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WATER QUALITY ADVISORY

METOLACHLOR

Criteria and Standards Division

Office of Water Regulations and Standards

United States

Environmental Protection Agency

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WATER QUALITY ADVISORY
Number 6 .

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Office of Water Regulations and Standards
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The advisory concentration for Metolachlor in ambient water for the protection of freshwater aquatic life is estimated to be 100 ug/L. No saltwater data were reviewed for this advisory, and no advisory concentration for the protection of saltwater aquatic organisms is estimated. Care should be taken in the application of this advisory, with consideration of its derivation, as stated in the attached support document.

A value given to protect aquatic life can be derived from no observed effect levels (NOEL), the lowest concentration found in the data which has been observed to cause acute or chronic toxicity or other experimental data which may be applicable. When there is no valid experimental evidence, a value may be derived from a model which uses structure-activity relationships (SAR) as its basis. The advisory concentrations should be used with caution, since they are derived from minimal experimental evidence, or in the case of SAR derived values, no data on the specific chemical.

The advisory concentration for Metolachlor in ambient water for the protection of human health is estimated to be 44 ug/L, based on data and information which are available to U.S. EPA. Care should be taken in the application of this advisory, with consideration of its derivation, as stated in the attached support document.

An advisory concentration can be derived from a number of sources: The Office of Drinking Water Health Effects Advisories; Acceptable Daily Intake(ADI) values from EPA; Office of Pesticides and Toxic Substances risk assessments; Carcinogen Assessment Group(CAG) cancer risk estimates; risk estimates derived from the open literature; or other sources which will be given in the support document. The advisory concentrations derived from these sources will vary in confidence and usefulness, based on the amount and quality of data used as well as the assumptions behind the original estimates. The user is advised to read the background information carefully to determine the strengths or deficiencies of the values given in the advisory.

HUMAN HEALTH AND AQUATIC LIFE LITERATURE SEARCH AND DATA BASE EVALUATION FOR METOLACHLOR

U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF WATER REGULATIONS AND STANDARDS
CRITERIA AND STANDARDS DIVISION
Washington, D.C. 20460

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INTRODUCTION

Metolachlor [2-chloro-N-(2 ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide] is a selective herbicide used to control annual grass weeds, yellow nutsedge, and certain broadleaf species in corn production. Corps which are sufficiently tolerant to metolachlor are soybeans, peanuts, potatoes, and certain vegetables (WSSA, 1979). Metolachlor is manufactured under the name Dual and is packaged in 6 and 8 lb/gallon emulsifiable concentrates. Metolachlor is also manufactured under the trade names of Bicep , Primagram , Primextra , CGA-24705, Codal and Milocep when it is combined with other herbicides such as propazine and atrazine which increase the spectrum of its effectiveness. It was developed by Ciba-Giegy in Basle, Switzerland, and patented in 1973 and 1976 (EPA, 1980).

Metalachlor is a white to tan liquid at room temperature with the following physical properties: (EPA, 1980)

Boiling point:	100 ^{o}C
Vapor pressure:	10^{-5} min Hg at 20 ^{o}C
Stability:	half-life of a 0.25 percent aqueous solution at 100 ^{o}C is 30 hours at pH3, 18 hours at pH7, and 1.5 hours at pH 10
Specific gravity:	1.085 $\pm$ 0.005 at 20 ^{o}C
Solubility in water:	530 ppm at 20 ^{o}C.

Metolachlor belongs to a category of herbicides known as chloroacetamides which inhibit growth and reduce cell division and enlargement. Metolachlor is a soil-applied herbicide and its particular mode of action is inhibition of root elongation (Ashton and Crafts, 1981). It is usually applied on or incorporated into the soil at a rate of 1.5-3.0 lb active ingredient per acre during or soon after planting but before sprouts emerge (EPA, 1980). Metolachlor has been shown to be resistant to hydrolysis and rapid metabolism in soil. It also has the tendency to leach extensively in low-organic soils (EPA, 1980).

