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DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ – 94-13216	89120000387	6/1/12

COMMENTS: COMMUN S (DECLASS)

DOES NOT CONTAIN CBI

MRH 345403

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

May 30, 2012

via Fed-Ex

Attention: TSCA Declassification Coordinator
U.S. EPA
Office of Pollution Prevention and Toxics
Confidential Business Information Center (CBIC)
EPA East Building, Room 6428
1201 Constitution Ave.
Washington, DC 20004-3302

Re: Declassification Activity-Health and Safety Filing
TSCA 8(e) Submission 8EHQ-94-13216 DCN: 88950000006

Dear Sir/Madam:

The Procter & Gamble Company (P&G) provides this submission to amend the Public Display Version of our TSCA Section 8(e) submission referenced above.

This amended submission is composed of the information provided in this cover letter and its attachment.

Please append this letter and attachment directly in front of EPA's existing Public Display Version of this TSCA 8(e) submission to create a new declassified Public Display Version. The newly created document discloses chemical identity information previously claimed CBI and replaces the existing Public Display copy of this TSCA 8(e) submission.

Any CBI substantiation for chemical identity which appeared in the original submission is no longer applicable as the chemical identity information is now disclosed in the revised submission described above.

Should you have any questions, 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

8 9 1 2 0 0 0 0 3 8 7

Attachment

CONTAINS NO CBI

Attachment

Non-Confidential Public Display Version
8EHQ-94-13216

Chemical	
Reaction Product Of	
L-Asparic acid	56-84-8
Ethane, 1,2-dibromo	106-93-4
Hydrochloric acid	7647-01-0
Sodium hydroxide	1310-73-2

of FedEx Express® Shipping

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KEN GASKINS
PROCTER & GAMBLE COMPANY
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UNITED STATES US

SHIP DATE: 31MAY12
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CAD: 0015729/CAFE2511

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Date Produced	Date Received	TSCA Section
10/05/94	10/07/94	8E
Submitting Organization		
PROCTOR & GAMBLE CO		
Contractor		
Document Title		
INITIAL SUBMISSION: 91-DAY SUBCHRONIC FEEDING STUDY IN RATS WITH COVER LETTER DATED 100594 (SANITIZED)		
Chemical Category		

Procter&Gamble

8EHQ-1094-13216S

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

Public Display Version

94 OCT -7 AM 7:41

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October 5, 1994

8EHQ-94-13216
INIT
88950000006

Document Processing Center (TS-790)
(Attention Section 8(e) Coordinator)
Office of Toxic Substances
U S Environmental Protection Agency
401 M Street, S W
Washington, D C 20460

COMPANY SANITIZED

RE TSCA Section 8(e) Submission

Reaction Product of organic acid, halogenated alkane, hydrochloric acid and sodium hydroxide CAS Number Not Known Not listed on the public portion of the TSCA Inventory

ATTN TSCA Section 8(e) Coordinator

This submission is made in accordance with TSCA Section 8(e) requirements and discharges any TSCA Section 8(e) responsibilities that exist for our Company regarding the information described herein We do not believe the data described in this submission reasonably support the conclusion that the subject material presents a substantial risk of injury to human health or the environment

The subject material is being studied solely for R&D purposes in the US We have not manufactured or processed this substance for commercial distribution We have handled and will continue to handle this material 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 substance by both labels and MSDS

This submission provides preliminary information (attached) from an un-audited, 91-day subchronic feeding study in rats The study included a 4-week recovery period, and the test material was dosed at 0, 50, 300, 700 and 1000 mg/kg/day Degeneration of seminiferous epithelium (testes) was observed in 7/10 animals in 1000 mg/kg group, and 3/10 animals in 700 mg/kg group. There was no evidence of degeneration in lower dose groups or in any group following the recovery period. In the 1000 mg/kg group a decrease in normal sperm was observed with a concomitant increase in head-only sperm (96 7% normal and 2 3% head-only sperm for the control group, compared to 85 5% normal and 12 7% head-only sperm in the 1000 mg/kg group) This effect was not observed following the 4 week recovery period, except in one rat. However, there was an increase in abnormal hook sperm in the 1000 mg/kg group (97% normal and 1% hook sperm for the control group, compared to 86% normal and 2 4% hook sperm in the 1000 mg/kg group).

