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OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Isoxaben - EAB Science Chapter for Registration

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Attached is the Exposure Assessment Branch (EAB) science chapter for the herbicide ISOXABEN. It includes Tasks I and II, Table A (Generic Data Requirements), an executive summary, and recommendations.

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

Also attached is the EAB Ground Water Team's assessment of the leaching potential of isoxaben for reaching ground water.

Attachments: (2)

cc: Branch Chiefs/HED

**ISOXABEN**

Final Report

**Task 1: Review and Evaluation of  
Individual Studies**

**Task 2: Environmental Fate  
Assessment**

**Contract No. 68-02-4250**

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ISOXABEN

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## INTRODUCTION

Isoxaben is an herbicide recommended for preemergent control of various broad-leaf weeds in terrestrial nonfood (noncrop areas) use sites. Single active ingredient formulations consist of 12.5 and 50% WP, and 75% FIC. According to the submitted label, isoxaben 50% WP should be applied at 0.5-1 lb/A to the soil surface using a low pressure sprayer.

CASE GS -- ISOXABEN STUDY 1 PM --

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CHEM 125851 Isoxaben

BRANCH EAB DISC --

FORMULATION 00 - ACTIVE INGREDIENT

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FICHE/MASTER ID 40097601 and 40059507 CONTENT CAT 01  
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, Green-  
field, Indiana.-----  
SUBST. CLASS = S.-----  
DIRECT RVW TIME = 12 (MH) START-DATE END DATE-----  
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CONCLUSIONS:Degradation - Photodegradation in Water

1. This study is scientifically sound and provides supplemental information towards the registration of isoxaben.
2. Carbonyl- and isoxazole ring-labeled [<sup>14</sup>C]isoxaben (radiochemical purities >99.5%), at 0.5 ppm, degraded with half-lives of 7-15 days (calculated 9 days) in sterile buffered (pH 7) solutions irradiated outdoors with natural sunlight in July of 1986 near Greenfield, Indiana. After 30 days of irradiation, isoxaben comprised 21.6% and 13.8% of the applied radioactivity of the carbonyl- and isoxazole ring-labeled solutions, respectively. Degradates included a pyrazolone, an isoquinolone, and a benzopyrrolidone. In the dark controls at 30 days posttreatment, isoxaben comprised >94.4% of the applied.
3. This study does not fulfill EPA Data Requirements for Registering Pesticides because degradates comprising >10% of the applied radioactivity were incompletely characterized and the intensity of the sunlight was not reported.

## MATERIALS AND METHODS:

Carbonyl- and isoxazole ring-labeled [ $^{14}\text{C}$ ]isoxaben (radiochemical purities >99.5%; specific activities 9.37 and 10.6  $\mu\text{Ci}/\text{mg}$ , respectively; Lilly Research Laboratories) in acetonitrile were added separately to solutions of sterile, distilled, buffered water (pH 7) at 0.5 ppm. The cosolvent concentration was 0.25% by volume. The treated solutions were sealed within 20-mL glass ampules which were opaque to light <280 nm. The test ampules, including dark controls (ampules wrapped in aluminum foil), were placed in a south-facing rack tilted 30°; the rack was placed outdoors in a flat open area near Greenfield, Indiana (40°N latitude) on July 9, 1986 (Table 1). Irradiated test solutions were sampled 0, 7, 15, 22, and 30 days posttreatment; dark controls were sampled 30 days posttreatment. All irradiated ampules were stored in the dark at 4°C for an unspecified time prior to analysis.

Total radioactivity in the solutions was determined using LSC. Aliquots of each sample were diluted with methanol and extracted three times with methylene chloride. An aliquot of the extract was condensed, redissolved in methanol:water (70:30), and analyzed for total isoxaben by HPLC using UV light detection. Additional aliquots of the extract were condensed by evaporation, diluted with additional methylene chloride, analyzed for total radioactivity by LSC, and analyzed by TLC on silica gel plates developed in chloroform:methanol:acetic acid (88:10:2). Radioactive compounds were located by autoradiography. The remaining extract was acidified with 1 N HCl (to pH 3) and extracted three times with methylene chloride. A portion was analyzed for total radioactivity by LSC, and the remainder was condensed and analyzed by TLC as described for the neutral solution above.

In order to identify degradates, an additional study was conducted using artificial light irradiation (four FS20T12 fluorescent sunlamps [Westinghouse] and four F20T12BL fluorescent black lights [General Electric] mounted vertically in a circle within an enclosed wooden cabinet). The registrants reported that this combination produced a spectral energy distribution similar to natural sunlight (data provided by the registrant comparing the artificial light and natural sunlight were illegible, but it could be determined that the sunlight data were not for the study site). Test solutions, prepared as described above, were placed 10 cm from the light circle; the temperature was maintained between 24°C and 31°C during the study. [ $^{14}\text{C}$ ]Residues were extracted as previously described and separated by TLC using chloroform:methanol:acetic acid (88:10:2) as the solvent system. Five radioactive zones were scraped from the plates and characterized by MS and NMR.

## REPORTED RESULTS:

Carbonyl-labeled [ $^{14}\text{C}$ ]isoxaben degraded with a half-life of 7-15 days (calculated 9 days) in sunlight-irradiated solutions (Table 2). By day 30, 21.6% of the applied radioactivity was isoxaben, 57.3% was "identified" as zones A through F, 7.9% was unidentified, and 9.1% was unextractable (Table 3).

Isoxazole ring-labeled [<sup>14</sup>C]isoxaben degraded with a half-life of 7-15 days (calculated 9 days) in sunlight-irradiated solutions (Table 2). By day 30, 13.8% of the applied radioactivity was isoxaben, 54.9% was "identified" as zones A through F, 21.6% was unidentified, and 13.9% was unextractable (Table 3).

In the dark controls, 100% and 94.4% of the applied radioactivity of the carbonyl- and isoxazole ring-labeled solutions, respectively, remained undegraded at 30 days posttreatment.

Under artificial light, isoxaben degraded with a half-life of 1-2 days. Zone A was further broken down into three compounds: A<sub>1</sub> (proposed as a pyralazone), A<sub>2</sub> (isoxaben), and A<sub>3</sub> (proposed as an isoquinolone). Zone B consisted of a benzopyrrolidone plus two minor unidentified components and Zone C was identified as benzamide; the remaining zones were not identified.

#### DISCUSSION:

1. Degradates were not completely characterized for radioactive zones A through C. The complete chemical structure of each degradate must be elucidated; furthermore, those zones containing a mixture of compounds must be further characterized and quantified accordingly (this pertains to zones A and B). R<sub>f</sub> values should be provided to evaluate the extent of separation.
2. The intensity of the natural sunlight at this site was not reported. Tables providing "typical" intensities and wavelengths for a "typical" site were provided, but were inapplicable.
3. The incubation temperature for samples irradiated both naturally and artificially was not 25 ± 1°C.
4. Wavelengths between 280 nm and 290 nm were not filtered out.
6. It was not reported whether known standards were cochromatographed along with the test solutions.
7. Method detection limits were not provided.
8. Data were not provided on storage-to-sampling intervals and on the rate of degradation under storage conditions; however, since degradation in dark controls and 0-day samples was minimal, the storage conditions may be considered acceptable.
9. The submitted study also included data on photodegradation in pond and river water. These data were not reviewed since they were not pertinent to data requirements. The degradates were not characterized.

Table 1. Meteorological conditions for the first 22 days of the 30-day sunlight irradiation study.

Day	Date (1986)	Temperature		Sky condition <sup>a</sup>
		High	Low	
0	7/9	88	68	CD
1	7/10	85	68	PC
2	7/11	88	70	PC
3	7/12	85	72	CD
4	7/13	90	73	PC
5	7/14	83	70	PC
6	7/15	90	74	CL
7	7/16	90	75	CL
8	7/17	91	76	CL
9	7/18	93	78	CL/HZ
10	7/19	96	80	CL/HZ
11	7/20	94	75	CL/HZ
12	7/21	84	60	CL
13	7/22	87	62	PC
14	7/23	NR <sup>b</sup>	NR	CL
15	7/24	NR	NR	CL
16	7/25	93	71	PC
17	7/26	90	72	CL
18	7/27	91	70	CL
19	7/28	88	65	PC
20	7/29	86	48	CL
21	7/30	87	66	CL
22	7/31	NR	NR	CD

<sup>a</sup> CD = Cloudy, PC = partly cloudy, CL = clear, HZ = hazy.

<sup>b</sup> NR = Not recorded.

Table 2. Isoxaben (ppm) in aqueous buffered (pH 7) solutions treated with [<sup>14</sup>C]isoxaben (purity 92.5%) at 0.5 ppm and irradiated with sunlight.

Sampling interval (days)	Carbonyl-labeled	Isoxazole ring-labeled
	<u>Irradiated</u>	
0	0.4669	0.3873
7	0.2781	0.2216
15	0.1318	0.1604
22	0.1545 <sup>a</sup>	0.1015
30	0.0681	0.0726
	<u>Dark control</u>	
30	0.4680	0.4603

<sup>a</sup> This value is considered to be an anomaly by the registrant.

