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EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Special Review Action Code 870 - Maneb Data Call-In [RCB No. 139]. Evaluation of Product Chemistry Data for Maneb Produced by Rohm and Haas Company: EPA Registration Nos. 707-48, -83, -101, -103, -124, -170, and -10176. (Accession No. 259328).

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and

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and

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THRU: Charles L. Trichilo, Ph.D., Chief
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Note: This EBDC data package has been submitted in connection with the NRDC lawsuit. All EBDC 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).

Rohm and Haas Company has submitted product chemistry data for maneb (Dithane®) in response to a Data Call-In dated October 19, 1984. According to the registrant, the subject submission dated September 5, 1985 supports the following Rohm and Haas Company registrations:

Dithane M-22 Agricultural Fungicide
 EPA Registration No. 707-48;
 Dithane M-22 Special
 EPA Registration No. 707-83;
 Dithane M-22 Special with Zinc Concentrate
 EPA Registration No. 707-101;
 Dithane M-22 Concentrate
 EPA Registration No. 707-103;
 Dithane S-31 Agricultural Fungicide
 EPA Registration No. 707-124;
 Dithane FZ Flowable Agricultural Fungicide with Zinc
 EPA Registration No. 707-170; and
 Dithane M-22
 Intrastate EPA Registration No. 707-10176.

It appears that Series 61 and 62 information, including certified limits, have been submitted for only EPA Registration No. 707-48.

The registrant states that information on physical and chemical characteristics (i.e., Series 63 data) have already been provided by the Maneb Data Task Force.

The data will be presented below 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: Certified limits for Dithane M-22 80WP (possibly equivalent to EPA Registration No. 707-48), plus information on the active ingredient (ai) such as CAS No. (1247-38-2), alternate names, and structural formula.

RCB's Comments/Conclusions: It is unclear for which maneb product(s) the submitted "certified limits" apply. Regardless of this, the registrant will need to submit a Confidential Statement of Formula (EPA Form 8570-4; Revised 2/85) for each registered product. The registrant should also be sure that all (intentionally added) inerts are cleared for use on growing crops or on rac's after harvest under 40 CFR 180.1001(c) or (d) or seek such clearance. Thus, the data requirements for Section 61-1 have not been adequately satisfied.

§61-2. Description of Beginning Materials and Manufacturing Process

Submission: Specifications and manufacturers' names for all starting material and a description of the manufacturing process.

RCB's Comments/Conclusions: A discussion of the manufacturing process is included in the Confidential Appendix attached to this review.

The data requirements of Section 61-2 are adequately satisfied.

§61-3. Discussion of the Formation of Impurities

Submission: A discussion of impurities identified or believed to be found in maneb presented for several individual compounds and classes of compounds (see Confidential Appendix of this review).

RCB's Comments/Conclusion: The data requirements of Section 61-3 are adequately satisfied.

Series 62: Analysis and Certification of Product Ingredients

§62-1. Preliminary Analysis of Product Samples

Submission: Analytical results of batch analyses for several lots designated only as Dithane M-22 (EPA Registration No. unknown). (Note: five maneb-containing products registered by Rohm and Haas include "Dithane M-22" in their names).

RCB's Comments/Conclusions: It is unclear for which maneb product(s) the batch analyses were performed. In any case, such analyses should be performed for all registered products containing the technical chemical for which preliminary analysis is not available, and should include the active ingredient, impurities present at ≥ 0.1 percent by weight, and any intentionally added inerts. The results of the batch analyses designated only as "Dithane M-22" are presented in the Confidential Appendix to this review.

§62-2. Certification of Ingredient Limits

Submission: Certified limits for "Dithane M-22" (EPA Registration No. unknown) (Note: five maneb-containing products registered by Rohm and Haas include "Dithane M-22" in their names). These limits are given in the Confidential Appendix attached to this review.

RCB's Comments/Conclusions: A Confidential Statement of Formula (CSF) containing certified limits will be required for all Rohm and Haas registered products containing maneb. The registrant should also insure that all intentionally added inerts are cleared under 40 CFR 180.1001.

§62-3. Analytical Methods to Verify Certified Limits

Submission: Analytical methods for the active ingredient and various impurities (see Confidential Appendix attached to this review).

RCB's Comments/Conclusions: Validation data are required for all methods as specified in the Product Chemistry Guidelines as well as a discussion of the precision and accuracy of each method. Also, the analytical method for determining one of the impurities included in the certified limits for "Dithane M-22" will need to be submitted (see Confidential Appendix for details).

Series 63: Physical and Chemical Characteristics

Submission: The registrant states that information concerning the physical and chemical characteristics have already been provided by the Maneb Data Task Force, except for Section 63-17 (Storage Stability) data for "Dithane M-22" (EPA Registration No. unknown).

RCB's Comments/Conclusions: The registrant will need to provide Series 63 physical and chemical properties data on the technical chemical (whether or not registered) and all manufacturing-use products and end-use products produced by an integrated formulation system currently registered. The physical and chemical properties are expected to vary from product to product. If the data supplied by the Maneb Task Force were generated on any Rohm and Haas products, these will be considered applicable only for the products upon which they were generated.

Finally, Series 63 data should be supported by raw data and descriptions of how the data were generated.

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 all registered Rohm and Haas 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 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 (7 pages)

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

cc:(without Attachment 1): Circu

RDI:JHonly-10/14/85:RDSchmitt-10/14/85

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

typed by Kendrick-10/21/85:edited by mpf-10/21/85

Maneb residue chemistry review

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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.