The most significant toxicity of metolachlor to nontarget species has been with aquatic organisms, particularly fish (Buccafusco, 1978; Sachsse and Ullman, 1974). Consequently, present concerns focus on releases of metolachlor into aquatic environments. Research needs include the identification of quantities of metolachlor which could reach aquatic systems unchanged by leaching or runoff from farm fields and the resultant effects of metolachlor on those aquatic systems.

SCOPE OF SEARCH

Sources were identified through a computerized literature search of TOXLINE, the Toxicological Data Base, TOXBACK, and NTIS files and through manual bibliographical searches of the available literature. The computerized literatures searches included published literature from 1965 to the present. Most of the sources cited in this document were listed in an EPA (1980) document, Metolachlor-Pesticide Registration Standard, which cited sources that were not published in the open literature but were evaluated by the EPA for validity. The search focused on controlled dose-response studies.

When available, information was obtained on the quality assurance/quality control (QA/QC) measures employed in the laboratory and field studies, specifically their use of controls, replicate treatments, and chemical analysis of test concentrations. Information also was sought on the bioaccumulation/biomagnification of metolachlor and other food chain, ecological, and health effects.

Studies were evaluated with respect to guidelines established by the U.S. EPA in "Guidelines and Methodology Used in Preparation of Health Effect Assessment Chapters of the Consent Decree Water Quality Criteria Documents" (FR 45:79347, Nov. 28, 1980), and the "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Life and Their Uses (Stephan et al., 1985). The search was not intended to be exhaustive, however it was intended to be thorough in its coverage of accessible, relevant data sources required for meaningful criteria development.

SUMMARY OF FINDINGS

Aquatic Toxicity

Most of the aquatic toxicity data were taken from a registration document for metolachlor (Table 1). The numbers presented in the document were from studies which were not published in journals or government reports, but were reviewed by EPA prior to acceptance of the chemical for registration. Although the orginal reports of the studies were not available, it was assumed that EPA required acceptable QA/QC measures.

According to the registration document (EPA, 1980), there are no data available on the toxicity of metolachlor to freshwater algae or aquatic plant species. However, Ellgehausen et al. (1980) present

TABLE 1. SUMMARY OF AQUATIC TOXICITY LITERATURE REVIEW OF METOLACHLOR

Aquatic Toxicity Test Species	LC_{50}[a] (ppm)	Test Duration	Exposure Medium	Quality Assurance Specifications	Miscellaneous Observed Effects	Reference
Rainbow trout	2.0	96 hr	Water	NR[b]		WSSA
Bluegill sunfish	15.0	96 hr	Water	NR		
Daphnia magna	25.1 (21.6 - 29.2)	48 hr	Water	EPA approved		Vilkas, 1976
Bluegill	10	96 hr	Water	EPA approved; satisfies EPA requirement		Buccafusco, 1978
Rainbow trout	3.9	96 hr	Water	EPA approved; satisfies EPA requirements		Buccafusco, 1978
Fathead minnow	11.0	96 hr	Water (static)	Does not satisfy EPA requirements		Dionne, 1978
Fathead minnow	9.2	96 hr	Water (flowing)	Does not satisfy EPA requirements		Dionne, 1978
Crucian carp	4.9	96 hr	Water	Does not satisfy EPA requirements		Sachsse and Ullman, 1974
Channel catfish	4.9	96 hr	Water	Does not satisfy EPA requirements		Sachsse and Ullman, 1974
Guppy	8.6	96 hr	Water	Does not satisfy EPA requirements		Sachsse and Ullman, 1974

[a] LC_{50} = Lethal concentration for 50 percent of test organisms (unless otherwise noted).

[b] NR = Not reported in source document.

