CASWELL FILE

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

MEMORANDUM

OFFICE OF TOXIC SUBSTANCES

SUBJECT: ~~Label Change~~ for Orthocide 4 Flowable, EPA Reg.#239-2437, CASWELL#159

FROM: Gary J. Burin, Toxicologist
Toxicology Branch, HED (TS-769)
e.f. 7/7/80

TO: Henry Jacoby (21)
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THRU: William Burnam, Acting Chief
Toxicology Branch, HED (TS-769)

Background Information: Orthocide 4 Flowable contains 35.9% Captan, an RPAR chemical. Chevron has previously contested the EPA recommended label and this reviewer has replied to the objections of Chevron (See my memo of November 8, 1979). Chevron has now replied to the EPA.

Recommendations: The numbering of the recommendations below correspond to items in the Chevron letter of May 1, 1980.

1) Available data is not adequate to justify removing the statement "Harmful if inhaled" as requested by Chevron. The study reviewed in memo of November 8, 1979 was classified as supplementary data because particle sizing was not performed and the reported exposure level was nominal rather than actual. Therefore, a core minimum study of this formulation does not exist. Inhalation studies of technical Captan have reported values which would place this compound either in category II or III (See Stevens et al, "The acute inhalation toxicity of technical captan and folpet. Toxicol. Appl. Pharm. 45:320, also see review of November 3, 1979 by S.A. Sterling). Regarding the likelihood of inhalation exposure, the normal method of application of this formulation is by spraying and, therefore, applicator exposure through inhalation of the aerosol is anticipated.

3) The dermal LD_{50} of this product supports a Tox. Category III classification (See review of February 9, 1978 by William Greear). On this basis, "Harmful if absorbed through the skin" is the appropriate precautionary statement.

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4) Chevron notes that the word "sanitation" should have been "sensitization". This is, of course, correct.

It must be noted, regarding skin sensitization, that the study requested by W. Greear in memo of 2-9-78 has not yet been submitted. It must also be noted that numerous case reports exist regarding skin sensitization by captan in humans (As an example, see Marzulli, F.N. and Maibach, F. "Antimicrobials: Experimental contact sensitization in man" J. Soc. Cosmet. Chem. 24,399-491 (1973).

5) A copy of the results of the dermal irritation study conducted by W. Teeters is attached. The results of this study do not indicate a label change for this product regarding dermal irritation potential.