FIFR88 File

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

SEP - 9 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Response to the Iprodione DCI: Product Chemistry (MRID #'s 41855501-02, CBRS # 9943, Barcode: D165907).

FROM: R. B. Perfetti Ph.D., Chemist
Reregistration Section 1
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

THRU: P. Deschamp, Acting Section Head
Reregistration Section 1
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: K Davis/B. Briscoe
Accelerated Reregistration Branch
Special Review & Reregistration Division (H7508W)

and

E. Saito, Acting Chief
Chemical Coordination Branch
Health Effects Division (H7509C)

Attached is a review of product chemistry responses to the iprodione reregistration DCI submitted by Rhone-Poulenc. This review was completed by Dynamac Corporation under supervision of CBRS, HED. It has undergone secondary review in the branch and has been revised to reflect Agency policies.

A revised product chemistry data summary sheet is included.

If you need additional input please advise.

Attachment 1: Iprodione Product Chemistry Data Review.

Attachment 2: Confidential Appendix For Iprodione Product Chemistry

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cc (With Attachments 1 and 2): RBP, Iprodione FIFRA '88 file, Iprodione Subject File and Dynamac.

cc (with Attachment 1): Circulation

cc (Without Attachments): RF.

DYNAMAC
CORPORATION
Environmental Services

Final Report

IPRODIONE
Shaughnessy No. 109801; Case 2335
(CBRS No. 9943; DP Barcode D165907)

TASK 4: Phase V - Product Chemistry Reregistration Review

September 1, 1992

Contract No. 68-D2-0053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA 22202

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

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IPRODIONE

Shaughnessy No. 109801

(CBRS No. 9943; DP Barcode D165907; Case 2335)

Task 4

PHASE V - REREGISTRATION REVIEW

BACKGROUND

In response to the Iprodione Phase IV Review dated 3/15/91, Rhone-Poulenc has submitted two volumes of product chemistry data (CBRS No. 9943; 1991; MRIDs 41855501 and 41855502) for the 95% technical (T; EPA Reg. No. 264-452). The submitted data and our conclusions are discussed below.

62-1. Preliminary Analysis

The Iprodione Phase IV Review dated 3/15/91 requires information pertaining to preliminary analysis of the Rhone-Poulenc 95% T (EPA Reg. No. 264-452). In response, Rhone-Poulenc has provided (1991; MRID 41855501) preliminary analysis data for five batches of the 95% T. These data are presented in the Confidential Appendix and satisfy the requirements of 40 CFR §158.170 (Guideline Reference No. 62-1) regarding preliminary analysis for the 95% T (EPA Reg. No. 264-452). No additional data are required.

62-2. Certification of Limits

The Iprodione Phase IV Review dated 3/15/91 requires information pertaining to certified limits for the Rhone-Poulenc 95% T (EPA Reg. No. 264-452). In response, Rhone-Poulenc has provided (1991; MRID 41855501) a table of certified limits and an explanation concerning how certified limits were determined for the 95% T. These data do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the Rhone-Poulenc 95% T (EPA Reg. No. 264-452) because certified limits must be submitted on EPA Form 8570-4 (Rev. 12-90). Additional data are required.

62-3. Enforcement Analytical Methods

The Iprodione Phase IV Review dated 3/15/91 requires information pertaining to analytical methods which are suitable for enforcement purposes for each active ingredient and additional impurity determined to be of toxicological concern in the Rhone-Poulenc 95% T (EPA Reg. No. 264-452). The analytical methods submitted by Rhone-Poulenc for determination of impurities in the 95% T are discussed in the Confidential Appendix. Representative chromatograms were submitted.

Rhone-Poulenc has submitted (1991; MRID 41855501) an HPLC method [I-568-10-90(E)] for the determination of iprodione per se in technical iprodione and formulated materials. Product samples and standards are dissolved in acetonitrile, with the internal standard propiphenone, and injected onto an HPLC equipped with a stainless steel column (25 cm x 4.0 mm i.d., packed with Nucleosil C18 5 μm) and a UV detector at 220 nm. Iprodione is quantitated from peak area ratios of the sample and standard. Inadequate validation data were submitted to support method I-568-10-90(E).