Table 3. Distribution of radioactivity (% of the applied) in aqueous buffered (pH 7) solutions treated with [<sup>14</sup>C]isoxaben (radiochemical purities >99.5%) at 0.5 ppm and irradiated with sunlight for 30 days.<sup>a</sup>

Sampling interval (days)	Isoxaben	Zones on TLC plates						Other <sup>b</sup>	Unextractable
		A	B	C	E	F			
		<u>Carbonyl-labeled</u>							
0	96.4	0.5	0.3	1.8	NDC	0.1	1.4	0.1	
7	61.4	7.7	6.4	14.0	ND	0.4	4.1	1.8	
15	30.9	14.4	13.2	22.3	ND	1.1	7.2	6.4	
22	41.2	10.6	10.4	19.4	ND	0.8	5.4	6.3	
30	21.6	16.2	15.1	25.2	ND	0.8	7.9	9.1	
30 (Dark control)	100.0	0.3	0.3	2.2	ND	ND	1.0	0.1	
		<u>Isoxazole ring-labeled</u>							
0	96.5	0.7	0.4	0.7	ND	0.1	2.1	0.3	
7	61.2	6.9	7.5	4.4	3.1	2.2	9.5	6.1	
15	35.4	12.0	12.0	4.3	5.4	4.5	15.6	9.7	
22	20.4	14.6	14.5	5.0	10.2	4.2	19.2	12.4	
30	13.8	16.0	16.7	5.7	12.0	4.5	21.6	13.9	
30 (Dark control)	94.4	0.7	0.5	0.7	0.2	0.5	2.9	0.4	

<sup>a</sup> Zones were tentatively identified as the following: A--a mixture of a pyrazolone, an isoquinolone and isoxaben; B--a benzopyrrolidone; C--a mixture containing benzamide; E--could not be identified (apparently volatilized following clean-up TLC), F--identification was not attempted.

<sup>b</sup> Total radioactivity recovered from TLC plates in the acid plus neutral extracts minus identified radioactivity.

<sup>c</sup> Not detected; the detection limit was not reported.

CASE GS -- ISOXABEN STUDY 2 PM --

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CHEM 125851 Isoxaben

BRANCH EAB DISC --

FORMULATION 00 - ACTIVE INGREDIENT

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FICHE/MASTER ID 00265370

CONTENT CAT 01

Rainey, D. P. The metabolism of [<sup>14</sup>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.

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CONCLUSIONS:Metabolism - Aerobic Soil

[<sup>14</sup>C]Isoxaben residues volatilized at ~0.007 ppm/week from loam soil treated with isoxazole ring- or carbonyl-labeled [<sup>14</sup>C]isoxaben at 1 ppm; volatiles totaled 12-15% of the applied radioactivity during the 36-week study period. During the same interval, the total radioactivity in the soil decreased by ~16% of the applied.

In the previous review of this study (EPA, 12/31/85), it was concluded that the study did not satisfy data requirements because the material balance was not complete (39% of the radioactivity applied to clay loam, 26% applied to loam, and 10% applied to sandy loam soils were unaccounted for at 12 months posttreatment). However, volatiles were not measured.

The registrant has supplied additional data pertaining to the volatilization of [<sup>14</sup>C]isoxaben residues from loam soil (used in the original study) treated at the original rate of 1 ppm with both isoxazole ring-labeled [<sup>14</sup>C]-isoxaben (radiochemical purity >99% and specific activity 11.21  $\mu$ Ci/mg,

Lilly Research Laboratories) and carbonyl-labeled [ $^{14}\text{C}$ ]isoxaben (radiochemical purity >99%, specific activity 9.78  $\mu\text{Ci}/\text{mg}$ , Lilly Research Laboratories). The treated soils were placed within separate incubation flasks wrapped with aluminum foil to exclude light and maintained at room temperature (temperature not further specified) for 36 weeks while air flowed through the system at 10-15 mL/minute. Exiting air passed successively through solutions of ethylene glycol, 0.1 N sulfuric acid, and 2 N potassium hydroxide to trap volatiles. The three trapping solutions were changed every two weeks, at which time samples were collected for analysis. The treated soils were sampled 0 days and 36 weeks post-treatment. Total radioactivity in the solutions and soils were analyzed using LSC and LSC following combustion, respectively.

By the end of the 36-week study period, 15.5% of the applied radioactivity had dissipated from the isoxazole ring-labeled [ $^{14}\text{C}$ ]isoxaben-treated soil. [ $^{14}\text{C}$ ]Residues in the potassium hydroxide trapping solutions totaled 12% of the applied radioactivity during the 36-week study period (Table 1). Radioactivity was not detected in the other two trapping solutions. Therefore, the material balance accounted for ~96% of the applied radioactivity. These data compare favorably with the original data from the aerobic metabolism study using isoxazole ring-labeled material, in which ~84% of the applied radioactivity was recovered from loam soil at ~32 weeks and ~81% was recovered at ~40 weeks post-treatment.

By the end of the 36-week study period, 15.9% of the total radioactivity had dissipated from the carbonyl-labeled [ $^{14}\text{C}$ ]isoxaben-treated soil. [ $^{14}\text{C}$ ]Residues in the trapping solutions totaled 15% of the applied radioactivity during the 36-week study period (Table 1). Total recovery was ~100% of the applied.

In conclusion, the aerobic soil metabolism study is now considered acceptable.

Table 1. Radioactivity (% of the applied) volatilized from loam soil treated with isoxazole ring-labeled or carbonyl ring-labeled [<sup>14</sup>C]isoxaben at 1 ppm.

Sampling interval (weeks)	Isoxazole ring-labeled	Carbonyl-labeled
2	0.72	0.47
4	1.06	0.83
6	2.14	1.84
8	3.46	3.00
10	3.78	3.48
12	4.92	5.60
14	6.06	7.41
16	7.17	9.24
18	7.49	9.65
20	7.72	9.98
22	8.42	10.87
24	9.13	11.89
26	9.61	12.52
28	10.13	13.28
30	10.54	13.65
32	10.95	14.15
34	11.30	14.60
36	11.72	15.07

CASE GS --                      ISOXABEN                      STUDY 3                      PM --

CHEM 125851                      Isoxaben

BRANCH EAB                      DISC --

FORMULATION 00 - ACTIVE INGREDIENT

FICHE/MASTER ID 00265730                      CONTENT CAT 01  
 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.

SUBST. CLASS = S.

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DATE: 2/2/88

CONCLUSIONS:

Mobility - Leaching and Adsorption/Desorption

1. The column leaching data in this study are acceptable.
2. Isoxazole ring-labeled [<sup>14</sup>C]isoxaben and aged (30-day) [<sup>14</sup>C]isoxaben residues were slightly mobile in columns (30-cm length, 1-cm diameter) of sand, sandy loam, loam, and clay loam soils leached with 20 inches of water over a 10-day period. Following leaching, <0.31% of the applied radioactivity was found in the leachate from the columns treated with unaged [<sup>14</sup>C]isoxaben and <3.61% of the applied was found in leachate from the columns treated with aged [<sup>14</sup>C]residues. The majority (>84% of the applied) of the [<sup>14</sup>C]residues remained in the upper 12 cm of the columns. Isoxaben (~81.4%) and N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide (6.6%; compound 201469) were the major [<sup>14</sup>C]compounds in the 30-day aged soil prior to leaching. Based on the column leaching study, K<sub>d</sub> values for the four soils ranged from 8.4 to 30. Using data from batch equilibrium studies with the same four soils, isoxaben was mobile and N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide was very mobile in the four soils, with K<sub>d</sub> values ranging from 6.4 to 8.0 and 0.53 to 0.96, respectively.

EAB concerns that isoxaben and its degradates are mobile enough to contaminate groundwater, an additional study using batch equilibrium techniques with four soils at four concentrations is required. The batch equilibrium data that were provided to support the column leaching study are of limited value because the study was conducted at only one concentration and desorption was not addressed.

## MATERIALS AND METHODS:

### Column Leaching

Sieved (2-mm), air-dried sand, sandy loam, loam, and clay loam soils (Table 1) were hand-packed to a depth of 30 cm in 1-cm diameter glass tube columns. The columns were treated with 4.35  $\mu\text{g}$  ( $\sim 0.51$  lb ai/A) of isoxazole ring-labeled [ $^{14}\text{C}$ ]isoxaben (labeled in the 5-C position, radiochemical purity 99%, specific activity 10.6  $\mu\text{Ci}/\text{mg}$ , Lilly Research Laboratories). The soils were air-dried for three days, and then eluted with 50.8 cm of water over a 10-day period. Leachates were collected in 12.7-cm fractions. Following leaching, the soil columns were separated into five 6-cm segments. Leachates and soil segments were analyzed for total radioactivity by LSC and LSC following combustion, respectively.

