

File

MEMORANDUM

November 27, 1984

TO: Dennis Edwards
TS-767 Registration Division

THRU: *Harry Craven* 12/26/84
Harry Craven
Registration Standard Coordinator

THRU: *for H.T. Craven* 12/26/84
Dave Crappage, Acting Branch Chief
Ecological Effects Branch

FROM: *Daniel Rieder* 11/27/84
Daniel Rieder
Wildlife Biologist

SUBJECT: Registration Standard Amendment for Amitraz

Attached is the amended registration standard for amitraz. It includes additional uses for which amitraz is proposed for registration.

cc: Amy Rispin
Judy Heckman
John Tice

Topical Summary

Effects on Birds

Seven bird studies in seven citations were received and evaluated under this topic. Five were used for performing a hazard assessment.

<u>Author</u>	<u>MRID #</u>
Fink	00030451
UpJohn Co.	00040868
Ross and Roberts	00030452
Ross and Roberts	00030453
Fink and Beavers	00072412
UpJohn Co.	00040869
Fink and Beavers	00072411

For the pear use and the proposed citrus and apple use, the minimum data requirements for establishing the toxicity of amitraz to birds are the results of one avian acute oral toxicity test with either an upland gamebird or a waterfowl and two 8-day dietary studies (one with an upland gamebird, the other with a waterfowl) (Subpart 158 series 71). These requirements have been partially fulfilled. The upland gamebird 8-day dietary study is still outstanding.

For the proposed cattle and swine use, which is considered an indoor use, only an 8-day dietary LC50 is required. Normally the upland gamebird study is preferred, but since the waterfowl study was an acceptable study, it can be used to fulfill this requirement.

Table 1. Acute Avian Studies using Technical Amitraz

<u>Species</u>	<u>Test Material</u>	<u>Results</u>	<u>Author</u>	<u>MRID #</u>	<u>Fulfills Rqmnts.</u>
Bobwhite quail	Tech.	LD ₅₀ = 788 mg/kg	Fink	00030451	yes
Japanese quail	Tech.	LC ₅₀ = 1800 ppm	Ross & Roberts	00030453	partial
Mallard duck	Tech.	LC ₅₀ = 7000 ppm	Ross & Roberts	00030452	yes

Testing formulated products on avian species may also be requested (Subpart 158 section 70). No such studies were required for amitraz.

Chronic testing with avian species may be required (section 71-4). Amitraz does not photodegrade readily on plant surfaces, may be applied repeatedly, and will persist on treated vegetation. Avian reproduction studies are required for the pear use and the proposed apple and citrus use. The studies submitted partially fulfill this requirement. Additional testing is required to fulfill the data requirements for the pear use and the proposed apple and citrus use. No avian chronic studies are required for the proposed cattle and swine use.

Table 2. Chronic Avian Testing Using Technical Product

<u>Species</u>	<u>T. M.</u>	<u>Results</u>	<u>Author</u>	<u>MRID #</u>	<u>Fulfills Rgmnts.</u>
Bobwhite quail	Tech.	NOEL < 40 ppm 1/	Fink & Beavers	00072412	partial
Mallard duck	Tech.	NOEL < 40 ppm 2/	Fink & Beavers	00072411	partial

Testing with degradation products may also be required (section 70-3(c)(3)(v)). Available data shows that a degradation product of amitraz (U-40,481) is substantially more toxic than the parent (U-36,059) to mammals. It is considered likely that the degradation product would also be more toxic than the parent to other organisms, including birds. Therefore, avian 8-day dietary LC₅₀ testing using the degradation product identified as U-40,481 is being reserved pending receipt of environmental fate data. Additional testing with this degradate may be required depending on the results of this reserved data.

The studies with the degradation product are also reserved for the proposed citrus and apple uses, however, they are not required for the proposed cattle and swine use.

The studies submitted show that amitraz is slightly toxic to birds but that it affects avian reproduction at less than 40 ppm.

Precautionary Labeling

Based on the available information, no toxicity statement for birds is required.

1/ Avian one-generation reproduction study. The specific impairments noted were increases in eggshell cracking and reduced percentages of three-week embryos that survived to become normal hatchlings at < 40 ppm. The mean body weights of chicks hatched were significantly affected in the 100 and 250 ppm groups, and egg weights and eggshell thickness was significantly reduced at 250 ppm.

