EXPEDITE

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

JUL 12 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Special Review Action Code 870
Mancozeb Data Call In. Product chemistry of Du Pont formulations.
Accession No. 258311, 258312 [RCB Nos. 1193, 1194, 1195]

From: Martha J. Bradley, Chemist
Residue Chemistry Branch
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Thru: Charles L. Trichilo, Chief
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To: H. Jacoby, PM 21
Registration Division (TS-767C)

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Hazard Evaluation Division (TS-769)

This EBDC data package was submitted in connection with the NRDC suit. It is being expedited at the request of the HED Deputy Director.

E. I. du Pont de Nemours & Company, Inc. has submitted product chemistry data for three formulations of mancozeb; Manzate® 200, EPA Reg. No. 352-341 and Tersan® LSR Turf Fungicide, EPA Reg. No. 352-343, Acc. No. 258311; Manzate® 200 Flowable Fungicide, EPA REG. No. 352-398, Acc. No. 258312.

The submitted items are listed below in the format of the Product Chemistry Guidelines, Subdivision D of 40 CFR 158 along with our comments/conclusions on the adequacy of the submission.

Series 61: Product Identity and Composition

Submission: Statement of Formula for Manzate® 200 and Manzate® 200 Flowable.

Comments/Conclusion: All of the inerts are cleared under 180.1001 (c) or (d) with the exception of one present in the Manzate 200 formulation (see Confidential Appendix).

The statement of Formula for Tersan® LSR Fungicide should be submitted and the uncleared inert should be cleared under 180.1001 (c) or (d).

61-2 Description of beginning materials and manufacturing process.

Submission: A list of the beginning materials and a brief description and flow chart of the manufacturing process.

Comments/conclusion: A detailed description of the beginning materials and manufacturing process as stated in the Product Chemistry Guidelines, Subdivision D, should be submitted.

61-3 Discussion of the formation of impurities.

Submission: The registrant has not submitted a discussion of the impurities that may be present in the products.

Comments/conslusion: A discussion of the formation of impurities that may be present in the products and why they may be present as required in the Product Chemistry Guidelines, Subdivision D should be submitted.

Series 62: Analysis and Certification of Product Ingredients

62-2 Certification of ingredient limits

Submission: Certification of limits for the EBDC and deliberately added ingredients; certified upper limits for zinc, [redacted] and for ETU.

Comments/conclusion: Certification of limits for impurities, in addition to ETU, found as a result of the requested discussion of possible impurities (61-3 above) at levels over 0.1% should be submitted.

62-3 Analytical methods to verify certified limits

Submission: Identity procedure to distinguish mancozeb from other EBDC fungicides, a CS_2 evolution method for mancozeb, a complete HPLC method for ETU, M20.1842 (R) or (E) dated 04/12/82 and an incomplete HPLC method for ETU, M20.184 (E) dated 06/21/82, a method for one of the intentionally added inert ingredients, and a method for total and water soluble zinc.

Comments/conclusion: The complete HPLC method for ETU, M20.184 (E) dated 06/21/82, should be submitted; only the odd numbered pages 1-11 were submitted. Validation data, including recovery studies, should be submitted for all methods.

Should additional impurities, found as a result of the discussion required in 61-3 above, be certified, analytical methodology for the additional products should be submitted.

Series 63: Physical and Chemical Characteristics

Submission: The physical and chemical characteristics required for end-use products with two exceptions; 63-14 oxidizing or reducing action is not discussed and 63-17 storage stability is not complete.

Comments/conclusion: For the Manzate® 200 Flowable formulation, a storage stability study for the parent compound only was conducted over a period of 6 months. For the other two formulations, there is only a statement that there is a loss of 0.15 and 0.5% ai per month depending on the storage conditions. No methodology for the submitted physical and chemical characteristics is given.

The methods used for the above characteristics should be submitted and complete storage stability studies for each formulation should be submitted as required by the Product Chemistry Guidelines, Subdivision D. The studies should be conducted over a period of at least one year and should include analyses for mancozeb and its deterioration or degradation products.

Recommendations

The registrant should be informed of the above deficiencies in the submitted product chemistry data. The complete product chemistry information as required by the Guidelines, 40 CFR 158, Subdivision D should be submitted.

Clearance should be sought for the inert discussed in the attached Confidential Appendix.

cc w CBI: PMSD/ISB (Eldridge), TOX, RF, PM21, Special Review F.(EBDC SF), Susan Lewis
cc: Reviewer, circu, Reg. Std. F., Amy Rispin
RDI:Section Head:RSQuick:Date:7/11/85:RDS:7/11/85
TS-769:RCB:Reviewer:MJBradley:MJB:CM#2:RM:810:557-7377:7/10/85

Mancozeb residue chemistry review

Page 4 is not included in this copy.

Pages _____ through _____ are not included in this copy.

The material not included contains the following type of information:

X 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.
