

US EPA ARCHIVE DOCUMENT



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

7-10-90 R.F.
CONFIDENTIAL

JUL 10 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

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) *S. Funk*

THRU: Andrew Rathman, Section Head
Special Registration Section I
Dietary Exposure Branch
Health Effects Division (H7509C) *ARR*

TO: E. Feris, PM 74
Special Review/
Reregistration Division (H7508C)

Background

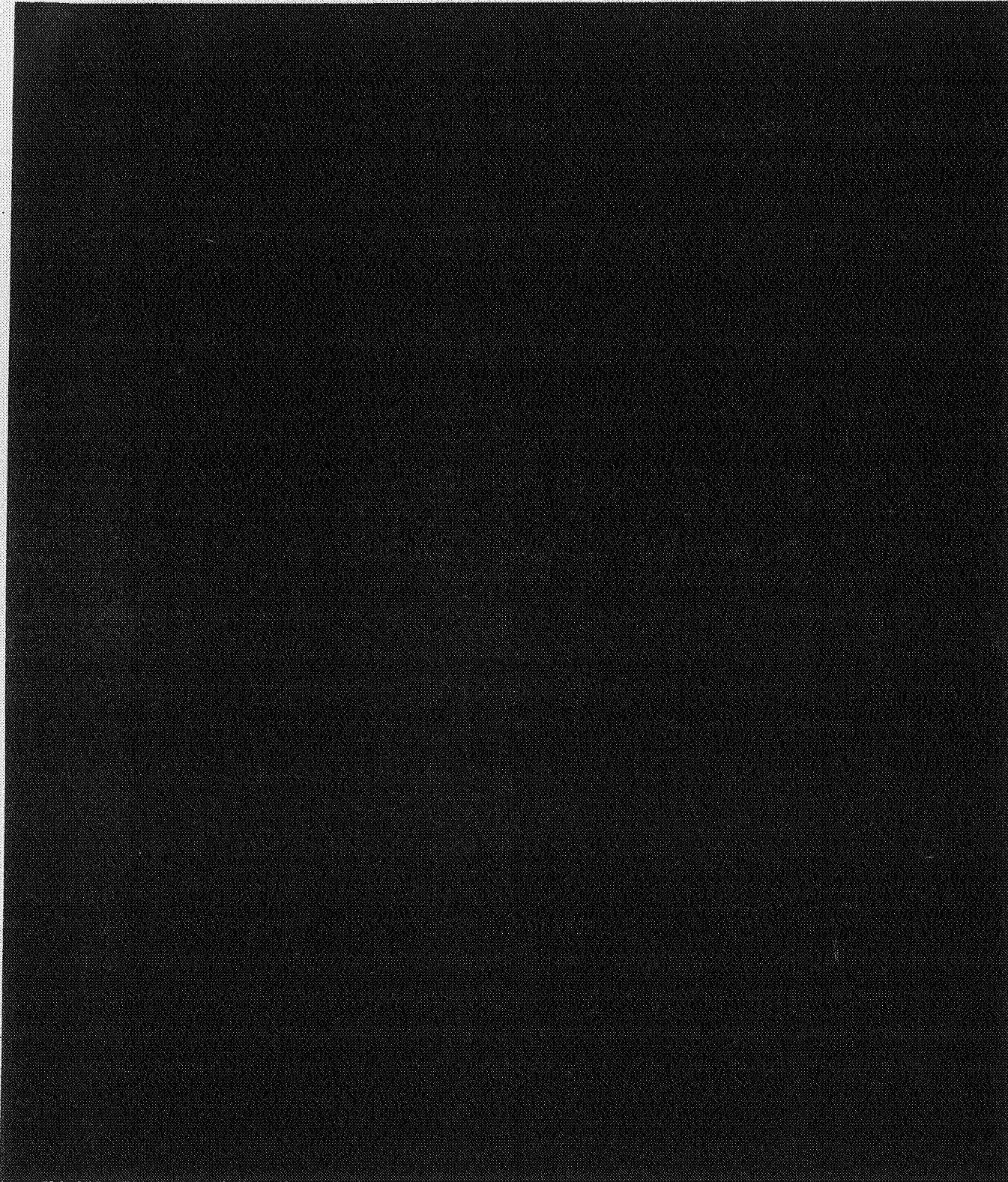
In response to a 06/87 DCI, Rhone-Poulenc Ag Company, Research Triangle Park, NC submitted (received 01/18/89) manufacturing data for the fungicide 3-(3,5-dichlorophenyl)-N-(1-methylethyl)-2,4-dioxo-1-imidazolidinecarboxamide, or iprodione. The registrant claims CBI status for the information supplied. 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):

