



CONFIDENTIAL

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

SEP 16 '88

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to Simazine Registration Standard,
Ciba-Geigy Corporation

ID NO(S). 100-541
RCB NO(S). 4295
MRID NO(S). 407651-01

FROM: H. Fonouni, Ph.D., Chemist *H. E. Fonouni*
Dietary Exposure Branch
Health Effects Division (TS-767C)

TO: R. Mountfort, PM 23
Registration Division (TS-767C)

THRU: William J. Boodee, Section Head *WJB*
Dietary Exposure Branch
Health Effects Division (TS-769C)

In response to the Simazine Registration Standard (Guidance Document, March 1, 1984), Ciba-Geigy Corporation has provided product chemistry information/data on a manufacturing-use product, "Simazine Technical" (EPA Registration No. 100-541).

The information/data submitted and our conclusions are discussed below. In addition, revised Tables A and B have been included to reflect the remaining product chemistry data requirements.

It should be noted that, the registrant in the correspondence requests approval from the Agency to use [REDACTED] in the Technical Simazine.

Although Dietary Exposure Branch has no objection to this request, as expressed in our previous memorandum (February 9, 1987, G. Makhijani) by definition and for the Agency's regulatory purpose a technical chemical (TGAI) should not contain intentionally added inert ingredients; products containing such ingredients are classified as manufacturing-use products. The registrant is referred to 40 CFR 158.190 (previous reference 40 CFR 158.120) and the Pesticide Assessment Guidelines,

INERT INGREDIENT INFORMATION IS NOT INCLUDED

Subdivision D for the information/data required from technical chemicals in support of the registration of manufacturing-use products.

61-2 Description of Beginning Materials and Manufacturing Process

MRID NO(S): 407651-01

A description of manufacturing process analogous to that provided previously has been submitted (EPA Accession No. 2525084); refer to our February 9, 1987 memorandum by G. Makhijani. In addition, specification and safety information/data has been provided for various ingredients.

The information/data provided satisfy the requirements for this topic.

62-1 Preliminary Analysis of Product Samples

MRID NO(S): 407651-01

The information provided appears in Confidential Appendix A.

The information/data provided satisfy the requirements of this topic.

62-2 Certification of Ingredient Limits

MRID NO(S): 407651-01

The information/data provided appears in Confidential Appendix B.

The information/data provided do not satisfy the requirements for this topic. Certified limits for nitrosamines must be reported on the Confidential Statement of Formula, EPA Form 8570 (Rev. 2-85); refer to Confidential Appendix B.

62-3 Analytical Methods to Verify Certified Limits

MRID NO(S): 407651-01

The information/data provided including references to two recently developed analytical methods, ASM-183-R and ASM-186-R appear in Confidential Appendix C.

The information/data provided do not satisfy the requirements for this topic. Complete descriptions of methods used to quantitate the active ingredient, simazine, and impurities with required certified limits must be provided.

63 Physical and Chemical Characteristics

MRID NO(S): 407651-01

The information/data provided on the pure simazine is presented below.

63-5 Melting Point (solids): 228.2 - 228.8 degrees C.

63-9 Vapor Pressure: 2.21×10^{-8} mm Hg

63-11 Octanol/water Partition
Coefficient: 122 (log p = 2.1)

The information/data provided satisfy the requirements for this topic.

Attachment I - Tables A (2 pages) and B (1 page)

cc: Simazine Registration Standard File, SF, Reviewer
(H. Fonouni), RBP, TOX (R. Coberly), PMSD/ISB (E. Eldredge),
PM 23 (R. Mountfort)

Attachment II - Confidential Appendix A (1 page)

Attachment III - Confidential Appendix B (2 pages)

Attachment IV - Confidential Appendix C (1 page)

cc: Simazine Registration Standard File, SF, Reviewer
(H. Fonouni), RBP, TOX (R. Coberly), PMSD/ISB (E. Eldredge),
PM 23 (R. Mountfort)

cc: Simazine Registration Standard File, SF, RF, Reviewer
(H. Fonouni), RBP, TOX (R. Coberly), PMSD/ISB (E. Eldredge),
PM 23 (R. Mountfort)

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TABLE A
GENERIC DATA REQUIREMENTS FOR TECHNICAL SIMAZINE

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Reference Citation (MIRD No.)
			[Yes]	[No]	
40 CFR 158.120 Product Chemistry					
Product Identity and Composition					
61-1 - Identity of Ingredients	TGAI	R	X		EPA Accession No. 2525084
61-2 - Materials and Process	TGAI	R	X		
61-3 - Formation of Impurities	TGAI	R	X		
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	TGAI	R	X		407651-01
62-2 - Certification of Ingredient Limits	TGAI	N/A			
62-3 - Analytical Methods to Verify Certified Limits	TGAI	N/A			
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	TGAI	R		X	407651-01
63-3 - Physical State	TGAI	R		X	
63-4 - Odor	TGAI	R		X	
63-5 - Melting Point	TGAI	R		X	
63-6 - Boiling Point	TGAI	R		X	
63-7 - Bulk Density	TGAI	R		X	
63-8 - Solubility	TGAI or PAI	R		X	
63-9 - Vapor Pressure	PAI	R		X	
63-10- Dissociation Constant	PAI	R		X	
63-11- Octanol/water Partition Coefficient	PAI	R		X	
63-12- PH	TGAI	R		X	

(Continued, footnotes follow)

(5)

TABLE A
GENERIC DATA REQUIREMENTS FOR TECHNICAL SIMAZINE

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Reference Citation (MIRD No.)
			[Yes]	[No]	
158.120 Product Chemistry (Cont'd) Physical and Chemical Characteristics					
63-13- Stability	TGAI	R		X	407651-01
Other Requirements					
64-1 - Submittal of Samples	TGAI and PAI	CR ¹		X	

TGAI = Technical Grade Active Ingredient (Technical Chemical); PAI = Purified Active Ingredient; R = Required;
CR = Conditionally Required; N/A = Not Applicable.

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

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TABLE B

DATA REQUIREMENTS FOR THE MANUFACTURING-USE PRODUCT CONTAINING SIMAZINE
(EPA REGISTRATION NO. 100-541)

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Additional Data Required?		Reference Citation (MIRD No.)
			[Yes]	[No]	
40 CFR 158.120 Product Chemistry					
<u>Product Identity and Composition</u>					
61-1 - Identity of Ingredients	MP	R		X	407651-01, EPA Accession No 2525084
61-2 - Materials and Process	MP	R		X	
61-3 - Formation of Impurities	MP	R		X	
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	MP	R		X	407651-01
62-2 - Certification of Ingredient Limits	MP	R	X		
62-3 - Analytical Methods to Verify Certified Limits	MP	R	X		
<u>Physical and Chemical Characteristics¹</u>					
<u>Other Requirements</u>					
64-1 - Submittal of Samples	MP	CR ²			
MP = Manufacturing-Use Product; N/A = Not Applicable; CR = Conditionally Required					

MP = Manufacturing-Use Product; N/A = Not Applicable; CR = Conditionally Required

1/ As requested by the Registration Division, Dietary Exposure Branch no longer reviews data pertaining to the physical/chemical properties of manufacturing-use products.

2/ If samples are needed, the Agency will request them.

SIMAZINE

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Page is not included in this copy.

Pages 7 through 10 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.
