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SHAUGHNESSEY NO.

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OCT 14 1987

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PETITION OR EXP. NO. _____

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TYPE PRODUCT(S) : I, D, H, F, N, R, S HERBICIDE

DATA ACCESSION NO(S). 400595-11

PRODUCT MANAGER NO. R. Mountfort (23)

PRODUCT NAME(S) (EL-107) Isoxaben Technical (1471-RLI)

(EL-107) Prolan 75 Dry Flowable (1471-RLO)

COMPANY NAME Elanco Products Company

SUBMISSION PURPOSE New Chemical screen for proposed technical product

and End-Use product for use on: Established turf, various ornamentals, nursery stock, noncroplands, non-bearing Fruit/Nut crop, and non-bearing vineyards

SHAUGHNESSEY NO. CHEMICAL, & FORMULATION % A.I.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MEMORANDUM

October 14, 1987

SUBJECT: Review of Isoxaben in Registration Standard Format

FROM: Daniel Rieder, Wildlife Biologist
Ecological Effects Branch
Hazard Evaluation Division

THRU: Norman J. Cook, Section Head, Section 2
Ecological Effects Branch
Hazard Evaluation Division

THRU: Henry T. Craven, Acting Chief
Ecological Effects Branch
Hazard Evaluation Division TS-769C

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

Attached is the review of the proposal to register Isoxaben as a technical product and for use on established turf, various ornamentals, nursery stock, noncroplands, non-bearing fruit/nut crop and non-bearing vineyard. The review is done in the Registration Standard format.

CONCURRENCES

SYMBOL	B769C	TS-769	TS 769C				
SURNAME	Rieder	Varghan	Craven				
DATE	10-14-87	10-14-87	10/21/87				



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

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

October 14, 1987

SUBJECT: Review of Isoxaben in Registration Standard Format

Daniel Rieder
FROM: Daniel Rieder, Wildlife Biologist
Ecological Effects Branch
Hazard Evaluation Division

for Allen W. Vaughan 10.14.87
THRU: Norman J. Cook, Section Head, Section 2
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Henry T. Craven
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Isoxaben

Ecological Effects Topical Summary

Effects on Birds

Five Studies in two documents were evaluated under this topic. All studies were acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>Accession No.</u>
Lake and Kehr	1982	250793
Lake and Cochrane	1984	073292

In order to establish the toxicity of Isoxaben to birds, the following tests are required using the technical grade material: Two subacute dietary studies on one species of waterfowl (preferably mallard duck) and one species of upland game bird (preferably bobwhite quail or ring-necked pheasant); An avian single - dose oral study on one species (preferably mallard duck or bobwhite quail).

The acute oral toxicity test is acceptable for use in a hazard assessment and is described below:

<u>Species</u>	<u>T.M.</u>	<u>LD50</u>	<u>Author</u>	<u>Date</u>	<u>Acc. No.</u>	<u>Fulfills Req.</u>
Bobwhite	92.4%	>2000 mg/kg	Lake & Kehr	1982	250793	yes

The guideline requirement (71-1) for an avian acute oral study has been satisfied.

The acceptable subacute dietary toxicity studies for use in a hazard assessment are listed below:

<u>Species</u>	<u>T.M.</u>	<u>LD50</u>	<u>Author</u>	<u>Date</u>	<u>Acc. No.</u>	<u>Fulfills Req.</u>
Bobwhite quail	92.4%	>5000 ppm	Lake & Kehr	1982	250793	yes
Mallard Duck	92.4%	>5000 ppm	Lake & Kehr	1982	250793	yes

The guideline requirements (71-2) for avian subacute dietary toxicity tests have been satisfied.

There is sufficient information on Isoxaben to characterize it as practically nontoxic to birds.

