

MAR -2 1990

Shaughnessey Number: 128845-5

Date out of EFGWB:

TO: R. Taylor
Product Manager #25
Registration Division (H7505C)

FROM: Paul Mastradone Ph.D., Chief *PM*
Environmental Chemistry, Review Section 1
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

THRU: Henry Jacoby, Chief *Henry Jacoby*
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (H7507C)

Attached, Please find the EFGWB review of:

Reg./File No: 352-446

Chemical Name: Methyl 3-[[[(4-methoxy-6-methyl-1,3,5-triazin -
2-yl)-amino] carbonyl] amino] sulfonyl]-2-
thiophencarboxylate

Common Name: DPX-M6316

Type Product: Herbicide

Product Name: Harmony

Company Name: E.I. duPont de Nemours and Company Inc.

Purpose: Review Anaerobic Soil Metabolism Protocol

Date Received: 3/14/89 Action Code: 352

Date Completed: 2/20/90 EFGWB #: 90430

Monitoring study Requested: Total Review Time: 2.0 Day

Deferrals to:

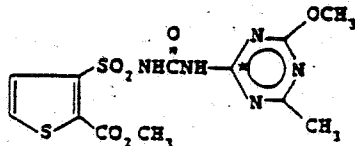
- Ecological Effects Branch, EFED
- Science Integration & Policy Staff, EFED
- Non-Dietary Exposure Branch, HED
- Dietary Exposure Branch, HED
- Toxicology Branch I&II, HED

1.0 CHEMICAL:

Chemical Name: Methyl 3-[[[(4-methoxy-1,3,5-triazin-2-yl)-amino] carbonyl] amino] sulfonyl]-2-thiophencarboxylate

Common Name: DPX-M6316

Structure:



Physical/Chemical Properties of Active Ingredient:

Empirical Formula: C₁₂H₁₃N₅O₆S₂

Molecular Weight: 387.40

Physical State: White crystalline solid

Vapor Pressure: 2.7 x 10⁻⁶ mm Hg at 25 C

Melting Point: 186 C

Solubility (25 C): Water (pH 4.0): 24 mg/L

Water (pH 5.0): 260 mg/L

Water (pH 6.0): 2400 mg/L

2.0 TEST MATERIAL:

DPX-M6316

3.0 STUDY /ACTION TYPE:

Review of Anaerobic Soil Metabolism Protocol.

4.0 STUDY IDENTIFICATION:

Stevenson, I.E. (study director). Starting date March 1989.

Anaerobic Soil Metabolism of [Triazine-2-¹⁴C] DPX-M6316.

E.I. duPont de Nemours and Company Inc., Wilmington, Delaware.

5.0 REVIEWED BY:

Elizabeth A. Resek, Chemist
Environmental Chemistry, Review Section 1
OPP/EFED/EFGWB

Signature: 

Date: 9/20/01

6.0 APPROVED BY:

Paul Mastradone Ph.D., Chief
Environmental Chemistry, Review Section 1
OPP/EFED/EFGWB

Signature:

Paul Mastradone
MAY - 2 1990

Date:

7.0 CONCLUSIONS/RECOMMENDATIONS:

EFGWB concludes that the protocol as submitted is not acceptable. Discussion points noted in Section 9.0 should be addressed prior to the initiation of the study.

8.0 BACKGROUND:

DPX-M6316 is a herbicide for selective, postemergent control of broadleaf weeds. The parent compound has a half life of 1 to 2 weeks and $K_d < 0.01$ in sandy soils. The principle ^{al} degradate is the triazine amine. It has a calculated half life of 6 to 8 months and a K_d of 0.44. This degradate has a significant potential to leach through soil and contaminate groundwater. Because there is only one application per season at a very low rate, low concentrations are generally found in the soils. A prospective monitoring study was requested by EPA.

