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OFFICE OF  
PREVENTION, PESTICIDES, AND  
TOXIC SUBSTANCES

MEMORANDUM

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SUBJECT: Ecological risk assessment evaluating Clethodim (PC 121011) for the proposed new use on corn.

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This memo summarizes the attached EFED Environmental Risk Assessment for the proposed new uses of clethodim on corn. It identifies major clethodim ecological risk issues, and uncertainties resulting from outstanding data requirements.



# **ENVIRONMENTAL FATE AND EFFECTS SCIENCE CHAPTER**

## **Environmental Fate and Ecological Risk Assessment**

### **Registration of New Use for Clethodim on Corn**

**USEPA PC Code: 121011**

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# **I. Executive Summary**

## **Environmental Risk Conclusions**

Based on the results of this baseline ecological risk assessment of clethodim and its total toxic residues (sulfoxide and sulfone), the proposed use of clethodim on corn:

- Poses risks above the Agency's Level of Concern (LOC) to listed and non-listed monocot terrestrial plant species inhabiting semiaquatic areas that receive drainage from clethodim use sites.
- Does not exceed the Agency's LOC to listed and non-listed monocot terrestrial plant species inhabiting upland (dry land) areas adjacent to clethodim use sites
- Does not exceed the Agency's LOC for direct toxic effects to listed and non-listed birds, mammals, aquatic invertebrate, fish, aquatic plants, and algae.

### *Risk to Terrestrial Plants*

Clethodim use at the proposed application rate is predicted to pose risks above the Agency's Level of Concern (LOC) to listed and non-listed monocot terrestrial plant species inhabiting semiaquatic areas that receive drainage from clethodim use sites (Risk Quotient [RQs] = 3.13 where the Agency's LOC = 1.00 for both listed and non-listed monocot plants). The proposed use does not exceed the Agency's LOC for dicot plants or terrestrial monocot plants not exposed to drainage from clethodim use sites.

### *Risk to Birds*

Based on the available data there are no LOC exceedances for birds from the proposed uses at the maximum proposed application rate.

### *Risk to Mammals*

Based on the available data there are no LOC exceedances for mammals from the proposed uses at the maximum proposed application rate.

### *Risk to Fish and Aquatic Invertebrates*

Based on the available data, there are no acute LOC exceedances for fish or aquatic invertebrates. There are no chronic toxicity data available for the Agency to assess chronic risk of clethodim to fish and aquatic invertebrates. Currently, the Agency assumes no chronic risk to fish and invertebrates because clethodim: 1) is only slightly toxic to fish and an aquatic invertebrate on an acute basis; 2) is only moderately persistent in aquatic environments; and 3)

poses a minimal risk of chronic toxic effects to birds and mammals. However, there is some uncertainty regarding the chronic risk of clethodim to fish and aquatic invertebrate because no aquatic organism chronic toxicity data have been submitted to the Agency. This data will help clarify the uncertainty regarding the chronic risk of clethodim to fish and aquatic invertebrates.

#### *Risk to Aquatic Plants and Algae*

Based on the available data, there are no acute LOC exceedances for aquatic plants or algae.

#### **Uncertainties regarding conclusions**

Based on the available data, there are no acute LOC exceedances for fish or aquatic invertebrates. There are no chronic toxicity data available for the Agency to assess chronic risk of clethodim to fish and aquatic invertebrates, however clethodim is only slightly toxic to fish and aquatic invertebrates on an acute basis, is only moderately persistent in aquatic environments, and poses a minimal risk of chronic toxic effects to birds and mammals. However, no aquatic organism chronic toxicity data have been submitted to the Agency. This data will help clarify the uncertainty regarding the chronic risk of clethodim to fish and aquatic invertebrates.



## II. Problem Formulation

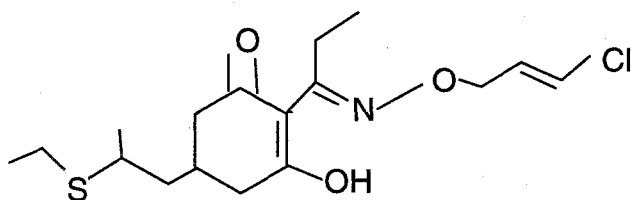
### A. Stressor Source and Distribution

Clethodim (Figure 1) is currently registered for use as a post-emergence selective herbicide against a wide range of annual and perennial grasses (monocotyledon plant species) in a wide variety of broad leaf crops including soybeans, cotton, flax, peanuts, sunflowers, sugar beets, potatoes, alfalfa and vegetables.

