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

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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

8-14-92

Dear Sir/Madam:

The purpose of this letter is to inform you, under TSCA Section 8(e), of results of preliminary environmental toxicity studies, communicated to us on July 29, 1992. We are conducting these studies at XXXXXX XXXXXXXXXXXX XXXXXXXX on a research material, a substituted pyrrole, XXX-XXXXXXX.

Compound Structure

XXX

1. ACUTE TOXICITY TEST IN MYSID SHRIMP Study 954-92-105

In two range-finding tests, groups of 10 Mysid shrimp were exposed to various concentrations of test material, ranging from 0.1 to 20 µg/L of test material (trial #1) or 0.78 to 10 µg/L (trial #2) in the water. Based on an evaluation of the preliminary results, the 96 hr LC50 is expected to be below 1 ppm. Further details may be found on the attached report summary.

2. ACUTE TOXICITY TEST WITH SHEEPSHEAD MINNOW Study 954-92-104

In two range-finding tests, groups of 3 Sheepshead minnows were exposed to various concentrations of test material, ranging from 1.0 µg/L to 100.0 µg/L (trial #1) or 0.5 mg/L to 100 mg/L (trial #2) of test material in the water. Based on an evaluation of the preliminary results, the 96 hr LC50 is expected to be between 0.1 and 0.5 mg/L. Further details may be found on the attached report summary.

3. EFFECTS ON NEW SHELL GROWTH IN THE EASTERN OYSTER Study 954-92-106

In a range-finding test, groups of 10 oysters were exposed to various concentrations of test material, ranging from 0.01 mg/L to 1.0 mg/L of test material in the water. Based on an evaluation of the preliminary results, the 96 hr LC50 is expected to be between 0.01 and 0.05 mg/L. Further details may be found on the attached report summary.

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

on a total of about 12.1 acres across approximately 45 test sites. Applications are being made by company personnel on land rented for this purpose. Applications are made directly to plants using backpack or small tank sprayers and the risk of run-off or drift is negligible. As the definitive studies are conducted we will determine if further action, including follow up actions and copies of the final reports to the EPA, are necessary. Pending the results of the current evaluations, we plan to apply for an experimental use permit during the fourth quarter of 1992. If further information is required in the interim, please contact Karl A. Traul, Ph.D. at 609-799-0400, ext 2701 or 2347.

Sincerely,



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

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Support Information for Confidentiality Claims

TSCA 8(e) Submission on

XXX
XXX

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 6 months (January 13, 1993) 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 company. At 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;

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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

The information that is to be held confidential about the chemical structure and name appears in a bulletin printed by the company for distribution to company personnel and university cooperators who are involved in the technical evaluation of the material in various field trials.

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 process for synthesis would jeopardize the proprietary nature of the material and would potentially cause the company to lose the advantage currently available through 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 toxicologic characteristics. Additional use patents have also not yet been filed. Disclosure could 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 acute toxicology data deriving from direct exposure of this 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 name this submission does not reveal any information related to the process, product composition or other information unrelated to human health effects or the environment

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ACUTE TOXICITY OF [REDACTED] TO THE MYSID SHRIMP
(Mysidopsis bahia)

RESULTS OF RANGE-FINDING TESTS

Study Number 954-92-105

Study Director - Dr. Joseph D. Wisk

Test Site - [REDACTED]

Principal Investigator - Darlene Lintott [REDACTED]

Introduction

Two range-finding tests were conducted at Toxikon Environmental Sciences in Jupiter, Florida, to estimate the acute toxicity of [REDACTED] to the mysid shrimp (Mysidopsis bahia). The results from these tests will be used to determine the concentrations that will be tested in the definitive concentration-effect test. The results from this study will satisfy U.S. EPA data requirement 40 CFR Series 72-3(c).

Methods

In the first range-finding test, groups of 10 mysids were exposed to various water concentrations of [REDACTED] for 96 hours under static test conditions. Stock solutions of [REDACTED] were prepared in dimethylformamide (DMF). Appropriate volumes of the DMF stocks were added directly to the dilution water in the test vessels prior to the addition of the mysids. The dilution water was filtered seawater that was diluted with freshwater to a salinity of approximately 20 parts per thousand. Control mysids were exposed to dilution water only (no-treatment control).

In the second range-finding test, groups of 20 mysids were exposed to various water concentrations of [REDACTED] for 96 hours under flow-through test conditions. A concentrated stock solution was prepared in DMF. A stock solution delivery system was used in conjunction with a proportional diluter to prepare and deliver the test solutions to the test vessels. No-treatment control mysids were exposed to dilution water only. Solvent control mysids were exposed to a concentration of DMF equivalent to the concentration of DMF in all of the test solutions.