2/ Avian one-generation reproduction study. Numbers of 14-day old survivors produced per week were significantly less than the control at <40 ppm (EEB review by T. Johnston, 10/2/81). Reductions in percentage of viable embryos that survived to 3 weeks and percentage of 3-week embryos that survived to become normal hatchlings were noted at the 250 ppm level but not at 40 and 100 ppm.

Effects on Freshwater Fish

Six studies in six citations were received and evaluated under this topic. Five studies were used in performing a hazard assessment.

<u>Author</u>	<u>MRID #</u>
Fraser and Jenkins	00030445
Buccafusco	00111861
Fraser and Jenkins	00030447
Nissan	00030444
Bentley	00030446
Fraser and Jenkins	00030448

For the pear use and the proposed apple and citrus use, the minimum data required for establishing the acute toxicity of amitraz to fish are the results from two 96-hour studies with the technical product. One with a coldwater species (e.g., rainbow trout), the other with a warmwater species (e.g., bluegill sunfish). See section 72-1 of Subdivision E, 1982.

The guideline requirement has been partially met. There are sufficient data to characterize the toxicity of technical amitraz to fish as highly toxic to coldwater fish and moderately toxic to warmwater fish. A warmwater fish 96-hour LC50 is still required.

For the proposed cattle and swine use only one study is required, a 96-hour LC50 with a coldwater fish. This requirement has been fulfilled.

Table 3. Acute Toxicity tests on Freshwater Fish Using Technical Amitraz

<u>Species</u>	<u>Test Material</u>	<u>96-hr Results LC50</u>	<u>Author</u>	<u>MRID #</u>	<u>Fulfills Rqmnts.</u>
Rainbow trout	Tech.	*2.7 to 4 ppm	Fraser & Jenkins	00030445	partial
Bluegill sunfish	Tech.	1.34 ppm	Fraser & Jenkins	00030447	partial
Rainbow trout	Tech.	0.74 ppm	Bentley	00030446	yes
Harlequin fish	Tech.	3.2 to 4.3 ppm	Fraser & Jenkins	00030448	partial
Carp	Tech.	**1.17 ppm	Nissan	00030444	partial

* 48-hour

** 120-hour

Acute aquatic studies with the formulated product may be required (Section 72-1 of Subdivision E of the 1982 guidelines). Such studies would not normally be required since this is not a direct application to water. However, they are considered essential since their results bring up questions of the toxicity of the inerts. Two studies suggest that technical amitraz may be more toxic when in a 20% EC formulation than by itself. The registrant explained that this probably was the result of some inert ingredient making the active ingredient more available to the fish. Two other studies did not show the 20% EC formulation to be more toxic.

4

Table 4. Acute Fish Studies with Freshwater Fish Using a 20% EC Formulation

<u>Species</u>	<u>Test Material</u>	<u>96-hr Results LC50</u>	<u>Author</u>	<u>MRID #</u>	<u>Fulfills Rqmts.</u>
Rainbow trout	20% E.C.	*0.2 to 0.4 ppm a.i.	Fraser & Jenkins	00030445	partial
Bluegill sunfish	20% E.C.	3.14 ppm a.i.	Fraser & Jenkins	00030447	partial
Harlequin fish	20% E.C.	8.74 ppm a.i.	Fraser & Jenkins	00030448	partial
Carp	20% E.C.	**0.56 ppm	Nissan	00030444	partial

* 48-hour

** 120-hour

Since tests using the 20% EC did not fulfill the guideline requirements, one of the studies needs to be repeated, preferably with a coldwater species. These studies would only be needed for the pear use and proposed apple and citrus use. These studies are not required for the proposed cattle and swine use.

Chronic tests may also be required (Section 72-4). Amitraz is highly toxic and may be applied repeatedly during the season. Furthermore, an estimate of the initial environmental concentration suggested that residues could be greater than 0.01 of the fish LC₅₀. An early life stage test with a freshwater fish species may be required for the pear use and the proposed apple and citrus use pending requested environmental fate data. No chronic studies are required for the proposed cattle and swine use.

Testing with degradation products may also be required (Section 70-3 (c)(3)(v)) for the pear use and the proposed apple and citrus use. Available data shows that a degradation product identified as U-40,481 is substantially more toxic to mammals than its parent, amitraz. It is considered possible that this degradate would be more toxic than amitraz to other organisms such as fish. Therefore, a 96-hour LC₅₀ with a fish species may be required pending receipt of fate data. A coldwater species would be recommended since both pears and apples are grown in states where coldwater species occur. Degradate testing is not required for the proposed cattle and swine use.

