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EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Special Review Action Code 870 - Maneb Data Call-In [RCB No. 138]. Evaluation of Product Chemistry Data for Maneb Produced by Pennwalt Corporation: Manufacturing-Use Product - Maneb Technical (EPA Registration No. 4581-355); and End-Use Product - Maneb 80 Fungicide (EPA Registration No. 4581-255). Accession Number 259165.

FROM: Michael P. Firestone, Ph.D., Chemist
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

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

TO: Susan Lewis
Data Call-In Program
Registration Division (TS-767C)

and

Henry M. Jacoby, PM #21
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

Note: This EDBC data package has been submitted in connection with the NRDC lawsuit. All EDBC reviews are being expedited per the request of Mr. Douglas D. Campt, Registration Division Director (see D. Campt memo of June 26, 1985, to J. Melone - HED Director).

Pennwalt Corporation (Agchem Division) has submitted product chemistry data for the following manufacturing-use product and end-use product:

EPA Registration No. 4581-355 - Maneb Technical;
EPA Registration No. 4581-255 - Maneb 80 Fungicide;

in response to a Data Call-In dated October 19, 1984.

The data will be presented in the format of the Product Chemistry Guidelines, Subdivision D of 40 CFR 158, along with RCB's comments/conclusions regarding the adequacy of the data.

Series 61: Product Identity and Composition

\$61-1. Product Identity and Disclosure of Ingredients

Submission: Confidential Statements of Formula (CSF) dated August 29, 1985, for both Maneb Technical and Maneb 80 Fungicide (see Confidential Appendix of this review), plus information on the active ingredient such as CAS Registration No. (1247-38-2), alternate names and various formulas.

RCB's Comments/Conclusions: Several inerts in the manufacturing-use product (EPA Registration No. 4581-355 - Maneb Technical) and the end-use product (EPA Registration No. 4581-255) have not been cleared for use on growing crops and/or raw agricultural commodities (rac's) after harvest under 40 CFR 180.1001.

If the end-use product (EUP) Maneb 80 Fungicide or any other EUP's made from Maneb Technical (EPA Registration No. 4581-355) are to be used on growing crops and/or rac's after harvest, the registrant will need to seek the appropriate exemptions from the requirement of a tolerance under 40 CFR 180.1001(c) or (d) for the inerts identified in the Confidential Appendix of this review as not already having such clearance.

\$61-2. Description of Beginning Materials and Manufacturing Process

Submission: A very brief summary of the manufacturing process, reaction equations, and product specifications of starting materials.

RCB's Comments/Conclusions: The registrant will need to submit a detailed description of the manufacturing process as specified in the Product Chemistry Guidelines (§61-2(b)(1-9)).

§61-3. Discussion of the Formation of Impurities

Submission: None

RCB's Comments/Conclusions: The registrant will need to submit a discussion, based on classical chemical theory, of the formation of impurities in accord with Section 61-3(b)(i through ix). This discussion must tell whether any impurities other than those listed in the CSF could possibly be formed during the manufacturing process including those formed by contaminants in the various starting materials. Sensitive analytical methods such as HPLC should be developed to determine the levels of these impurities present at ≥ 0.1 percent by weight as required in Section 62-1 below, and the results should be submitted to EPA.

Series 62: Analysis and Certification of Product Ingredients§62-1. Preliminary Analysis of Product Samples

Submission: Analytical results of five representative samples of Maneb 80 Fungicide (see Confidential Appendix of this review).

RCB's Comments/Conclusions: The results for Maneb 80 Fungicide cover analyses for maneb and only one impurity. More extensive studies are required for characterizing all components in Maneb 80 Fungicide found at ≥ 0.1 percent by weight.

In addition, the registrant should submit the results of batch analyses of the MUP Maneb Technical (EPA Registration No. 4581-355).

Thus, the data requirements for Section 62-1 are not adequately satisfied by the current submission.

§62-2. Certification of Ingredient Limits

Submission: CSF's for EPA Registration Nos. 4581-355 and 4581-255 (Maneb Technical and Maneb 80 Fungicide, respectively) which include certified limits.

RCB's Comments/Conclusions: The data submitted for this Section §62-2) cannot be considered satisfactory at this time. After the data gap cited under Section 62-1 above has been adequately resolved, the registrant may need to submit new CSF's for Maneb Technical and Maneb 80 Fungicide.