Results

Test # 1 (static)

<u>Nominal Concentrations</u>	<u>Percent Mortality</u>
No-treatment control	0
0.1 µg/L	0
1 µg/L	0
5 µg/L	70
10 µg/L	90
15 µg/L	100
20 µg/L	100

Test # 2 (flow-through)

<u>Nominal Concentrations</u>	<u>Percent Mortality</u>
No-treatment control	0
Solvent controls	0
0.78 µg/L	0
1.3 µg/L	0
2.2 µg/L	0
3.6 µg/L	0
6.0 µg/L	60
10.0 µg/L	100

Summary

Based on these range-finding results, the LC50 is expected to be between 3.6 and 6.0 µg of [REDACTED] L (parts per billion). The following concentrations will be tested in the definitive concentration-effect test: 0.78, 1.3, 2.2, 3.6, 6.0 and 10.0 µg of [REDACTED] L.

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EFFECT OF [REDACTED] ON NEW SHELL GROWTH IN THE
EASTERN OYSTER, (*Crassostrea virginica*)
RESULTS OF A RANGE-FINDING TEST
Study Number 954-92-106

Study Director - Dr. Joseph D. Wisk

Test Site - [REDACTED]

Principal Investigator - Darlene Lintott ([REDACTED])

Introduction

A range-finding test was conducted at Toxikon Environmental Sciences in Jupiter, Florida, to estimate the acute toxicity of [REDACTED] to the eastern oyster (*Crassostrea virginica*). The criteria for effect were mortality and inhibition of new shell growth. The results from this test will be used to determine the concentrations to be tested in a definitive concentration-effect test. The results from this study will satisfy U.S. EPA data requirements 40 CFR Series 72-3(b).

Methods

Groups of 10 oysters were exposed to various water concentrations of [REDACTED] [REDACTED] for 96 hours under flow-through test conditions. A concentrated stock solution of [REDACTED] was prepared in dimethylformamide (DMF). A stock solution delivery system was used in conjunction with a continuous-flow series diluter to prepare and deliver the test solutions to the test vessels. The dilution water was natural, unfiltered seawater. No-treatment control oysters were exposed to dilution water only. The solvent

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control oysters were exposed to a concentration of DMF equivalent to the concentration of DMF in the high concentration exposure group.

Results

<u>Nominal Concentrations</u>	<u>Percent Mortality</u>
No-Treatment Control	0
Solvent Control	0
0.01 mg/L	0
0.05 mg/L	100
0.1 mg/L	100
1 mg/L	100

Effects on shell growth could not be evaluated due to inadequate shell growth in the controls.

Summary

Based on these range-finding results, the 96-hour EC50 based on mortality is expected to be between 0.05 and 0.01 mg of [REDACTED]/L (parts per million). Due to inadequate shell growth in the controls, the concentrations that will result in the inhibition of new shell growth could not be evaluated. An additional range-finding test will be conducted prior to determining the concentrations that will be tested in the definitive concentration-effect test.

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ACUTE TOXICITY OF [REDACTED] TO THE SHEEPSHEAD MINNOW

(*Cyprinodon varigatus*)

RESULTS OF RANGE-FINDING TESTS

Study Number 954-92-104

Study Director - Dr. Joseph D. Wisk

Test Site - [REDACTED]

Principal Investigator - Darlene Lintott [REDACTED]

Introduction

Two range-finding tests were conducted at Toxikon Environmental Sciences in Jupiter, Florida, to estimate the acute toxicity of [REDACTED] to the sheepshead minnow (*Cyprinodon varigatus*). The results from these tests will be used to determine the concentrations of [REDACTED] that will be tested in a definitive concentration-effect test. The results from this study will satisfy U.S. EPA data requirement 40 CFR Series 72-3(a).

Methods

Groups of 3 sheepshead minnow were exposed to various water concentrations of [REDACTED] for 96 hours under static test conditions. Stock solutions of [REDACTED] were prepared in dimethylformamide (DMF). In both tests, appropriate volumes of the DMF stocks were added directly to the dilution water prior to the addition of the sheepshead. The dilution water was filtered seawater that was diluted with freshwater to a salinity of approximately 20 parts per thousand. Control sheepshead were exposed to dilution water only (no-treatment control).

