



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

CASWELL FILE

864

NOV - 2 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: DEF, Dose Selection for 90-day OPDN Study

TO: Robert Taylor PM-25
Registration Division (H7505C)

FROM: *[Signature]* Robert P. Zendzian Ph.D. 10/31/89
Senior Pharmacologist
SACB, HED (H7509C)

THROUGH: Albin Kocialski Ph.D.
Head
Registration Standards and Special Review Section

Reto Engler Ph.D.
Chief
Science Analysis and Coordination Branch

ABK 11/2/89

Compound; DEF

Tox Chem #864

Registration #3125-282

Registrant; Mobay

Accession #N/A

Tox Project #0-0053

Action Requested

The registrant has completed a rangefinding study for a 90-day delayed neurotoxicity study, by the dermal route, in the hen and requested our comments on the doses for the main study and a minor protocol change.

Response

Based on the results of the rangefinding study the doses proposed, 2.5, 10 and 40 ul/kg, appear to be acceptable. The rationale for not wiping the test site, that the test material does not appear to accumulate and the possibility of irritation to the site, is reasonable. Using a dermal dose of TOCP based on the literature appears rational.

Mobay



Mobay Corporation
A Bayer USA INC COMPANY

Agricultural Chemicals Division

September 26, 1989

Mr. Robert J. Taylor
Product Manager (25)
Environmental Protection Agency
Registration Division H7505C
401 M Street, SW
Washington, D.C. 20460

P O Box 4913
Hawthorn Road
Kansas City, MO 64120-0013
Cable: Kemagro Kansas City
Telephone: 816/242-2000

Subject: DEF 6, EPA Reg. No. 3125-282
90-Day Delayed Neurotoxicity Study, Hen (82-5)

Dear Mr. Taylor:

On August 25, 1989, we received your letter notifying us that our protocol for the subject study was acceptable to the EPA. We have since completed the range-finding study and as a result of this study have made some changes in the proposed rates and procedures of the protocol for the main study. Our Dr. Sangha discussed these changes with Dr. Robert Zendzian on September 11, 1989 and has requested that we send the enclosed summary of the discussion and rationale to document the needed changes. A separate copy of this summary is being forwarded directly to Dr. Zendzian.

Yours very truly,

MOBAY CORPORATION
AGRICULTURAL CHEMICALS DIVISION

A handwritten signature in cursive script that reads "John S. Thornton".

John S. Thornton, Manager
Registrations
Research and Development

JST:MKT:brh
Enclosure

cc: Mr. Robert P. Zendzian
Health Effects Division H7509C (w/encl)

Ms. M.A. Cherny
Rhone-Poulenc (w/encl)