

8EHP-92-13200  
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October 6, 1992

Document Processing Center (TS-790)  
Office of Pollution Prevention and Toxics  
Environmental Protection Agency  
401 M Street., S.W.  
Washington, D.C. 20460

8EHP-92-13200  
208920011003  
CAP

Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

SECAP- [ ]

On behalf of the Regulatee and pursuant to Units II B.1.b; II C and II D of the [ ] CAP Agreement, [ ] hereby submits (in triplicate) the attached information. Submission of the information in this letter is made voluntarily under a recently published TSCA §8(e) reporting Q/A, June 1991 TSCA 8(e) Reporting Guide ("Reporting Guide") and is not to be construed as a waiver of due process rights, or as an admission of TSCA violation or that Regulatee's activities with the study compound(s) reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which was not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide" states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due process issues and

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4/1/95

clouds the appropriate reporting standard by which regulated persons can assure TSCA §8(e) compliance.

Regulatee is claiming certain bracketed "[ ]" information in this submission as Confidential Business Information and has provided substantiation and a redacted copy for the public file.

For Regulatee,

{

}

Attachment 1

Substantiation of Confidential Business Information Claims

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CAP Confidentiality Claim: Submitter ID (including internal codes and personnel), Mixture Composition, Mixture ID, Use.

(This is a research mixture)

1. Confidential treatment should be afforded for an initial period of ten years. At that time the submitter will review business needs and, if warranted, may request reasonable extensions to that time period. Technology represented by the mixture is not easily protected from competitors by obtaining patents, therefore, the submitter has maintained these compositions as trade secrets.

A ten year period is requested because the current lifetime of most [ ] is generally ten years. However, the technology base of [ ] may exceed ten years. In such cases extensions may be requested.

2. No.

3. No. Not to our knowledge. The submitter's practice is to disclose composition identity to outside parties only under terms of a security agreement or to the government with claims of confidentiality or trade secrecy.

4. All documents which reveal proprietary chemicals which comprise the mixture composition are stored in locked, limited access facilities. These documents are identified as being proprietary, secret, or confidential. As a condition of employment, employees are contractually prohibited from disclosing confidential information outside the company.

5(a) No.

(b) No.

(c) No.

(d) No.

6. [ ] quality is critical to product performance and directly impacts market share. An estimated 10-20 million dollars is required to improve manufacturing processes in order to produce [ ] with improved [ ] manufacture. The entire value of this improvement can be eliminated by the choice [ ]

Additionally [ ] are now evaluated based on environmental impact, [ ] uniformity and performance characteristics, and safety. All of these qualities must be "engineered in" to our [ ] at some substantial investment. An estimated minimum value of commercializing a [ ] can exceed \$50,000.

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Disclosure of [ ] composition would impact the submitter's competitive position per the following:

- If a competitor sees several formulas containing similar materials he could be reasonably sure that these materials are of on-going interest to the submitter, and therefore have competitive value.
  - Disclosure of the mixture composition (chemical identity of the components) would disclose the specific [ ] formula or would make it easy for a competitor to produce the same or a similar mixture with significantly less R & D investment since the choice of mixture components would be disclosed.
  - A competitor could determine a time sequence in testing based on the dates of the disclosed studies, and determine what research direction the submitter is following. For example it would be possible to track progression from one major component [ ] to another. Although the use of [ ] is generally known, competitors do not know which of these materials is considered "better" and worthy of pursuing commercially.
  - Knowing that toxicity testing is not cheap, a competitor can readily assume that any composition tested by the submitter has some commercial / competitive value.
  - Although the toxicity test does not identify which [ ] the [ ] is applied to, a general knowledge of [ ] requirements in the marketplace would make it easy to determine the [ ] based on the [ ] components.
7. Submitter does not agree that chemical identity is "health and safety data". Without waiving this objection submitter answers the following:
- (a) No.
  - (b) Yes. This information could be established based on a precise listing of the components.
  - (c) Yes. Chemical identity information, internal codes, and personnel could disclose submitter identity and would enable our competitors to benefit from our investment in new technology.

### Submitter Identity

Because the submitter is recognized for its [ ] technology, competitors could search submissions selectively for [ ] and, with limited investment and testing required, try them on their own products.

1. Submitter's participation in the CAP is now a matter of public record.
2. The tested mixtures are generally similar in that they are composed of [ ]
3. It is likely that a competitor skilled in the art of [ ] production or [ ] will recognize or guess that, even with generic descriptions of components, the mixtures end use is that of a [ ].
4. Disclosure of submitter ID with generic composition ID will make it much easier for a competitor to know that the tested material is, in fact, a [ ] as submitter is recognized as a leader in [ ] production.

### Composition

Revealing specific [ ] would open the door for our competitors to precisely reproduce formulations which have been developed at significant expense. Our competitors may well be able to establish a composition as [ ] solely on the basis of the nature of its ingredients even without making an association with the submitter or the use.

### Use

Competitors could quickly scan submissions for this application, and use this information to develop a database re. trends in [ ] technology without incurring R&D and testing costs which have been borne by the submitter.