In a study of aged residues, air-dried sandy loam soil was treated with 43.7  $\mu\text{g}$  of [ $^{14}\text{C}$ ]isoxaben. The solvent was allowed to evaporate and additional soil was added to make a final soil concentration of 1.1 ppm. The soil was moistened to 75% of 0.33 bar moisture and incubated in the dark at  $\sim 22^\circ\text{C}$  for 30 days. Following incubation, the soil was analyzed for total radioactivity by LSC following combustion. The aged soil was placed onto the top ( $\sim 5$ -cm depth) of glass columns packed with the four soils described above. The columns were leached as previously described. Soil samples were refluxed in methanol:water (80:20) and vacuum-filtered. The sediment and extract were analyzed for total radioactivity by LSC. An aliquot of the extract was treated with 5% aqueous sodium chloride and partitioned three times into methylene chloride, and an aliquot from each fraction was analyzed for total radioactivity by LSC. The methylene chloride fraction was analyzed using TLC on silica gel plates developed with either chloroform:methanol:acetic acid (88:10:2) or ethyl acetate:toluene:acetic acid (80:20:2). Radioactive compounds were located by autoradiography. Leachates were extracted with methylene chloride and analyzed by TLC as described above.

### Batch Equilibrium

Adsorption studies were conducted on the four soils by treating duplicate soil samples with a solution of 0.01 M calcium chloride containing 0.05 ppm of [ $^{14}\text{C}$ ]isoxaben or 10 ppm of unlabeled 201469 (N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide). The soil:solution slurries were shaken for 24 hours and then centrifuged for 30 minutes. The supernatants were analyzed either for total radioactivity by LSC or for 201469 by HPLC following dilution with water. Three centrifuge tubes were prepared without soil and treated with the [ $^{14}\text{C}$ ]isoxaben solution to determine the extent of adsorption to glass.

## REPORTED RESULTS:

### Column Leaching

[<sup>14</sup>C]Isoxaben and aged (30-day) [<sup>14</sup>C]isoxaben residues were slightly mobile in sand, sandy loam, loam, and clay loam soils; >84% of the applied radioactivity remained in the upper 12 cm of the soil columns (Table 2). Calculated  $K_{ads}$  values for isoxaben were 8.4-30 (Table 3). Following leaching, <0.31% of the applied radioactivity was found in the leachate from the columns treated with unaged isoxaben and <3.61% of the applied in leachate from the columns treated with aged [<sup>14</sup>C]residues (Table 2).

After 30 days of aging, the treated sandy loam soil contained 97.2% of the original radioactivity, of which 81.4% was isoxaben, 6.6% was 201469, 1.5% was an unknown degradate, and ~10% was unextractable from the soil.

### Batch Equilibrium

Isoxaben was mobile in the four soils, with  $K_d$  values ranging from 6.4 to 8.0 (Table 3). The degradate 201469 was very mobile in the soils, with  $K_d$  values ranging from 0.53 to 0.96.

## DISCUSSION:

### Column Leaching

1. [<sup>14</sup>C]Residues in soil columns and leachate were not characterized; however, it is unlikely that additional degradation occurred during the 10 days of leaching.
2. In the aged soil study, the identification of 201469 was made by comparing the TLC  $R_f$  value with that from the literature, rather than by co-chromatography with a reference standard.

### Batch Equilibrium

1. Judged solely on its own merits, the batch equilibrium study is unacceptable because it was done at only one concentration and desorption was not addressed. However, the registrant's intent in performing this study was to provide data to support the conclusions of the column leaching study.
2. Because of EAB concerns that isoxaben and its degradates are mobile enough to contaminate groundwater, an additional study using batch equilibrium techniques with four soils at four concentrations is required.

Table 1. Soil characteristics.

Texture	Sand	Silt	Clay	Organic matter	pH	CEC (meq/100 g)
	%					
Sand	91.6	4.8	3.6	1.0	8.1	8.6
Sandy loam	61.9	23.2	15.2	1.2	7.2	8.1
Loam	37.6	41.2	21.2	1.9	6.1	9.1
Clay loam	29.6	37.2	33.2	3.1	6.4	19.0

Table 2. Distribution of [<sup>14</sup>C]residues (% of the applied) in columns of soil treated with isoxazole ring-labeled [<sup>14</sup>C]isoxaben or aged (30-day) [<sup>14</sup>C]isoxaben residues and leached with 20 inches of water.

Sampling depth (cm)	Sand	Sandy loam	Loam	Clay loam
		<u>Isoxaben</u>		
0-6	46.30	53.30	58.80	77.33
6-12	44.50	42.73	43.18	25.72
12-18	6.93	9.35	3.40	0.30
18-24	0.30	0.97	0.27	0.02
24-30	0.30	0.19	0.04	ND <sup>a</sup>
Leachate	0.17	0.31	0.07	0.01
Total	98.17	106.85	105.76	103.38
		<u>Aged isoxaben residues</u>		
0-6	59.50	49.41	52.39	57.32
6-12	33.24	35.07	36.22	32.32
12-18	3.70	8.69	6.78	3.07
18-24	1.59	1.80	1.93	1.96
24-30	0.82	1.38	1.19	1.34
Leachate	1.81	3.60	3.61	1.85
Total	100.76	99.95	102.12	97.86

<sup>a</sup> Not detected; the detection limit was not reported.

Table 3.  $K_{ads}$  values for isoxaben and its degradate 201469 (N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide) as determined by column leaching (isoxaben only) and batch equilibrium studies.

Texture	Column leaching		Batch equilibrium			
	Isoxaben		Isoxaben		21469	
	$K_{ads}$	$K_{oc}$	$K_{ads}$	$K_{oc}$	$K_{ads}$	$K_{oc}$
Sand	8.4	1500	7.7	1300	0.62	107
Sandy loam	10	1400	6.4	920	0.53	76
Loam	16	1500	8.0	730	0.67	61
Clay loam	30	1700	13.0	730	0.96	54

CASE GS --                      ISOXABEN                      STUDY 4                      PM --

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CHEM 125851                      Isoxaben

BRANCH EAB                      DISC --

FORMULATION 14 - FLOWABLE CONCENTRATE (F1C)

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FICHE/MASTER ID 40059508                      CONTENT CAT 01  
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, Greenfield, IN.

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CONCLUSIONS:

Field Dissipation - Terrestrial

1. This study is scientifically sound and provides supplemental data towards the registration of isoxaben.
2. Isoxaben (75% F1C), at 1 lb ai/A, degraded with a half-life of 30-40 days in spring-treated sand soil in Florida and loam soil in Indiana; it de degraded with a half-life of 60-182 days in autumntreated sand soil in Florida and sandy loam soil in Texas. Isoxaben was <0.02 lb ai/A in samples from the 6- to 12-, 12- to 18-, and 18- to 24-inch depths at all sites. The degradate N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide was <0.09 lb ai/A in the 0- to 6-inch depth at all four sites and <0.01 lb ai/A at greater depths. The soil residue concentration of isoxaben was expressed in lbs ai/A by converting ppm data values with a formula (ppm x bag wt x conversion factor) provided by the registrant, Elanco Products Company. (For details see the attached description and table).
3. This study does not fulfill EPA Data Requirements for Registering Pesticides because the frequency of sampling the deeper soil layers was insufficient to adequately assess the leaching potential of isoxaben.

## Ancillary Study - Freezer Storage Stability

1. This study is scientifically sound and provides supplemental information towards the registration of isoxaben.
2. Isoxaben (75% FIC) and its degradate N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide (201469), at 0.025 ppm, were stable in soil frozen (4°C) for up to 302 days after treatment.

## MATERIALS AND METHODS:

### Field Dissipation - Terrestrial

Isoxaben (75% FIC) was applied at 1.0 lb ai/A to plots of established hybrid Bermuda grass (clipped to putting green length) in Gulf Breeze, Florida, and to plots of bare soil in Greenfield, Indiana and Pilot Point, Texas, in the fall of 1985 or the spring of 1986 (Table 1). Turf applications were made by a backpack sprayer and bare soil applications by a tractor-drawn boom. All sites had a level grade; subsurface drainage occurred only in the Indiana site, which was tiled with 4-inch diameter laterals 50 feet on center, 36 inches deep, sloped 2 feet per 100 linear feet. The depth to the water table for the Florida sites was 15-30 inches for 9 months of the year, <10 inches for up to 4 months a year, and >40 inches during severely dry seasons; the depths to the water table were 12 feet for the Indiana site and 230 feet for the Texas site. The Florida sites were irrigated with 0.2 inches (spring application) and 0.5 inches (fall application) of water following treatment and were fertilized periodically with nitrogen throughout the study; additional irrigation occurred during May-September if <0.1 inch of rainfall/day occurred. The Indiana and Texas sites were plowed, disced, and harrowed prior to treatment, and received no further maintenance for the duration of the study. Each site had one control plot. Soil and soil/turf samples (0- to 6-, 6- to 12-, 12- to 18-, and 18- to 24-inch depths) were collected immediately after treatment and at monthly intervals up to 10 months posttreatment. Turf from the soil/turf samples was cut from the plug, frozen in liquid nitrogen, ground, and then remixed with the soil from the same sample prior to storage. Samples were stored at 4°C prior to analysis.

