5/22/86

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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: 53218-EUP-1,2. 5G3204. Cyhalothrin (Grenade™). Application for Experimental Use Permit and Temporary Tolerance to Support Use on Cattle.

Tox. Chem. No. 271F

TO: George LaRocca (PM Team #15)
Registration Division (TS-767c)

FROM: Pamela M. Hurley, Toxicologist Pamela M. Hurley
Section II, Toxicology Branch
Hazard Evaluation Division (TS-769c)

THRU: Edwin R. Budd, Section Head
Section II, Toxicology Branch
Hazard Evaluation Division (TS-769c)

Budd 5/19/86
5/22/86

Background:

Coopers Animal Health, Inc. requested an Experimental Use Permit (EUP) for Grenade™ (Cyhalothrin active ingredient) insecticide on cattle. In a memorandum to George LaRocca dated May 5, 1986, Toxicology Branch (TB) responded to the request. In the section entitled, "Comments on the Toxicity Data Base for Cyhalothrin", the TB comment on the three-generation reproduction study in rats was inadvertantly omitted. The following paragraphs state TB's position on this key study.

The rat three-generation reproduction study on cyhalothrin was reviewed by EPA's Contractor and was assigned a classification of SUPPLEMENTARY on the basis of "compound-related toxicity" in the offspring at all dose levels and on the basis of discrepancies between the summary tables and the individual animal data. TB has reviewed the data and has determined that the study should be reassigned a classification of: CORE GUIDELINE for the following reasons:

1. The effect noted by the Contractor in the offspring at all dose levels was decreased body weight gain during the weaning period. The data indicate that at the lowest dose level (10 ppm), there was a decrease in body weight gain in the F_1A females on postnatal day 5, but at none of the succeeding days on which the animals were weighed (days 11, 22, and 29). Only one other group at this dose

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level showed this effect. F_3A males displayed a significantly decreased bodyweight gain and postnatal days 11 and 22. None of the other data points at this dose level were less than control values. TB believes that since there was no consistency in this response at this dose level, the data do not indicate a meaningful toxicologic response. Therefore, the NOEL and LOEL for offspring toxicity are determined to be 10 ppm and 30 ppm, respectively. The NOEL and LOEL for parental toxicity remain at 10 ppm and 30 ppm, respectively.

2. The discrepancies between the summary tables and the individual animal data are minor and do not affect the outcome of the study.

3. The study is determined to be CORE GUIDELINE because the design and conduct reflect modern-day standards.

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