#### 1. Pesticide Type, Class, and Mode of Action

Clethodim is a member of the cyclohexenone or cyclohexanedione class of herbicides. The mode of action for this herbicide is lipid biosynthesis inhibition. Sensitivity or selectivity of grasses has been demonstrated to be due to a greater susceptibility at the acetyl-CoA carboxylase (ACCase) enzyme of grass species. These grass species are killed by the inhibition of the ACCase enzyme, which is a key enzyme in the lipid biosynthetic pathway. The proposed new use is also for control of a wide range of annual and perennial grasses, in corn fields before crop planting. This risk assessment evaluates the ecological risk of this proposed new Section 3 label use.

Figure 1 Clethodim Chemical Structure



#### 2. Physical/Chemical/Fate and Transport Properties

Known important physical, chemical, and fate and transport property values for clethodim and its major degradates are listed in Table 1 and 2. The only significant routes of dissipation of clethodim are microbial degradation in soil and movement by leaching or runoff. Parent clethodim is moderately persistent to hydrolysis at pH 5 with half-lives of 26-42 days and stable at pH 7 and 9 with half-lives of greater than 300 days. Even though acceptable water and soil photolysis studies show half-lives of 1.5 to 9.3 days, this may not be an important route of dissipation because of suspended sediment and shading. Photolysis is only an important route of dissipation in shallow, well-mixed surface water with no shading. The half-lives in aerobic soil

are 2-3 days for parent clethodim, and 30-38 days for total toxic residues (parent + sulfoxide + sulfone). The sulfoxide (Figure 2) and sulfone (Figure 3) metabolites are more persistent than parent clethodim and are formed in significant quantities in soil. Clethodim sulfoxide degradate, peaked at 60.7-64.6% of the applied at 7 days post treatment, while clethodim sulfone (nonvolatile), which was formed from the oxidation of the sulfoxide, peaked at 10.1-11.7% of the applied at 62 days post-treatment. Other degradates identified include: clethodim oxazole sulfone (9% at 125 days); clethodim oxazole sulfoxide (4% at 125 days); and clethodim imine sulfoxide (2% at 7-14 days).

All residues of clethodim (parent and metabolites) are very mobile in soil with five out of six soil adsorption coefficients ( $K_d$ ) less than one. The field dissipation studies show that parent clethodim was only found at levels at or near the quantitation limit of 0.02 ppm, which is consistent with the rapid degradation in soil. Clethodim sulfoxide had an apparent half-life of 2.5 to 3.7 days.

**Table 1 Environmental Fate Properties of Clethodim**

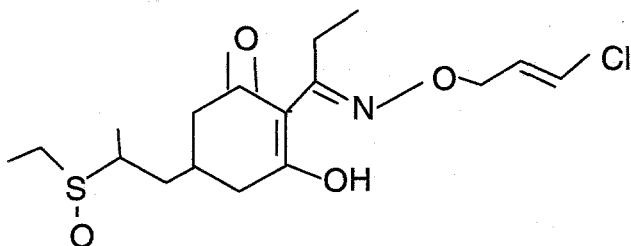
<b>Clethodim</b>		
<b>Property</b>	<b>Value</b>	<b>Source</b>
CAS number	99129-21-2	Tomlin 2003
Molecular weight	359.9	Tomlin 2003
Molecular formula	C <sub>17</sub> H <sub>26</sub> ClNO <sub>3</sub> S	Tomlin 2003
Water solubility	49.9 mg/L	MRID 409745-20
log K <sub>ow</sub>	1.6	FOOTPRINT*
Vapor pressure	<1.2 mPa at 20 °C	Tomlin 2003
Henry's Law constant	1.2x10 <sup>-11</sup> atm-m <sup>3</sup> /mol	EPIWIN 2006
Soil adsorption coefficient K <sub>oc</sub> (L/kg)	5-270	MRID 409745-23
Hydrolysis half-Life pH = 5 pH = 7 pH = 9	26 days 300 days 300 days	MRID 409745-20
Photolysis half-life in water	1.39 days (pH 5), 4.05days (pH 7), and 5.43 days (pH 9) 1.5 days (pH 5), 6.4days (pH 7), and 9.3 days (pH 9)	MRID 410301-33 MRID 410301-34
Photolysis half-life in soil	Biodegradation occurred too rapidly to adequately measure the soil photolysis half-life.	MRID 410301-35
Aerobic metabolism half-life in soil	2.6 days 1.06 days	MRID 413768-01
Fish bioconcentration factors	0.71and 2.1 for edible tissue; 3 and 4 for non-edible; 2.3 and 3.6 for whole fish	MRID 409745-31 MRID 409745-24

