



4-11-89

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

APR 11 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Pennwalt Corporation - Response to the Reregistration
Guidance Document for Maneb (RCB No. 5004)

FROM: Gobind P. Makhijani, Chemist *G. Makhijani*
Dietary Exposure Branch
Health Effects Division (H7509C)

TO: Susan Lewis/Carl Grable, PM Team 21
Fungicide-Herbicide Branch
Registration Division (H7505C)

THRU: William J. Boodee, Section Chief *WJB*
Reregistration Section
Dietary Exposure Branch
Health Effects Division (H7509C)

On February 10, 1989, Pennwalt Corporation submitted to EPA their response to the Reregistration Guidance Document for Maneb issued by the Agency in October 1988.

Dietary Exposure Branch has been requested by the Registration Division to verify the accuracy of the response submitted by the registrant.

Tables giving our comments regarding the registrant's response to the data gaps in the product and residue chemistry chapters are attached. The PM should note that the residue data referenced by the registrant have been reviewed only for compliance with the earlier Special Review Data Call-In Notice of 3/31/87, and not for compliance with the Maneb Reg. Std. [See S. Hummel reviews of 6/30/88, (DEB #3530, 3531, 3552, 3553, 3555) 8/25/88, and 12/13/88 (DEB #4570)].

Attachment

cc: Maneb Standard File, S.F., R.F., GPM, RBP, Susan Hummel, Circ., S. Lewis (PM 21), PMSD/ISB (E. Eldredge), TOX (Coberly).

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PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988

Data Requirement	Due to EPA	Registrant Response	DEB Comments
Part 158 <u>Subpart C - Product Chemistry</u>			
Confidential Statement of Formula (MP & EP)	02/89	Submitted 02/08/89.	DEB has not yet received the updated Confidential Statement of Formula.
<u>Product Identity</u>			
61-2 - Description of Beginning Materials and Manufacturing Process (TGAI)	10/87	Submitted 03/10/88. MRID No. 405534-01	The references cited by the registrant are correct. The data were included in the "Maneb Update No. 3, Product Chemistry Chapter," dated April 29, 1988. No further information is required from the registrant.
61-3 - Discussion of Formation of Impurities (TGAI)	10/87	Submitted 03/10/88. MRID No. 405534-01	
<u>Analysis and Certification of Product Ingredients</u>			
62-1 - Preliminary Analysis (TGAI)	04/88	Submitted 03/10/88. MRID No. 405534-02	do.
<u>Physical and Chemical Characteristics</u>			
63-2 - Color (TGAI)	10/87	Submitted 03/10/88. MRID No. 405534-03	do.
63-3 - Physical State (TGAI)	10/87	Submitted 03/10/88. MRID No. 405534-03	do.

PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
<u>Physical and Chemical Characteristics</u> (cont'd)			
63-4 - Odor (TGAI)	10/87	Submitted 03/10/88. MRID No. 405534-03	do.
63-5 - Melting Point (TGAI)		N/A	do.
63-6 - Boiling Point (TGAI)		N/A	do.
63-7 - Density, Bulk Density, or Specific Gravity (TGAI)	10/87	Submitted 03/10/88. MRID No. 405534-03	do.
63-8 - Solubility (TGAI or PAI)	10/87	Submitted 03/10/88. MRID No. 405534-03	do.
63-9 - Vapor Pressure (TGAI or PAI)	10/87	Submitted 03/10/88. MRID No. 405534-03	do.
63-10 - Dissociation Constant (TGAI or PAI)	10/87	Submitted 03/10/88. MRID No. 405534-03	do.
63-11 - Octanol/Water Partition Coefficient (PAI)	10/87	Submitted 03/10/88. MRID No. 405534-03 ETU Submitted 06/07/88. MRID No. 40651001	do.
63-12 - pH (TGAI)	10/87	Submitted 03/10/88. MRID No. 405534-04	do.
63-13 - Stability (TGAI)	10/87	Submitted 03/10/88. MRID No. 405534-04	do.

PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
<u>Other Requirements</u> 64-1 - Submittal of Samples <u>\$158.240 - Residue Chemistry</u> 171-2 - Chemical Identity		N/A N/A (See Product Chemistry Requirements)	
171-2 - Directions for Use 171-4 - Nature of Residue (Metabolism) - Plants (PAIRA)	05/10/89 10/88	To be submitted. Pennwalt has requested extensions until 12/89. ¹⁴ C-maneb has been synthesized. Studies have been initiated on three (3) crops: tomatoes, potatoes, lettuce. Apple trials will not be conducted.	Residue data using dust formulations not submitted. DEB recommends cancellation of all registrations using dusts. Request reviewed by DEB (S. Hummel) on 02/27/89. DEB recommended denial. DEB recommends that PM take appropriate action (DEB No. 4229).
- Livestock (PAIRA & Plant Metabolites)	10/88	Pennwalt has requested extensions until 12/89. ¹⁴ C-maneb has been synthesized. Poultry will be dosed in 2/89; goat 4/89.	do.

PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
174-4 - Residue Analytical Method (TCAI & Metabolites)		Submitted 07/12/88. MRID No. 407320-01	A confirmatory enforcement method capable of differentiating among the various EBDCs and other pesticides which degrade to CS ₂ is still needed. Multiresidue method was reviewed by DEB (L. Cheng) on September 16, 1988 (DEB No. 4215).
171-4 - Storage Stability (TEP & Metabolites)	09/88	As per agreement with Agency, the following RAC storage stability has been submitted for: Apples, MRID No. 405401-16, Lettuce, MRID No. 405401-17, Potatoes, MRID No. 405402-18, Spinach, MRID No. 405401-19, Tomatoes, MRID No. 405401-14, Processing storage stability has been conducted for: Apples, MRID No. 405401-24, Grapes, MRID No. 405401-22 Green Beans, MRID No. 405401-20, Potatoes, MRID No. 405401-21, Sugar Beets, MRID No. 40540123, Tomatoes, MRID No. 405401-15.	References cited by the registrant were reviewed by DEB (S. Hummel) on June 30, 1988. Data adequate only for residue studies conducted at the same time as storage stability studies for 1987 growing season. All future residue studies also need new storage stability data run at the same time. Previous storage stability data are invalid due to poor storage stability of maneb and ETU. All residue samples should be analyzed as soon as possible after harvest. The registrants references have been corrected.
174-4 - Magnitude of the Residue Residue Studies for Each Food Use			

PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
<u>Crop Group No. 1 - Root & Tuber Vegetables</u>			
Crop 1 - Carrots - Crop Field Trials	10/88	Not on current label. Trials will not be conducted.	DEB recommends that carrots be removed from all maneb labels and tolerances be revoked.
Crop 2 - Potatoes - Crop Field Tests (TEP) - Processed Food/Feed (EP)	10/88 04/89	MRID Nos. 405401-10 and 408362-08. Waiver requested, no residues in 5X RAC.	See DEB reviews dated June 30 and December 18, 1988. Request for waiver for processed potatoes not received. Registrant's reference corrected.
Crop 3 - Sugar Beet Roots - Crop Field Trials (TEP)	10/88	MRID No. 405873-05	
- Processed Food/Feed (EP)	04/89	MRID No. 405401-12	Registrant's reference was corrected.
Crop 4 - Turnip Roots - Crop Field Trials (TEP)		N/A, sugar beet data will support.	We agree.
<u>Crop Group No. 2 - Leaves of Root & Tuber Vegetables</u>			
Crop 1 - Sugar Beet Top - Crop Field Trials (TEP)	10/88	Feeding restriction on label. Trials will not be conducted. MRID No. 405873-05	No record of feeding restriction on label. The label should be amended. We note that residue data were submitted.

PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
Crop 2 - Turnip Tops - Crop Field Trials (TEP)		Feeding restriction on label. Trials will not be conducted.	do.
<u>Crop Group No. 3 - Bulb Vegetables</u>			
Crop 1 - Onions - Crop Field Trials (TEP)	10/88	Green onions, MRID Nos. 405401-13 and 408362-06. Bulb onions, study in progress.	The data are overdue. The PM should take appropriate action.
<u>Crop Group 4 - Leafy Vegetables</u>			
Crop 1 - Celery - Crop Field Trials (TEP)	10/88	Not on label. Trials will not be conducted.	Remove celery from all maneb labels and revoke tolerance.
Crop 2 - Endive - Crop Field Trials (TEP)	10/88	N/A, lettuce data will support.	We agree.
Crop 3 - Lettuce - Crop Field Trials (TEP)	10/88	MRID 405401-09	Data received from California only.
Crop 4 - Rhubarb - Crop Field Trials (TEP)	10/88	Will not support.	Remove rhubarb from the label and revoke tolerance.
Crop 5 - Spinach - Crop Field Trials (TEP)	10/88	MRID Nos. 405401-11 and 408362-04. Requested extension for AZ data until March 31, 1989.	The data were reviewed by DEB (S. Hummel) on 01/27/89 and recommended for extension of date.

PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
Crop Group No. 5 - Brassica Leafy Vegetables			
Crop 1 - Broccoli - Crop Field Trials (TEP)	10/88	MRID No. 405401-07	Data received from California only.
Crop 2 - Brussels Sprouts - Crop Field Trials (TEP)		N/A, broccoli data will support - not on label.	We agree.
Crop 3 - Cabbage - Crop Field Trials (TEP)	10/88	MRID Nos. 405401-06 and 408362-02	Data reviewed by DEB (S. Hummel (DEB No. 4570)).
Crop 4 - Cauliflower - Crop Field Trials (TEP)		N/A, broccoli data will support - not on label.	We agree.
Crop 5 - Chinese Cabbage - Crop Field Trials (TEP)	10/88	Will not support.	Remove Chinese cabbage from <u>all</u> labels and revoke tolerance.
Crop 6 - Collards - Crop Field Trials (TEP)		N/A, spinach data will support.	We agree.
Crop 7 - Kale - Crop Field Trials (TEP)	10/88	MRIDs Nos. 405401-08 and 40836205	Data were reviewed by DEB (S. Hummel) (DEB No. 4570).
Crop 8 - Kohlrabi - Crop Field Trials (TEP)		N/A, broccoli data will support - not on label.	We agree.
Crop 9 - Mustard Green - Crop Field Trials (TEP)		N/A, spinach data will support - not on label.	We agree.