The no observed effect levels for the observations cited above are well abcve the maximum anticipated exposures of the test substance We estimate safety factors greater than 400,000-fold for the effects summarized here

We arc requesting that the designated information in this submission be treated as confidential We have not publicly disclosed any plans regarding the commercialization of this material and have taken specific measurss to protec such information 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 this material has been carefully restricted to employees who have a need to know

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
Regulatory & Government Affairs
The Procter & Gamble Company
Telephone 513/627-6368

Attachment

SPERM MORPHOLOGY (%) (CONT'D)

AFTER 13 WEEKS

ANIMAL NUMBER	LEFT VAS DEFERENS						RIGHT VAS DEFERENS					
	A	B	C	D	E	F	A	B	C	D	E	F
GROUP 4												
42	95.2	4.2	0.0	0.6	0.0	0.0	96.4	3.2	0.0	0.4	0.0	0.0
43	99.2	0.6	0.0	0.2	0.0	0.0	99.4	0.4	0.0	0.2	0.0	0.0
48	94.0	3.8	0.0	1.8	0.0	0.4	91.4	4.6	0.0	4.0	0.0	0.0
49	97.8	1.2	0.0	1.0	0.0	0.0	98.6	1.2	0.0	0.2	0.0	0.0
50	97.2	1.8	0.0	0.8	0.0	0.2	99.8	3.2	0.0	0.8	0.0	0.2
MEAN	96.7	2.3	0.0	0.9	0.0	0.1	96.3	2.3	0.0	1.0	0.0	0.0
ST.DEV	2.1	1.6	0.0	0.6	0.0	0.2	3.1	1.7	0.0	1.6	0.0	0.1
N	5	5	5	5	5	5	5	5	5	5	5	5
GROUP 5												
54	91.8	7.4	0.0	0.8	0.0	0.0	91.6	7.2	0.0	1.2	0.0	0.0
55	93.6	5.4	0.0	0.8	0.2	0.0	92.4	7.2	0.0	0.4	0.0	0.0
56	78.6	18.4	0.0	2.2	0.0	0.8	77.0	21.2	0.2	1.2	0.0	0.4
59	90.2	9.0	0.0	0.8	0.0	0.0	85.4	14.4	0.0	0.0	0.2	0.0
60	73.4	23.2	0.0	2.2	0.0	1.2	81.0	14.0	0.0	4.0	0.0	1.0
MEAN	85.3*	12.7*	0.0	1.4	0.0	0.4	85.5*	12.8*	0.0	1.4	0.0	0.3
ST.DEV	9.0	7.7	0.0	0.8	0.1	0.4	6.7	5.9	0.0	1.6	0.1	0.5
N	5	5	5	5	5	5	5	5	5	5	5	5

Code	Description
A	Normal
B	Head Only
C	Misshapen
D	Abnormal Hook
E	Reversed Head
F	Abnormal Hook only

* : Dunnet-Test based on pooled variance significant at 5% level

Attachment

SPERM MORPHOLOGY (%)

