

US EPA ARCHIVE DOCUMENT

#080803 7/2



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

OCT 18 1985

SUBJECT: Denial of Waiver Request for AATREX Field Dissipation Studies

FROM: John H. Jordan, Ph.D. *John H. Jordan*
Microbiologist
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

TO: Jim Yowell/ R. Taylor
Product Manager #25
Registration Division (TS-767)

THRU: Emil Regelman *ER*
Acting Chief, Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

On 10/4/84 and 11/19/84 EAB approved a forest dissipation protocol using only the 90 percent a.i. formulation AATREX NINE-O instead of 80-W, 4L and NINE-O. All of the three formulations are registered for forest use. EAB approved the protocol primarily because AATREX NINE-O is the major forest use and no food/feed residues are involved.

Recently the registrant requested a waiver of the field dissipation data requirement (in support of proposed terrestrial food and non-food uses) based on data generated in the forestry dissipation study. EAB could not approve the second request (waiver) because "worst case" residues, per se, are not the critical factor. Possible interactions are the potential problem, because of some different additives in the three end-use products. If interaction of additives and a.i. does occur, degradation rates and products, and mobility could be affected. Plant uptake of residues and adsorption/desorption may also be affected. Therefore, on September 24, 1985, the waiver request was denied until data are supplied by the registrant to show that interactions do not occur.

Attachments (3)

Shaughnessy #: 080803

Date out of EAB: SEP 24 1985

Signature: 

To: R. Taylor
Product Manager # 25
Registration Division (TS-767)

From: Emil Regelman, Acting Chief
Registration Standards, Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)



Attached please find the EAB review of:

Reg./File No.: 100-497, 439, 585

Chemical: Atrazine

Type Product: Herbicide

Product Name: AAtrex

Company Name: CIBA Geigy

Submission Purpose: Waiver of 2 field dissipation studies

Action Code: 650

Date In: 8/14/85

EAB # 5869-5871

Date Completed: SEP 24 1985

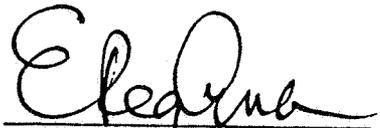
TAIS (level II) Days

Deferrals To: 61 2

 Ecological Effects Branch

 Residue Chemistry Branch

 Toxicology Branch

1. CHEMICAL: Atrazine (AAtrex) 2-chloro-4-(ethylamino)-6-(isopropylamino)-s-triazine
2. TEST MATERIAL: Proposed test material is AATREX-Nine-O (90% a.i.)
3. STUDY/ACTION TYPE: Request for waiver of Field Dissipation data requirement.
4. STUDY IDENTIFICATION: None.
5. REVIEWED BY:
John H. Jordan
Microbiologist
EAB/HED/OPP
Signature: 
Date: 9/23/85
6. APPROVED BY:
Emil Regelman
Acting Chief
Review Section #3,
EAB/HED/OPP
Signature: 
Date: SEP 24 1985
7. CONCLUSIONS: EAB cannot concur with the requested waiver of the field dissipation data requirement. There is a potential problem of interaction of a.i. and additives which could cause variation in field degradation rates of each of the three products. All three atrazine products must be tested in order to determine interaction unless data showing no interactions are presented to EAB.
8. RECOMMENDATIONS: The registrant must submit data to confirm that no product specific interactions occur or acceptable field dissipation studies must be completed for the three products.
9. BACKGROUND: Ciba Geigy requested waivers for two Atrazine end-use products, liquid 4L and W.P. 80 W. The registrant manufactures another formulation, a 90 percent a.i. called AATREX-Nine-O. The company would prefer to field test their "Nine-O" product, only. They believe that higher a.i. residues from the 90 percent a.i. product would present a "worst case" that would suffice for the 4L and the W.P. 80 product field dissipation data. However, residues, per se, are not the critical factor. Potential interactions of some different

additives and a.i. could occur and, therefore, degradation rates and products, mobility and adsorption/ desorption could be affected in each of the three products.

The registrant has received a waiver, for forestry soil dissipation, and they are now asking for a waiver of the terrestrial food and non-food uses. The forestry waiver appears to be justifiable.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES: None.
11. COMPLETION OF ONE-LINER: Not pertinent to this action.
12. CBI APPENDIX: There is no CBI involved in this Agency response; however, the company's formulae information are CBI and must be treated as such by all who handle the package.

