

106701

NOV 04 1985

Date Out EAB:

To: G. Werdig
Product Manager 50
Registration Division (TS-767)

From: Samuel M. Creeger, Chief
Environmental Chemistry Review Section 1
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

Attached please find the environmental fate review of:

Reg./File No.: _____

Chemical: Fosamine Ammonium

Type Product: Herbicide

Product Name: KRENITE

Company Name: Dupont

Submission Purpose: Submission in Response to GWDCI

ACTION CODE: _____

EAB # 5929

TAIS (level II) Days

1.0

Date In: 9/13/85

Date Completed: NOV 04 1985

Deferrals To:

_____ Ecological Effects Branch

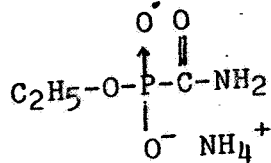
_____ Residue Chemistry Branch

_____ Toxicology Branch

Monitoring study requested by EAB:

Monitoring study voluntarily conducted by registrant:

CHEMICAL: Fosamine Ammonium, Krenite®



Solubility: 100%

REVIEWED BY:

Catherine Eiden
Chemist
Exposure Assessment Branch

Catherine Eiden
10/31/85

APPROVED BY:

Samuel Creeger
Section Chief, #1
Exposure Assessment Branch

Samuel Creeger
NOV 04 1985

INTRODUCTION

DuPont's scientists have submitted additional data and explanations to their original environmental fate data submitted in response to the Data Call-In Notice, in hopes of completing the environmental fate data requirements for fosamine ammonium (DuPont Krenite® Brush Control Agent). This submission is in response to a previous EAB review dated 10/17/84 concerning this same chemical. This submission has been considered together with the previous EAB review (dated 10/17/84) and current data submitted under the Data Call-In Notice of October 31, 1984. The EAB review (dated 10/17/84) was prepared in response to a request from the registrant to amend the current product label to allow for an increased use rate. In that review, EAB found the environmental fate studies submitted to be inadequate to support the increased use rate for fosamine ammonium; EAB also found the studies to be inadequate to support environmental fate data requirements. It is in response to this latter finding that the registrant has submitted additional information.

DISCUSSION:

Included in this submission are data that were previously lacking. Specifically they are:

- o The sample purity, specific activity, and location of the radiolabel in the parent compound, fosamine ammonium, used

in these studies.

- A discussion of analytical methods used for extractions and chromatographic analysis of fosamine ammonium from soils and water.

- The "pattern of decline" for carbamoylphosphoric acid (CPA) the major breakdown product from fosamine ammonium degradation in soils, has been established in the field studies. The previous EAB review found the field dissipation and soil metabolism studies to be lacking in half-life calculations for CPA. Although no half-life was calculated, "the pattern of decline" has been established in 3 field soils; by 3-6 months, CPA residues have declined to <1 ppm, and they reach a maximum concentration in 2-6 weeks. These studies were carried out for a year. Guideline requirements state that,

"Data must be collected until patterns of decline of the parent compound and patterns of formation and decline of degradation products are established in soil or for 1 year, whichever comes first".

The exact "pattern of decline" for CPA residues was not established in the soil metabolism studies nor was a half-life calculated; however, based on the field studies data, the documented rate of CO₂ evolution during the aerobic soil metabolism study (45-75% of the initial ¹⁴C fosamine ammonium is oxidized to CO₂ by day 90) and the simplicity of the chemical structure of CPA (PO₃-CO-NH₂) EAB concludes that CPA is not a persistent metabolite and that the environmental fate data requirement to establish its pattern of formation and decline has been satisfied.

Although soils used for an experiment employing "sterile" soil conditions were not completely sterilized, it was shown that with a soil of reduced microbial population, the production of CO₂ from fosamine ammonium drops to 8-18% vs 45-75% at 90 days from non-autoclaved soils. This study does show that microbial degradation is an important degradation pathway for fosamine ammonium. EAB considers this to be additional evidence of fosamine ammonium's rapid degradation.

Two data gaps outlined in the EAB review dated 10/17/84 were not addressed in the registrant's submission. Specifically they are:

- No adsorption/desorption isotherms from the Freundlich isotherm experiments used to generate K_d values nor equations were submitted.
- The sterility of the water used in the hydrolysis and aqueous photolysis experiments has not been convincingly shown. There is evidence in both studies that not all the reaction flasks contained sterile water. Because of this, some of the results

are confusing.

