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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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MEMORANDUM (CONFIDENTIAL)

Subject: Reregistration of Iprodione. Rhone-Poulenc Response to Phase 4 Review of Product Chemistry and Dioxin DCI. DP Barcode D170343. MRID No. 41790801, CBRS No. 8863.

From: Stephen Funk, Ph.D., Chemist
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Through: Andrew Rathman, Section Head
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To: Kathryn Davis
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Background

Rhone-Poulenc Ag Company has responded to ten specific information/data requests related to an evaluation of the potential for halogenated dibenzo-p-dioxin/dibenzofuran contaminant formation during the iprodione manufacture (07/10/90 Memorandum, S. Funk, DEB No. 6452) and to the Phase 4 request for product chemistry data (GLN 61). The submission is entitled "Iprodione--EPA Reg. No. 264-452: Product Chemistry Series 61"; Volume 2 of 2, 02/20/91.

Discussion

Phase 4 Reregistration

The Phase 4 requirements for product chemistry are addressed by guideline number.

GLN 61-1: Product Identity and Disclosure of Ingredients

Iprodione, or 3-(3,5-dichlorophenyl)-2,4-dioxo-N-(1-methylethyl)-1-imidazolidinecarboxamide, C.A.S. Registry Number 36734-19-7, Company Code No. RP 26019, has a molecular weight of 330.17 and the empirical formula $C_{13}H_{13}Cl_2N_3O_3$. The statement of formula for the fungicide lists [REDACTED] ingredients, as summarized in Table 1. The registrant presents structural and molecular weight information for each of the impurities [REDACTED].

RIN 5704-93

IPRODIONE REVIEW

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Pages 3 through 5 are not included.

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.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Dioxin/Dibenzofuran Manufacturing Data DCI

CBRS was unable to determine the potential for dioxin/dibenzofuran formation in the manufacture of technical iprodione based upon a previous submission and requested additional information. The ten manufacturing data issues raised in conjunction with a review of the dioxin/dibenzofuran contamination potential (07/10/90 Memorandum, S. Funk, DEB No. 6452) were addressed on a question-by-question basis by the registrant. The issue, the registrant's response, and the CBRS evaluation of the response follow.

RIN 5704-93

IPRODIONE REVIEW

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Pages 7 through 10 are not included.

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.
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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.

Conclusion

Rhone-Poulenc has satisfied the data requirements of Guideline No. 61, Product Identity and Composition, as specified in the Phase 4 Review. No additional information is required for this product chemistry category for the reregistration process.

In response to the issues raised in a 01/10/90 Memorandum (S. Funk, DEB No. 6452), Rhone-Poulenc has provided sufficient additional iprodione manufacturing information to permit CBRS to evaluate the potential for polyhalogenated dibenzo-p-dioxin and/or polyhalogenated dibenzofuran formation during the process. Reaction conditions are not amenable to dioxin/dibenzofuran formation.

Recommendation

CBRS recommends that no additional product chemistry iprodione manufacturing data are required to evaluate the potential for dioxin/dibenzofuran formation. The registrant has fulfilled the requirements of the dioxin DCI. CBRS recommends that analyses of production samples for dioxin/dibenzofuran NOT be required, because the potential for formation of dioxins/dibenzofurans has been determined to be very low.

CBRS further recommends that no additional manufacturing data are required to satisfy the Guideline Number 61 requirements for product chemistry for iprodione for purposes of reregistration.

The requirement has been fulfilled. Note that the registrant has not submitted GLN 62 product chemistry.

cc: RF, List B Iprodione File, Iprodione SF, Dioxin SF, , S. Funk, C.Furlow (PIB, FOD).

RDI: A. Rathman:02/03/92:M. Metzger:02/03/92:E. Zager:02/03/92:

H7509C:CBRS:S.Funk:305-5430:CM#2:RM803-A:SF(0192.3):01/28/92.