Avian reproduction tests are required for an end-use pesticide when birds may be exposed to repeated or continuous residues through persistence, bioaccumulation or multiple applications or if mammalian reproduction tests indicate reproductive hazard. Since Isoxaben is extremely persistent in certain environmental compartments, avian reproduction tests are required for all outdoor uses including ornamental, turf and noncropland treatment. The following are acceptable avian reproduction tests:

<u>Species</u>	<u>T.M.</u>	<u>Results</u>	<u>Author</u>	<u>Date</u>	<u>Acc. No.</u>	<u>Fulfills Req.</u>
Mallard duck	95.5%	NOEL=300 ppm LEL=1000 ppm* *reduction in hatchability of eggs	Lake & Cochrane	1984	073292	yes
Bobwhite quail	95.5%	NOEL=1000 ppm (highest level tested)	Lake & Cochrane	1984	073292	yes

The avian reproduction guideline requirement (71-4) has been fulfilled.

Precautionary Labeling

Based on avian toxicity data, no label statement for birds is required.

Effects on Fish

Five studies in two documents were evaluated under this topic. All studies were acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>Accession No.</u>
Lake, Francis and Grothe	1984	252915
Lake, Sauter and Meyerhoff	1983	252915
Lake, Meyerhoff and Sauter	1983	252915
Lake, Grothe and Francis	1982	250793
Lake, Grothe and Francis	1982	250793

The minimum data requirements for establishing the acute toxicity to fish are the results from two 96-hour studies with the technical grade material. The studies are to be performed on one coldwater species (preferably rainbow trout) and one warmwater species. (preferably bluegill sunfish).

The acceptable acute toxicity studies are presented below:

<u>Species</u>	<u>T.M.</u>	<u>LC50</u>	<u>Author</u>	<u>Date</u>	<u>Acc. No.</u>	<u>Fulfill Req.</u>
Japanese carp (<u>Cyprinum carpio</u>)	92.4%	>1.09 ppm.	Lake, Francis and Grothe	1984	252915	partial ^{1/}

1/ Inappropriate test species and low solubility.

Rainbow trout (<u>Salmo gairdneri</u>)	92.4%	>1.1 ppm	Lake, Grothe and Francis	1982	250793	partial ^{1/}
Bluegill sunfish (<u>Lepomis macrochirus</u>)	92.4%	>1.1 ppm	Lake, Grothe and Francis	1982	250793	partial ^{1/}

There is sufficient information to characterize the toxicity of Isoxaben as no more than moderately toxic to fish. It does not have an observable acute effect at its level of maximum solubility. The guideline requirement for fish acute toxicity testing (72-1) has not been satisfied. However, these tests are adequate for risk assessments if aquatic exposure does not exceed 1 ppm.

Data from a fish early life stage test is required if an active ingredient is persistent in water. Isoxaben is persistent in water with no degradation after 32 days. The following tests are acceptable fish early life stage tests.

<u>Species</u>	<u>T.M.</u>	<u>Results</u>	<u>Author</u>	<u>Date</u>	<u>Acc No.</u>	<u>Fulfill Req.</u>
Fathead minnow (<u>Pimephales promelas</u>)	95.5%	NOEL= 0.4 ppm*	Lake, Sauter and Meyerhoff	1983	252915	partial ^{2/}
Rainbow Trout (<u>Salmo gairdneri</u>)	95.5%	NOEL= 0.42 ppm*	Lake, Meyerhoff and Sauter	1983	252915	partial ^{2/}

* highest level tested.

The guideline requirement (72-4) has not been fulfilled, however, these data are adequate to show that Isoxaben has no apparent chronic effect on embryo-larval development at 0.4 and 0.42 ppm and could be used in a hazard assessment where chronic aquatic concentrations do not exceed these levels.

Precautionary Labeling

No toxicity statement for fish is required based on available data.

- ^{1/} Test material solubility was approximately 1.1 ppm. Test concentrations were measured, therefore, these tests fulfill the intent of the requirement by showing that Isoxaben is apparently not acutely toxic at its maximum solubility.
- ^{2/} An effect level was not determined.