Turf and soil samples were analyzed for isoxaben and its degradate, 201469 (N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide), using Lilly Research Laboratory Analytical Method No. AM-AA-CA-R042-AC-755. Soil samples were blended with methanol:water (80:20), heated, and allowed to cool while the solids settled. An aliquot of the supernatant was removed, treated with 5% sodium chloride solution, and partitioned three times into methylene chloride. The combined extracts were filtered through sodium sulfate and cleaned up on an aluminum column washed with methylene chloride:ethyl acetate (80:20) followed by methylene chloride:methanol (99:1). Isoxaben and 201469 were eluted three times with methylene chloride:methanol (99:1, 98:2, and then 97:3). The fractions were each evaporated to dryness and then redissolved in methanol:water (same proportions as the appropriate mobile phase) prior to quantification by HPLC. The detection limit was 0.01 lb ai/A. Recovery efficiencies from 61 soil samples fortified with 0.025-0.376 ppm isoxaben and 61 soil

samples fortified with 0.025-0.376 ppm of 201469 were 87.5-119.3% and 38.7-94.6%, respectively.

### Storage Stability

Control soil samples, from selected test sites and sampling intervals, were fortified with 0.025 ppm of isoxaben and 201469, and stored at 4°C with the treated samples to determine storage stability. Samples were stored for 0 to 302 days prior to analysis.

### REPORTED RESULTS:

#### Terrestrial Field Dissipation

During the studies, air temperatures ranged from 19 to 102°F in Florida, 34 to 97°F in Indiana, and 14 to 90°F in Texas. Soil temperatures ranged from 46 to 89°F in Florida (46-86°F for fall-treated and 78-89°F for spring-planted) and 66 to 80°F in Indiana; in Texas, soil temperatures were 54°F in the month following planting. A total of ~73.7 inches of rain (plus irrigation) were received in Florida (fall treatment), 13.2 inches in Indiana, and 20.75 in Texas (Tables 2-5).

Isoxaben degraded with a half-life of 30-41 days in spring-treated sand soil in Florida and loam soil in Indiana; it degraded with a half-life of 60-182 days in autumn-treated sand soil in Florida and sandy loam soil in Texas (Tables 2-5). Isoxaben was < 0.02 lb ai/A in samples from the 6- to 12-, 12- to 18-, and 18- to 24-inch depths at all sites. The degradate N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide was <0.09 lb ai/A in the 0- to 6-inch depth at all four sites and <0.01 lb ai/A at deeper depths. No isoxaben or degradates were detected in the controls from any test site.

#### Storage Stability

Recovery values were 86.8-120.6% of the applied for isoxaben and 50.1-122.5% of the applied for 201469 (Table 6).

### DISCUSSION:

#### Terrestrial Field Dissipation

1. The frequency of sampling the deeper soil layers was insufficient to adequately assess the leaching potential of isoxaben.
2. Data should have been expressed as ppm rather than lb/A.

#### Storage Stability

The storage stability data appear to have been obtained from a separate sample for each storage interval, rather than from a single sample with subsamples analyzed over various intervals; therefore, the variability in the data may be due to differences in application rather than the storage interval.

Table 1. Field test data.

Location	Treatment date	Plot size	Soil texture	Sampling depth (inches)	Sand	Silt %	Clay	Organic matter	pH	CEC (meq/100 g)
Gulf Breeze, Florida	09/15/85	30 x 40 feet	Sand	0-6	93	3	4	2.7	7.0	6.14
			Sand	6-12	93	3	4	0.8	5.7	4.34
			Sand	12-18	93	3	4	0.7	6.3	1.80
			Sand	18-24	95	1	4	0.2	5.9	1.51
Gulf Breeze, Florida	05/20/86	30 x 40 feet	Sand	0-6	95	3	2	2.2	6.7	4.81
			Sand	6-12	95	3	2	1.1	5.5	1.62
Greenfield, Indiana	04/30/86	30 x 30 feet	Loam	0-6	35	43	22	1.4	6.9	9.23
			Clay loam	6-12	33	39	28	1.1	6.6	10.52
Pilot Point, Texas	11/11/85	30 x 30 feet	Sandy loam	0-6	59	26	15	0.8	5.9	8.08
			Sandy loam	6-12	63	21	16	0.9	6.0	8.36

The ppm values obtained can be converted to lb/A units according to the following formula:

$$\text{ppm} \times \text{bag weight} \times \text{C.F.} = \text{lb./A}$$

Where:

bag weight = total weight of sample received  
C.F. = lb./A conversion factor derived from  
the number of core subsamples and core  
diameter of the subsample.

Table I contains a list of conversion factors based on the sampling tube diameter.

TABLE I  
SAMPLE TUBE DIAMETER AND POUND PER ACRE FACTOR

<u>Tube Diameter (Inches)</u>	<u>Pound/Acre Factor</u>
4 7/8	.74
4 1/4	.97
3	1.95
1 1/4	11.26

Table 2. Isoxaben and its degradate 201469 (lb ai/A) in soil from turf plots in Florida treated with isoxaben (75% FIC) at 1 lb ai/A on November 15, 1985.

Sampling interval (days)	Date	Sampling depth (inches)				Cumulative precipitation and/or irrigation (inches)
		0-6	6-12	12-18	18-24	
<u>Isoxaben</u>						
0	11/15/85	0.66	--	--	--	--
0 <sup>a</sup>	11/15/85	0.57	--	--	--	--
36	12/21/85	0.43	ND <sup>b</sup>	--	--	9.10
70	01/24/86	0.41	ND	--	--	11.05
99	02/22/86	0.32	0.01	--	--	21.86
129	03/24/86	0.36	0.02	0.01	--	22.96
185	05/19/86	0.17	0.01	--	--	36.46
285	08/27/86	0.07	0.01	ND	ND	61.56
313	09/24/86	0.03	0.01	ND	ND	73.66
<u>201469<sup>c</sup></u>						
0	11/15/85	ND	--	--	--	--
0	11/15/85	0.01	--	--	--	--
36	12/21/85	0.05	ND	--	--	9.10
70	01/24/86	0.04	ND	--	--	11.05
99	02/22/86	0.04	0.01	--	--	21.86
129	03/24/86	0.05	0.01	ND	--	22.96
185	05/19/86	0.05	0.01	--	--	36.46
285	08/27/86	0.04	0.01	ND	ND	61.56
313	09/24/86	0.03	0.01	--	ND	73.66

<sup>a</sup> Sampled following 0.2 inches of irrigation.

<sup>b</sup> Not detected; the detection limit was 0.01 lb ai/A for both compounds.

<sup>c</sup> N-[3-(2-Hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide.

Table 3. Isoxaben and its degradate 201469 (1b ai/A) in soil from turf plots in Florida treated with isoxaben (75% FIC) at 1 lb ai/A on May 20, 1986.

Sampling interval (days)	Date	Sampling depth (inches)				Cumulative precipitation and/or irrigation (inches)
		0-6	6-12	12-18	18-24	
<u>Isoxaben</u>						
0	05/20/86	0.61	ND <sup>a</sup>	--	--	--
30	06/17/86	0.31	0.01	--	--	6.78
60	07/15/86	0.14	ND	--	--	15.58
90	08/19/86	0.08	ND	--	--	21.98
127	09/24/86	0.05	ND	ND	ND	35.28
<u>201469<sup>b</sup></u>						
0	05/20/86	0.03	ND	--	--	--
30	06/17/86	0.06	ND	--	--	6.78
60	07/15/86	0.09	0.01	--	--	15.58
90	08/19/86	0.08	0.01	--	--	21.98
127	09/24/86	0.05	0.01	ND	ND	35.28

<sup>a</sup> Not detected; the detection limit was 0.01 lb ai/A for both compounds.

<sup>b</sup> N-[3-(2-Hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide.

Table 4. Isoxaben and its degradate 201469 (1b ai/A) in soil from unvegetated plots in Indiana treated with isoxaben (75% F1C) at 1 lb ai/A on April 30, 1986.

Sampling interval (days)	Date	Sampling depth (inches)		Cumulative precipitation and/or irrigation (inches)
		0-6	6-12	
<u>Isoxaben</u>				
0	04/30/86	0.77	--	--
41	06/10/86	0.38	ND <sup>a</sup>	7.37
70	07/09/86	0.28	0.01	10.21
90	07/29/86	0.15	ND	13.21
127	09/04/86	0.18	ND	--
<u>201469<sup>b</sup></u>				
0	04/30/86	ND	--	--
41	06/10/86	0.07	ND	7.37
70	07/09/86	0.05	ND	10.21
90	07/29/86	0.04	ND	13.21
127	09/04/86	0.03	ND	--

<sup>a</sup> Not detected; the detection limit was 0.01 lb ai/A for both compounds.

<sup>b</sup> N-[3-(2-Hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide.

Table 5. Isoxaben and its degradate 201469 (1b ai/A) in soil from unwegetated plots in Texas treated with isoxaben (75% FIC) at 1 lb ai/A on November 11, 1985.

Sampling interval (days)	Date	<u>Sampling depth (inches)</u>		Cumulative precipitation and/or irrigation (inches)
		0-6	6-12	
<u>Isoxaben</u>				
0	11/11/85	0.80	--	--
30	12/11/85	0.68	ND <sup>a</sup>	2.00
60	01/11/86	0.54	0.01	2.00
90	02/11/86	0.36	ND	9.61
122	03/14/86	0.42	ND	10.75
182	05/12/86	0.35	ND	20.75
<u>201469<sup>b</sup></u>				
0	11/11/85	ND	0.01	--
30	12/11/85	0.02	ND	2.00
60	01/11/86	0.02	ND	2.00
90	02/11/86	0.01	ND	9.61
122	03/14/86	0.02	ND	10.75
182	05/12/86	0.03	ND	20.75

<sup>a</sup> Not detected; the detection limit was 0.01 lb ai/A for both compounds.

