Contains No CBI

8e initial

DuPont Central Research
and Development
Haskell Laboratory for Toxicology
and Industrial Medicine
P.O. Box 50, Elkton Road
Newark, DE 19714-0050
Fax: (302) 366-5207

DuPont Central Research
and Development

A

September 27, 1993

8EHQ-0993-12703

EXPRESS MAIL - RETURN RECEIPT REQUESTED

8EHQ-93-12703
INIT 09/30/93

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

88930000468

93 SEP 30 AM 8:15

Dear Coordinator:

1H-cyclopentapyrimidine-2,4(3H,5H)-dione, 3-cyclohexyl-6,7-dihydro-
[CAS Registry Number: 2164-08-1]

This letter is to inform you of the preliminary results obtained from an 18-month oncogenicity study in mice with the referenced test material. Four groups of 80 male mice and four groups of 80 female mice were fed diets containing 0, 100, 2,500 or 7,000 ppm. All surviving mice were sacrificed after approximately 18 months; histopathological evaluation revealed an increased incidence of hepatocellular adenomas only in male mice at 7,000 ppm.

Under these experimental conditions, the hepatic effects observed in male mice at 7,000 ppm would appear to be reportable based on EPA guidance regarding TSCA section 8(e) criteria.

Sincerely,

Charles F. Reinhardt

Charles F. Reinhardt, M.D.
Director

CFR/DEM:jd
Phone: (302)366-5285

RECEIVED
10-22-93

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

Dr. Charles F. Reinhardt
E. I. Du Pont De Nemours and Company
Haskell Laboratory for Toxicology and Industrial Medicine
P.O. Box 50, Elkton Road
Newark, Delaware 19714-0050

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

APR 19 1994

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 this 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

12703 A

Printed on Recycled Paper

CECATS DATA:
Submission # 8EHQ-0993-12703 SEQ. A

TYPE: INT SUPP FLWP

SUBMITTER NAME: E.I. Dupont de Nemours & Company

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

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

SUB. DATE: 09/27/93 OTS DATE: 09/30/93 CSRAD DATE: 10/22/93

CHEMICAL NAME:
1H-cyclopentapyrimidine-2,4(3H,5H)-dione, 3-cyclohexyl-6,7-dihydro-

CAS#
2164-08-1

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL. TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
021[illegible]	HUMAN EXPOS (PROD CONTAM)	01 02 04
021[illegible]	HUMAN EXPOS (ACCIDENTAL)	01 02 04
021[illegible]	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
022[illegible]	ALLERG (ANIMAL)	01 02 04
02[illegible]	METAB/PHARMACO (ANIMAL)	01 02 04
02[illegible]	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA

NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
YES (CONTINUE)	YES (DROP/REFER)	mus	LOW		
NO (DROP)	NO (CONTINUE)		MED		
DETERMINE	REFER:		HIGH		

COMMENTS: Non-Cap Mice fed test material for 18 months, at 0, 100, 2500 and 7000 ppm hepatocellular adenomas were noted at 7000 ppm.