


US EPA ARCHIVE DOCUMENT

Shaughnessy No.: 080803

Date Out of EAB: AUG 18 1986

Signature: 

To: Robert Taylor/Grubbs
Product Manager # 25
Registration Division (TS-767)

From: Emil Regelman, Supervisory Chemist
Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769) 

Attached, please find the EAB review of...

Reg./File # : 100-5857; 100-529; 100-497; 100-439

Chemical Name: Atrazine

Type Product : Herbicide

Product Name : AATREX

Company Name : Ciba-Geigy

Purpose : Request for Waivers; and submission of field
dissipation protocols and amendments for EAB review

ACTION CODE: 650 ; 660

EAB #(s) : 6326; 6327; 6328
6329; 6595; 6596

Date Received: 4/28/ - 6/13 1986

TAIS Code: 65

Date Completed: 8/18/86

Total Reviewing Time: 3.0 days

Monitoring study requested: _____

Monitoring study voluntarily: _____

Referrals to:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

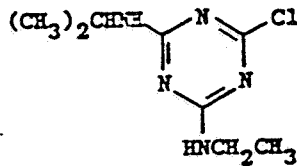
_____ Toxicology Branch

1. Chemical: Common name: Atrazine

Chemical name: 2-chloro-4-(ethylamino)-6-(isopropylamino)-s-triazine

Trade name(s): Aatrex , Gesaprim, Primatol

Structure:



Formulations: Aatrex 80 W, 4L , Aatrex NINE-O 90% Granular

Physical/Chemical Properties:

Molecular formula: $C_8H_{14}ClN_5$

Molecular weight: 215.7

Physical state: White, crystalline

Vapor pressure: 3.0×10^{-7} at $20^\circ C$

Solubility: in water at $27^\circ C = 33$ ppmw

2. TEST MATERIAL: Proposed - Aatrex NINE-O, 90% ai granules

3. STUDY/ACTION TYPE: Request for waivers ; submission of protocols and amendments for field dissipation studies

4. STUDY IDENTIFICATION: Protocols submitted for EAB review

5. REVIEWED BY:

John H. Jordan, Ph.D.
Microbiologist
EAB/HED/OPP

Signature: *John H. Jordan*

Date: 5/19/86

6. APPROVED BY:

Emil Regelman
Supervisory Chemist
Review Section #3
EAB/HED/OPP

Signature: *Emil Regelman*

Date: AUG 18 1986

1. CONCLUSIONS:

(a) Request for Waivers

EAB addressed Ciba-Geigy's waiver request in Actions # 5864-5871 on September 24, 1985. Because of potential interactions, EAB concluded that the liquid 4L and WP 80 must be tested, as well as the 90% NINE-O formulation, in field dissipation studies. EPA concern centers on the potentially different degradate formations of the three formulations, not only the 2-hydroxy analogue, e.g., but also the N-dealkylated derivatives, and possibly others.

The 1968 data, submitted by Geigy to show no interaction among formulations, does not address potential interactions / degradate formation in soil. EAB will review the NINE-O field dissipation studies proposed, and determine if the data indicate significant interaction.

If additional studies with the liquid 4L and WP 80 formulations are required, additional time will be granted.

(b) Field Dissipation Protocols and Amendments

The protocols and the 5/2/86 amendments are acceptable except degradate analyses, e.g., analyses are planned for one degradate only, the 2-hydroxy analogue. N-dealkylated analyses are required, because hydroxyatrazine and N-dealkylated metabolites have been found in field soils and water. Unless the registrant can show that the N-dealkylated degradates are of minor importance, analyses for N-dealkylated derivatives and all other degradates identified in aerobic metabolism are required.

Analyses for the N-dealkylated derivatives and the patterns of parent decline and formation and decline of degradates are also required.

It is requested that storage stability studies be conducted at the soil residue concentration.

2. RECOMMENDATIONS:

It is recommended that the registrant initiate degradate analyses, and establish patterns of parent decline and formation and decline of degradates as indicated in the Conclusion.

3. BACKGROUND: A. Introduction

Ciba-Geigy submitted 1968 field data to show no significant formulation interactions in soil, and that the three formulations (Section 1) would be represented by the NINE-O formulation in field dissipation studies.

Waivers for field dissipation studies using the 4L and the WP 80 were requested.

