

8E HQ-1192-13194
COMPANY SANITATION

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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

8E HQ-92-13194
8892001099
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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3/1/95

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

"PUBLIC COPY"

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

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.

①

Chem/CAS: []
Generic Identity: A cationically- and nonionically-dispersed
fluoroalkyl- substituted carbamate.
Title: Inhalation Approximate Lethal Concentration (ALC) of
Date: 1-13-86
Summary of Effects: Extremely toxic

102-31

"PUBLIC COPY"

Inhalation Approximate Lethal Concentration (ALC) of

Date Issued: January 13, 1986

"PUBLIC COPY"

Inhalation Approximate Lethal Concentration (ALC) of

SUMMARY

Groups of 6 male Cr1:CD⁰(SD)BR rats were exposed to aerosol atmospheres of [redacted] for a single, 4-hour period. Under the conditions of this test, the ALC for [redacted] was 78 mg/m³ of particulate. This material is considered extremely toxic on an acute inhalation basis.

Work by:

Study Director:

Approved by:

"PUBLIC COPY"

Material Tested:

Sponsor:

Material Submitted By:

Test Facility:

Study Initiated - Completed: 1/28/85 - 2/25/85

There are 7 pages in this report.

Distribution:

INTRODUCTION

In a previous test, [redacted] was extremely toxic on an acute inhalation basis (ALC of 76 mg/m³); [redacted]. The purpose of this study was to determine a 4-hour inhalation ALC for a sample of [redacted] that was produced during a commercial production run. 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. None of the deviations noted affected the validity of this study.

MATERIALS AND METHODS

A. Animal Husbandry

Young adult male CrI:CD®(SD)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 one week prior to testing, and were weighed and observed twice 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.

B. Exposure Protocol

Groups of 6 rats, 8 weeks old and weighing between 227 and 274 grams, were restrained in perforated, stainless steel cylinders with conical nose pieces. Each group was exposed nose-only for a single, 4-hour period to an aerosol atmosphere of [redacted] 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 included when warranted by the rats' condition.

C. Test Material

Physical Form: Gray liquid

Composition: An aqueous dispersion containing 20.4% solids. The solids consisted of:

Contaminants:

Synonym:

Other Code:

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

D. Atmosphere Generation

Aerosol atmospheres of _____ were generated by pumping the liquid test material into a Spraying Systems nebulizer. Air introduced at the nebulizer aerosolized the test material, and swept the aerosol stream through a 1-liter glass cyclone elutriator. The cyclone removed large particles by inertial impaction, while aerodynamic particles passed through the cyclone and into the 38-liter glass exposure chamber. For some exposures, additional dilution air was added to the aerosol stream prior to its entering the exposure chamber. The chamber exhaust was drawn through a cold trap and a MSA cartridge filter prior to being discharged into the hood.

E. Analytical

The atmospheric concentration of _____ was determined at approximately 30-minute intervals during each exposure by gravimetric analysis. Calibrated volumes of chamber atmosphere were drawn from the rats' breathing zone through preweighed Gelman® glass fiber filters. Filters were weighed on a Cahn Model 26 Automatic Electrobalance®. The atmospheric concentration of particulate was calculated from the difference between the pre- and post-sampling filter weights.

Particle size (mass median aerodynamic diameter and percent respirable) was determined with a Sierra Series 210 cascade impactor at least once during each exposure. During each exposure, chamber

temperature was measured with a mercury thermometer, relative humidity was measured with a Bendix Model 566 psychrometer, and chamber oxygen content was measured with a BioMarine® Model 225 oxygen analyzer.

F. Records Retention

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

RESULTS

A. Exposure Conditions and Associated Mortality

A mist was visible in the chamber during all exposures with the aid of a flashlight and a darkened room. Chamber temperature ranged between 21-23°C, relative humidity ranged from 26-38%, and chamber oxygen content was 21%. Atmospheric characterization and associated rat mortality data are summarized below.

**Characterization of Atmospheres
and Associated Rat Mortality**

| <u>Particulate^a Concentration (mg/m³)</u> | | | <u>% Respirable^b</u> | <u>MMD(um)^c</u> | <u>Mortality (# deaths/# exposed)</u> |
|---|-------------|--------------|-------------------------------------|----------------------------|---|
| <u>Mean</u> | <u>S.D.</u> | <u>Range</u> | | | |
| 51 | 6.1 | 45 - 62 | 96 | 0.90 | 0/6 |
| 78 | 13 | 67 - 100 | 97 | 0.84 | 1/6 |
| 79 | 25 | 49 - 130 | 98 | 1.4 | 0/6 |
| 100 | 8.0 | 90 - 110 | 98 | 0.70 | 5/6 |
| 130 | 13 | 100 - 140 | >99 ^d | 0.38 ^d | 6/6 |

^a Represents the concentration of active ingredients only (water excluded).
^b Percent by weight of particles with aerodynamic diameter less than 10 um.
^c Mass median aerodynamic diameter.
^d Two particle size samples were taken during this exposure. The reported value is an average of the two samples.