AFTER 17 WEEKS

ANIMAL NUMBER	LEFT VAS DEFERENS						RIGHT VAS DEFERENS					
	A	B	C	D	E	F	A	B	C	D	E	F
GROUP 1												
11	98.4	1.0	0.0	0.6	0.0	0.0	98.4	0.4	0.0	1.2	0.0	0.0
12	97.2	2.8	0.0	0.8	0.0	0.0	97.6	1.8	0.0	0.6	0.0	0.0
13	96.0	2.2	0.0	1.6	0.2	0.0	97.2	1.4	0.0	1.2	0.0	0.2
14	93.6	2.8	0.0	3.4	0.0	0.0	96.8	1.8	0.0	1.4	0.0	0.0
15	98.8	0.8	0.0	0.4	0.0	0.0	97.6	2.0	0.0	0.4	0.0	0.0
16	98.0	1.2	0.0	0.8	0.0	0.0	97.4	1.8	0.8	0.8	0.0	0.0
17	98.8	0.8	0.0	0.2	0.0	0.2	99.6	0.4	0.0	0.0	0.0	0.0
18	98.6	0.8	0.0	0.6	0.0	0.0	98.0	1.8	0.0	0.2	0.0	0.0
19	93.8	0.8	0.0	3.4	0.0	0.0	96.4	0.6	0.0	2.4	0.0	0.4
20	98.8	1.0	0.0	0.2	0.0	0.0	98.0	1.2	0.0	0.6	0.0	0.2
MEAN	97.6	1.3	0.0	1.1	0.0	0.0	97.7	1.3	0.0	0.9	0.0	0.1
ST.DEV	1.3	0.6	0.0	1.1	0.1	0.1	0.9	0.6	0.0	0.7	0.0	0.1
N	10	10	10	10	10	10	10	10	10	10	10	10
GROUP 5												
61	96.0	1.6	0.0	2.4	0.0	0.0	96.6	0.6	0.0	2.6	0.0	0.0
62	93.2	1.0	0.0	5.6	0.0	0.2	93.4	1.8	0.0	4.2	0.2	0.4
63	95.2	2.4	0.0	2.4	0.0	0.0	94.6	3.2	0.0	2.0	0.0	0.2
64	96.6	0.4	0.0	3.0	0.0	0.0	96.0	1.2	0.0	2.4	0.0	0.4
65	NV	NV	NV	NV	NV	NV	94.4	2.0	0.0	3.6	0.0	0.0
66	93.4	2.2	0.0	3.8	0.0	0.6	93.6	3.0	0.0	2.8	0.0	0.6
67	99.2	0.4	0.0	0.4	0.0	0.0	98.0	0.6	0.0	0.6	0.0	0.0
68	92.4	3.4	0.0	3.6	0.0	0.6	93.8	2.2	0.0	4.0	0.0	0.0
69	98.8	0.8	0.0	0.4	0.0	0.0	98.4	0.4	0.0	1.0	0.0	0.2
70	13.6	82.0	0.0	1.2	0.0	3.0	3.2	90.8	0.0	0.4	0.0	5.6
(A) MEAN	95.9	1.9	0.0	2.3*	0.0	0.2	95.9*	1.7	0.0	2.6*	0.0	0.2
ST.DEV	2.4	1.1	0.0	1.4	0.0	0.3	2.1	1.0	0.0	1.3	0.1	0.2
N	8	8	8	8	8	8	9	9	9	9	9	9
(B) MEAN	86.7	10.3	0.0	2.3	0.0	0.5	86.3+	10.6	0.0	2.4+	0.0	0.7
ST.DEV	27.4	26.8	0.0	1.3	0.0	1.6	29.3	28.2	0.0	1.4	0.1	1.7
N	9	9	9	9	9	9	10	10	10	10	10	10

NV = No sperm was obtained due to technical difficulties during sampling

(A) = Values of animal no 70 were excluded from the mean
* : Dunnet-Test based on pooled variance significant at 5% level

(B) = Values of animal no 70 were included in the mean
+ : Steel-Test significant at 5% level

Attachment

RESULTS (continued)

Testes	The reviewing pathologist considered that there was an effect of treatment in the testes consisting of degeneration of the seminiferous epithelium in 7/10 animals, dosed at 1000 mg/kg/day and 3/10 dosed at 700 mg/kg/day. An effect of treatment was not noted in the Draft Pathology Report. There was no evidence of an effect of treatment in animals dosed at 30 or 300 mg/kg/day or in animals from the recovery group. Bilateral atrophy was noted in 2/10 main test males and 2/10 recovery group males dosed at 1000 mg/kg/day. As this change may occur spontaneously in rats of this age, the significance of these findings remains equivocal, despite the absence of similar changes in control rats from this study.

Attachment

Contract Lab Pathologist

PATHOLOGY REPORT (DRAFT)
PRINCIPAL SECTION

TEST ARTICLE : E-4589.01
TEST SYSTEM : RAT, Subchronic 13-week , Feed DATE : 14-JUL-94
SPONSOR : Procter & Gamble PATHDATA SYSTEM V3.5d

RESULTS

The remainder of microscopic findings did not vary significantly in incidence or severity between control and treated groups, nor between rats sacrificed at the end of the treatment period or following the recovery phase. They were all of a spontaneous nature and within the normal range of background morphologic alterations which may be recorded in Wistar rats of this strain at these ages.

TESTES	NO.EXAM.:	10	10
- Atrophy, tubular			2

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CERTIFICATE OF AUTHENTICITY

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