9.0 DISCUSSION OF INDIVIDUAL STUDIES:

The following points found in the submitted protocol should be addressed prior to the initiation of an anaerobic soil metabolism study:

1. Complete description of the soil source and soil characteristics should be supplied.
2. Flooding the soil to reach anaerobic conditions is suggested, however, if the soil is adjusted to 75% of its water holding capacity and then purged with humidified nitrogen (as stated in the submitted protocol), then some measure of anaerobicity should be provided (e.g. redox potentials, Eh).
3. Because of the extremely low application rate (0.05 ppm) sound science dictates that levels below 0.01 ppm need to be quantitated and residues identified. Since the protocol states that the concentration of DPX-M6316 which will be added to the soil is 0.05 ppm, then measurements in the range of 0.005 ppm would be appropriate. Alternatively an elevated rate of addition might be used as the

degradates of DPX-M6316 are of interest as well as the kinetics of degradation.

4. The protocol states that extracts would be analyzed by appropriate chromatographic techniques and unless they are taken to fairly exhaustive end will usually not yield sufficient information. Therefore, MS identification of degradates, where possible is suggested.

10.0 COMPLETION OF ONE-LINER:

N.A.

11.0 CBI APPENDIX:

N.A.

Use this form for individual studies & to submit pesticide applications.



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

Data Review Record

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

Pack Number

49100

EFED

Date Received

3-14-89

1. Product Name

Chemical Name

Harmony

DPX-M6316

2. Identifying Number	3. Record Number	4. Action Code	5. MRID/Accession Number	6. Study Guideline or Narrative
352-446	241655	352		Environmental Mit Protocol

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
1	2/10/89	Taylor/Keller	25	3/14/89	5/14/89	

Instructions

Review attached ~~Environmental~~ Mit Protocol

Chem Code: 128845-5

This Section Applies to Review of Studies Only

14. Check Applicable Box	15. No. of Individual Studies Submitted
<input type="checkbox"/> Adverse 6(a)(2) Data (405) <input type="checkbox"/> Special Review Data (870)	<input type="checkbox"/> Generic Data (Reregistration)(660) <input type="checkbox"/> Product Specific Data (Reregistration)(655)
16. Have any of the above studies (in whole or in part) been previously submitted for review?	17. Related Actions
<input type="checkbox"/> Yes (Please identify the study(ies)) <input type="checkbox"/> No	

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

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

Label Attached

HARMONY

128845

Page _____ is not included in this copy.

Pages 6 through 13 are not included.

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.

January 9, 1989

M. HEALTH AND SAFETY

The oral LD₅₀ of DPX-M6316 in rats is >5000 mg/kg.

The study will be conducted according to the Du Pont Experimental Station Safety and Fire Guide, and the appropriate Du Pont Agricultural Products Department Metabolism Group SOP's.

N. RECORDS RETENTION

All raw data will be recorded and retained according to Good Laboratory Practices (Reference 4). Records to be maintained by the Study Director include but are not limited to: all raw data; the original signed protocol and any amendments thereto; all letters, memos or notes pertaining to the study; and the original signed final report. All data should be archived as soon as possible.

O. GOOD LABORATORY PRACTICE

The Good Laboratory Practice Regulations do not apply to a study of this type when the study is started. Nevertheless, it will be conducted and reported in the spirit of the Good Laboratory Practice Regulations (Reference 4). Signatures of the Study Director, collaborating scientists, and supervisory personnel will attest to the authenticity of the study.

P. REFERENCES

1. U.S. Environmental Protection Agency, Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate, Section 162-2, Anaerobic Soil Metabolism Studies.
2. "Aerobic Soil Metabolism of DPX-M6316 [Thiophene-2-¹⁴C]". Rapisarda, C., E. I. du Pont de Nemours & Co., Inc., Agricultural Chemicals Department Document AMR-236-84.
3. U.S. Environmental Protection Agency, Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate, Section 162-1, Aerobic Soil Metabolism Studies.
4. U.S. Environmental Protection Agency, "40 Code of Federal Regulations Part 160, Pesticide Programs, "Good Laboratory Practice Standards."