US ERA ARCHIVE DOCUMENT

Gentlemen:

Subject: Thiram Registration Standard EPA Registration No. 45728-1

Your Letters Dated June 28 and October 11, 1985

The product chemistry data submitted under your letter of October 11, 1985 and identified by EPA Accession Number 259809 have been reviewed. We enclose a copy of the review for your records. The data gap Section 63-10 (Dissociation Constant) has been resolved. Please note the following product chemistry data must be submitted to fulfill the required product chemistry data for this product:

Section 62-3 - Analytical methods to verify certified limits

Section 63-14 - Oxidizing or reducing action

Section 63-17 - Storage stability

Section 63-20 - Corrosion characteristics

Section 64-1 - Submittal of samples

The ecological effects data (48-hour LC50 on Daphnia magna, EPA Accession No. 259249) jointly submitted by UCB Chemicals Corporation and Gustafson have been reviewed and found inadequate. A copy of the review is enclosed for your records.

The toxicology data identified by EPA Accession Number 259250 have been reviewed and a copy of the review is enclosed for your records. data satisfy the following product-specific toxicological data requirements for the subject product.

Section 81-2 - Dermal LD50

Section 81-4 - Primary Eye Irritation - Rabbit

Section 81-5 - Primary Dermal Irritation

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Based on the eye irritation data your product labeling must bear the Toxicity Category II signal word and appropriate precautionary labeling.

The product chemistry data identified by EPA Accession Number 259248 have been reviewed and a copy of the review in enclosed for your records. The requirement, Section 63-9 (Vapor Pressure) was filled by the data submitted. The requirement, Section 62-3 (Analytical Methods to Verify Certified Limits) was not filled by the data submitted.

The solubility (Section 63-8) information submitted on May 2, 1985 has been reviewed and found to be acceptable. A copy of the review is enclosed.

The Confidential Statement of Formula (CSF) dated March 14, 1985 must be updated and submitted on the enclosed revised EPA Form 8570-4 (Rev. 2-85). A complete description of the inert ingrediental must be submitted with the revised CSF.

The proposed labeling submitted in your March 14, 1985 letter is unacceptable, as the signal word must be WARNING based on the eye irritation data mentioned above. The following Precautionary Statements are appropriate.

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear goggles or face shield. Harmful if swallowed. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

In addition, the following Statements of Practical Treatment must be added:

If in eyes: Plush with plenty of water.

Call a physician.

If swallowed: Drink promptly a large quantity of

milk, egg whites, gelatin solution or, if these are not available, drink large quantities of water.

Avoid alcohol.

Further changes to these statements may be required, pending results of the outstanding acute studies for this product. Our records indicate you have not fullfilled the following product-specific data requirements for this product:

Section 81-1 - Acute Oral ID_{50} - Rat Section 81-3 - Inhalation IC_{50} - Rat Section 81-6 - Dermal Sensitization

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Please note that data mentioned above as needed or overdue should have been submitted in accordance with the timeframes specified in the Thiram Registration Standard.

Further action must await your response to the deficiencies and the comments mentioned above.

Sincerely yours,

Henry M. Jacoby"
Product Manager (21)
Pungicide-Herbicide Branch
Registration Division (TS-767C)

Enclosures (6)

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