

Shaughnessy No.:128850

Date Out of EAB: JUN 05 1985

To: Dick Mountfort
Product Manager 23
Registration Division (TS-767)

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

Attached, please find the EAB review of...

Reg./File # : 8340-EUP-RN
Chemical Name: HOE 39866
Type Product : Herbicide
Product Name : ?
Company Name : American Hoechst
Purpose : Response to review of 12/20/84

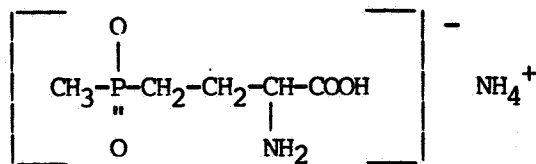
Action Code(s):	<u>711</u>	EAB #(s) :	<u>5402</u>
Date Received:	<u>2/28/85</u>	TAIS Code:	<u>52</u>
Date Completed:	<u>6/4/85</u>	Total Reviewing Time:	<u>2.5 days</u>

Deferrals to: Ecological Effects Branch
 Residue Chemistry Branch
 Toxicology Branch

1. CHEMICAL:

HOE 39866

monoammonium 2-amino-4-(hydroxymethylphosphinyl)-butanoate



2. TEST MATERIAL:

Various

3. STUDY/ACTION TYPE:

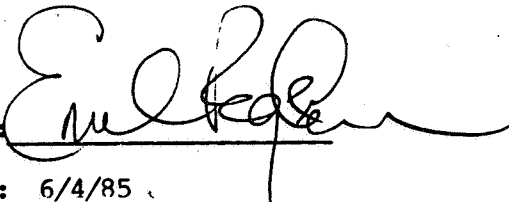
Response to EAB review of 12/20/84.

4. STUDY IDENTIFICATION:

See §10, below.

5. REVIEWED BY:

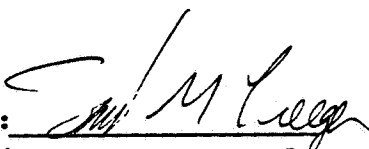
Emil Regelman
Chemist
EAB/HED/OPP

Signature: 

Date: 6/4/85

6. APPROVED BY:

Samuel Creeger
Chief
Review Section #1, EAB/HED/OPP

Signature: 

Date: JUN 05 1985

7. CONCLUSIONS:

- 7.1 Submitted data are inadequate to support the hydrolysis, aerobic soil or leaching data requirements. The registrant has failed to satisfactorily address the numerous deficiencies cited in the earlier reviews by the submission of adequate supportive data, but has relied instead on force of argument.

It seems unlikely that any of the previously submitted studies can be adequately amended to bring them into compliance with Subpart N data requirements.

8. RECOMMENDATIONS:

The registrant should be referred to Subpart N for details of conducting requisite testing for the proposed usage. Studies should be conducted which are consistent with these Guidelines, then submitted for EAB evaluation.

We suggest that the registrant submit experimental protocols for EAB evaluation for each study they propose to conduct, prior to initiation of any additional testing.

Alternatively, RD could arrange a meeting with representatives of Hoechst, at which time they could make a presentation of proposed testing.

9. BACKGROUND:

A. Introduction

On 12/20/84, EAB completed its review of HOE 39866. Hoechst had requested an EUP for use on soybeans. At that time, EAB could not concur with the proposed EUP due to a number of deficiencies.

The current submission, in accession 256760, is the registrant's response to the deficiencies cited in the 12/20/84 review.

B. Directions for Use

None submitted with this action.

10.0 DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

10.1 Summary of Deficiencies and Registrant's Responses Thereto

10.1.1 HYDROLYSIS

HOE-39866. Stability in Water. Translation of document number A 22668. DR. C.V. Waldow and C. Klockner. Tab No. D-3-1. Acc. No. 072974.

Deficiency: No detailed procedures given. Study cannot be evaluated.

Response: A new hydrolysis study is submitted at Tab D-3-1 which should satisfy Guidelines requirements (see review in §10.2, below).

10.1.2 AEROBIC SOIL METABOLISM

Aerobic Soil Metabolism Study of the Herbicide Hoe 039833 After Application of Hoe 035956, the Free Acid of Hoe 039866. Dr. H. Gildemeister and H.J. Jordan. Report No. (B)73/83. Tab No. D-3-3. Acc. No. 072974.

Also... Supplement of Report (B)73/83 (Document N. A 27116). Tab No. D-3-3.

Also... Behavior of the Active Ingredients of Crop Protection Agents in the Soil. Dr. Gildemeister. Report No. (B)126-82. Tab No. D-3-4.

Also... Hoe 35956-¹⁴Cm ¹⁴CO₂ evolution in the Soil After Application. Dr. W. Thier, Fischer, R. and Wagner, U. Report No. (B)-37/79. Tab No. D-3-5.

10.1.2a Deficiency: The soils used were not completely characterized. The moisture capacity, bulk density, cation exchange capacity and percent sand, silt and clay were not given.

Response: The soils are completely characterized under Tab D-3-2 in the current submission (see review in §10.3 below).

10.1.2b Deficiency: Samples were not taken until the patterns of decline of the test substance and patterns of formation and decline of degradation products were established in the soil. The sampling should have continued for at least 1 1/2 to 3 half-lives to obtain accurate rate constants. The soils were sampled and analyzed at only one time (35 days). No indication of the pattern of formation and decline of the degradation products other than CO₂ evolution were given.

Response: A complete discussion of this formation and decline of degradation products is provided under Tab D-3-2 in the current submission (see review in §10.3, below).

