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October 1, 1992

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

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

Dear Coordinator:

8ECAP-[]

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

3/9/95

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

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) Yes. The internally-used MSDS sheet includes a coded ingredient list, however the specific proprietary chemicals comprising [] are not identified by chemical name or CAS#. Coded ingredient names are designated "trade secret" on The internal MSDS. Submitter does not distribute or sell the proprietary mixtures to other users outside the company (excluding subsidiaries).

(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.

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.

COMPANY SANITIZED

CAS #

Generic Name: An anionically dispersed fluoroalkyl-surfactant-substituted urethane with an ethoxylated vegetable oil and a nonionic fluorochemical.

Title: Inhalation Approximate Lethal Concentration (ALC)

Date: 9/20/88

Summary of Effects: Highly toxic

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Study Title

Inhalation Approximate Lethal Concentration (ALC)
of (17% Emulsion)

Study Completed On

September 20, 1988

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GENERAL INFORMATION

Material Tested:

-
-

Physical Form:

Liquid emulsion

Composition:

4

Other Codes:

Stability:

The test material was assumed to be stable throughout the exposure phase of the study.

Sponsor:

Material Submitted By:

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GENERAL INFORMATION (Cont'd)

In-Life Phase
Initiated - Completed: 8/11/88 - 8/31/88

Notebook: -
 -

There are 8 pages in this report.

Distribution:

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Inhalation Approximate Lethal Concentration (ALC)
of (17% Emulsion)

SUMMARY

Groups of 6 male Crl:CD®BR rats were exposed for a single, 4-hour period to atmospheres of (17% emulsion) in air. Test atmospheres were generated by atomizing the liquid test material with a nebulizer. Atmospheric concentrations of aerosol were measured by gravimetric analysis. After exposure, rats were observed for clinical signs of toxicity during a 14-day recovery period.

Deaths occurred following exposure to at aerosol concentrations of 140 mg/m³ or greater; all deaths occurred within 1 day of exposure. Clinical signs of toxicity included ocular, nasal or oral discharges and labored breathing immediately after exposure and slight to moderate weight losses during the recovery period. Under the conditions of this study, is considered to be highly toxic on an acute inhalation basis.

Work by:

Study Director:

Reviewed and Approved for Issue:

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QUALITY ASSURANCE DOCUMENTATION

STUDY: Inhalation Approximate Lethal Concentration (ALC)
of (17% Emulsion)

AUDITS:

<u>Items Audited</u>	<u>Audit Dates</u>
Protocol, Records, and Final Report	9/14-15/88

SHORT-TERM AUDIT REPORT NUMBER:
DATE FINDINGS REPORTED TO MANAGEMENT AND STUDY DIRECTOR: 9/15/88

In-life critical phases from a representative study of this test type are inspected quarterly. Since short-term studies are numerous and routine in nature, the in-life critical phases from one study exemplify the conduct of other studies from the same test type.

Reported by:

9/16/88
Date

INTRODUCTION

The purpose of this study was to determine a 4-hour inhalation ALC for in male rats. The ALC was defined as the lowest atmospheric concentration tested that caused the death of 1 or more rats either on the day of exposure or within 14 days post exposure. Except as documented in the study records, this study was conducted according to the applicable Good Laboratory Practice Regulations.

MATERIALS AND METHODS

A. Animal Husbandry

Young adult male CrI:CD®BR rats were received from Charles River Breeding Laboratories, Kingston, New York. Each rat was assigned a unique 6-digit identification number which corresponded to a numbered card affixed to the cage. Rats were quarantined for approximately one week prior to testing, and were weighed and observed three times during the quarantine period. During the test, rats were housed in pairs in 8" x 14" x 8" suspended, stainless steel, wire-mesh cages. The rat assigned the lower number in each cage was identified by a slash in the right ear. Prior to exposure, rats' tails and cage cards were color-coded with water-insoluble markers so that individual rats could be identified after exposure. Except during exposure, Purina Certified Rodent Chow® #5002 and water were available ad libitum.

Animal rooms were maintained on a timer-controlled, 12 hour/12 hour light/dark cycle. Environmental conditions of the rooms were targeted for a temperature of $23 \pm 2^\circ\text{C}$ and relative humidity of $50 \pm 10\%$. Excursions outside these ranges were judged to have been of insufficient magnitude and/or duration to have adversely affected the validity of the study.

B. Exposure Protocol

Groups of 6 rats, 8 weeks old and weighing between 233 and 283 grams, were restrained in perforated, stainless steel cylinders with conical nose pieces. The restrainers were inserted into a face plate on the exposure chamber such that only the nose of each rat protruded into the chamber. Each group was exposed nose-only for a single, 4-hour period to aerosol atmospheres of _____ in air. Rats were weighed prior to exposure, and were observed for clinical signs of toxicity during exposure. Surviving rats were weighed and observed daily for 14 days post exposure, weekends and holidays excluded.

C. Atmosphere Generation

Test atmospheres of _____ were generated by atomization. The test material was metered into a Spraying Systems nebulizer with a Harvard® Model 975 Compact Infusion Pump. Air introduced at the nebulizer (approximately 12-18 L/min) atomized the test material and swept the resulting aerosol into a 38-L cylindrical glass exposure chamber. Test atmospheres were dispersed with a baffle within the chamber to promote uniform distribution. Chamber atmospheres were exhausted through a dry-ice cold trap and a MSA cartridge filter prior to discharge into a fume hood.

