1

(7/26/89)

Shaughnessy No. 121301

Date Out EAB: JUL 26

TO: Hutton/Mendelsohn
Product Manager 17
Registration Division (H7505C)

FROM: Patrick W. Holden, Chief
Ground-Water Technology Section
Environmental Fate & Ground Water Branch (H7507C)

THRU: Hank Jacoby, Acting Chief
Environmental Fate & Ground Water Branch (H7507C)

Attached please find the environmental fate review of:

Reg./File No.: _____

Chemical: Cyromazine

Type Product: Herbicide

Product Name: Trigard

Company Name: Ciba-Geigy Company

Purpose: Response to meeting with the registrant for cyromazine on ground-water monitoring study requirements.

ACTION CODE: 400

Date Received: 07-20-89 EFGWB # 90679

Date Completed: 07-25-89 Total Review Time: 3.0 day

Monitoring study requested: / X /

Monitoring study voluntarily conducted by registrant: /___/

Deferrals To: _____ Biological Effects Branch

_____ Science Integration and Policy Staff, EFED

_____ Non-Dietary Exposure Branch, HED

United States Environmental Protection Agency
Office of Pesticide Programs
Washington, DC 20460

EPA Data Review Record

Confidential Business Information - Does not contain National Security Information (E.O. 12065)

Pack Number	Date Received
49522 EFED	7/20/89

1. Product Name: Trigard

Chemical Name: Cyromazine

2. Identifying Number	3 Record Number	4. Action Code	5. MRID/ Accession Number	6. Study Guideline or Narrative
100-654	248,218	400		

7. Reference No.	8. Date Rec'd (EPA)	9. Prod/Review Mgr/DCI	10. PM/RM Team No.	11. Date to HED/ EFED/RD/BEAD	12. Proj Return Date	13. Date Returned to RD/SRRD
	7/18/89	Hutton/Mendelsohn	17	7/18/89	8/18/89	

Instructions

Note to Emil Regelman: Per conversation w/ Catherine Eiden this bean should be routed to her for additional review she is conducting regarding soil metabolism studies for the subject product. Mike Mendelsohn

This Section Applies to Review of Studies Only

14. Check Applicable Box

- ☐ Adverse 6(a)(2) Data (405)
- ☐ Special Review Data (870)
- ☐ Generic Data (Reregistration) (660)
- ☐ Product Specific Data (Reregistration) (655)

15. No. of Individual Studies Submitted

16. Have any of the above studies (in whole or in part) been previously submitted for review?

- ☐ Yes *(Please identify the study(ies))*
- ☐ No

17. Related Actions

18.	To	Type of Review	19. Reviews Also Sent to	20. Data Review Criteria
HED		Science Analysis & Coordination	☐ SAC ☐ PC	A. Policy Note No. 31
		Toxicology/HFA	☐ TOX/HFA ☐ PL	☐ 1 = data which meet 6(a)(2) or meet 3(c)(2)(B) flagging criteria
		Toxicology/IR	☐ TOX/IR	
		Dietary Exposure	☐ DEB ☐ EA	☐ 2 = data of particular concern from registration standard
		Nondietary Exposure	☐ NDE ☐ AC ☐ BA	
EFED		Ecological Effects	☐ EEB	☐ 3 = data necessary to determine tiered testing requirements
	✓	Environmental Fate & Groundwater	☐ EFGWB	
SRRD		Special Review	☐ SR	
		Reregistration	☐ RER	B. Section 18
		Generic Chemical Support	☐ GSC	☐ 1 = data in support of section 3 in lieu of section 18
RD		Insecticide-Rodenticide	☐ IR	
		Fungicide-Herbicide	☐ FH	C. Inert Ingredients
		Antimicrobial	☐ AM	☐ 1 = data in support of continued use of List 1 inert
		Product Chemistry		
		Precautionary Labeling		
BEAD		Economic Analysis		
		Analytical Chemistry		
		Biological Analysis		

☐ Confidential Statement of Formula (EPA Form 8570-4) Attached *(Trade Secrets)*

☐ Label Attached

EPA Form 8570-17 (Rev. 11-88)
Previous editions are obsolete.