TABLE 1. (Continued)

Aquatic Toxicity Test Species	LC_{50}[a] (ppm)	Test Duration	Exposure Medium	Quality Assurance Specifications	Miscellaneous Observed Effects	Reference
Fathead minnow	0.78 - 16.0 Maximum Acceptable Toxicant Concentration	>4 wks	Water	EPA approved	Fish were exposed to greater than 1.6 ppm. Fewer first and second generation fry survived	Dionne, 1978
Algae	Accumulated 10.4	90 min	Water	NR[b]	2 ppm after 2-hr depuration	Ellgehausen, 1977
Daphnia	Accumulated 0.6	24 hr	Water	NR	50% loss after 8 hr of depuration	Ellgehausen, 1977
Catfish *Ictalurus melas*		96 hr	Water	NR	Exposed to 0.1 ppm; accumulated 1.2 ppm; a plateau was not reached	Ellgehausen, 1977
Catfish	Exposed to 0.08	30 days	Water	NR	Bioaccumulation factors 6.5 - 9.0 for edible portions; 55.0-92.4 in the viscera. After 14 days' depuration, 0.72 ppm ± 0.03 ppm in edible tissues; 7.39 ppm ± 0.18 ppm in viscera.	Smith, 1977
Bluegill		70 days	Water (flow-through)	NR	1.2 mean exposure. Exposed to 1000 µg/l Accumulated 28 ppm in edible tissue, 702 ppm in nonedible tissues. After 28 days' depuration, residues in edible portions dropped to 11.7 ppm.	Barrows, 1974

[a] LC_{50} = Lethal concentration for 50 percent of test organisms (unless otherwise noted).

[b] NR = Not reported in source document.

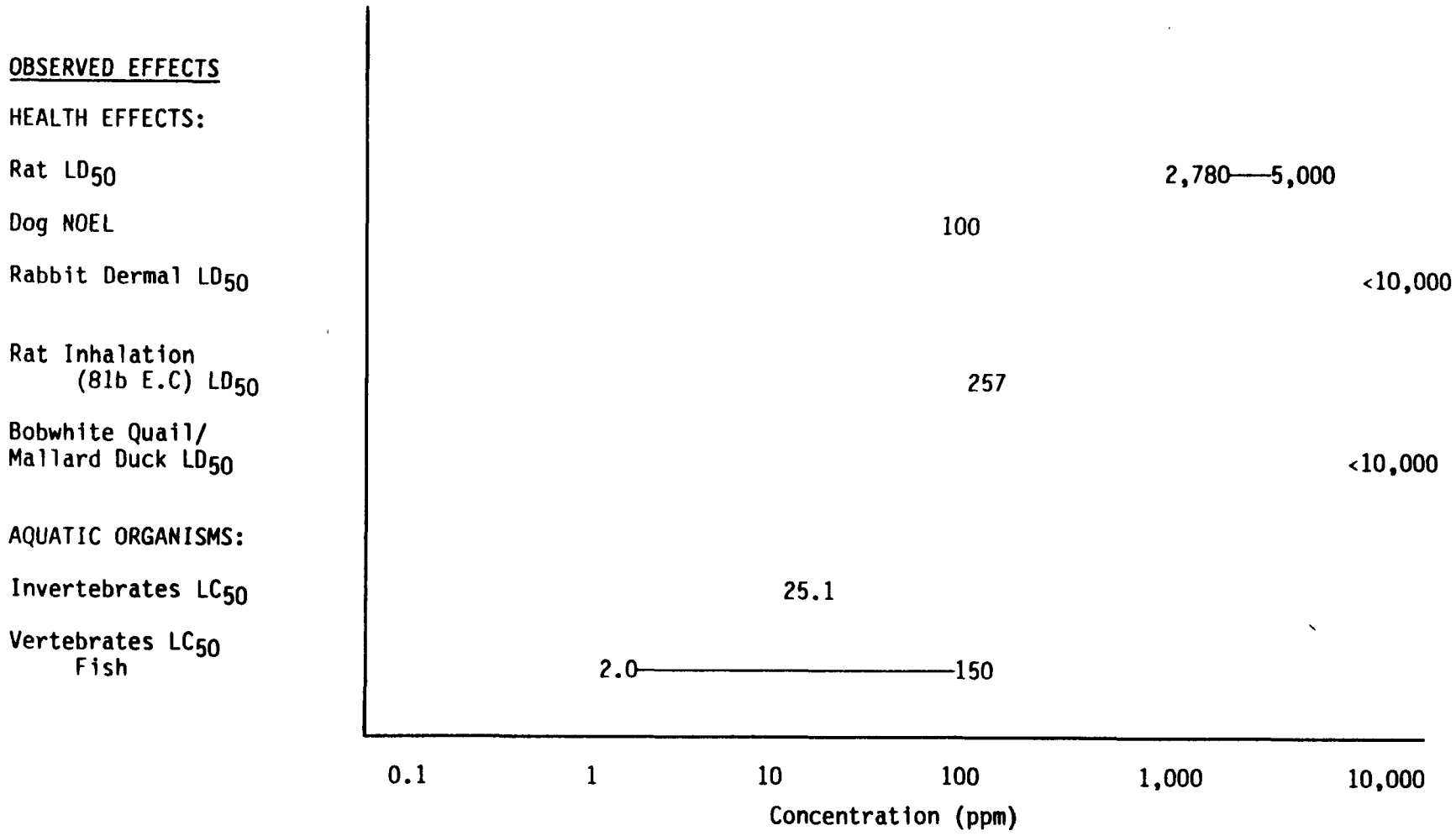

FIGURE 1. SUMMARY OF TOXICITY DATA FOR METOLACHLOR

data on the bioaccumulation of metolachlor in aquatic organisms including the alga Scenedesmus acutus. In order to establish exposure concentrations for the bioaccumulation study, they determined a no-effect-level of 0.1 ppm for this species after an unspecified period of exposure. Other details on the acute toxicity study were not provided.

The only acceptable study (lethal concentration for 50 percent of test organisms) on the toxicity of metolachlor to invertebrates (Figure 1) was a 48-hour LC50 of 25.1 ppm (Vilkas, 1976, as cited in EPA, 1980). The EPA determined that results from this test were adequate to characterize the toxicity of metolachlor to invertebrates. Ellgehausen et al. (1980) determined a no-effect-level for Daphnia magna of 0.1 ppm; however, no QA/QC measures other than concentration measurement were reported. Toxicity data on other species of invertebrates were not available.

Most of the toxicity data on fish species were from the EPA registration document (EPA, 1980). The EPA approved studies generating LC50 data for bluegill sunfish (10.0 ppm) and rainbow trout (3.9 ppm). Acute studies exposing fathead minnows, crucian carp, channel catfish, as well as a flow-through test exposing fathead minnows were judged inadequate by the EPA (EPA, 1980). In a separate study, Ellgehausen et al. (1980) determined a no-effect-level for catfish, Ictalurus melas, of 0.1 ppm after 96 hours of exposure. Again, there was no report of quality assurance measures other than concentration measurement.

A chronic test of the effects of 97.4 percent metolachlor on reproduction of the fathead minnow reported a maximum acceptable toxicant concentration (MATC) between 0.78 and 1.60 ppm (Dionne, 1978, as cited in EPA, 1980). When the fish were exposed to concentrations higher than the MATC, significantly fewer first and second generation fry survived.

Metolachlor was reported to accumulate in algae, Daphnia and fish tissues after exposure times ranging from 90 minutes for algae to 96 hours for catfish (Ellgehausen et al., 1977 and 1980). However, the concentrations were significantly reduced after depuration periods in all three cases. The primary source of the accumulated metolachlor was water, rather than contaminated food organisms. In accumulation studies of 30-70 days of exposure using catfish (Smith, 1977) and bluegills (Barrows, 1974), metolachlor accumulated in the fish during the exposure period and dropped to significantly lower levels after depuration. A bioaccumulation factor was not calculated in any of the studies because metolachlor was rapidly metabolized.

Health Effects

Many studies have been conducted on the health effects of metolachlor (Table 2), but the studies were not published in open literature. The data evaluated in this section were taken from studies cited in the pesticide registration document for metolachlor (EPA, 1980).

Mammalian acute toxicity studies have shown the LD50s for metolachlor to range from 0.3->10,000 mg/kg depending on the route of exposure (oral, dermal) and the species of test animal (rat, rabbit) (EPA, 1980). These values also are representative of the toxicity data from tests of the emulsifiable concentrates of 6 or 8 lb metolachlor/gal. Toxicity studies on beagle dogs showed an "emetic dose" of 19.0 mg/kg. This level was not sufficiently toxic to establish an acute LC50 (AMRI, 1974b).

Draise tests conducted on rabbits using both technical grade metolachlor and the 8 lb/gal emulsifiable concentrate produced moderate but reversible irritation and corneal opacity in the eyes. The 6 lb/gal emulsifiable concentrate, however, produced an irreversible corneal opacity in the rabbit eye. Because the amount of active ingredient in the 6 lb/gal emulsifiable concentrate is less than that in the 8 lb/gal, it is likely that the irritation was due to the inert ingredients of the emulsifiable concentrate rather than to metolachlor. Another acute effect of technical grade metolachlor was a positive skin sensitization reaction when applied through intradermal injection in guinea pigs (Sachsse, 1977).

Metolachlor apparently does not accumulate in mammals because it is rapidly absorbed and metabolized. Studies have shown ingested metolachlor to be completely metabolized in rats, goats, and poultry with no unchanged metolachlor detected in the urine or feces (Hambock, 1974). The metabolic pathway of metolachlor is not yet understood (EPA, 1980).

A chronic feeding study exposing dogs to metolachlor over a 6-month period reported a no-observed-effect-level (NOEL) of 100 ppm (EPA, 1980). Another chronic study showed metolachlor to produce no oncogenic effects in mice at a level of 3000 ppm (IBT, 1975). Kennedy (1976) performed a 2-year feeding study on rats which showed no oncogenic effects. However, the integrity of the rat study was questioned by EPA because of protocol deficiencies and lack of concentration verification. The study was redone and the results indicate the possibility of neoplasm formation at high (3000 ppm) doses. OPP considers the study to be core minimum, and have tentatively set the non-neoplastic NOEL at 30 ppm. Tests on the mutagenicity and fetotoxicity of metolachlor have also produced negative results (Arni and Miller, 1976; Ciba Geigy Ltd., 1976; Fritz, 1976).

TABLE 2. SUMMARY OF HEALTH EFFECTS LITERATURE REVIEW OF METOLACHLOR

Health Effects Test Species	Exposure Level	Test Duration	Exposure Medium	Quality Assurance Specifications	Other Effects (Epidemiological Information)	References
Rat	LD_{50}: 2780 mg/kg (2180 - 3545)	NR[b]	Oral	EPA approved	NR	Bathe, 1973
Rat	LD_{50}: >2,000 but <5,000 mg/kg	NR	Oral; 6 lb/gal emulsifiable concentrate	EPA approved		Bathe, 1973
Rat	LD_{50}: 2530 mg/kg (1,890 - 3,400)	NR	Oral; 8 lb/gal emulsifiable concentrate	EPA approved		Nham and Harrison, 1977
Albino Rats	1.752 mg/l	4 hr	Inhalation	NR	No deaths reported	Sachsse and Ullman, 1974
	>257 mg/l	4 hr	Inhalation	NR; 6 lb/gal formulation		Affiliated Medical Research, Inc., 1974e
	257 mg/l	4 hr	Inhalation; 8 lb/gal formulation	No particle size analysis; results suspect	Produced areas of consolidation on the lobes of the lungs	Affiliated Medical Research, Inc., 1974e
Rat	NR	2 yr	Oral	Not EPA approved	No oncogenic effects seen	Kennedy, 1976
Sprague-Dawley Rats	360 mg/kg/day	6-15 days	Oral	EPA approved	No fetotoxic effects of the compound observed. Decrease in food consumption at the highest concentration.	Fritz, 1976

[a] LD_{50} = Lethal dose for 50 percent of test organisms (unless otherwise noted).

[b] NR = Not reported in source document.

TABLE 2. (Continued)

Health Effects Test Species	Exposure Level	Test Duration	Exposure Medium	Quality Assurance Specifications	Other Effects (Epidemiological Information)	References
Beagle Dogs	Emetic Dose 19.0 (±9.7) mg/kg	NR	Oral; technical grade metolachlor in corn oil	EPA approved	Emetic to the extent that it prevented establishment of an LD_{50}.	Affiliated Medical Research, Inc., 1974
Dogs (Beagle)	NOEL[a] 100 ppm	6 mo	Oral-diet	EPA approved	NR	IRDC, 1979
New Zealand Rabbit	LD_{50}: >10,000 mg/kg	NR	Unabraded dermal	NR		Affiliated Medical Research, Inc., 1974c
	LD_{50}: >10,000 mg/kg	NR	Intact dermal	NR; 6 lb/gal emulsifiable concentrate		Affiliated Medical Research, Inc., 1974c
	LD_{50}: >3,038 mg/kg	NR	Intact dermal	NR; 8 lb/gal emulsifiable concentrate		Nham and Harrison, 1977
Rabbit	--	24 hrs and 7 days	Eyes; 0.1 ml technical grade metolachlor	NR	Nonirritating to the rabbit eye	Sachsse, 1973a
		NR	Eyes; 6 lb/gal emulsifiable concentrate	NR	Severe irritant causing irreversible corneal opacity in the unrinsed albino rabbit eye.	Affiliated Medical Research, Inc., 1974a
		NR	Eyes; 8 lb/gal emulsifiable concentrate	NR	Moderate effects which were reversed 7 days after exposure	Scribor, 1977a

[a] NOEL = No observed effect level.

TABLE 2. (Continued)

Health Effects Test Species	Exposure Level	Test Duration	Exposure Medium	Quality Assurance Specifications	Other Effects (Epidemiological Information)	References
Guinea Pigs	--	NR	Intradermal injection; technical grade metolachlor	EPA approved	Caused a positive reaction - determined to be a skin sensitizer	Sachsse, 1977
Mice	3,000 ppm in diet	18 mo (male); 20 mo (female)	Oral	Some discrepancies in methods but otherwise EPA approved	No oncogenic effects	Industrial Bio-Test Laboratories, 1975
Salmonella (Bacteria)	10,000 mg/plate	NR	Agar	NR	No mutagenicity found	Arni and Miller, 1976

CRITERIA EVALUATION AND RECOMMENDATION

Aquatic Life

While the data base required to derive criterion lacks approximately half of the information needed according to the guidelines specified in Stephan, et al (1985), sufficient data were found to calculate an advisory concentration.

An Aquatic Life Criterion consists of a Criterion Maximum Concentration (CMC) and a Criterion Continuous Concentration (CCC).

The CMC is equal to one-half the Final Acute Value (FAV). An estimated Final Acute Value was calculated using the following equations.

$$\text{Final Acute Value} = e^{A}$$

where:

$$A = S(0.05) + L$$

$$L = (\ln GMAV - S((p))/4)$$

$$S^2 = ((\ln GMAV)^2) - ((\ln GMAV))^2/4)$$
$$(P) - ((P))^2/4)$$

GMAV = Genus Mean Acute Value (the geometric mean of the species mean acute values for the genus)

P = Cumulative probability as R/N+1

R = Rank from "1" for the lowest to "N" for the highest GMAV.

