3-28-88

212240
Record No.

128825
Shaughnessey No.

Review No.

EEB REVIEW

DATE: IN 01-25-88 OUT 03-28-88

FILE NUMBER 279-3055

DATE OF SUBMISSION 12-18-87

DATE RECEIVED BY HED 01-15-88

RD REQUESTED COMPLETION DATE 04-04-88

EEB ESTIMATED COMPLETION DATE 04-04-88

RD ACTION CODE 331

TYPE PRODUCT Insecticide (synthetic pyrethroid)

DATA ACCESSION NO.

PRODUCT MANAGER G. LaRocca (15)

PRODUCT NAME Biphenthrin

COMPANY NAME FMC Corporation

SUBMISSION PURPOSE Registrant response to previous EEB review.

SHAUGHNESSEY NO.	CHEMICAL	%AI
128825	bifenthrin	

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

MAR 30 1988

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EEB Response to FMC's Rebuttal Comments

FROM: Les Touart, Fisheries Biologist
Ecological Effects Branch

THRU: Raymond Matheny, Head, Section I
Ecological Effects Branch

THRU: Henry T. Craven, Acting Chief
Ecological Effects Branch
Hazard Evaluation Division (TS-769)

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

FMC has raised several questions concerning EEB review of pertinent data with respect to their proposed cotton registration. EEB responds as follows:

- estuarine mollusc acute toxicity test (72-3)

The reviewed studies in this category have been determined to be unacceptable for a variety of reasons, as accurately reflected by FMC. EEB's rationale for such a conclusion is based on the combination of deficiencies and not a specific deficiency alone as implied by FMC. An oyster embryo-larvae test has been submitted which may fulfill this requirement, but has yet to be reviewed. EEB defers further comment on this particular test requirement until that study review has been completed.

- aquatic invertebrate life cycle (freshwater) test (72-4)

FMC disagrees with EEB's conclusion that the submitted test in this category fails to report a NOEL. FMC argues that a variety of statistical tests which they have employed do not detect a difference from controls in the lowest test level. EEB employs a Duncan's multiple range test for separating means after an ANOVA. Duncan's does identify the lowest test level as significnatly differnt from control.

Additionally, EEB has performed a Williams' test of mean separation which is similar to the Dunnett's test except Williams' test is more sensitive to a response due to increasing concentration of a toxicant. This test clearly identifies that all treatment levels are significantly different from control. The lowest treatment level differed from control by 18.5% and the highest treatment level differd by 27.8%. EEB has concluded that an additional life-cycle test with a freshwater invertebrate is necessary to determine a laboratory derived NOEL due to the strong environmental concerns associated with this compound. The NOEL is needed to compare with field evidence to assess the safety of the compound.

- aquatic invertebrate life cycle (estuarine) test (72-4)

FMC questions the need for such a test. EEB has concluded that cotton represents substantial acreage in coastal counties which could lead to exposure through drift and/or runoff into estuarine habitat. The acute estuarine test with the mysid has indicated that bifenthrin is very highly toxic to these animals (LC50 = 4 parts per trillion) and is roughly 30 times more sensitive than are freshwater invertebrates (LC50 = 110 parts per trillion). Considering that the NOEL for freshwater invertebrates is less than 0.1 parts per trillion, bifenthrin could conceivably be chronically toxic to estuarine fauna in the low parts per quadrillion. EEB is very firm in requiring this test.

- finfish life cycle (reproduction) test (72-5)

FMC has indicated that this test is currently in progress and should be submitted in the near future.

- aquatic organism accumulation test (72-6)

FMC has reffered EEB to an EAB review of a bluegill test which was judged supplemental. EEB is presently reserving this test requirement until it has received and reviewed the fish life cycle study and the field study. Information provided from these tests in combination with information in the EAB review may be sufficient to satisfy this requirement. If not, specific test requirments will be detailed at that time.

- simulated or actual aquatic field test (72-7)

FMC has indicated that this test has been completed and expects to submit the results in the near future.

- honey bee - toxicity of residue on foliage (145-2)

This test requirement has been fulfilled.