

US EPA ARCHIVE DOCUMENT

DP Barcode : D185469  
 PC Code No : 080807  
 EEB Out : FEB 19 1993

To: Walter Waldrop  
 Product Manager 71  
 Special Review and Reregistration Division (H7508W)

From: Anthony F. Maciorowski, Chief  
 Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 080807  
 Chemical Name : Simazine  
 Type Product : Herbicide  
 Product Name : \_\_\_\_\_  
 Company Name : Ciba-Geigy Corporation  
 Purpose : Data review (122-1a) for reregistration.

Action Code : 627 Date Due : 3/07/93  
 Reviewer : Tracy L. Perry

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)	425666-02	N
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2		
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur  
 P=Partial (Study partially fulfilled Guideline but additional information is needed)  
 S=Supplemental (Study provided useful information but Guideline was not satisfied)  
 N=Unacceptable (Study was rejected)/Nonconcur

DP BARCODE: D185469

REREG CASE #

CASE: 819251  
SUBMISSION: S430780

DATA PACKAGE RECORD  
BEAN SHEET

DATE: 12/08/92  
Page 1 of 1

\*\*\* CASE/SUBMISSION INFORMATION \*\*\*

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION  
CHEMICALS: 080807 Simazine (ANSI) 100.00

ID#: 080807  
COMPANY:  
PRODUCT MANAGER: 71 WALTER WALDROP 703-308-8062 ROOM: CS1 3B3  
PM TEAM REVIEWER: VENUS EAGLE 703-308-8045 ROOM: CS1 33B5  
RECEIVED DATE: 11/25/92 DUE OUT DATE: 02/23/93

\*\*\* DATA PACKAGE INFORMATION \*\*\*

DP BARCODE: 185469 EXPEDITE: N DATE SENT: 12/07/92 DATE RET.: / /  
CHEMICAL: 080807 Simazine (ANSI)  
DP TYPE: 001 Submission Related Data Package  
ADMIN DUE DATE: 03/07/93 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	12/15/92	/ /
BRAN: EEB	12/15/92	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

\*\*\* DATA REVIEW INSTRUCTIONS \*\*\*

PLEASE REVIEW MRID# 42566602 FOR SIMAZINE  
TO SEE IF THIS STUDY FULFILLS GL 123-1.  
THANKS,  
VENUS

\*\*\* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \*\*\*

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

FEB 19 1993

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**MEMORANDUM**

**SUBJECT:** Simazine: review of data submitted in support of reregistration.

**FROM:** Anthony F. Maciorowski, Branch Chief *A.F. Maciorowski*  
Ecological Effects Branch  
Environmental Fate and Effects Division (H7507C)

**TO:** Walter Waldrop, PM 71  
Reregistration Branch  
Special Review and Reregistration Division (H7508W)

As part of the reregistration process for the List A herbicide, simazine, the registrant has submitted the following study:

Chetram, R.S. 1992. Tier 2 Seed Germination Non-Target Phytotoxicity Study Using Simazine. Laboratory Study No. 92057. Conducted by Pan-Agricultural Laboratories, Inc., Madera, CA. Submitted by Ciba-Geigy Corporation, Greensboro, NC. MRID No. 425666-02.

This study was evaluated by EEB and classified as supplemental as the maximum use rate (9.6 lbs ai/A for grapefruit in Florida) was not tested. Therefore, the guideline requirement for a Tier 2 nontarget plant germination study (123-1a) is still outstanding.

All applicable data requirements for simazine and their statuses can be found in the attached table. If you have any questions, please contact Tracy Perry at 305-6451 or Henry Craven at 305-5320.



