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

MEMORANDUM

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: METOLACHLOR

FROM: Anthony F. Maciorowski
Ecological Effects Branch

TO: Kathy Monk
SACS

Enclosed are the following:

1. RED for Metolachlor
2. Response to CIBA-GEIGY in relation to avian reproduction studies and other aquatic studies
3. DER's for aquatic studies
4. Data Requirement Table

The following are the Levels of Concern that were exceeded:

1. High risk LOC for avian chronic at the lowest application rate of 2 lbs ai/acre

2. Restricted Use LOC for the meadow vole at the highest application rate of 6 lb ai/acre

3. Restricted use LOC for aquatic organisms on an acute basis for rights of way use

4. High risk LOC for aquatic organisms on a chronic basis for the rights of way use.

5. Endangered species LOC was triggered for
   a. avian acute and chronic
   b. small mammals
   c. aquatic organisms acute (rights of way use) and chronic

If you have any questions please contact Conchi Rodríguez (308-2805) or Harry Craven (305-5320).

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ECOLOGICAL EFFECTS BRANCH
SCIENCE CHAPTER FOR
REREGISTRATION ELIGIBILITY DOCUMENT
FOR METOLACHLOR

A. Ecological Hazard

1. Topical Summaries

a. Effects to Non-Target Birds

The following studies have been evaluated under this topic. Four studies were used in performing a risk assessment.

Author	MRID#
Fink	15547
Fink	16426
Fink	16425
Ciba-Geigy	162292
Ciba-Geigy	162293

In order to establish the toxicity of metolachlor to birds, the minimum data required on the technical material are:

- An avian single-dose LD50 test with either one species of waterfowl, preferably the mallard, or one species of upland gamebird, preferably bobwhite (section 71-1); and

- Two avian dietary LC50 tests, one with a species of waterfowl, preferably the mallard, and one with a species of upland gamebird, preferably the bobwhite (section 71-2).

Avian Acute Oral Toxicity - Technical

An acceptable acute oral toxicity study on metolachlor is listed below.

Species	Test Material	Results (ai)	Author	Date	MRID	Fulfills Req.
Mallard	Tech	LD50=4640 mg/kg	Fink	1978	15547	yes

Avian Dietary Toxicity - Technical

The acceptable avian dietary toxicity studies on technical metolachlor are listed below:

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Species	Test Material	Results (ai)	Author	Date	MRID	Fulfills Req.
Mallard	Tech	LC50>10,000 ppm	Fink	1974	16425	yes
Bobwhite	Tech	LC50>10,000 ppm	Fink	1974	16426	yes

The guideline requirements for acute avian toxicity testing have been fulfilled. These test results show that metolachlor is practically non-toxic to birds.

Avian Reproduction Studies - Technical Metolachlor

Avian reproduction studies are required because of repeat application to peanuts, corn, and potatoes and because this is a persistent chemical (half life ranging from 7 to 292 days). In order to establish the chronic toxicity of metolachlor to birds, the data required on the technical material are:

- Two avian reproduction studies, one with a species of waterfowl, preferably the mallard, and one with a species of upland gamebird, preferably the bobwhite quail.

Avian reproduction studies on technical metolachlor are listed below.

Species	Test Material	Results (ai)	Author	Date	MRID	Fulfills Req.
Bobwhite	97.0%	LOEL 10 ppm	Ciba-Geigy	1978	162393	No[1]
Mallard	97.0%	LOEL 10 ppm	Ciba-Geigy	1978	162392	No[2]

b. Effects to Non-Target Fish

Seven studies contained in four citations have been evaluated under this topic. Two studies were used in performing a risk assessment.

Author	MRID#
Buccafusco	18722
Buccafusco	18723
Sachsse et al.	15534
EG&G Bionomics	470257-23

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[1]Study was found unacceptable because the percentage of eggs cracked was very high at all doses (10, 300, 1000 ppm). A new study is required.

[2]Study is classified as supplemental. A new study is required to confirm the results of the study.

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Fish Acute Toxicity Tests - Technical

The minimum data required for establishing the acute toxicity of metolachlor to fish are the results from two 96-hour studies with the technical product. One with coldwater species, preferably rainbow trout, the other with a warm water species, preferably bluegill sunfish (section 72-1). The fish studies are listed below.

Species	Test Material	Results (ai)	Author	Date	MRID	Fulfills Req.
Rainbow trout	Tech.	LC50=3.9 ppm	Buccafusco	1978	18722	yes
bluegill sunfish	Tech.	LC50=10 ppm	Buccafusco	1978	18723	yes
Bluegill sunfish	Tech.	LC50=15 ppm	Sachsse et al.	1974	15534	no[3]
Crusian carp	Tech.	LC50=4.9 ppm	Sachsse et al.	1974	15534	no[4]
Channel catfish	Tech.	LC50=4.9 ppm	Sachsse et al.	1974	15534	yes
Guppy	Tech.	LC50=8.6 ppm	Sachsse et al.	1974	15534	no[4]

Three of the studies fulfill the guideline requirement for fish acute toxicity tests for metolachlor with technical material. They show that technical metolachlor is moderately toxic to freshwater fish in acute exposures.

