Reg # 3125-319 PM-22 1 of 5

MAR 14 1991

Mr. John Thornton
Mobay Corporation
P.O. Box 4913
Kansas City, MO 64120

Dear Mr. Thornton:

Subject: Acute Toxicity Data and Revised Precautionary Statements
Bayleton Technical
EPA Registration No. 3125-319
Your Submission Dated September 5, 1990

The amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Make the labeling changes listed below before you release the product for shipment bearing the amended labeling.

   a. In the precautionary statement, "Causes eye irritation" may be deleted.

   b. In the Statement of Practical Treatment, "If in eyes - flush with plenty of water" should suffice.

2. Submit one (1) copy of your final printed labeling before you release the product for shipment.

A stamped copy of the labeling is enclosed for your records.

Precautionary Review Section, Registration Support Branch has reviewed the subject submission and has the following conclusions:

1. The three studies performed at the Toxicology Department of The Mobay Company are acceptable support for this product.

54393:I:Stone:L21-11:KEVRIC:03/11/91:04/06/91:CL:WO:DD:CL

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

2. The inhalation study is guideline data in toxicology Category III.

3. The acute eye irritation is considered Core-Minimum data because:

   a. Penlight is not adequate light source for the observation of ocular lesions.

   b. Fluorescent dye was not used to confirm the observed irritation.

   c. Eighteen-week-old animals, the weights of which were not stated, may have been too heavy and, consequently, too old to be used in the test.

   d. The redness was not observed at 48 hours.

4. The Dermal Irritation test is considered Core-Minimum data because 19-week-old animals may have been too heavy to be used for testing. Providing weight information would have eliminated any doubts.

5. All the studies under EPA Accession No. 2401439-02 are considered Supplementary data for the following reasons:

   a. Emulsifiers and solvents were not well defined. The test material was emulsified in 1:10 mixture of acetone and oil of unspecific identity. It is not stated why acetone was necessary for emulsification as it adds a variable to the test system. This mixture was used in oral, dermal, and intraperitoneal studies as well as dermal irritation. The inhalation study was conducted by dissolving the test material in a 1:1 mixture of ethanol and lutrol with no indication of the strength of either component.

   b. These were no vehicle controls. This was necessary since the emulsifying agents (acetone and oil) or solvents (ethanol and lutrol) can have toxic effects of their own. Control groups were needed.

   c. The weight of the animals was either not mentioned or not specific, or, at times as in the case of oral, dermal, and inhalation rabbits, the animals were overweight. The weight changes during the test are not recorded. Possible weight loss as a toxic symptom is not addressed.

   d. Symptoms of toxicity are not addressed specifically. "General health impairment" is used as description of toxicity, which does not clarify the mode of manifestation. Necropsy information is missing in the majority of cases, which if

BEST AVAILABLE COPY

present would have clarified toxicity to some extent. The exception to this was the oral toxicity study in rats.

e. Inhalation Study

1) The Inhalation study did not present any particle size or size distribution.

2) The chamber atmosphere conditions were conducted according to Eben: Test material was absorbed from the atmosphere in cotton wool, then eluted in benzene and analyzed by gas chromatography. It is not clear for how long the cotton wool was exposed or how often this was done.

3) It is not specified if all the species were exposed at the same time. The exposure of all species at the same time is not acceptable.

4) The chamber concentrations in general were low. It is not stated if these concentration were the highest attainable or other concentrations were not tried.

There were no vehicle controls. Ethanol and lutrol have toxicity of their own which was not addressed.

6. There were no quality assurance statements because use studies were performed in 1974.

7. The Monsanto Corporation says that the eye irritation study is in Toxicity Category III. There is no indication that it is. The guidelines find grade I irritation in the conjunctiva unremarkable. Therefore, it is rated practically not irritating and placed in Toxicity Category IV.

Sincerely yours,

Susan Lewis
Product Manager (21)
Fungicide-Herbicide Branch
Registration Division (H7505C)

BEST AVAILABLE COPY

319-712[illegible].YLD

Base Pre-Reg. (7123)

U.S. LABEL

Reason to Issue: To revise precautionary statements. 10/5/90 Draft: Revise Statements of Practical Treatment.

Date of Draft: 10/5/90 Pre-Reg (T)
Supersedes Pre-Reg Draft Dated: 2/5/90

EPA Reg. No. 3125-319

TO BE PRINTED AS A SINGLE PANEL LABEL

BAYLETON®

Technical

FUNGICIDE

FOR USE IN THE MANUFACTURE OF FUNGICIDES

ACTIVE INGREDIENT: 1-(4-Chlorophenoxy)-3,3-dimethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanone	90%
INERT INGREDIENTS	10%
	100%

EPA Reg. No. 3125-319

U.S. Patent No. 3,912,752

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAR 14 1991

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 3125-319

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

BEST AVAILABLE COPY

KEEP OUT OF THE REACH OF CHILDREN

WARNING

May be fatal if swallowed. Harmful if inhaled or absorbed through skin. Causes eye irritation. Prolonged or frequently repeated skin contact may cause allergic skin reactions in some susceptible individuals. Avoid breathing dust and contact with skin, eyes or clothing. Wash thoroughly with soap and warm water after handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash separately with soap and hot water before reuse.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Detailed information on chemical and physical properties and other formulating recommendations for BAYLETON are available upon request from Mobay. Obtain and read this information before undertaking the formulation of BAYLETON in order to avoid formulation hazards and insure a satisfactory finished product.

Labeling for products formulated from this product must conform to that which is currently registered with the U.S. Environmental Protection Agency. For specific information on federally registered uses, contact Mobay. Any variance from the federally registered labeling for products containing BAYLETON will have to be supported by data provided by the formulator.

BAYLETON is a Reg. TM of Bayer AG, Germany.

NET CONTENTS _____ POUNDS

MOBAY CORPORATION
A Bayer USA INC. COMPANY
AGRICULTURAL CHEMICALS DIVISION
Box 4913, Kansas City, Mo. 64120