

US EPA ARCHIVE DOCUMENT



CONFIDENTIAL

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

JUN 10 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Data Call In for Products Containing Mancozeb
Mancozeb Registration Standard

ID NO(S). 352-341, 398, 343, 449
RCB NO(S). 3044, 3405, 3406, 3407
MRID NO(S). 405175-00, 01, and 02

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Hazard Evaluation Division (TS-769C)

TO: Lois Rossi (PM-21)
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THRU: William J. Boodee, Section Head *WJB*
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Hazard Evaluation Division (TS-769C)

In response to the data call in for products containing mancozeb as the active ingredient, E. I. du Pont de Nemours & Company (Inc.) has submitted reports on the product chemistry, on the unregistered technical chemical and a method for determination of the active ingredient in the mancozeb products. The information/data provided and our conclusions are discussed below. In addition, Table A is included to reflect the remaining product chemistry data requirements.

61-1 product Identity and Disclosure of Ingredients

No additional information is required on this topic.

61-2 Description of Beginning Materials and Manufacturing Process

The information provided appears in Confidential Appendix A.

No additional information is required to satisfy the data requirements for this topic.

(2)

61-3 Discussion of Formation of Impurities

The registrant has provided a discussion on the formation of impurities, no additional information is needed.

62-3 Analytical Methods to Verify Certified Limits

The information/data provided appears in Appendix B.

Methodology suitable for distinguishing mancozeb from other potential carbon disulfide producing contaminants must be provided. The method(s) must be accompanied by validation studies indicating accuracy and precision.

63-Series Physical and Chemical properties

The physical and chemical properties for mancozeb as reported by the manufacturer are as follows.

- 63-2 - Color: Yellow
- 63-3 - physical State: Powder
- 63-4 - Odor: Slight sulfur
- 63-7 - density: 33.8
- 63-8 - Solubility: Product exists as an insoluble polymer.
- 63-9 - Vapor Pressure: N/A
- 63-10- Dissociation Constant: Dissolving the product in water results in its destruction.
- 63-11- Octanol/Water Partition Coefficient: N/A, due to explanations provided for 63-8 and 63-10.
- 63-12- pH: 7.6 (10% slurry).
- 63-13- Stability: A loss of 0.5% activity/month at 28-31 degrees C, test period = 24 months.

ATTACHMENTS:

Attachment I - Table A (2 pages)

cc: Mancozeb Registration Standard File, SF, Reviewer
(H. Fonouni), RBP, TOX (R. Coberly), PMSD/ISB (E. Eldredge),
PM 21 (L. Rossi)

Attachment II - Confidential Appendix A (1 page)

Attachment III - Confidential Appendix B (2 pages)

cc: Mancozeb Registration Standard File, SF, Reviewer
(H. Fonouni), RBP, TOX (R. Coberly), PMSD/ISB (E. Eldredge),
PM 21 (L. Rossi).

cc: Mancozeb Registration Standard File, SF, RF, Reviewer
(H. Fonouni), RBP, TOX (R. Coberly), PMSD/ISB (E. Eldredge);
PM 21 (L. Rossi), Circu.

(3)

TABLE A
 GENERIC DATA REQUIREMENTS FOR THE UNREGISTERED TECHNICAL MANCOZEB, E. I. DU PONT DE NEMOURS & COMPANY, INC.

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Reference Citation (MTRD No.)
			[Yes]	[No]	
<u>40 CFR 158.120 Product Chemistry</u>					
<u>Product Identity and Composition</u>					
61-1 - Identity of Ingredients	TGAI	R		X	405175-02
61-2 - Materials and Process	TGAI	R		X	405175-02
61-3 - Formation of Impurities	TGAI	R		X	405175-02
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	TGAI	R	X ¹		
62-2 - Certification of Ingredient Limits	TGAI	R	X		
62-3 - Analytical Methods to Verify Certified Limits	TGAI	R	X ¹		405175-01
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	TGAI	R		X	405175-02
63-3 - Physical State	TGAI	R		X	405175-02
63-4 - Odor	TGAI	R		X	405175-02
63-5 - Melting Point	TGAI	R		X	405175-02
63-6 - Boiling Point	TGAI	N/A ²			
63-7 - Bulk Density	TGAI	R		X	405175-02
63-8 - Solubility	TGAI or PAI	R	X		405175-02
63-9 - Vapor Pressure	PAI	R		X	405175-02
63-10 - Dissociation Constant	PAI	R	X		405175-02
63-11 - Octanol/Water Partition Coefficient	PAI	R	X		405175-02
63-12 - PH	TGAI	R		X	405175-02

(Continued, footnotes follow)

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TABLE A
GENERIC DATA REQUIREMENTS FOR THE UNREGISTERED TECHNICAL MANCOZEB, E. I. DU PONT DE NEMOURS & COMPANY, INC.

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Reference Citation (MIRD No.)
			[Yes]	[No]	
158.120 Product Chemistry (Cont'd)					
Physical and Chemical Characteristics					
63-13- Stability	TGAI	R	X		405175-02
<u>Other Requirements</u>					
64-1 - Submittal of Samples	TGAI and PAI	CR ³		X	

TGAI = Technical Grade Active Ingredient (Technical Chemical); PAI = Purified Active Ingredient; R = Required; CR = Conditionally Required; N/A = Not Applicable.

1/ A complete description of each analytical method used to analyze the active ingredient and each impurity present at a level $\geq 0.1\%$ (w/w) of the product must be provided. The methods used for the analysis of the active ingredient must distinguish mancozeb from other potential carbon disulfide producing contaminants.

2/ Not applicable, since the product is a solid at room temperature.

3/ If samples are needed, the Agency will request them.

Page _____ is not included in this copy.

Pages 5 through 7 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
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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.
