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

MAR 2 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTA

MEMORANDUM

SUBJECT: TS Bifenthrin Impurity

TO: Mr. George LaRocca, PM-15
Registration Division (TS-767C)

FROM: Byron T. Backus, Toxicologist
Toxicology Branch (TS-769C)

THROUGH: Marcia van Gemert, Ph.D.
Section Head, Review Section III
Toxicology Branch (TS-769C)

and

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Branch Chief
Toxicology Branch (TS-769C)

EPA Record No. 207194

Project No. 8-0329

Tox. Chem. 554C (554C is an impurity in 463F)

EPA Reg. No. 279-3055

Action Requested:

Review 4 mutagenicity studies (Ames assay, CHO/HGPRT assay, CHO chromosomal aberration, and UDS assay), as well as a rat oral LD_{50} study conducted on an impurity [redacted] otherwise known as TS Bifenthrin impurity) present in technical Biphenthrin at levels of up to [redacted] The material reviewed includes additional information submitted by the registrant February 5, 1988.

Comments and Recommendations:

1. The Ames assay, CHO chromosomal aberration and UDS assay have been classified as acceptable studies.

There is no indication, under the conditions that these assays were performed (including - where appropriate - with S-9 metabolic activation) that exposure to TS Bifenthrin impurity results in induction of a mutagenic response.

2. In the CHO/HGPRT assay there was also no indication of mutagenic activity, either with or without S-9 activation. The maximum dose level given (in both the activated and non-activated assays) was 1000 ug/ml. The Agency does not agree that 1000 ug/ml is normally an acceptable maximum concentration level in the absence of cytotoxicity (as is indicated in the letter of February 1, 1988 from the laboratory to the registrant). 1000 ug/ml is acceptable in this case only because it was found to be the solubility and osmolality limit of FMC 102032 in the same solvent in another study (Chromosome Aberrations in CHO Cells) at the same laboratory. The assay under non-activated conditions is therefore acceptable. The assay under activated conditions has been classified as not acceptable, as the S-9 fraction used was prepared from male rats which had received an intraperitoneal injection of Aroclor-1254 two days (instead of the usual five days, as in the CHO chromosomal aberration study conducted at the same laboratory). In order for this assay to be classified as acceptable, the registrant must justify the use of S-9 fraction prepared in this manner.

3. The rat oral LD_{50} study has been classified as core minimum. The technical form of TS Bifenthrin impurity is in toxicity category IV (LD_{50} > 5 g/kg in rats) by the oral exposure route.