

US EPA ARCHIVE DOCUMENT



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

DEC 4 1987

MEMORANDUM

SUBJECT: Prometryn - EPA Registration No. 100-542
Ciba-Geigy's Response to the Product Chemistry
Chapter (MRID Nos. 403560-01 and 403560-02)
Dated September 25, 1987 - RCB No. 2907

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

TO: Robert J. Taylor/Joanne I. Miller, PM Team 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Amy S. Rispin, Ph.D., Chief
Science Integration Staff
Hazard Evaluation Division (TS-769C)

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

In response to the Prometryn Reregistration Guidance Document (issued March 20, 1987), Ciba-Geigy Corporation has submitted additional product chemistry data consisting of two volumes, dated September 25, 1987 (MRID Nos. 403560-01 and 403560-02).

Revised tables A and B are provided at the end of this report.

It should be noted that the prometryn to which Ciba-Geigy Corporation refers as the technical material (EPA Registration No. 100-542) has inert ingredients added in the final step of production. Therefore, by definition, this product is a manufacturing-use product (MP). The following discussions refer therefore to the MP.

61-1 - Product Identity and Disclosure of Ingredients

A. Information on Product Identity

The required information (MRID No. 403560-01) needed for fulfillment of the requirements of this topic has been submitted by the registrant.

No further information is needed on this topic.

B. Confidential Statement of Formula (CSF)

The registrant has submitted a revised CSF, dated September 25, 1987. This revision is necessary because of the results of analytical work. This revised CSF also incorporates the inert ingredients added to the MP in the final step of production.

These data will be reexamined by RCB, after the receipt of the preliminary analysis of five batches of prometryn.

The CSF is given in Confidential Appendix A.

61-2 - Description of Beginning Materials and Manufacturing Process

The registrant has submitted the names and addresses of the suppliers of the beginning materials and their specifications along with a detailed manufacturing process (MRID No. 403560-01).

A discussion of the manufacturing process is given in Confidential Appendix B.

No further information is needed on this topic.

61-3 - Discussion of Formation of Impurities

The registrant has provided a theoretical discussion of the formation of impurities during the production of prometryn (MRID No. 403560-01).

No further information is needed on this topic.

62-1, -2, and -3 - Preliminary Analysis, Certification of
Ingredient Limits, and Analytical Methods
to Verify the Certified Limits

The required information will be submitted by the registrant in March 1988.

A data gap still exists here.

Series 63 - Physical and Chemical Properties

The updated physical and chemical properties as reported by the registrant are as follows (MRID No. 402560-02):

63-2 - Color: White to tan

63-3 - Physical State: Powder

63-4 - Odor: Odorless

63-5 - Melting Point: 118 to 120 °C

63-7 - Density: 1.16 g/mL at 20 °C

63-8 - Solubility: Water--33 ppm at 20 °C
n-Hexane--0.55 g/100 mL at 20 °C
n-Octanol--10 g/100 mL at 20 °C
Methanol--16 g/100 mL at 20 °C
Toluene--17 g/100 mL at 20 °C
Acetone--24 g/100 mL at 20 °C
Methylene chloride--30 g/100 mL
at 20 °C

63-9 - Vapor Pressure: 1×10^{-6} mm Hg at 25 °C

63-10 - Dissociation Constant: pKa = 4.09 at 20 °C

63-11 - Octanol/Water

Partition Coefficient: P_{ow} 1212 (Log P = 3.1)
at 25 ± 1 °C
(Details of the experiment
submitted by the registrant
and the data are acceptable
to RCB.)

63-12 - pH: 6.7 at 20 ± 2 °C (saturated solution)

63-13 - Stability: The stability of prometryn in containers fabricated from carbon steel was studied at temperatures of 50 °C for a period of 2 weeks.

The metal ion levels detected were:
Fe⁺⁺, Fe⁺⁺⁺ < 10 ppm
Cr⁺³, Cr⁺⁶ None detected
Zn⁺⁺ None detected

63-14 - Oxidizing and Reducing Action: None observed

63-16 - Explodability: NFPA Codes - 0 = No danger
4 = Explodable

Safety Classification

- 1.1 - Drying (T) 1
Grinding (M) 1
Dust Explosion (St) 1
- 1.2 - Maximum Allowable Temperature of heating medium 120° C

Airborne Dust Explosion Data

Modified Hartmann apparatus: 1
Minimum Ignition Energy (J): <10
Bam Ignition Temperature (°C): >600
Particle Size: 1% >63 um

63-17 - Storage Stability: Less than 1% decomposition:
When stored at room temperature for 12 months.
When stored at 38 °C for 28 weeks.
When stored at 50 °C for 28 weeks.
When stored at 70 °C for 7 weeks.

63-19 - Miscibility: Forms a suspension in water at 25 °C.

63-20 - Corrosion Characteristics: Carbon steel coupon at 50 °C. Corrosion rate: 0.01164 mil/year. No corrosion or pitting were detected.