Recycled/Recyclable  
Printed with Soy/Canola Ink on paper that  
contains at least 50% recycled fiber

Date: 02/16/93  
 Case No: 819251  
 Chemical No: 080807

PHASE IV  
 DATA REQUIREMENTS FOR  
 ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition <sup>1</sup>	Use Pattern <sup>2</sup>	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
<b>6 Basic Studies in Bold</b>					
<b>71-1(a) Acute Avian Oral, Quail/Duck</b>	(TGAD)	A,B,C,D,E,J	YES	72798	NO
<b>71-1(b) Acute Avian Oral, Quail/Duck</b>	(TEP)	-	-	-	-
<b>71-2(a) Acute Avian Diet, Quail</b>	(TGAD)	A,B,C,D,E,J	YES	00022923	NO
<b>71-2(b) Acute Avian Diet, Duck</b>	(TGAD)	A,B,C,D,E,J	YES	00022923, 00139393	NO
<b>71-3 Wild Mammal Toxicity</b>	(TGAD)	-	-	-	-
<b>71-4(a) Avian Reproduction Quail</b>	(TGAD)	A,B,C,D,E,J	YES	163134	NO
<b>71-4(b) Avian Reproduction Duck</b>	(TGAD)	A,B,C,D,E,J	NO	43678	YES <sup>3</sup>
<b>71-5(a) Simulated Terrestrial Field Study</b>	(TEP)	-	-	-	-
<b>71-5(b) Actual Terrestrial Field Study</b>	(TEP)	-	-	-	-
<b>72-1(a) Acute Fish Toxicity Bluegill</b>	(TGAD)	A,B,C,D,E,J	YES	0043674	NO
<b>72-1(b) Acute Fish Toxicity Bluegill</b>	(TEP)	E,J	YES	40098001, 0002543	NO
<b>72-1(c) Acute Fish Toxicity Rainbow Trout</b>	(TGAD)	A,B,C,D,E,J	YES	43666	NO
<b>72-1(d) Acute Fish Toxicity Rainbow Trout</b>	(TEP)	E,J	YES	40245701	NO
<b>72-2(a) Acute Aquatic Invertebrate Toxicity</b>	(TGAD)	A,B,C,D,E,J	YES	0003503	NO
<b>72-2(b) Acute Aquatic Invertebrate Toxicity</b>	(TEP)	E,J	YES	40098001, 43676	NO
<b>72-3(a) Acute Estu/Mari Tox Fish</b>	(TGAD)	A,B,C,D,E,J	YES	42503702	NO
<b>72-3(b) Acute Estu/Mari Tox Mollusk</b>	(TGAD)	A,B,C,D,E,J	YES	42503703	NO
<b>72-3(c) Acute Estu.Mari Tox Shrimp</b>	(TGAD)	A,B,C,D,E,J	YES	23331	NO

\* In Bibliographic Citation column indicates study may be upgradeable

Date: 02/16/93  
 Case No: 819251  
 Chemical No: 080807

PHASE IV  
 DATA REQUIREMENTS FOR  
 ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition <sup>1</sup>	Use Pattern <sup>2</sup>	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
72-3(d) Acute Estu/Mari Tox Fish	(TEP)	-	-	-	-
72-3(e) Acute Estu/Mari Tox Mollusk	(TEP)	-	-	-	-
72-3(f) Acute Estu/Mari Tox Shrimp	(TEP)	-	-	-	-
72-4(e) Early Life-Stage Fish	(TGAI)	A,B,C,D,E,J	YES	43676, 43668	NO
72-4(b) Live-Cycle Aquatic Invertebrate	(TGAI)	A,B,C,D,E,J	YES	43676	NO
72-5 Life-Cycle Fish	(TGAI)	-	-	-	-
72-6 Aquatic Org. Accumulation	(TGAI)	E,J	YES	43668, 43670	NO
72-7(a) Simulated Aquatic Field Study	(TEP)	E,J	NO	-	NO <sup>6</sup>
72-7(b) Actual Aquatic Field Study	(TEP)	-	-	-	-
122-1(e) Seed Germ./Seedling Emerg.	(TGAI)	A,B,C,D,E,J	YES	42566602	NO <sup>6</sup>
122-1(b) Vegetative Vigor	(TGAI)	-	-	-	-
122-2 Aquatic Plant Growth	(TGAI)	-	-	-	-
123-1(e) Seed Germ./Seedling Emerg.	(TGAI)	A,B,C,D,E,J	NO	-	YES <sup>6</sup>
123-1(b) Vegetative Vigor	(TGAI)	A,B,C,D,E,J	NO	-	YES <sup>6</sup>
123-2 Aquatic Plant Growth	(TGAI)	A,B,C,D,E,J	YES	425037-04,05,06,07	YES <sup>7</sup>
124-1 Terrestrial Field Study	(TEP)	-	-	-	-
124-2 Aquatic Field Study	(TEP)	A,B,C,D,E,J	NO	-	YES <sup>6</sup>
141-1 Honey Bee Acute Contact	(TGAI)	A,B,C,D,E,J	YES	00036935	NO
141-2 Honey Bee Residue on Foliage	(TEP)	-	-	-	-
141-5 Field Test for Pollinators	(TEP)	-	-	-	-

<sup>6</sup> In Bibliographic Citation column indicates study may be upgradeable

1. Composition: TGA1=Technical grade of the active ingredient; PARA=Pure active ingredient, radiolabeled; TEP=Typical end-use product
2. Use Patterns: A=Terrestrial Food Crop; B=Terrestrial Feed Crop; C=Terrestrial Non-Food Crop; D=Aquatic Food Crop; E=Aquatic Non-Food Outdoor; F=Aquatic Non-Food Industrial; G=Aquatic Non-Food Residential; H=Greenhouse Food Crop; I=Greenhouse Non-Food Crop; J=Forestry; K=Outdoor Residential; L=Indoor Food; M=Indoor Non-Food; N=Indoor Medical; O=Indoor Residential; Z=Use Group for Site 00000

3. As stated in the Simazine Second Round Review (3/8/89) and as confirmed by the registrant in their April 7, 1992 meeting with EEB, the avian reproduction study with the mallard must be repeated. The maximum concentration tested (20 ppm) in the initial study was well below residue levels reasonably expected on waterfowl food items.

4. Based on new Agency policy, this data requirement is waived. However, EEB is still concerned with the risk to aquatic organisms associated with certain aquatic use patterns (i.e. fish ponds and hatcheries) and use rates greater than 10 lbs a.i./A (noncropland). These concerns need to be addressed by the registrant. One possible risk mitigation option was suggested by the registrant in its April 7, 1992 meeting with EEB. In this meeting, the registrant proposed cancelling all aquatic uses and use rates above 10 lbs a.i./A.

5. This study does not satisfy guideline requirements as the maximum use rate (9.6 ai/A) was not tested.

6. Required for all terrestrial non-food and aquatic uses.

7. The four aquatic studies conducted with Selenastrum capricornutum, Lemna gibba, Navicula pelliculosa, and Skeletonema costatum are all core. However, the aquatic plant study using Anabaena flos-aquae is still outstanding.

8. Tier III aquatic plant testing is required for use rates  $\geq$  15 lbs. a.i./A. Prior to beginning a Tier III study, the registrant must submit a protocol to the Agency for review. However, at this time, all Tier III requirements are postponed pending development of a guidance document.

## DATA EVALUATION RECORD

1. **CHEMICAL:** Simazine.  
Shaughnessey No. 080807.
2. **TEST MATERIAL:** Princep® 4L herbicide; CAS No. 122-34-9; Lot No. FL-910375; 45.06% purity; a light tan liquid.
3. **STUDY TYPE:** 122-1(a). Non-Target Plants: Seed Germination Phytotoxicity Test - Tier 1. Species Tested: Soybean, Lettuce, Radish, Tomato, Cucumber, Cabbage, Oat, Ryegrass, Corn, and Onion.
4. **CITATION:** Chetram, R.S. 1992. Tier 2 Seed Germination Non-Target Phytotoxicity Study Using Simazine. Laboratory Study No. 92057. Conducted by Pan-Agricultural Laboratories, Inc., Madera, CA. Submitted by Ciba-Geigy Corporation, Greensboro, NC. EPA MRID No. 425666-02.

5. **REVIEWED BY:**

Tracy L. Perry  
Wildlife Biologist  
Ecological Effects Branch

Signature: *Tracy L Perry*  
Date: *2/16/93*

6. **APPROVED BY:**

Henry T. Craven  
Head, Section 4  
Ecological Effects Branch

Signature: *Henry T. Craven*  
Date: *2/19/93*

7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for a Tier 1 non-target plant germination study as the maximum use rate (9.6 lbs ai/a) was not tested. No significant decreases in germination were observed between the control and any rate of simazine for the ten species tested. The NOEC for all plants was 4.0 lb ai/A. No EC values could be determined due to the lack of dose responses.