\*: FOOTPRINT\* Pesticide Properties Database

**Table 2. Available environmental fate properties of Clethodim degradates: Clethodim Sulfoxide and Clethodim Sulfone**

	Sulfoxide	Sulfone	
Property	Value		Source
CAS number	N/A		
Molecular weight	368.0	376.0	FOOTPRINT
Molecular formula	2,6-diethyl-N-methoxymethyl-2-sulfoacetanilide		FOOTPRINT
Water solubility			
log K <sub>ow</sub>			
Vapor pressure			
Henry's Law constant	N/A	N/A	
Soil adsorption coefficient K <sub>oc</sub> (L/kg)	44	22	FOOTPRINT
Hydrolysis half-Life pH = 5 pH = 7 pH = 9	N/A	N/A	
Photolysis half-life in water			
Photolysis half-life in soil	N/A	N/A	
Aerobic metabolism half-life in soil	30-35 days	30-90	Estimated; MRID 409745-22
Fish bioconcentration factors	N/A	N/A	

### Figure 2 Clethodim Sulfoxide



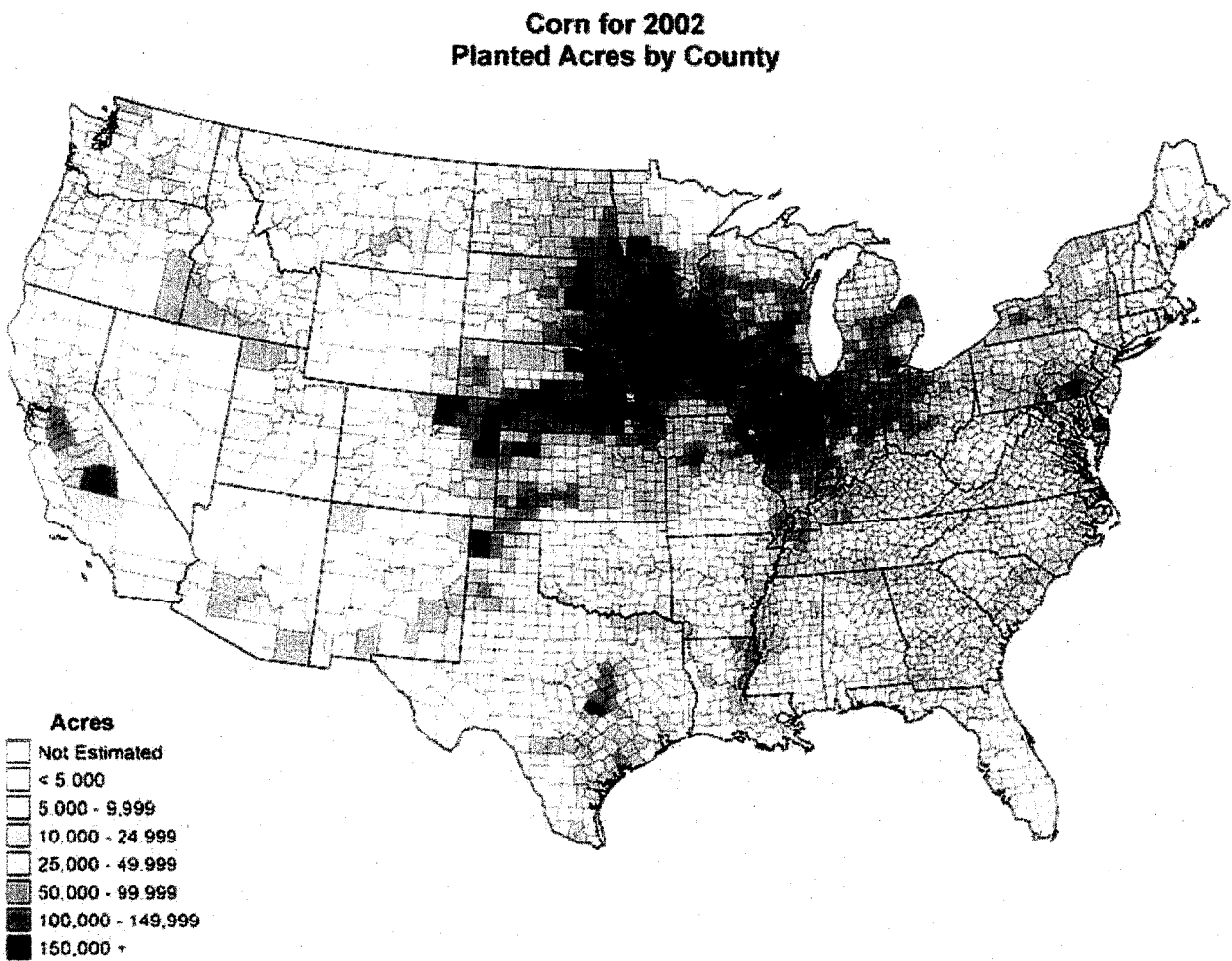
CCSCC(C)CCC1=C(O)C(=O)C(=C1)/C=N/O/C=C/Cl

[<sup>14</sup>C] clethodim residues did not significantly accumulate in bluegill sunfish. Maximum bioconcentration factors were 0.7-2.1 for edible tissues, 3.0-4.0 for non-edible tissues, and 2.3-3.6 for whole fish. Allyl-labeled [<sup>14</sup>C] residues that did accumulate during the 28 day exposure period were depurated gradually, representing only 49% depuration from edible tissues, 75% from non-edible tissues, and 72% from the whole fish). In contrast, cyclohexene-labeled [<sup>14</sup>C] residues that did accumulate were depurated rapidly, [<sup>14</sup>C] residues were non-detectable in edible tissues (<0.0358 ppm), non-edible tissues (<0.0365 ppm), and whole fish (<0.0364 ppm), indicating rapid depuration rates from the fish.