<sup>b</sup> N-[3-(2-Hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide.

Table 6. Storage stability of isoxaben and its degradate N-[3-(2-hydroxybut-2-yl)-isoxazol-5-yl]-2,6-dimethoxybenzamide (201469) in soil fortified with 0.025 ppm of either isoxaben or 201469.<sup>a</sup>

Sampling interval (days)	Isoxaben		201469	
	Number of samples	Recovery (% of applied)	Number of samples	Recovery (% of applied)
0	1	87.5	1	82.6
2	2	18.2 <sup>b</sup> , 107.8	-	--
5	1	94.9	-	88.2
6	-	92.8	1	67.2
9	1	--	1	53.6
11	1	108.3	1	50.1
13	-	97, 103.7	2	62.2, 84.2
22	1	--	1	95.7
26	1	91.2	1	78.6
29	2	92.2	-	--
44	1	90.1, 112.8	2	90.1, 112.8
60	1	102.6	1	95.8
78	4	111.4, 120.6	4	96.6, 110.6
91	2	92.8, 98.1	2	56.6, 82.0
109	2	99.4, 103.2	2	111.8, 122.5
167	2	105.9, 109.3	2	102.4, 112.5
191	2	93.2, 108.9	2	77.9, 100
199	2	109.3, 114.3	2	93.8, 100
209	2	92.3, 104.8	2	86.6, 113.4
300	2	97.0, 109.9	2	110.1, 129.6
301	2	98.9, 105.3	2	80.3, 105.4
302	2	86.8, 106.2 <sup>b</sup>	2	105.3

<sup>a</sup> All values were corrected for procedural recoveries.

<sup>b</sup> This value was considered to be an anomaly by the registrants.

CASE GS --                      ISOXABEN                      STUDY 5                      PM --

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CHEM 125851                      Isoxaben

BRANCH EAB                      DISC --

FORMULATION 00 - ACTIVE INGREDIENT

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FICHE/MASTER ID 40059509                      CONTENT CAT 01  
Magnussen, J.D. and D.P. Rainey. 1987. Laboratory studies of <sup>14</sup>C EL-107  
accumulation in fish. Laboratory project identification ABC-0342, ABC-0354.  
Prepared and submitted by Eli Lilly and Company, Greenfield, IN.  
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CONCLUSIONS:

Laboratory Accumulation - Fish

1. This study is scientifically sound and provides supplemental information towards the registration of isoxaben.
2. [<sup>14</sup>C]Isoxaben residues accumulated in bluegill sunfish with maximum bioconcentration factors of 14x in edible tissues (fillet), 134x in non-edible tissues (head and viscera), and 70x in whole fish, during 28 days of exposure. The fish were exposed to isoxazole ring-labeled [<sup>14</sup>C]isoxaben at 0.25 ppm in a flow-through system. After 21-28 days of exposure, isoxaben comprised 52% of the recovered radioactivity from the edible tissues and 17% from the nonedible tissue. Degradates identified in the edible and nonedible tissues were the diastereomers of N-[3-(2-hydroxy-3-methylpent-3-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide (20H A and 20H B) at <33% of the recovered radioactivity; N-[3-(1-hydroxy-3-methylpent-3-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide (30H) at <23% of the recovered; N-[3-(methylpent-3-yl)isoxazole-5-yl]-2-hydroxy-6-methoxybenzamide (Metabolite A) at <4% of the recovered; N-[3-(2-hydroxy-3-methylpent-3-yl)isoxazole-5-yl]-2-hydroxy-6-methoxybenzamide (Metabolite B) at <2%; and N-[3-(1-hydroxy-3-methylpent-3-yl)isoxazole-5-yl]-2-hydroxy-6-methoxybenzamide (Metabolite C) at <2%. Residues accumulated by

exposure day 28 were depurated quickly; at day 14 of depuration, [<sup>14</sup>C]residues were ~0.28 ppm in edible, nonedible, and whole fish tissues.

3. This study does not fulfill EPA Data Requirements for Registering Pesticides because [<sup>14</sup>C]residues were incompletely characterized and residues in whole fish were not determined experimentally but by calculation.

#### MATERIALS AND METHODS:

Bluegill sunfish (Lepomis macrochirus; average weight 0.5-1.0 g) were held at 29-30°C for 54 days under a 16-hour daylight photoperiod prior to study initiation in culture tanks, and were fed tetracycline-treated food for two weeks to treat disease. Twelve days prior to study initiation, the temperature was reduced to 21-22°C. Flow-through aquatic exposure systems were prepared using two 144-L glass aquaria containing 70-L of aerated well water (pH 7.8-8.0, dissolved oxygen 5.8-9.2 mg/L, alkalinity 130-150 mg/L CaCO<sub>3</sub>, hardness 103-137 mg/L CaCO<sub>3</sub>, conductivity 240-250 µS/cm, temperature 20.7-23.4°C), which was replaced at 6 turn-overs per day.

Bluegill sunfish (200) were placed in each aquarium, and one aquarium was continuously treated with isoxazole ring-labeled [<sup>14</sup>C]isoxaben (radiochemical purity >98%, specific activity 19.3 µCi/mg, Lilly Research Laboratories) at a rate of 0.25 ppm. The second aquarium served as an untreated control. Following a 28-day exposure period, the [<sup>14</sup>C]-isoxaben-treated fish were transferred to a second aquarium containing no isoxaben for a 14-day depuration period. Water samples were collected immediately posttreatment, and water and fish samples (4) were collected on days 0.25, 1, 2, 7, 14, 21, and 28 of the exposure period and days 1, 3, 7, 10 and 14 of the depuration period.

Total radioactivity in the water samples was quantified using LSC. Aliquots from the 0, 7, 14, 21, and 28 day samples were dried onto silica particles, which were then placed on top of a silica gel-packed column. Radioactivity was eluted using aliquots of toluene:ethyl acetate (an increasingly polar gradient was used with each elution) followed by a column wash with methanol. Aliquots of each eluting solvent fraction were analyzed for total radioactivity by LSC; additional aliquots were analyzed with unlabeled isoxaben by TLC on silica gel plates developed in toluene:ethyl acetate (90:10) and chloroform:methanol (90:10). Unlabeled isoxaben was detected with UV light; radioactivity was located by autoradiography or by spark chamber radiochromatography. [<sup>14</sup>C]Residues were quantified by LSC.

Pooled samples (4 fish) of edible tissues (fillet) and nonedible tissues (head and viscera) were analyzed for total radioactivity using LSC following combustion. Tissues were extracted twice with methanol by blending. Total radioactivity in the extract and extracted tissues was analyzed using LSC and LSC following combustion, respectively. The extract was condensed, diluted with water, adjusted to pH 7, and extracted three times with methylene chloride. The extracted aqueous solution was acidified, refluxed with methanol, adjusted to pH 5, and extracted three times

with ethyl acetate. The ethyl acetate extract, the methanol fraction, and the extracted aqueous fraction were analyzed for radioactivity by LSC. Extracts from the 21- and 28-day intervals were analyzed by TLC as described. Residues in whole fish were calculated by summing [<sup>14</sup>C]residues in edible and nonedible tissues. Degradates were identified by MS following HPLC and/or reverse-phase chromatography. Results were compared to reference standards of isoxaben, 20H-A, 20H-B, and 30H; other degradates were assigned structures based on MS results alone.

#### REPORTED RESULTS:

Total isoxaben residues in the treated water ranged from 0.277 ppm to 0.249 ppm during the exposure period (Table 1). Parent isoxaben comprised >93% of the [<sup>14</sup>C]residues.

Mortality was <1% in the exposure tanks. Maximum accumulation of [<sup>14</sup>C]-residues in the tissues occurred between days 21 and 28 of the exposure period with bioconcentration factors of 8.7-13.8x in edible tissues, 120.7-134.2x in nonedible tissues, and (calculated) 61.1-70.5x in whole fish (Table 1). Maximum concentration of [<sup>14</sup>C]residues during the exposure period were 3.35 ppm in edible tissues, 32.6 ppm in nonedible tissues, and 17.1 ppm (calculated) in whole fish, all of which occurred on day 28 (Table 1). Parent isoxaben averaged 52% of the total radioactivity in edible tissues and 16.7% in nonedible tissues from the 21- and 28-day exposure period (Table 2). Other degradates in the edible tissues, each comprising <10% of the total, were 20H-A, 20H-B, 30H, and Metabolites A, B, and C. The same degradates were identified in nonedible tissues at <10% of the total, with the exception of 20H-B and 30H which each comprised 23% of the total radioactivity (Table 2). After 14 days of depuration, [<sup>14</sup>C]residues in edible, nonedible, and whole fish were 0.27 ppm, 0.28 ppm, and (calculated) 0.28 ppm, respectively.