1. 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-

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



MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

RIN 5704-93

IPRODIONE REVIEW

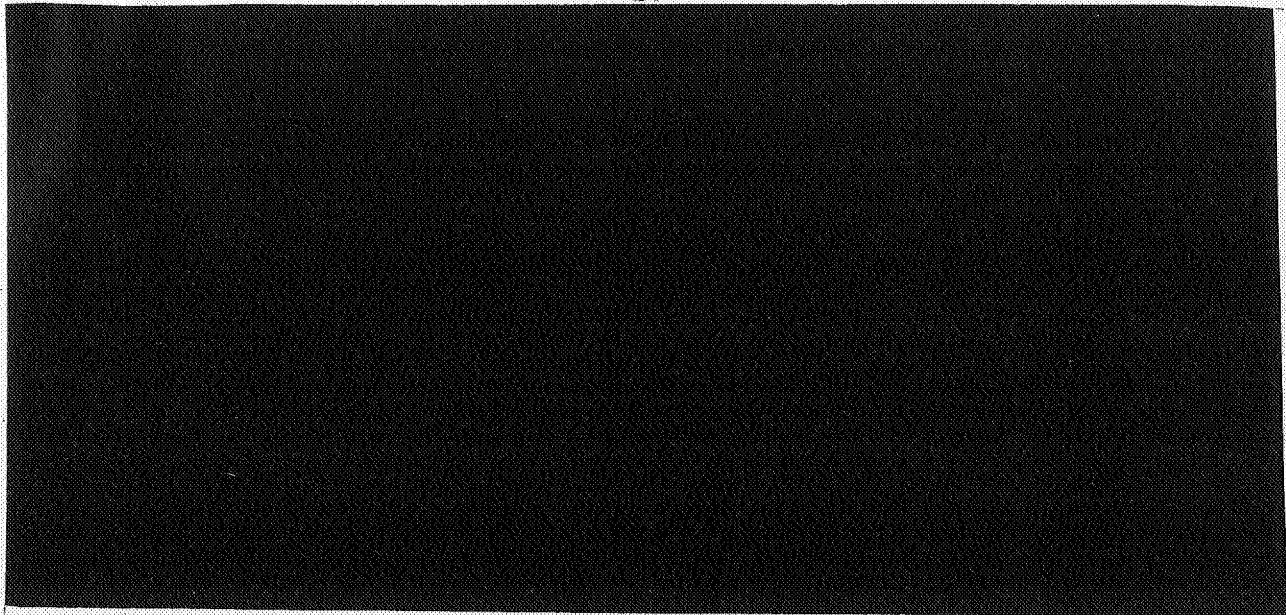
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Pages 3 through 9 are not included.

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.



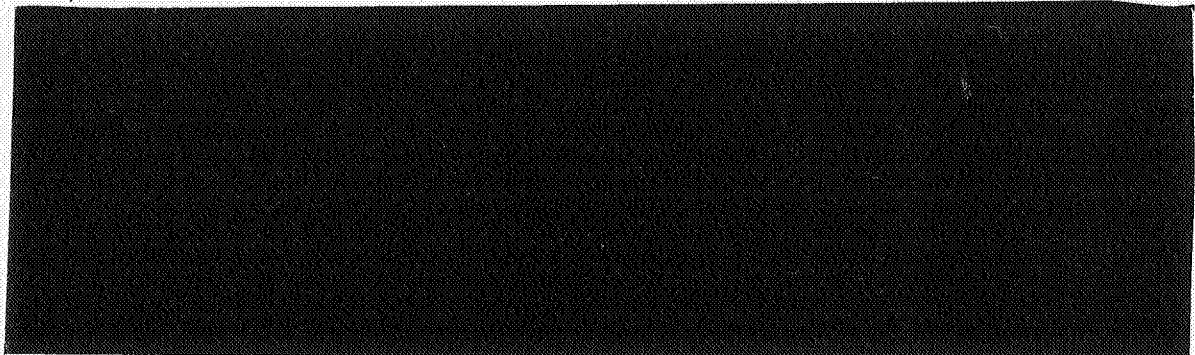
No accuracy or precision data were presented for any of the methods.

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 may exist the potential for chlorinated dibenzo-p-dioxin and/or dibenzofuran contaminant formation during the manufacture of iprodione.

