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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

8EMQ-1192-8600S

Attention: Section 8(e) Coordinator

Dear Sir/Madam:

The purpose of this letter is to inform you, under TSCA Section 8(e), of results of an environmental toxicity study with Daphnia magna communicated to us on October 30, 1992. The study was conducted with XXXXXXXX a research material, a substituted pyrazole, XXXXXXXXXXXXXXXXXXXXXXX-XXXXXXXXXXXXXXXXXXXX-X-XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX, also identified as XX XXXXXX XXXXXXXXXXXXXXX.

Compound Structure

XXX

1. Chronic Toxicity of XX XXXXXXX on Daphnia magna 954-92-108

Daphnia magna were exposed to various concentrations of test material, ranging from 2.4 to 36 µg/L for 21 days along with non treated and vehicle controls. There was no significant effect to survival, however there were significant effects on time to brood at 18 and 36 µg/L and on the number of offspring at doses of 4.6 µg/L and greater. Based on the data analyses the NOEC was 2.4 µg/L. The maximum acceptable toxicant concentration was 3.3 µg/L.

We are currently evaluating the significance of these results. This material is under research and development as an acaricide. The material and its formulations are not manufactured, sold or distributed in the United States and the target market is outside the U.S. Since laboratory experimentation is in progress in the United States, we believe that the agency may be interested in this information. For such laboratory experimentation, applications are being made by company personnel or contractors on limited areas of 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. We would appreciate definitive advice from the agency about the submissibility of such data.

8EMQ 928600S init  
889300000P25

4 pgs.



If further information is required in the interim, 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

**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 6 months (April 28, 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 pyrazole 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

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 contracted 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 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 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 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.