8EHQ-0395-13393

Procter&Gamble

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

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March 28, 1995

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(Attention: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S. W.
Washington, D. C. 20460

8EHQ-95-13393
8495000077

RE: TSCA Section 8(e) Submission

ATTN: TSCA Section 8(e) Coordinator

This submission is made in accordance with TSCA Section 8(e) requirements. We do not believe the data described in this submission reasonably support the conclusion that the subject materials present a substantial risk of injury to human health or the environment.

This communicates data on the effects of the oral administration of fourteen preparations to mice as part of a research program. The composition of the preparations tested are described in Attachment I.

The data reported here were developed outside the U.S. as part of an R&D program. In these R&D tests, 5 mls/kg of a test mixture was administered to six mice (3 males/3 females) by oral gavage (Attachment I). The animals were observed during the first 2 hours after dosing and were scored for the occurrence of the following symptoms: ataxia, excited movements, recumbency, and loss of righting reaction.

The observed symptoms ranged from mild ataxia to prolonged anesthesia, and differed in time of onset and duration for all the materials tested. All animals fully recovered within four hours and showed no abnormalities upon necropsy.

We have handled and will continue to handle these materials with appropriate caution in our laboratory work in keeping with our standard procedure for handling all chemical substances. We will continue our practice of communicating appropriate hazard information for the test substances by both labels and MSDS

We are requesting that the portions of a mixtures for the test materials be treated as confidential information in this submission. We have not publicly disclosed any business interest or plans regarding the test mixtures. Measures to protect confidential information include "need to know" internal restrictions within the Company, confidential disclosure agreements with potential suppliers, and confidentiality restrictions imposed upon information shared with the agency. Security at our technical centers is excellent and knowledge of R&D activities pertaining to these materials has been carefully restricted to employees who have a need to know. Disclosure of the specific chemical identity of the test material would provide competitors with valuable knowledge which is not otherwise available and which could significantly reduce the competitive advantage normally associated with the development and commercialization of new products.

4/6/95

Please note that we have bracketed the information which we regard as legally confidential. This bracketed information has been deleted from a second, public display version of this submission. In the event of a proposed disclosure, notice should be given to J. T. O'Reilly at 513/983-4225.

If you wish further information, please contact me.

Very truly yours,

THE PROCTER AND GAMBLE COMPANY

W. E. Bishop, Ph. D.
Manager
Risk, Policy & Regulatory Sciences Dept.
Telephone: 513/627-6145

Test Material Description

A sample of each solution (A through N) was dosed by oral gavage at 5 mls/kg body weight per animal, six animals/mixture. The composition of the test mixtures is shown below. A description of each ingredient which includes the abbreviation used in the attached data tables, the CAS number, and the chemical name is also shown below.

Concentration (mM) of ingredients in water.
Test mixtures A through N

Ingredient	A*	B*	C*	D*	E*	F*	G	H	I	J	K	L	M	N
C12EO5														
C12-14AS														
C6EO5														
C8EO5														
C8AS														
C12-14EO30														
BDGE														
Xantan gum														

* Twelve animals were used per group (6 male/6 female)

Abbreviation	CAS#	Chemical name
C12EO5	3055-95-6	3,6,9,12,15-Pentaoxaheptacosan-1-ol
C12-14AS	151-21-3	Sulfuric acid, monododecyl ester, sodium salt
C6EO5	86674-95-5	3,6,9,12,15-Pentaoxaheneicosan-1-ol
C8EO5	19327-40-3	3,6,9,12,15-Pentaoxatricosan-1-ol
C8AS	142-31-4	Sulfuric acid, monooctyl ester, sodium salt
C12-14EO30	68439-50-9	Alcohols, C12-14, ethoxylated
BDGE	112-34-5	Ethanol, 2-(2-butoxyethoxy)-
Xantan gum	11138-66-2	Xantan gum

Mixture A	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	0	0	0	0
10	0	0	0	0
15	2	0	0	0
20	2	2	3	0
25	2	2	3	0
30	2	2	3	0
45	3	2	2	0
60	2	1	1	0
120	2	0	0	0