Precautionary Labeling

The environmental hazard label statement must indicate: "This pesticide is toxic to fish."

5

Effects on Aquatic Invertebrates

One study was received and used to perform the hazard assessment on aquatic invertebrates.

<u>Author</u>	<u>MRID #</u>
Douglas et. al.	RIOAMI01

The minimum data requirements for establishing the acute toxicity of amitraz to aquatic invertebrates is the result from one 48-hour acute toxicity test with the technical active ingredient (Section 72-2). This guideline requirement has been fulfilled.

Table 5. Acute Toxicity Study with Technical Amitraz and an Aquatic Invertebrate

<u>Species</u>	<u>Test Material</u>	<u>Results</u>	<u>Author</u>	<u>MRID #</u>	<u>Fulfills Rqmnts.</u>
<u>Daphnia magna</u>	<u>Tech.</u>	LC ₅₀ = 35 ppb	Douglas et. al.	RIOAMI01	yes

This 48-hour acute study shows amitraz to be very highly toxic to aquatic invertebrates.

Acute testing on aquatic invertebrates with formulated products may be required (Section 72-2). There is data to suggest that amitraz is more toxic to some fish in a 20% EC than when administered as a technical product. There is a possibility for direct exposure through drift to aquatic habitats. A 48-hour LC₅₀ with an aquatic invertebrate and the 20% formulation of amitraz is required. Formulated product testing is not required for the proposed cattle and swine use.

Chronic testing may be required for aquatic invertebrates (Section 72-4) for the pear use and the proposed apple and citrus use. Amitraz is very highly toxic to daphnids and may be applied repeatedly during the season. Furthermore, an estimate of environmental concentrations suggested that residues could exceed the daphnid LC₅₀ under some conditions. Therefore, a chronic study with aquatic invertebrates may be required depending on the results of requested fate data. Chronic aquatic invertebrate testing is not required for the proposed cattle and swine use.

Testing with a degradation product may also be required (Section 70.3(c) (3)(v)) for the pear use and the proposed apple and citrus use. Available data shows that a degradation product of amitraz, identified as U-40,481 is substantially more toxic to mammals than the parent, amitraz. It is possible that this degradate is also more toxic to aquatic invertebrates than the parent. Therefore, pending receipt of fate data a 48-hour LC₅₀ with an aquatic invertebrate may be required. Degradate testing for the proposed cattle and swine use is not needed.

Precautionary Labeling

An environmental hazards labeling statements indicating toxicity to aquatic invertebrates would be required, but the fish statement takes precedence.

6

Effects on Marine Organisms

Two studies were received and validated under this topic.

<u>Author</u> Sleight Bentley	<u>MRID #</u> RIOAMIO2 00030450
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The data requirements for establishing the toxicity of amitraz to estuarine organisms are the results from 96-hour LC₅₀'s for shrimp and fish and either a 48-hour LC₅₀ for embryolarvae molluscs or a 96-hour EC₅₀ mollusc shell deposition study (Section 72-3). These studies are required for the proposed citrus use. The submitted studies would partially fulfill such a requirement. Still outstanding is the estuarine fish 96-hour LC₅₀. The pear use and the proposed apple and cattle and swine uses do not require estuarine studies.

Table 6. Toxicity Studies with Estuarine/Marine Organisms

<u>Species</u>	<u>Test Material</u>	<u>Results</u>	<u>Author</u>	<u>MRID #</u>	<u>Fulfills Rmmts</u>
Atlantic oyster	95%	48-hr EL TL ₅₀ = 0.85 ppm	Sleight	RIOAMIO2	yes
Grass shrimp	Tech.	96-hr LC ₅₀ = 65.1 ppm	Bentley	00030450	yes
Fiddler crab		96-hr LC ₅₀ > 1000 ppm			partially

Based upon the above data, technical amitraz can be considered highly toxic to estuarine organisms (i.e. molluscs).

Acute testing on estuarine organisms with formulated products may be required (Section 72-3). There is data to suggest that amitraz is more toxic to some fish in a 20% EC than when administered as a technical product. Based on the proposed citrus use, there is a possibility for direct exposure through drift to estuarine habitats. These three estuarine studies with the formulation are required for the proposed citrus use. Formulated product testing with estuarine organisms is not required for the pear use or the proposed apple and cattle and swine use.