The Genus Mean Acute Values (GMAVs) were obtained from the reviewed literature (Table 1). The values used in calculating the estimated FAV are presented in Table 3. There are as mentioned above, insufficient data to calculate a criterion, but the incomplete data base can be used in calculating an advisory.

Substituting values from Table 3 into the formulae gave an estimated Final Acute Value of 0.77 ppm.

An estimated maximum concentration for metolachlor was calculated according to the following:

$$\text{Maximum concentration} = \frac{\text{Final Acute Value}}{2}$$

$$= \frac{0.77}{2} = 0.39 \text{ ppm.}$$

TABLE 3. VALUES USED TO CALCULATE THE FINAL ACUTE VALUE

	LC_{50} (ppm)	GMAV (ppm)	R	P
Salmonid				
Rainbow trout	2.0	2.79	1	0.2
Rainbow trout	3.9			
Centrarchid				
(Warm water species)				
Bluegill sunfish	10	12.25	3	0.6
Bluegill sunfish	15			
Another Family				
Channel catfish	4.9	4.9	2	0.4
Planktonic crustacean				
Daphnia magna	25.1	25.1	4	0.8

The estimated Final Chronic Value is equal to the estimated FAV divided by the Final Acute-Chronic Ratio. Data for calculating an Acute-Chronic Ratio were available only for fathead minnows (Table 1):

$$\frac{9.2 \text{ ppm}}{1.17 \text{ ppm}} = 7.96$$

The ratio is based on an acute 96-hr LC50 from a fathead minnow test and the geometric mean of the Maximum Acceptable Toxicant Concentration (EPA, 1980).

The estimated advisory concentration was calculated by the following:

$$\text{Advisory concentration} = \frac{\text{Final Acute Value}}{\text{Final Acute-Chronic Ratio}}$$

$$= \frac{0.77 \text{ ppm}}{7.9} = 0.10 \text{ ppm.}$$

Because there currently are no acceptable data on plants, a Final Plant Value cannot be calculated. Similarly, a Final Residue Value cannot be calculated because data on either FDA levels in fish or long-term wildlife acceptable daily intake have not been located. While there is bioaccumulation information available, as was previously mentioned, none of the studies allows determination of a bioaccumulation factor. Therefore, the estimated advisory concentration is equal to 0.10 ppm because it is the only chronic value calculated.

Because these estimates were derived from a partial data base they cannot be rigorously applied, but should be used as guidance in interpreting levels of metholachlor in environmental samples.

These estimates were derived from an acceptable, yet partial, data base. The acceptability of many of the test results was assumed. The estimates could be improved with expansion of the data base. The estimates provided here are not rigorous in their derivation but can be used to provide guidance in the interpretation of concentrations of metolachlor found in environmental samples.

The data set for calculating a criterion is currently lacking the following elements (Table 4): LC50s for a benthic crustacean, an aquatic insect species, a phylum other than Arthropoda or Chordata, and another insect family; acute/chronic data on an invertebrate and another freshwater species; acceptable test results with a freshwater algae or an aquatic vascular plant.

TABLE 4. DATA REQUIREMENTS FOR CALCULATION OF AQUATIC LIFE INTERIM CRITERIA--METOLACHLOR

Criterion Requirements Aquatic Toxicity	Available Data	Acceptability of Available Data
Acute test results from tests on:		
a. A salmonid (class Osteichthyes)	YES	YES EPA approved
b. A warm water species commercially or recreationally important (class Osteichthyes)	YES	YES EPA approved
c. Another family in the phylum Chordata (fish, amphibian, etc.)	YES	YES EPA approved
d. A planktonic crustacean (cladoceran, copepod, etc.)	YES	YES EPA approved
e. Benthic crustacean (ostracod, isopod, scud, crayfish, etc.)	NO	--
f. Insect (mayfly, dragonfly, damselfly, stonefly, mosquito, etc.)	NO	--
g. Phylum other than Arthropoda/ Chordata (Rotifera, Annelida, Mollusca)	NO	--
h. Another family of insect	NO	--
Acute-chronic ratios with species from three different families:		
a. One fish	YES	YES EPA approved
b. One invertebrate	NO	--
c. Acutely sensitive freshwater animal species	NO	--
Acceptable test results from a test with:		
a. Freshwater algae	NO	--
b. A vascular plant	NO	--
Bioaccumulation factor with a freshwater species (if a maximum permissible tissue concentration is available)	NO	--