Mixture B	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	3	3	1	0
10	3	4	1	0
15	3	4	1	0
20	2	1	0	0
25	2	0	0	0
30	0	0	0	0
45	0	0	0	0
60	0	0	0	0
120	0	0	0	0

Legend

Symptom

1 ATAXIA
2 EXITED MOVEMENTS
3 RECUMBANCY
4 LOSS OF RIGHTING REACTION

TIME IN MINUTES AFTER DOSING

Mixture C	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	0	0	0	0
10	0	0	0	0
15	1	0	0	0
20	2	1	0	0
25	3	0	1	0
30	3	0	1	0
45	1	0	1	0
60	0	0	1	0
120	0	0	0	0

Mixture D	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	0	0	0	0
10	0	0	0	0
15	3	0	0	0
20	2	2	0	0
25	1	4	0	0
30	2	1	1	0
45	1	0	1	0
60	0	1	0	0
120	0	1	0	0

Legend

Symptom

1 ATAXIA
2 EXITED MOVEMENTS
3 RECUMBANCY
4 LOSS OF RIGHTING REACTION

TIME IN MINUTES AFTER DOSING

Mixture E	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	1	3	0	1
10	3	3	0	2
15	2	1	3	1
20	0	0	4	0
25	2	0	2	0
30	3	0	1	0
45	1	0	0	0
60	0	0	0	0
120	0	0	0	0

Mixture F	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	7	0	1	0
10	3	3	3	1
15	3	2	4	1
20	2	0	4	1
25	2	0	2	1
30	0	0	2	1
45	1	1	0	0
60	0	0	0	0
120	0	0	0	0

Legend

Symptom

1 ATAXIA
2 EXITED MOVEMENTS
3 RECUMBANCY
4 LOSS OF RIGHTING REACTION

TIME IN MINUTES AFTER DOSING

Mixture G	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	0	2	2	2
10	0	2	2	2
15	0	1	3	2
20	1	2	3	0
25	3	0	3	0
30	0	0	5	0
45	0	0	5	0
60	0	0	0	0
120	0	0	0	0

Mixture H	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	0	0	0	2
10	0	0	0	2
15	0	1	3	2
20	1	0	4	0
25	1	0	4	0
30	1	0	4	0
45	0	0	4	0
60	1	0	3	0
120	1	0	2	0

Legend

Symptom

1 ATAXIA
2 EXITED MOVEMENTS
3 RECUMBANCY
4 LOSS OF RIGHTING REACTION

TIME IN MINUTES AFTER DOSING

Mixture I	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	5	0	0	0
10	5	0	2	0
15	1	0	5	0
20	1	0	5	0
25	0	0	5	0
30	0	0	3	0
45	0	0	1	0
60	0	0	0	0
120	0	0	0	0

Mixture J	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	0	0	0	0
10	0	0	0	0
15	0	0	0	0
20	1	0	0	0
25	1	0	0	0
30	0	0	1	0
45	0	0	1	0
60	1	0	0	0
120	0	0	0	0

Legend

Symptom

1 ATAXIA
2 EXITED MOVEMENTS
3 RECUMBANCY
4 LOSS OF RIGHTING REACTION

TIME IN MINUTES AFTER DOSING

Mixture K	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	1	1	0	1
10	0	2	1	1
15	0	0	3	1
20	0	0	3	1
25	0	0	3	1
30	0	0	3	1
45	0	0	1	1
60	0	0	1	0
120	0	0	1	0

Mixture L	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	0	0	0	0
10	0	0	0	0
15	0	1	0	0
20	1	0	2	0
25	1	0	3	0
30	1	0	2	0
45	1	0	2	0
60	1	0	1	0
120	0	0	1	0

Legend

Symptom

1 ATAXIA
2 EXITED MOVEMENTS
3 RECUMBANCY
4 LOSS OF RIGHTING REACTION

TIME IN MINUTES AFTER DOSING

Mixture M	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	0	0	0	0
10	0	0	2	0
15	0	0	3	0
20	0	0	3	0
25	0	0	3	0
30	0	0	3	0
45	0	0	3	0
60	1	0	2	0
120	0	0	2	0

