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

NOV 7 1985

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Special Review Action Code 870 - Mancozeb Data Call-In [RCB Numbers 1479 and 1480]. Evaluation of Product Chemistry Data for Two Pennwalt Products (EPA Reg. Numbers 4581-357 and 4581-358). Accession No. 258939.

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Michael P. Firestone

THRU: Charles L. Trichilo, Ph.D., Chief
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TO: Henry M. Jacoby, Product Manager No. 21
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and

Susan Lewis
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and

Toxicology Branch
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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 has submitted product chemistry data in support of two mancozeb products, originally registered by Aceto Agricultural Chemical Corporation, which are currently in suspension. These products are:

Penncozeb™ Turf and Ornamental Fungicide - EPA Reg. No. 4581-357;

Penncozeb™ Fungicide - EPA Reg. No. 4581-358.

At this time, RCB is unable to fully evaluate the submitted material since it is unclear whether the data pertains to one or both of the Penncozeb™ products.

The registrant will need to submit a Confidential Statement of Formula (EPA Form 8570-4; Revised 2/85) for each of the two products and state what type product each is (i.e., technical, manufacturing use and/or end use product).

The registrant should consult EPA's Pesticide Assessment Guidelines, Subdivision D, Product Chemistry for assistance in preparing an adequately detailed product chemistry submission.

If the two products are indeed unique, product chemistry data on only one product will not be considered adequate.

RCB will make some brief comments below on the data contained in the subject (7/31/85) submission and give some guidance as to what data are needed.

61-1. Product Identity and Disclosure of Ingredients

A CSF will be required for each product (EPA Form 8570-4 Dated 2/85) in which the following should be included:

a) Upper and lower limits for each active ingredient (ai) and each inert ingredient;

b) Upper limits for each impurity;

c) The purpose of each ai and each intentionally-added inert;

d) Chemical Abstracts Service Registry Number for each ai;

e) Chemical information on each ai (the type of information submitted under Section I(A)(3) is adequate).

61-2. Description of Beginning Materials and Manufacturing Process

Although information concerning the beginning materials is adequately presented, a detailed description of the manufacturing process as stated in the Guidelines must be submitted instead of the brief summary included in the present submission.

61-3. Discussion of the Formation of Impurities

A detailed discussion of the formation of impurities based on established chemical theory must be submitted. The registrant should note that the Guidelines for manufacturing use products and those end use products produced by an integrated formulation system are different than those for end use products not produced by an integrated formulation system.

62-1. Preliminary Analysis of Product Samples

The registrant must submit the analyses of at least 5 representative batches for both products in which all compounds (including impurities) present at levels $\geq$0.1% (weight basis) are quantitated (not just mancozeb and a single impurity as presented in the subject submission).

62.2. Certification of Ingredient Limit

As specified in the Guidelines, the registrant should submit certified limits for both products (note: if one of these products is not a technical product, the certified limits must include upper and lower limits for impurities present in the technical chemical at $\geq$0.1%).

62-3. Analytical Methods to Verify Certified Limits

With regard to all methods, validation data including representative chromatograms if applicable will be required, in addition to a discussion of the precision and accuracy of the methods.

The method used to determine mancozeb involves quantification of any chemical in technical mancozeb that decomposes to CS_2 under the conditions of the test. Additional analysis of technical mancozeb is required by suitable methodology such as HPLC or GC/MS that will characterize the individual chemical components of technical mancozeb.

Series 63 - Physical and Chemical Characteristics

These properties must be detailed for both products (i.e., EPA Reg. No. 4581-357 and 4581-358). In addition, the registrant must submit validation data where applicable and describe how these properties were determined. Finally, Series 63 data will also be required for the technical chemical, whether it is registered or not.

Recommendation

The registrant should consult the EPA Guidelines, Subdivision D (Product Chemistry) for assistance in determining the type of product chemistry data required in support of mancozeb registration.

At this time, the available product chemistry data for both EPA Reg. Nos. 4581-357 and 4581-358 are not acceptable to satisfy 40 CFR 158 requirements.

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

TS-769:RCB:M.Firestone:vg:CM#2:Rm810:X77484:11/4/85
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RDI: J.Onley, 10/30/85; R.Schmitt, 10/31/85