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areas for the new use. A map of corn planted in the U.S. is provided in Figure 4. As seen in the map, the proposed use is expected to span a wide range of environmental conditions.

**Figure 4 Distribution of Corn planted in the Contiguous United States**



**B. Exposure Pathways and Receptors**

Agricultural use of clethodim (including its major degradates: sulfoxide and sulfone) may cause exposure of non-target organisms by direct contact, by run-off of precipitation from treated fields, by spray drift, or by a combination of routes. Directly exposed monocot plants may die, suffer reduced growth, or may have difficulty reproducing.

Indirect effects may also occur when population changes in directly exposed organisms cause non-exposed organisms to suffer changes in food supply, habitat thereby causing mortality, reduced growth, reduced reproduction or population changes in the non-exposed organism.

### **C. Assessment Endpoints**

Assessment endpoints are defined as "explicit expressions of the actual environmental value that is to be protected." Defining an assessment endpoint involves two steps: 1) identifying the valued attributes of the environment that are considered to be at risk; and 2) operationally defining the assessment endpoint in terms of an ecological entity (i.e., a community of fish and aquatic invertebrates) and its attributes (i.e., survival and reproduction). Therefore, selection of the assessment endpoints is based on valued entities (i.e., ecological receptors), the ecosystems potentially at risk, the migration pathways of pesticides, and the routes by which ecological receptors are exposed to pesticide-related contamination. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Changes to assessment endpoints are typically estimated from the available toxicity studies, which are used as the measures of effects to characterize potential ecological risks associated with exposure to a pesticide.

To estimate exposure concentrations, the ecological risk assessment considers application at the maximum rate to fields that have vulnerable soils. If multiple applications are allowed, the maximum amount per application and minimum interval between applications are used provided that maximum total annual application amounts are also included in this configuration. The most sensitive toxicity endpoints are used from surrogate test species to estimate treatment-related direct effects on acute mortality and chronic reproductive, growth and survival assessment endpoints. Toxicity tests are intended to determine effects of pesticide exposure on birds, mammals, fish, terrestrial and aquatic invertebrates, and plants. These tests include short-term acute, sub-acute, and reproduction studies and are typically arranged in a hierarchical or tiered system that progresses from basic laboratory tests to applied field studies. The toxicity studies are used to evaluate the potential of a pesticide to cause adverse effects, to determine whether further testing is required, and to determine the need for precautionary label statements to minimize the potential adverse effects to non-target animals and plants. The assessment endpoints used in the assessment of the proposed use of clethodim on corn are presented in Table 3.

Table 3. Assessment endpoints for Clethodim.

Parameter	Study Type	Species	Exposure Duration	Toxicity Value	Reference (Study Classification)
1. Abundance (i.e., survival, reproduction, and growth) of individual birds	1a. Acute (Dose-based)	Bobwhite quail ( <i>Colinus virginianus</i> )	Single oral dose	>2000 mg/kg-bw (LD50)	409745-25
	1b. Acute (Dietary-based)	Bobwhite quail ( <i>Colinus virginianus</i> )	5-Day dietary	>4,270 ppm (LC50)	409745-26
	1c. Chronic (Dietary-based)	Bobwhite quail ( <i>Colinus virginianus</i> )	Avian reproduction study	250 ppm (NOAEC)	410302-06 * (Supplemental)
2. Abundance (i.e., survival, reproduction, and growth) of individual mammal	2a. Acute	Rat ( <i>Rattus norvegicus</i> )	Single oral dose	1,360 mg a.i./kg-bw (LD <sub>50</sub> )	409745-07
	2b. Chronic	Rat ( <i>Rattus norvegicus</i> )	2-Generation reproduction study	500 ppm a.i (NOAEC)	410301-20
3. Survival and reproduction of freshwater fish and invertebrates	<b>Freshwater Fish</b>				
	3a. Acute	Rainbow trout ( <i>Oncorhynchus mykiss</i> )	96 hours	15 mg a.i./L (LC50)	409745-28
	3b. Chronic	N/A	N/A	N/A	N/A
	<b>Freshwater Invertebrates</b>				
	3c. Acute	Water flea ( <i>Daphnia magna</i> )	48 hours	5.7 mg/L a.i. (LC50)	4 1685 1-01
	3d. Chronic	N/A	N/A	N/A	N/A
4. Survival and reproduction of estuarine/marine fish and invertebrates	<b>Estuarine/Marine Fish</b>				
	4a. Acute	N/A	N/A	N/A	N/A
	Chronic	N/A	N/A	N/A	N/A
	<b>Estuarine/Marine Invertebrates</b>				
	4b.	N/A	N/A	N/A	N/A