#### DISCUSSION:

1. Two degradates (unknowns 1 and 2) in the edible and nonedible tissues that were 0.53-0.56 ppm were not characterized. Polar degradates (origin) in the edible and nonedible tissue that were 0.11 and 5.17 ppm, respectively, were not characterized.
2. Reported radioactivities in whole fish were obtained by calculation by the registrant, using the data from edible and nonedible tissue for each fish rather than combusting and measuring the radioactivity from the whole fish.
3. The detection limits were not provided for the analytical methods.
4. The registrants reported the nature of the residues in water; however, no data were provided along with the text regarding the characterization of these residues.

Table 1. Total [<sup>14</sup>C]isoxaben residues (ppm) in water and fish tissues during a 28-day exposure period and a 14-day depuration period.<sup>a</sup>

Sampling interval (days)	Water	Edible tissue <sup>b</sup>		Nonedible tissue <sup>c</sup>		Whole fish <sup>d</sup>	
		ppm	BCF <sup>e</sup>	ppm	BCF <sup>e</sup>	ppm	BCF <sup>e</sup>
Exposure 0	0.243	--	--	--	--	--	--
0.25	0.227	1.64	6.75	9.33	38.4	5.26	21.6
1	0.236	1.76	7.24	19.66	80.9	10.32	42.5
3	0.237	1.73	7.12	30.03	123.6	14.69	60.5
7	0.248	2.25	9.26	29.97	123.3	12.22	50.3
14	0.240	2.27	9.34	26.82	110.4	14.47	59.5
21	0.246	2.12	8.72	29.33	120.7	14.85	61.1
28	0.249	3.35	13.79	32.62	134.2	17.14	70.5
Depuration 1	ND <sup>f</sup>	0.64	--	6.11	--	3.11	--
3	ND	0.31	--	0.58	--	0.44	--
7	ND	0.28	--	0.34	--	0.31	--
10	ND	0.23	--	0.26	--	0.24	--
14	ND	0.27	--	0.28	--	0.28	--

<sup>a</sup> Average values from four fish samples.

<sup>b</sup> Represents fillet.

<sup>c</sup> Represents head and viscera.

<sup>d</sup> These values were calculated by summing the values for the edible and nonedible tissues.

<sup>e</sup> The daily bioconcentration factor was obtained by dividing the concentration in tissue by the mean measured water concentration of 0.243 ppm during the exposure period.

<sup>f</sup> Not detected; the detection limit was not reported.

Table 2. Distribution of radioactivity in extracts from tissues of bluegill sunfish exposed to isoxazole ring-labeled [<sup>14</sup>C]isoxaben (radiochemical purity >98%) at ~0.243 ppm for 28 days.<sup>a</sup>

	Edible tissue		Nonedible tissue	
	Percent of recovered	ppm	Percent of recovered	ppm
Isoxaben	52.4	1.44	16.7	5.17
20H A	4.8	0.13	4.4	1.36
20H B	8.7	0.24	22.7	7.03
30H	5.5	0.15	22.7	7.03
A	3.8	0.10	2.4	0.74
B	1.0	<0.03	1.3	0.40
C	<1.0	<0.03	1.3	0.40
Unknown I	1.0	<0.03	1.7	0.53
Unknown II	<1.0	<0.03	1.8	0.56
Origin	4.0	0.11	16.7	5.17
Unextractable	11.8	NR <sup>b</sup>	4.4	NR <sup>b</sup>

<sup>a</sup> Values are averages derived from the 21-day and 28-day tissue samples.

<sup>b</sup> Not reported as ppm.

## EXECUTIVE SUMMARY

The following findings are derived from those reviewed studies which have met the requirements of 40 CFR Part 158.130 and the guidance of Subdivision N, and were also deemed acceptable.

In a previously reviewed hydrolysis study (EAB 9/29/83) degradation of isoxaben did not occur during hydrolysis in sterilized buffered solutions of pH 5, 7, and 9.

Isoxazole ring-labeled [<sup>14</sup>C]isoxaben and aged (30-day) [<sup>14</sup>C]isoxaben residues were slightly mobile in columns (30-cm length, 1-cm diameter) of sand, sandy loam, loam, and clay loam soil leached with 20 inches of water over a 10-day period. Following leaching, <0.31% of the applied radioactivity was found in the leachate from the columns treated with unaged [<sup>14</sup>C]isoxaben and <3.61% of the applied in leachate from the columns treated with aged [<sup>14</sup>C]residues; the majority (>84% of the applied) of the [<sup>14</sup>C]residues remained in the upper 12 cm of the columns. Isoxaben ( 81.4%) and N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide (6.6%; compound 201469) were the major [<sup>14</sup>C]compounds in the 30-day aged sandy loam soil prior to leaching. Based on the column leaching study, K<sub>d</sub> values for the four soils ranged from 8.4 to 30. Using data from batch equilibrium studies with the same four soils, isoxaben was mobile and N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide was very mobile in the four soils, with K<sub>d</sub> values ranging from 6.4 to 8.0 and 0.53 to 0.96, respectively.

The following findings are derived from those reviewed studies which have not met the requirements of 40 CFR 158.130 and/or the guidance of Subdivision N, but have been deemed good studies following generally sound scientific practice. They thereby provide supplemental information on the fate of isoxaben.

Carbonyl- and isoxazole ring-labeled [<sup>14</sup>C]isoxaben (radiochemical purities >99.5%), at 0.5 ppm, degraded with half-lives of 7-15 days (calculated 9 days) in sterile buffered (pH 7) solutions irradiated outdoors with natural sunlight in July of 1986 near Greenfield, Indiana. After 30 days of irradiation, isoxaben comprised 21.6% and 13.8% of the applied radioactivity of the carbonyl- and isoxazole ring-labeled solutions, respectively. Degradates included a pyrazolone, an isoquinolone, and a benzopyrrolidone. In the dark controls at 30 days posttreatment, isoxaben comprised >94.4% of the applied.

Isoxaben (75% FlC), at 1 lb ai/A, degraded with a half-life of 30-41 days in spring-treated sand soil in Florida and loam soil in Indiana; it degraded with a half-life of 60-182 days in autumn treated sand soil in Florida and sandy loam soil in Texas. Isoxaben was < 0.02 lb ai/A in samples from the 6- to 12-, 12- to 18-, and 18- to 24-inch depths at all sites. The degradate N-[3-(2-hydroxybut-2-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide was < 0.09 lb ai/A in the 0- to 6-inch depth at all four sites and < 0.01 lb ai/A at deeper depths.

[<sup>14</sup>C]Isoxaben residues accumulated in bluegill sunfish with maximum bioconcentration factors of 14x, 134x, and 70x in edible tissues (fillet), nonedible tissues (head and viscera), and whole fish, respectively, during 28 days of exposure to isoxazole ring-labeled [<sup>14</sup>C]isoxaben at 0.25 ppm in a flow-through system. After 21-28 days of exposure, isoxaben comprised 52% of the recovered radioactivity from the edible tissues and 17% from the nonedible tissue. Degradates identified in the edible and nonedible tissues were diastereomers of

N-[3-(2-hydroxy-3-methylpent-3-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide (20H A and 20H B) at < 33% of the recovered radioactivity; N-[3-(1-hydroxy-3-methylpent-3-yl)isoxazol-5-yl]-2,6-dimethoxybenzamide (30H) at < 23% of the recovered; N-[3-(methylpent-3-yl)isoxazole-5-yl]-2-hydroxy-6-methoxybenzamide (Metabolite A) at < 4% of the recovered; N-[3-(2-hydroxy-3-methylpent-3-yl)isoxazole-5-yl]-2-hydroxy-6-methoxybenzamide (Metabolite B) at < 2%; and N-[3-(1-hydroxy-3-methylpent-3-yl)isoxazole-5-yl]-2-hydroxy-6-methoxybenzamide (Metabolite C) at < 2%. Residues accumulated by exposure day 28 were depurated quickly; at day 14 of depuration, [<sup>14</sup>C]residues were 0.28 ppm in edible, nonedible, and whole fish tissues.

#### RECOMMENDATIONS

Available data are insufficient to fully assess the environmental fate and transport of isoxaben. The submission of data relevant to registration requirements (Subdivision N) for terrestrial nonfood use sites only is summarized below:

The following data requirements are partially fulfilled:

Photodegradation studies in water: One study (Saunders et al., 40097601 and 40059507) was reviewed. This study is scientifically sound and is currently considered supplemental. This study does not fulfill data requirements because degradates comprising >10% of the applied radioactivity were incompletely characterized and the intensity of the sunlight was not reported.

Aerobic soil metabolism studies: One previously submitted study (Graper, 00073607, in EAB review dated December 31, 1985) of the aerobic soil metabolism of isoxazole ring-labeled [<sup>14</sup>C]isoxaben was accepted on the condition that the registrant account for missing material. Volatiles were not measured in this study. One study (Rainey, 00265370, Reference 2) was reviewed for this submission in which volatiles were measured after treating loam soil with [<sup>14</sup>C]-isoxaben. Volatiles were roughly equivalent to the amount of material unaccounted for in the previous study. The aerobic soil metabolism study is now considered acceptable. Data for the aerobic soil metabolism of phenyl ring-labeled [<sup>14</sup>C]isoxaben are required.

Leaching and adsorption/desorption studies: One study (Saunders et al., 00265730, Reference 1) was reviewed and is acceptable. This study contributes toward the fulfillment of data requirements by providing information on the mobility of isoxaben and aged isoxazole ring-labeled isoxaben residues in sand, sandy loam, loam, and clay loam soil. Because of EAB concerns that isoxaben and its degradates are mobile enough to contaminate groundwater, an additional studies for both parent and its major degradate using batch equilibrium techniques with four soils at four concentrations are required.

Terrestrial field dissipation studies: One study (Rutherford and Decker, 40059508) was reviewed. This study is scientifically sound and is currently considered supplemental. This study does not fulfill data requirements because the frequency of sampling was insufficient to adequately assess the leaching potential of isoxaben.

Laboratory studies of pesticide accumulation in fish: One study (Magnussen and Rainey, 40059509) was reviewed. This study is scientifically sound and is currently considered supplemental. This study does not fulfill data requirements because [<sup>14</sup>C]residues were incompletely characterized and residues in whole fish were not determined experimentally but by calculation.

The following data requirement is fulfilled:

Hydrolysis studies: No data were reviewed. Based on previously submitted data, no additional data are required.

The following data requirements are deferred or are not required for the currently proposed use only:

Photodegradation studies on soil: No data are required for the terrestrial nonfood use.

Photodegradation studies in air: No data are required for the terrestrial nonfood use.

Anaerobic soil metabolism studies: No data are required for the terrestrial nonfood use.

Anaerobic aquatic metabolism studies: No data were reviewed; however, no data are required because isoxaben has no aquatic or aquatic impact uses.

Aerobic aquatic metabolism studies: No data were reviewed; however, no data are required because isoxaben has no aquatic or aquatic impact uses.

Laboratory volatility studies: No data are required for the terrestrial nonfood use.

Field volatility studies: No data are required for the terrestrial nonfood use.

Aquatic field dissipation studies: No data were reviewed; however, no data are required because isoxaben has no aquatic or aquatic impact uses.

Forestry dissipation studies: No data were reviewed; however, no data are required because isoxaben currently has no registered forestry uses.

Dissipation studies for combination products and tank mix uses: No data were reviewed; however, no data are required because data requirements for combination products and tank mix uses are currently not being imposed.

Long-term field dissipation studies: No data are required for the terrestrial nonfood use.

Confined accumulation studies on rotational crops: No data are required for the terrestrial nonfood use.

Field accumulation studies on rotational crops: No data are required for the terrestrial nonfood use.

Accumulation studies on irrigated crops: No data were reviewed; however, no data are required because isoxaben has no aquatic food crop or aquatic nonfood uses.

Field accumulation studies on aquatic nontarget organisms: No data were reviewed. The data requirement is deferred pending the results of the laboratory fish accumulation studies.

Reentry studies: No data are required. The toxicological category of isoxaben is established to be 4.

#### REFERENCES

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

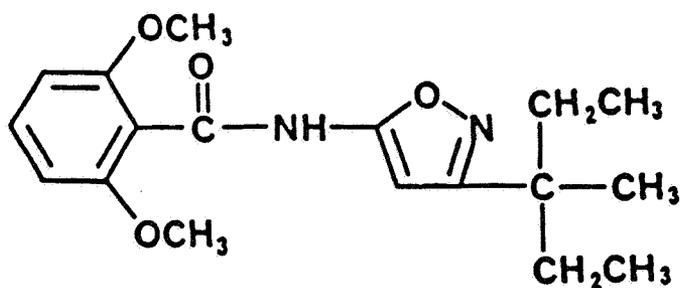
Rainey, D. P. The metabolism of [<sup>14</sup>C]EL-107 in soil: characterization of volatile radiolabeled degradation products. Experiment ABC-0226. Prepared and submitted by Eli Lilly and Company, Greenfield, IN. Reference 2. (Acc#00265370)

Rutherford, B.S., and O.D. Decker. 1986. Isoxaben soil/turf field dissipation study. Project ID No. AAC8521. Prepared and submitted by Lilly Research Laboratories, Division of Eli Lilly and Company, Greenfield, IN. (MRID#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. (MRID# 40097601 and MRID#40059507)

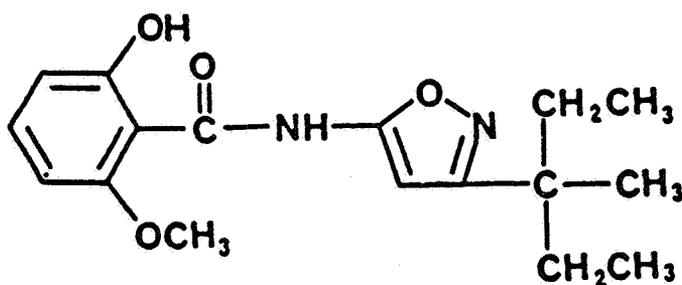
Saunders, D.G., S.K. Smith, and J.W. Mosier. 1985. Mobility of EL-107 and a soil metabolite in soil. Report No. EWD8442. Prepared and submitted by Eli Lilly and Company, Greenfield, IN. Reference 1. (Acc#00265730)

APPENDIX  
ISOXABEN AND ITS DEGRADATES



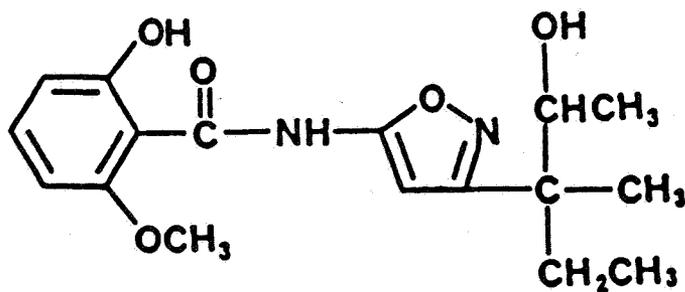
N-[3-(methylpent-3-yl)isoxazol-5-yl]-  
2,6-dimethoxybenzamide

(Isoxaben, EL-107)



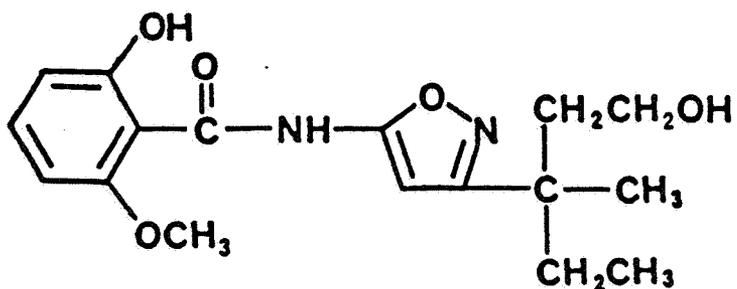
N-[3-(methylpent-3-yl)isoxazol-5-yl]-  
2-hydroxy-6-methoxybenzamide

(Metabolite A)



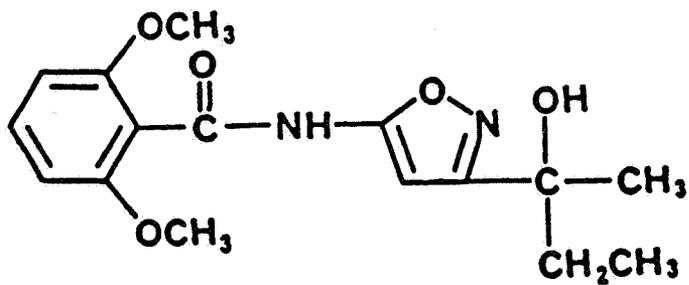
N-[3-(2-Hydroxy-3-methylpent-3-yl)  
isoxazol-5-yl]-2-hydroxy-6-methoxybenzamide

(Metabolite B)



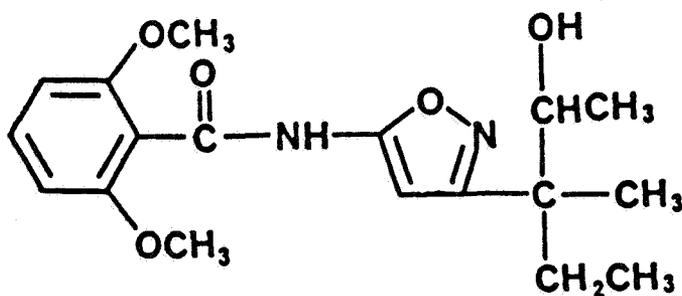
N-[3-(1-Hydroxy-3-methylpent-3-yl)  
isoxazol-5-yl]-2-hydroxy-6-methoxybenzamide

(Metabolite C)



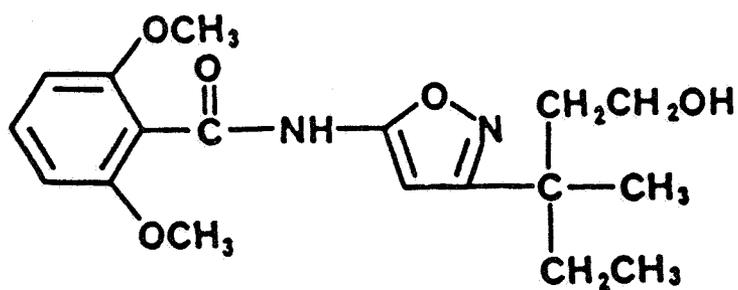
N-[3-(2-Hydroxybut-2-yl)isoxazol-5-yl]-  
2,6-dimethoxybenzamide