Attachment I: Tables A and B (4 pages)

Prometryn Registration Standard, S.F., Reviewer,
RBP, PMSD/ISB (E. Eldredge), R.Taylor (PM 25), TOX
(Coberly)

Attachment II: Confidential Appendices A and B (4 pages)

Prometryn Registration Standard, S.F., Reviewer,
RBP, PMSD/ISB (E. Eldredge), R.Taylor (PM 25), TOX
(Coberly)

cc: Prometryn Registration Standard, S.F., R.F., Reviewer,
PMSD/ISB (E. Eldredge), R.Taylor (PM 25), Circu, RBP,
TOX (Coberly)

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Table A
 Generic Data Requirements for Technical Prometryn (cont'd)
 (EPA Registration No. 100-542)

| Guideline Citation and Name of Test | Test Substance | Guidelines Status | Are Additional Data Required? | | Reference Citation |
|---|----------------|-------------------|-------------------------------------|-------------------------------------|--------------------|
| | | | [Yes] | [No] | |
| <u>§158.120 Product Chemistry</u> | | | | | |
| <u>Physical and Chemical Characteristics (cont'd)</u> | | | | | |
| 63-7 - Bulk Density | TGAI | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-8 - Solubility | TGAI or PAI | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-9 - Vapor Pressure | PAI | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-10 - Dissociation Constant | PAI | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-11 - Octanol/Water Partition Coefficient | PAI | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-12 - pH | TGAI | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-13 - Stability | TGAI | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| <u>Other Requirements</u> | | | | | |
| 64-1 - Submittal of Samples | TGAI or PAI | R | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

DATA REQUIREMENT FOOTNOTES:

TGAI = Technical Grade of the Active Ingredient; PAI = Purified Active Ingredient; R = Required; N/A = Not applicable.
 * If samples are needed, the Agency will request them.

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Table B
 Product-Specific Data Requirements for Manufacturing-Use Products Containing Prometryn
 (EPA Registration No. 100-542)

| Guideline Citation and Name of Test | Test Substance | Guidelines Status | Are Additional Data Required? | | Reference Citation |
|---|----------------|-------------------|-------------------------------------|-------------------------------------|--------------------|
| | | | [Yes] | [No] | |
| <u>§158.120 Product Chemistry</u> | | | | | |
| <u>Product Identity</u> | | | | | |
| 61-1 - Product Identity and Disclosure of Ingredients | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 61-2 - Description of Beginning Materials and Manufacturing Process | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 61-3 - Discussion of Formation of Impurities | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| <u>Analysis and Certification of Product Ingredients</u> | | | | | |
| 62-1 - Preliminary Analysis | MP | CR | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 62-2 - Certification of Ingredient Limits | MP | R | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| 62-3 - Analytical Methods to Verify Certified Limits | MP | R | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |
| <u>Physical and Chemical Characteristics</u> | | | | | |
| 63-2 - Color | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-3 - Physical State | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-4 - Odor | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-7 - Density, Bulk Density, or Specific Gravity | MP | R | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |

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Table B
 Product-Specific Data Requirements for Manufacturing-Use Products Containing Prometryn (cont'd)
 (EPA Registration No. 100-542)

| Guideline Citation and Name of Test | Test Substance | Guidelines Status | Are Additional Data Required? | | Reference Citation |
|---|----------------|-------------------|-------------------------------------|-------------------------------------|--------------------|
| | | | [Yes] | [No] | |
| <u>§158.120 Product Chemistry</u> | | | | | |
| <u>Physical and Chemical Characteristics (cont'd)</u> | | | | | |
| 63-12 - pH | MP | CR | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-14 - Oxidizing or Reducing Action | MP | CR | <input type="checkbox"/> | <input checked="" type="checkbox"/> | MRID No. 403560-02 |
| 63-15 - Flammability | MP | N/A | <input type="checkbox"/> | <input type="checkbox"/> | |
| 63-16 - Explodability | MP | R | <input type="checkbox"/> | <input type="checkbox"/> | MRID No. 403560-02 |
| 63-17 - Storage Stability | MP | R | <input type="checkbox"/> | <input type="checkbox"/> | MRID No. 403560-02 |
| 63-18 - Viscosity | MP | N/A | <input type="checkbox"/> | <input type="checkbox"/> | |
| 63-19 - Miscibility | MP | CR | <input type="checkbox"/> | <input type="checkbox"/> | MRID No. 403560-02 |
| <u>Other Requirements</u> | | | | | |
| 64-1 - Submittal of Samples | EP, TGAI, PAI | CR | <input checked="" type="checkbox"/> | <input type="checkbox"/> | |

DATA REQUIREMENT FOOTNOTES:

R = Required; CR = Conditionally Required; EP = End-Use Product; MP = Manufacturing-Use Product; TGAI = Technical Grade of the Active Ingredient; PAI = Purified Active Ingredient; N/A = Not applicable.

* If samples are needed, the Agency will request them.

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PROMETRYN

Page _____ is not included in this copy.

Pages 9 through 12 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.

CONFIDENTIAL APPENDICES

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.