8. **RECOMMENDATIONS:** N/A.


9. **BACKGROUND:**



## DATA EVALUATION RECORD

1. **CHEMICAL:** Simazine.  
Shaughnessey No. 080807.
2. **TEST MATERIAL:** Princep® 4L herbicide; CAS No. 122-34-9; Lot No. FL-910375; 45.06% purity; a light tan liquid.
3. **STUDY TYPE:** 123-1. Non-Target Plants: Seed Germination Phytotoxicity Test - Tier 2. Species Tested: Soybean, Lettuce, Radish, Tomato, Cucumber, Cabbage, Oat, Ryegrass, Corn, and Onion.
4. **CITATION:** Chetram, R.S. 1992. Tier 2 Seed Germination Non-Target Phytotoxicity Study Using Simazine. Laboratory Study No. 92057. Conducted by Pan-Agricultural Laboratories, Inc., Madera, CA. Submitted by Ciba-Geigy Corporation, Greensboro, NC. EPA MRID No. 425666-02.
5. **REVIEWED BY:**  

Mark A. Mossler, M.S. Agronomist KBN Engineering and Applied Sciences, Inc.	Signature:  Date: 1/4/93
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6. **APPROVED BY:**  

Pim Kosalwat, Ph.D. Senior Scientist KBN Engineering and Applied Sciences, Inc.	Signature: P. Kosalwat Date: 1/4/93
Henry T. Craven, M.S. Supervisor, EEB/EFED USEPA	Signature:  2/19/93 Date: Tracy L. Perry 2/16/93
7. **CONCLUSIONS:** This study is scientifically sound but does not meet the guideline requirements for a Tier 2 non-target plant germination study. A second measure of test material effect was not reported. No significant decreases in germination were observed between the control and any rate of simazine for the ten species tested. The NOEC for all plants was 4.0 lb ai/A. No EC values could be determined due to the lack of dose responses.
8. **RECOMMENDATIONS:** N/A.
9. **BACKGROUND:**

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

A. Test Plants: Dicotyledon plants were represented by six species from five families (i.e., soybean, lettuce, radish, tomato, cucumber, and cabbage). Monocotyledon plants were represented by four species from two families (i.e., corn, oat, ryegrass, and onion). Cultivars, lot numbers, sources, and germination ratings were provided in the report.

B. Test System: Two circles of blue blotter were placed in the bottom of a glass petri plate. Twelve milliliters of the test solution were added to each plate of soybean, cucumber, oat, and corn. Ten milliliters were added to plates of lettuce, radish, tomato, cabbage, ryegrass, and onion.

Ten seeds of each crop were added to each petri plate after the test solution was absorbed into the paper. The plates were then impartially placed in plastic boxes (12.25 x 9.0 x 4.1 inches) with tight-fitting lids to prevent moisture loss. The petri plates were incubated in the dark at 23-24°C, except lettuce, which was incubated at 19-20°C, for six days.

C. Dosage: The highest test solution was prepared with deionized water and then diluted serially to achieve the lower concentrations. Simazine was applied at the rates of 0.25, 0.50, 1.0, 2.0, and 4.0 lb active ingredient (ai)/acre (A) to all plant species. The test solutions were corrected for the percent purity of the test material (45.06%).

D. Design: Each treatment/crop combination was replicated four times (i.e., 10 seeds/plate, 4 plates/treatment). After incubation, the seeds were removed from the petri plates and the radicle lengths were observed. Percent seed germination was calculated for all germinated seeds. Seeds were considered germinated if the radicle was at least 5 mm long.

Samples of the germination solutions were analyzed for simazine by gas-liquid chromatography.