Fish Full Life Cycle Test - Technical Metolachlor

A fish early life stage study is required because of repeat application to peanuts, corn, and potatoes and because this is a persistent chemical (half life ranging from 7 to 292 days). In order to establish the chronic toxicity of metolachlor to fish, the data required on the technical material is the following:

- A fish early life stage with one of the recommended species

The fish full life cycle study is listed below.

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[3] Study was classified as supplemental because of deviations from the recommended temperature.

[4] This is not an acceptable test species.

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Species	Test Material	Results[5] (ppm)	Author	Date	MRID	Fulfills Req.
Fathead minnow	97.4%	NOEC=0.78 LOEC=1.6 GM = 1.17	EG&G Bionomics	1978	470257-23	part.[6]

c. Effects to Non-Target Aquatic Invertebrates

Two study has been reviewed and one study was used to perform a risk assessment on aquatic invertebrates.

Author	MRID#
Vilkas Rufli	430446-03

Acute Aquatic Invertebrate Testing - Technical

The minimum data requirement for establishing the acute toxicity of metolachlor to aquatic invertebrates is the result from one 48-hour acute toxicity test with the technical product (section 72-2). The acceptable test is listed below.

Species	Test Material	Results (ai)	Author	Date	MRID	Fulfills Req.
Daphnia magna	Tech.	EC50=25.1 ppm	Vilkas	1977		yes

This study fulfills the requirements for an acute toxicity test with aquatic invertebrates and shows that metolachlor is slightly toxic to aquatic invertebrates in acute exposures.

Aquatic Invertebrate Reproduction Testing - Technical

This study is required because of repeat application to peanuts, corn, and potatoes and because this is a persistent chemical (half life ranging from 7 to 292 days). In order to establish the chronic toxicity to aquatic invertebrates the following study is required:

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[5]The most sensitive parameter was length.

[6]Study was classified as supplemental. The results will be used in the risk assessment. The study will be considered as a Fish Early Life Stage 74-4(a).

- An aquatic invertebrate reproductive test with the water flea, Daphnia magna

The following study does not fulfill guideline requirements

Species	Test Material	Results (ppm)	Author	Date	MRID	Fulfills Req.
Daphnia magna	96.4%	NOEC=0.5 LOEC=2.8 GM = 1.2	Rufli	1989	43044303	No[7]

d. Effects to Non-Target Estuarine and Marine Organisms

Metolachlor is registered for uses which will expose estuarine organisms to the pesticide. Such uses include cotton, corn, peanuts, turf, sorghum, soybeans, and right of way. To establish the toxicity of metolachlor to non-target estuarine/marine organisms, the following studies are required:

72-3(a) Acute Estuarine/Marine Toxicity Fish
72-3(b) Acute Estuarine/Marine Toxicity Mollusk
72-3(c) Acute Estuarine/Marine Toxicity Shrimp

Two studies contained in one citation has been evaluated under this topic. The studies were used in performing the risk assessment.

Author	MRID No.
Ward	1980

Estuarine/Marine Fish Toxicity Tests - Technical

The submitted fish study is listed below.

Species	Test Material	Results	Author	Date	MRID	Fulfills Req.
Sheepshead minnow	97.0%	LC50 = 7.9 ppm	Ward	1980	430446-02	Part.[8]

[7]The study is classified as invalid because the number of young daphnids produced at the control was very low. Also the concentrations of the fresh solutions were not measured.

[8]The combination of the acute fish toxicity study and the fish early life stage will fulfill the guideline requirements.

The guideline requirement is fulfilled for the esturine/marine fish. The study shows that technical metolachlor is slightly toxic to estuarine marine fish. The guideline requirements are not fulfilled for the shrimp and oyster.

Fish Early Life Stage

Chronic estuarine/marine fish toxicity study was submitted. The study is the following:

Species	Test Material	Results[9] (ppm)	Author	Date	MRID	Fulfills Req.
Sheepshead minnow	97.0%	NOEC=1.0 LOEC=2.2 GM = 1.48	Ward	1980	430446-02	Part.[1]

The studies shows that the geometric mean of the NOEC and LOEC for sheepshead minnow is 1.48 ppm based on length which was the most sensitive parameter.

A esturine/marine invertebrate life cycle study (72-4(b)) is placed in reserved pending the results of the other acute estuarine studies.

e. Effects to Non-Target Plants

Non-target plant studies are required for any herbicide used on terrestrial food and terrestrial non-food sites if they are applied by ground rigs and the water solubility is greater than 10 ppm (metolachlor solubility is 530 ppm), or the vapor pressure is greater than 1.0×10^5 mmg Hg at 25 C (metolachlor vapor pressure is 1.3×10^5 mmg Hg at 25 C). and the TEP is not thoroughly incorporated immediately after application (aerial application and chemigation). To establish the toxicity of metolachlor to non-target plants, the following studies are required:

- A seed germination/seedling emergence study
- A vegetative vigor study
- An aquatic plant growth study

No studies were submitted for evaluation. The following studies are required:

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[9]The most sensitive parameter was length.

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123-1(a) Seed Germination\Seedling Emergence
123-1(b) Vegetative Vigor
123-2 Aquatic Plant Growth[10]

B. Disciplinary Review

1. Non-Target Terrestrial

Studies show that metolachlor is practically nontoxic to birds. An acute oral study resulted in an LD50 = 4640 mg/kg for mallard duck (MRID No. 15547). Avian dietary studies demonstrate an LC50 of >10,000 ppm for both mallard (MRID No. 16425) and bobwhite quail (MRID No. 16426).

