

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

MAR 2 4 1993

010115

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ID. No. 099101, Benchyl, Information to Upgrade Subchronic Inhalation Study

> Tox. Chem. No.: 075A DP Barcode: D182581 Record No.: \$425270

FROM: Melba S. Morrow, D.V.M. Now 3/11/93

Review Section II, Toxicology Branch I

Health Effects Division (H7509C)

Jan 3/12/93 Linda Propst/ Susan Cerrelli, PM 73

Reregistration Division (H7508W)

Karl Baetcke, Ph.D. THRU:

Chief,

Toxicology Branch I

Health Effects Division (H7509C)

CONCLUSIONS:

The registrant has provided information to upgrade their subchronic inhalation study. This information included data on the particle size distribution and the range of mass median aerodynamic diameters during a 90 day inhalation study. the information provided, the study can be upgraded to core minimum. A summary of the supplementary information follows.

DISCUSSION:

With regard to MMAD at 10, 50 and 200 mg/m3, the range was from 1.7 to 2.3 microns, with the smaller MMADs being reported at the lowest concentration. The ranges were determined from 13 or 14 samples. The percent of particles that were < 10um ranged from 94/95 to 100% for the three concentrations. The range of particles < 3um was from 76 - 92, 68 - 76 and 60 - 76 for the low, mid and high concentrations, respectively. Based on the information provided, it is concluded that an adequate concentration of the test material reached the lungs.

In reference to a question raised on the monitoring of food consumption, the registrant states that the decision to monitor food consumption was made following an observation of weight decrements in the high concentration animals.

DP BARCODE: D189392

DATA PACKAGE RECORD BEAN SHEET

SUBMISSION: S437330

DATE: 03/22/93 Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: MISCELLANEOUS ACTION: 405 6(A)(2) ADVERSE DATA

CHEMICALS: ** UNKNOWN **

ID#: 284523

COMPANY: E. I. DU PONT DE NEMOURS AND CO, INC.

PRODUCT MANAGER: 21 SUSAN LEWIS
PM TEAM REVIEWER: CARL GRABLE 703-305-6900 ROOM: CM2 229 703-305-7392 ROOM: CM2 223

RECEIVED DATE: 02/15/93 DUE OUT DATE: 04/26/93

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 189392 EXPEDITE: N DATE SENT: 03/22/93 DATE RET.: /

Unknown

DP TYPE: 001 Submission Related Data Package

ADMIN DUE DATE: 04/16/93 CSF: N LABEL: N

03753793 ASSIGNED TO DATE OUT DIV: EFED 03 13419 BRAN: EEB SECT: REVR: CONTR:

* * * DATA REVIEW INSTRUCTIONS * * *

ATTN: Dan Rieder. MRID #s: 426885-01, 426886-01 and 426879-01. Please review.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL