

US EPA ARCHIVE DOCUMENT



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

JUL 30 1992

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Reregistration of Simazine. Ciba Geigy Response to Product Chemistry Requirements: CBRS # 9496: DP Barcode D175034: MRID No. 42181501.

FROM: William Smith, Chemist *William D. Smith*
Reregistration Section I
Chemistry Branch II: Reregistration Support (CBRS)
Health Effects Division (H7509C)

THROUGH: E. Zager, Chief *Edward Zager*
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: Walter Waldrop/Venus Eagle
Reregistration Branch
Special Review & Reregistration Division (H7508W)

Attached is the review of product chemistry data submitted in support of reregistration of the Ciba-Geigy Simazine 97% T (EPA Reg. No. 100-541). This information was reviewed by Dynamac Corporation under supervision of CBRS, HED. The data assessment has undergone secondary review in the Branch and has been revised to reflect Branch policies.

A revised product chemistry data summary sheet is included.

Attachment 1: Simazine CBRS No. 9496; DP Barcode D176690.
Registrant's Response to Product Chemistry Data Requirements.

Attachment 2: Confidential Appendix to Simazine CBRS No. 9496

cc (with attachments 1 & 2): W Smith (CBRS), Simazine Reg. Std. File, SF, Dynamac.
cc (without attachments): RF

H7509C:CBRS:WOS:wos:CM#2:Rm805A:703-305-5353: 07/27/92
RDI: MMetzger:07/27/92 EZager:07/27/92

Final Report

SIMAZINE
Shaughnessy No. 080807
(CBRS No. 9496; DP Barcode D175034;
Case 0070)

TASK 4
Registrant's Response to Product
Chemistry Data Requirements

July 6, 1992

Contract No. 68-D2-0053

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

Submitted by:
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The Dynamac Building
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Rockville, MD 20850-3268

SIMAZINE

Shaughnessy No. 080807

(CBRS No. 9496; DP Barcode D175034; Case 0070)

Task 4

REGISTRANT'S RESPONSE TO PRODUCT CHEMISTRY DATA REQUIREMENTS

BACKGROUND

In response to a Simazine DCI dated 9/12/91 Ciba-Geigy Corporation has submitted a single volume of product chemistry data (CBRS No. 9496; 1992; MRID 42181501) for the 97% technical (T; EPA Reg. No. 100-541). The product chemistry requirements in this DCI are derived from the Simazine SRR Product Chemistry Chapter dated 1/30/89. The data submitted by the registrant and our conclusions are discussed below.

62-1. Preliminary Analysis

Ciba-Geigy has resubmitted (1992; MRID 42181501) data concerning the preliminary analysis of the 97% T. These data were previously reviewed in the Simazine SRR Product Chemistry Chapter dated 1/30/89 and found to satisfy data requirements. The registrant has resubmitted these data to correct data that had been inadvertently reversed between batches. This resubmission does not alter the conclusion of the Registration Standard and these data are presented in the Confidential Appendix for informational purposes only. No additional data are required.

62-2. Certification of Limits

The Simazine SRR Product Chemistry Chapter requires that the certified limits of nitrosamines for the 97% T (EPA Reg. No. 100-541) be reported on EPA Form 8570-4 (Rev. 12/90). In response, Ciba-Geigy has submitted a statement of formula (1992; MRID 42181501) for the 97% T which is presented in the Confidential Appendix. These data do not satisfy the requirements of 40 CFR §158.175 (Guideline Reference No. 62-2) regarding certified limits for the 97% T (EPA Reg. No. 100-541) because certified limits were not submitted on EPA Form 8570-4 (Rev. 12/90). Additional data are required.

62-3. Enforcement Analytical Methods

The Simazine SRR Product Chemistry Chapter dated 1/30/89 requires complete descriptions of the analytical methods, ASM-183-R and ASM-186-R, used to quantitate simazine and its impurities in the 97% T (EPA Reg. No. 100-541). The analytical methods submitted by Ciba-Geigy for the determination of simazine and its impurities, including nitrosamines, are discussed in the Confidential Appendix. These data do not satisfy the requirements of 40 CFR §158.180 (Guideline Reference No. 62-3) regarding enforcement analytical methods for the 97% T (EPA Reg. No. 100-541) because an enforcement analytical method to determine an impurity was not submitted. In addition, a complete description of the method and complete validation data were not submitted for the method used to determine nitrosamines. Additional data are required.

MASTER RECORD IDENTIFICATION NUMBERS

References (used):

42181501 Lail, L.J. (1992) Technical Simazine. Product Chemistry. Unpublished compilation prepared by Ciba-Geigy Corporation. 62 p.

PRODUCT CHEMISTRY DATA SUMMARY
Ciba-Geigy 97% T (EPA Reg. No. 100-541)

Guideline Number	Requirement	Requirement Fulfilled? ^a	MRID Number
61-1	Product Identity and Disclosure of Ingredients	Y	
61-2	Beginning Materials and Manufacturing Process	Y	
61-3	Discussion of Formation of Impurities	Y	
62-1	Preliminary Analysis	Y	42181501
62-2	Certification of Ingredient Limits	N ^b	42181501
62-3	Analytical Methods to Verify the Certified Limits	N ^c	42181501
63-2	Color	Y	
63-3	Physical State	Y	
63-4	Odor	Y	
63-5	Melting Point	Y	
63-6	Boiling Point	N/A	
63-7	Density, Bulk Density or Specific Gravity	Y	
63-8	Solubility	Y	
63-9	Vapor Pressure	Y	
63-10	Dissociation Constant	Y	
63-11	Octanol/Water Partition Coefficient	Y	
63-12	pH	Y	
63-13	Stability	Y	
63-14	Oxidizing or Reducing Action	Y	
63-15	Flammability	Y	
63-16	Explodability	Y	
63-17	Storage Stability	Y	
63-18	Viscosity	N/A	
63-19	Miscibility	N/A	
63-20	Corrosion Characteristics	N	

a. Y = Yes, N = No, N/A = Not Applicable. Data requirements footnoted in this table reflect conclusions determined in this document only.

b. The registrant must submit the certified limits on EPA Form 8570-4 (Rev. 12/90).

c. The registrant must submit an enforcement analytical method to determine an impurity not quantitated by the submitted methods. In addition, a complete description of the method and complete validation data must be submitted for the method used to determine nitrosamines.

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SIMAZINE (CIBA-GEIGY; CBRS NO. 9496)

PRODUCT CHEMISTRY

TASK 4

(Final Report)

CONFIDENTIAL APPENDIX

3 Page(s)

Confidential Appendix to the Scientific Review of a Registration Standard Follow up Report for the pesticide simazine by the Chemistry Branch II Reregistration Support [Confidential FIFRA Trade Secret/CBI].

SIMAZINE

080807

Page ___ is not included in this copy.

Pages 7 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.

CONFIDENTIAL APPENDIX

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.