Response to CIBA Geigy Field Dissipation Waiver Request

The registrant requested waivers for two Atrazine end-use products, liquid 4L and W.P. 80W.

CIBA-Geigy markets three end-use atrazine formulation liquids 4L, W.P. 80W and a 90 percent water dispersible granule (AATREX-nine-O). The registrant requested that they be required to test only one of the three formulations to support the field dissipation data requirement. Geigy's choice for use in the field tests is their AATREX-Nine-O, because they believe that the "nine-o" formulation represents a "worst case" residue. A dissipation study (for food and non-food use) using AATREX-Nine-o would substitute for the liquid 4L and W.P. 80 products. However, guidelines specify that..... "a seperate (dissipation) study must be performed with a typical end-use product for each such category."

Residues, per se, are not the critical factor in denial of the waiver; possible interactions are the potential problem. Additives in the three end-use products are sufficiently different to suspect interaction. If interaction of additives and a.i. does occur, it could affect degradation rates and products, and mobility. Adsorption/desorption may also be affected.

Therefore, the waiver cannot be granted unless data are available to show that interaction does not occur.


John H. Jordan

Shaughnessy No.: 080803

Date out of EAB: 04 OCT 1984 

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

From: Lionel A. Richardson, Chief
Environmental Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached, please find the EAB review of:

Reg./File No.: 100-585

Chemical: Atrazine

Type Product: Herbicide

Product Name: _____

Company Name: Ciba-Geigy

Submission Purpose: Response to registration standard

ZBB Code: _____

Action Code: 655

Date In: 10/01/84

EAB No.: 5002

Date Completed: 10/03/84

TAIS (Level II) Days

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Deferrals To:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch



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

OCT 4 1984

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Registration Action - Atrazine - Code 080803 Identity
100-585/655

FROM: Hudson Boyd, Chemist *JB*
Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

TO: Robert Taylor
Product Manager #25
Registration Division (TS-767C)

THRU: Lionel A. Richardson, Ph.D, Chief *L.A. Richardson*
Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

In their letter dated 5 September 1984, the registrant requested permission to use their granular formulation AAtrex Nine-O® (a water dispersible granule) for their studies of field dissipation - forestry (Sec. 164-3) and field accumulation - non - target organisms (Sec. 165-5), stating that AAtrex Nine-O® is the formulation of predominant use in forests. The registrant also requested our waiving requirements that their other formulations be tested.

The use of AAtrex Nine-O® only for the two mentioned tests is acceptable provided that the registrant first presents a test protocol for our review and acceptance. It is to be understood that the test procedure(s) will develop data required by the Guidelines for Registration Subdivision N.

Shaughnessy #: 08083

EAB Logout Date: FEB 08 1985

Init: 

To: R. Taylor/J. Yowell
Product Manager #25
Registration Division (TS-767)

From: Lionel A. Richardson, Chief
Environmental Chemistry Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769c)

Attached please find the EAB review of...

Reg./File No.: 100 - 585

Chemical: Atrazine

Type Product: H

Product Name: _____

Company Name: Ciba - Geigy

Submission Purpose: Review of protocol for forestry study

ZBB Code: _____

ACTION CODE: 655

Date In: 1-11-85

EAB # 5246

Date Completed: 1/23/85

TAIS (level II) Days

Deferrals To:

46

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_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Protocol for combined field dissipation and aquatic non-target organism accumulation studies: AATREX® NINE-0® (atrazine) for forestry use - submitted by Ciba-Geigy Corp. November 19, 1984

FROM: Hudson Boyd, Chemist
Review Section #3
Exposure Assessment Branch *JB*
Hazard Evaluation Division (TS-769e)

TO: James Yowell
Product Manager #25
Registration Division (TS-769e)

Subject protocol has been evaluated and found to be acceptable with a few minor exceptions as discussed with the RD representative and Company representatives Stumpf and Balor on January 23, 1985.

Our main concern as expressed at the meeting, is that the water samples be handled and tested in a manner that will preclude hydrolysis of any atrazine residues arising from non-target contamination of the stream/pond by AATREX® NINE O® between the time of spraying/sampling and analysis. We asked that Ciba-Geigy substantiate that hydrolysis did not occur during the sampling/handling/storage/analysis period.

Ciba-Geigy was also asked to change the wording "should be" to "will be" or "must be" in the several paragraphs of the proposed protocol.