MEMORANDUM

Subject: Addition of [REDACTED] new impurities from a new manufacturing process for Bifenthrin, RCB referral

To: George La Rocca (PM-15)
Registration Division, TS-767C

From: Marcia van Gemert, Ph.D.
Head, Section III
Toxicology Branch, HED

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

Chemical: Bifenthrin

Project No: 7-0576
Caswell No: 763F
EPA ID NO: 279-3055

Action Requested:
Review alternative manufacturing process per RCB review.

Comments:
The FMC Corporation has submitted an application to amend the registration of its synthetic pyrethroid, bifenthrin. The alternative manufacturing process will result in the formation of a technical bifenthrin that is a waxy solid rather than a crystalline solid. [REDACTED] new impurities will be introduced to this new product, which have not previously been present, and were not present when the product was tested toxicologically. These new chemical impurities are:
Based on the fact that a significant amount of these new impurities will be coming into the technical bifenthrin, and all the toxicology studies done have to date not incorporated this new impurity into their testing, the Toxicology Branch will require that an acute oral toxicity study and a full mutagenicity battery (similar to that submitted for the original bifenthrin technical for comparison) be performed on each of the new impurities and be submitted for our review before this new manufacturing process replaces the old one.