Parameter	Study Type	Species	Exposure Duration	Toxicity Value	Reference (Study Classification)
	Acute				
	4c. Chronic	N/A	N/A	N/A	N/A
5. Perpetuation of individuals and populations of non-target terrestrial plants (crops and non-crop plant species)	<b>Plants - seedling emergence</b>				
	5a. Monocot	Oat, rye grass, corn, onion	Single application	0.004 lbs TEP /acre (NOAEC)	416851-04
				0.0063 lb TEP/acre (EC <sub>25</sub> )	
	5b. Dicot	N/A	Single application	> 0.25 lbs/acre	41685102
	<b>Plants - vegetative vigor</b>				
	5c. Monocot	Oat, rye grass, corn, onion	Single application	0.003 lbs TEP/acre (NOAEC)	416851-05
				0.003 lb TEP/acre (EC <sub>25</sub> )	
	5d. Dicot	N/A	Single application	> 0.25 lbs TEP/acre	41685103
6. Survival of beneficial insects	6a. Acute Contact	Honey Bee ( <i>Apis mellifera</i> )	48 hours	> 100 ug/bee	410302-05
7. Maintenance and growth of aquatic plants from standing crop or biomass	6b. Vascular	Duckweed ( <i>Lemna gibba</i> )	14 days	1.1 mg a.i. /L (EC <sub>50</sub> )	420297-01
				0.30 mg/L (NOAEC)	
	6c. Algae	Freshwater alga ( <i>Selenastrum capricornutum</i> )	120 hours	11.0 mg a.i./L (EC <sub>50</sub> )	42029706
		Freshwater diatom ( <i>Navicula pelliculosa</i> )		3.1 mg a.i./L (NOAEC)	



Parameter	Study Type	Species	Exposure Duration	Toxicity Value	Reference (Study Classification)
	6d. Algae	Marine alga ( <i>Skeletonema costatum</i> )	120 hours	8.6 mg a.i./L (EC <sub>50</sub> )  5.4 mg a.i./L (NOAEC)	420297-04

\* Note: The study is classified as supplemental because it was determined to be scientifically sound but does not fulfill the requirements for an avian reproductive test, since a high rate of adult mortality was not adequately explained.

## D. Conceptual Model

### 1. Risk Hypotheses

Based on the exposure pathways, exposure media, and potential receptors of concern (Section II.B), specific risk hypotheses formulated to characterize direct effects of clethodim following application by ground or aerial spray on corn fields to selected assessment endpoints (Section II.C) is provided below. The analysis plan is in Section II.E., and outlines the approach and methods used in this risk assessment to evaluate these risk hypotheses.

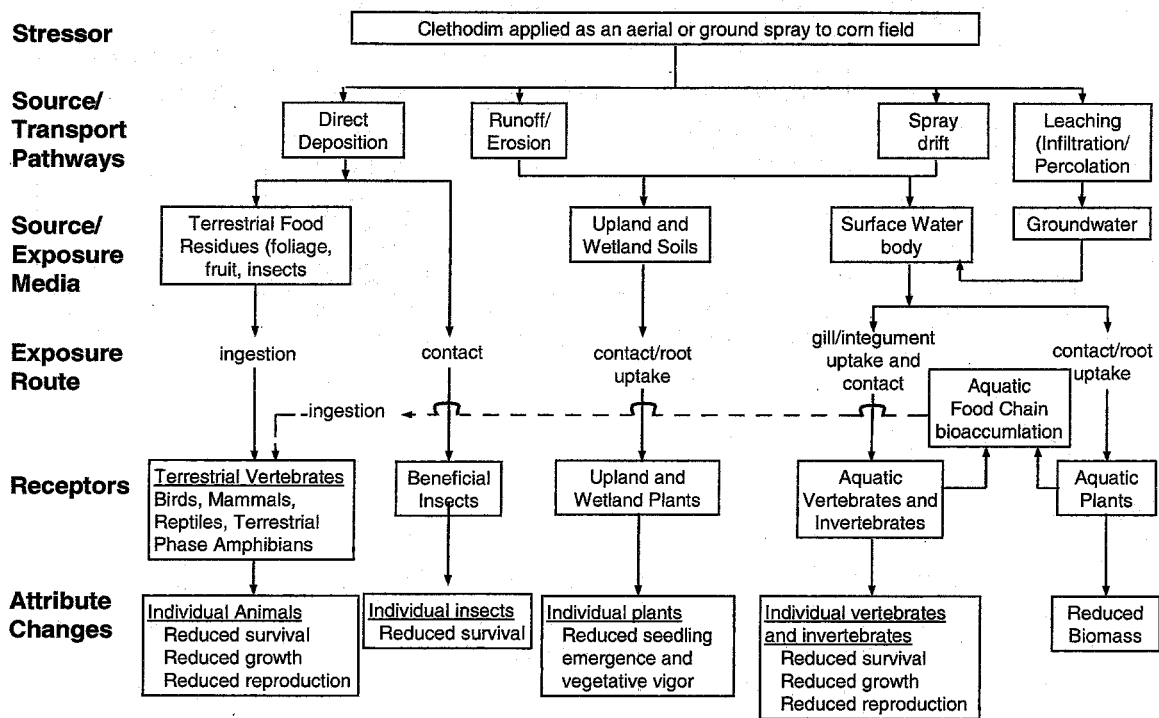
#### *a. Aquatic Environment Risk Hypotheses for Emulsified Clethodim Uses*

