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CONFIDENTIAL

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

JUL 28 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Pennwalt Corporation's Response to the Mancozeb Registration Standard

ID NO(S). 4581-357, 4581-358
RCB NO(S). 4020
MRID NO(S). 406522-00, 01

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

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

THRU: William J. Boodee, Section Head
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), Pennwalt Corporation has forwarded product chemistry information/data to an unregistered technical chemical. The information/data submitted and our conclusions are discussed below. In addition, a revised Table A has been included to reflect the remaining product chemistry data requirements for this material.

62-1 Preliminary Analysis of Product Samples

The information/data provided appear in Confidential Appendix A.

The information/data provided do not satisfy the requirements for this topic. Compositional analysis must be provided for the unregistered technical using method(s) which would distinguish mancozeb per se from other potential carbon disulfide producing contaminants.

Validation data must be provided for the analytical methods used; refer to Confidential Appendix C.

62-2 Certification of Ingredient Limits

The information/data provided appear in Confidential Appendix B.

The information/data provided do not satisfy the requirements for this topic. Certified limits must be established for products containing the unregistered technical using method(s) which would distinguish mancozeb per se from other potential carbon disulfide producing contaminants.

Certified limits must be established based on the actual variability of various ingredients in mancozeb products as indicated from preliminary analysis of the product samples; refer to Confidential Appendix B. In addition, certified limits must 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 appear in Confidential Appendix C. Analytical methodologies have been provided for various ingredients.

The information/data provided do not satisfy the requirements for this topic; detailed descriptions of analytical method(s) capable of distinguishing mancozeb per se from other potential carbon disulfide producing contaminants must be provided.

Validation data should be submitted for the methods which have been provided (refer to Confidential Appendix C).

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)
Attachment IV - Confidential Appendix C (3 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.

TABLE A
GENERIC DATA REQUIREMENTS FOR THE UNREGISTERED TECHNICAL MANCOZEB, PENNWALT CORPORATION

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required? [Yes]	[No]	Reference Citation (MIRD No.)
40 CFR 158.120 Product Chemistry					403812-01
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	
Analysis and Certification of Product Ingredients					406522-01
62-1 - Preliminary Analysis	TGAI	R	X[1]		
62-2 - Certification of Ingredient Limits	TGAI	R	X[2]		
62-3 - Analytical Methods to Verify Certified Limits	TGAI	R	X[3]		
Physical and Chemical Characteristics					403812-02
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[4]		X	
63-7 - Bulk Density	TGAI	R		X	
63-8 - Solubility	TGAI or PAI	R		X	
63-9 - Vapor Pressure	PAI	R		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)

TABLE A
GENERIC DATA REQUIREMENTS FOR THE UNREGISTERED TECHNICAL MANCOZEB, PENNWALT CORPORATION

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required? [Yes]	[No]	Reference Citation (MIRD No.)
158.120 Product Chemistry (Cont'd)					
Physical and Chemical Characteristics					
63-13- Stability	TGAI	R	X		
Other Requirements					
64-1 - Submittal of Samples	TGAI and PAI	CR[5]		X	

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

1/ Compositional analysis must be provided using method(s) which would distinguish mancozeb per se from other potential carbon disulfide producing contaminants.

2/ Certified limits must be established for products containing the unregistered technical using analytical method(s) which would be specific for mancozeb per se. Certified limits should be based on the actual variability of ingredients in the product.

3/ A complete description of analytical method(s) capable of distinguishing mancozeb per se from other potential carbon disulfide producing contaminants must be provided. Validation data should be submitted for the methods used.

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

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

Mancozeb residue chemistry review

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

X 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.

Mancozeb residue chemistry review

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Pages 8 through 10 are not included in this copy.

The material not included contains the following type of information:

___ Identity of product inert ingredients

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