovery if any signs are observed.*

*YAS
7/2/87*

PROTOCOL NO. CSA (cont'd)

ACUTE ORAL TOXICITY IN THE DOG

Issue Date: January 19, 1988

Necropsy: Any animal that dies should be necropsied with a veterinarian present. Examine any tissue as required to elucidate the cause of death. Collect and fix in 10% neutral buffered formalin for histopathology sections of lesions observed that, in the judgment of the attending veterinarian, might represent a direct toxic effect of the test substance.

Protocol Changes: If it becomes necessary to change the approved protocol, verbal agreement to make this change should be made between the Study Director or his designate 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 amendment.

Report: Report dates of initiation and completion of the in-life portion of the study, individual animal observations including onset, duration and number of each toxic symptom, and any other observation made in the course of the study. In the case of death, report observations made during the necropsy and histopathological results (if any).

Sponsor: J. Harold Sawyer 530 3557
Divisional Toxicologist Telephone No.

Date Approved by Sponsor's Divisional Toxicologist 7-19-89 JA
~~6-20-89~~

Proposed Starting Date: 7/27/89)
)
Defined as Day of Dosing)
)
Proposed Completion Date: To Be Determined)
)
Defined as Last Day of Observation or Endoscopic Examination) To be com-
) the Test pleted by
) Facility

Study Director: D.K. Hysell 1066E JPH)
)
Date: 7-26-89)
)

Protocol Amendment

Study # : B89-6043
DRD # : BSETS 1138

Date Of Decision 08/09/89

Test Type : Acute Oral Toxicity In The Dog.

Excess test substance B1462.01 from Acute Oral Toxicity Study
B89-6043 was used to complete the ED50 study B89-6044.

Study Director : *D.K. Hysell*
D.K. Hysell - Date

Divisional Toxicologist : *J.H. Saylor 8/9/89*
J.H. Saylor - Date

Protocol Amendment

Study # B89-6043
DRD # BSBTS 1138
TSIN # B1462.01

Test Type : Acute Oral Toxicity In The Dog.

In a series of phone conversations with the Toxicologist on July 31, 1989 thru August 8, 1989, the dose levels and the number of dogs dosed at each level were changed. Each new dose level was chosen based on the effects on the dogs at the previous dose level.

Sequence

# of dogs	Dose Level	Date
2	3 ml/kg	07/27/89
2	5 ml/kg	07/28/89
4	10 ml/kg	07/31/89
2	3 ml/kg	08/04/89
2	5 ml/kg	08/04/89
2	3 ml/kg	08/07/89

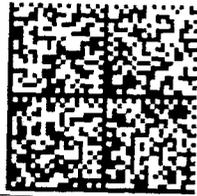
No dogs were dosed at 1 ml/kg as required by the protocol.

Study Director

D.K. Hysell
D.K. Hysell - Date

Divisional Toxicologist

J.H. Saylor 8/29/89
J.H. Saylor - Date



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049J82034979

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