



8 EHP-95-13298

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American Cyanamid Company
One Cyanamid Plaza
Wayne, NJ 07470

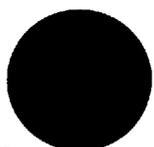
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H. Michael D. Utidjian, M.D.
Corporate Medical Director

December 27, 1994
Project #954-94-191

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street S.W.
Washington, DC 20460

(A)



Attention: Section 8(e) Coordinator

COMPANY SANITIZED

Dear Sir/Madam:

The purpose of this letter is to inform you, under TSCA Section 8(e), of preliminary data from acute toxicity screening studies in Mallard Ducks communicated to us on December 12, 1994. The studies are being conducted with XX XXX,XXX a research material, designated XXXXXXXXXXXXXXXXXXXX XXXX, X,X,X XXXXXXXXXXXX-X-XXXXXXXX-XXXXXX XXXX XXXXXXXX described generically as, a substituted pyrrole.

Compound Structure

XXX

Acute Toxicity Screening Study in Mallard Ducks

The 7-day LD₅₀ for Mallards is less than 25 mg/kg but greater than 5 mg/kg.

We are currently evaluating the significance of these results. This material is under research and development as an insecticide.

If further information is required, please contact K.A. Traul, Ph.D. at 609-799-0400, Ext. 2701.

Sincerely,

K.A. Traul for H.M.D.U.

H. Michael D. Utidjian, M.D.
Corporate Medical Director

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2/24/95

Support Information for Confidentiality Claims**TSCA 8(e) Submission on**

XX

1. For what period of time do you assert this claim of confidentiality? Explain why the information should remain confidential until such event or time.

Confidentiality is claimed for a period of 10 years from the date of this submission pending finalization of the application for a patent on the test material and the process for its synthesis. It is suggested that the generic name substituted pyrrole be used in reference to this 8(e) submission.

2. Have there been any confidentiality determinations made by the EPA, other Federal agencies or courts in connection with this information?

No.

3. Has any of the information that you are claiming as confidential been disclosed to individuals outside your company? Will it be disclosed to such persons in the future? If so, what restrictions, if any, apply to use or further disclosure of the information.

Information regarding the name and structure have not been disclosed to persons outside the employ of the company. Until such time as patents are issued for the structure and the processes for synthesis of the material we do not plan to disclose such information to persons outside the company who would not be under an agreement of confidentiality regarding such information. Such persons would include laboratory or field personnel conducting studies with this material under contract to the company or expert consultants we may retain. Other persons outside the company will become informed after the above referred patents are obtained and our evaluation of the material is complete.

4. Briefly describe any physical or procedural restrictions within the company relating to the use and storage of the information you are claiming confidential. What other steps, if any, have you taken to prevent undesired disclosure of the information during its use or when an employee leaves the company.

The information has been given to only those individuals with a need to know. The information is considered "company confidential" and all employees who have access to this information are required to keep it confidential. Employees who have access to this information have signed confidentiality statements with regard to any such proprietary information.

5. Does the information claimed as confidential appear or is it referred to in any of the items listed below?

- advertising or promotional materials for the chemical or the end product containing it ;
- safety data sheets or other such materials for the chemical or the end product containing it;
- professional or trade publications;
- any other media available to the public or to your competitors:

If you answered yes to any of the above questions, you must indicate where the information appears and explain why it should, nonetheless, be treated as confidential.

No.

6. Would disclosure of this information be likely to result in substantial harm to your competitive position?

Disclosure of this information, prior to issue of the patents for the material and the processes for synthesis would jeopardize the proprietary nature of the material and would potentially cause the company to lose the advantage currently available though the fact that this information is not available to the competition in this market. The company is synthesizing and filing patents on analogs of this chemistry. Release of the information requested to be held confidential would aid competitive companies in analog synthesis. The technical attributes are still under investigation for this compound and the analogs, which may possess more favorable biological characteristics. Additional use patents have also not yet been filed. Disclosure could also jeopardize our patent positions in foreign countries. Although patent protection is guaranteed in the U.S. by FIFRA, there is no guarantee of protection in other countries. Further, misinterpretation or misrepresentation of these preliminary data could cause undue alarm to our customers and, thereby, damage our potential customer base.

The use of this chemistry is directed at terrestrial crops and direct application to water is not contemplated. The potential for exposure of aquatic habitats to this chemistry is low. The use of acute toxicology data deriving from direct exposure of aquatic species is not indicative of true exposure under use and could cause undue alarm when presented out of context.

7. If the information in question is "health and safety data" pursuant to 40 CFR part 2.306 (3) (i), do you assert that disclosure of the information you are claiming confidential would reveal:

- confidential process information;
- confidential portions of a mixture; or
- information unrelated to the effects of the substance on human health or the environment ?

Aside from the chemical structure and names this submission does not reveal any information related to the process, product composition or other information unrelated to human health effects or the environment.



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

H. Michael D. Utidjian, M.D.
Corporate Medical Director
American Cyanamid Company
One Cyanamid Plaza
Wayne, New Jersey 07470

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 24 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 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

Terry R. O'Bryan
Risk Analysis Branch

Enclosure

13298A



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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: 4/18/95

NON-CAP

CAP

Submission number: 13296A

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: <u>D</u> 0 1 2 pages <u>—</u>	pages <u>1</u>
Notes:	
Contractor reviewer: <u>FOR</u>	Date: <u>4/21/95</u>

CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # 8E10 0195-13298 3 SEQ. A

TYPE: INT SUPP FLWP

SUBMITTER NAME: American Cyanamid Company

SUB. DATE: 12/27/94 OTS DATE: 01/03/95 CSRAD DATE: 02/24/95

CHEMICAL NAME: Pyroble, substituted

CAS# Confident

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 HUMAN)
 0403 NOTIFICATION OF WORKERS
 0404 LABELING (HUMAN)
 0405 PROFESSIONAL USE (HUMAN)
 0406 APP. USE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

INFORMATION TYPE:	P	F	C	INFORMATION TYPE:	P	F	C
0201 ONCO (HUMAN)	01	02	04	EPICLIN	01	02	04
0202 ONCO (ANIMAL)	01	02	04	HUMAN EXPOS (PROD CONTAM)	01	02	04
0203 CELL. TRANS (IN VITRO)	01	02	04	HUMAN EXPOS (ACCIDENTAL)	01	02	04
0204 MUTA (IN VITRO)	01	02	04	HUMAN EXPOS (MONITORING)	01	02	04
0205 MUTA (IN VIVO)	01	02	04	ECO/AQUA TOX	01	02	04
0206 REPRO/TERATO (HUMAN)	01	02	04	ENV. OCCUREL/FATE	01	02	04
0207 REPRO/TERATO (ANIMAL)	01	02	04	EMER INCI OF ENV CONTAM	01	02	04
0208 NEURO (HUMAN)	01	02	04	RESPONSE REQUEST DELAY	01	02	04
0209 NEURO (ANIMAL)	01	02	04	PROD/COMP/CHEM ID	01	02	04
0210 ACUTE TOX. (HUMAN)	01	02	04	REPORTING RATIONALE	01	02	04
0211 CHR. 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

TRIAGE DATA NON-CBI INVENTORY ONGOING REVIEW SPECIES TOXICOLOGICAL CONCERN: USE: PRODUCTION:

YES NO YES (DROP/REFER) NO (CONTINUE) REFTR DUCK LOW MED HIGH

CAS SR NO IN TERMINI R.D. Insecticide

UNCLASSIFIED Non-CBI