

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

008298

MAR 20 1991

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Zinc Borate (Firebrake ZB) - Additional Information on
a Dermal Sensitization Study in Guinea Pigs.

TOX Chem. No. 909B

FROM: Yiannakis M. Ioannou, Ph.D., Section Head
Review Section I, Toxicology Branch II (HFAS)
Health Effects Division (H7509C) *J.M. Ioannou*
3/14/91

TO: Susan Lewis, PM21
Fungicide - Herbicide Branch
Registration Division (H7505C)

THRU: Marcia van Gemert, Ph.D., Branch Chief
Toxicology Branch II (HFAS)
Health Effects Division (H7509C) *mvGemert*
3/15/91

Registrant: U.S. Borax and Chemical Corporation
Los Angeles, CA 90010

Action Requested: Review of additional information on the dermal sensitization of Firebrake ZB in guinea pigs and determine if the study can be upgraded to core-minimum.

Recommendations: Based on the additional data and/or justifications provided by the Registrant this study is upgraded to a Core-Minimum classification.

Background and Considerations

Toxicology Branch II (HFAS) has recently evaluated a dermal sensitization study with Firebrake ZB in guinea pigs (Document No.: 008047; dated 7/20/91). The study was classified as Core-Supplementary due mainly to the lack of positive control data.

In the present submission, the Registrant provided the Agency with positive control data, obtained from Hill Top Biolabs, Inc. (the performing Lab for the Firebrake ZB sensitization study), using DNCB (1-chloro-2,4-Dinitro-benzene) as the sensitizing agent. These data demonstrate that the procedure used is sufficiently sensitive to detect sensitizing agents, and we agree that such data can be used as the positive control data to support the dermal sensitization study with Firebrake ZB. According to Hill Top Biolabs, Inc., this procedure is re-validated every 6 months using DNCB as the sensitizer.

Conclusions

Based on the aforementioned additional data on positive controls and/or justifications provided by the Registrant the dermal sensitization study in guinea pigs with Firebrake ZB is upgraded to Core-Minimum classification.