- A reduction in the number of aquatic invertebrates and fish will occur in areas adjacent to a field following clethodim application if runoff results in water concentrations that reach levels of concern for acute mortality or reproductive effects.
- A reduction in aquatic plants will occur in areas adjacent to a field following clethodim application if runoff results in water concentrations that reach levels of concern for cyanobacteria and algal population growth or vascular plant population growth.

#### *b. Terrestrial Environment Risk Hypotheses for Emulsified Clethodim Uses*

- A reduction in the number of terrestrial animals will occur from residues on dietary items following clethodim applications to the field by ground or aerial spray.

## 2. Diagram



**Figure 5. Conceptual Model of Exposure Pathways, Receptors, and Assessment Endpoints for the Assessment of Clethodim Use as a Preemergent Herbicide for Corn Crops**

## E. Analysis Plan

### 1. Measures of Exposure

#### a. Terrestrial Animals

Exposure of terrestrial animals to on-field residues of clethodim is quantified by using T-REX, a model which automates calculation of dietary exposure based on application rate and number of applications and the Hoerger-Kenaga nomogram for residue on foliage, modified for insects and seeds. Several food item types and body weight classes for the exposed organisms are considered for both dose based and dietary based exposures.

#### b. Terrestrial and Riparian or Wetland Plants

Exposure of off-field upland terrestrial plants and wetland or riparian plants is quantified by using TerrPlant, a model that estimates run-off and spray drift loading to off-field locations.

*c. Aquatic Animals and Plants*

Exposure of aquatic organisms is quantified by using the GENEEC model to simulate water concentrations in a 2-meter deep standing surface water body adjacent to the treated field. These exposures are compared to toxicity endpoints derived from standard guideline studies for acute and chronic effects.

**2. Estimates of Risk**

The Risk Quotient Method is the means used to integrate the results of exposure and ecotoxicity data, for evaluation of formulated clethodim risk hypotheses (Section II.D). For this method, risk quotients (RQs) are calculated by dividing exposure estimates for given media and exposure routes (Section II.E.1) by ecotoxicity values (Section II.E.2), both acute and chronic (Equation 1).

**Equation 1**

$$\text{Risk Quotient (RQ)} = \frac{\text{Exposure (Concentration or Dose)}}{\text{Toxicity Value (Concentration or Dose)}}$$

RQs are then compared to OPP’s risk presumptive levels of concern (LOCs), which are provided in Table 4. These LOCs are criteria used by OPP to indicate potential risk to non-target organisms and the need to consider regulatory action. LOCs have been defined for acute risk for non-listed species, potential restricted use classification, acute listed species risks, and chronic risks .

**Table 4 Risk Presumption Levels of Concern**

Risk Presumption	RQ	LOC
Birds and Wild Mammals		
Acute Risk	Dietary based: EEC <sup>a</sup> (ppm <sup>b</sup> ) / LC <sub>50</sub> (ppm)	0.5
	Dose based: EEC (mg/kg-bw/d) / LD <sub>50</sub> (mg/kg-bw/d <sup>c</sup> )	
Acute Restricted Use	Dietary based: EEC (ppm) / LC <sub>50</sub> (ppm)	0.2
	Dose based: EEC (mg/kg-bw/d) / LD <sub>50</sub> (mg/kg-bw/d)	
Acute Listed Species	Dietary based: EEC (ppm) / LC <sub>50</sub> (ppm)	0.1
	Dose based: EEC (mg/kg-bw/d) / LD <sub>50</sub> (mg/kg-bw/d)	
Chronic Risk	Dietary based: EEC (ppm) / NOAEC (ppm)	1.0
	Dose based: EEC (mg/kg-bw/d) / NOAEL (mg/kg-bw/d)	
Aquatic Animals		

