

US EPA ARCHIVE DOCUMENT



CONFIDENTIAL

11172

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

JUL 1 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Mancozeb Registration Standard

ID NO(S). 707-78, 707-102
RCB NO(S). 3835, 3839, 3889
MRID NO(S). 406059-00, 01; 406060-00, 01; 406207-00,
01

FROM: H. Fonouni, Ph.D., Chemist *H. E. Fonouni*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Lois Rossi (PM-21)
Herbicide/Fungicide Branch
Registration Division (TS-767C)

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

In response to the Mancozeb Registration Standard (Guidance Document, April 1987 and Task 1, September 10, 1986), Rohm and Haas Company has forwarded product chemistry information/data on both the unregistered technical chemical and a manufacturing-use product, Dithane M-45^R Concentrate (EPA Registration No. 707-102). The information/data submitted and our conclusions are discussed below. In addition, revised Tables A and B have been included to reflect the remaining product chemistry data requirements.

62-1 Preliminary Analysis of Product Samples

The information/data provided appears in Appendixes A and B for the unregistered technical chemical and the manufacturing-use product, respectively.

The information/data provided does not satisfy the requirements for this topic. Compositional analysis must be provided for the manufacturing-use product, including its impurities, using method(s) which would distinguish mancozeb from other potential carbon disulfide producing contaminants.

62-2 Certification of Ingredient Limits

The information/data provided for the manufacturing-use product (Dithane^R M-45 Concentrate) appears in Confidential Appendix C.

Certified limits reported for the active ingredient/impurities are not adequate. Certified limits must be established for the product, including its impurities, using method(s) which would distinguish mancozeb per se from other potential carbon disulfide producing contaminants. In addition, certified limits (upper) must be established for any other impurity which is found to be present at $\geq 0.1\%$ (w/w) of the product (refer to Confidential Appendix C). Certified limit (upper) must also be established for nitrosamines using a validated methodology.

Certified limits must be reported on EPA Form 8570 (Rev. 2-85).

62-3 Analytical Methods to Verify Certified Limits

The information/data submitted appears in Confidential Appendix D. Analytical methodologies have been provided for the active ingredient and various impurities/inerts. A number of the submitted methods were found to be identical to those provided previously (EPA Accession Nos. 257953, 262839). The new submissions have been reviewed in Confidential Appendix D.

Information/data gaps remain for this topic; refer to Confidential Appendix D.

Attachment I - Tables A and B (4 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 (2 pages)
Attachment III - Confidential Appendix B (2 pages)
Attachment IV - Confidential Appendix C (3 pages)
Attachment V - Confidential Appendix D (4 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 MANCOZEB¹, ROHM AND HAAS COMPANY

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Reference Citation (MIRD No.)
			[Yes]	[No]	
<u>40 CFR 158.120 Product Chemistry</u>					
Product Identity and Composition					
61-1 - Identity of Ingredients	TGAI	R		X	
61-2 - Materials and Process	TGAI	R	X		
61-3 - Formation of Impurities	TGAI	R	X		
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	TGAI	R		X	406059-02
62-2 - Certification of Ingredient Limits	TGAI	N/A		X	
62-3 - Analytical Methods to Verify Certified Limits	TGAI	N/A		X	
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	TGAI	R	X		
63-3 - Physical State	TGAI	R	X		
63-4 - Odor	TGAI	R	X		
63-5 - Melting Point	TGAI	R	X		
63-6 - Boiling Point	TGAI	N/A ²		X	
63-7 - Bulk Density	TGAI	R	X		
63-8 - Solubility	TGAI or PAI	R	X		
63-9 - Vapor Pressure	PAI	N/A		X	
63-10- Dissociation Constant	PAI	R	X		
63-11- Octanol/Water Partition Coefficient	PAI	R	X		
63-12- PH	TGAI	R	X		

(Continued, footnotes follow)

W

(4)

TABLE A
 GENERIC DATA REQUIREMENTS FOR THE UNREGISTERED TECHNICAL MANCOZEB¹, ROHM AND HAAS COMPANY

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	TGAI	R	X		
63-13- Stability					
Other Requirements					
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/ [REDACTED] The technical material was specifically produced in the laboratory to satisfy the data requirements.
 2/ Not applicable, since the product is a solid at room temperature.
 3/ If samples are needed, the Agency will request them.

(5)

TABLE B

DATA REQUIREMENTS FOR THE MANUFACTURING-USE PRODUCT CONTAINING MANCOZEB, ROHM AND HAAS COMPANY
(DIITHANE[®] M-45 CONCENTRATE, EPA REGISTRATION NO. 707-102)

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Reference Citation (MRD No.)
			[Yes]	[No]	
<u>40 CFR 158.120 Product Chemistry</u>					
<u>Product Identity and Composition</u>					
61-1 - Identity of Ingredients	MP	R		X	
61-2 - Materials and Process	MP	R	X		
61-3 - Formation of Impurities	MP	R	X		
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	MP	R	X ¹		406207-01
62-2 - Certification of Ingredient Limits	MP	R	X		406207-01, 40373401 ²
62-3 - Analytical Methods to Verify Certified Limits	MP	R	X		406207-01 ³
<u>Physical and Chemical Characteristics⁴</u>					
<u>Other Requirements</u>					
64-1 - Submittal of Samples	MP	CR ⁵			

MP = Manufacturing-Use Product; N/A = Not Applicable; CR = Conditionally Required
1/ Compositional analysis must be provided for the manufacturing-use product, including its impurities, using method(s) which would distinguish mancozeb per se from other potential carbon disulfide producing contaminants

2/ Data has also been provided on EPA Form 8570 attached to a letter dated July 6, 1987.

(6)

(Footnotes continued)

- 3/ Information/data has also been submitted in reports with EPA Accession Nos. 257953 and 262839.
- 4/ As requested by the Registration Division, The Residue Chemistry Branch no longer reviews the physical/chemical properties of manufacturing-use products.
- 5/ If samples are needed, the Agency will request them.

Page _____ is not included in this copy.

Pages 7 through 13 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.

Page _____ is not included in this copy.

Pages 14 through 17 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.
