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

JUN 16 1987

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Impurities found in the new manufacturing process for Bifenthrin (solid wax formulation)

To: Kris Dively
Registration Division

From: Marcia van Gemert, Ph.D.
Head, Section III
Toxicology Branch, HED
M. van Gemert 6/10/87

Thru: Theodore M. Farber, Ph.D.
Chief, Toxicology Branch, HED

Caswell No: 463F

Project No: 7-0743

Firm: FMC Corp.

In a letter to EPA dated May 22, 1987, the FMC Corp. provided further comments concerning the [redacted] impurities found in their new manufacturing process. Based on the original information furnished on these [redacted] impurities by FMC the EPA recommended that a battery of mutagenicity studies and an acute oral LD_{50} be provided to the Agency on each of the [redacted] new impurities.

In this present submission, FMC states that impurites [redacted] were represented to the extent of [redacted] and [redacted] respectively in the original technical grade used for the chronic studies. In the present manufacturing process these impurities are [redacted] and [redacted] respectively. Therefore, FMC argues that these [redacted] impurities have been adequately tested, and the Toxicology Branch concurs.

[redacted] FMC has stated that this impurity is formed as a result of the acid chloride manufacturing process and did not appear in the original technical Bifenthrin fed in the chronic studies. [redacted] to TFP acid on contact with water and TFP acid has the following toxicology data base in the Agency:

Acute oral toxicity- rat > 5000 mg/kg
Dermal toxicity: - rat > 2000 mg/kg
skin irritation
eye irritation
skin sensitization
chronic toxicity
Ames test

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Since the [redacted] will most likely become TFP acid under biological conditions, and has a fair data base available, it doesn't appear necessary now to test the [redacted] as previously stated.

Conclusion: EPA agrees with FMC's argument that the [redacted] impurities found in the new Bifenthrin manufacturing process do not need to be further tested toxicologically.

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