



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

JAN 9 1989
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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration Nos. 3125-320 and 3125-340 -
Classification of Acute Inhalation Study on Bayleton
503 WP

Caswell No.: 862AA
Accession No.: 408191-02

FROM: George Z. Ghali, Ph.D.
Science Analysis and Coordination Branch
Health Effects Division (TS-769C)

G. Ghali

TO: Lois A. Rossi, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

THRU: John Quest, Ph.D.
Science Analysis and Coordination Branch
Health Effects Division (TS-769C)

and

Reto Engler, Ph.D., Chief
Science Analysis and Coordination Branch
Health Effects Division (TS-769C)

Reto Engler
[Signature]

Registrant: Mobay Chemical Corporation
Kansas City, MO

Action Requested

A response to Mobay's letter of July 12, 1988 regarding
the classification of an acute inhalation study on Bayleton 503
WP (letter attached).

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HED's Response

The subject study was evaluated by G. Ghali (memorandum dated March 10, 1988). The study is of Core-Minimum quality but was considered to be supplemental or additional information since another acute inhalation study (classified as Core-Minimum) exists in our files.

The subject study is acceptable as Core-Minimum. An action will be taken to revise the records to reflect this fact and clarify this issue.

Attachment

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SUPPLEMENTAL SUBMISSION TO EPA ACCESSION NO. 254697

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8-15-90

Addendum to Report No. 86389

Acute Inhalation Toxicity Study with BAYLETON 50%
Wettable Powder in Rats

Data Requirements

U.S. EPA-FIFRA 158.135
Requirement 81-3

Author

J. P. Rieth

Report Date

June 28, 1987

Performing Laboratory

Mobay Corporation
Health, Environment and Safety
Corporate Toxicology - Data Evaluation Department
17745 South Metcalf
Stillwell, KS 66085-9104

Laboratory Project ID

Report No. 86389

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REQUEST FOR REEVALUATION OF STUDY #86389

As part of the review of a number of studies on the human safety data of BAYLETON (under cover memo dated 5/16/88 from Rossi to Thornton), acute inhalation study #86389 on BAYLETON 50% WP was evaluated. The core-classification applied to this study was supplementary. Mobay does not agree with this classification and requests a reevaluation of the study.

We have evaluated study #86389 against EPA guidelines (NTIS Pub. PB86-113438) and in our opinion, the study is in accordance with accepted protocols. The data evaluation record (DER) submitted by EPA shows the classification of the study as supplementary, but no specific justification is provided to support the classification. Because our analysis indicates that study #86389 is adequate, and, further, because the DER submitted by EPA lists no specific comments, defects or limitations regarding the study, we request that it be reevaluated and the defects, if any, be specified.

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