Microfiche

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

APR 8 - 1993

010156

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: RfD/Peer Review Meeting on Cyhalothrin/Lambdacyhalothrin; Changes in RfD and NOEL's for Several Studies

Shaughnessy No. 128867
Tox. Chem. No. 725C

TO: George Z. Ghali, Manager
RfD/Quality Assurance Peer Review
Health Effects Division (H7509C)

FROM: Pamela M. Hurley, Toxicologist Pamela M. Hurley 4/1/93
Section I, Toxicology Branch I
Health Effects Division (H7509C)

THRU: Roger L. Gardner, Section Head
Section I, Toxicology Branch I
Health Effects Division (H7509C) Roger Gardner 4-1-93 KB 4/2/93

On February 12, 1993, the Health Effects Division RfD/Peer Review Committee met to reassess the Reference Dose for Cyhalothrin/Lambdacyhalothrin in light of additional data. As stated in the memorandum from G. Ghali to J. Kariya, dated 2/17/93, "the RfD/Peer Review Committee recommended that an RfD should be established based upon a NOEL of 0.1 mg/kg/day for clinical signs of neurotoxicity and other effects observed at 0.5 mg/kg/day in a long-term study in dogs. An uncertaintly factor (UF) of 100 was also recommended to account for the inter-species extrapolation and intra-species variability. The RfD was calculated to be 0.001 mg/kg/day."

Several other decisions were made at the February 12 meeting:

1. The NOEL for the 1-year feeding study conducted with Lambdacyhalothrin (Karate, PP321) on dogs is to be changed from 0.5 mg/kg/day to 0.1 mg/kg/day and the LOEL is to be changed from 3.5 to 0.5 mg/kg/day, based upon clinical signs of neurotoxicity.

2. The NOEL for reproductive/systemic effects in the 3-generation reproduction study conducted with Cyhalothrin on rats is to be changed from less than 10 ppm to 30 ppm and the LOEL is to be changed from 30 ppm to 100 ppm, based on decreases in both parental and pup body weights. In

10 2

010156

addition, the developmental NOEL is to be set at 100 ppm (highest dose tested).

3. Several questions were raised concerning the mouse oncogenicity study conducted with Cyhalothrin. The first question involved whether or not the study was tested at a sufficiently high dose for a negative study and the second question concerned the incidence of mammary tumors in females. The Committee requested any relevant data supporting the dose levels selected for the study and any available historical control data for the mammary tumors before any final decisions will be made concerning this study.

Copies of the revised 1-liners are attached.

2