

CODING FORMS FOR SRC INDEXING

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Submitting Organization		CONFIDENTIAL			
Contractor					
Document Title		INITIAL SUBMISSION: LETTER FROM [] TO USEPA REGARDING POSSIBLE EXPOSURE TO THIONYL CHLORIDE OF A SINGLE EMPLOYEE, W/ & DATED 092500 (SANITIZED)			
Chemical Category		THIONYL CHLORIDE			

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September 25, 2000

Document Control Office (7407)
Office of Pollution Prevention and Toxics
U. S. Environmental Protection Agency
401 M Street
Washington, DC 20460-001
ATTN: TSCA Section 8(e) Coordinator

Company Sanitized

Dear Sir or Madam:

Subject: Report submitted in accordance with U. S. Environmental Protection Agency Statement of Interpretation and Enforcement policy; Notification of Substantial Risk-Section 8(e) TSCA.

The following information is submitted in accordance with the above statement. The submission pertains to thionyl chloride (CAS # 7719-09-7) and is being submitted because of CNS effects observed in a single employee who may have been exposed to thionyl chloride, a reaction product of thionyl chloride, or some unidentified chemical.

We do not believe that the information in this letter reasonably supports the conclusion of substantial risk. It is, however, being submitted to enable the Agency to draw its own conclusions. We have already recorded this information in our TSCA 8(c) file.

The affected employee, who was not wearing respiratory protection, entered an area where another employee (wearing a Tyvek™ suit and using an air-supplied respirator) was rinsing out emptied thionyl chloride-containing drums with water to remove any residual thionyl chloride prior to disposal. Subsequent to a 10-20 second inhalation exposure ("2-3 breaths"), the affected employee exhibited the following signs and symptoms: rhinitis, lacrimation, sore throat and coughing. In addition, the employee demonstrated impaired cerebellar function - ataxia (Romberg's sign present), markedly impaired hand-eye coordination, slurred speech; significantly impaired memory (short, intermediate and long term); and impaired executive function and judgment.

All clinical signs improved dramatically during the first 6 hours following exposure. Twenty-four hours after the exposure, cerebellar function and standard memory/executive/judgment screening tests were within normal limits; however, no baseline data for the employee were available. At 72 hours post exposure, all subjective concerns were completely resolved.

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To our knowledge, the affected employee was not exposed to any material immediately prior to this event. Air monitoring was not conducted in the wash area prior to or following the event; therefore, quantitative exposure information for this incident is lacking. A literature search for information on thionyl chloride did not identify any similar case reports or animal studies linking it to previously reported signs and symptoms. However, due to the timing of the clinical events with the exposure and the absence of other known exposures, the exposure to thionyl chloride appears to be responsible for the effects observed.

We have claimed parts of this letter as confidential (denoted by encircling on this copy). A public file version of this submission is also enclosed. Information to substantiate our claim of confidentiality is included in the enclosed attachment.

Please contact me if additional information is required.

Sincerely,

SUPPORT INFORMATION FOR CONFIDENTIALITY CLAIMS

Specific information is provided below:

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.**

We are asserting the company name confidentiality claim on our own behalf.

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?**

Confidential treatment should be given for the company name to protect proprietary manufacturing information.

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.**

To the best of our knowledge, the information being claimed as confidential has not been disclosed to any other governmental agency or to the U. S. Environmental Protection Agency prior to this submission.

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

Standard methods of protecting confidential business information have been used including classification of documents, limited and controlled distribution of documents, secure storage areas for documents, transmission of documents by certified mail or courier service, employee education programs, and special security procedures for computer files. In addition, employees upon joining the company sign an "Employee's Agreement", part of which states that they will not, either during their employment or thereafter, disclose to anyone outside the company or make use of confidential business information that they may acquire during their employment with the company. Confidential information that is distributed outside the company is only done so under the terms of a confidentiality agreement.

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).**

To the best of our knowledge, there has been no accidental or intentional disclosure of this information to individuals outside our company. There are no plans for disclosure of this information to individuals outside our company in the future.

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

- a. **Advertising or promotional material for the chemical substance or the resulting end product;**
- 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);**
- c. **Professional or trade publication; or**
- d. **Any other media or publications available to the public or to your competitors.**

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.

The information claimed as confidential does not appear in advertising or promotional materials, material safety data sheets, professional or trade publications, or any other media available to the public or to our competitors.

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.**

To the best of our knowledge, there have been no confidentiality determinations by EPA, any federal agency, or any court in connection with this information.

- 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.**

The claim of confidentiality is limited to the company name. The company name is being claimed confidential to protect knowledge about proprietary manufacturing processes including starting materials from disclosure to competitors. Knowledge of even minor details of manufacturing processes can allow competitors to deduce significant details about manufacturing processes. Nothing is being claimed confidential with regard to the chemical name and the signs and symptoms observed, thus, the CBI claim has no impact on the ability of the Agency or others to assess the significance of the information being provided.

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

To the best of our knowledge, there is no issued or pending patent for these substances in the U.S. or elsewhere.

- 10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?**
- a. If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.?**
- 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.**
- c. What is the substance used for and what type of product(s) does it appear in?**

Thionyl chloride is commercially available and is a commonly used laboratory intermediate.

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

Thionyl chloride is a commonly used reaction intermediate.

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

- a. confidential processes used in manufacturing the substance;
- b. if in a mixture, the actual portions of the substance in the mixture; or
- c. information unrelated to the effects of the substance on human health or the environment?

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

No. Thionyl chloride is a commonly used reaction intermediate.

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.

The CAS Registry Numbers assigned to thionyl chloride is 7719-09-7.

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

To the best of our knowledge, the substance and other information claimed CBI are not the subject of FIFRA regulation or reporting.

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.

Date produced 05 25 2001 Mary Furber
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