B. Directions for use

Atrazine is a selective use herbicide for control of broad-leaf and grassy weeds in corn, sorghum, sugarcane, orchards, pineapple, and turf grass. Atrazine is also used for non-cropland vegetative control. From 2 to 4 lb/A are used for selective weed control; higher rates are used for non-selective control. Preplant / preemergence is practiced; however preemergence is preferred. Aerial or ground application is used, according to the use pattern and need.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: Protocols were reviewed and comments were made in the Conclusions and Recommendations Sections.

11. COMPLETION OF ONE-LINER: Not completed at this time

12. CBI APPENDIX: No CBI appendix attached

CIBA-GEIGY

Agricultural Division
CIBA-GEIGY Corporation
P.O. Box 18300
Greensboro, North Carolina 27419
Telephone 919 292 7100

May 27, 1986

Mr. Robert J. Taylor
Product Manager (25)
Registration Division (TS-767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall 2 - Room 245
Arlington, VA 22202

Dear Mr. Taylor:

**SUBJECT: AMENDMENT TO ATRAZINE FIELD DISSIPATION
PROTOCOL SUBMITTED FEBRUARY 6, 1986**

Recently, CIBA-GEIGY inquired about the status of the subject protocols to the Agency. In conversations with the Exposure Assessment Branch reviewer, John Jordon, concerning this protocol, a number of revisions were suggested. These revisions in the protocol are summarized as follows:

1) SOIL SAMPLING METHOD FOR ATRAZINE SOIL DISSIPATION STUDY

Soil samples will be obtained to a depth of four feet or to the first impermeable soil layer. The top foot will be excavated in six-inch increments. The next three feet will be sampled with a bucket auger fitted with an acetate tube. The acetate tubes will be frozen intact so that they may be sectioned at the laboratory into the appropriate increments for analyses. At each sample interval, three subsamples will be randomly obtained from each plot. Each subsample will be individually analyzed.

2) SOIL ANALYSIS

Soil samples at 0-6", 6-12" and additional one foot increments up to 4 feet will be analyzed. Soil segments in 2-3 foot sections will be analyzed at all intervals and if these results show no detectable residues, soil segments at other depths excluding the 0-6" and 6-12" will not be analyzed. If detectable residues are found in 2-3 foot sections, all soil segments below 6-12" will be analyzed in one foot increments until a residue-free segment is reached.

Mr. Robert J. Taylor

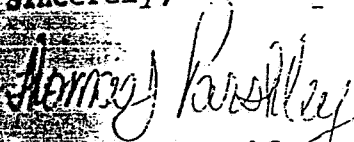
May 2, 1986

Page 2

CIBA-GEIGY would appreciate, for the sake of expediency, having this letter serve as the amendment to our protocol in lieu of submitting a completed revised protocol.

If there are any questions concerning matters contained in this submission, please do not hesitate to contact us.

Sincerely,



Thomas J. Parshley
Regulatory Specialist

TJP/mg/0506

CIBA-GEIGY

Agricultural Division
CIBA-GEIGY Corporation
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February 6, 1986

Mr. Robert J. Taylor
Product Manager (25)
Registration Division (TS-767C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall 2 - Room 245
Arlington, VA 22202

Dear Mr. Taylor:

SUBJECT: ATRAZINE REGISTRATION STANDARD ⁵⁸⁵
AATREX® NINE-0®, EPA REG. NO. 100-~~439~~
ATRAZINE TECHNICAL, EPA REG. NO. 100-529
PROTOCOLS FOR TERRESTRIAL FIELD DISSIPATION
STUDIES AND MINUTES OF JANUARY 16, 1986 MEETING

Enclosed for your review, and comment if necessary, are the following documents concerning atrazine:

1. Two copies of protocols for terrestrial field dissipation studies (non-crop and crop).
2. Two copies of our minutes from the atrazine meeting held January 16, 1986.

There are two separate protocols being provided, one to support crop use and one for non-crop use. Suggestions made by Emil Regelman of the Exposure Assessment Branch in the January 16, 1986 meeting have been incorporated into these protocols. CIBA-GEIGY should point out that the protocols propose testing our product Aatrex Nine-0, a water dispersible granular formulation. In the January 16 meeting it was suggested that this could be done and a separate submission of a waiver request be made to address the need to test the Aatrex 4L and 80W formulations.