A point not raised in the previous review regards the field dissipation study. In the submitted study, stainless steel cylinders were used (10 cm x 38 cm). The purpose of using the stainless steel cylinders is to allow the use of radiolabeled compounds in the field for those compounds applied at very low rates making the detection of those residues with conventional methods very difficult, even after immediate application. EPA has agreed to consider this method on a case-by-case basis per chemical. In this case, fosamine ammonium is applied at 11.3 kg/ha (field spraying concentrations approximate 5000 ppm); therefore, a very high application rate is used making the steel cylinder method unnecessary.

As a final point, no Soil Photolysis (161-3) study has been submitted.

CONCLUSIONS:

- 1) The registrant should submit data and isotherms to support the adsorption/desorption experiments, before this study can be validated.
- 2) Because the results of the hydrolysis (161-1) and aqueous photolysis (161-2) studies are confusing, and because the sterility of the water used in these studies cannot be verified, these studies do not satisfy the environmental fate data requirements.
- 3) EAB concludes that the field dissipation study does not meet Guideline requirements, because of the high application rates for fosamine ammonium in the field. EAB concludes that a standard method field dissipation (164-1) study is necessary. The two studies can then be compared to a reference.
- 4) All other environmental fate data requirements have been satisfied for fosamine ammonium, except for the following:
 - Soil Photolysis (161-3)
 - Adsorption/desorption (163-1) (pending the submission of missing data and graphs).
 - Field Dissipation (164-1)

RECOMMENDATIONS:

Additional data is needed to satisfy environmental fate data requirements:

- 1) Submit a new Hydrolysis study (161-1) using sterilized water.

- 2) Submit a new Aqueous Photolysis study (162-1) using sterilized water.
- 3) Submit additional data needed to complete environmental fate data requirements for Adsorption/Desorption (163-1).
- 4) Submit a Soil Photolysis study (161-3)
- 5) Submit a new Field Dissipation study using the standard procedure (164-1).

REGISTRATION DATA REVIEW RECEIVED TO BE LIST FOR REVIEW OF STATIS PFA ONLY
 Confidential Business Information
 Does Not Contain National Security Info. (E.O. 12958)

FAIR NO.: 11817 9/13/85
 (RC PROVIDE) BRAGNESSY I-3
 106701

CHEMICAL NAME: Fosamine Ammonium

Identifying Number	Action Code	Reference Number	Record Number	Study Guideline or Narrative Description	Reg. Std. Review Submission Criteria (SEE BEIR)	Accession Number	(RSERB Provide) MRID Number	(HEB/BUD/TSS Complete) Review Results: Acceptable (A)/ Unacceptable (U)
106701	495		158344	Groundwater		259259		

RD BRANCH CHIEF INITIALS: *SD*

E. Werdig SD
 08-21-85

- APPLICABLE DATA:
- Adverse Effects Data (405,406)
 - Suspect Data (415,416)
 - IRT Data (485,486)
 - Groundwater Data (495,496)
 - Data Waiver Request (Exregistration) (650,651)
 - Population Data and Labeling (Reregistration) (655,656)
 - Generic Data (Reregistration) (660,661)
 - Special Review Data (870,871)

INDIVIDUAL STUDIES SUBMITTED: *Groundwater*
 Record # *156767*
 DuPont submitted comments concerning the Agency's review of the *Fosamine Ammonium* environmental fate data. This data to be incorporated into the Fosamine Ammonium package # *156767*

TO BE COMPLETED BY RSERB:
 DATE SENT TO HEB/BUD/TSS: *9-13-85*
 PRIORITY NUMBER: *50*
 PROJECTED RETURN DATE: *11-13-85*
 DATE RETURNED TO RD (HEB/BUSINESS PROVIDE):

TO: *X* TSS EUD: FEAR TSS

	NUMBER OF ACTIONS		
	Reregistration	Special Review	Other
Acute Tox.			
Chronic Tox.			
Ecological Effects			
Human Health			
Product Use			
Efficacy			
Precautionary Labeling			
Science Support			
Economic			

Sam Loege

FOR DATA SUBMITTED UNDER A REGISTRATION STANDARD REVIEW SUBMISSION CRITERIA:

Policy Note 331

- 1 - Data which meet 3(a)(2) or meet 3(c)(2)(B) flagging criteria
- 2 - Date of particular concern
- 3 - Data necessary to determine tiered testing requirements

NOTE TO TSS: Return 1 Copy To RSERB