Effects on Freshwater Invertebrate

Two studies in two documents were evaluated. Both studies were acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>Accession No.</u>
Lake, Francis and Grothe	1984	252915
Lake, Francis and Grothe	1982	250793

The minimum data required to establish the acute toxicity to freshwater invertebrates is a 48-hr aquatic study with the technical material. The preferred test species is Daphnia magna. The acceptable toxicity test is presented below.

<u>Species</u>	<u>T.M.</u>	<u>LC50</u>	<u>Author</u>	<u>Date</u>	<u>Acc No.</u>	<u>Fulfill Req.</u>
<u>Daphnia magna</u>	92.4%	>1.3 ppm	Lake, Francis and Grothe	1982	250793	partial ^{1/}

This test does not fulfill the guideline requirement (72-2) for acute testing with aquatic invertebrates. It is adequate to assess risk provided aquatic exposure is unlikely to exceed 1.3 ppm. Isoxaben is no more than moderately toxic to aquatic invertebrates.

Data from an freshwater aquatic invertebrate life-cycle test are required if an active ingredient is persistent in water. Isoxaben is persistent in water with no degradation after 32 days. The aquatic invertebrate life-cycle test is required. The acceptable life-cycle test is provided below.

<u>Species</u>	<u>T.M.</u>	<u>Result</u>	<u>Author</u>	<u>Date</u>	<u>Acc No.</u>	<u>Fulfill Req.</u>
<u>Daphnia magna</u>	95.5%	NOEL= 0.69 LEL=1.01 ppm 2/	Lake, Francis and Grothe	1984	252915	yes

1/The test material was insoluble at above 1.3 ppm, which was the measured test concentration, nominal was 100 ppm.

2/ Statistically significant effects on growth and brood size.

This test fulfills the requirement (72.4) for an aquatic invertebrate life-cycle test.

Precautionary Labeling

No precautionary label statement is required for aquatic invertebrates.

Effects on Beneficial Insects

One study in one document was evaluated under this topic. The study was acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>Accession No.</u>
Akins	1984	073292

The minimum data requirement to establish the acute toxicity to honey bees is an acute oral LD50 study with the technical material. The acceptable test is presented below.

<u>Species</u>	<u>T.M.</u>	<u>LD50</u>	<u>Author</u>	<u>Data</u>	<u>Acc No.</u>	<u>Fulfills Req.</u>
Honey bee <u>Apis mellifera</u>	95.5%	>101.7 ug/Bee	Akins	1984	073229	yes

This test fulfills the requirement for acute toxicity testing with honey bees. There is sufficient information to characterize Isoxaben as practically nontoxic to bees.

Precautionary Labeling

Based on the above data, no toxicity statement is required.

Plant Protection

One study in one document was evaluated under this topic. It was considered acceptable.

<u>Author</u>	<u>Date</u>	<u>Accession No.</u>
Lake, Francis and Grothe	1982	250793

Tier I phytotoxicity data are required for terrestrial nonfood uses such as ornamentals and noncropland. The studies required are a seedling germination/seedling emergence, vegetative vigor and aquatic plant growth. The following study fulfills the requirement for a Tier I aquatic plant growth test (122.2).

<u>Species</u>	<u>T.M.</u>	<u>Results</u>	<u>Author</u>	<u>Date</u>	<u>Acc. No.</u>	<u>Fulfills Req.</u>
Algae (<u>Selenastrum capricornutum</u>)	92.4%	NOEL=1.4 ppm (max. solubility)	Lake, Francis and Grothe	1982	250793	yes

Tier 1 data to fulfill the requirement for the seed germination/seedling emergence (122-1) and the vegetative vigor tests (122-1) have not been provided.

Tier 2 terrestrial phytotoxicity testing is required if Tier 1 testing indicates that plants are affected at the maximum application rate. Since Tier 1 terrestrial phytotoxicity test results are not available, the determination cannot be made. Tier 2 aquatic phytotoxicity testing is required if the direct application of the maximum use rate to 6" of water would result in concentrations exceeding the Tier 1 aquatic plant NOEL. This is not the case, as the maximum use rate is 1 lb ai/acre which would result in 734 ppb which is less than the NOEL of 1.4 ppm.