The minutes of the meeting are self-explanatory insofar as they provide documentation of our understanding of what was discussed. We would ask that the Agency inform us if the minutes are inaccurate in any way.

Please do not hesitate to contact us for clarification of matters contained in either this letter or in the enclosures.

Sincerely,

Thomas J. Parshley
Thomas J. Parshley
Regulatory Specialist

TJP/mg/0405

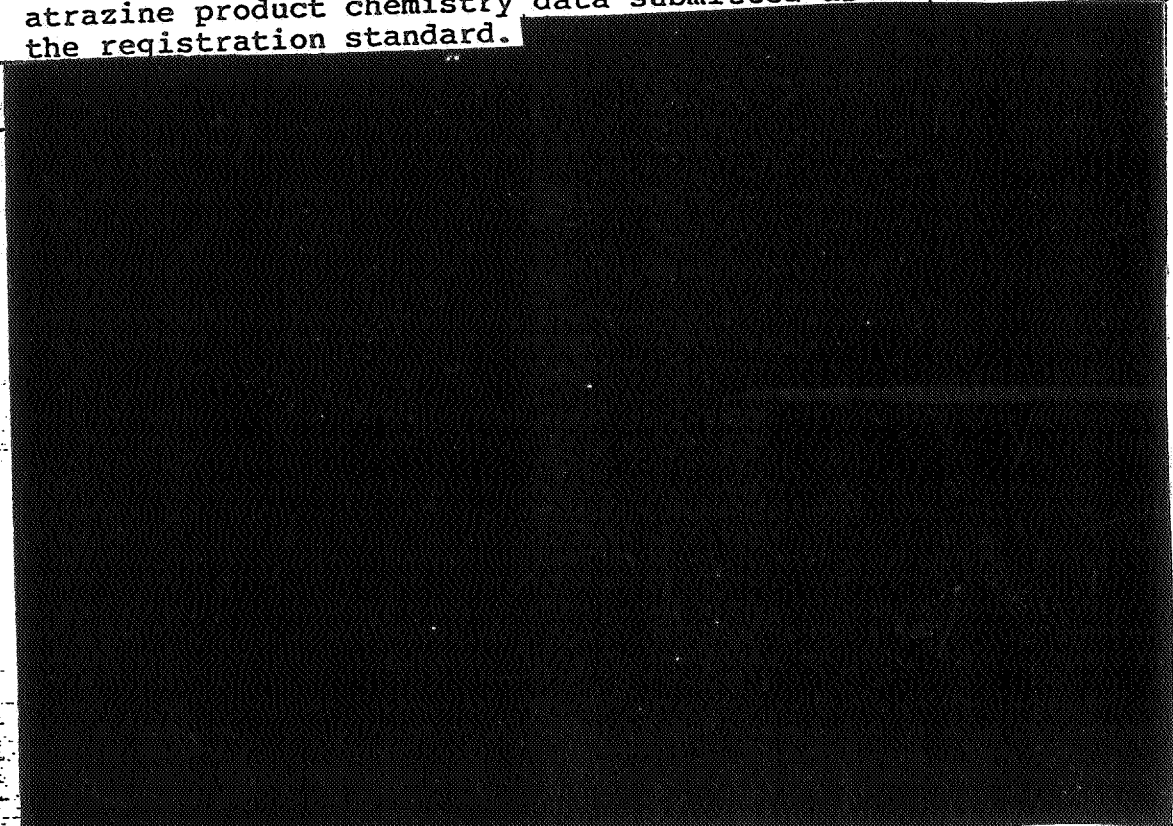
MINUTES OF MEETING
HELD JANUARY 16, 1986

SUBJECT: See attached agenda.

ATTENDEES: Claire Grubbs, EPA
Emil Regelman, EPA
Randy Perfetti, EPA
Gobin Makhijani, EPA
Thomas Parshley, CIBA-GEIGY
Darrell Sumner, CIBA-GEIGY
Thomas Bade, CIBA-GEIGY
Larry Gasper, CIBA-GEIGY
K. Balu, CIBA-GEIGY

II. ATRAZINE GENERIC PRODUCT CHEMISTRY DATA

T. Parshley summarized EPA's review of CIBA-GEIGY's atrazine product chemistry data submitted as required by the registration standard.



