

US EPA ARCHIVE DOCUMENT



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

6-8-94

MEMORANDUM:

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Methyl Anthranilate Reregistration Eligibility Document

FROM: *[Signature]* Anthony F. Maciorowski, Chief
Ecological Effects Branch
Environmental Fate and Effects Division (7507C) *6/8/94*

TO: Daniel Peacock
Product Manager 14 Team
Registration Division (7505C)

Attached are the Disciplinary Review, Topical Summary, and Data Requirements for the Ecological Effects Chapter of the Methyl Anthranilate Registration Document. Avian dietary, freshwater fish and aquatic invertebrates studies submitted do not meet requirements due to technical problems. The deficiencies categorized these studies as supplemental. In addition, most of the labels were incomplete. Therefore, only a preliminary risk assessment could be performed on some of the proposed product uses. The following is a list of studies needed to complete EEB's ecological risk assessment on Methyl Anthranilate.

- 154-7 Avian acute dietary
- 71-4 Avian reproduction
- 154-8 Acute freshwater fish LC₅₀ study with rainbow trout.
- 72-4 Fish early life-stage (only for end-use products where directly applied to water)
- 154-11 Beneficial insect study.

Tier II Fate data are triggered by the available non-target organism data.

In addition, labels need to include the amount of active ingredient to be applied per application per acre; maximum number of applications per year; and minimum number of days between each application.

If there are any questions to the above, please contact Regina Hirsch (305-5366).



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

**Methyl Anthranilate
ECOLOGICAL EFFECTS TOPICAL SUMMARIES**

EFFECTS ON BIRDS

Four studies were evaluated under this topic. Three studies were considered Supplemental and one study was Core and acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>MRID Number</u>
Ahmed, M.S.	1993	429669-02
Askham, L.R.	1991	429669-03
Campbell, S.M. & M. Jaber	1992	426088-07
Campbell, S.M. & M. Jaber	1992	426088-08

To establish the toxicity of Methyl Anthranilate to birds the following tests are required using the technical material:

A. One avian single-dose oral study on either a waterfowl species or an upland game species (preferably the bobwhite quail).

B. One avian dietary studies on one species of waterfowl or one species of upland game bird (preferably the bobwhite).

Avian Single-Dose Oral LD₅₀ - Technical

The acceptable acute oral toxicity data for use in hazard assessment are listed below:

<u>Species</u>	<u>% a.i. LD₅₀ (mg/kg)</u>	<u>Author</u>	<u>Date</u>	<u>ID No.</u>	<u>Fulfills Requirement</u>
Bobwhite quail	>99.6% >2036	Ahmed	1993	42966902	Core
Mallard duck	>99.9% >292	Campbell	1992	42608807	Supplemental

The data indicate that technical Methyl Anthranilate is practically non-toxic to upland game species on an acute oral basis. The Guideline requirements for an avian acute oral toxicity study are fulfilled.

Avian Dietary - Technical

The Supplemental avian dietary toxicity studies for use in a hazard assessment are listed below:

<u>Species</u>	<u>% a.i. LC₅₀ (ppm)</u>	<u>Author</u>	<u>Date</u>	<u>ID No.</u>	<u>Fulfills Requirement</u>
White-crowned sparrow	98.9% >2200*	Askham		1991 42966903	Supplemental
Oregon junco House finch Ring-necked pheasant Mallard duck	99.9% >5620	Campbell	1992	42608808	Supplemental**

* A true LC₅₀ could not be determined due to no treated diet being consumed.

** Study may be upgraded to Core if results of the chemical analyses of the test diets are submitted.

The data indicate that technical Methyl Anthranilate is Potentially **practically non-toxic** to passerine, upland game birds, and waterfowl on a subacute dietary basis. These avian dietary LC50 Guideline requirements have **not** been fulfilled.

Avian Reproduction

Avian reproduction tests **are** required for a pesticide when: birds may be subjected to repeated or continuous exposure, the pesticide is stable in the environment, the pesticide is stored or accumulated in plant or animal tissues, or reproduction in terrestrial vertebrates may be adversely affected based on information from mammalian reproduction studies. Avian reproduction studies are required to support registration of Methyl Anthranilate due to the repeated applications of some of the products. It is assumed that with these usage patterns (high use rate and many applications) avian species have a greater chance of exposure.