Isoxaben Ecological
Effects Disciplinary Review

I. Ecological Effects Profile

A. Manufacturing Use

1. Avian Studies

The avian acute oral LD50's of >2000 mg/kg (Bobwhite quail, Lake & Kehr, 1982, 250793) and the avian dietary LC50's of >5000 ppm for both Bobwhite quail and Mallards (Lake and Kehr, 1982, 250793) indicate that Isoxaben is practically non-toxic to birds. The avian reproductive NOEL and LEL for Mallards are 300 ppm and 1000 ppm, respectively, (Lake and Cochrans, 1984, 073292). The reproductive NOEL for Bobwhite is 100 ppm (Lake and Cochrane, 1984, 073292).

2. Aquatic Studies

The fish LC50 for Rainbow trout is > 1.09 ppm and for Bluegill it is >1.1 ppm (Lake, Grothe and Francis, 1982, 250793) indicating that Isoxaben is no more than moderately toxic to fish. The early life stage chronic NOEL's for Fathead minnow and Rainbow trout are 0.4 ppm and 0.42 ppm, respectively, (Lake, Sauter, and Sauter, 1983, 252915).

The LC50 of >1.3 ppm for Daphnia magna (Lake, Francis and Grothe, 1982, 250793) indicates that Isoxaben is no more than moderately toxic to aquatic invertebrates. The aquatic invertebrate life-cycle NOEL and LEL for Daphnia magna are 0.69 ppm and 1.01 ppm, respectively (Lake, Frances and Grothe, 1984, 252915).

Isoxaben is practically nontoxic to mammals with acute oral LD50's of >2000 mg/kg and >10,000 mg/kg for rat and mouse respectively. In a 3-generation rat reproduction study, the reproductive NOEL =2500 ppm and LEL = 12,500 ppm (Toxicology Branch One-Liner).

B. Formulated Product

No tests with formulated products are required nor have any been provided.

II Ecological Effects Hazard Assessment

A Use

Isoxaben is proposed for registration to control broad leaf weeds on established turf, landscape ornamentals, container grown ornamentals, ground covers, nursery stock, non-bearing fruit and nut crops, non bearing vineyards and noncropland. Noncropland is identified as industrial sites, utility substations, highway guard rails, sign posts and delineators. At higher use rates of 0.75 to 1 lb. ai/acre, some grasses are suppressed or partially controlled.

Prolan 75 Dry flowable contains 75% a.i. (Isoxaben) and is a preemergence herbicide. The label indicates it will not control established weeds. It is stable on soil surfaces but must be activated by one - half inch rainfall or irrigation to be effective.

The use categories for which Isoxaben is proposed are terrestrial food (non-bearing fruit and nut crops and vineyards) and terrestrial nonfood.

B Environmental Fate

1. Soil

The aerobic soil metabolism half-lives for clay loam, loam, and sandy loam are 4.3, 5.6 and 10.6 months, respectively. The octanal/water partition coefficient is 434.

2. Water

Isoxaben is stable to hydrolysis with no degradation after 32 days (various pH's).

3. Plant

No information was available on plant uptake or metabolism. There is no information on the photolysis of Isoxaben on surfaces.

4. Animal

No bioaccumulation or animal metabolism data are available. An aquatic organism accumulation study is required.

C. Manufacturing-Use

The EEB does not perform a hazard assessment for manufacturing of pesticides.

D. End-Use Product

Prolan, which is 75% a.i. is the only end-use product proposed for registration.

1. Terrestrial

The maximum application rate is 1 lb ai/acre. At that rate the following residues (ppm) are expected on terrestrial food items.

