PUBLIC DISPLAY VERSION

8EHQ-0394-12918

Procter & Gamble

OFFICE OF POLLUTION PREVENTION AND TOXICS

94 MAR -7 PM 2:37

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

March 4, 1994

(A)

COMPANY SANITIZED

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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

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 U. S. 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 data from a dose setting pre-study conducted to identify appropriate dose levels for a definitive, larger scale developmental toxicity study.

Maternal toxicity was evident at the three (3) highest dose levels (16,000, 24,000 and 40,000 ppm) on a dose-related basis. Two (2) females from Group 6 (40,000 ppm) died during the course of the study on Gestation Days 16 and 17. Body weight loss was evident in the 3 highest dose groups over Gestation Days 6-9. The weight loss continued in the two (2) highest dose groups while the animals in the 16,000 ppm group gained only 17 grams during the dose administration period as compared to 43 grams for the control group. A rebound effect was seen in body weight gain following cessation of treatment, however, the body weight gain remained lower for each of the highest 3 dose levels as compared to the control group. The effect on body weight was most pronounced in the high dose group which experienced a net weight loss during the study. Net weight gain was depressed in the 16,000 and 24,000 ppm groups.

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3 pgs.

Clinical observations of soft stool and decreased defecation were observed in the top three dose levels with a dose dependent increase in the incidence and number of animals effected. One (1) of 5 animals in Group 5 (24,000 ppm) and all animals in the high dose group appeared emaciated following several days of treatment. The ventral body surface was stained in three (3) of five (5) animals in the high dose group.

Developmental toxicity was also evident in the three (3) highest dose levels (16,000, 24,000, and 40,000 ppm) as compared to the control group. Whole litter resorption occurred in 1 of 5 females in the 24,000 ppm group and 5 of 5 females in the 40,000 ppm group. Post-implantation losses were increased dramatically in the 24,000 and 40,000 ppm groups as compared to the control group. Relative fetal body weight was reduced in the 16,000 and 24,000 ppm groups as compared to the control group.

In the 24,000 ppm group there was one severely malformed litter. This uterus was opened to determine the viability of the implants which could not be determined from the external uterine exam. At least one other litter may have been similarly affected according to its external appearance.

The results of the range-finding study indicate the test material is toxic both maternally and developmentally at the 16,000 ppm level and above. We are conducting the definitive developmental toxicity study. A copy of the final results of this definitive study will be forwarded to the EPA when available.

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

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

Attachment

Study Title Range-finding Development Toxicity Study in Rats

TERATOLOGY OBSERVATION SUMMARY

Test Article E-4589.01 Termination Date 2/3/94 Study Number 191-1598

Target Dosage (mg/kg/day):	0	50	200	400	600	1000
ppm	0	2000	8000	16000	24000	40000
Gestation Day	Group Mean Maternal Body Weight (g)					
0	250	246	253	247	244	243
6	277	274	270	272	265	267
9	284	282	280	271	233	228
12	297	301	288	285	233	207
16	320	318	315	289	209	179
20	379	377	383	349	269	228
Gestation Interval	Group Mean Maternal Body Weight Change(g)					
0-6	27	29	17	25	21	23
6-9	7	8	10	-1	-32	-39
9-12	14	18	8	14	-1	-20
12-16	22	17	27	4	-23	-27
16-20	59	60	68	60	60	47
6-16	43	43	45	17	-56	-82
0-20	129	131	130	102	25	-16
Abnormal Clinical findings (+ Present - Absent)				+ ++	+ ++	+ ++ +++

+ soft stool
++ decreased defecation
+++ emaciated

Target Dosage (mg/kg/day):	0	50	200	400	600	1000
ppm	0	2000	8000	16000	24000	40000
Number on Study	5	5	5	5	5	5
Number of Deaths	0	0	0	0	0	2
Number Gravid	4	5	5	5	4	5
Number Nongravid	1	0	0	0	1	0
Gravid w/Litter at Uterine Examination/ Cesarean Section	4	5	5	5	3	(
Number of Dams with Resorptions Only	0	0	0	0	1	5
Number of Post-Implantation Losses (mean/dam)	0.5	0.2	1.6	0.8	7.8	12.
Mean Gravid Uterine Weight (g)	77.6	73.3	82.9	63.3	21.6	NA
Average Viable Fetuses/Dam	14.5	13.8	14.8	13.6	5.3	NA
Relative Fetal Weight (g)	5.2	5.2	5.1	4.4	1.9	NA
Average Litter Size/Dam	15.0	14.0	16.4	14.4	13.0	NA
Total Fetuses Examined	-	-	-	-	-	-

Summary of External/Visceral Malformations:

Verified by [signature] Date 2/4/94