CASWELL FILE

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

AUG 9 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: E.P.A. Reg. #241-233-AA: Label Ammendment for Use of Cygon© 400 on Cotton.

TO: Mr. William Miller, PM Team #16
Registration Division (TS-767)

FROM: Karen L. Hamernik, Ph.D., Toxicologist
Toxicology Branch, Section VII
Hazard Evaluation Division (TS-769)

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Tox. Chem. File No. 358

Background

American Cyanamid Company, Princeton, N.J., is requesting a label revision for the use of their systemic insecticide product Cygon 400 on cotton. The registrant wishes the label to read that the product may be diluted and applied in either once-refined vegetable oil or, as originally indicated on the label, in water (see attached label and ammendment). Cygon 400 contains the active ingredient Dimethoate at approximately 50% of the formulation by weight.

In its recommendation that this request for an ammended registration be granted, Residue Chemistry Branch noted that "the application of Dimethoate in oil as a ULV spray to cotton under the revised usage pattern will result in residues in or on cottonseed below the current tolerance and comparable to those found within conventional aqueous sprays" (see attached review by J. Garbus, Chemist, dated May 28, 1985).

Toxicology Branch Considerations

1. The ADI of 0.0200 mg/kg/day was based on a human cholinesterase inhibition No Observable Effect Level of 0.200 mg/kg.

2. If approval of this registration action is granted, the percent of the ADI occupied would remain, with respect to published tolerances, at 42.92% and there would be no increase in the the TMRC which is currently 0.5150 mg/day (1.5 kg) (see attached printout).

3. There are no known existing regulatory actions against registration of this product and its RPAR status is clear.

4. The status [redacted] inerts used in the Cygon 400 formulation (inerts as listed on the attached, most recent copy of the Cygon 400 Confidential Statement of Formulation available to Toxicology Branch) is unclear. [redacted] clearance sheet). The registrant should provide identification of the components of these two inerts as soon as possible.

5. Toxicology Branch files contain no record that acute toxicity data (acute oral, acute dermal, acute inhalation, primary eye irritation, primary dermal, and dermal sensitization data) for Cygon 400 were submitted and reviewed. If such data exist and have been previously evaluated by the Agency, Toxicology Branch respectfully requests that the registrant provide evidence to this effect. Other than this, the registration action is supported by the existing data base (see attached 1-liner).

Toxicology Branch Conclusions and Recommendations

No obvious additional toxicological hazard is anticipated if Cygon 400 is diluted and applied in once-refined vegetable oil. Therefore Toxicology Branch has no objection to the requested label ammendment providing the following conditions are met:

1. [redacted] currently in an unclear status should be further identified as to their components and must then be cleared by Toxicology Branch;

2. The registrant is kindly asked to provide evidence that the acute data (listed above) for Cygon 400 has been previously submitted and reviewed, if such data exists;

3. The Cygon 400 label (attached) indicates that the percent of Dimethoate in the formulation is 43.5% while the attached confidential statement of formulation lists Dimethoate at 50.3% of the formulation by weight (purity of Dimethoate is not stated). The registrant should explain this discrepancy.