White - Data Coordinator
Yellow - Data Review Section
Pink - PM/RM/DCI
Green - Return with completed review

United States Environmental Protection Agency
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	7/18/89	Hutton/Mendelsohn	17	7/18/89	8/18/89	

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		Nondietary Exposure	☐ NDE ☐ AC ☐ BA	
EFED		Ecological Effects	☐ EEB	☐ 2 = data of particular concern from registration standard
	✓	Environmental Fate & Groundwater	☐ EFGWB	
SRRD		Special Review	☐ SR	☐ 3 = data necessary to determine tiered testing requirements
		Reregistration	☐ RER	
		Generic Chemical Support	☐ GSC	
RD		Insecticide-Rodenticide		B. Section 18
		Fungicide-Herbicide		☐ 1 = data in support of section 3 in lieu of section 18
		Antimicrobial	☐ IR	
		Product Chemistry	☐ FH	C. Inert Ingredients
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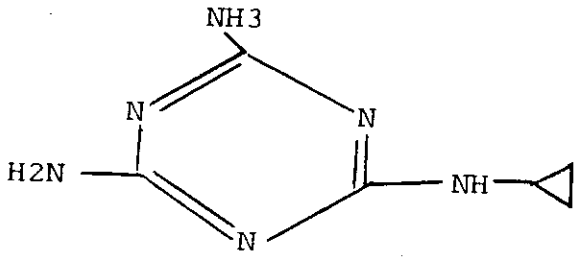
1. Chemical:

Common name: Cyromazine, Armor
Chemical name: M-cyclopropyl-1,3,5 - Triazine-2,4,6 - Triamine

Structure:



2. Test Material:

The test material was U-triazine-^{14}C-CGA-72662 (NV-XIII-16; specific activity 16.6 uCi/mg). It was received from CIBA-GEIGY on February 22, 1984 and assigned Biospherics identification 84-E-016. Analytical standards of CGA-72662 (Code No. 65390; purity 96.5%) and melamine (Code No. 66285: purity 99%) were received from CIBA-GEIGY February 10, 1984, and given Biospherics identification 84-E-013 and -014. Standards of ammeline (GS-17791) and 2,4-diamino-6-cyclopropylamino-1-methyl-1,3,5-triazinium chloride (GAN-II-48; methylcyromazine) were received from CIBA-GEIGY on March 6, 1985, and assigned Biospherics identifications 85-E-115 and -116, respectively. All standards were stored in a freezer at -10°C.

^{14}C-CGA-72662 (NV-XIII-16) was dissolved in pH 7.2 buffered water to provide a dosing stock at 1.07 mg/ml. The dosing solution was prepared and used on the date prepared. After use, all remaining dose stock was stored in a freezer at -10 C.

TLC standards were prepared at approximately 1 mg/ml in either water or methanol, depending on solubility.

3. Study/Action:

This is a data submission on cyromazine. Included in this submission are data on the aerobic/anaerobic soil metabolism of cyromazine. These data were reviewed to determine if the studies are scientifically valid and satisfy the EFGWB requirements for aerobic/anaerobic soil metabolism.

4. Study Identification:

SPONSOR: CIBA-GEIGY Corporation

SPONSOR REPRESENTATIVE: Dr. R. Honeycutt

STUDY DIRECTOR: William Spare April 3 - August 15, 1984
John Martinson August 15, 1984-December 20, 1985
Nancy Cargile December 20, 1985-present

PROTOCOL: Soil Metabolism of CGA-72662, R.C. Honeycutt, November 2, 1983 and Addendum

PROJECT NUMBER: 84-E-016

NOTEBOOK NUMBERS: 120, 136, 166, 223

DATE INITIATED: April 3, 1984

DATE COMPLETED: November 12, 1985

DATE ISSUED: March, 1986

5. Reviewed by:

Catherine Eiden, Acting Chief 7/25/87
Environmental Chemistry Assessment Section
Evironmental Fate and Ground Water Branch

6. Approved by:

for Patrick Holden, Chief
Ground-Water Technology Section
Environmental Fate and Ground-Water Branch

7. Conclusions:

The aerobic/anaerobic soil metabolism studies partially fulfill the data requirements for environmental fate studies 162-1 and 162-2.