These data do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the Rhone-Poulenc 95% T (EPA Reg. No. 264-452) because inadequate validation data were submitted for the methods used to determine the active ingredient and one of the impurities. Additional data are required.

PHYSICAL AND CHEMICAL CHARACTERISTICS

The Iprodione Phase IV Review dated 3/15/91 requires information pertaining to the physicochemical properties of the 95% T (EPA Reg. No. 264-452). In response Rhone-Poulenc has submitted (1991; MRID 41855501 and 41855502) physical and chemical characteristics for the 95% T. These properties are presented in Table 1. The submitted data satisfy the requirements of 40 CFR §158.190 (Guideline Reference Nos. 63-2, -3, -4, -5, and -8) for the 95% T (EPA Reg. No. 264-452). Data requirements for octanol/water partition coefficient (Guideline Reference No. 63-11) remain outstanding. Additional data are required.

Table 1. Physical and chemical properties of the 95% T (EPA Reg. No. 264-452).

Guidelines Reference No., 40 CFR §158.190; Name of Property		Description [Method] (MRID)
63-2.	Color	white (41855501)
63-3.	Physical state	powder (41855501)
63-4.	Odor	odorless (41855501)
63-5.	Melting point	128-128.5 C (41855501)
63-8.	Solubility	Solubility at 20 C Solvent — g/100 mL acetone — 34.2 acetonitrile — 16.8 dichloromethane — 45.0 ethylacetate — 22.5 hexane — 0.06 1-octanol — 1.0 toluene — 14.7 water — 0.0012 [HPLC] (41855502)

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MASTER RECORD IDENTIFICATION NUMBERS

References (used):

41855501 Chabassol, Yves C. and Chabert, Michel S. (1991) Iprodione Technical Grade; Analysis and Certification of Product Ingredients. Unpublished study prepared by Rhone-Poulenc Agriculture Company. 327 p.

41855502 Chabassol, Yves C. and Gomez Joe-Luis (1991) Iprodione Technical Grade; Solubility at 20 C. Unpublished study prepared by Rhone-Poulenc Agriculture Company. 33 p.

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Case No. 2335
Chemical No. 109801

Case Name: Iprodione
Registrant: Rhone-Poulenc
Product(s): 95% T (EPA Reg. No. 264-452)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Requirement Fulfilled? [a]	MRID Number
61-1	Product Identity and Disclosure of Ingredients	Y [b]	
61-2	Beginning Materials and Manufacturing Process	Y [b]	
61-3	Discussion of Formation of Impurities	Y [b]	
62-1	Preliminary Analysis	Y	41855501
62-2	Certification of Ingredient Limits	N [c]	41855501
62-3	Analytical Methods to Verify the Certified Limits	N [d]	41855501
63-2	Color	Y	41855501
63-3	Physical State	Y	41855501
63-4	Odor	Y	41855501
63-5	Melting Point	Y	41855501
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y [e]	
63-8	Solubility	Y	41855502
63-9	Vapor Pressure	Y [f]	
63-10	Dissociation Constant	N/A	
63-11	Octanol/Water Partition Coefficient	N	
63-12	pH	N/A	
63-13	Stability	Y [g]	

[a] Y = Yes; N = No; N/A = Not Applicable.

[b] CBRS No. 8863, S. Funk, dated 2/4/92.

[c] The registrant must submit certified limits on EPA Form 8570-4 (Rev. 12-90).

[d] The registrant must submit additional validation data for the methods used to determine the active ingredient and one of the impurities.

[e] According to the Iprodione Phase IV Review dated 3/15/91, MRID 41517601 is a candidate for Phase V review to fulfill requirements for this guideline.

[f] According to the Iprodione Phase IV Review dated 3/15/91, MRIDs 41230502 and 41230503 are candidates for Phase V review to fulfill requirements for this guideline.

[g] CBRS No. 9165, S. Funk, dated 6/9/92.

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