

US EPA ARCHIVE DOCUMENT



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

R.F.
8-6-87

AUG 6 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Chlorothalonil - EPA Registration No. 50534-7
Fermenta Plant Protection Company's Response to
the Product Chemistry Chapter (MRID Nos. 402025-01
to -03 and 400476-00 to -01 dated May 12, 1987)
RCB No. 2429

FROM: Gobind P. Makhijani, Chemist *G.P. Makhijani*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Lois Rossi/R. Forrest, PM Team 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Amy Rispin
Science Integration Staff
Hazard Evaluation Division (TS-769C)

THRU: William J. Boodee, Section Chief
Reregistration Section
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C) *WJB*

In response to the Residue Chemistry Branch review (Michael P. Firestone) dated September 1985, Fermenta Plant Protection Company (new name for SDS Biotech) has submitted additional data, dated May 12, 1987 (MRID Nos. 400476-00, 400476-01, 402025-01, 402025-02, and 402025-03, a total of nine volumes) in connection with the product chemistry of its technical chlorothalonil (EPA Registration No. 50534-7).

This information and our conclusions are discussed below. Also, revised tables A and B are provided at the end of this report.

61-2 - Description of Beginning Materials and Manufacturing Process

The registrant had previously submitted (EPA Accession No. 257516, dated April 1, 1985) details of the manufacturing process along with the names of suppliers of the starting materials. This was reviewed by RCB (M. Firestone) on September 10, 1986.

The registrant has now submitted (MRID No. 402025-01, dated December 12, 1986) further clarification for the other registered technical and manufacturing-use products. This information is discussed in the Confidential Appendix A attached to this report.

No further information is required about this topic.

61-3 - Discussion of the Formulation of Impurities

The registrant has submitted further studies (MRID No. 402025-02) in connection with the [REDACTED] This information is discussed in the Confidential Appendix B attached to this report.

No further information is required about this topic.

62-1 - Preliminary Analysis

The registrant has submitted (MRID No. 402025-02) average levels of the four impurities greater than 0.1%, in five samples. These values are not acceptable to RCB.

The following data are still needed from the registrant: Analysis for each of the five samples must be reported separately and must include individual values for:

- a. the amount of active ingredients, and
- b. each impurity for which a certified limit is required.

A data gap still exists here.

IMPURITY INFO NOT INCLUDED

63-2 - Certification of Limits

The registrant has submitted a "Confidential Statement of Formula" (EPA Form 8570-4, Rev. February 1985) in which lower and upper limits have been certified for the active ingredient and the upper limits have been certified for the impurities present > 0.1% by weight.

This information is discussed in the Confidential Appendix C attached to this report.

RCB cannot offer any final conclusions on this topic until a complete preliminary analysis (five batches) for chlorothalonil is submitted by the registrant.

62-3 - Analytical Methods to Verify Certified Limits

The registrant has submitted (MRID No. 402025-03) an analytical method for the determination of known impurities in the technical product, along with validation data.

A summary of the analytical method is discussed in the Confidential Appendix D.

No further information is needed on this topic.

Physical and Chemical Characteristics

The physical and chemical properties not reported previously by the registrant are as follows (MRID No. 400476-01):

63-7 - Bulk Density - 0.702 g/mL

63-17 - Storage Stability - 30 pounds of technical material was stored in Ohio in a sealed metal drum with plastic liner, at ambient room temperature of approximately 50 °F and high of approximately 100 °F, from September 30, 1980 to October 25, 1985. Subsamples were taken for analyses 10 times during the period.

Over the 3- to 5-year storage test, the chlorothalonil assay ranged from 97.7 to 98.2% with an average of 98.1%. Likewise, no significant trends were observed in the results of analysis of any impurities.

63-18 - Viscosity - Not applicable, since it is a solid at ambient temperature.

63-19 - Miscibility - Not applicable, since it is a solid at ambient temperature.

63-20 - Corrosive Characteristics - Noncorrosive. The bulk bags are made from polypropylene and storage time for the technical material is less than 2 months.

Attachment I - Tables A and B (4 pages)

cc: Chlorothalonil Registration Standard, S.F., Reviewer, RBP, PMSD/ISB (E. Eldredge), L. Rossi (PM 21), R.F., Circu., Tox (Coberly).

Attachment II - Confidential Appendix (4 pages)

cc: Chlorothalonil Registration Standard, S.F., Reviewer, RBP, PMSD/ISB (E. Eldredge), L. Rossi (PM 21), Tox (Coberly).

cc: Chlorothalonil Registration Standard, S.F., R.F., Reviewer, PMSD/ISB (E. Eldredge), L. Rossi (PM 21), Circu., RBP, Tox (Coberly).

