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

JUN 15 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 3125-319; Bayleton: 6(a)(2) Data

FROM: George Z. Ghali, Ph.D.
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TO: Lois Rossi, Product Manager #21
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THRU: Reto Engler, Chief
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Toxicology Branch/HED (TS-769)

Registrant: Mobay Chemical Corp.
Kansas City, MO 64120

Action Requested:

Reevaluation of the Agency's regulatory position on Bayleton in light of new oncogenicity data.

Backgound Information:

Bayleton is a triazole fungicide produced by Mobay Chemical Corporation, and was registered with the Agency in early 1980's for use on a variety of agricultural food commodities.

Data submitted by the registrant in support of the Bayleton registration indicated that the chemical was negative for oncogenicity in both Wistar rats and the CF1 mice. In both studies the MTD was reached.

A recent submission by Mobay Chemical Corporation (draft report) indicated that dietary administration of Bayleton was associated with a statistically significant increase in the incidence of hepatic adenomas in both males and females of the NMRI mice at the highest dose tested. However, in both mouse studies the same dose regimen was used.

Conclusions and Recommendations:

The final report on the subject study has not been submitted to the Agency to date. Pursuant to Section 6(a)(2) of FIFRA as amended, the registrant is requested to submit the final report for the oncogenicity testing in the NMRI mice within a reasonable period of time, along with an adequate historical control summary for the incidence of liver tumors in the NMRI mice and information about the purity of the test chemical.

It is also recommended that no further action be taken regarding Bayleton or additional uses be granted until the subject report is submitted to the Agency and a final decision is made by the Toxicology Branch Peer Review Committee regarding the appropriate classification of Bayleton as an oncogen.

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