One supplemental avian reproduction study for the mallard duck shows that the LOEL level is 10 ppm based on egg shell thickness (MRID No. 162292). No acceptable avian reproduction study is available for bobwhite quail.

2. Non-Target Aquatic

Metolachlor has been demonstrated to be moderately toxic to freshwater fish with a 96-hr LC50 of 10 ppm for the bluegill (MRID No. 18723), and 3.9 ppm for the rainbow trout (MRID No. 18722).

An acute aquatic invertebrate study shows a 48-hr EC50 of 25.1 ppm to *Daphnia magna* which characterizes metolachlor as slightly toxic to aquatic invertebrates in acute exposures (MRID No.).

A supplemental acute estuarine marine fish study shows that metolachlor is slightly toxic to fish with and LC50 of 7.9 ppm (MRID No. 430446-02).

A supplemental fish early life study shows that the MATC for the fathead minnow is 1.17 ppm (MRID No.470257-23). The most sensitive parameter was length. A supplemental fish early life stage for an estuarine/marine shows that the most affected parameter was length. The MATC is 1.48 ppm (MRID No. 430446-02).

No data is available for the life cycle aquatic invertebrate not for the estuarine/marine mollusk and shrimp.

3. Non-Target Plants

No data is available.

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[10] The study should be conducted on each of the following species: *Selenastrum capricornutum*, *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom.

C. Ecological Effects Risk Assessment

1. Use Profile

Metolachlor is a herbicide used to control grassy weeds and certain broadleafs. Metolachlor is formulated as a granular, emulsifiable concentrate, and a liquid form not identified in the LUIS report.

Terrestrial Food/Feed uses include (from LUIS Report): alfalfa, cabbage, corn (unspecified) corn field, corn pop, corn sweet, cotton (unspecified), legume vegetables, lupine, peanuts (unspecified), peas (unspecified), pepper (chili type), pepper (tabasco), potato white/irish, radish, safflower (unspecified), sorghum, sorghum (unspecified), soybeans (unspecified), stone fruits, tree nuts.

Terrestrial Non-Food uses include (from LUIS Report): agricultural rights of way/fencerows/hedgerows, airport/landing fields, apple, cherry, Christmas tree plantations, commercial/industrial lawns, crabapple, forest tress (softwood, conifers), golf course turf, grapes, non agricultural rights of way/fencerows/hedgerows, non agricultural uncultivated areas/soils, ornamental and/or shade trees, ornamental herbaceous plants, ornamental lawns and turf, ornamental non-flowering plants, ornamental woody shrubs and vines pear, recreation area lawns, recreation areas, residential lawns.

The information on application rates for terrestrial food/feed uses is from Residue Chemistry Branch. The information on application rates for terrestrial non-food uses is from the LUIS Report.

2. Environmental Fate Profile

Although the environmental fate data base is not complete the information from all acceptable and upgradeable environmental fate data from the 1980 Registration Standard to present indicate that parent metolachlor appears to be **moderately persistent** to **persistent**. It also ranges from **mobile** to **highly mobile** in different soils and it has been detected in ground water. Metolachlor is stable to hydrolysis under normal environmental conditions of pH 5.0, 7.0, and 9.0. Metolachlor degradation appears to be dependent on microbial mediated (aerobic soil metabolism t 1/2 = 67 days, anaerobic soil metabolism t1/2 = 81 days) and abiotic processes (photodegradation in water t 1/2 = 70 days under natural sunlight and photodegradation on soil t1/2 = 8 days under natural sunlight).

Depending on the soil characteristics metolachlor has the potential to range from moderately mobile to highly mobile material (Kd values ranging from 0.08 to 4.81). Upgradeable field dissipation studies indicate that metolachlor is persistent in the

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surface soil (t1/2 ranging form 7 days to 292 days in the upper 6 inch soil layer). Metolachlor was reportedly detected as far as the 36 to 48 inch soil layer in some of the studies. Some of the degradates were also detected as far as 36 to 48 inch depth.

Metolachlor appears to have a low potential to bioaccumulate in fish with a reported whole body bioconcentration factor of 69 and a whole body elimination of 93% after 14 days depuration. In an upgradeable confined accumulation in rotational crop study 14C metolachlor residues accumulated in lettuce, beets, and wheat planted 115 days after metolachlor was applied. Total 14C residues were 0.32 ppm, 0.14 ppm, and 1.17 ppm in wheat stalks, grain, and hulls respectively.

The pesticide in ground water data base indicates that residues of metolachlor were detected in wells in 20 states. Levels exceeded the Health Advisory level (100 ppm) in 3 wells in Wisconsin, New York, and Montana. In 8 other states concentrations in some well waters exceeded 10% of the HA.

3. Risk Assessment

a. Non-Endangered Terrestrial Organisms

Metolachlor is registered for numerous outdoor uses. Exposure to non-target organisms can result from direct applications, spray drift from treated areas and runoff from treated areas. Such exposures can be both chronic as well as acute.

Granular Products

The acute oral study showed that metolachlor is practically non-toxic. The maximum application rate as a granular formulation is 4 lb ai/acre. For broadcast application with no incorporation the LD50/ft^2 = 0.007. ~~The LD50 per day was calculated as 0.008 (See Appendix 1 for calculations)~~. These values do not exceed the levels of concern (Table 1). We are assuming the same LD50/ft^2 for banding. See Appendix 1 for calculations.

