

PMSD/ISB
0250-E



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

EXPEDITE

OCT 31 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Registration No. 707-78. Special Review Action Code 870. Mancozeb Data Call-In. Product Chemistry of Rohm & Haas Dithane M-45®. Submission of April 25, 1985. Accession No. 257953. [RCB No. 87]

FROM: Martha J. Bradley, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

R. J. Quick for

TO: Henry Jacoby, PM 21
Insecticide-Rodenticide Branch
Registration Division (TS-767C)

and

Susan Lewis,
Data Call-In
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

A large, stylized handwritten signature in black ink, likely belonging to Charles L. Trichilo.

This EBDC data package was submitted in connection with the NRDC suit. It is being expedited at the request of the HED Deputy Director.

Rohm & Haas has submitted product chemistry data for Dithane M-45®, EPA Registration Nos. 707-78, 707-97, 707-102, 707-7617, 707-7618, and 707-7621.

The submitted items are listed below in the format of the Product Chemistry Guidelines, Subdivision D of 40 CFR 158 along with our comments/conclusions on the adequacy of the submission.

Series 61: Product Identity and Disclosure of Ingredients

Rohm & Haas Response:

(61-1A) Product Identity

Mancozeb is [[1,2-ethanediy]bis[carbamo]dithioato]](2-) manganese and [[1,2-ethanediy]bis[carbamo]dithioato]](2-) zinc. The trade name is Dithane M-45®, CAS No. 8018-01-7, company code 6-2423, other name zinc-manganese (II) ethylenebis dithiocarbamate. Mancozeb is a coordination complex of zinc and maneb containing 20 percent manganese and 2.5 percent zinc. Mancozeb is a polymeric, noncrystalline solid according to X-ray diffraction studies. Molecular weight distributions are unknown for this solid, however, the molecular weight for its monomeric composition is calculated to be 271.

The structural formula is:
$$\left[-\text{Mn} \overset{\text{S}}{\parallel} \text{NHC} \text{H} \text{CH}_2 \text{CH}_2 \text{NHC} \overset{\text{S}}{\parallel} \text{S} - \right]_x (\text{Zn})_y$$

(61-1B) Disclosure of Ingredients

Dithane M-45® 80 WP is manufactured as an end-use product.

Certified limits and analytical accountability data are included on page 1 of the Confidential Appendix, attachment 2 of this review.

(61-1C) Purpose of Active Ingredients and Intentionally Added Inert Ingredients

Dithane M-45® is used to protect fruit, vegetables, nut, and field crops from a wide spectrum of plant diseases.

For each intentionally added inert ingredient, the name, purpose, and CAS No. are included on page 2 of the Confidential Appendix, attachment 2 of this review.

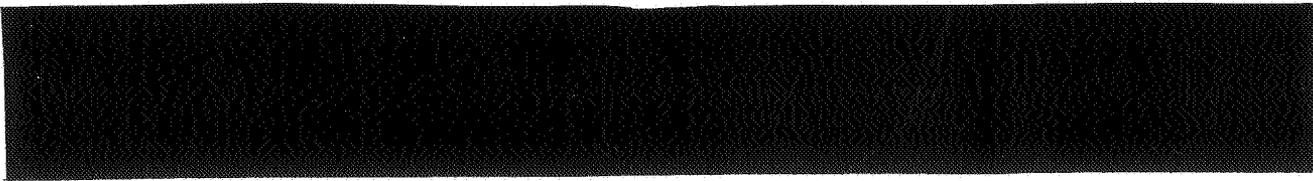
Conclusion 61-1

Rohm & Haas has complied with the data requirements under 61-1 of the Product Chemistry Guidelines, Subdivision D.

(61-2) Description of Beginning Materials and Manufacturing Process

Rohm & Haas Response:

(61-2A) Description of Beginning and Intermediate Materials



(61-2B) Basic Manufacturing Process



A brief summary of the manufacturing process is included on page 2 of the Confidential Appendix, attachment 2 of this review.

Conclusion 61-2

Rohm & Haas has complied with the data requirements under 61-2 of the Product Chemistry Guidelines, Subdivision D.

(61-3) Discussion of the Formation of Impurities

Rohm & Haas Response:

Impurities present or believed to be present in Dithane M-45® are discussed in terms of their formation based upon

INFORMATION WHICH MAY REVEAL A MANUFACTURING PROCESS IS NOT INCLUDED

experience or actual analysis. This discussion is divided in the following manner:



A list of all of the known and potential Dithane M-45® impurities according to their accepted chemical name, common name, acronym, and Chemical Abstracts Registry number (where available) are included on pages 3 and 4 of the Confidential Appendix, attachment 2 of this review.

A discussion of these impurities is also included on pages [5 thru 10] of the Confidential Appendix, attachment 2 of this review.

Conclusion 61-3

Rohm & Haas has complied with the data requirements under 61-3 of the Product Chemistry Guidelines, Subdivision D.

