APR 3 1995

MEMORANDUM

Subject: EPA File Symbol/EPA Reg. No.:TIM-BOR/1624-39

From: Carol E. Glasgow, Ph.D., Toxicologist Carol
Precautionary Review Section
Registration Support Branch (7505W)
Registration Division (7505C)

To: Robert Taylor, PM 25
Fungicide-Herbicide Branch
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Applicant: U.S. Borax & Chemical Corporation
3075 Wilshire Blvd.
Los Angeles, CA 90010

FORMULATION FROM LABEL:

Active Ingredient (s):	% by weight
Disodium Octaborate Tetrahydrate ($Na_2B_8O_{13} \cdot 4H_2O$)	98
Inert ingredient(s)	2

BACKGROUND: U.S. Borax & Chemical Corp. submitted three studies (two primary eye irritation studies and one dermal irritation study) for registration. All three studies were performed by Hill Top Biolabs, Inc. MRID numbers were 425210-01 through 03. These studies were reviewed by Clement International Corporation.

RECOMMENDATION: RSB/PRS findings are as follows:

1. Both primary eye irritation studies are rated **Unacceptable**. Dose in the first study was 0.049 g and in the second study, 0.053 g. Guideline requires 0.1 g.

2. The primary dermal irritation study is rated **Supplementary**. Important details of study not included:
   - o study protocol stated animals would be kept for at least one day before use, but the actual time the test animals were kept was not given -- guideline requires animals be acclimated in the study room for at least 5 days before use
   - o hair noted at irritation sites when evaluating for erythema, but not mentioned for edema -- as sites are the same, the presence of hair causes problems in reading for the possibility of edematous tissue -- why wasn t hair clipped again before reading at 48 hours and subsequently?

TOXICITY PROFILES

Primary eye irritation	Unacceptable
Primary dermal irritation	Supplementary

LABELING: The label will be revised upon submission and acceptance of new data.