Table 1. Comparison of LD50/ft^2 ~~and LD50/day~~ to the LOC for the highest granular application rate of metolachlor. (LD50 = 4640)

Maximum Application Rate	Method of Application	LD50/ft^2	~~LD50/day~~	LOC
4 lbs ai	Broadcast (no incorporation)	0.007	~~0.008~~	High Risk ≥ 0.5 RU ≥ 0.2 ES ≥ 0.1

RU = Restricted Use ES = Endangered Species

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Non Granular Products

Studies show that metolachlor is practically non toxic to birds on an acute dietary basis. Acute effects are not expected at any application rate for waterfowl or upland game birds. At the highest application rate of 6 lbs ai/acre, the risk quotient is less than the LOC (Table 2). The LOC for endangered birds is exceeded. Please refer to the Endangered Species Section.

Table 2. Risk Quotient and LOC for the lowest and highest application rate of metolachlor. (LC50 = 10,000 ppm See Appendix 2 for EEC table)

Use Site	Application Rate	Substrate (EEC)	Risk Quotient (EEC/LC50)	LOC
Cabbage, Pepper Chili,Cotton, Seed Radish	2 lbs ai	Short Grass (480)	0.048	High Risk ≥ 0.5 RU ≥ 0.2 ES ≥ 0.1
Corn, Peanuts, Alfalfa, Potatoes	6 lbs ai	Short Grass (1440)	0.144	High Risk ≥ 0.5 RU ≥ 0.2 ES ≥ 0.1

RU = Restricted Use ES = Endangered Species

Preliminary chronic effects can be assessed only for waterfowl. A mallard duck reproduction study was submitted to the Agency and reviewed in 1979. This study was classified as core at that time. However, the Agency reevaluated this study and determined it to be supplemental. A preliminary evaluation of the study shows that the LOEL is 10 ppm. Based on that LOEL, chronic effects are expected as a result of the use of metolachlor. As seen on Table 2, the risk quotients exceed the LOC at all application rates.

Table 2. Chronic Risk Quotient and LOC for the lowest and highest application rate of metolachlor, based on a LOEL of 10 ppm.

Use Site	Application Rate	Substrate (EEC)	Risk Quotient (EEC/LOEL)	LOC
Cabbage, Pepper Chili, Cotton, Seed Radish	2 lb ai	Short Grass(480)	48	High Risk ≥ 1
		Seeds (24)	2.4	
Corn, Peanuts	6 lbs ai	Short Grass (1440)	144	
		Seeds (72)	7.2	

There is no available information to conduct a risk assessment on non-target terrestrial plants. However, since metolachlor is a herbicide, risk to terrestrial non-target plant is expected.

Small Mammals

An acute rat study indicated that the LD50 for the rat is 2780 mg ai/kg. EEB estimates the LC50 from the LD50, body weight and food consumption (See Appendix 2). A representative of an herbivore (meadow vole LC50 = 4567 ppm), a granivore (deer mouse LC50 = 17,209 ppm) and of an insectivore (least shrew LC50 = 2528) are used to estimate the risk to small mammals. Application of 2 lb ai of metolachlor (lowest application rate) does not pose a risk to non-endangered small mammals since the estimated risk quotient does not exceed the Level of Concern for any of the species (Table 3). Application of 6 lbs ai/acre triggers the restricted use for meadow vole posing a risk to granivores. The risk quotient of 0.31 is higher than the LOC of 0.2. Rates below 3.75 lbs ai/a do not exceed the risk quotient. The LOC is exceeded for endangered species at application rates > 2 lbs ai/acre. Please refer to Endangered Species Section.

Table 3. Expected foods, estimated environmental concentration and LC50 for three small mammals representing different food preferences. See Appendix 2 for EEC calculations.

Use Sites	Maximum Application	Species (LC50)	Expected Food (EEC ppm)	Risk Quotient	LOC
Cabbage, Pepper, Chili, Cotton, Seed Radish	2 lbs ai	Meadow Vole (4567 ppm)	Grasses (480)	0.1	HR ≥ 0.5 RU ≥ 0.2 ES ≥ 0.1
		Least Shrew (2528 ppm)	Insects (116)	0.04	
		Deer Mouse (17,209 ppm)	Seeds (24)	0.001	
Corn, Peanuts	6 lbs ai	Meadow Vole (4567 ppm)	Grasses (1440)	0.31	HR ≥ 0.5 RU ≥ 0.2 ES ≥ 0.1
		Least Shrew (2528 ppm)	Insects (348)	0.13	
		Deer Mouse (17,209 ppm)	Seeds (72)	0.003	

HR = High Risk, RU = Restricted Use, ES = Endangered Species

Aquatic Organisms

The available information indicates that metolachlor is moderately to slightly toxic to fish or aquatic invertebrates on an acute basis. No acute effects are expected as a result of the use of metolachlor when a 6 foot scenario is employed. The risk quotients are less than the levels of concern at the lowest and highest application rate (Table 4). However, for the right of way use a shallower pond scenario is used. Application of 4 lb ai/acre triggers the restricted use and endangered species LOC for a pond 1 foot or less deep (see Table 4).

triggers the restricted use and endangered species LOC for a pond 1 foot or less deep (see Table 4).