Chronic testing may be required for estuarine organisms (Section 72-4) for the proposed citrus use. Amitraz is very highly toxic to estuarine organisms and may be applied repeatedly during the season. Therefore, a requirement for chronic studies with estuarine organisms is reserved pending results of requested toxicity data and environmental fate data. No chronic estuarine studies are needed for the pear use or the proposed apple or cattle and swine use.

Testing with a degradation product may also be required (Section 70.3(c)(3)(v)) for the proposed citrus use. Available data shows that a degradation product of amitraz, identified as U-40,481 is substantially more toxic to mammals than the parent, amitraz. It is possible that this degradate is also more toxic to estuarine organisms than the parent. Therefore, acute and chronic estuarine studies may be required depending on the required fate data and the results of freshwater toxicity data with the degradate. Degradate testing with estuarine species is not needed for the pear use or the proposed apple and cattle and swine uses.

Precautionary Labeling

The existing use (pears) and the proposed apple and cattle and swine uses do not require a statement of toxicity for estuarine/marine species. The citrus use would require a toxicity statement.

DISCIPLINARY REVIEW
Ecological Effects Profile

Technical Amitraz

Five Studies can be used to characterize the acute and chronic toxicity of technical Amitraz to birds. A bobwhite quail acute oral study (Fink, 00030451) provided an LD₅₀ of 788 mg/kg. Two 8-day dietary studies (both by Ross and Roberts) resulted in an LC₅₀ of 1800 ppm for Japanese quail (MRID # 00030453) and an LC₅₀ of 7000 ppm for Mallard ducks (MRID # 00030452). Two avian reproduction studies, both by Fink and Beavers, showed that technical Amitraz will effect Mallard duck reproduction at less than 40 ppm (MRID # 00072411) and Bobwhite quail reproduction at less than 40 ppm (MRID # 00072412). These studies show that Amitraz is slightly toxic to birds.

Acute fish studies using technical Amitraz showed the 96-hour LC₅₀ to be 0.74 ppm for Rainbow trout (Bentley, 00030446) and the 96-hour LC₅₀ of technical Amitraz to Bluegill to be 1.34 ppm a.i., (Fraser and Jenkins, 00030447). These studies show that technical Amitraz is highly to moderately toxic to fish.

One study is available to show the toxicity of technical Amitraz to aquatic invertebrates. The 48-hour LC₅₀ with Daphnia magna is 0.035 ppm (Douglas et. al., RIOAMI01). This shows that Amitraz is very highly toxic to some aquatic invertebrates.

Two acute studies with estuarine species were available. One, by Sleight (RIOAMI02) using technical Amitraz on Atlantic oyster larvae, yielded a 48-hour TL₅₀ of 0.85 ppm. The second (Bentley, 00030450) tested both grass shrimp and fiddler crab with technical Amitraz. The results were a shrimp 96-hour LC₅₀ of 65.1 ppm and a fiddler crab LC₅₀ of > 1000 ppm. This shows the Amitraz is highly toxic to some estuarine species such as molluscs but it is slightly toxic to shrimp and practically non-toxic to some species of crabs.

Formulated Products Containing Amitraz (20% EC)

Four fish acute studies were conducted. One by Fraser and Jenkins (00030447) resulted in a 96-hour LC₅₀ to bluegill of 3.14 ppm a.i. A second study by Fraser and Jenkins (00030448) which tested the Harlequin fish resulted in a 96-hour LC₅₀ of 8.74 ppm a.i. The third study was a 48-hour test with Rainbow trout (Fraser and Jenkins, 00030445) resulting in an LC₅₀ of between 0.2 and 0.4 ppm a.i. The fourth was a 120 hour LC₅₀ with carp (Nissan, 00030444) which resulted in an LC₅₀ of 0.56 ppm for the 20% EC.

These studies show that the formulated product is moderately toxic to bluegill and Harlequin fish. However, the Rainbow trout and carp study suggested that the 20% E.C. was highly toxic and more toxic than technical Amitraz.

