Elanco file

Shaughnessy No.: 125851

Date Out of EAB: JAN 6 1988

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

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

for ER

THRU: Paul F. Schuda, Ph.D., Chief
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Paul F. Schuda

Attached, please find the EAB review of...

Reg./File # : ~~1471-EUP-TN~~

Chemical Name: Isoxaben

Type Product : Herbicide

Product Name : EL-107, Prolan, Flexidor

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

Purpose : EUP use on wheat and barley

Date Received: 10/28/86

Action Code(s): 711

Date Completed: 1/6/88

EAB #(s) : ~~70377-78~~ 70061

Monitoring study requested: ____

Total EAB Reviewing Time: 1 day

Monitoring study voluntarily: ____

Deferrals to:

____ Ecological Effects Branch

____ Residue Chemistry Branch

____ Toxicology Branch

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1. CHEMICAL: Common name:

Isoxaben

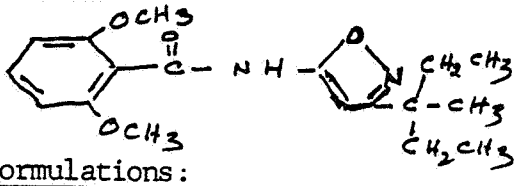
Chemical name:

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

Trade 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°C
Solubility in water:	1.0-2.0 ppm

2. TEST MATERIAL:

See individual studies.

3. STUDY/ACTION TYPE:

Application for Experimental Use Permit to use isoxaben as a herbicide to control various broadleaf weeds in wheat and barley.

4. STUDY IDENTIFICATION:

Studies submitted for review on 10/28/86, are:

Magnussen, J.D. and D.P. Rainey. 1987. Laboratory studies of ^{14}C EL-107 accumulation in fish. Laboratory project identification ABC-0342, ABC-0354. Prepared and submitted by Eli Lilly and Company, Greenfield, IN. (40059509)

Rainey, D. P. The metabolism of [^{14}C]EL-107 in soil: characterization of volatile radiolabeled degradation products. Experiment ABC-0226. Prepared and submitted by Eli Lilly and Company, Greenfield, IN. Reference 2. (00265370)

Rutherford, B.S., and O.D. Decker. 1986. Isoxaben soil/turf field dissipation study. Project ID No. AAC8521. Prepared and submitted by Eli Lilly and Company, Greenfied, IN. (40059508)

Saunders, D.G., J.W. Moran, and G.E. Babitt. 1986. Photolysis of isoxaben in aqueous solution. Prepared and submitted by Eli Lilly and Company, Greenfield, IN. (40097601 and 40059507)

Saunders, D.G., S.K. Smith, and J.W. Mosier. 1985. Mobility of EL-107 and a soil metabolite in soil. Report No. EWD8442. Prepared and submitted by Eli Lilly and Company, Greenfield, IN. Reference 1. (00265730)

5. REVIEWED BY:

P. Datta, Ph.D.
Chemist
Review Section #3
EAB/HED/OPP

Signature: PRDatta

Date: 1/6/88

6. APPROVED BY:

Emil Regelman
Supervisory Chemist
Review Section #3,
EAB/HED/OPP

Signature: For Emil Regelman

Date: January 6, 1988

7. CONCLUSIONS:

EAB cannot concur with the request for the experimental use permit (1471-EUP-TN) of isoxaben for the application on wheat and barley crops because the submitted data for the EUP terrestrial food crop use sites (wheat and barley) are inadequate. The data requirements of 40 CFR §158.130 are not fulfilled. (For details, see the Science Chapter for the Isoxaben Registration Standard, 11/23/87).

The data requirements for this EUP and their current status are:

161-1 - Hydrolysis: fulfilled (EFB review #3446, 9/29/83);
162-1 - Aerobic soil metabolism: partially fulfilled;
163-1 - Leaching and adsorption/desorption: partially fulfilled;
165-1 - Confined accumulation on rotational crops: studies not submitted;
165-4 - Fish accumulation studies: partially fulfilled.

8. RECOMMENDATIONS:

EAB recommends RD inform the registrant, Elanco Products Company, to submit: (a) studies on confined accumulation on rotational crops (165-1); (b) a fish accumulation study (165-4) providing a complete characterization of residues in whole and edible tissues of fish measured experimentally; (c) an aerobic soil metabolism study (162-1) providing information on soil metabolism of phenyl ring-labeled [^{14}C] isoxaben; and (d) leaching and adsorption/ desorption study (163-1) providing additional data on the mobility of aged phenyl ring-labeled isoxaben residues in soil.

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

MAY 2 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Isoxaben-Addendum to the EAB Science Chapter for the Registration Standard

FROM: Padma R. Datta, Ph.D., Chemist
Environmental Chemistry Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

TO: Richard Mountfort, PM #23
Herbicide - Fungicide Branch
Registration Division (TS-767C)

and

Amy S. Rispin, Chief
Science Integration Staff
Hazard Evaluation Division (TS-769C)

THRU: Emil Regelman, Supervisory Chemist
Review Section #3
Exposure Assessment Branch/HED (TS-769C)

and

THRU: Paul F. Schuda, Ph.D., Chief
Exposure Assessment Branch
Hazard Evaluation Division (TS-769C)

Attached is supplemental information to update the Exposure Assessment Branch (EAB) Science Chapter for the new chemical Registration Standard of the herbicide ISOXABEN. It includes Tasks I and II, Table A (Generic Data Requirements), an executive summary, and recommendations.

This addendum was in response to the additional data and information submitted by Eli Lilly and Company on 2/29/88.

The EAB Science Chapter on Isoxaben issued 2/2/88 identified data gaps for six environmental fate studies. On 2/29/88, Eli Lilly and Company submitted additional data and information as an amendment to address these deficiencies, and these have now been reviewed by Dynamac.

The status of those studies is summarized below:

GUIDELINES REF #	STUDIES	STUDY STATUS Science chapter Review (2/2/88)	STUDY STATUS Science chapter Review (4/28/88)
° 161-2	Photodegradation in water	U***	A*
° 162-2	Aerobic soil metabolism	U	A
° 163-1	Leaching and adsorption/desorption	P**	P
° 164-1	Terrestrial field dissipation (IN, TX, & FL)	P	P
° 164-1	Terrestrial field dissipation (IL)	U	U
° 165-4	Fish accumulation	P	U

*A = Acceptable
**P = Partially acceptable
*** U = Unacceptable

The data submitted to date are still inadequate to support registration of isoxaben for terrestrial non-food use (turf).

The EAB Ground Water Team's assessment of the leaching potential of isoxaben was attached to the 2/2/88 EAB Science Chapter, and is still applicable.

At the present time, reentry, spray drift, and human exposure monitoring data are not required since the toxicological category of isoxaben is assigned to be 4 (low toxicity) in the science chapter produced by the Toxicology Branch (12/15/87).

Attachments: (1)

cc: Branch Chiefs/HED