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PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
<u>Crop Group No. 6 - Legume Vegetables</u>			
Crop 1 - Beans (Succulent and Dry)			
- Crop Field Trials (TEP)	10/88	MRID Nos. 405401-05 and 405873-03	References are correct.
- Processed Food/Feed (EP)	04/89	MRID No. 405873-02	
<u>Crop Group No. 7 - Fruiting Vegetables</u>			
Crop 1 - Eggplant			
- Crop Field Trials (TEP)		N/A, tomato data will support.	We agree.
Crop 2 - Peppers			
- Crop Field Trials (TEP)	10/88	MRID Nos. 405401-04 and 408362-03	References corrected.
Crop 3 - Tomatoes			
- Crop Field Trials (TEP)	10/88	MRID No. 405873-07	We agree.
- Processed Food/Feed (EP)	04/89	MRID No. 405873-06	
<u>Crop Group No. 8 - Cucurbit Vegetables</u>			
Crop 1 - Cucumbers			
- Crop Field Trials (TEP)	10/88	MRID Nos. 405873-01 and 408362-07	We agree.
Crop 2 - Melons			
- Crop Field Trials (TEP)	10/88	MRID Nos. 405401-03 and 408362-01	We agree.
Crop 3 - Pumpkins			
- Crop Field Trials (TEP)		N/A, melon data will support.	We agree.

PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
Crop 4 - Squash - Crop Field Trials (TEP)		N/A, cucumber data will support.	We agree.
<u>Crop Group No. 9 - Pome Fruit</u>			
Crop 1 - Apples - Crop Field Trials (TEP) - Processed Food/Feed (EP)	10/88 04/89	MRID 405542-02 Study in progress.	The studies were rejected as the samples were stored too long. New data needed for RAC (S. Hummel memo of 08/26/88).
<u>Crop Group No. 10 - Stone Fruit</u>			
Crop 1 - Apricots - Crop Field Trials (TEP)	10/88	Not on label - previous data submitted.	Not supported by storage stability data. Reviewed in Registration Standard Update Samples stored too long (250 days). PM should take appropriate Action.
Crop 2 - Nectarines - Crop Field Trials (TEP)		N/A, peach data will support.	We agree, but no data on peaches were submitted. PM should take appropriate action.
Crop 3 - Peaches - Crop Field Trials (TEP)	10/88	1988 season crops. Studies are near completion - not on label.	The data are overdue. The PM should take appropriate action.

PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
<u>Crop Group 11 - Small Fruits & Berries</u>			
Crop 1 - Cranberries - Crop Field Trials (TEP)	10/88	Removed from label, not supporting.	Cranberries should be removed from <u>all</u> labels and tolerances should be revoked.
Crop 2 - Grapes - Crop Field Trials (TEP)	10/88 04/89	MRID No. 405542-04 MRID No. 405542-03	We agree.
<u>Crop Group 12 - Tree Nuts</u>			
Crop 1 - Almonds - Crop Field Trials (TEP)	10/88	1988 season crops. Studies are near completion.	The data are overdue. The PM should take appropriate action
<u>Crop Group 13 - Cereal Grains</u>			
Crop 1 - Corn, Sweet - Crop Field Trials (TEP) - Processed Food/Feed	10/88 04/89	MRID No. 405873-04 Study being conducted.	We agree.
<u>Crop Group No. 14 - Forage, Fodder, & Straw of Cereal Grains</u>			
Crop 1 - Corn Forage, Fodder, & Silage - Crop Field Trials (TEP)	10/88	MRID No. 405873-04	We agree.

PENNWALT'S RESPONSE TO THE MANEB REREGISTRATION STANDARD OF NOVEMBER 10, 1988 (cont'd)

Data Requirement	Due to EPA	Registrant Response	DEB Comments
<u>Crop Group 15 - Miscellaneous Commodities</u>			
Crop 1 - Asparagus - Crop Field Trials (TEP)	10/88	Not supporting, not on label.	The crops should be removed from <u>all</u> maneb labels and tolerances should be revoked.
Crop 2 - Bananas - Crop Field Trials (TEP)	10/88	Not supporting.	do.
Crop 3 - Figs - Crop Field Trials (TEP) - Processed Food/Feed (EP)	10/88 04/89	Not supporting.	do.
Crop 4 - Papayas - Crop Field Trials (TEP)	10/88	Not supporting.	do.
Crop 5 - Seed, Seed Piece, Planting Stock, & Propagation Stock - Crop Field Trials (TEP)	10/88	Not supporting.	do.
Crop 6 - Tobacco - Crop Field Trials (TEP) - Processed Food/Feed (EP)	10/88 04/89	Not supporting.	do.
171-4 - Magnitude of the Residue in Meat/Milk/Poultry/Eggs TCAI or Plant Metabolites		Reserved	do.

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