

8EHQ-0295-13327

PUBLIC NOTICE COPY

8EHQ-95-13327

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February 6, 1995

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 253 155 586

95 FEB 13 AM 8:07

RECEIVED

OPPT Document Processing Center (7407)
ATTN: Section 8(e) Coordinator
Office of Pollution Prevention and Toxics (OPPT)
US Environmental Protection Agency
Washington, DC 20460

COMPANY SANITIZED

RE: TSCA Section 8(e) Notice

Dear Sir or Madam:

This notice is being submitted by Rhône-Poulenc Ag Company (RPAC) to the Environmental Protection Agency (EPA) in accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), 15 USC § 2607 (e).

We are submitting the results of a toxicity study in rats on . Only limited quantities of this compound have been synthesized for research and development purposes.

RPAC claims the alpha-numeric designation and the specific chemical identity of the substance at issue to be confidential business information (CBI). The chemical substance may be nonconfidentially identified as a "heterocycle".

Test material was administered by gavage at doses of 1, 5, and 15 mg/kg/day (7 male rats/group) for 14 days. Five animals died at the top dose. Decreases in thyroxine and increases in liver weight were observed at 5 and 15 mg/kg/day. Increases in thyroid stimulating hormone, hepatic hypertrophy, and thyroid follicular hyperplasia were reported at all doses.

SUPPORT INFORMATION OF CONFIDENTIALITY CLAIMS

1. Claims of confidentiality are being made on behalf of RPAC.
2. RPAC asserts this claim of confidentiality until such time as a specific chemical is approved for use in the United States. In the event that the chemical is never approved, RPAC asserts that the CBI information should be provided permanent protection. The structure and use of the chemical are unique. Disclosure of this information would provide our competitors with information on facets of our business that would be detrimental to our competitive position.

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3/1/95

3. The information claimed as confidential has not been previously disclosed to any other governmental agency or to EPA.
4. This information has been disclosed to only a very limited number of investigators outside of RPAC who have performed either toxicity or efficacy testing. These individuals operate under a strict secrecy agreement. Any individuals who may work with the chemical will have all health/toxicology information disclosed to them as well, but only on the basis of strict secrecy and respect for the CBI nature of the information.
5. Any individuals to whom the CBI is revealed are warned of the nature of the information. Further, they are informed of their obligations to maintain secrecy should they terminate their employment with RPAC.
6. None of the information claimed as confidential appears in or is referred to in any advertising or promotional materials for the chemical or the end product containing it, professional or trade publications, or any other media available to the public or to our competitors. Appropriate warnings do appear on safety data sheets, as RPAC considers that individuals who are requested to work with the chemicals have every right to know as much about the chemicals' toxicity as possible. Further, the information is only considered to be CBI with respect to the general public, insofar as our competitors could use the information in an unfairly competitive nature.
7. No previous confidentiality determinations have been made by EPA, other Federal agencies or courts in connection with this information.
8. RPAC believes that disclosure of this information to the general public would be likely to result in substantial harm to its competitive position. Disclosure of the **alpha numeric designation** and **chemical name** would provide some competitors with information about the specific chemistry of this area of our research and our business. Further, the type of toxicological testing being reported in the TSCA 8(e) notice would provide competitive information about this chemical's status in the research and development process and, therefore, the time remaining until commercialization.
9. A patent has not been issued for the specific chemical structure. However, the generic chemical structure is covered by a patent that is currently pending.
10. The chemical is not available commercially. It is in the earliest stages of research and development for pesticide use and is unlikely to be developed into a commercial product.
11. We believe that disclosure of the chemical name would allow a competitor to synthesize this chemical. RPAC has invested a large amount of time and money into research of this particular chemical family, and information on specific chemical structures would harm our competitive position.
12. Disclosure of the chemical structure might reveal information on processes used to synthesize this compound.
13. CAS number has not yet been assigned.
14. Currently, the chemical is not the subject of FIFRA regulation or reporting.

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Further questions regarding this submission may be directed to the undersigned at 919-549-2222.

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Sincerely,



Glenn S. Simon, PhD, DABT
Director of Toxicology



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

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Director of Toxicology
Rhône-Poulenc
P.O. Box 1214
2 T.W. Alexander Drive
Research Triangle Park, North Carolina 27709

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section (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 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

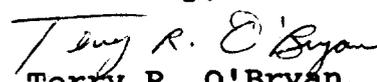
All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should 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
Risk Analysis Branch

Enclosure

13327A



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Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: APR 19 1995

NON-CAP

CAP

Submission number: 13327A

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 1,2,3

pages 1,2,3

Notes:

Contractor reviewer: PAZ

Date: 4/3/95

CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ: 0895-13327 3 REQ. A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: Rhone - Paulens

Ag Company

SUB. DATE: 02/06/95 OTS DATE: 02/13/95 CSRAD DATE: 02/01/95

CHEMICAL NAME: Heterocycle CAS# Confident

- EX VOLUNTARY ACTIONS:
- 0400 NO ACTION REPORT ID
 - 0402 STUDIES PLANNED IN HWAY
 - 0403 NOTIFICATION OF WORK IN PROGRESS
 - 0404 LABELING CHANGES
 - 0405 PROCESSING/CHANGING
 - 0406 APP USE 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:
- 0639 REFER TO CHEMICAL SCREENING
 - 0678 CAP NOTICE

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUREL/FATE	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQEST DELAY	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04
0215 CHRONIC TOX (ANIMAL)	01 02 04	0230 METAB/PHARMACO (HUMAN)	01 02 04
		0231	01 02 04
		0239	01 02 04

TRIAJE DATA: NON-CBI INVENTORY YES NO (IN HUMAN)

ONGOING REVIEW YES (DROP/PREFER) NO (CONTINUE) REFTR

SPECIES: RAT TOXICOLOGICAL CONCERN: LOW MED HIGH

USE: R: D pesticide PRODUCTION:

UNCLASSIFIED Non-Cap

8(E)-13327A

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SUBACUTE ORAL TOXICITY IN MALE RATS IS OF HIGH CONCERN BASED ON LETHALITY. DOSAGES (GAVAGE, 14 DAYS) AND MORTALITY DATA ARE AS FOLLOWS: 1 MG/KG/DAY (0/7); 5 MG/KG/DAY (0/7); AND 15 MG/KG/DAY (5/7). DECREASES IN THYROXINE AND INCREASES IN LIVER WEIGHT WERE OBSERVED AT 5 AND 15 MG/KG/DAY. INCREASES IN THYROID STIMULATING HORMONE, HEPATIC HYPERTROPHY, AND THYROID FOLLICULAR HYPERPLASIA WERE OBSERVED AT ALL DOSES.