(62-2) Certification of Ingredient Limits

Rohm & Haas Response:

Upper and lower limits are certified for the active ingredient and each intentionally added inert ingredient in Dithane M-45®. Upper limits are certified for various impurities. This information is on page 1 of the Confidential Appendix, attachment 2 of this review.

Conclusion 62-2

Rohm & Haas has complied with the data requirements under 62-2 of the Product Chemistry Guidelines, Subdivision D.

(62-3) Analytical Methods to Verify Certified Limits

Rohm & Haas Response:

Analytical methods for the certification of ingredients have been submitted. "Identity Procedures to Distinguish Mancozeb from other EBDC Fungicides" are also submitted.

The analytical methodology is discussed on page 6 of the Confidential Appendix, attachment 2 of this review.

Conclusion 62-3

Recovery data are needed for the analytical methods to verify certified limits. See conclusions on page 8 of the Confidential Appendix, attachment 2 of this review for details of needed data.

(63-1) Physical and Chemical Properties

The submitted physical and chemical properties are listed on page 8 of the Confidential Appendix, attachment 2 of this review.

Conclusion 63-1

The following additional information should be submitted:

1. Units of the bulk density.
2. Temperature of bulk density and water solubility tests.

Conclusions and Recommendations

1. With three exceptions, Rohm & Haas has complied with the data requirements of the Product Chemistry Guidelines, Subdivision D.
2. Recovery data for the analytical methods to verify certified limits should be submitted. See Conclusions 62-3 on page 6 of the Confidential Appendix, attachment 2 of this review for details of the needed data and our comments on certified limits of one of the manufacturing impurities.

3. The units of the bulk density and temperature of the bulk density and water solubility tests should be submitted.
4. The registrant should be informed that upon completion of our review of all relevant metabolism and residue data requested and the metabolism/degradation products of toxicological concern are identified, additional product chemistry information may be requested.

Attachment 1: Table A (2 pages)

Attachment 2: Confidential Appendix (10 pages)

cc: with Attachments 1 and 2: M. Bradley, R.F., EBDC SF, TOX, H. Jacoby (PM#21), PMSD/ISB (Eldridge)

cc: with Attachment 1: F. Sanders, S. Lewis, Amy Rispin, circu

RDI:Section Head:R.Quick:Date:10/22/85:RSQ:10/22/85

TABLE A
 GENERIC DATA REQUIREMENTS FOR CHEMICAL: Dithane M-45®

\$158.120 - PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required? Yes No	Footnote Number
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Product Identity:

61-2 - Product Identity and Disclosure of Ingredients	TGAI	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	_____
61-3 - Discussion of Formation of Impurities	TGAI	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	_____

Analysis and Certification of Product Ingredients

62-1 - Preliminary Analysis	TGAI	CR	<input type="checkbox"/> <input checked="" type="checkbox"/>	_____
62-2 - Certification of Limits	TGAI	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	_____
62-3 - Analytical Methods to Verify Certified Limit	TGAI	R	<input checked="" type="checkbox"/> <input type="checkbox"/>	<u>Validation data</u>

Physical and Chemical Characteristics

63-2 - Color	TGAI	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	_____
63-3 - Physical State	TGAI	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	_____
63-4 - Odor	TGAI	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	_____
63-5 - Melting Point	TGAI	R	<input type="checkbox"/> <input checked="" type="checkbox"/>	_____
63-6 - Boiling Point	TGAI	N/A	<input type="checkbox"/> <input checked="" type="checkbox"/>	_____

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DATA REQUIREMENT FOOTNOTES:

CHEMISTRY WORKTABLES

TABLE A
 GENERIC DATA REQUIREMENTS FOR CHEMICAL: Dithane M-45®

S158.120 - PRODUCT CHEMISTRY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required?		Footnote Number
			Yes	No	

Physical and Chemical Characteristics
 (Continued)

63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	temp, units
63-8 - Solubility	TGAI or PAI	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	temp
63-9 - Vapor Pressure	PAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
63-10 - Dissociation constant	PAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
63-11 - Octanol/water partition Coefficient	PAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
63-12 - PH	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
63-13 - Stability	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
<u>Other Requirements:</u>					
64-1 - Submittal of samples	TGAI, PAI	CR	<input type="checkbox"/>	<input type="checkbox"/>	

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 R = Required; CR = Conditionally Required; TGAI = Technical Grade of the Active Ingredient;
 PAI = Pure Active Ingredient

DATA REQUIREMENT FOOTNOTES:

Page _____ is not included in this copy.

Pages 9 through 18 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients
 - Identity of product impurities
 - Description of the product manufacturing process
 - Description of product quality control procedures
 - Identity of the source of product ingredients
 - Sales or other commercial/financial information
 - A draft product label
 - The product confidential statement of formula
 - Information about a pending registration action
 - FIFRA registration data
 - The document is a duplicate of page(s) _____
 - The document is not responsive to the request
-

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