Ecological Effects Hazard AssessmentDiscussion of Exposure and Hazards

Amitraz is registered for use on pears in two types of formulations, a 50% a.i. WP and a 19.8% EC. Both labels specify a maximum rate of 1.5 lbs a.i. per acre. About 100,000 lbs of active ingredient are used annually. According to the "Registration Standard's Phase 1 Qualitative use Assessment for Insecticidal uses of Amitraz" by John W. Kliever and M.J. Thompson, July 1983, 40% of the total pear acreage (45,000 acres) is treated annually with Amitraz. Pears are grown in New England and the far west (California, Washington and Oregon).

At the request of the Registration Division, several proposed uses for amitraz will be addressed in this assessment. These uses are: apples, citrus and cattle and swine. The apples and citrus will be discussed with the pear use. The citrus maximum application rate is 1.5 lbs a.i. per acre and the apple maximum rate is 1.125 lbs a.i. per acre. Cattle and swine are treated indoors.

PEAR, CITRUS AND APPLE USESAquatic

Amitraz is highly toxic to fish and very highly toxic to aquatic invertebrates.

Residues from treated pear and apple orchards and citrus groves could reach aquatic or estuarine habitat via drift and/or runoff.

Drift EEC:

An EAB review by Robert Holst on Tilt dated 7/3/84 will be used as a guide for extent of drift when spraying orchards. In that review, it was estimated that 11% of the pesticide applied to a 1 acre orchard would end up in an adjacent 1 acre pond. In this case, 1.5 lbs would be sprayed on one acre of pears or citrus.

$1.5 \text{ lbs} \times 0.11 = 0.166 \text{ lbs a.i. per acre in the adjacent 1 acre pond.}$
EEC from nomograph for 0.166 lbs a.i. per acre = 20 ppb in 3 feet.

Runoff EEC:

If the same field which provided drift also drained into the pond, residues could occur from runoff. In this scenario, developed in EEB, it is assumed that 10 acres drains into the 1 acre pond which is 3 feet deep..

$1.5 \text{ lbs} \times 0.60^* = 0.9 \text{ lbs/acre}$
 $10 \text{ acres} \times 0.9 \text{ lbs} = 9 \text{ lbs a.i. on 10 acres}$
1% runoff assumed:
 $9 \text{ lbs} \times 0.01^{**} = 0.009 \text{ lbs into 1 acre} = 11 \text{ ppb}$
5% runoff assumed:
 $9 \text{ lbs} \times 0.05^\dagger = 0.45 \text{ lbs into 1 acre} = 55 \text{ ppb}$

* Only 60% reaches the target, the rest drifts to non-target areas.

**1% of the applied pesticide is transported from the treated area via runoff.

† 5% of the applied pesticide is transported from the treated area via runoff.

Total EEC:

Cummulative residue in the pond could reach: 31 ppb if 1% runoff (11 + 20); or 75 ppb if 5% runoff (55 + 20). Since there is a question of the toxicity of the formulation, the drift EEC will be presented as ppb of formulated product. If the drift resulted in 20 ppb a.i., it would result in about 100 ppb formulation.

Multiple applications

If a second application was made after at least two weeks, the initial residues would have essentially degraded since the halflife at around pH 7 is 15 hrs. There should be no accumulation of amitraz in the environment. This is based on existing fate data in EEB files.

Hazards to Aquatic/Marine Organisms

These estimated environmental concentrations (EEC's) would be high enough to cause acute hazard to aquatic invertebrates. Furthermore, since the labels allows repeat applications, there is potential for chronic exposure. At the estimated levels, chronic exposure would have adverse effects on aquatic invertebrates. The extent of this exposure cannot be determined without environmental fate data. Depending on this data, a 21-day early life stage study with Daphnia magna may be required. Acute testing with the formulation is required because results from acute fish tests suggest that amitraz in the formulation is more toxic than technical amitraz.

The EEC's would not be likely to cause acute hazards to fish. However, the trigger for chronic concern is 0.01 of the fish LC₅₀ (0.01 x 740 ppb = 7.4 ppb). Since the EEC's exceed this and the label allows repeat applications, chronic exposure is possible. Environmental fate data is necessary to determine the extent of this exposure. Depending on this data, a freshwater fish early life stage study may be required. Furthermore, the formulation is expected to drift into aquatic habitat resulting in residues 0.1 the fish LC₅₀ for the formulation. The study generating that information does not meet guideline requirements so the extent of this hazard cannot be determined without acceptable formulation testing with freshwater fish.

It is noted that the degradate identified as U-40,481 is substantially more toxic to mammals than the parent (U-36,059). Depending on environmental fate data, more toxicity information on this degradate may be needed with aquatic and/or estuarine organisms.