Avian reproductive tests have not been fulfilled.

Precautionary Labeling

Based upon the above studies, it has not been determined if a precautionary statement for technical Methyl Anthranilate is needed for birds.

EFFECTS ON FRESHWATER FISH

Four studies were evaluated under this topic. These studies are not completely acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>MRID Number</u>
Clark, L.	1992	426998-02, 426998-03, 427182-02, 429669-01

To establish the toxicity of Methyl Anthranilate to freshwater fish, the following test is required using the technical grade active ingredient (TGAI):

- A. One 96-hour acute study using TGAI. The preferred coldwater species is rainbow trout.

Species	% a.i.	LC ₅₀ (ppm)	Author	Date	MRID No.	Fulfills Requirement
Rainbow trout	>98%	22.91	Clark	1992	42699802, 42966901	Supplemental
Channel catfish	>98%	16.23	Clark	1992	42718202, 42966901	Supplemental
Atlantic salmon	>98%	32.35	Clark	1992	42699802, 42966901	Supplemental
Bluegill sunfish	>98%	9.12	Clark	1992	42699803, 42966901	Supplemental

Studies were classified as **supplemental**, due to degradation of Methyl Anthranilate in the test solutions, the actual concentrations to which the test fish were exposed are unknown for the rainbow trout and Atlantic salmon, whereas, in the bluegill sunfish and channel catfish studies the test material was measured, however both concentration and dissolved oxygen decreased substantially throughout the test. The data suggest that Methyl Anthranilate is moderately toxic to bluegill sunfish and slightly toxic to channel catfish, Atlantic salmon, and rainbow trout. However, due to unmeasured and decreased concentrations and decreased dissolved oxygen it can not be determined the true toxicity of Methyl Anthranilate to freshwater fish. Therefore, these studies can not solely be used in a risk assessment.

In addition, as two proposed products will apply Methyl Anthranilate directly to standing water, an acute study with the typical end-use product (TEP) will also be required.

Fish Early Life Stage Test

Data from fish early life stage tests are required to support the registration of an end-use product that is expected to be transported to water from the intended use site when certain conditions, including any of the following apply:

- * Any LC₅₀/value in acute tests is less than 1 mg/L.
- * The EEC in water is equal to or greater than 0.01 of any EC₅₀ or LC₅₀ from acute testing.
- * The EEC is less than 0.01 of LC₅₀/values and the pesticide is persistent in water.

As two proposed products are to apply Methyl Anthranilate directly to standing water, this study is required for those products.

Fish Life Cycle Studies

Data from fish life cycle tests are required to support the registration of an end-use product that is expected to be transported to water from the intended use site when any of the

following conditions apply:

* If the estimated EEC is > 1/10 of the no effect level in the fish early life stage or invertebrate life cycle test.

* If studies of other organisms indicate that the reproductive physiology of the fish may be affected.

This study is reserved pending results of a confirming freshwater fish acute toxicity test.

Precautionary Labeling

Based on the above data, it has not been determined if a precautionary statement for technical Methyl Anthranilate is needed for fish.

EFFECTS ON FRESHWATER INVERTEBRATES

One study was evaluated under this topic. This study is not completely acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>MRID Number</u>
Clark, L.	1992	42718203, 42995101

To establish the toxicity of Methyl Anthranilate to aquatic invertebrates, the following test is required using technical grade active ingredient (TGAI):

A. 48-hour acute study using TGAI. Test organisms should be first instar Daphnia magna.

<u>Species</u>	<u>% a.i.</u>	<u>EC₅₀ (ppm)</u>	<u>Author</u>	<u>Date</u>	<u>MRID No.</u>	<u>Fulfills Requirement</u>
<u>Daphnia magna</u>	N/A	18.2	Clark	1992	42718203 42995103	Supplemental*

* Study was classified as supplemental, as the percent active ingredient was not reported. May be upgraded to core once data are submitted.