10.1.2c Deficiency: There was no indication of whether replicate samples were taken.

Response: None.

10.1.2d Deficiency: The dates on which the study began and ended and when the samples were analyzed were not given.

Response: None.

10.1.2e Deficiency: The axes of the graphs of the decline of the parent compound were not readable.

Response: None.

10.1.2f Deficiency: The rates of formation and decline of the degradation products were not given.

Response: A complete discussion of this formation and decline of degradation products is provided under Tab D-3-2 in the current submission (see review in §10.3, below).

10.1.2g Deficiency: The degradation rate of the parent was not given and the method of calculation of the half-life estimate was not given.

Response: None.

10.1.3 LEACHING

Leaching Study of Hoe 035956 (= Free Acid of the Herbicide Hoe 039866) and its Degradates. Dr. H. Gildemeister and H.J. Jordan. Report No. (B)73/83. Tab No. D-3-6. Acc. No. 072974.

10.1.3a Deficiency: The soils used were not completely characterized. The moisture capacity, bulk density, cation exchange capacity and percent sand, silt and clay were not given.

Response: Information on the soil characteristics is provided in the current submission.

10.1.3b Deficiency: Values of soil/water relationships (K_d) were not reported for HOE 039866 and its degradates. (Sample calculations used in determining K_d values should also be provided.)

Response: None.

5

10.1.3c Deficiency: There was no indication of whether replicate samples were taken.

Response: None.

10.1.3d Deficiency: The dates on which the study began and ended and when the samples were analyzed were not given.

Response: None.

10.1.3e Deficiency: The volume of water used to elute the columns was not equal to 20 inches (50.8 cm) times the cross sectional area of the columns and the columns were slightly below the minimum 30 cm height.

Response: None.

10.1.3f Deficiency: Only 3 soils were used instead of the required minimum of 4 soils.

Response: A fourth soil experiment was provided, but was too sketchy to be reviewed.

10.2 A. Study Identification

Gorlitz, G. and C. Klockner. 1985. Behavior of Plant Protection Products in Water (translation from the German) Analytical Laboratory, Hoechst Aktiengesellschaft. February 18, 1985.

B. Materials and Methods (Protocols)

1. Test Method

a. Description of Protocol

This study is little more than a cursory outline of an experimental procedure, with very little technical detail.

b. Description of Chemical method used.

An unknown, unlabeled formulation of HOE-039866 was added to unspecified buffer solutions at pH values of 5, 7, and 9, and maintained at 50°C in a thermostatically controlled water bath for 5 days. Solutions were withdrawn and injected into an HPLC for identification and quantification by comparison with an unspecified standard.

C. Reported Results

Virtually no hydrolysis was detected after 5 days.

D. Study Author's Conclusions/Quality Assurance Measures

HOE 39866 appears to be refractory to hydrolysis at all pH values.

E. Reviewer's Discussion and Interpretation of Study Results

This study is grossly inadequate in support of the hydrolysis data requirement. Numerous deficiencies include inadequate experimental detail, inadequate analytical methodology and failure to provide sample chromatograms. In addition, the experiment should have been conducted at 25°C for a 30 day period, especially considering the apparently refractory nature of HOE 39866.

10.3 A. Study Identification

Gorbach, S. 1985. EPA Review of Hoe 039866, Environmental Fate Data. Letter to Dr. O'Grodnick. February 19, 1985.

B. Materials and Methods (Protocols)

None.

C. Reported Results

The registrant's response to the cited deficiencies were as follows:

General: Submitted studies were adequate for EUP purposes.

Hydrolysis: Since prolonged heating at elevated temperatures did not result in significant hydrolysis, HOE 039866 must be considered to be not hydrolyzed under sterile conditions.

Aerobic Soil Metabolism: Detailed soil characteristics are as follows (table below was transcribed in toto from the registrant's response):

	Soil 2.2	Soil 2.3	Soil 2.1
Moisture Capacity	36.7	29.6	30.0 g/100g soil
Bulk Density	1.51	1.59	1.70 g/cm ³
Cation Exch. Cap.	11.98	9.65	2.75 meq/100g soil
Sand	79.5	70.8	91.8 %
Silt	17.7	25.5	6.3 %
Clay	2.8	3.7	1.9 %

With reference to the formation and decline of degradation products, the registrant argues that the submitted data were adequate, but provided no additional confirmatory data.

Leaching: With reference to computation of the K_d , the registrant reports a measured K_{oc} of 8.4, suggesting little correlation between soil organic carbon and mobility of the apparently highly water soluble compound. The registrant suggested that soil leaching is controlled more by the clay and mineral composition of the soil, but this was not supported by the submitted studies.

The soil characteristics were as summarized above.

An additional soil experiment (one page summary only) was included, but was too sketchy to be evaluated.

D. Study Author's Conclusions/Quality Assurance Measures

None.

E. Reviewer's Discussion and Interpretation of Study Results

Hydrolysis: Registrant's arguments are not persuasive.

Aerobic Soil Metabolism: Soil characterization is mostly complete. However several deficiencies still exist. Soil organic carbon was not reported. The foreign soils used in these studies may differ significantly from domestic soils in the areas of proposed usage. Characteristics which should be addressed include soil class, % organic matter, soil pH and ratio of populations of soil bacteria, soil fungi and soil actinomycetes to populations of the same in U.S. soils common to the proposed use areas.

Leaching: Registrant's arguments are not persuasive.

11. COMPLETION OF ONE-LINER:

No additional data were added to the ongoing one-line data summary.

12. CBI APPENDIX:

There is no CBI appendix.