Even though a complete aquatic hazard assessment cannot be performed, it is likely that on a limited basis aquatic invertebrates are being acutely and chronically affected by the use of amitraz on pears. Fish may be experiencing chronic effects from the use of amitraz on pears. These effects are limited by the total acreage treated. They are also limited to organisms in ponds or slow-moving small streams adjacent to pear orchards. The EEC's were based on drift or runoff to standing water. It is expected that moving water would dilute the residues substantially to below hazardous levels.

11

This exposure would increase substantially with the addition of apples. The use of amitraz on apples would result in increased exposure in the east as well as the west. Apples are grown in New York, Michigan, Virginia, West Virginia and Pennsylvania as well as Washington, Oregon and California. Data requirements for this use are the same as for the pear use.

This exposure would be further increased with the addition of citrus, not only to include more acres but also different habitat. Citrus is grown mostly in Florida and California. In Florida exposure to estuarine species is possible. Data show that this should not have an acute adverse effect on shrimp or molluscs. However, a complete hazard assessment on this use cannot be completed without additional testing. Data requirements include those mentioned for the pear and apple use as well as an estuarine fish 96-hour LC50 using technical amitraz. Acute estuarine tests with the formulated product are required. Testing with the degradate on estuarine species may be required depending on the results of environmental fate data. Estuarine chronic or life-cycle studies may be necessary for the citrus use also depending on results of environmental fate data and requested freshwater toxicity data.

Terrestrial

Amitraz is slightly toxic to birds and moderately toxic to mammals. Under the worst case conditions residues on vegetation may reach the following levels.

rate lbs/acre	short grass	long grass	Residues (ppm)		seed pods	fruit
			leafy crops	forage		
1.5	360	165	188	87	18	11

These levels are lower than the avian dietary LC₅₀'s available. At the label rate of 1.5 lbs a.i. (681,000 mg) per acre, a 1 kg bird would have to eat all the amitraz in 50 ft² to receive a LD₅₀.

681,000 mg per acre

788 mg = LD₅₀ for a 1 kg bird

681,000/788 = 864. There is enough amitraz in one acre for 864 1 kg birds to receive their LD₅₀.

43560 square feet per acre

43560/864 = 50 square feet worth of vegetation treated with amitraz would provide an LD₅₀ to a 1 kg bird.

Amitraz is not likely to cause an acute hazard to birds. However, the label allows repeat applications so there is potential for chronic exposure. Avian reproduction studies were conducted but did not fulfill guideline requirements. The results did not provide a NOEL. An avian reproductive test will have to be redone using lower test levels. Also, since one of the avian 8-day dietary studies is with an unacceptable species, an upland gamebird dietary study will have to be redone.

Mammalian toxicity data show that the degradate, U-40,481, is more toxic to mice, rats, and dogs than the parent. An avian 8-day dietary toxicity study with the degradate may be required depending on environmental fate data.

Using the same estimations as for birds it is not likely that amitraz is having an acute effect on mammals as the LD₅₀ for the rat is 938 mg/kg. However, it is not possible to estimate how much of the degradate is available. More environmental fate data is needed on this degradate showing its half-life and the residues that could occur on terrestrial food items.

When the outstanding fate and toxicity data requirements are fulfilled, EEB will complete a hazard assessment for the use of Amitraz on pears, apples and citrus.

CATTLE AND SWINE

Cattle and swine treatment is considered an indoor use because it involves treating domestic livestock in pens and treating the pens for the control of ectoparasites. It is unlikely that a significant amount of amitraz a.i. or formulation would transport to aquatic or estuarine habitats. This use is not expected to have an adverse effect on either terrestrial, or aquatic/estuarine non-target organisms.

Endangered Species

No OES opinion has been provided on any pear use. A few opinions have been rendered on apples and citrus. There are endangered bird, fish, mollusc and insect species associated with these uses.

Pears

There is insufficient data to complete a hazard assessment at this time. Further data requirements include additional acute and chronic toxicity tests, environmental chemistry information and an EEC from EAB.

The following endangered aquatic species occur in counties where pears are grown.