The toxicity of technical Methyl Anthranilate to freshwater invertebrates is tentatively characterized as slightly toxic. Therefore, this study can not solely be used in a risk assessment until missing active ingredient data is submitted.

In addition, as two proposed products will apply Methyl Anthranilate directly to standing water, an acute study with the typical end-use product (TEP) will also be required.

Aquatic Invertebrate Life Cycle Test

Data from an aquatic invertebrate life cycle test are required to support the registration of an end-use product that is expected to be transported to water from the intended use site when certain conditions, including any of the following, apply:

- * Any EC_{50} /value in acute tests is less than 1 mg/L.
- * The EEC in water is equal to or greater than 0.01 of EC_{50}/LC_{50} values from acute testing.
- * The EEC is less than 0.01 of EC_{50} /values and the pesticide is persistent in water.

This is required for the products that will be sprayed directly to water.

Precautionary Labeling

Based on the above data, precautionary statement for technical Methyl Anthranilate is not needed for freshwater invertebrates.

EFFECTS ON ESTUARINE AND MARINE ORGANISMS

Data describing the acute toxicity of the pesticide to estuarine and marine organisms are required to support the registration of an end-use product intended for direct application to the estuarine or marine environment or if it is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.

Testing of technical Methyl Anthranilate on estuarine/marine species will not be required.

EFFECTS ON NON-TARGET INSECTS

The minimum data requirements for determining toxicity to non-target insects is listed below.

- * 154-11 Nontarget insect testing for beneficial insects (e.g., honey bees) using technical grade material (TGAI).

No studies were submitted. Study is required for terrestrial food and nonfood uses (e.g., orchards, turf, etc.).

Precautionary Labeling

It has not been determined whether label statement is needed.

EFFECTS TO NON-TARGET PLANTS

None submitted. These studies will be waived based on a lack of exposure and infectivity to plants.

The minimum data requirements for determining toxicity to non-target plants is listed below.

* Nontarget plant testing using technical grade material (TGAI).

The guideline requirement is fulfilled by granting of a waiver for this data requirement.

Precautionary Labeling

None needed.

Ecological Effects Disciplinary Review

I. Ecological Effects Profile

A. Manufacturing-Use Methyl Anthranilate

1. Non-Target Terrestrial Studies

There is sufficient information to characterize technical Methyl Anthranilate as **practically non-toxic** to birds on an acute oral basis. Acute single-dose oral LD₅₀ values to bobwhite quail and mallard duck were determined to be >2036 mg/kg (Ahmed 1993, 42966902) and >292 mg/kg (Campbell 1992, 42608807), respectively. When administered through the diet, technical Methyl Anthranilate was found to be **practically non-toxic** to Mallard duck with a LC₅₀ >5620 ppm (Campbell 1992, 42608808), and White-crowned sparrow, Oregon junco, House finch, and Ring-necked pheasant with a LC₅₀ >2200 ppm (Askam 1991, 42966903). These studies were considered scientifically sound but do not fulfill the guideline requirements due to no treated diet being consumed in the Mallard duck study and no chemical analyses submitted on the test diets in the passerine and upland game bird studies.

An avian reproductive study is required as many of the end-use products are intended for avian repellency and can have multiple applications, therefore, high exposure to birds is expected.

An small mammal acute toxicity study was conducted using the rat. The LD₅₀ = 3288 mg/kg (M/F = 3633/3000 mg/kg, respectively) (MRID 42608802). Therefore, Methyl Anthranilate is considered **practically non-toxic** to small

mammals.

2. Non-Target Aquatic Studies

There is **not** enough information to characterize technical Methyl Anthranilate's toxicity to freshwater fish species or freshwater invertebrates. From the **supplemental** data submitted it appears that Methyl Anthranilate may be **moderately to slightly toxic** to freshwater fish species: LC₅₀ = 22.91 ppm for rainbow trout (Clark 1992, 42699802, 42966901), Channel catfish LC₅₀ = 16.23 ppm (Clark 1992, 42718202, 42966901), Atlantic salmon LC₅₀ = 32.35 ppm (Clark 1992, 42699802, 42966901), and Bluegill sunfish LC₅₀ = 9.12 ppm (Clark 1992, 42699803, 42966901). In addition, Methyl Anthranilate is **potentially slightly toxic** to freshwater aquatic invertebrates. The EC₅₀ = 18.2 ppm for Daphnids (Clark 1992, 42718203, 42995103). To complete a risk assessment additional data must be submitted.

