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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 12-OCT-00

SUBJECT: PP# 8F04954, ID# 010182-UUU. **Mesotrione (Proposed Common Name).** MRID#: none. DP Barcodes: D266968, D269331, D269076. Chemical #: 122990. Case #: 289589, 063670. Submission #: S541377, S585939.

FROM: Sarah Levy, Chemist
David Nixon, Toxicologist
Registration Action Branch 1 (RAB1)/Health Effects Division (HED) (7509C)

THROUGH: George Kramer, Ph.D., Chemist
Marion Copley, DVM 10/12/00
G. Jeffrey Herndon, Acting Branch Senior Scientist
RAB1/HED (7509C)

TO: James Stone/Jim Tompkins, PM Team 25
Herbicide Branch
Registration Division (RD) (7505C)

BACKGROUND

An anonymous letter was received by the Agency from a worker at the petitioner's company, Zeneca, concerning the presence of a mutagenic impurity, in technical Mesotrione. The letter stated "This mutagenic impurity, which was found on the basis of positive Ames testing of the manufactured herbicide, was found on testing to be extremely mutagenic in standard Ames assays, yet it continues to be present in the commercial product." RD reviewed the letter, product chemistry data (including the manufacturing process) (MRID#s 44394201, 44505003 (supplemental 45216101), and 4450504), and Zeneca's response to additional questions regarding [redacted] (MRID# 45216100). The impurity in question was detected in the initial samples of the technical synthesized; however, the manufacturing process was revised in order to reduce the levels of the impurity. RD requested that HED concur with RD's conclusions concerning the lack of mutagenic concerns for the impurity in Zeneca's ZA1296 Technical Mesotrione.

CONCLUSIONS

HED concurs with RD that the impurity in question, [redacted] which was found in the initial samples synthesized and whose levels are reduced during the manufacturing process as a result of [redacted] would be reduced below levels of toxicological significance. The technical product was evaluated in a bacterial reverse gene mutation assay that used both standard plate incorporation and liquid pre-incubation techniques. The latter technique is sensitive to the presence of strong mutagens and should have had a positive result if the impurity was present in sufficient amounts. All submitted mutagenicity studies for the technical product were negative.

cc: S. Levy (RAB1), D. Nixon (RAB1), H. Podall (RD:7505C)
RDI: Chemists (10/12/00), G. Kramer (10/12/00), M. Copley (10/12/00), G. Herndon (10/12/00)
S. Levy:806T:CM#2:(703)305-0783:7509C:RAB1

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Impurity

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