Table 4. Acute Risk Quotient and LOC for the lowest and highest application rate of metolachlor. (LC50 = 3.9 ppm, for EEC calculation see Appendix 2)

Use Site	Application Rate	Depth (EEC ppm)	Risk Quotient (EEC/LC50)	LOC
Cabbage, Pepper Chili, Cotton, Seed Radish	2 lbs ai	6 ft (0.061)	0.01	High Risk ≥ 0.5 RU ≥ 0.1 ES ≥ 0.05
Rights of Way	4 lbs ai	6 ft	0.03	High Risk ≥ 0.5 RU ≥ 0.1 ES ≥ 0.05
		1 ft	0.17	
		6 inches	0.3	
Corn, Peanuts, Alfalfa, Potatoes	6 lbs ai	6 ft (0.186)	0.04	High Risk ≥ 0.5 RU ≥ 0.1 ES ≥ 0.05

RU = Restricted Use ES = Endangered Species

No chronic effects to freshwater or estuarine/marine fish are expected from the use of metolachlor when a scenario of a 6 foot pond is considered. The risk quotients for the lowest and highest application rate do not exceed the level of concern (Table 5). However, chronic effects are expected from the rights of way use. An application rate of 4 lbs ai/acre triggers the LOC for a 6 inch deep pond scenario (see Table 5).

Table 5. Chronic Risk Quotient and LOC for the lowest and highest application rate of metolachlor. (Geometric Mean (GM) of NOEL and LOEL = 1.17 ppm)

Use Site	Application Rate	Depth (EEC ppm)	Risk Quotient (EEC/GM)	LOC
Cabbage, Pepper Chili, Cotton, Seed Radish	2 lbs ai	6 ft (0.061)	0.05	High Risk ≥ 1
Rights of Way	4 lbs ai	6 ft (0.122)	0.07	High Risk ≥ 1
		1 ft (0.735)	0.62	
		6 inches (1.4)	1.19	
Corn, Peanuts, Alfalfa, Potatoes	6 lbs ai	6 ft (0.186)	0.15	High Risk ≥ 1

RU = Restricted Use ES = Endangered Species

No data is available to perform a risk assessment for estuarine/marine invertebrates and for a chronic risk assessment for a freshwater invertebrate. Based on the available aquatic

data, the risk to estuarine and freshwater invertebrates is not expected to be substantially different than the risk to fish.

An aquatic plant risk assessment cannot be performed. No data is available. However since metolachlor is a herbicide risk to aquatic plants is expected.

b. Endangered Species

The level of concern for endangered birds on an acute basis is triggered. At application rates less than 4 lb ai/acre, there are no acute concerns for endangered birds. At application rates higher than 4 lbs ai/acre the risk quotient exceeds the level of concern (Table 6). Chronic effects are expected for endangered birds (See Table 3).

Table 6. Risk Quotient and LOC showing the application rate at which the level of concern is not triggered for endangered species in comparison to the highest application rate of metolachlor

Use Site	Maximum Application Rate	Substrate (EEC)	Risk Quotient (EEC/LC50)	LOC
Cabbage, Pepper Chili, Cotton, Seed Radish	2 lbs ai	Short Grass (480)	0.05	High Risk ≥ 0.5 RU ≥ 0.2 ES ≥ 0.1
Soybeans, Tree Nuts, Grapes, Stone Fruits, Citrus, Tabasco, Pepper	4 lbs ai	Short Grass (960)	0.09	High Risk ≥ 0.5 RU ≥ 0.2 ES ≥ 0.1
Corn, Peanuts, Alfalfa, Potatoes	6 lbs ai	Short Grass (1440)	0.14	High Risk ≥ 0.5 RU ≥ 0.2 ES ≥ 0.1

RU = Restricted Use ES = Endangered Species

No acute or chronic effects are expected for endangered freshwater and estuarine/marine fish except for the rights of way use. This use represent an acute and chronic concern for endangered fish (Tables 4 and 5). No risk assessment can be performed for endangered freshwater invertebrates and estuarine/marine invertebrates and mollusk.

No plant data is available to conduct a risk assessment. However, since metolachlor is a herbicide, risk to endangered plants is expected.

The Endangered Species Protection Program is expected to become final in 1994. Metolachlor has existing biological opinions for which EPA will require generic endangered species label statement (or equivalently protective alternative) when the program is in place. Additional consultation with the Fish and Wildlife Service will be required to address newly listed species and also any use sites not previously considered. However, no additional label changes are anticipated as a result of consultation if the label already contains the generic label statement

c. Risk Mitigation

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The **maximum expected residues** on all avian food items for all uses of non granular metolachlor exceed our avian chronic level of concern of 10 ppm. Residues higher than 10 ppm are expected at the lowest application rate of 2 lbs ai/A. An exposure scenario using **typical residues** for an application rate of 2 lbs ai/A also predicts residues on most avian food items higher than 10 ppm (Table 7). Even residues six weeks after application are within our levels of concern since the data available does not provide a no effect level. This shows that even when looking at **typical** residues, the use of metolachlor still poses a chronic risk for avian species.

Table 7. Typical Residues and residues six weeks after application of Metolachlor on different avian food items for an application rate of 2 lbs ai/a.

Substrate	Typical Residues (ppm)	Residues 6 Weeks After Application (ppm)
Short Grass	250	10
Long Grass	184	2-10
Leaves and Leafy Crops	70	<2
Forage, (alfalfa) Insects	66	<2
Pods Containing Seeds	6	<2
Fruit	3	0.4

Reduction in the rate of application is a way of mitigating the risk. If the rate is reduced to 0.08 lb ai/a the risk to birds is minimized (Table 8). This application rate reduces the expected typical residues even to short grass to values of 10 ppm and lower. However, since a no effect level is not known these values may still represent levels of concern.

Table 8. Maximum and typical residues on avian food items after an application rate of 0.08 lb ai/A

Substrate	Maximum Residues	Typical Residues
Short Grass	19.2	10
Long Grass	8.8	7.36
Leaves and Leafy Crops	10	2.8
Forage (Alfalfa), Insects	4.64	2.64
Pods Containing Seeds	0.96	0.24
Fruits	0.56	0.12

Another way for mitigation will be to examine the application methods and try to reduce the exposure. Application methods include incorporated, non-incorporated and air application. The incorporated methods reduce the exposure to wildlife. However, several of the uses of metolachlor require broadcast application to the crop itself thereby exposing wildlife to the pesticide.

Our major concern is for the application methods that are not incorporated (See Appendix 3). In the case of alfalfa and other

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crops, application is directly over the crop creating a scenario where residues are going to be found on the food items. Residues in alfalfa itself exceed our level of concern. If only incorporated methods are allowed then there will be a reduction in the exposure consequently reducing the risk to birds.

Air application to bare soil and crops represent another concern because of drift. Residues on vegetation at the edges of the fields receive direct application and contain residues that exceed the avian chronic level of concern. Assuming a 5% drift, residues in short grass, long grass, leaves and leafy crops exceeds our level of concern of 10 ppm (Table 9).

Table 9. Residues found on avian food items the edge of the field after an application of 2 lbs ai/A assuming 5% drift.

Substrate	EEC Assuming 5% Drift (ppm)
Short Grass	24
Long Grass	11
Leaves and Leafy Crops	12
Forage (Alfalfa), Insects	5.8
Pod Containing Seeds	1.2
Fruit	0.7

We are proposing the following risk mitigation measures to protect non-endangered and endangered aquatic and terrestrial organisms: to reduce the application rate, to permit incorporation only, to reduce the number of applications to one, to prohibit aerial application.

Added Value of the Information

At the present, an acute risk assessment for estuarine/marine invertebrates, a chronic risk assessment for freshwater invertebrate and for plants, cannot be completed. A definitive chronic risk assessment cannot be completed for birds because under the conditions of high egg cracking a NOEL value could not be determined.

A risk assessment based on a single application to alfalfa (site with highest application rate) shows that there are no **acute** concerns for freshwater fish or aquatic invertebrates. However, a single application shows there is chronic risk to birds. Not only is metolachlor considered to be persistent, but at least one site, peanuts, allows for three applications in a season. Consequently, there is additional certainty as to the chronic effects birds and unknown certainty for aquatic organisms. Metolachlor is one of the most heavily used herbicides in the United States therefore, a complete data base should be in the Agency in order to conduct a more thorough risk assessment.

C. Labeling

a. Manufacturing Use

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

b. End-Use

Granular and Non Granular End-Use Products

"Do not apply directly to water, or to areas where surface after is present or to intertidal areas below the mean high-water mark. Do not contaminate water when disposing of equipment washwater or rinsate."

D. Data Requirements

The guideline requirements for avian reproduction study for the quail are not fulfilled. The following is a data requirement:

71-4 (a) Avian Reproduction Quail
71-4 (b) Avian Reproduction Duck

This study is required because of the repeated applications and persistence of the chemical.

The guideline requirements for estuarine/marine studies are not fulfill. The following studies are required:

72-3(b) Acute Estuarine/Marine Toxicity Mollusk
72-3(c) Acute Estuarine/Marine Toxicity Shrimp

The studies are required because the following use patterns are associated with estuarine/marine areas: corn, cotton, peanuts, sorghum, soybeans, and golf course turf.

The guideline requirement for life cycle aquatic invertebrate is not fulfill. The following study is required.

72-4(b) Life Cycle Aquatic Invertebrate

This study is required because of the repeated applications and persistence of the chemical.

The guideline requirements for non-target plants are not fulfilled. The following studies are data gaps:

123-1(a) Seed Germination\Seedling Emergence
123-1(b) Vegetative Vigor

123-2 Aquatic Plant Growth[11]

Non-target plant studies are required for any herbicide used on terrestrial food and terrestrial non-food sites if they are applied by ground rigs and the water solubility is greater than 10 ppm (metolachlor solubility is 530 ppm), or the vapor pressure is greater than 1.0×10^5 mmg Hg at 25 C (metolachlor vapor pressure is 1.3×10^5 mmg Hg at 25 C). and the TEP is not thoroughly incorporated immediately after application (aerial application and chemigation).

[11] The study should be conducted on each of the following species: Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, and a freshwater diatom.

APPENDIX 1

Calculation of Number of Single Dose Oral LD50's per Square Foot
LD50 = 4640 mg/kg

1. For Broadcast Application

mg/ft^2 = lbs ai/acre X 453,590 mg/lb ÷ 43,560 ft^2/acre

= 4 lbs ai/acre X 453,590 mg/lb ÷ 43,560 ft^2/acre

= 41.65 mg/ft^2

$LD50/ft^2$ = mg/ft^2 ÷ (LD50) X (weight bird kg)

= 41.65 mg/ft^2 ÷ (4640 mg/kg) X (1.2 kg)

= 0.0067 $LD50/ft^2$

LD50 per day = (highest expected residue) X (% body weight eaten/day) ÷ LD50

= (4 lb ai X 240 ppm) X (0.04) ÷ 4640

= 0.008

APPENDIX 2

Maximum EEC expected immediately after a single application for different application rates (lbs ai/A) on different avian food items.

Application Rate	Short Grass	Long Grass	Leaves and Leafy Crops	Forage	Pod Containing Seeds	Fruits
2 lbs[12]	480	220	250	116	24	14
2.5 lbs[13]	600	275	312.5	145	30	17.5
3 lbs[14]	720	330	375	174	36	21
4 lbs[15]	960	440	500	232	48	28
5 lbs[16]	1200	550	625	290	60	35
5.5 lbs[17]	1320	605	687.5	319	66	38.5
6 lbs[18]	1440	660	750	348	72	42

[12]Cabbage, Pepper Chili, Cotton, Seed Radish

[13]Sorghum (all types)

[14]Pod Crops (peas), Safflower

[15]Soybeans, Tree Nuts, Grapes, Stone Fruits, Citrus, Tabasco, Pepper, Apple, Cherry, Crabapple, Pears, Airport Landing fields, Christmas Tree Plantations, Commercial/Industrial Lawns, Non/Agricultural Uncultivated Areas/Soils, Ornamental and or Shade Tree, Ornamental Herbaceous Plants, Ornamental Lawns and Turf, Residential Lawns, Recreational Areas, Recreational Areas Lawn, Ornamental Non Flowering Plants, Golf Course Turf, Non Agricultural Rights of Way, Forest Tree (Softwood, Conifers)

[16]Alfalfa

[17]Potatoes, seasonal application

[18]Corn, Peanuts seasonal application

APPENDIX 3

CALCULATION SHEET FOR ESTIMATED ENVIRONMENTAL CONCENTRATION (EEC)

For ground application of Metolachlor for 2 lbs ai/acre and a seasonal rate of 6 lbs ai/acre to corn or peanuts. Metolachlor solubility is 560 ppm.

A. 2 lbs ai/acre unincorporated ground application

2 lbs	X	0.05 (5% runoff)	x	10 (A) (10 A drainage basin)	=	1 lbs Total Runoff

EEC of 1 lb ai direct application to 1 acre pond 6-feet deep is 61 ppb.

Therefore EEC = 61 ppb X 1 lbs = 61 ppb = 0.61 ppm

B. 4 lbs ai/acre unincorporated ground application

4 lbs	X	0.05 (5% runoff)	X	10 (A) (10 A drainage basin)	= 2 lbs Total Runoff

EEC of 1 lb ai direct application to 1 acre pond:
6 feet deep = 61 ppb
1 foot deep = 367.2
6 inches deep = 734

Therefore:

EEC for 6 feet	=	61	X	2 lbs	=	122 ppb	= 0.122 ppm
EEC for 1 foot	=	367.2	X	2 lbs	=	735 ppb	= 0.735 ppm
EEC for 6 inches	=	734	X	2 lbs	=	1468 ppb	= 1.468 ppm

C. 6 lbs ai/acre unincorporated ground application

6 lbs	X	0.05 (5% runoff)	x	10 (A) (10 A drainage basin)	=	3 lbs Total Runoff

EEC of 1 lb ai direct application to 1 acre pond 6-feet deep is 61 ppb.

Therefore EEC = 61 ppb X 3 lbs = 186 ppb = 0.186 ppm

APPENDIX 4

Method of application, maximum application rates and number or applications for the crops where metolachlor is applied unincorporated.

Crop	Method of Application	Maximum Application (lbs ai/A)	Numbers of Applications
Cabbage	Pre and Post transplant, Do not incorporate	2	1
Potatoes	Broadcast Application Preemergene or Hilling/ Lay-By	4	2
Pod crops	Broadcast Application Preemergence	3	1
Soybeans	Broadcast Application Preplant Surface or Preemergence	4	1
Chili peppers	Postemergence Directed Spray or Over-The-Top Spray	2	2
Tabasco Peppers	Postemergence Directed Spray	2	1
Citrus, Stone Fruits, Grapes, Tree Nuts	Broadcast to Weed-Free Soil	4	1
Corn	Broadcast Application Preplant Surface or Preemergence or Postemergence or Lay-By	4	2
Sorghum	Broadcast Application Preplant or Preemergence or Lay-By	2.5	1
Alfalfa	Surface Broadcast Application	5	No Limit
Peanuts	Broadcast Application During or After Planting, Lay-By	2	2-3
Safflower	Broadcast Application During or After Planting, Air Application	3	1
Cotton	Broadcast Application During or After Planting	2	1

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Date: 3/18/94
Case No: 0001
Chemical No: 108801 METOLACHLOR

PHASE IV
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
6 Basic Studies in Bold					
71-1(a) Acute Avian Oral, Quail/Duck	TGAI	A,B,C,K	YES	15547	NO
71-1(b) Acute Avian Oral, Quail/Duck	(TEP)	---	---	--	---
71-2(a) Acute Avian Diet, Quail	TGAI	A,B,C,K	YES	16426	NO
71-2(b) Acute Avian Diet, Duck	TGAI	A,B,C,K	YES	16425	NO
71-3 Wild Mammal Toxicity	---	---	---	--	---
71-4(a) Avian Reproduction Quail	TGAI	A,B,C,K	NO	162293	YES[3]
71-4(b) Avian Reproduction Duck	TGAI	A,B,C,K	NO	162292	YES[4]
71-5(a) Simulated Terrestrial Field Study	---	---	---	--	---
71-5(b) Actual Terrestrial Field Study	---	---	---	--	---
72-1(a) Acute Fish Toxicity Bluegill	TGAI	A,B,C,K	YES	18723	NO
72-1(b) Acute Fish Toxicity Bluegill	(TEP)	---	---	--	---
72-1(c) Acute Fish Toxicity Rainbow Trout	TGAI	A,B,C,K	YES*	18723	NO
72-1(d) Acute Fish Toxicity Rainbow Trout	(TEP)	---	---	--	---
72-2(a) Acute Aquatic Invertebrate Toxicity	TGAI	A,B,C,K	YES		NO
72-2(b) Acute Aquatic Invertebrate Toxicity	(TEP)	---	---	--	---
72-3(a) Acute Estu/Mari Tox Fish	TGAI	A,B,C	YES	430446-02	NO
72-3(b) Acute Estu/Mari Tox Mollusk	TGAI	A,B,C	NO	--	YES[5]
72-3(c) Acute Estu.Mari Tox Shrimp	TGAI	A,B,C	NO	--	YES[5]

* In Bibliographic Citation column indicates study may be upgradeable

Date: 3/18/94
Case No: 0001
Chemical No: 108801 METOLACHLOR

PHASE IV
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition[1]	Use Pattern[2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
72-3(d) Acute Estu/Mari Tox Fish	(TEP)	--	--	--	---
72-3(e) Acute Estu/Mari Tox Mollusk	(TEP)	--	--	--	---
72-3(f) Acute Estu/Mari Tox Shrimp	(TEP)	--	--	--	---
72-4(a) Early Life-Stage Fish	TGAI	A,B,C	YES	430446-02, 470257-23	NO
72-4(b) Live-Cycle Aquatic Invertebrate	TGAI	A,B,C	NO	430446-03	YES[6]
72-5 Life-Cycle Fish	---	--	--	--	---
72-6 Aquatic Org. Accumulation	---	--	--	--	---
72-7(a) Simulated Aquatic Field Study	---	--	--	--	---
72-7(b) Actual Aquatic Field Study	---	--	--	--	---
122-1(a) Seed,Germ./Seedling Emerg.	---	--	--	--	---
122-1(b) Vegetative Vigor	---	--	--	--	---
122-2 Aquatic Plant Growth	---	--	--	--	---
123-1(a) Seed Germ./Seedling Emerg.	TGAI	A,B,C,K	NO	--	YES[7]
123-1(b) Vegetative Vigor	TGAI	A,B,C,K	NO	--	YES[8]
123-2 Aquatic Plant Growth	TGAI	A,B,C,K	NO	--	YES[8]
124-1 Terrestrial Field Study	---	--	--	--	---
124-2 Aquatic Field Study	---	--	--	--	---
141-1 Honey Bee Acute Contact	---	--	--	--	---
141-2 Honey Bee Residue on Foliage	---	--	--	--	---
141-5 Field Test for Pollinators	---	--	--	--	---

* In Bibliographic Citation column indicates study may be upgradeable

1.Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product

2.Use Patterns: A = Terrestrial Food Crop; B = Terrestrial Feed Crop; C = Terrestrial Non-Food Crop; D = Aquatic Food Crop; E = Aquatic Non-Food Outdoor; F = Aquatic Non-Food Industrial; G = Aquatic Non-Food Residential; H = Greenhouse Food Crop; I = Greenhouse Non-Food Crop; J = Forestry; K = Outdoor Residential; L = Indoor Food; M = Indoor Non-Food; N = Indoor Medical; O = Indoor Residential; Z = Use Group for Site 00000

3.Study was found unacceptable because the percentage of eggs cracked was very high. A new study is required.

4.The study does not satisfy guideline requirements. A NOEL was not achieved. A new study is required.

5. The study is required because the following use patterns are associated with estuarine/marine areas: corn, cotton, peanuts, sorghum, soybeans, and golf course turf.

6.The study is required because of multiple applications and persistence of the chemical (> 4 days). The submitted study was found unacceptable because the number of young produced was very low and the concentrations of the fresh test solutions were not measured. An estuarine/marine invertebrate life cycle study is on reserved pending the results of the acute estuarine/marine studies and the fresh water invertebrate life cycle study.

7.Non-target plant studies are required for any herbicide used on terrestrial food and terrestrial non-food sites if they are applied by ground rigs and the water solubility is greater than 10 ppm (metolachlor solubility is 530 ppm), or the vapor pressure is greater than 1.0×10^5 mmg Hg at 25 C (metolachlor vapor pressure is 1.3×10^5 mmg Hg at 25 C). and the TEP is not thoroughly incorporated immediately after application (aerial application and chemigation).

8.The study should be conducted on each of the following species: Selenastrum capricornutum, Lemna gibba, Skeletonema costatum, Anabaena flos-aquae, and a freshwater diatom.