

PUBLIC COPY
DOES NOT CONTAIN
CONFIDENTIAL BUSINESS
INFORMATION

RECEIVED
2003 FEB 11

2003 FEB 11 11:14

MRA 309789

Company Sanitized

FEDERAL EXPRESS

February 8, 2008

Document Control Office (7407)
EPA East - Room 6428
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics (OPPT)
U.S. Environmental Protection Agency
1201 Constitution Avenue
Washington, DC 20460-0001

Dear Section 8(e) Coordinator:



RE:

This letter is to inform you of preliminary toxicity test results which we feel meet the criteria of significant risk in Section 8(e) of TSCA, according to guidelines in the Federal Register, Vol. 68, No. 106, 2003.

An Acute Toxicity Study, compliant with OECD 201 Guidelines, was conducted on the above material with freshwater algae *Desmodesmus subspicatus*. The material is minimally soluble in the aqueous test media, and was found to be unstable over the time period of the study. Quantitative analysis was performed on the dose concentrations utilized in the study, with the finding that the concentrations decreased up to 70% during the study. Accounting for this decrease, the ErC50 value (0 - 72 h) was calculated to be 0.15 mg/l.

The final report of this study will be forwarded to you when it becomes available.

As this correspondence contains confidential business information, a sanitized version is attached.

If you have any questions or comments please contact me at (203)321-2303.

Sincerely,



Introduction. A study was performed to assess the effect of the test material on the growth of the green alga *Desmodesmus subspicatus*. The method followed that described in the OECD Guidelines for Testing of Chemicals (2006) No 201, "Freshwater Alga and Cyanobacteria, Growth Inhibition Test" referenced as Method C.3 of Commission Directive 92/69/EEC (which constitutes Annex V of Council Directive 67/548/EEC).

Methods. A determination of the General Physico-Chemical Properties study conducted on the test material (Safepharm Laboratories Project Number: 2337/0003) showed the water solubility value of the test material was 1.69 mg/l. A pre-study media preparation trial indicated that a dissolved test material concentration of approximately 1.5 mg/l was obtained from a saturated solution method of preparation indicating this to be the limit of water solubility of this material under test conditions.

Following a preliminary range-finding test *Desmodesmus subspicatus* was exposed to solutions of the test material at nominal concentrations of 0.015, 0.048, 0.15, 0.48 and 1.5 mg/l (three replicate flasks per concentration) for 72 hours, under constant illumination and shaking at a temperature of $24 \pm 1^\circ\text{C}$. The test material solutions were prepared by stirring an excess (50 mg/l) of test material in culture medium using a propeller stirrer at approximately 1500 rpm at a temperature of 21°C for 24 hours. After the stirring period any undissolved test material was removed by filtration (0.2 μm Sartorius Sartopore filter, first approximate 1 litre discarded in order to pre-condition the filter) to produce a saturated solution of the test material with a nominal concentration of 1.5 mg/l*. This saturated solution was then further diluted as necessary, to provide the remaining test groups.

Samples of the algal populations were removed daily and cell concentrations determined for each control and treatment group, using a Coulter[®] Multisizer Particle Counter.

Results. In terms of growth rate, exposure of *Desmodesmus subspicatus* to the test material gave an E_rC_{50} (0 - 72 h) value of 0.31 mg/l; 95% confidence limits 0.27 - 0.36 mg/l. The Lowest Observed Effect Concentration based on inhibition of growth rate was 0.048 mg/l and the No Observed Effect Concentration was 0.015 mg/l.

* Concentration determined by analysis of a saturated solution prepared in an identical manner during the pre-study media preparation trial.

In terms of yield, exposure of *Desmodesmus subspicatus* to the test material gave an E_yC_{50} (0 - 72 h) value of 0.11 mg/l; 95% confidence limits 0.084 - 0.15 mg/l. The Lowest Observed Effect Concentration based on yield was 0.048 mg/l and the No Observed Effect Concentration was 0.015 mg/l.

In terms of biomass integral (area under growth curve), exposure of *Desmodesmus subspicatus* to the test material gave an E_bC_{50} (0 - 72 h) value of 0.13 mg/l; 95% confidence limits 0.10 - 0.18 mg/l. The Lowest Observed Effect Concentration based on inhibition of biomass integral was 0.048 mg/l and the No Observed Effect Concentration was 0.015 mg/l.

Analysis of the test preparations at 0 hours showed measured test concentrations to range from 84% to 121% of nominal. Analysis of the test preparations at 72 hours showed a decline in measured test concentrations in the range of less than 1% of nominal to 71% of nominal. This decline was inline with the stability analyses conducted which indicated that the test material was unstable in culture medium over the test duration particularly at the lower test concentrations employed. A further decline in excess of that seen in the stability analyses was considered to be due possible adsorption of the test material to the algal cells present particularly at the lower test concentrations employed. This effect was considered to be due to there being greater numbers of algal cells in the lower test concentrations and hence greater surface area for adsorption to occur. Whilst no immediate adsorption was observed in the recovery analyses conducted in the presence of algal cells this does not preclude long-term adsorption over the test period. Adsorption was not a factor in the stability analyses as no algal cells were present.

Given this decline in measured test concentrations it was considered justifiable to base the results on the geometric mean measured test concentrations in order to give a "worst case" analysis of the data. The E_rC_{50} (0 - 72 h) based on the geometric mean measured test concentrations was 0.15 mg/l; 95% confidence limits 0.10 - 0.23 mg/l, the E_yC_{50} (0 - 72 h) was 0.010 mg/l; 95% confidence limits 0.00070 - 0.014 mg/l, and the E_bC_{50} (0 - 72 h) was 0.014 mg/l; 95% confidence limits 0.010 - 0.021 mg/l. The Lowest Observed Effect Concentration based on inhibition of growth rate, yield and biomass integral was 0.0045 mg/l and the No Observed Effect Concentration was 0.0018 mg/l.

SUPPORT INFORMATION FOR CONFIDENTIALITY CLAIMS

8(e) Submission On

Substantiation Questions

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.

This confidentiality claim is made on behalf of Cytec Industries Inc.

2. For what period of time 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.

The confidentiality claim should remain in effect as long as the chemical remains an article of commerce. Disclosure of the CBI information would lead to disclosure of the active ingredients in the product which could lead to substantial loss of market share.

3. Has 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 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 this information you are claiming CBI.

The information has been given only to those with a need-to-know. Information has appeared only in Company documents which have limited circulation and which are considered Cytec Confidential information. All employees must sign an agreement which binds them from

disclosing Cytec Confidential information when they leave.

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).

Information claimed as confidential has only been released to those with a bona fide need-to-know.

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 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 publications; 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.

None of the information which is claimed as confidential has been disclosed in any public document.

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.

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 disclose 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 competitor's access to your customers. Address each piece of information claimed CBI separately.

The CBI information would disclose the identity of the company and affiliated commercial product trade names. Disclosure of this information to our competitors could result in a decrease in or total loss of sales.

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

Yes, patent pending.

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

No

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.

Final stages of global commercialization; anticipated to be placed on market within one year.

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

Mineral extraction.

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

Knowing the composition of the product would enable others to copy this chemistry and potential product formulations.

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

a. confidential processes used in manufacturing the substance;

Yes.

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

Not applicable.

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

Yes.

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

Disclosure of the CBI information would identify the active substance in the product. By identifying this CBI, certain information regarding the manufacturing process would be apparent. This substance and any formulations are considered company confidential with very restricted access and is only released to company personnel on a need-to-know basis.

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# assigned is CAS #

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

No.