Chem/CAS: [ ]  
Generic Identity: A fluoroalkyl-substituted urethane with a modified acrylic resin, an alkylated vegetable oil, a polyether copolymer and a small amount of an anionic fatty acid soap.  
Title: Inhalation Approximate Lethal Concentration (ALC)  
Date: 6-30-80

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Material Tested

Other Codes/Synonyms  
None

Study Initiated/Completed  
5/7/80 - 5/29/80

INHALATION APPROXIMATE LETHAL CONCENTRATION (ALC)

Procedure: Groups of 6 male ChL-CD® rats, weighing between 230 and 284 grams, were exposed for single 4-hour periods to off-gases from \_\_\_\_\_ All rats were observed during the exposure and clinical signs were noted. Following exposure, surviving rats were returned in pairs to suspended, stainless steel, wire-mesh cages and supplied Purina® Rodent Chow and water ad libitum. All rats were weighed and observed daily (except weekends) for 14 days post exposure

Generation: Aerosol atmospheres of Finish \_\_\_\_\_ were generated by syringe driving the finish through a Spraying Systems nebulizer onto the heated (225°C) surface of an Instatherm® flask. Houseline air swept \_\_\_\_\_ into a 20-l glass exposure chamber.

Analytical: To analyze test chamber atmosphere, gravimetric samples were collected at 1/2 hour intervals. Known volumes of atmosphere were drawn through Gelman glass fiber filters (Type A-E, 47 mm). The atmospheric concentration of test material was determined from weight gain of the filter.

Results:

<u>Concentration (ng/l)</u>		<u>Standard Deviation</u>	<u>Range</u>	<u>Fractional Mortality # deaths/ # Exposed</u>
<u>Mean</u>	<u>Mean (Dry Weight Basis)</u>			
0.07	0.01	0.005	0.003-0.014	0/6
0.50	0.07	0.02	0.04-0.12	1/6
1.43	0.20	0.07	0.04-0.27	6/6
4.92	0.69	0.07	0.61-0.79	6/6
5.50	0.77	0.23	0.25-0.94	6/6

All deaths occurred either during exposure or within 24 hours following exposure.

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Observations

Exposure: Restlessness, rapid breathing, decreased response to sound, clear ocular and nasal discharge, wet fur and reddish ears.

Post Exposure: No overt clinical signs in survivors.

Summary: The acute inhalation toxicity of \_\_\_\_\_ was evaluated in groups of male rats given single 4-hour exposures. The Approximate Lethal Concentration (ALC) on a dry weight basis is 0.07 mg/l which is considered extremely toxic. The calculated ALC for \_\_\_\_\_ (with approximately 86% water) is 0.5 mg/l which is highly toxic. Adequate ventilation needs to be available and good industrial hygiene practices should be followed when using this material.

Report by:

Approved by:

Date Issued: June 30, 1980

Date Reissued: July 17, 1980

**Triage of 8(e) Submissions**

Date sent to triage: 2/5/96

NON-CAP

CAP

Submission number: 13200A

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**

<b>For Contractor Use Only</b>	
entire document: <u>0</u> 1 2 pages <u>4, 2, 1st tab</u>	pages <u>[REDACTED]</u>
Notes:	<u>12/6/95</u>
Contractor reviewer: <u>LPS</u>	Date: <u>[REDACTED]</u>

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # 8EHO-1192-132003 SEQ. A  
 TYPE: INT SUPP FLWT  
 SUBMITTER NAME: Confidential

INFORMATION REQUESTED: FLWT DATE: \_\_\_\_\_  
 0501 NO INFO REQUESTED  
 0502 INFO REQUESTED (TECH)  
 0503 INFO REQUESTED (VOL ACTIONS)  
 0504 INFO REQUESTED (REPORTING RATIONAL.F)  
 DISPOSITION:  
 0505 REFER TO CHEMICAL SCREENING  
 0506 CAP NOTICE

SUB. DATE: 10/06/92 OTS DATE: 11/02/92 CSRAD DATE: 01/01/95

CHEMICAL NAME: Fluoroalkyl-substituted methane with a modified acrylic resin, an alkylated vegetable oil, a polyether Copolymer and a small amount of an anionic fatty acid soap  
 CASE: Confident

VOLUNTARY ACTIONS:  
 0401 (M) ACTION REPORT ID  
 0402 STUDIES PLANNED IN THE WAY  
 0403 NOTIFICATION OF WORKING METHODS  
 0404 LABELS/MSDS CHANGES  
 0405 PROCESS/AND/OR CHANGES  
 0406 APPAUSE DISCONTINUED  
 0407 PRODUCTION DISCONTINUED  
 0408 CONFIDENTIAL

INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.
0201 ONCO (HUMAN)	01 02 04	EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEMPHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	ECOAQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	ENV. OCCUREL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	RESPONSE REQUEST DELAY	01 02 04	0248 PRODUCE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	PRODCOMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	METABPHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	METABPHARMACO (HUMAN)	01 02 04		

TRIAGE DATA: NON-CBI INVENTORY  
 YES  
 CAS SR NO  
 YES (DROP/REFER)  
 NO (CONTINUE)  
 REFTR

SPECIES: RAT  
 TOXICOLOGICAL CONCERN:  
 LOW  
 MED  
 HIGH

USE:  
 PRODUCTION:  
Acute Inhalation Toxicity

#13200A

H

Acute inhalation toxicity is of high concern based on the mortality in rats exposed for 4 hours. Mortality and corresponding doses ( $\text{g}/\text{m}^3$  dry weight,  $\text{g}/\text{m}^3$  with 86% water) were 0/6 (0.01, 0.07), 1/6 (0.07, 0.50) and 6/6 (0.2, 1.43; 0.69, 4.92; 0.77, 5.5). Clinical signs included restlessness, rapid breathing and decreased response to sound.