

8EQ-1297-14085

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November 20, 1997

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(Attn.: Section 8(e) Coordinator)  
Office of Toxic Substances  
U.S. Environmental Protection Agency  
401 "M" Street, S.W.  
Washington, D.C. 20460

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EPA Document Control No: 8EQ-1092-0932

Dear Sir/Madame:

is submitting a supplemental TSCA 8(e) notification for Boric acid, C13-rich, C11-14 isoalkyl pentyl esters; Chemical Abstract Number 166747-78-6 based on the preliminary results obtained from a Guinea Pig Maximization Test. The original TSCA 8(e) identified by the Document Control Number cited above, reported transient signs of neurotoxicity lasting less than one hour at high oral doses. The trade names for this material, which has application as an additive for various lubricants, are . We do not believe that these results demonstrate a significant risk to human health or the environment, but the findings are being submitted because of uncertainty in interpreting EPA criteria for reporting results of dermal sensitization studies.

**Guinea Pig Maximization Test Results**

In this study, the test material was administered at a concentration of 5.0% for intradermal induction, and at 100% for topical induction of 10 male guinea pigs. Approximately fourteen days after the last induction exposure, the animals were challenged topically at two separate sites with concentrations of 50.0% and 100%.

At challenge, seven (7) of the ten induction animals had dermal responses indicative of contact sensitization. Only one (1) of the five challenge control animals had a weak irritant reaction to this material.

In summary, preliminary results from this study indicate that this material may have the potential to cause delayed-type contact hypersensitivity/sensitization in humans. A copy of the final study will be submitted to EPA upon completion.

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Confidentiality is being claimed for the company name, names of company employees, and trade name. All pages containing this information have been stamped "Confidential". Two copies of the notification are being submitted; the confidential information has been circled in one copy and excised from the other. The latter is intended for the EPA's Public File. The substantiation for this confidentiality claim is attached.

Sincerely,

Attachment

*Note: This report is being made in compliance with Section 8(e) of the Toxic Substances Control Act (15 U.S.C. 2607), pursuant to our understanding of the Statement of Interpretation and Enforcement Policy (43 Fed. Reg. 11110 et.seq.). It has been compiled based on information available within the time period given. While we believe the tests reported were properly performed, no representation can be made as to their accuracy of content. The corporation and individual signator also reserve the right to supplement any or all of the data contained herein and to revise or amend any conclusion drawn therefrom.*

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## SUBSTANTIATION OF CONFIDENTIALITY CLAIM

- 1) Confidentiality is being claimed for the test article trade name, submitter's identity, and the names of company scientists which appear in the submission.
- 2) This confidentiality claim is being asserted on the submitter's behalf.
- 3) No time limit is specified for this claim since we cannot assign a time at which this material will no longer be of commercial interest.
- 4) The information is kept in an Archive and other company confidential files to which access is restricted to authorized personnel.
- 5) Except for government authorities, no one outside to the information claimed as confidential.
- 6) The information for which confidentiality is being claimed does not appear in any advertising or promotional material, professional or trade publication, or any other media available to the public or to our competitors.
- 7) To our knowledge, no confidentiality determinations have been made by the EPA, other federal agency, or court in connection with this information.
- 8) Disclosure of the information claimed confidential may do damage to our competitive position by informing competitors of a current line of research in product development.
- 9) Since the chemical identify of the material is being disclosed, reverse engineering is not needed to recreate it.
- 10) Disclosure of the trade name of the material being reported would not reveal confidential processes or compositional product information. The information claimed confidential is unrelated to the effects of the substance on human health or the environment.
- 11) The subject of this notification and the information being claimed confidential are not subject to FIFRA regulation or reporting.

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