Mixture N	# animals showing the symptoms			
Symptom	1	2	3	4
Time				
0	0	0	0	0
5	0	0	0	0
10	0	0	0	0
15	1	0	1	0
20	1	0	2	0
25	0	0	3	0
30	1	0	2	0
45	2	0	1	0
60	0	0	1	0
120	0	0	1	0

Legend

Symptom

1 ATAXIA
2 EXITED MOVEMENTS
3 RECUMBANCY
4 LOSS OF RIGHTING REACTION

TIME IN MINUTES AFTER DOSING

Triage of 8(e) Submissions

Date sent to triage: _____ NON-CAP CAP

Submission number: 13393A TSCA Inventory: Y N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX	CTOX	EPI	RTOX	GTOX
STOX/ONCO	CTOX/ONCO	IMMUNO	CYTO	NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 **pages** 1 **pages** _____

Notes:

Contractor reviewer : JW **Date:** 1/24/96

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 0395 - 13393 (5) SEQ. A

TYPE: (INT) SUPP FLWP

SUBMITTER NAME: Procter & Gamble Company

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
0678 CAP NOTICE

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS
(0404) LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 03/28/95 OTS DATE: 03/29/95 CSRAD DATE: 04/06/95

CHEMICAL NAME:	CAS#	
3,6,9,12,15 - Pentaoxaheneicosan-1-ol	86674-95-5	142-31-4
3,6,9,12,15 - Pentaoxatricosan-1-ol	19327-40-3	68439-50-9
	3055-95-6	112-34-5
	151-21-3	11138-66-2

INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C	INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04	0216	EPI/CLIN	01 02 04	0241	IMMUNO (ANIMAL)	01 02 04
0202	ONCO (ANIMAL)	01 02 04	0217	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242	IMMUNO (HUMAN)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04	0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243	CHEM/PHYS PROP	01 02 04
0204	MUTA (IN VITRO)	01 02 04	0219	HUMAN EXPOS (MONITORING)	01 02 04	0244	CLASTO (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04	0220	ECO/AQUA TOX	01 02 04	0245	CLASTO (ANIMAL)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04	0221	ENV. OCCC/REL/FATE	01 02 04	0246	CLASTO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04	0222	EMER INCI OF ENV CONTAM	01 02 04	0247	DNA DAM/REPAIR	01 02 04
0208	NEURO (HUMAN)	01 02 04	0223	RESPONSE REQEST DELAY	01 02 04	(0248)	PROD/USE/PROC	01 02 04
(0209)	NEURO (ANIMAL)	01 02 04	0224	PROD/COMP/CHEM ID	01 02 04	0251	MSDS	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04	0225	REPORTING RATIONALE	01 02 04	0299	OTHER	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04	0226	CONFIDENTIAL	01 02 04			
(0212)	ACUTE TOX. (ANIMAL)	01 02 04	0227	ALLERG (HUMAN)	01 02 04			
0213	SUB ACUTE TOX (ANIMAL)	01 02 04	0228	ALLERG (ANIMAL)	01 02 04			
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04	0239	METAB/PHARMACO (ANIMAL)	01 02 04			
0215	CHRONIC TOX (ANIMAL)	01 02 04	0240	METAB/PHARMACO (HUMAN)	01 02 04			

TRIAGE DATA: NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
(YES)	YES (DROP/REFER)	MOS	(LOW) Acute Oral Toxicity	R&D	
NO	NO (CONTINUE)		MED		
(DETERMINE)	REFER:		HIGH		

COMMENTS: Non-Cap

13393A

14 Mixtures (A-N) (Composition percentages of mixtures was not reported)

L

For all mixtures evaluated, acute oral toxicity in mice is low based on 0% mortality (0/12 [Mixtures A-F] or 0/6 [Mixtures G-N]) in male and female mice (6/sex/group for Mixtures A-F; 3/sex/group for Mixtures G-N) dosed with 5000 mg/kg (assume density = 1, 5 mL/kg). Clinical signs included ataxia (all mixtures), excited movements (Mixtures A-H, K,L), recumbancy (all mixtures), and loss of righting reaction (Mixtures E, F, G, H, K).