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		TSCA Section	8E
Submitting Organization	CONFIDENTIAL		
Contractor			
Document Title	INITIAL SUBMISSION: LETTER FROM [] TO USEPA REPORTING RESULTS OF 28-DAY DIETARY TOXICITY STUDY IN PUREBRED BEAGLE DOGS WITH [], A SUBSTITUTED AROYL ESTER, DATED 120999 (SANITIZED)		
Chemical Category	SUBSTITUTED AROYL ESTER (CONFIDENTIAL)		

**INITIAL
SUB-
MISSION**

8EHQ-1299-14616S

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99 DEC 15 AM 9:25

December 9, 1999

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

8EHQ-99-14616
88000000056S

Attention: Section 8(e) Coordinator

Dear Sir/Madam:

The purpose of this letter is to inform you, under TSCA Section 8(e), results of a 28-Day Dietary Toxicity Study in Purebred Beagles Dogs. The research material is identified as:

XXXXXXXXX designated as XXXXXXXXXXXXXXXXXXXXXXXX designated generically as a substituted aroyl ester.

Compound Structure: XXX

28-Day Dietary Toxicity Study in Purebred Beagle Dogs (Protocol No. TOX-99-119)

The test substance was administered at 2500 and 5000 ppm in two animals/group (1/sex/dose). One male dog at 2500 ppm and both dogs at 5000 ppm exhibited unilateral corneal dystrophy. The abnormality appeared to be localized in the superficial layers of the cornea. There was no indication of corneal ulceration or irritation.

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

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If further information is required, please contact J.M. Provenzano-Gray, Regulatory Compliance Manager at 609-716-2780.

Sincerely


L.R. Miko
Vice President Global Quality Assurance & Information Technology

Company Sanitized

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 aroyl ester be used in reference to this 8(e) submission. The period between the synthesis of a research chemical and full determination of its uses is often quite long. It is important for an R&D organization to protect the confidentiality of its key resource library of chemicals.

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 name may appear in a Material Safety Data Sheet prepared 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. Such persons will have signed confidentiality agreements.

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 period between the synthesis of a research chemical and full determination of its uses is often quite long. It is important for an R&D chemical organization to protect the confidentiality of its key resource library of chemicals.

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.

CERTIFICATE OF AUTHENTICITY

THIS IS TO CERTIFY that the microimages appearing on this microfiche are accurate and complete reproductions of the records of U.S. Environmental Protection Agency documents as delivered in the regular course of business for microfilming.

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