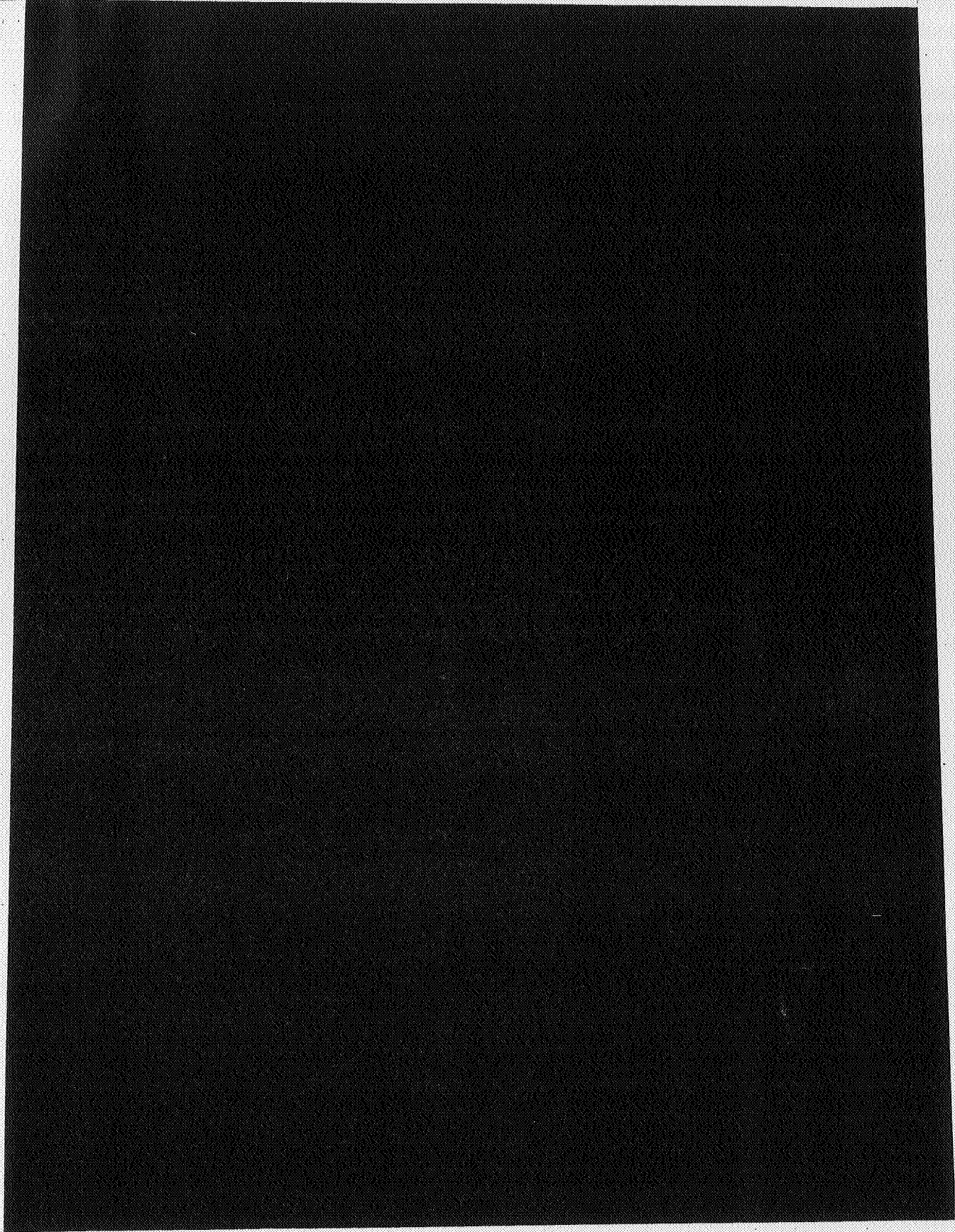


Before making a decision, however, additional information will be needed, as follows:

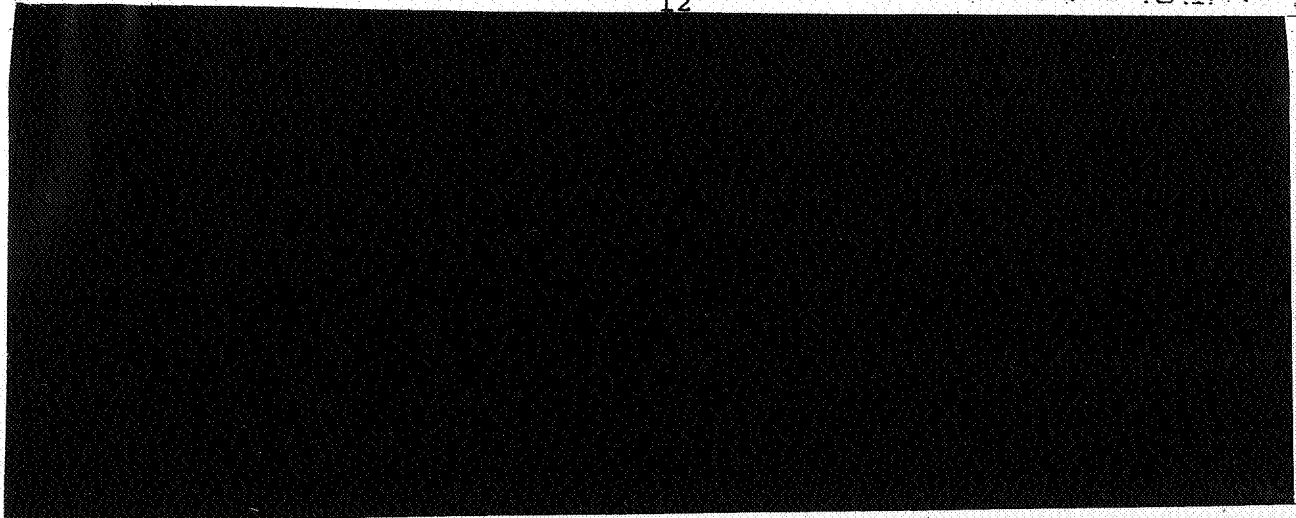


MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

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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.