No information was provided on estuarine and marine organisms to determine potential toxicity to Methyl Anthranilate.

3. Non-Target Insects Studies

No information was provided to determine toxicity of Methyl Anthranilate to honey bees. Due to the proposed use patterns a study on toxicity to beneficial insects will be required.

4. Non-Target Plant Studies

No information was provided to determine toxicity of Methyl Anthranilate to non-plant species. However, due to the nature of the compound these studies are waived.

II. Ecological Effects Risk Assessment

Submission Purpose and Pesticide Use

Methyl Anthranilate's proposed registration is as a bird repellent for use 1) in orchards (cherries, blueberries, and grapes) 2) at roost sites for Starlings and Sparrows 3) on golf courses and other turf areas 4) water impoundments and chemigation systems 5) landfills 6) standing water.

Table 1
Use Patterns for Methyl Anthranilate

Use Site	Formulation	Appl. Method	Max. Appl. Rate (active ingredient)	Max. No. of Appl. per Year	Pest Species
Orchards (cherries, blueberries, and grapes)	liquid concentrate	commercial or back pack, hand held hose or pressurized applicator	mix 1 part Bird Shield Repellent with 99 parts water	Apply every 6 to 8 days. Repeat as necessary.	Robins, Starlings, Cedar waxwings and native sparrow sp.
Structures, roosts, and nests	liquid concentrate	paint brush, hand-held sprayer, back-pack or pressurized applicator	full strength concentrate or dilute 1 part concentrate with 1 part water	Reapply as necessary to maintain repellency	Starlings and swallows
Water impoundments and chemigation systems	liquid concentrate	Not specified	Mix 1 part concentrate with 99 parts water	Repeat as necessary	Starlings
Golf courses and turf areas	liquid concentrate	Garden spray pump or commercial power sprayer (power blast)	11.6 lbs/acre (5.5 gal/acre spray mixture)	Repeat every four days. Repeat as necessary	Canada geese
Landfills	liquid concentrate	ground driven equipment or airplane	20 kg/ha (20 lbs/acre)	Repeat as necessary	Starlings, brown-headed cowbirds, ring-billed gulls, Canada geese, and mallards
Standing water (tailing ponds, impoundments)	liquid concentrate	apply directly to water	20 kg/ha (20 lbs/acre)	3-4 weeks	Starlings, brown-headed cowbirds, ring-billed gulls, Canada geese, and mallards

There are many gaps in the labels (as shown above) which makes it difficult to complete a risk assessment. In addition, to the available information given above, the labels should also include: maximum amount of ai to be applied per application; maximum number of applications per year; and minimum number of days between each application. Without this information being clearly addressed on the label, it is difficult to accurately determine the amount of ai to be applied and to complete a full risk assessment.

Environmental Persistence

According to EFGWB review based on unpublished draft copy of partial results of research on degradation of methyl anthranilate (Clark, DPBarcode D192327), found methyl anthranilate did not hydrolyze at pH 5 and 7 at 25°C. At pH 9, minor (less than 10%) did occur. UV radiation (intensity not stated) degraded 44% of the parent compound in 19 days. Aerobic microbial metabolism reduced the amount of parent compound by 12, 30, and 42% after 7, 16, and 27 days, respectively when the solutions were illuminated. Aerobic microbial metabolism in the dark reduced methyl anthranilate levels by 22 and 100% in 9 and 20 days, respectively.

Risk to Terrestrial Organisms

End-use Products: for Orchards, Structures, Roosts and Nests, and Water Impoundments and Chemigation Systems

For these products the exposure estimate can not be determined as the application rate (lbs/acre) and maximum number of applications were not included on the label. Therefore, a risk assessment can not be performed on these products.