(201469)



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

(20H)



N-[3-(1-Hydroxy-3-methylpent-3-yl)  
isoxazol-5-yl]-2,6-dimethoxybenzamide

(30H)

TABLE A  
GENERIC DATA REQUIREMENTS FOR ISOXABEN

Data Requirement	Test Substance <sup>1</sup> /	Use Pattern <sup>2</sup> /	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? (Yes or No) <sup>3</sup> /
<u>\$158.130 Environmental Fate</u>					
<u>DEGRADATION STUDIES-LAB:</u>					
161-1 - Hydrolysis	TGAI or PAIRA	B	Yes	I-EWD-82-05	No
<u>PHOTODEGRADATION</u>					
161-2 - In water	TGAI or PAIRA	B	Partially	MRID# 400595-07 MRID# 400976-01	Yes <sup>4</sup> /
161-3 - On soil	TGAI or PAIRA	N/A	No	None	No
161-4 - In air	TGAI or PAIRA	N/A	No	None	No
<u>METABOLISM STUDIES-LAB:</u>					
162-1 - Aerobic soil	TGAI or PAIRA	B	Partially	Acc# 00265370	Yes <sup>5</sup> /
162-2 - Anaerobic soil	TGAI or PAIRA	N/A	No	None	No
162-3 - Anaerobic aquatic	TGAI or PAIRA	N/A	No	None	No
162-4 - Aerobic aquatic	TGAI or PAIRA	N/A	No	None	No
<u>MOBILITY STUDIES:</u>					
163-1 - Leaching and adsorption/desorption	TGAI or PAIRA	B	Partially	Acc# 00265730	Yes <sup>6</sup> /
163-2 - Volatility (Lab)	TEP	N/A	No	None	No
163-3 - Volatility (Field)	TEP	N/A	No	None	No

TABLE A  
 GENERIC DATA REQUIREMENTS FOR ISOXABEN

Data Requirement	Test Substance <sup>1/</sup>	Use Pattern <sup>2/</sup>	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? (Yes or No) <sup>3/</sup>
<u>§158.130 Environmental Fate (continued)</u>					
<u>DISSIPATION STUDIES-FIELD:</u>					
164-1 - Soil	TEP	B	Partially	MRID# 4005 9508	Yes <sup>4/</sup>
164-2 - Aquatic (sediment)	TEP	N/A	No	None	No
164-3 - Forestry	TEP	N/A	No	None	No
164-4 - Combination and Tank Mixes	TEP	B	No	None	No <sup>7/</sup>
164-5 - Soil, long-term	TEP	N/A	No	None	No
<u>ACCUMULATION STUDIES:</u>					
165-1 - Rotational crops (Confined)	PAIRA	N/A	No	None	No
165-2 - Rotational crops (Field)	TEP	N/A	No	None	No
165-3 - Irrigated crops	TEP	N/A	No	None	No
165-4 - In fish	TGAI or PAIRA	B	Partially	MRID# 4005 9509	Yes <sup>4/</sup>
165-5 - In aquatic nontarget organisms	TEP	B	No	None	Reserved <sup>8/</sup>

TABLE A  
 GENERIC DATA REQUIREMENTS FOR ISOXABEN

Data Requirement	Test Substance <sup>1/</sup>	Use Pattern <sup>2/</sup>	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? (Yes or No) <sup>3/</sup>
<u>§158.140 Reentry Protection</u>					
132-1 - Foliar dissipation	TEP	B	No	None	No
132-1 - Soil dissipation	TEP	B	No	None	No
133-3 - Dermal exposure	TEP	B	No	None	No
133-4 - Inhalation exposure	TEP	B	No	None	No
<u>§158.142 Spray Drift</u>					
201-1 - Droplet size spectrum	TEP	B	No	None	No
201-1 - Drift field evaluation	TEP	B	No	None	No
§158.75 Human exposure data	TEP	B	No	None	No
Other exposure data	TEP	B	No	None	No

TABLE A  
GENERIC DATA REQUIREMENTS FOR ISOXABEN

FOOTNOTES:

- 1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
- 2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
- 3/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).
- 4/ The study does not fulfill data requirements because incomplete data were submitted.
- 5/ Data for aerobic soil metabolism of phenyl ring-labeled [<sup>14</sup>C] isoxaben are required.
- 6/ The Ground Water Team requires that a new leaching study be conducted using batch equilibrium technique and in accordance with Subdivision N of the Pesticide Assessment Guidelines to assess ground water contamination.
- 7/ Currently not being imposed for this product.
- 8/ Pending the results of the fish accumulation study (165-4).

TABLE A  
 GENERIC DATA REQUIREMENTS FOR ISOXABEN

Data Requirement	Test Substance <sup>1/</sup>	Use Pattern <sup>2/</sup>	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? (Yes or No ) <sup>3/</sup>
<u>\$158.130 Environmental Fate</u>					
<u>DEGRADATION STUDIES-LAB:</u>					
161-1 - Hydrolysis	TGAI or PAIRA	B	Yes	I-EWD-82-05	No
<u>PHOTODEGRADATION</u>					
161-2 - In water	TGAI or PAIRA	B	Yes	MRID# 400595-07 MRID# 400976-01	No
161-3 - On soil	TGAI or PAIRA	N/A	No	None	No
161-4 - In air	TGAI or PAIRA	N/A	No	None	No
<u>METABOLISM STUDIES-LAB:</u>					
162-1 - Aerobic soil	TGAI or PAIRA	B	Yes	ACC# 00073607 ACC# 00265370	No
162-2 - Anaerobic soil	TGAI or PAIRA	N/A	No	None	No
162-3 - Anaerobic aquatic	TGAI or PAIRA	N/A	No	None	No
162-4 - Aerobic aquatic	TGAI or PAIRA	N/A	No	None	No
<u>MOBILITY STUDIES:</u>					
163-1 - Leaching and adsorption/desorption	TGAI or PAIRA	B	Partially	Acc# 00265730	Yes <sup>4/</sup>
163-2 - Volatility (Lab)	TEP	N/A	No	None	No
163-3 - Volatility (Field)	TEP	N/A	No	None	No

TABLE A  
 GENERIC DATA REQUIREMENTS FOR ISOXABEN

Data Requirement	Test Substance <sup>1</sup> / Pattern <sup>2</sup> / Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? (Yes or No) <sup>3</sup> / Reserved <sup>7</sup> / No
<u>§158.130 Environmental Fate (continued)</u>				
<u>DISSIPATION STUDIES-FIELD:</u>				
164-1 - Soil	TEP B	Yes	MRID# 40532102 MRID# 40532108 MRID# 40059508	No
164-2 - Aquatic (sediment)	TEP N/A	No	None	No
164-3 - Forestry	TEP N/A	No	None	No
164-4 - Combination and Tank Mixes	TEP B	No	None	No <sup>5</sup> / No
164-5 - Soil, long-term	TEP N/A	No	None	No
<u>ACCUMULATION STUDIES:</u>				
165-1 - Rotational crops (Confined)	PAIRA N/A	No	None	No
165-2 - Rotational crops (Field)	TEP N/A	No	None	No
165-3 - Irrigated crops	TEP N/A	No	None	No
165-4 - In fish	TGAI or PAIRA B	No 3/21/89 No Yes	MRID# 40059509	No Yes/ No
165-5 - In aquatic nontarget organisms	TEP B	No	None	Reserved <sup>7</sup> / No

TABLE A  
 GENERIC DATA REQUIREMENTS FOR ISOXABEN

Data Requirement	Test Substance <sup>1</sup> / Pattern <sup>2</sup> / Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA § 3(c)(2)(B)? (Yes or No) <sup>3</sup> / 3/
<u>§158.140 Reentry Protection</u>				
132-1 - Foliar dissipation	TEP B	No	None	No
132-1 - Soil dissipation	TEP B	No	None	No
133-3 - Dermal exposure	TEP B	No	None	No
133-4 - Inhalation exposure	TEP B	No	None	No
<u>§158.142 Spray Drift</u>				
201-1 - Droplet size spectrum	TEP B	No	None	No
201-1 - Drift field evaluation	TEP B	No	None	No
§158.75 Human exposure data	TEP B	No	None	No
Other exposure data	TEP B	No	None	No

TABLE A  
GENERIC DATA REQUIREMENTS FOR ISOXABEN

FOOTNOTES:

- 1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabelled; TEP = Typical end-use product.
- 2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
- 3/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).
- 4/ The Ground Water Team requires that a new leaching study be conducted using batch equilibrium technique and in accordance with Subdivision N of the Pesticide Assessment Guidelines to assess ground water contamination.
- 5/ Currently not being imposed for this product.
- 6/ Require detailed results of TLC separation and characterization of polar conjugates.
- 7/ Pending the results of the fish accumulation study (165-4).