

8EHQ-0395-13374

DuPont Central Research
and Development
Haskell Laboratory for Toxicology
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P.O. Box 50, Elkton Road
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DuPont Central Research
and Development

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(A)

ORIGINAL

March 21, 1995

EXPRESS MAIL - RETURN RECEIPT REQUESTED

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Document Processing Center (TS-790)
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U. S. Environmental Protection Agency
401 M Street SW
Washington, D.C. 20460



Dear 8(e) Coordinator:

Propanoic acid, 2,3,3,3-tetrafluoro-2-[1,1,2,3,3,3-hexafluoro-2-(heptafluoropropoxy)propoxy]-, ammonium salt. CAS No. 13043-05-5

In the course of R&D work on a related compound, we recently reviewed several toxicity studies issued during 1961-1968 on the subject chemical. Our review suggested that the following findings are reportable based on EPA's June 1991 guidance criteria for TSCA Section 8(e). The subject chemical is not a commercial product and to our knowledge, is not reported on the TSCA inventory.

In acute oral studies in rats, a single administration produced dose-related liver toxicity characterized by hepatomegaly, hepatic cytopathologic changes (hepatocellular hypertrophy, nuclear and cytoplasmic vacuolation and isolated cellular necrosis) and biochemical alterations in xenobiotic metabolism as measured by a marked reduction in sodium pentobarbital sleeping time. These effects persisted for at least 2 months after a single administration of 12 mg/kg.

Similar histopathologic liver injury was seen in a 2-week repeated dose gavage study in rats at 0.6 mg/kg/day.

In an acute dermal study in rabbits, the approximate lethal dose was 130 mg/kg; histopathologic liver injury similar to that seen in rats was also noted.



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Based on changes in serum enzyme activities and cholesterol concentrations, evidence of hepatic injury was also seen in beagle dogs administered a single dose at concentrations of 4-60 mg/kg; however, corroborative histopathologic or organ weight evaluations were not performed in this study. Biochemical indicators of hepatic injury generally approximated pre-exposure levels within 2 months of dosing, but concurrent control animals for comparison were not included.

Sincerely,

A. Michael Kaplan
for CFR

Charles F. Reinhardt, M.D.
Director

CFR/RV:dj
Phone: (302) 366-5285



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 10 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). ~~Please cite the assigned first number when submitting follow-up or supplemental information, and refer to the reverse side of this page for "EPA Information Requests".~~

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

13374A



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Triage of 8(e) Submissions

Date sent to triage: MAY 09 1995

NON-CAP

CAP

Submission number: 13374A

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 pages 1, 2

Notes:

Contractor reviewer: PRZ Date: 4/21/95

CECATS DATA: GEHO: 0395-13374 SEQ: A

TYPE: INT SUPP FLWP

SHOOTER NAME: Dept. Central Research and Development

INFORMATION REQUESTED: FLWP DATE: 03/22/95
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECI)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING NATIONAL P)
0505 INFO REQUESTED (REPORTING NATIONAL P)
0506 INFO REQUESTED (REPORTING NATIONAL P)
0507 INFO REQUESTED (REPORTING NATIONAL P)
0508 INFO REQUESTED (REPORTING NATIONAL P)

VOLUNTARY ACTIONS:
0501 NO ACTION REPORTED
0502 STRIKE PLANNING (HUMAN)
0503 INTERVIEWING (HUMAN)
0504 LABOR AIDS (TEAM'S)
0505 PROSECUTION (TEAM'S)
0506 APP. AUSE. DISCONTINUED
0507 PRODUCTION DISCONTINUED
0508 CONFIDENTIAL

SUB DATE: 03/21/95 OHS DATE: 03/22/95 CRAD DATE: 04/03/95

CHEMICAL NAME: Propoxy - gamma-butyrolactone salt

Propoxy - gamma-butyrolactone salt

CAS: 13043-05-5

INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.
0201 ONCO (HUMAN)	01 02 04	0206 BRUCLIN	01 02 04	0201 BEALNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0207 HUMAN EXPOS (PROD CONTAM)	01 02 04	0202 BEALNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0208 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0203 CHEMISTS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0209 HUMAN EXPOS (ADMINISTR)	01 02 04	0204 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0210 BOWLING TOX	01 02 04	0205 CLASTO (ANIMAL)	01 02 04
0206 REGENERATOR (HUMAN)	01 02 04	0211 ENV. OCCURRENCE/FATE	01 02 04	0206 CLASTO (HUMAN)	01 02 04
0207 REGENERATOR (ANIMAL)	01 02 04	0212 ENER. BCI OF ENV CONTAM	01 02 04	0207 DNA DAMAGE/FAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0213 RESPONSE REQUEST DELAY	01 02 04	0208 PRODUSE/PROD	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0214 PRODUCTION RATIONALS	01 02 04	0209 OTHER	01 02 04
0210 ACUTE TOX (HUMAN)	01 02 04	0215 CONFIDENTIAL	01 02 04		
0211 ACUTE TOX (ANIMAL)	01 02 04				
0212 SUB ACUTE TOX (ANIMAL)	01 02 04				
0213 SUB CHRONIC TOX (ANIMAL)	01 02 04				
0214 CHRONIC TOX (ANIMAL)	01 02 04				
0215 CHRONIC TOX (ANIMAL)	01 02 04				

TOXICOLOGICAL CONCERNS

TOXICITY: NON-CM INVENTORIAL
 YES
 CAS SR: NO
 IN N RANGE
 NON - Cap

STRESS
 RAT
 RET
 Doc

TOXICOLOGICAL CONCERNS
 LOW
 MED
 HIGH

USE
 R: D
 ND

PRODUCTION

-CPSS- 0927952113

0 0 0 0 0 0 0 0 0 0 0

> <ID NUMBER>

8(E)-13374A

> <TOX CONCERN>

ND/H

> <COMMENT>

A LETTER FROM THE SUBMITTER WAS RECEIVED. ACUTE DERMAL TOXICITY IN RABBITS IS HIGH CONCERN. THE APPROXIMATE LETHAL DOSE WAS 130 MG/KG AND HISTOPATHOLOGICAL LIVER INJURY SIMILAR TO THE ORAL STUDY WAS NOTED. ACUTE DERMAL TOXICITY IN BEAGLE DOGS CANNOT BE DETERMINED. ANIMALS WERE GIVEN BETWEEN 4 - 60 MG/KG OF TEST MATERIAL AND EVIDENCE OF HEPATIC INJURY WAS NOTED. NO OTHER INFORMATION GIVEN.

ACUTE ORAL TOXICITY IN RATS CANNOT BE DETERMINED. A SINGLE DOSING OF 12 MG/KG OF TEST MATERIAL RESULTED IN DOSE-RELATED EFFECTS OF LIVER TOXICITY, WHICH PERSISTED FOR AT LEAST 2 MONTHS.

SUBACUTE ORAL TOXICITY IN RATS CANNOT BE DETERMINED. FOR 2 WEEKS ANIMALS WERE ADMINISTERED 0.6 MG/KG/DAY OF TEST MATERIAL. SIMILAR HISTOPATHOLOGICAL LIVER EFFECTS TO THE ACUTE ORAL STUDY WERE NOTED.

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