	<u>Short</u> <u>grass</u>	<u>long</u> <u>grass</u>	<u>leafy</u> <u>crops</u>	<u>insects</u> <u>forage</u>	<u>seed</u> <u>Pods</u>	<u>Fruit</u>
maximum	240	110	125	58	12	7
typical	125	92	35	33	3	1.5

The maximum expected residue does not exceed the lowest avian reproductive NOEL of 300 ppm (Mallards, Lake & Cochrane, 1984, 073292).

This primary exposure is expected to cause minimal adverse acute and chronic effects to birds. Secondary exposure from accumulated residues cannot be assessed until a bioaccumulation study is provided. Based on an LD50 of >2000 mg/kg for mice, a one day LC50 can be calculated.

$$\frac{20 \text{ grams (weight of mouse)} \times 2000 \text{ mg/kg (LD50)}}{3 \text{ grams (consumed per day)}} = 13,333 \text{ ppm}$$

No adverse acute effects to mammals are expected from primary exposure. The estimated residues are also on less than the mammalian reproductive NOEL of 2500 ppm. No chronic effects through primary exposure are expected.

Possible adverse effects to mammals from secondary exposure through accumulated residues cannot be assessed until the bioaccumulation study results are available.

2. Aquatic

Because of its solubility, Isoxaben is expected to runoff to a moderate extent (1%). Using the 10-acre treated field draining into a 1 acre pond 6 feet deep, the following estimated aquatic concentration is calculated:

$$10 \text{ acres} \times 1 \text{ lb ai/acre} \times 0.01 \text{ runoff} \times 61 \text{ ppb} = 6.1 \text{ ppb}$$

This estimated concentration is substantially lower than the fish chronic NOEL's of 0.40 and 0.42 ppm for minnow and Rainbow trout, respectively (Lake, Sauter, and Meyerhoff, 1983, 252915). It is also lower than the Daphnia magna life-cycle NOEL of 690 ppb (Lake, Francis and Grothe, 1984, 252915). Minimal adverse acute or chronic effects to aquatic organisms are expected from ambient exposure. Bioaccumulation potential in aquatic organisms cannot be assessed until the bioaccumulation study has been completed.

The uses for which Prolan 75 Dry Flowable is proposed are generally not considered conducive to aerial application. However, the label does not exclude this method, therefore, it will be addressed. If 5% of the aerially applied 1 lb ai/acre drifted into 6 inches of water, the resulting concentration would be 36.7 ppb. This is substantially less than the chronic NOEL's presented earlier. Minimal adverse effects from this exposure are expected.

3 Endangered Species

Residues on terrestrial food items are less than the chronic NOEL for birds, therefore, adverse effects to endangered birds from ingesting contaminated food items is not expected.

Endangered mammals will not be exposed to residues exceeding the 3-generation reproduction NOEL of 2500 ppm. Therefore, no effects to endangered mammals through ingestion of contaminated food material are expected.

Potential for bioaccumulation cannot be assessed until the bioaccumulation study results are available.

Aquatic

Estimated residues from runoff or drift do not exceed aquatic organism chronic NOEL's. Adverse effects to endangered aquatic organisms through ambient exposure are not expected. The potential for bioaccumulation cannot be assessed until the bioaccumulation study data are provided.

Plants

Because it is a herbicide, Isoxaben is expected to adversely effect exposed endangered plant species. The only use where exposure is considered possible is the noncropland use which was addressed in the noncropland cluster already submitted to the USFWS. Their opinion may apply to Isoxaben depending on its toxicity to plants. The phytotoxicity data are required before EEB can complete this assessment. The EEB is proposing neither consultation with USFWS nor label restrictions to protect endangered plants at this time.

Risk Summary

Minimal adverse acute and chronic effects are expected to nonendangered and endangered terrestrial and aquatic organisms. Adverse effects to exposed endangered plants are possible. Bioaccumulation potential in all organisms cannot be determined without further data.

A risk assessment cannot be completed until additional data are available.

III. Precautionary Labeling

A. Manufacturing-Use Product

The following statement is required:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

B. End-Use Product

Terrestrial food and Terrestrial nonfood

The following statement is required:

"Do not apply directly to water or wetlands (swamps, marshes, bogs, and potholes). Do not contaminate water by cleaning of equipment or dispose of wastes."

