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**TSCA NON-CONFIDENTIAL BUSINESS INFORMATION**

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

COMMENTS: COMMUN S (DECLASS)

**DOES NOT CONTAIN CBI**

MR# 345403

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

May 30, 2012

2012 JUN -1 AM 10: 53

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Any CBI substantiation for chemical identity which appeared in the original submission is no longer applicable as the chemical identity information is now disclosed in the revised submission described above.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



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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PROCTER & GAMBLE COMPANY  
TWO PROCTER & GAMBLE PLAZA

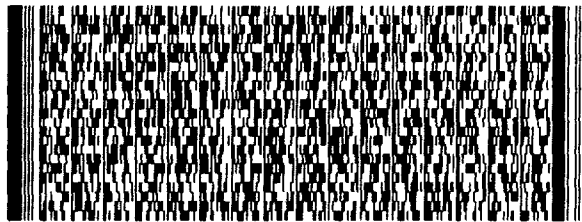
SHIP DATE: 31MAY12  
ACTWGT 0.4 LB  
CAD 0015729/CAFE2511

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UNITED STATES US

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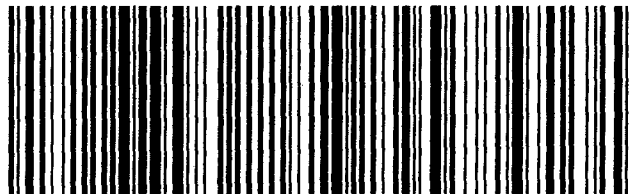
TRK# 4493 3604 9517  
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DC-US DCA

Part # 156148-434 NRIT V3 12-08



# CODING FORMS FOR SRC INDEXING

Microfiche No.		OTS0590057	
New Doc ID		Old Doc ID	
88-950000006S		8EHQ-1094-13216S	
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-1094-132165

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

Public Display Version

October 5, 1994

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

8EHQ-94-13216  
INVT  
8895 0000006 0

94 OCT - 7 AM 7:41

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EPA

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 above the maximum anticipated exposures of the test substance. We estimate safety factors greater than 400,000-fold for the effects summarized here.

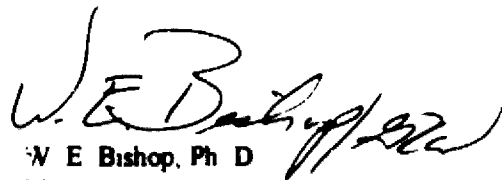
We are requesting that the designated information in this submission be treated as confidential. We have not publicly disclosed any plans regarding the commercialization of this material and have taken specific measures to protect such information. Measures to protect confidential information include "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

A handwritten signature in dark ink, appearing to read "W. E. Bishop". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

W. E. Bishop, Ph. D.  
Manager  
Regulatory & Government Affairs  
The Procter & Gamble Company  
Telephone 513/627-6368

# 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
<b>GROUP 4</b>												
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	0.3	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	0.0	77.8	21.2	0.0	1.2	0.0	0.0
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	25.2	0.0	2.2	0.0	1.2	81.0	14.0	0.0	4.0	0.0	1.0
MEAN	83.5*	12.7*	0.0	1.4	0.0	0.4	83.5*	12.8*	0.0	1.4	0.0	0.3
ST. DEV	9.0	7.7	0.0	0.8	0.1	0.6	6.7	5.9	0.0	1.6	0.1	0.3
N	5	5	5	5	5	5	5	5	5	5	5	5

<u>Code</u>	<u>DESCRIPTION</u>
A	Normal
B	HEAD ONLY
C	Misshapen
D	Abnormal Hook
E	REVERSED HEAD
F	Abnormal Hook only

\* : Dunnett's test based on pooled variance significant at 5% level

# SPERM MORPHOLOGY (%)

## AFTER 17 WEEKS

ANIMAL NUMBER	LEFT VAS DEPERENS						RIGHT VAS DEPERENS					
	A	B	C	D	E	F	A	B	C	D	E	F
<b>GROUP 1</b>												
11	98.4	1.0	0.0	0.4	0.0	0.0	98.4	0.4	0.0	1.2	0.0	0.0
12	97.2	2.0	0.0	0.8	0.0	0.0	97.6	1.0	0.0	0.4	0.0	0.0
13	96.0	2.2	0.0	1.4	0.2	0.0	97.2	1.4	0.0	1.2	0.0	0.2
14	99.6	2.0	0.0	2.4	0.0	0.0	98.8	1.8	0.0	1.4	0.0	0.0
15	98.0	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	1.0	0.0	0.8	0.0	0.0
17	98.8	0.8	0.0	0.2	0.0	0.2	99.4	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	1.0	0.0	0.2	0.0	0.0
19	99.8	0.8	0.0	3.4	0.0	0.0	96.4	0.6	0.0	2.4	0.0	0.4
20	98.0	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	0.2	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
<b>GROUP 5</b>												
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	99.2	1.0	0.0	3.6	0.0	0.2	93.4	1.8	0.0	4.2	0.2	0.4
63	99.2	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	99.4	3.2	0.0	3.6	0.0	0.4	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	0.4	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	19.8	82.0	0.0	1.2	0.0	3.0	3.2	98.0	0.0	0.4	0.0	3.6
(A) MEAN	99.9	1.9	0.0	2.9*	0.0	0.2	99.9*	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	84.7	10.3	0.0	2.9	0.0	0.3	84.3*	10.6	0.0	2.4*	0.0	0.7
ST.DEV	27.4	24.8	0.0	1.3	0.0	1.0	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

1st Draft  
23 August 1994

Peer Review - Subchronic 13-Week Oral (Feeding) Toxicity  
Study with E-4589.01 in the Rat

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## 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 50 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  
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**RESULTS**  
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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  
.....

**COMPANY SANITIZED**

### CERTIFICATE OF AUTHENTICITY

THIS IS TO CERTIFY that the microimages appearing on this microfiche are accurate and complete reproductions of the records of U.S. Environmental Protection Agency documents as delivered in the regular course of business for microfilming.

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END