E. Statistics: Percent germination was determined and all data were entered into a Lotus 1-2-3 spreadsheet. The spreadsheet calculated replicate means, treatment means, standard deviations, percent detrimental effect,

and analysis of variance tables. Treatment means were used to calculate the percent effect resulting from the treatment. The percent detrimental effect was calculated using the following equation:

$$\% \text{ effect} = \frac{(\text{treatment mean} - \text{control mean})}{\text{control mean}} \times 100$$

A randomized complete block analysis of variance was performed on the treatment level x replicate means. Treatment level means were subjected to Dunnett's test to determine treatment differences from the control level. The statistical no-observed-effect concentration (NOEC) was the highest treatment level not statistically different from the control. The significance level was  $p < 0.05$ .

Regression analysis was not conducted due to a lack of significant treatment effects.

12. **REPORTED RESULTS:** Measured concentrations of test and spiked samples resulted in recoveries between 91 and 100% (Table I, attached).

No significant difference in percent germination existed for any of the test species. The NOEC for all species was 4.0 lb ai/A. No  $EC_{25}$  or  $EC_{50}$  values were computed due to the lack of significant treatment effects (Tables II and III, attached).

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:**  
 "A no-effect concentration was reached on germination percentage for all crops.  $EC_{25}$  and  $EC_{50}$  values were not calculated for the ten crops due to lack of significant treatment effects. The lowest no-effect concentration for germination percentage was 4.0 lb ai/A for all ten crops."

Statements of Good Laboratory Practice (GLP) Standards compliance and Quality Assurance were enclosed in the report, indicating adherence to 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

- A. **Test Procedure:** The test procedures followed the SEP and Subdivision J guidelines, except for the following:

The test was conducted with a formulated product rather than the technical material.

- B. Statistical Analysis:** Dunnett's comparison test was conducted on onion germination (the most sensitive species) data. The reviewer determined that germination was significantly reduced at the 1.0 lb ai/A level, but not at the two higher rates of 2.0 and 4.0 lb ai/A (see attached printout). Therefore, the NOEC for onion is 4.0 lb ai/A.
- C. Discussion/Results:** Since measured concentrations were within 91 to 100% of nominal, the reviewer believes that the nominal rates used to report the results are representative of those applied.

While testing with the technical grade of the active ingredient is generally required, exceptions can be made in cases where the technical material is insoluble in acceptable levels of suitable solvents. In previous studies (MRID Nos. 42503702, 42503703), the insolubility of the technical material was well demonstrated. Therefore, use of a formulated product in this study is acceptable.

No significant decreases in germination were observed between the control and any rate of simazine for the ten species tested. The NOEC for all plants was 4.0 lb ai/A. As LOEC and EC values could not be determined, this study can only be classified as a Tier 1 plant germination study.

This study is scientifically sound but does not meet the guideline requirements for a Tier 1 non-target plant germination study as the maximum use rate (9.6 lbs ai/A) was not tested.

**D. Adequacy of the Study:**

- (1) **Classification:** Supplemental.
- (2) **Rationale:** The maximum use rate (9.6 lbs ai/A) was not tested.
- (3) **Repairability:** N/A.

**15. COMPLETION OF ONE-LINER:** Yes, 12-31-92.

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RIN 1646-93 SIMAZINE 080708

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Page \_\_\_ is not included in this copy.

Pages 12 through 14 are not included.

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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.
- 

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.

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onion germination

Summary Statistics and ANOVA

Transformation =		None		
Group	n	Mean	s.d.	cv%
1 = control	4	9.5000	.5774	6.1
2 0.25	4	9.0000	.8165	9.1
3 0.5	4	9.5000	.5774	6.1
4* 1.0	4	8.2500	.5000	6.1
5 2.0	4	8.7500	.9574	10.9
6 4.0	4	9.2500	.5000	5.4

Since no sig effects above  
 1.0 16 ai/A NOEC=  
 4.0 16 ai/A

\* ) the mean for this group is significantly less than the control mean at alpha = 0.05 (1-sided) by Dunnett's test

Minimum detectable difference for Dunnett's test = -1.153700  
 This difference corresponds to -12.14 percent of control

Between groups sum of squares = 4.708333 with 5 degrees of freedom.

Error mean square = .458333 with 18 degrees of freedom.

Bartlett's test p-value for equality of variances = .833