3-31-86
CASWELL FILE

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 31 1986

MEMORANDUM

SUBJECT: Mancozeb (NRDC) - Screening of Data Submitted Under Accession Nos. 261535, 261536, 261537, 261538, 261539

Caswell No. 913A

FROM: Irving Mauer, Ph.D.
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3-21-86

TO: Arvella Farmer, PM 61
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THRU: Jane E. Harris, Ph.D., Head
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JEH 3/25/86
3/31/86

Registrant: Rohm & Haas Company

Action Requested

(870) Assess the adequacy of the following studies submitted in response to Data Call-In (DCI):

1. Mancozeb: Hazard Identification, Evaluation, and Extrapolation to Humans, P.K. Chan, November 7, 1985 (EPA Accession No. 261535).

2. Mancozeb: Three-Month Dietary Toxicity Study in Rats, P.R. Goldman, H.J. Bernacki, and D.L. Quinn, Report Number 85P-134, February 27, 1986 (EPA Accession No. 261536).

3. Three-Month Dietary Toxicity Study with Mancozeb in Dogs, R.H. Cox, Report Number 86RC-7, February 26, 1986 (EPA Accession No. 261537).

4. Mancozeb: Two-Week Inhalation Toxicity Study in Rats, R.C. Baldwin, J.V. Hagan, and J.R. Fisher, Report Number 85R-0190, February 27, 1986 (EPA Accession No. 261538).

5. Mancozeb: Subchronic Inhalation Toxicity Study in Rats/13-Week Interim Report, R.C. Baldwin, J.V. Hagan, and J.R. Fisher, Report Number 86R-0003, February 27, 1986 and Mancozeb/ETU: Rat Inhalation Study - Exposure Phase: Analysis of Urine, Blood, and Thyroids, Report Number ARM-477-86, February 27, 1986 (EPA Accession No. 261539).

Toxicology Branch Conclusions

This memorandum only addresses that portion of Registration Division's request for an assessment whether the data submitted may satisfy data requirements for the Mancozeb Registration Standard ("re-assessment"). These studies are currently under review for full evaluation and grading, to be available in due course.

From a preliminary screening, it would appear that these studies represent those necessary for satisfying data requirements for subchronic testing in rat and dog by the dietary route, and in the rat by the inhalation route. The following summarizes the reported toxicological data submitted:

Study (1): A comprehensive review of Mancozeb and ETU, containing background toxicological information, hazard identification and evaluation, and extrapolations to humans; appendices on other degradation products and contaminants (EBIS, EU), pharmacokinetics, exposure estimates, and thyroid dysfunction/tumorigenesis interrelationship.

Study (2): Subchronic dietary - rat

Doses fed: 0, 30, 60, 125, 250, and 1000 ppm of Mancozeb; 250 ppm ETU.

Effects: None for Mancozeb at or below 125 ppm; slight change in hormone levels in females fed 250 ppm; depressed body weight and histological changes in thyroid at 1000 ppm.

NOEL: 125 ppm, equivalent to 7.4 and 9.2 mg ai/kg in males and females, respectively.

Study (3): Subchronic dietary - dog

Doses fed: 0, 10, 100, 1000, and 5000 ppm

Effects: None at or below 100 ppm; depressed feed consumption and body weight at 1000 ppm and higher; reduced survival and thyroid effects at 5000 ppm.

NOEL: 100 ppm, equivalent to 3.0 to 3.4 mg ai/kg bw.

Study (4): Subacute inhalation - rat

(To select doses and compare effects of whole body exposure to those of nose-only for 13-week inhalation, study-5.)

Doses tested: 0, 11, 55, and 258 mg/m^3 (respirable conc.).

Results: For whole-body exposure, the "maximum" NOEL was 11 mg/m^3, and LOEL was 55 mg/m^3 (lower body weight gain and T3 levels in males, T4 levels in both sexes). For nose-only exposure, NOEL was 55 mg/m^3 and LOEL 258 mg/m^3 (lower male body weight gains and T3/T4 levels; histopathological changes in respiratory tract of both sexes).

Study (5): Subchronic inhalation - rat

Doses tested: 0, 18, 79, and 326 mg/m^3 (nose-only aerosol concentration).

Interim sacrifice: One-half each group at 13 weeks.

Effects: None at or below 79 mg/m^3; body weight changes and thyroid effects at HDT (326 mg/m^3).

Terminal sacrifice: (No Mancozeb exposure for ensuing 13-week period, in order to study reversibility and recovery.)

[NB: Results of this recovery phase not submitted.. Final Report due May 1, 1986.]

cc: Judy Hauswirth
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