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Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20004

8EHQ-0112-18532A
88120000075s



Dear 8(e) Coordinator:

Fluorocarbon

This letter is to inform you of the results of an acute inhalation study in rats with the above referenced R&D test substance. To the best of our knowledge, this substance is not on the TSCA inventory.

An Inhalation Approximate Lethal Concentration Study was conducted in which 2 groups of 2 rats of each sex were exposed to test substance vapor in air. The first exposure group was scheduled to be exposed whole-body for a single 1-hour period to a design concentration of approximately 100,000 ppm in air. Approximately 20 minutes after the exposure started, the rats began gasping and appeared to be struggling for air. After 24 minutes, the rats began to display violent convulsions; therefore, the test substance supply was shut off. While the chamber concentration was decreasing, the rats continued to display gasping, no startle response and eventually became prostrate. Approximately 15 minutes after the test substance vapor had been shut off, all rats were dead. The mean chamber concentration was approximately 66,000 ppm. The second group of 2 male and 2 female rats was exposed for 1 hour to a mean concentration of 9,800 ppm. All rats displayed normal alerting response throughout the exposure; however, their activity level decreased throughout the exposure. Other clinical signs of toxicity observed during the exposure were low carriage and labored breathing. While the chamber concentration was decreasing following cessation of the exposure, the rats displayed gasping, no startle response, pale eyes, lacrimation and eventually, the rats became prostrate. Both male rats were found dead approximately 75 minutes and the 2 female rats were found dead 3 hours after the exposure was over.

Sincerely,



Company Sanitized

TSCA §8(e) SUBMISSION
SUBSTANTIATION OF CONFIDENTIALITY CLAIM

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

Yes.

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point. CBI is requested for a period of [] years. The substance is still early in its development, and may undergo additional toxicity testing prior to commercialization. It is expected that a significant amount of time might be needed prior to commercialization to complete these activities.

3. Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

No.

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

Submitter maintains the substance identity as proprietary information; documents containing the specific substance identity are marked as Company Confidential or other appropriate designation. Disclosure of the substance identity within the Company is on a "need-to-know" basis. []

5. If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

No one outside of our company has access to the information claimed CBI.

[]

6. Does the information claimed as confidential appear or is it referred to in any of the following:

a. Advertising or promotional material for the chemical substance or the resulting and product;

No

b. Material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);

the No. Material Safety Data Sheets for the test substance disclose only the generic name of substance.

c. Professional or trade publications; or

No

d. Any other media or publications available to the public or to your competitors.

No

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

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

No. There are no known pertinent confidentiality determinations by EPA or other Federal agencies

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors access to your customers. Address each piece of information claimed CBI separately.

Disclosure of the claimed CBI would result in harmful effects on submitter's competitive position since the submitter has committed, or expects to commit, a significant amount of time, resources, and dollars to the research and development the test substance. This knowledge could allow the competitor to patent in and around our methods and inventions. Disclosure of the claimed CBI would permit a competitor to specifically know and understand the submitter's research efforts with this test substance [].

9. Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

The test substance has been disclosed in patent filings[].

10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?

No. Substance is not commercially available.

- a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.? Not applicable.

- b. If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.

Substance is in the initial investigatory stages of R&D; []

- c. What is the substance used for and what type of product(s) does it appear in.

Includes applications where Fluorocarbons are typically used today such as [.]

11. Describe whether a competitor could employ reverse engineering to identically recreate the substance?

A competitor would be able to determine chemical structure with various analytical techniques [] Knowledge of the structure would allow a competitor to produce the substance using various chemical processes.

12. Do you assert that disclosure of this information you are claiming CBI would reveal:

- a. confidential processes used in manufacturing the substance;

[]

No

b. if a mixture, the actual portions of the substance in the mixture; or

No

c. information unrelated to the effects of the substance on human health or the environment?

No

If your answer to any of the above questions is yes, explain how such information would be revealed.

13. Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.

CAS number [].

14. Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

No