End-use Products: Golf Courses, Turf Areas, Landfills, Standing Water

A qualitative risk assessment can be performed with the Supplemental acute avian toxicity data and limited use and application information on Methyl Anthranilate. The product for golf courses is to be used at a maximum rate of 11.6 lbs/acre (1.68 lbs ai/ac). In addition, the maximum application rate landfills and standing water is 20 lbs/ac (10 lbs ai/ac). At these rates of application, the following maximum amount of residues available to terrestrial species can be calculated.

Maximum Residues (ppm) Immediately After Application from the Listed Application Rate (lbs ai/acre)

Substrate	1.68	10.0
Short grass	403.2	2400
Long grass	184.8	1100
Leaves & leafy crops	210.0	1250
Forage (alfalfa & clover)/insects	97.4	580
Pods containing seeds	20.2	120
Fruit	11.8	70

From these predicted residue calculations and the Supplemental data from the avian dietary studies it appears that the maximum residue predicted would be approximately equal to (passerine species and upland game species) or half (mallard duck) of the no observed mortality levels. Therefore, minimal acute effects are can be expected.

However, since these products will be applied in high application rates at least two times per week during avian reproductive season a valid chronic study is needed to complete a full risk assessment.

Risk to Aquatic Organisms

A preliminary risk assessment can be performed with the supplemental acute freshwater toxicity data and limited use and application information on Methyl Anthranilate. This risk assessment was based on the information on the liquid concentrate used for golf courses and turf. Ground application of Methyl Anthranilate for golf courses and turf is 11.6 lbs/ac (1.68 lbs ai/ ac) every four days to control Canada geese. Many golf courses contain water bodies including: wetlands, lakes, ponds, rivers, streams and estuaries, therefore, possible exposure of aquatic organisms to Methyl Anthranilate may occur.

Direct Application Model

This model is used when aquatic habitat is in close proximity to the target site; assumes direct application to a 6 inch and 6 foot body of water.

Application rate (lbs a.i./A) X 734 ppb (61 ppb) = EEC

Calculation for 6 inch water layer:

1.68 lbs a.i./A X 734 ppb = 1233.1 ppb (1.233 ppm)

Calculation for 6 foot body of water:

1.68 lbs a.i./A X 61 ppb = 102.5 ppb (0.102 ppm)

Runoff Model

Application rate (lbs ai/A) X 5% (loss rate) X 10 A basin = runoff

1.68 lbs ai/A X 0.05 X 10 A = 0.84 lbs

Indirect exposure

Lbs runoff X 61 ppb = EEC

0.84 lbs X 61 ppb = 51.2 ppb (0.051 ppm)

Potential Risk from Exposure to Methyl Anthranilate in Surface Water to Both Non-Target Organisms and Endangered Species.

	Restricted Use (ppm) (1/10 LC ₅₀)	Endangered Species (ppm) 1/20 LC ₅₀)
Fish -- bluegill	0.91 ¹	0.46 ¹
Invertebrates	1.82 ¹	0.91 ¹

¹. Calculations based on supplemental data, therefore only an estimate.

The preliminary results from the risk assessment with liquid concentrate using the above exposure model and supplemental toxicity data, indicate that triggers are exceeded for both restricted use and endangered species for freshwater fish in the direct application model. Endangered species triggers are exceeded for aquatic invertebrates in the direct application model, as well.

To mitigate any possible effects to aquatic species a 100 foot buffer zone from the edge of any water body is recommended for areas not containing endangered species and 200 foot buffer zone for areas where endangered species occur.

Endangered Species

Based on the available data and use patterns for golf courses and turf the amount of active ingredient used, potential adverse acute effects to avian and mammalian endangered species would be minimal. However, for applications on landfills at the high rates proposed, potential adverse effects to avian and mammalian species may occur.

For fish and aquatic invertebrates endangered species concerns were triggered for use on golf courses and turf areas. Therefore, to mitigate concerns for aquatic species an 200 foot buffer zone is required where endangered species occur.