<b>Risk Presumption</b>	<b>RQ</b>	<b>LOC</b>
Acute Risk	EEC (ppm) / (LC <sub>50</sub> (ppm) or EC <sub>50</sub> (ppm))	0.5
Acute Restricted Use	EEC (ppm) / (LC <sub>50</sub> (ppm) or EC <sub>50</sub> (ppm))	0.1
Acute Listed Species	EEC (ppm) / (LC <sub>50</sub> (ppm) or EC <sub>50</sub> (ppm))	0.05
Chronic Risk	EEC (ppm) / NOAEC (ppm)	1.0
<b>Terrestrial Plants and Plants Inhabiting Semi-Aquatic Areas</b>		
Acute Risk	EEC (lbs ai/A) / EC <sub>25</sub> (lbs ai/A)	1.0
Acute Listed Use	EEC (lbs ai/A) / (EC <sub>05</sub> or NOAEC (lbs ai/A))	1.0
<b>Aquatic Plants</b>		
Risk	EEC (ppm) / EC <sub>50</sub> (ppm)	1.0
Listed Species	EEC (ppm) / (EC <sub>05</sub> or NOAEC (ppm))	1.0

<sup>a</sup> EEC = estimated environmental concentration

<sup>b</sup> ppm = parts per million

<sup>c</sup> mg/kg-bw/d = milligrams per kilogram of body weight per day

III. Analysis

A. Exposure Characterization

1. Aquatic Exposure Assessment

a. Aquatic Exposure Modeling

The exposure assessment for aquatic ecosystems is based on clethodim and total toxic clethodim metabolic residues (sulfoxide and sulfone). Exposure concentrations were estimated using the aquatic Tier 1 model GENEEC v.2.0 (GENEEC2, 2001). The GENEEC (GENeric Estimated Environmental Concentration) model uses the soil/water partition coefficient and degradation kinetic data to estimate run-off from a ten hectare field into a one hectare by two meter deep “standard” impoundment. This Tier I model was designed as a screen, and estimates conservative pesticide concentrations in surface water from a few basic chemical parameters and pesticide label use and application information.

Input values for GENEEC2 model are listed in Table 5. The estimated 90<sup>th</sup> percentile annual instantaneous peak, and 90<sup>th</sup> percentile annual peak 4-day, 21-day, 60-day, and 90-day average concentrations of clethodim total toxic residues (clethodim plus clethodim sulfoxide plus clethodim sulfone) predicted by the GENEEC2 model are presented in Table 6.

Table 5 Surface Water Exposure Inputs for GENEEC2 for Clethodim

Parameter	Input Value and Unit	Source
Maximum Application Rate	0.05 lb a.i./acre	IR-4 label (same as label maximum rate)
Number of Applications Per Crop Season	1	IR-4 label
K <sub>oc</sub>		
Parent only	5	Lowest non-sand Koc from 5 soils (MRID 40974523), range of 5-270 for parent and 6-172 for sulfone.
Total Toxic Residue	6	Total Toxic residue = parent + sulfoxide + sulfone.
Aerobic Soil Metabolic Half-time (days)		
Parent	1.6	Upper 90th confidence bounds of half-lives for parent clethodim and total toxic residue. Half-lives 1.06-2.6 days for parent and 30.1-38.6 days for total toxic residue
Total Toxic Residue	35.4	(MRID 41376801)
Is pesticide wetted-in?	No	Proposed use information on label.
Method of application	aerial	IR-4 label
Nozzle Height	B	High boom (20-50 inches, EFED default)
Spray Quality	A	Fine spray (EFED Default)
Width of no-spray zone	0	None specified
Incorporation depth	0	Broadcast application
Solubility in water (mg/L)	49.9	MRID 40974520

Parameter	Input Value and Unit	Source
Aerobic Aquatic Metabolic Halftime (days) Parent Total Toxic Residue	3.2 70.8	Aerobic soil metabolism half-lives multiplied by 2 in the absence of data to account for a change in media. This is standard guidance in surface water modeling (GENEEC and PRZM-EXAMS) when no acceptable aerobic aquatic metabolism data are available and the compound is stable to hydrolysis.
Photolysis Halftime (days) Parent and Total Toxic Residue	6.4	MRID's 41030133 and 41030134 Acc. nos. 099727and099728

**Table 6 EECs of Clethodim Total Toxic Residues in Surface Water, Modeled Using GENEEC2**

Peak (ppb)	4-day (ppb)	21-day (ppb)	60-day (ppb)	90-day (ppb)
2.90	2.88	2.74	2.45	2.26

***b. Surface Water Monitoring***

No surface water monitoring data for clethodim or its major degradates were found in the literature or the U.S. Geological Survey NAWQA database.

