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

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NOV 21, 1986

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MEMORANDUM

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA Reg. No. 279-2032; Metiram (Polyram)®; Mutagenicity Data. Accession No. 257072, Caswell #41A

FROM: George Z. Ghali, Ph.D.
Scientific Mission Support Staff
Toxicology Branch/HED (TS-769)

G. Ghali 11.14.86

TO: Henry Jacoby, Product Manager #21
Registration Division (TS-767)

THRU: Reto Engler, Ph.D., Chief
Scientific Mission Support Staff
Toxicology Branch/HED (TS-769)

Registrant: FMC Corporation
Philadelphia, PA 19104

Action Requested:

Review and evaluation of the following mutagenicity data submitted in response to the data call-in notice of January 17, 1983.

1. Reverse mutation assay in S. typhimurium

2. Primary hepatocyte unscheduled DNA synthesis in the rat

Conclusions and Recommendations:

1. Reverse mutation assay in S. typhimurium:

The data as submitted could not be evaluated. All the even numbered pages are missing from the final report.

2. Rat Primary Hepatocyte Unscheduled DNA Synthesis:

Under the test conditions, "the test material did not induce significant changes in the nuclear labeling of primary hepatocytes up to 49.2 u/ml of the test material and 25.6% cell survival rate."

The study is acceptable and partially fulfills mutagenicity data requirements for one category, i.e. other mechanisms of mutagenicity.

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DATA EVALUATION RECORDS

Reverse Mutation Assay in S. typhimurium. Geloke, H. P. and Engelhardt, G. (1985). Standard Plate Test with S. typhimurium. Report No. 85/020, dated February 7, 1985, prepared by Litton Bionetics. EPA Accession No. 257072.

No Data Evaluation Records were prepared for this study. All even numbered pages are missing from the final report.

DATA EVALUATION RECORDS

Rat Primary Hepatocyte Unscheduled DNA Synthesis, Cifone, M. A. and Myhr, B. C. (1984). Evaluation of Metiram Technical in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay, an unpublished report prepared for BASF Aktiengesellschaft, W. Germany by Litton Bionetics, Inc., Project No. 20991, Report No. 7419 dated July, 1984. EPA Accession No. 257072.

TEST CHEMICAL: Metiram technical, Patch No. K 38/33A 84/28 described as yellow powder.

TESTING LABORATORY: Litton Bionetics, Inc., Kensington, Maryland

EXPERIMENTAL PROTOCOL: The test was conducted according to the standard protocol attached (Appendix A).

RESULTS: Under the test conditions Metiram did not induce significant changes in the nuclear labeling of primary rat hepatocytes for concentrations ranged from 49.2 ug/ml to 0.492 ug/ml, and a cell survival range of 25.8% to 107.2%. Higher concentrations were tried and proven to be completely lethal.

CONCLUSIONS: None of the criteria used to indicate unscheduled DNA synthesis were approached under the test conditions. Therefore, Metiram is considered inactive in this test. However, the study was not repeated to confirm the findings as it is usually recommended for this test (although not necessarily required). In addition, only male rats were used in this test, females were not included.

CORE CLASSIFICATION: Not applicable, but the study is considered acceptable.

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METIRAM

Page_____ is not included in this copy.

Pages 4 through 10 are not included.

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.

X FIFRA registration data.

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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.