One additional exposure was attempted but not completed due to difficulties with the generation system.

B. Clinical Observations

During or immediately following exposure, rats in all groups had red nasal or ocular discharges. Rats exposed to 100 mg/m^3 and rats exposed to 130 mg/m^3 had labored or rapid breathing, lethargy and partially closed eyes. One rat exposed to 78 mg/m^3 and one rat exposed to 130 mg/m^3 died during exposure. In addition, 2 rats exposed to 130 mg/m^3 died within 3 hours after exposure.

During the postexposure period, most rat deaths occurred within 1 day after exposure, although 1 rat exposed to 100 mg/m^3 died 3 days after exposure, and 1 rat exposed to 130 mg/m^3 died 2 days after exposure. Rats that survived exposure to 100 mg/m^3 had minimal weight loss (average less than 2% of initial body weight) 1 day after exposure, followed by normal weight gain. Three of 6 rats exposed to 79 mg/m^3 had lung noise 1 day after exposure, and 1 of 5 rats that survived exposure to 78 mg/m^3 had hair loss from the perineal area on the 4th to 14th day after exposure. No other adverse clinical signs were observed in rats that survived exposure to 100 mg/m^3 .

The 1 rat that died 3 days following exposure to 100 mg/m^3 lost 17% of initial body weight and had labored breathing, pallor, yellow-stained perineum and hunched posture before it died. The 1 rat that died 2 days after exposure to 130 mg/m^3 lost 12% of initial body weight and had dry red nasal and ocular discharges before it died.

CONCLUSION

Under the conditions of this study, the ALC for was 78 mg/m^3 of particulate. This material is considered extremely toxic on an acute inhalation basis (ALC less than 80 mg/m^3).

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: _____

NON-CAP

CAP

Submission number: 13194A

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

For Contractor Use Only

entire document: 0 1 2 pages 17 pages _____

Notes:

Contractor reviewer : JW Date: 1/24/96

CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ. 1192 - 13194 (3) SEQ. A

TYPE: (INT) SUPP FLWP
SUBMITTER NAME: Confidential

SUB. DATE: 10/06/92 OTS DATE: 11/02/92 CSRAD DATE: 03/01/95

CHEMICAL NAME: carbamate
cat ionically - and nonionically - dispersed
fluoroalkyl - substituted carbamate

CASE: Confident

- VOLUNTARY ACTIONS:
 0401 NO ACTION REPORTED
 0402 STUDIES PLANNED/IN PROGRESS
 0403 NOTIFICATION OF WORKING METHODS
 0404 LABELS/MSDS CHANGES
 0405 APPROUSE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

- INFORMATION REQUESTED: FLWP DATE:
 0501 NO INFO REQUESTED
 0502 INFO REQUESTED (TECH)
 0503 INFO REQUESTED (VOL. ACTIONS)
 0504 INFO REQUESTED (REPORTING RATIONALE)
 DISPOSITION:
 0505 REFER TO CHEMICAL SCREENING
 0506 CAP NOTICE

| 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 | ECO/AQUA TOX | 01 02 04 | 0245 CLASTO (ANIMAL) | 01 02 04 |
| 0206 REPRO/TERATO (HUMAN) | 01 02 04 | ENV. OCCUR/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 REQEST DELAY | 01 02 04 | 0248 PROD/USE/PROC | 01 02 04 |
| 0209 NEURO (ANIMAL) | 01 02 04 | PROD/COMP/CHEM ID | 01 02 04 | 0251 MSDS | 01 02 04 |
| 0210 ACUTE TOX. (HUMAN) | 01 02 04 | REPORTING RATIONALE | 01 02 04 | 0259 OTHER | 01 02 04 |
| 0211 CHIR. 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 | METAB/PHARMACO (ANIMAL) | 01 02 04 | | |
| 0215 CHRONIC TOX (ANIMAL) | 01 02 04 | METAB/PHARMACO (HUMAN) | 01 02 04 | | |

PRODUCTION:

USE:

TOXICOLOGICAL CONCERN:

SPECIES:

ONGOING REVIEW:

NON-CBI INVENTORY:

LOW

RAT

YES (DROP/REFER)

YES

MED

NO (CONTINUE)

NO

HIGH Acute Inhalation Toxicity

REFER

IN INVENTORY

UNCLASSIFIED

13194A

H

Acute inhalation toxicity in the male rat is of high concern based on an approximate lethal concentration of 78 mg/m^3 following a single 4-hour exposure. Exposure concentrations (mg/m^3) and mortalities were 51 (0/6), 78 (1/6), 79 (0/6), 100 (5/6), 130 (6/6). Clinical signs included labored or rapid breathing, lethargy, partially closed eyes (100, 130 mg/m^3), lung noise, hair loss from perineal area (78 mg/m^3), pallor, yellow-stained perineum, hunched posture (100 mg/m^3), and red nasal and ocular discharges (130 mg/m^3).