Mohave chub (Gila bicolor mohavensis)
Unarmored three-spine stickleback (Gasterosteus aculeatus williamsoni)
Lahontan cutthroat trout (Salmo clarki henshawi)
Little kern golden trout (Salmo aquabonita whitei)
Greenback cutthroat trout (Salmo clarki stomias)
Slackwater darter (Etheostoma boschungii)
Yellowfin madtom (Noturus falvipinnis)
Fountain darter (Etheostoma fonticola)
Pecos gambusia (Gambusia nobilis)
Comanche Springs pupfish (Cyprinodon elagans)
Woundfin (Plagopterus argentissimus)

Texas blind salamander (Typhlomolge rathbuni)
Houston toad (Bufo houstonensis)

Listed mussels

Apples

Amitraz has been proposed for use on apples. The following species were included in an opinion from the Office of Endangered Species received by EEB July 6, 1981, concerning the use of chlorpyrifos (Lorsban 50W) on apples.

Woundfin (Plagopterus argentissimus)

Pecos gambusia (Gambusia nobilis)

Gila trout (Salmo gilae)

All listed mussels

All listed insects

Citrus

Based on a comparison of counties where citrus is grown and counties where endangered species occur, the following endangered aquatic species could be exposed to amitraz depending on further data.

Gila topminnow (Poeciliopsis occidentalis)

Shortnose sturgeon (Acipenser brevirostrum)

Mohave chub (Gila bicolor mohavensis)

Unarmored three-spine stickleback (Gasterosteus aculeatus williamsoni)

Lahontan cutthroat trout (Salmo clarki henshawi)

Little kern golden trout (Salmo aquabonita whitei)

Desert slender salamander (Batrachoseps aridus)

Santa-Cruz long-toed salamander (Ambystoma macrodactylum croceum)

Everglades kite (Rostrhamus sociabilis plumbeus)

It is unlikely that the swine and cattle use would have an adverse effect on any endangered species.

Note that the species listed for pears and citrus are included based on a county comparison. No attempt was made to determine if the crops are actually grown adjacent to habitat of the endangered species listed. Furthermore, unless amitraz is found to be persistent (t1/2 greater than 4-6 days), there should be no affect to endangered fish or amphibian species; even those adjacent to treated orchards or groves.

Ecological Effects Labeling Requirements

The following environmental precautions are appropriate.

Manufacturing Use

This pesticide is toxic to fish. 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 in writing. For guidance contact your State Water Board or Regional Office of the EPA.

14

End-UseIndoor Use (livestock):

This pesticide is toxic to fish. Do not contaminate water by cleaning of equipment or disposal of wastes.

Terrestrial food-crop: non-citrus

This pesticide is toxic to fish. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to fish in adjacent sites. Do not contaminate water by cleaning of equipment or disposal of wastes.

Terrestrial food-crop: citrus

This pesticide is toxic to fish and estuarine organisms. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to fish and estuarine organisms in adjacent sites. Do not contaminate water by cleaning of equipment or disposal of wastes.

Summary of Data Gaps

See table A for a summary of data gaps.

The following studies are required with technical Amitraz:

- Avian 8-day dietary LC₅₀ with an upland gamebird; - 12/22/88
- Avian reproductive test with an upland gamebird; - 5/1/89
- Warmwater fish 96-hour LC₅₀; and
- Estuarine fish 96-hour LC₅₀.

The following studies are required with a 20% EC formulation:

- Coldwater fish 96-hour LC₅₀; - Supple. 12/22/88
- Aquatic invertebrate LC₅₀; - 12/22/88
- Estuarine fish LC₅₀; - 12/22/88
- Shrimp LC₅₀; and - 12/22/88
- Acute mollusc testing. - 12/22/88

The following studies may be required using technical amitraz depending on requested fate and toxicity data:

- estuarine fish full life-cycle study;
- mysid shrimp life-cycle test;
- Fish early-life stage study; and Supple. 2/20/89
- Aquatic invertebrate 21-day life cycle study. Supple. 12/22/88

The following studies may be required using U-40481 as the test material depending on environmental fate data:

- Freshwater fish 96-hour LC₅₀;
- Aquatic invertebrate 48-hour LC₅₀;
- Avian 8-day dietary with an upland gamebird; and
- Estuarine acute toxicity tests.

