

Shaughnessy No.: 125851

Date Out of EFGWB: SEP 14 1988

To: Richard Mountfort  
Product Manager #23  
Fungicide-Herbicide Branch  
Registration Division (TS-767C)

From: Emil Regelman, Supervisory Chemist  
Review Section #2  
Environmental Fate & Ground Water Branch  
Environmental Fate & Effects Division (TS-769C)

Thru: Paul F. Schuda, Ph.D., Chief  
Environmental Fate & Ground Water Branch  
Environmental Fate & Effects Division (TS-769C)

Attached, please find the EFGWB review of...

Reg./File # : 1471-RLI and 1471-RLO

Common Name: Isoxaben

Type Product : Herbicide

Product Name : EL-107, Prolan, Flexidor

Company Name : Elanco Products Company (Eli Lilly Research Laboratories)

Purpose : Review additional information on fish accumulation (165-4)  
and leaching and adsorption/desorption studies (163-1).

Date Received: 6/3/88

Action Code(s): 126, 126

Date Completed: 9/12/88

EFGWB #(s): 80807, 80808

Monitoring study requested:       

Total Reviewing Time: 1 day

Monitoring study voluntarily:       

Deferrals to:        Ecological Effects Branch/EFED

       Dietary Exposure Branch/HED

       Toxicology Branch-HFA Support/HED

1. CHEMICAL: Common name:

Isoxaben

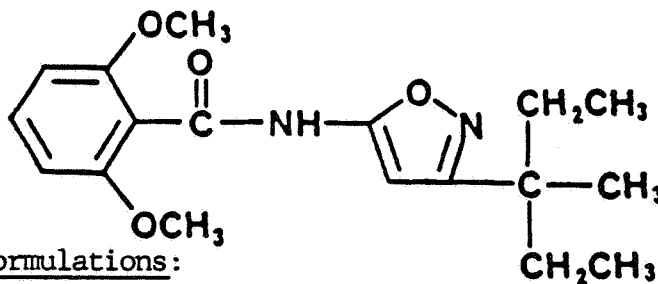
Chemical name:

N-[3-(methylpent-3-yl)isoxazol-5-yl]-  
2,6-dimethoxybenzamide

Other name(s):

EL-107, Prolan, Flexidor

Structure:



Formulations:

12.5 and 50% WP, 75% FlC

Physical/Chemical properties:

Molecular formula:  $C_{18}H_{12}N_2O_4$   
Physical state: White, crystalline solid  
Melting point:  $176-179^{\circ}C$   
Solubility in water: 1.0-2.0 ppm

2. TEST MATERIAL:

N/A.

3. STUDY/ACTION TYPE:

Review the additional information re quantitative identification of metabolites in fish and requirement of batch equilibrium study to assess ground water contamination.

4. STUDY IDENTIFICATION:

N/A.

5. REVIEWED BY:


P. Datta, Ph.D.  
Chemist  
Review Section #2  
ERGW/EFED/OPP

Signature: PR Datta

Date: 9/12/88

6. APPROVED BY:

Emil Regelman  
Supervisory Chemist  
Review Section #2,  
EFGWB/EFED/OPP

Signature: 

Date: SEP 14 1988

7. CONCLUSIONS:

EFGWB cannot accept the summary of the statement of clarification without laboratory TLC data on quantitation of the metabolites which were present in the origin material of the TLC plate data provided for isoxaben residues in fish tissues. Furthermore, residue data on whole fish were not submitted. Therefore, this fish accumulation study does not fulfill the data requirement for a fish accumulation study (§165-4).

The Ground Water Team of EFGWB does not require any additional study because the registrant satisfactorily completed the column leaching study to fulfill the data requirement for a leaching and adsorption/desorption study (§163-1). (See attached note from Patrick Holden of GWT/EFGWB).

8. RECOMMENDATION:

EFGWB recommends RD inform the registrant, Elanco Products Company: (1) to submit a new fish accumulation study (§165-4) providing a complete characterization of residues in whole, edible and non-edible tissues of fish measured experimentally, and (2) that the data requirement for a leaching and adsorption/desorption study (§163-1) is fulfilled.

9. BACKGROUND:

On 5/26/88, the registrant, Elanco Products Company, sent a letter to RD with clarification re the fish accumulation study (§165-4) and a rebuttal response to the Ground Water Team re the leaching and adsorption/desorption study (§163-1).

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

N/A.

11. COMPLETION OF ONE-LINER:

See attached on one-liner sheet.

12. CBI APPENDIX:

N/A.