CONFIDENTIAL

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

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MAR 12 1990

MEMORANDUM:

SUBJECT: ID #060101,-02. Thiabendazole: Product Chemistry in response to Data Call-In. [DEB: #6043,-44,-45] [Supplement to MRID #00047895, #00047980, #00051865, #00029108, #00125601; amendment to MRID #407898-14; and #408355-01]; #411920-01; #412582-04.

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THRU: Francis B. Suhre, Section Head
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TO: Franklin D. Rubis, PM #50
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The Merck & Co., Rahway, NJ has responded, in part, to the comprehensive Data Call-In notice [3/24/88] by providing the following data for the fungicide, thiabendazole as the technical grade active ingredient and as a manufacturing use product [MERTECT FUNGICIDE, EPA Reg. #618-67]:

I. Chemical Identity: [MRID #412582-04]; Amendment to MRID #407898-14; subdivision O; Residue Chemistry; Series §171.2.

II. Product Chemistry: Supplement to MRID #00047895; #00047980; #00051865; #00029108; #00125601; Amendment to MRID #408355-01; 40 CFR 158.120; Subdivision D:

Series §61-1 Product identity and disclosure of ingredients.

Series §61-2 Beginning materials and manufacturing process.

Series §61-3 Discussion on the formation of impurities.

III. Product Chemistry: MRID #411920-01; 40 CFR 158.120; Subdivision D; Series §63.20 Corrosive characteristics.

DETAILED CONSIDERATIONS

Series 61 PRODUCT IDENTITY AND COMPOSITION

§61-1: Product identity and disclosure of ingredients
These data were submitted as required under the Pesticide Assessment Guidelines Subdivision § 61-1: (a) Product Identity and (b) Confidential Statement of Formula [CSF]. For a discussion of these data see CONFIDENTIAL APPENDIX to this review.

DEB's Comment: No further information is needed.

§61-2:(a) Beginning Materials & (b) Manufacturing Process.
Copies of technical specification sheets for each beginning material were submitted, including the qualitative and quantitative composition of each material. Beginning materials and the manufacturing process are discussed in the CONFIDENTIAL APPENDIX to this review.

DEB.s Comment: The information given for the beginning materials & the manufacturing processess have been adequately described.

§61-3: Discussion of formation of Impurities.
Impurities in the technical thiabendazole are discussed in the CONFIDENTIAL APPENDIX to this review, § 61-1.

DEB's Comment:The potential formation of the impurities have been adequately discussed.

Series 63 PHYSICAL AND CHEMICAL CHARACTERISTIC.

§63.20: Corrosion Characteristics
The requirement for data on the corrosion characteristics of a manufacturing use product in order to support its registration, requires that the product be tested for changes, which may occur, following contact of the product with metal, plastic, or paper containers or enclosures commercially packaged.

In response to this data requirement, the registrant provided a study on the effects of thiabendazole on polyethylene packaging.

Preparation of samples: The polyethylene film packaging was cut without any special cleaning or pre-treatment into standard Type I tensile specimens [ASTM D638-87]. Samples of the packaging specimens were exposed to the technical thiabendazole for 30, 60, and 90 days at 48 ± 2° C. The exposed specimens were cleaned with compressed air prior to evaluation. Visual comparisons were made between the exposed and the control specimens for evidence of pits, cracks, discoloration, and brittleness.

The exposed and control specimens were analyzed for tensile strength at break and the per cent elongation at break using an Instron Tensile Tester. The polyethylene film specimens were tested per ASTM D638-87 [2" gauge length, 2.0"/minute crosshead speed]. Quantitation was determined as follows

(a) Tensile strength/lbs/square inch = failure force in lbs/cross-sectional area/in^2

(b) Per cent elongation = [extension at break/inches/gauge length in inches] x 100%

No difference in appearances were observed when comparing the control and sample specimens exposed to thiabendazole; nor were there any statistically meaningful changes in either the tensile strength or per cent elongation.

DEB Comment: The requirement to determine the corrosive characteristics of thiabendazole in/on commercial polyethylene packaging have been satisfied.

Conclusions

1. The product chemistry data requirement described under §171-2, for the chemical identity of thiabendazole is satisfied.

2. Pertinent product chemistry data described under §61-2 (a) and §61-2 (b) which require a detailed description of the beginning materials and the manufacturing product chemistry process have been satisfied.

3. Pertinent product chemistry information described under §61-3 on the formation of impurities has been provided and is acceptable.

4. The product chemistry data requirement described under §63.20, determining the corrosiveness of thiabendazole in/on commercial packaging has been satisfied.

Recommendation

We recommend that the registrant be made aware of our conclusions as stated above.

Note to PM: Additional product chemistry data for thiabendazole have been reviewed by DEB: See F.Suhre,12/4/87; K. Docktor, 4/20/89; M.Nelson, 6/13/89 7/15/89, 9/20/89; G.Makhijani, 7/17/89.

CC: [With attachment]: Confidential Appendix;Reviewer;SF[Thiabendazole]; RF;PMSD/ISB,R.Schmitt..
CC: [Without Attachment]: Circulation.
RDI: FBS;3/1/90;EZ,3/1/90.
07509C: WLA;wla;CM-2;Rm.812;X557-4351;3/7/90.

Page ___ is not included in this copy.

Pages 4 through 8 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 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.