File

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

004502

JUN 24 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Experimental Use Permit for FMC 54800 (Biphenthrin, Brigade, Capture) and Temporary Tolerances for Cottonseed and Apples.
Caswell 463F

TO: Mr. Tim Gardner
Product Manager 17

FROM: Byron T. Backus
Toxicology Branch
HED (TS-769)

Byron T. Backus 6-21-85

THROUGH: Clint Skinner, Ph.D., Head
Review Section III
and
Ted Farber, Ph.D., Chief
Toxicology Branch

Clint Skinner 6-21-85

6/24/85

Compound: Cyclopropanecarboxylic acid, 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethyl-,(2-methyl [1,1'-biphenyl]-3-yl) methyl ester, FMC 54800, Biphenthrin, Talstar, Brigade, Capture

Registration No. 279-EUP-RNG

Action Requested:

The registrant has asked for temporary tolerances on cottonseed (0.5 ppm) and apples (2.5 ppm). In conjunction with the temporary tolerance on cottonseed, the registrant is requesting an EUP for a total of 7425 acres (involving use of the a.i. at 1 lb/acre, or a total of 7425 lbs of biphenthrin).

Background:

Data previously reviewed include 2 teratology studies (a rat study is in acc. 254409; a rabbit study is in acc. 254410), as well as 13-week dog (acc. 254408) and 90-day rat (acc. 254407) feeding studies.

The rabbit teratology study has been accepted as Core

402

004502

Minimum Data, while the rat teratology study is currently classified as Supplementary (see the review by B. Backus, dated June, 1985).

Comments and Recommendations:

1. Although the rabbit teratology study has been classified as Core Minimum Data, and the rat teratology study has been classified as Supplementary, the latter study defines a lower NOEL (1 mg/kg/day on the basis of both maternal and fetal toxicity, whereas the NOEL in the rabbit study was 2.67 mg/kg/day in terms of maternal toxicity). The rat study then has been used to set the NOEL for the purposes of these temporary tolerances. It is noted that the rat study was classified as Supplementary ~~because there was a question as whether the highest dose was at or near the maternal MTD.~~ Core minimum C.S.

2. Applying a safety factor of 100 to a NOEL of 1 mg/kg/day yields an ADI of 0.0100 mg/kg/day. There are no current published tolerances for Biphenthrin; the two proposed temporary tolerances would result in a TMRC of 0.0960 mg/day, or 16.00% of the ADI.

3. While no long term chronic studies have been received for this active ingredient, it was not mutagenic in an Ames study (acc. 251726) previously reviewed and found acceptable. A number of additional mutagenicity studies have also been received; while not yet formally reviewed as to acceptability, there are no indications of any pronounced mutagenic effects.

4. The Toxicology Branch has no objections to issuance of these proposed tolerances, or to the proposed EUP involving use of 7425 lbs of the active ingredient on 7425 acres of cotton.

5. The reference articles in acc. 073175 are from the open literature; while pertinent to the mutagenicity studies which have been received from the registrant, no formal review of these reference articles is necessary.

Attachment:

1. Unverified printout (DRAFT): acceptable daily intake for FMC 54800.

403