Upon submission of this information, CIBA-GEIGY will have complied with all the product chemistry requirements of the registration standard except for

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

8

providing validation data for CIBA-GEIGY's analytical methodology.

[REDACTED]

R. Perfetti said the idea seemed sensible. Of course, the Agency would need to have a written proposal to comment on formally. T. Parshley suggested a meeting could be the forum for presenting the proposal. There was general agreement on this item.

II. ATRAZINE TERRESTRIAL FIELD DISSIPATION STUDY

K. Balu reviewed the draft protocol provided to EPA for the meeting. E. Regelman made suggestions regarding revisions that should be made to the protocol. Some discussion focused on the proposed rate typically labeled for food-crop use 4# a.i./A versus the industrial weed control rate (currently at 40# a.i./A. It was suggested by E. Regelman that a separate plot at one of the field sites could be set up to conduct a separate trial using the higher non-crop rate. Therefore, an additional protocol will need to be provided for this separate field study. There was agreement from the participants on this issue.

CIBA-GEIGY then presented a discussion of information to address the issue of which formulations to test in the dissipation study. In previous correspondence between CIBA-GEIGY and EPA regarding this study, EPA raised concerns about potential interaction of the various inerts in the three major atrazine formulations which could affect mobility and degradation of atrazine in the soil. CIBA-GEIGY reiterated their position that it is necessary to test only the AAtrex[®] Nine-0[®] formulation, and provided a summary of information relative to some formulation comparisons for the three products, as well as residue trials conducted in the 1960's which compared soil residues and half-life of many formulations of atrazine including data on tank mix residues. Much discussion of the information presented ensued. While no clear cut decisions resulted from these discussions regarding the interaction issue, indications from the EPA representatives were that it was likely the Agency

would be in a better position to give favorable consideration to a formal waiver if the presentation of the available information presented could be altered. T. Parshley pointed out that CIBA-GEIGY's position regarding the requirement to test all formulations of their products must be extended to other companies' atrazine formulations, since they would likely have different inerts. Regelman said he doubted EPA would go that far with the requirement.

E. Regelman suggested that CIBA-GEIGY should submit a formal waiver request along with the data summarized in the meeting. Also, because the field dissipation study needed to be initiated this spring to meet the EPA due date for submission of the study report, it was suggested that CIBA-GEIGY request an expedited review of the waiver and protocol be conducted in-house at EPA, since protocol reviews were currently taking 5-6 months.

If for some reason EPA cannot respond to our waiver request by the time the study is scheduled to start, Regelman suggested CIBA-GEIGY could conduct the study using the Nine-0 formulation and submit it to fill the requirement. Then, if EPA reviewed the study and felt more field work on other formulations was necessary, CIBA-GEIGY would be so advised.

The final area of discussion centered on degradate analysis for the field dissipation study. D. Sumner presented the issue for discussion. Included was a depiction of the metabolic pathway of atrazine in soils and information available to CIBA-GEIGY at present regarding the amounts and identity of the soil metabolites. The question raised to EPA was which degradation products should be analyzed by CIBA-GEIGY. Regelman recommended that the analysis should include parent and the hydroxy degradate only. CIBA-GEIGY was satisfied with this since their analytical chemists believe they have developed an adequate method for identification of this metabolite.

AGENDA

LOCATION: CM #2, Room 1119
TIME: 9:00 a.m. - 11:00 a.m.

- I. INTRODUCTION - T. Parshley
- II. EPA REVIEW OF CIBA-GEIGY ATRAZINE GENERIC PRODUCT CHEMISTRY DATA
 - A. Discussion of Outstanding Product Chemistry Data Requirements - T. Parshley
 - B. How CIBA-GEIGY Atrazine is Produced - L. Gasper
- III. ATRAZINE TERRESTRIAL FIELD DISSIPATION STUDY
 - A. Protocol - K. Balu
 - B. Discussion of Formulations to be Tested - T. Parshley/K. Balu
 - i) Inert Ingredients, Interaction Issue
 - ii) Summary of Soil Residue Studies on Different Formulations
 - C. Discussion of Degradate Analysis - D. Sumner
 - D. Discussion of Other Issues - All
- IV. SUMMARY - T. Parshley