D. Analytical

The atmospheric concentration of aerosol was determined at approximately 30-minute intervals by gravimetric analysis. Known volumes of chamber atmospheres were drawn through preweighed, Gelman glass fiber (Type A/E) filters. Filters were weighed on a Cahn Model 26 Automatic Electrobalance®. The atmospheric concentration of aerosol was calculated from the difference in the pre- and post-sampling filter weights.

Particle size (mass median aerodynamic diameter and percent less than 3 and 10 μm) was determined with a Sierra Series 210 cascade impactor during each exposure. During each exposure, chamber temperature was monitored using a thermocouple and chamber oxygen concentration was measured with a Biosystems® Model 3100R oxygen analyzer. Although relative humidity was measured with a Bendix Model 566 psychrometer during each exposure, the relative humidity values were incorrect due to improper sampling procedure.

E. Records Retention

All raw data and the final report will be stored in the archives of _____

RESULTS

A. Exposure Conditions and Associated Mortality

Aerosols of _____ were readily observed during the exposures. Chamber temperature ranged from 19-22°C and chamber oxygen concentration was 21.0%. Atmospheric aerosol concentrations and rat mortality data for each exposure are summarized in the following table.

Characterization of Atmospheres
and Rat Mortality

Aerosol Concentration (mg/m ³) ^a				% Particles ^b		MMD ^c	Mortality
Mean	S.D.	Range	n	<3 μ m	<10 μ m	(μ m)	(# deaths/# exposed)
82	7.2	76 - 96	6	38	94	3.6	0/6
94	8.3	83 - 100	6	26	92	4.4	0/6
140	18	110 - 160	6	24	84	5.0	2/6
300	50	240 - 380	8	33	88	4.3	6/6

- ^a Values shown represent the mean, standard deviation (S.D.), range and number of observations (n) for each exposure. Aerosol concentrations were based on wet filter weights. Since no significant weight losses were noted after desiccation of filter samples, the filter mass was assumed to represent the total amount of polymer present.
- ^b Percent by weight of particles with aerodynamic diameter less than 3 and 10 μ m.
- ^c Mass median aerodynamic diameter.

B. Clinical Observations

No clinical signs of toxicity were observed during exposure. Upon release from the restrainers at the end of exposure, rats exhibited ocular, nasal or oral discharges and labored breathing.

Deaths occurred following exposure to _____ at aerosol concentrations of 140 mg/m³ or greater. All deaths occurred within 1 day of exposure. Other than slight to moderate weight losses (up to 7% of initial body weight) in some rats within 1 day of exposure, no clinical signs of toxicity were observed during the recovery period. All surviving rats began to regain weight by day 2 post exposure.

DISCUSSION AND CONCLUSION

Under the conditions of this study, the ALC for _____ is 140 mg/m³ of aerosol. This material is considered to be highly toxic on an acute inhalation basis (ALC between 80 and 200 mg/m³).

¹ Calculation described in Sierra Instruments, Inc., Bulletin 7-79-219IM, Instruction Manual: Series 210 Ambient Cascade Impactors and Cyclone Preseparators.

Triage of 8(e) Submissions

Date sent to triage: MAY 09 1995

NON-CAP

CAP

Submission number: 12417A

TSCA Inventory:

Y

NO

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:	<u>0</u>	1 2	pages <u>1, 1st 2nd</u>	pages <u>1, 1st 2nd</u>	
Notes:					
Contractor reviewer:	<u>PRR</u>			Date:	<u>4/26/95</u>

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ.1092-12417 3 REG. A

TYPE INT SUPP FLWP
 SUBMITTER NAME: Confidential

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/IN PROGRESS
 0403 NOTIFICATION OF WORKER RIGHTS
 0404 LABEL/MSDS CHANGES
 0405 PROCESS/HANDLING CHANGES
 0406 APP/USE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

SUB DATE: 10/01/92 OTS DATE: 10/14/92 CSRAD DATE: 03/09/95

CHEMICAL NAME: anionically dispersed fluoroalkyl surfactant - substituted urethane with an ethoxylated vegetable oil and a non-ionic Fluorochemical
 CAS# Confident

INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	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. OCCUR/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	CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0226 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0227 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0228 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAGE DATA: NON-CBI INVENTORY
 YES NO
 CAS SR NO
 Ongoing Review: YES (DROP/REFER) NO (CONTINUE) REFTR
 Species: RAT
 Toxicological Concern: LOW MED HIGH
 USE: _____
 PRODUCTION: _____

-CPSS- 0927952113

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> <ID NUMBER>

8(E)-12417A

> <TOX CONCERN>

H

> <COMMENT>

ACUTE INHALATION TOXICITY IN MALE RATS IS HIGH CONCERN BASED ON AN LC50 OF 140 MG/M3 FOR A 4 HOUR EXPOSURE. DOSE (MG/M3) AND MORTALITY: 82 (0/6), 94 (0/6), 140 (2/6), AND 300 (6/6). CLINICAL SIGNS INCLUDED OCULAR, NASAL, OR ORAL DISCHARGES, LABORED BREATHING, AND SLIGHT TO MODERATE WEIGHT LOSS.

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