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

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SEP 24 1985

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: FMC 54800 TECHNICAL

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

FROM: Byron T. Backus
Toxicologist
Toxicology Branch

THROUGH: Clint Skinner, Ph.D.
Head, Section III
and
Theodore M. Farber, Ph.D.
Chief, Toxicology Branch
Hazard Evaluation Division (TS-769)

SEP 23-85
[Handwritten signature]

Registration number: 279-3055

Registrant: FMC Corporation

Tox. Chem. 463F

Action Requested:

Review of a set of 5 mutagenicity studies.

Background:

These are the last two mutagenicity studies (out of the original 5).

Comments and Conclusions:

The following is a listing of the studies which have been reviewed (refer to the attached data evaluation reviews), along with a short summary of the comments made regarding their acceptability or unacceptability:

1. Chromosome Aberrations in Chinese Hamster Ovary (CHO) Cells. Study conducted by Microbiological Associates; study no. A83-1105. Report dated 01/05/84.

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This study is acceptable. FMC 54800 at doses ranging from 100 to 10,000 ug/ml with and without S9 activation did not cause chromosomal aberrations in CHO cells.

2. CHO/HGPRT Mutation Assay in the Presence and Absence of Exogenous Metabolic Activation. Study conducted by Microbiological Associates; study no. A83-1144. Report dated 7/11/84.

This study is not acceptable. Results in both activated and nonactivated tests were considered inconclusive. There was test material precipitation at all doses (250, 500, 750 and 1000 ug/ml) without S9 activation. For S9 activation there was a significant increase in mutation frequency at 20 ug/mlm (LDT) but not at higher doses (30, 40, 50 ug/ml).

Copies of the attached data evaluation reviews should be provided to the registrant.

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