Results

Test # 1

<u>Nominal Concentrations</u>	<u>Percent Mortality</u>
No-Treatment Control	0
1 µg/L	0
10 µg/L	0
25 µg/L	0
50 µg/L	0
100 µg/L	0

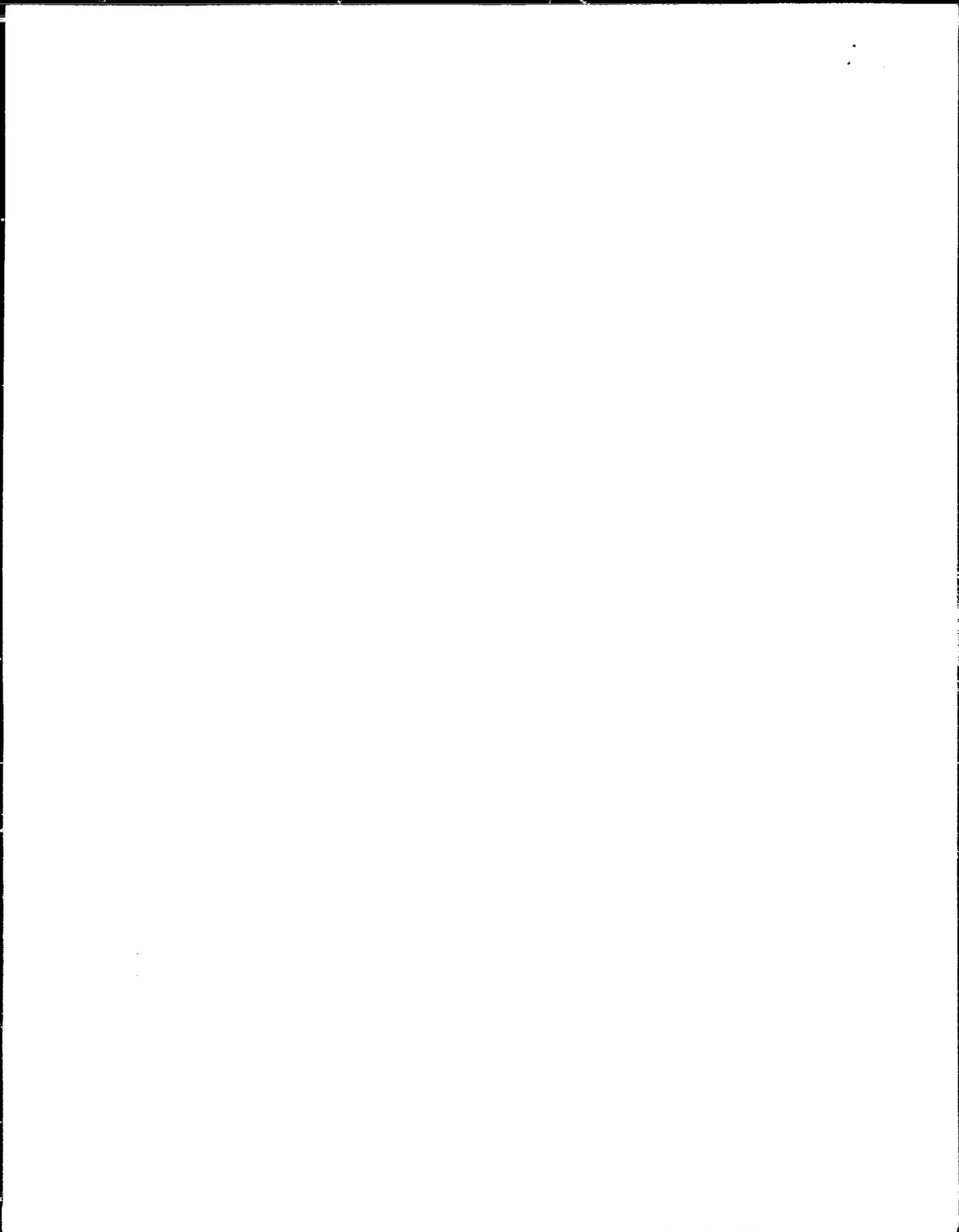
Test # 2

<u>Nominal Concentration</u>	<u>Percent Mortality</u>
No-Treatment Control	0
0.5 mg/L	100
1 mg/L	67
5 mg/L	100
10 mg/L	100
100 mg/L	100

Summary

Based on the range-finding results, the 96-hour LC50 is expected to be between 0.1 and 0.5 mg of [REDACTED] /L (parts per million). An additional range-finding test will be conducted under flow-through test conditions prior to determining the concentrations that will be tested in the definitive test.

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