IV Data Requirements

A fish bioaccumulation study is required. See the data tables.

Table A
Isoxaben Generic Data Requirements

Data Requirement	Composition ¹ / Pattern ² / Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>§158.145 Wildlife and Aquatic Organisms</u>				
<u>AVIAN AND MAMMALIAN TESTING</u>				
71-1 - Avian Oral LD50	TGAI A, B	yes	250793	No
71-2 - Avian Dietary LC50				
a. Upland Game Bird	TGAI A, B	yes	250793	No
b. Waterfowl	TGAI A, B	yes	250793	No
71-3 - Wild Mammal Toxicity	TGAI A, B	no		No 3/
71-4 - Avian Reproduction	TGAI A, B	yes	073292	No
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP A, B	no		No. 4/

Table A
Isoxaben Generic Data Requirements (continued)

Data Requirement	Composition ¹ / Pattern ² /	Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>§158.145 Wildlife and Aquatic Organisms (cont'd)</u>					
<u>AQUATIC ORGANISM TESTING</u>					
72-1 - Freshwater Fish LC50					
a. Warmwater	TGAI	A, B	yes	250793	no
b. Coldwater	TGAI	A, B	yes	250793	no
72-2 - Acute LC50 Freshwater Invertebrates	TGAI	A, B	yes	250793	no
72-3 - Acute LC50 Estuarine and Marine Organisms	TGAI		no		no
72-4 - Fish Early Life Stage and Aquatic Invert. Life Cycle	TGAI	A, B	yes	252915	no

Table A
Isoxaben Generic Data Requirements (continued)

Data Requirement	Composition ¹ / Pattern ² / Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>§158.145 Wildlife and Aquatic Organisms (cont'd)</u>				
<u>AQUATIC ORGANISM TESTING</u>				
72-5 - Fish Life Cycle	TGAI A,B	no		No 4/
72-6 - Aquatic Organisms Accumulation	TGAI A,B	no		yes
72-7 - Simulated or Actual Field Testing Aquatic Organisms	TEP A,B	no		no 4/

Table A
Isoxaben Generic Data Requirements (continued)

Data Requirement	Composition ¹ / Pattern ² / Use	TEP	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>§158.150 Plant Protection</u>					
<u>121-1 - TARGET AREA PHYTOTOXICITY</u>	A, B		no		no 3/
<u>NONTARGET AREA PHYTOTOXICITY</u>					
<u>TIER I</u>					
122-1 - Seed Germination/ Seedling Emergence	TGAI	A, B	no		yes
122-1 - Vegetative Vigor	TGAI	A, B	no		yes
122-2 - Aquatic Plant Growth	TGAI	A, B	yes	250793	no
<u>TIER II</u>					
123-1 - Seed Germination/ Seedling Emergence	TGAI	A, B	no		reserved 5/
123-1 - Vegetative Vigor	TGAI	A, B	no		reserved 5/
123-2 - Aquatic Plant Growth	TGAI	A, B	no		no 4/

Table A
Isoxaben Generic Data Requirements (continued)

Data Requirement	Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No Or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.150 Plant Protection (cont'd)				
<u>TIER III</u>				
124-1 - Terrestrial Field	TEP	A, B	no	reserved 5/
124-2 - Aquatic Field	TEP	A, B	no	no 4/

- 1/ Composition: TGAI = Technical Grade of the Active Ingredient; PAI = Pure Active Ingredient.
TEP= Typical End-Use Product
- 2/ The use patterns are coded as follows: A = Terrestrial, food crop; B = Terrestrial, nonfood; C= Aquatic food crop D = Aquatic, nonfood; E = Greenhouse, food crop; F = Greenhouse, nonfood; G = Forestry; H = Domestic outdoor; I = Indoor.
- 3/ Not currently a requirement.
- 4/ Lower tier data indicate test is not required.
- 5/ Reserved pending results of lower tier testing.