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

MAR 19 1987

MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCI

Subject: Addition of new impurity to bifenthrin technical

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

From: Marcia van Gemert, Ph.D. M. van Gemert 3/18/87
Head, Section III
Toxicology Branch, HED

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

3/19/87

Chemical: Bifenthrin, Talstar, FMC 54800

Project No: 7-0484

Caswell No: 763F

EPA ID NO.: 279-3055

Action Requested: Registration Division has sent a request to Toxicology Branch to determine if additional toxicology data are necessary to approve this formulation change.

Comments: FMC has submitted information concerning their new manufacturing process that introduces a new impurity into the final technical bifenthrin. TFP acid, the starting material for bifenthrin, is the compound [redacted] (referred to as TS acid impurity). During the manufacturing process TFP acid is esterified. In addition this new impurity is esterified into [redacted] (referred to as TS bifenthrin impurity).

This TS acid impurity can be present at levels as high as [redacted] FMC claims that this impurity cannot be realistically reduced below about [redacted] FMC also states that a high percent of the impurity present is probably transferred into the ester impurity in the Bifenthrin technical.

Based on the fact that a significant amount of this new impurity will be coming into the technical bifenthrin, and all the toxicology studies done to date have 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 this new TS bifenthrin impurity and submitted for our review before this new formulation can replace the old one.

Structures of bifenthrin, TS acid impurity and TS bifenthrin impurity are on appended page 1.

Page 3 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

✓ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.