Health Effects

Standards exist for tolerance limits of metolachlor residues in raw agricultural commodities (40 CFR 180.368). These levels range from 0.02 ppm to 3.0 ppm in fruits, vegetables. and livestock.

A no-observed-effect-level (NOEL) of 100 ppm has been determined based on a 6-month dog feeding study (U.S. EPA, 1980).

According to the methods outlined in "Guidelines and Methodology Used in Preparation of Health Effects Assessment Chapters of the Consent Decree Water Quality Criteria Documents," ideally a NOAEL, LOEL, or LOAEL would be used to derive an ADI. However, only the NOEL for metolachlor is available. The Office of Pesticide Programs calculated an ADI using the NOEL (U.S. EPA, 1980). A safety factor of 2000 is applied to the NOEL because there are no long-term or acute data on humans and few studies on experimental animals with no indication of carcinogenicity (EPA, 1980; Federal Register. 1980) (Table 5). Using the data from the dog study, a dietary exposure of 100 ppm parts food is equivalent to a NOEL of 2.5 mg/kg/day. Applying the safety factor of 2000 and the average adult human weight (70 kg), instead of 60 kg used by OPP, the ADI is calculated as follows:

$$\text{ADI} = \frac{(2.5 \text{ mg/kg/day})(70 \text{ kg})}{2000} = 0.088 \text{ mg/day}.$$

The ADI is then divided by 2 l/day (average adult human water consumption) to arrive at an interim advisory concentration of 0.044 mg/L. This value does not reflect consumption of fish contaminated with metolachlor, but given the low bioconcentration estimate due to rapid depuration and metabolism, the advisory is expected to be protective in the event of consumption of contaminated organisms.

This estimate is based on a study approved by the EPA. All other data used in derivation of the criteria are from unpublished studies whose QA/QC measures are unknown. The estimate, therefore, should not be considered firm, but rather as an interim value to provide guidance until more data become available.

TABLE 5. DATA REQUIREMENTS FOR CALCULATION OF HUMAN HEALTH INTERIM CRITERIA--METOLACHLOR

Criterion Requirements Human Health Effects	Available Data	Acceptability Of Available Data
NonThreshold:		
Carcinogen	YES	?
Tumor incidence tests (Incidence of tumor formation significantly more than the control for at least one dose level), or	Noncarcinogenic	
Data set which can be used to estimate carcinogenic risk, or	NA*	--
Lifetime average exposure tests, or	NA	--
Human epidemiology studies (if available, not required)	NA	--
Threshold:		
Noncarcinogens	YES	YES EPA approved
No observed adverse effect level (at least 90-day), or	NO**	--**
Lowest observed effect level	NO	--
Lowest observed adverse effect level	NO	--
Acceptable Daily Intake:	YES	YES
Daily water consumption	YES	EPA Approved
Daily fish consumption	YES	EPA Approved
Bioconcentration factor	NO	--
Nonfish dietary intake	NO	--
Daily intake by inhalation	NO	--
Threshold Limit Value: (Based on 8-hour time-weighted average concentrations in air)	NO	--
Inhalation Studies:	NO	--
Available pharmacokinetic data		
Measurements of absorption efficiency		
Comparative excretion data		

* Not applicable.
? - Results equivocal.
** NOEL available (EPA approved).

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