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

FEB 9 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Ciba-Geigy's Response to the Product Chemistry
Chapter - Simazine Registration Standard
(EPA Accession No. 255084) - RCB No. 1791

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

Gobind P. Makhijani

TO: Richard F. Mountfort, PM 23
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

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

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

W.B.

In response to the Simazine Reregistration Guidance Document published on March 1, 1984, Ciba-Geigy has submitted additional product chemistry data dated October 17, 1984 (EPA Accession No. 255084). These data and our conclusions are discussed below. Also, revised tables A and B are provided at the end of this report.

It should be noted that the simazine that is defined as technical material by Ciba-Geigy (EPA Registration No. 100-541) has ingredients added to it as [REDACTED]. By definition, this makes simazine a manufacturing-use product (MP). In light of this, only a few outstanding data gaps for the technical grade active ingredient have been fulfilled in this submission. The discussion of the following topics refer solely to the MP.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

61-2 Description of Beginning Materials and Manufacturing Process

The registrant has submitted the names and addresses of suppliers of beginning materials and their specifications along with the detailed manufacturing process. This method has already been discussed in the Product Chemistry Chapter (Confidential Section) of the Simazine Registration Standard.

This fulfills the requirements of this topic and no other information is needed.

61-3 Discussion of Formation of Impurities

The registrant has submitted a discussion of the formation of possible impurities during the manufacture of the simazine MP. This fulfills the requirements of this topic and no other information is needed.

62-1 Preliminary Analysis

The preliminary analysis of five batches of simazine MP submitted by the registrant (Accession No. 255084) indicated that two batches, BA 12 and BA 15, contain [REDACTED]. The results of preliminary analysis of simazine MP are discussed in Confidential Appendix A. A data gap still exists here. All impurities occurring at > 0.1% in the technical product or MP must be identified and quantitated using appropriate and validated techniques and methodology. If the impurities listed as "unknown" are a number of different components each of which is present at < 0.1% in the technical material or MP, this should be demonstrated. Additional information is needed under this topic.

62-2 Certification of Limits

The registrant has submitted the required information (dated October 9, 1985) giving only the lower limits for active ingredients (ai) and upper limits for impurities in the MP on an obsolete Form 8570-4 (Rev. 10-81). These limits are discussed in Confidential Appendix B. This information, however, must be submitted on EPA Form 8570-4 (Rev. 2-85), and the impurities listed as "unknowns" must be identified and quantitated.

A data gap still exists here.

62-3 Analytical Methods to Verify Certified Limits

The registrant has submitted methods for the quantitation of simazine ai and impurities in the technical product as well as in the MP. The methods of analysis previously submitted by the registrant for atrazine were also used for simazine. The procedures are discussed in Confidential Appendix C.

All these methods have been validated as per EPA Accession No. 265847 (see our report in connection with atrazine dated January 16, 1987). The registrant should clarify whether Method No. SDCG-C-20, "Analysis of Technical Atrazine for Minor Impurities by Capillary Gas Chromatography" was also used for analysis of simazine.

A data gap still exists here.

Physical and Chemical Properties

The physical and chemical characteristics for simazine have been submitted by the registrant and are as follows:

- | | |
|---|--------------------|
| 63-10 - Dissociation Constant | pka = 1.61 @ 20 °C |
| 63-11 - Octanol/Water Partition Coefficient | Log p = 4.18 |

Detailed experimental data should be submitted by the registrant.

- | | |
|---|------|
| 63-14 - Oxidizing or Reducing Potential | None |
|---|------|

- 63-15 - Flammability

Constant exothermic reaction:
No exothermic reaction
during 8 hours at 160 °C

DSC: Three exothermic reactions:

1. starting at 234 °C,
 $\Delta H = 60 \text{ cal/g}$;
2. starting at 256 °C,
 $\Delta H = 97 \text{ cal/g}$; and
3. starting at 290 °C,
 $\Delta H = 94 \text{ cal/g}$.

TGA: Zero percent weight

GAS: 1.0 L/kg at 200 °C.
Gas in air is non-
flammable (held
for 30 min).
11.0 L/kg at 240 °C.
Gas is flammable
(held for 30 min).

