

8EHQ-95-13352



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88950000141

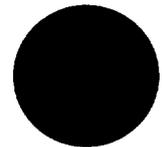
American Cyanamid Company
One Cyanamid Plaza
Wayne, NJ 07470

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

(A)

January 27, 1995
Project #94-114

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



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 rats communicated to us on January 23, 1995. 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 Oral Toxicity Study in Rats Study No. 94-114

The oral LD₅₀ for rats is 44 mg/kg and the compound is judged to be highly toxic for rats.

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,

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

3/21/95

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

13352A



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

Triage of 8(e) Submissions

Date sent to triage: 12/14/95

NON-CAP

CAP

Submission number: 13352A

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 7-8	pages <u>14</u>
Notes:	<u>Red Dot</u>
Contractor reviewer: <u>LPS</u>	Date: <u>4/14/95</u>

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: SUBMISSION # BEHQ: 0295-13352 ³ SEQ. A

TYPE: INT. SUPP FLWP

SUBMITTER NAME: American Cyanamid Company

SUB. DATE: 01/27/95 OTS DATE: 02/07/95 CSRAD DATE: 03/21/95

CHEMICAL NAME: Pyrethrin, substituted
Confident

VOLUNTARY ACTIONS:

- 0401 NO ACTION REQUIRED
- 0402 STUDIES PLANNED/IN PROGRESS
- 0403 NOTIFICATION OF WORKER/RESIDENTS
- 0404 LABELS/SDS CHANGES
- 0405 PROCESS/HANDLING CHANGES
- 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:
 0505 REFER TO CHEMICAL SCREENING
 0506 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 REQST 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 ACUTE TOX (ANIMAL)	01 02 04	0226 CONFIDENTIAL	01 02 04
0212 SUB ACUTE TOX (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04
0213 SUB CHRONIC TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04
0214 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

USE:

TOXICOLOGICAL CONCERN:

SPECIES:

ONGOING REVIEW:

NON-CBI INVENTORY:

R: D
 Insecticide

LOW

RAT

YES (DROP/REFER)
 NO (CONTINUE)

YES

NO (CONTINUE)

CAS SR

HIGH Acute Oral Toxicity

REF:R

IN IT RMINI

UNCLASSIFIED Non-Cap

13352A

Acute Oral Toxicity - High

Acute oral toxicity is high based on an LD₅₀ of 44 mg/kg in rats.