§62-3. Analytical Methods to Verify Certified Limits

Submission: Methods of analysis for the ai, impurities, and intentionally added inerts (see Confidential Appendix of this review).

RCB's Comments/Conclusions: The registrant will need to satisfy the requirements of Section 62-3 by especially submitting information concerning the precision and accuracy, and validation data for the submitted analytical methods. For further guidance, the registrant should refer to Section 62-3 of the Agency's Product Chemistry Guidelines - Subdivision D.

Finally, the registrant must develop analytical methods such as HPLC, or GC/MS to determine compounds other than maneb present at ≥ 0.1 percent by weight which could mistakenly be determined as maneb by Method No. PH-M 012.1.3 (see also method 1 under Section C - Analytical Methods to Verify Certified Limits in the Confidential Appendix to this review).

Series 63: Physical and Chemical Properties

Submission: The following information concerning the physical and chemical properties of maneb has been submitted although it is not clear whether the data apply to Maneb Technical - EPA Registration No. 4581-355 or Maneb 80 Fungicide - EPA Registration No. 4581-255.

A. Color	Yellow to buff.
B. Physical state	Powder.
C. Odor	Slight odor (sulfurous).
D. Melting point	Decomposes before melting.
E. Boiling point	Solid - not applicable.
F. Bulk density	0.45 g/mL.
G. Solubility (water)	150 to 200 ppm at room temperature.
H. Vapor pressure	Negligible at room temperature (polymeric).
I. Dissociation constant	Not applicable because of insolubility.
J. Octanol/Water partition co-efficient	Not applicable (polymeric).
K. pH	7 to 9 (aqueous dispersion) 4

- L. Stability Stable under normal conditions but may decompose at elevated temperatures especially when water and air are present. If on fire, some gaseous products including carbon disulfide are produced.
- M. Oxidizing or reducing action Not applicable - product contains no oxidizing or reducing agents.
- N. Flammability Not applicable - product contains no combustible liquids.
- O. Explodability Not applicable - product not potentially explosive.
- P. Storage stability Two years in the original unopened container. Material should be stored under cool, dry conditions in unopened or reclosed containers.
- Q. Viscosity Not applicable - product is not a liquid.
- R. Miscibility Not applicable - product is not a liquid and is not to be diluted with petroleum solvents.
- S. Corrosion Characteristics not corrosive.
- T. Dielectric breakdown voltage Not applicable - product is not a liquid and is not to be used around electrical equipment.

RCB's Comments/Conclusions: The registrant will need to discuss for which product the Series 63 physical and chemical properties information applies before RCB can reach any conclusions regarding the adequacy of the data submitted here.

The registrant should be advised that listing the physical and chemical properties is not enough. Supporting raw data and descriptions of how the data were generated will be required.

Finally, the registrant will also need to generate Series 63 data on the technical chemical (regardless of whether registered) and all manufacturing-use products and end-use products produced by an integrated formulation system currently registered since the physical and chemical properties are expected to vary from one product to the next.

Recommendations:

The registrant should be informed of the above deficiencies in the submitted product chemistry data. The complete product chemistry data as required by the Guidelines 40 CFR 158, Subdivision D should be submitted for the various Pennwalt Corporation products containing maneb.

Separate Series 63 data should be submitted for each maneb manufacturing-use product (MUP) and end-use product (EUP) produced by an integrated formulation system, and also the technical chemical (whether registered or not).

The registrant should be informed that upon completion of RCB's review of all relevant metabolism and residue data requested so that the metabolism/degradation products of toxicological concern are identified, additional product chemistry information may be requested.

Attachment 1: Confidential Appendix (3 pages)

cc(with Attachment 1): MPFirestone, EDBC S.F., R.F., PMSD/ISB,
TOX, PM#21, SLewis(RD)

cc:(without Attachment 1): Circu

RDI:JHOnley-10/5/85:RDSchmitt-10/7/85

TS-769:MPFirestone:CM#2:Rm800b:557-7484

typed by Kendrick-10/15/85:edited by wh-10/18/85

Maneb residue chemistry review

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Pages 7 through 9 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.