Studies for Which Abbreviated Reviews were Done

00040869
00040868

The Following MRID Numbers were for Duplicate Studies

Reported No.
00030446

Duplicate No.
00051924

TABLE A
GENERIC DATA REQUIREMENTS FOR AMITRAZ

Data Requirement	1/ Composition	Use 2/ Pattern	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)?
\$158.145 Wildlife and Aquatic Organisms					3/
<u>AVIAN AND MAMMALIAN TESTING</u>					
71-1 - Avian Oral LD ₅₀	TGAI	A	Yes	00030451*	No
71-2 - Avian Dietary LC ₅₀	TGAI	A, I 19/		00030452*	No
a-waterfowl	TGAI	A	Partially	00030453**4/	Yes5/
b-upland game	U-404816/	A	No		Reserved7/
71-3 - Wild Mammal Toxicity	TGAI	---	---	---	No
71-4 - Avian Reproduction	TGAI	A	Partially	00072411**	Yes8/
a-waterfowl		A		00072412**	
b-upland game					
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A			Reserved
<u>AQUATIC ORGANISM TESTING</u>					
72-1 - Acute Toxicity Freshwater Fish	TGAI	A	Partially	00030447**	Yes
a. warmwater				00030448**	
b. coldwater	TGAI	A, I 19/	Yes	00030444**	No
c. warmwater	TEP 208EC	A	Partially	00030446*	No
d. coldwater	TEP 208EC			00030445**	
	U-40481	A	Partially	00030447**	Yes9/
			No	00030448**	Reserved10/
				00030444**	
				00030445**	

TABLE A CONT'D
GENERIC DATA REQUIREMENTS FOR AMITRAZ

Data Requirement	Composition	1/ Use 2/ Pattern	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)?
72-2 - Acute LC ₅₀ Freshwater Invertebrates	TGAI TEP 20%EC U-40481	A, I 19/ A A	Yes No No	RIQAMI01*	No Yes ^{11/} Reserved ^{12/}
72-3 - Acute LC ₅₀ Estuarine and Marine Organisms	TGAI TEP 20%EC U-40481	A A A	Partially No No	RIQAMI02* 00030450*	Yes ^{13/} Yes ^{14/} Reserved ^{15/}
72-4 Fish Early Life Stage and Aquatic Invertebrate Life-Cycle	TGAI	A	No		Yes ^{16/}
72-5 Fish full life-cycle	TGAI	A	No		Reserved ^{17/}
72-6 Aquatic Organism Accumulation	TGAI				
72-7 Simulated or Actual Field Testing - Aquatic Organisms	TEP	A	No		Reserved 18/

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, Non-Food Crop; 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 no later than _____.

- 4/ This test was conducted with Japanese quail, which is not a recommended species.
- 5/ An 8-day dietary LC50 with technical amitraz and bobwhite quail is required.
- 6/ U-40481 is a primary degradate of amitraz.
- 7/ The 8-day dietary study using the degradate is being reserved until required environmental fate data are available from EAB.
- 8/ Only one avian reproduction study needs to be repeated, preferably with an upland gamebird (the bobwhite quail is recommended).
- 9/ The 96-hour coldwater fish LC50 with the 20% EC formulation is required because test results suggest that amitraz in the 20% EC formulation is more toxic to fish than as technical amitraz.
- 10/ A 96-hour LC50 using the degradate of amitraz (U-40481) on a coldwater fish may be required pending environmental fate data from EAB.
- 11/ A 48-hour aquatic invertebrate LC50 with the 20% EC is required because test results suggest that amitraz in the 20% formulation is more toxic to fish than as technical amitraz.
- 12/ A 48-hour aquatic invertebrate LC50 with the degradate is being reserved pending results of environmental fate data from EAB.
- 13/ Marine/estuarine testing is not required for the pear use and the proposed apple use. However, these tests are required for the proposed citrus use. Present data fulfill requirements for oyster and shrimp, but the estuarine acute fish LC50 is required.
- 14/ Acute testing with all three estuarine species (fish, shrimp, & molluscs) on the formulated EC is required.
- 15/ Acute testing with all three estuarine species (fish, shrimp, & molluscs) may be required pending results of degradate tests on freshwater species and environmental fate data.
- 16/ Both a fish and an aquatic invertebrate study are required because label permits repeat applications. May include estuarine species pending results of chronic studies on freshwater species.
- 17/ May be required pending results of environmental fate data and the fish early life stage study.
- 18/ Pending results of the environmental fate data from EAB.
- 19/ Required to support the manufacturing use product used to formulate these end use products

* Study fulfills guideline requirement on its own.

** Study could fulfill guideline requirement in conjunction with other studies.

18