63-16 - Explodability

The product presents a possible dust explosion hazard. The material can be spray dried at a maximum outlet temperature of 100 °C in dryers rated for an S1 dust explosive hazard.

The material is not shock sensitive and presents no friction hazard.

Attachment I - Tables A and B (5 pages)

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

Attachment II - Confidential Appendix A, B, and C (4 pages)

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

cc: Simazine Registration Standard File, R.F., Reviewer, PMSD/ISB (E. Eldredge), S.F., Circ., R. Taylor (PM 25), TB (Coberly), RBP.

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TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: TECHNICAL SIMAZINE
EPA Registration No. 100-541

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</u>					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
61-3 - Discussion of Formation of Impurities	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Accession No. 255084
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	TGAI	CR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Accession No. 255084
62-2 - Certification of Ingredient Limits	TGAI	R	<input checked="" type="checkbox"/> ^{1/}	<input type="checkbox"/>	EPA Accession No. 255084
62-3 - Analytical Methods to Verify Certified Limits	TGAI	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Accession No. 255084

1/ Certification should be reported on EPA Form 8570-4 (Rev. 2-85).

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: TECHNICAL SIMAZINE
EPA Registration No. 100-541

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required?		Reference
			Yes	No	
<u>§158.120 Product Chemistry (continued)</u>					
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
63-3 - Physical State	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
63-4 - Odor	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
63-5 - Melting Point	PAI	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
63-8 - Solubility	TGAI or PAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
63-9 - Vapor Pressure	PAI	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
63-10 - Dissociation Constant	PAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
63-11 - Octanol/Water Partition Coefficient	PAI	R	^{2/} <input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Accession No. 255084

^{2/} Detailed experimental data should be submitted.

TABLE A

GENERIC DATA REQUIREMENTS FOR CHEMICAL: TECHNICAL SIMAZINE
EPA Registration No. 100-541

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required?		Reference
			Yes	No	
<u>§158.120 Product Chemistry (continued)</u>					
63-12 - pH	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
63-13 - Stability	TGAI	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
<u>Other Requirements:</u>					
64-1 - Submittal of Samples	TGAI, PAI	CR	<input type="checkbox"/>	<input checked="" type="checkbox"/> ^{3/}	

3/ If samples are needed the Agency will request them.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL: SIMAZINE
EPA Registration No. 100-541

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</u>					
61-1 - Product Identity and Disclosure of Ingredients	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
61-2 - Description of Beginning Materials and Manufacturing Process	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
61-3 - Discussion of Formation of Impurities	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Accession No. 255084
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis	MP	CR	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Accession No. 255084
62-2 - Certification of Limits	MP	R	<input checked="" type="checkbox"/> ^{1/}	<input type="checkbox"/>	EPA Accession No. 255084

1/ This information should be submitted on EPA Form 8570-4 (Rev. 2-85).

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING CHEMICAL: SIMAZINE
EPA Registration No. 100-541

Guideline Citation and Name of Test	Test Substance	Guidelines Status	Are Data Required?		Reference
			Yes	No	
<u>\$158.120 Product Chemistry (continued)</u>					
<u>Analysis and Certification of Product Ingredients (continued)</u>					
62-3 - Analytical Methods to Verify Certified Limits	MP	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	EPA Accession Nos. 255804 and 265847
<u>Physical and Chemical Characteristics</u>					
63-14 - Oxidizing or Reducing Action	MP	CR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Accession No. 255084
63-15 - Flammability	MP	CR	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Accession No. 255084
63-16 - Explodability	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	EPA Accession No. 255084
63-17 - Storage Stability	MP	R	<input type="checkbox"/>	<input checked="" type="checkbox"/>	See Registration Standard
63-18 - Viscosity	MP	N/A	<input type="checkbox"/>	<input type="checkbox"/>	
63-19 - Miscibility	MP	N/A	<input type="checkbox"/>	<input type="checkbox"/>	
63-20 - Corrosion Characteristics	MP	R	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

SIMAZINE

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Page _____ is not included in this copy.

Pages 10 through 13 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.

X 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.