TABLE A

GENERIC DATA REQUIREMENTS FOR CHLOROTHALONIL; TGAI (EPA Registration No. 50534-7)

| Guideline Citation and Name of Test | Test Substance | Guidelines Status | Are Data Required? | | Reference |
|---|----------------|-------------------|--------------------|-----|---|
| | | | Yes | No | |
| <u>§158.120 Product Chemistry</u> | | | | | |
| <u>Product Identity and Composition</u> | | | | | |
| 61-2 - Description of Beginning Materials and Manufacturing Process | TGAI | R | [] | [X] | EPA Accession No. 257516 and MRID No. 402025-01 |
| 61-3 - Discussion of Formation of Impurities | TGAI | R | [] | [X] | EPA Accession No. 257516 and MRID No. 402025-02 |
| <u>Analysis and Certification of Product Ingredients</u> | | | | | |
| 62-1 - Preliminary Analysis of Product Samples | TGAI | CR | [X] | [] | |
| 62-2 - Certification of Ingredient Limits | TGAI | R | [] | [X] | CSF dated December 12, 1986 |
| 62-3 - Analytical Methods to Verify Certified Limits | TGAI | R | [] | [X] | EPA Accession No. 257516 MRID No.s402025-03 |
| <u>Physical and Chemical Characteristics</u> | | | | | |
| 63-2 - Color | TGAI | R | [] | [X] | See Registration Standard |
| 63-3 - Physical State | TGAI | R | [] | [X] | See Registration Standard |
| 63-4 - Odor | TGAI | R | [] | [X] | See Registration Standard |

TABLE A
 GENERIC DATA REQUIREMENTS FOR CHLOROTHALONIL; TGAI (EPA Registration No. 50534-7)

| Guideline Citation and Name of Test | Test Substance | Guidelines Status | Are Data Required? | | Reference |
|---|----------------|-------------------|--------------------|-------------------|---|
| | | | Yes | No | |
| <u>§158.120 Product Chemistry (cont'd)</u> | | | | | |
| <u>Physical and Chemical Characteristics (cont'd)</u> | | | | | |
| 63-5 - Melting Point | TGAI | R | [] | [X] | See Registration Standard |
| 63-6 - Boiling Point | TGAI | N/A | [] | [X] | |
| 63-7 - Density, Bulk Density, or Specific Gravity | TGAI | R | [] | [X] | MRID No. 400476-01 |
| 63-8 - Solubility | TGAI or PAI | R | [] | [X] | See Registration Standard |
| 63-9 - Vapor Pressure | PAI | R | [] | [X] | See Registration Standard EPA Accession No. 257517 |
| 63-10 - Dissociation Constant | PAI | N/A | [] | [X] | EPA Accession No. 257517 |
| 63-11 - Octanol/Water Partition Coefficient | PAI | R | [] | [X] | EPA Accession No. 257517 |
| 63-12 - pH | TGAI | N/A | [] | [X] | EPA Accession No. 257517 |
| 63-13 - Stability | TGAI | R | [] | [X] | See Registration Standard |
| <u>Other Requirements</u> | | | | | |
| 64-1 - Submittal of Samples | TGAI or PAI | CR | [] | [X] ^{1/} | |

^{1/}If samples are needed, the Agency will request them.

TABLE B
 PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLOROTHALONIL
 EPA Registration No. 50534-7

| Guideline Citation and Name of Test | Test Substance | Guidelines Status | Are Data Required? | | Reference |
|---|----------------|-------------------|--------------------|-----|--|
| | | | Yes | No | |
| <u>§158.120 Product Chemistry</u> | | | | | |
| <u>Product Identity and Composition</u> | | | | | |
| 61-1 - Product Identity and Disclosure of Ingredients | MP | R | [] | [X] | See Registration Standard |
| 61-2 - Description of Beginning Materials and Manufacturing Process | MP | R | [] | [X] | EPA Accession No. 257516 MRID No. 402025-01 |
| 61-3 - Discussion of Formation of Impurities | MP | R | [] | [X] | EPA Accession No. 257516 MRID No. 402025-02 |
| <u>Analysis and Certification of Product Ingredients</u> | | | | | |
| 62-1 - Preliminary Analysis | MP | CR | [X] | [] | |
| 62-2 - Certification of Limits | MP | R | [] | [X] | CSF dated December 12, 1986 |
| 62-3 - Analytical Methods to Verify Certified Limits | MP | R | [] | [X] | EPA Accession No. 257516 MRID No. 402025-03 |
| <u>Physical and Chemical Characteristics</u> | | | | | |
| 63-14 - Oxidizing or Reducing Action | MP | CR | [] | [X] | EPA Accession No. 257517 |

TABLE B
 PRODUCT-SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHLOROTHALONIL
 EPA Registration No. 50534-7

| Guideline Citation and Name of Test | Test Substance | Guidelines Status | Are Data Required? | | Reference |
|---|----------------|-------------------|--------------------------|-------------------------------------|--------------------------|
| | | | Yes | No | |
| <u>§158.120 Product Chemistry (cont'd)</u> | | | | | |
| <u>Physical and Chemical Characteristics (cont'd)</u> | | | | | |
| 63-15 - Flammability | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | EPA Accession No. 257517 |
| 63-16 - Explodability | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | EPA Accession No. 257517 |
| 63-17 - Storage Stability | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 400476-01 |
| 63-18 - Viscosity | MP | N/A | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 400476-01 |
| 63-19 - Miscibility | MP | N/A | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 400476-01 |
| 63-2- - Corrosion Characteristics | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 400476-01 |
| <u>Other Requirements</u> | | | | | |
| 64-1 - Submittal of Samples | TGAI or PAI | CR | <input type="checkbox"/> | <input checked="" type="checkbox"/> | ^{1/} |

^{1/}The Agency will request samples if needed.