MEMORANDUM

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

To: Kris Dively
Registration Division

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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 impurities found in their new manufacturing process. Based on the original information furnished on these impurities by FMC the EPA recommended that a battery of mutagenicity studies and an acute oral LD50 be provided to the Agency on each of the new impurities.

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

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. 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
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.