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

003399

11/30/83

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: ~~September 13, 1983~~

SUBJECT: EPA Registration No. 10182-TR. Registrant's response to Toxicology Branch's questions concerning gross pathology reports and clinical responses for an acute oral LD_{50} study with the product DEMON® containing cypermethrin and changes in the precautionary statements for this product.

Tox Chem. No. 271DD

TO: T. A. Gardner, PM#17
Registration Division (TS-767)

Background:

TOXICOLOGY BRANCH (TB) previously reviewed several acute toxicity studies for the product DEMON® WP containing cypermethrin (see J. Doherty review dated Oct. 12, 1982 concerning EPA Reg. No. 10182-EUP-GE, FAP 2H5362). In this review it was indicated that the rat acute oral LD_{50} study was determined to be incomplete pending necropsy reports and tables showing the individual animal behavioral signs with dose and time. The report as originally presented indicated possible lung tissue damage in the survivors. A subsequent memo (see J. Doherty memo dated Dec. 14, 1982 concerning EPA Reg. No. 10182-TR) advised that certain changes in the precautionary statements of the label should be made.

In response to TB's request, the registrant (ICI Americas) has provided the requested raw data and has made the suggested changes in the precautionary statements.

Recommendations and Comments:

1. The acute oral LD_{50} study with DEMON® 40 WP (#WIL-81329 dated Feb. 9, 1982) may be upgraded to CORE MINIMUM.

   Based on the gross necropsy reports as submitted, it is apparent that the rats in all of the dosed groups had evidence of the same lung

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pathology described as an "old" hemorrhage." There was no evidence that this "hemorrhage" was a result of the treatment.

The tables showing the individual clinical observations confirmed that in some rats (particularly those dosed with 1.0 mg/kg or above) had some minor signs of toxicity still evident up to 7 days after dosing.

2. The label was revised in response to TB's suggestions. A copy of the revised label is attached.

3. Toxicology Branch will address the recommendation for the registration of this product after the analysis on the oncogenic potential and risk assessment of cypermethrin is completed.

John Doherty
Toxicology Branch
Hazard Evaluation Division (TS-769)

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Attachment

CYPERMETHRIN TOXICOLOGY REVIEWS

Page _____ is not included in this copy.

Pages 3 through 5 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

___ Identity of product impurities

___ Description of the product manufacturing process

___ Description of product quality control procedures

___ Identity of the source of product ingredients

___ Sales or other commercial/financial information

X A draft product label

___ The product confidential statement of formula

___ Information about a pending registration action

___ FIFRA registration data

___ The document is a duplicate of page(s) _____

___ The document is not responsive to the request

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