The data submitted provide the EFGWB with the information noted as lacking previously. Specifically, for the aerobic study: the purity of the test substance (93%), and additional information on two degradates (ammeline and methyl cyromazine) other than melamine. There were up to three unknown (unidentified) compounds listed as degradates. At the end of the study period (365 days) one of these unknowns persisted at >10% of the application of cyromazine to sand muck soil incubated aerobically, and one of the unknowns persisted at 365 days >10% of the cyromazine application in the sand loam soil aerobically incubated. The registrant should explain why these compounds were not identified. Was the identification analysis not feasible?

Other than this the soil moisture content of the soils during

the experimental incubation was not reported. The registrant should report this.

Specifically, for the anaerobic study: the purity of the test substance (93%), poor materials balance, and no sampling at the 60-day interval. The material balance for the anaerobic studies are reasonable and acceptable, greater than 80% for all sampling intervals except the final sample (60-day) for the sand loam soil. Data for the 60-day interval were included.

8. Recommendation:

1. The registrant must submit data on the soil moisture content of the soils during the study.

2. The registrant must explain why the unidentified degradates in the aerobic portion of the study were not identified for the two compounds at > 10% of the cyromazine application of day 365.

These additional pieces of information should complete the study. Upon receipt of these data the study can be deemed fully acceptable.

9. Background:

These data have been submitted to clarify and complete outstanding environmental fate data requirements for cyromazine, as well as ground-water monitoring requirements. Cyromazine is used as a larvacide in poultry, and an herbicide.

10. Duscussion of Individual Studies:

A. Study Identification: (See No. 4.)

B. Materials and methods
(attached)

C. Reported Results:
(attached)

D/E. Reviewer's Conclusions:

The metabolism of CGA-72 was investigated over twelve months under laboratory conditions in two soil types, sandy loam and sand (muck). The soils were treated with 10.7 ppm triazole 14C-CGA-72662 and incubated aerobically. After one month, a portion of the aged soil was made anaerobic by addition of water. A sterile soil control was incubated aerobically for three months. At intervals, water and emitted volatiles were analyzed for radioactive CGA-72662 and metabolites.

Sterile Incubation:

The sterile incubations showed no significant degradation of CGA-72662 as analyzable compounds, but did show a significant increase in nonextractable residues. Most of the extractable radioactivity was characterized as parent compound.

Aerobic Incubation:

In sandy loam soil, CAG-72662 had a calculated half-life of 142 days with a rate constant of 0.0049. The major degradation product was characterized as melamine, based on TLC comparison to the standard. This product represented 3.1% of the theoretical dose as zero time, reached a maximum of 31.1% at 31 days of aerobic incubation and declined to 10.0% after 367 days (12 months). Nonextractable radioactivity increased from 7.8% to 43.3% at 367 days. Volatiles represented a maximum of 0.7% at 367 days, including apparently CO2, non polar materials.

In sand (muck), CGA-72662 had a half life of 107 days with a rate constant of 0.0065. Apparent melamine residues increased from 0.7 to 4.1% at 92 days, declining to 2.0% at 12 months. Nonextractable radioactivity increased from 29.6 to 49.3% of theoretical dose. Volatiles represented a maximum of 3.4% of the applied dose at 92 days, primarily as CO_2.

Anaerobic Incubation:

During 61 days of anaerobic incubation, the radioactivity in the sandy loam soil characterized as CGA-72662 and melamine declined from 35.3 to 9.0% and from 31.1 to 2.3%, respectively, of the applied dose. Nonextractable soil residues increased from 23.2 to 52.5%. Radioactivity released into the supernatant water accounted for a maximum of 5.7% of the applied dose after 61 days. Volatile radioactivity was <0.1% of the dose.

During anaerobic incubation of the sand (muck) soil, CGA-72662 and melamine declined from 27.6 to 10.4% and from 1.8 to 0.5, respectively, of the theoretical dose. Nonextractable soil radioactivity increased from 62.6 to 78.6%. The water layer contained 1.5% of the dose. As in the sandy loam soil, volatiles represented <0.1% of the dose.

However, the registrant did not explain why degradates other than melamine were not identified, if they appeared at >10% of the original cyromazine application. This is clearly the case for two of the unknowns.

Degradation appears to be more rapid under anaerobic soil conditions than aerobic.

Cyromazine and melamine are persistent.

Page ___ is not included in this copy.

Pages 8 through 39 are not included in this copy.

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.