Adequacy of Toxicity Data

The following list of studies are needed to complete EEB's ecological risk assessment on Methyl Anthranilate for products not contained in a solid matrix or impregnated material.

- 154-7 Avian acute dietary
- 71-4 Avian reproduction
- 154-8 Acute freshwater fish LC₅₀ study with rainbow trout using both TGAI and TEP.
- 72-4 Fish early life-stage (only for end-use products where directly applied to water)
- 154-11 Beneficial insect study.

Fate data are also requested (soil half-life, and solubility).

Precautionary Labeling

Do not contaminate water when disposing of equipment washwater or rinsate.

In addition, the labels need to include the amount of active ingredient to be applied per application per acre; maximum number of applications per year; minimum number of days between each application, and density of formulations.

CONCLUSIONS:

EEB has reviewed the proposed registration of Methyl Anthranilate as a bird repellent in orchards (blueberries, cherries, and grapes), golf courses, landfills, roost sites, standing water, and water impoundments and chemigation sites. Due to the lack of Core data and incomplete information on use patterns (labels) risk assessments could not be completed on all proposed uses for Methyl Anthranilate.

A preliminary risk assessment using for terrestrial species for proposed use on golf courses and landfills was done. Results indicate minimal acute effects expected when the product is applied to golf courses, turf, and landfills.

For aquatic exposure a preliminary risk assessment was done using supplemental data for the product to be applied on golf courses and turf. The results indicate that triggers are exceeded for both restricted use and endangered species for freshwater fish for the direct application model. Endangered species triggers are exceeded for aquatic invertebrates in the direct application model, as well. To mitigate any possible effects to aquatic species a 100 foot buffer zone from the edge of any water body is recommended and 200 foot buffer zone for areas where endangered species occur.

Date: 3 June 1994
 Case No: 8125
 Chemical No: 128725
 Chemical: Methyl Anthranilate

**PHASE V
 DATA REQUIREMENTS FOR
 ECOLOGICAL EFFECTS BRANCH**

Data Requirement ¹	Test ¹ Substance	Use ² Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	
<u>§158.740 Biochemical Pesticide Nontarget Organism - Tier I</u>						
<u>Avian Testing</u>						
154-6	Avian Acute Oral					
	- upland gamebird	TGAI	A,B,D	Yes	42966902	No
	- waterfowl	TGAI	A,B,D	Yes	4260880	No
154-7	Avian Dietary					
	- passerine species	TGAI	A,B,D	Yes	42966903	No
	- waterfowl	TGAI	A,B,D	Yes	42608808	Yes
71-4	Avian Reproduction					
	- upland gamebird	TGAI	A,B,D	No		Yes
	- waterfowl					
<u>Aquatic Organism Testing</u>						
154-8	Freshwater Fish LC ₅₀					
	- rainbow trout	TGAI TEP	A,B,D D	Yes No	42699802,42966901 ---	Yes ³ Yes ⁴
	- bluegill sunfish	TGAI	A,B,D	Yes	42699803,42966901	Yes ³
154-9	Freshwater Invertebrate					
	- <u>Daphnia magna</u>	TGAI TEP	A,B,D D	Yes No	42718203,42995103 ---	No Yes ⁴
72-3	Estuarine and Marine					
	- estuarine fish	TGAI	A,B,D	No	---	No
	- shrimp	TGAI	A,B,D	No	---	No
	- mollusc	TGAI	A,B,D	No	---	No
154-13	Aquatic animal testing (Tier III)					
	fish early life	TGAI	D	No	---	Yes
	- <u>Daphnia magna</u> life-cycle (72-4)	TGAI	A,B,D	No	---	Reserved
<u>Additional Testing</u>						
154-10	Nontarget plant studies					

- terrestrial	TGAI	A,B,D	No	---	Waived
- aquatic	TGAI	A,B,D	No	---	Waived
154-11 Nontarget insect testing					
- honey bee	TGAI	A,B,D	No	---	Yes

1/ TGAI = Technical Grade of the 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/ Only one freshwater fish study is required.

4/ These data are required to support all aquatic nonfood uses.