

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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

JUL 1 0 1990

MEMORANDUM (CONFIDENTIAL)

SUBJECT:

Product Chemistry Data Review for Iprodione Technical to Determine the Potential for Halogenated Dibenzo-p-Dioxin/Dibenzofuran Formation. I. D. No. 359-684. Record No. 260630. MRID/Accession Nos. 40968100,

40968101. DEB No. 6452

FROM:

Stephen Funk, Chemist
Special Registration Section I

Dietary Exposure Branch

Health Effects Division (H7509C)

THRU:

Andrew Rathman, Section Head Special Registration Section I

Dietary Exposure Branch

Health Effects Division (H7509C)

TO:

E. Feris, PM 74 Special Review/

Reregistration Division (H7508C)

Background

In response to a 06/87 DCI, Rhone-Poulenc Ag Company, Research Triangle Park, NC submitted (received 01/18/89) manufacturing data for the fungicide 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide, or iprodione. The registrant claims CBI status for the information supplied. The purpose of the DCI is to acquire information on the potential for formation of halogenated dibenzo-p-dioxin or dibenzofuran contaminants during certain manufacturing processes. Three specific types of information were requested (Pesticide Assessment Guidelines, Subdivision D, Sections 61-1, 61-2, and 61-3):

Product identity and ingredients.

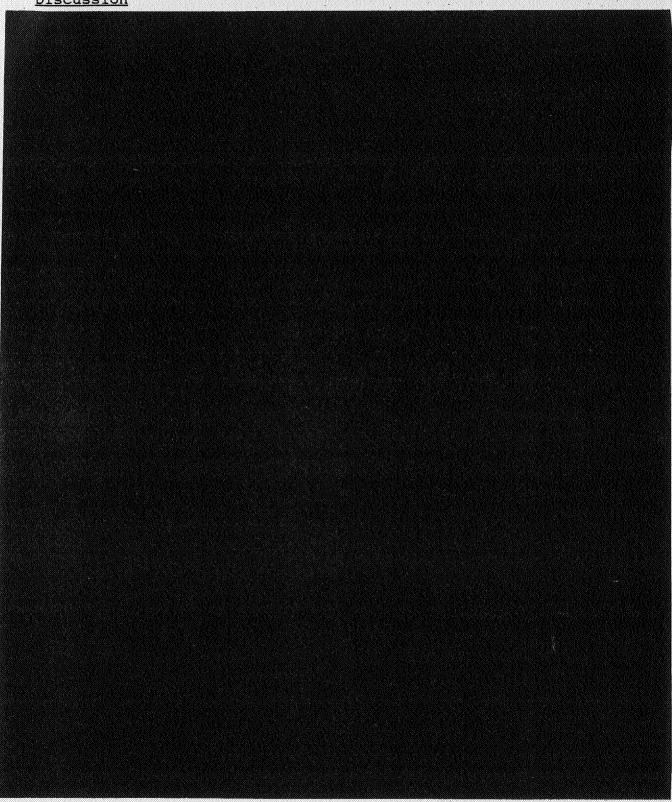
- 2. Description of beginning materials and manufacturing process.
- 3. Discussion of the formation of impurities.

The registrant also submitted the analytical methods (I-454-11-

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 $87\,(E)\,,$ I-465-02-88(E), I-516-11-88E, and I-517-11-88E) used to certify the limits in the Confidential Statement of Formula, per Sec. 62.3.

Discussion



RIN 5704-93 IPRODIONE REVIEW

| Pages 3 through 9 are not included. The material not included contains the following type 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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| Identity of the source of product ingredients. | • |
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| | |
| A draft product label. | |
| The product confidential statement of formula. | |
| Information about a pending registration action. | |
| FIFRA registration data. | • |
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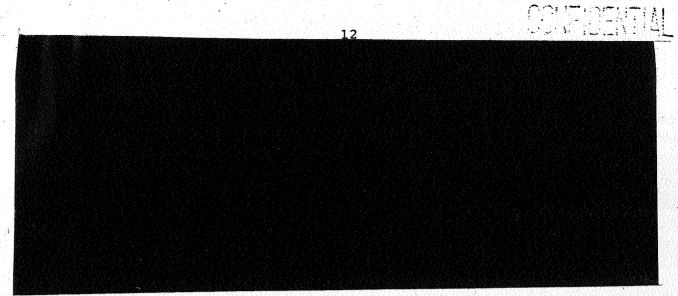
No accuracy or precision data were presented for any of the methods.

Conclusion

Rhone-Poulenc Ag Company has complied substantially with the data call-in notice for manufacturing data on technical iprodione. Based on the manufacturing data presented, there <u>may</u> exist the potential for chlorinated dibenzo-p-dioxin and/or dibenzofuran contaminant formation during the manufacture of iprodione.

making a decision, however, additional information will be needed, as follows:

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED



Recommendation

DEB cannot render a decision on the need for analytical chemistry data for chlorinated dibenzo-p-dioxin/dibenzofuran contaminants in technical iprodione because certain critical information was not submitted. DEB recommends that the Rhone Poulenc Ag Company be requested to supply the data/information of item nos. 1 - 10 of the Conclusion. This additional material will be reviewed and a decision made on the need for analytical chemistry data for chlorinated dibenzo-p-dioxins/dibenzofurans in iprodione.

Additionally, DEB finds several problems in the analytical methods used to verify CSF impurity levels. These concerns are outlined in the Conclusion, along with suggestions for correction, and should be addressed by the registrant.

cc: Dioxin SF, RF, Iprodione SF, R. Schmitt (Branch Chief), Funk, C. Furlow (PIB, FOB).

RDI:A. Rathman:07/06/90:R. Loranger:07/06/90:

H7509C:DEB:S. Funk:557-1439:CM#2:Rm803-A:SF (DIOX.46):04/13/90.