***c. Field Study Data***

**Mississippi (MRID 410302-07)** In a field study in Mississippi, clethodim in the form of Select 2EC was applied twice at 0.25 lb a.i./A/application to a mature cotton crop. Five 90-cm soil cores were collected pre-treatment, day 0-treatment 1, day 0-treatment 2, and at 1, 2, 3, 4, 7, 14, 21, 28 days and 2, 3, and 4 months after the last treatment. Total rainfall and irrigation data during the field study were not reported. The soil cores were analyzed for clethodim and potential metabolites clethodim sulfone, clethodim oxazole sulfoxide, and clethodim oxazole sulfone. The parent clethodim was only found at levels at or near the limit of quantitation (0.02 ppm). The major metabolite, clethodim sulfoxide, showed a maximum concentration of 0.01 ppm and quickly dissipated such that none was detected at 14 days; a half-life of 3.7 days was calculated for this degradate. The metabolites clethodim sulfone, clethodim oxazole sulfoxide, and clethodim oxazole sulfone, were only found at levels at or below the limit of quantitation (0.02 ppm). In all cases, the 28 day samples showed no residues of any kind.

**California (MIRD 410302-08)** In a field study in California, clethodim in the form of Select 2EC was applied twice at 0.25 lb a.i./A/application to a cotton crop (first application was at the 2nd-square growth stage and the second application at the late-flowering stage). Total rainfall and irrigation data during the field study were not reported. Five 90-cm soil cores were collected pre-treatment, day 0-treatment 1, day 0-treatment 2, and at 1, 2, 3, 4, 7, 14, 21, 28 days and 2, 3, and 4 months after the last treatment. The soil cores were analyzed for clethodim and potential

metabolites clethodim sulfone, clethodim oxazole sulfoxide, and clethodim oxazole sulfone. The parent clethodim was only found at levels at or near the limit of quantitation (0.02 ppm). The major metabolite, clethodim sulfoxide, showed a maximum concentration of 0.04 ppm and quickly dissipated such that none was detected at 7 days; a half-life of 2.5 days was calculated for this degradate. The metabolites, clethodim sulfone, clethodim oxazole sulfoxide, and clethodim oxazole sulfone, were only found at levels at or below the limit of quantitation (0.02 ppm). In all cases, the 21 day samples showed no residues of any kind.

While no movement of residues was detected in either study, this does not necessarily mean that no movement occurred. Levels of residue were likely undetectable due to the low initial levels of clethodim applied, together with the rapid rate of metabolism of clethodim and its degradates. Laboratory studies show that leaching might be a concern if the compound were persistent.

**2. Terrestrial Exposure Assessment**

***a. Bird and Mammal Exposure***

The T-REX model (v1.2.3, USEPA, 2005) was used to estimate the terrestrial animal exposure values resulting from possible dietary ingestion of clethodim residues on vegetative matter and insects. The EEC values were calculated based on the default foliar dissipation half-life of 35 days for the parent and degradates due to the lack of foliar dissipation data. The terrestrial EECs were calculated based on the proposed single maximum label application rate (0.05 lbs a.i./A). The predicted maximum residues of clethodim that may be expected to occur on selected avian or mammalian food items immediately following application are presented in Table 7.

**Table 7 EECs of Clethodim Residues on Avian and Mammalian Dietary Items**

APPLICATIONS: Rate	EEC (ppm)			
	Short grass	Tall grass	Broadleaf plants/ small insects	Fruits/pods/ large insects
One application of 0.05 lbs a.i./acre at yearly intervals	12	5.5	6.75	0.75

***b. Exposure Modeling for Non-Target Plants***

Terrestrial and semi-aquatic plant exposure characterization employs runoff and spray drift scenarios contained in OPP’s TERRPLANT model (See Appendix D). Exposure calculations are based on a pesticide’s water solubility and the amount of pesticide present on the surface soil within the first inch of depth. For dry areas, the loading of pesticide active ingredient from runoff to an adjacent non-target area is assumed to occur from one acre of treatment to one acre of non-target area; for semi-aquatic (wetland) areas, runoff is considered to occur from a larger source area with active ingredient loading originating from 10 acres of treated area to a single acre of non-target wetland. Default spray drift assumptions are 1% for ground applications and

5% for aerial, airblast, forced air, and chemigation applications. Terrestrial plant EECs for non-granular formulations are summarized in Table 8.

**Table 8 Soil EECs (lb a.i./A) in Upland Terrestrial and Semi-Aquatic Soils Adjacent to a Clethodim Treated Corn Field**

Rate of App in lbs. ai/A (Method)	Runoff Value (lb a.i./A)	Total Loading to Adjacent Areas (EEC = Sheet Runoff + Drift) (lb a.i./A)	Total Loading to Semi- aquatic Areas (EEC = Channelized Runoff + Drift) (lb a.i./A)	DRIFT EEC (lb a.i./A)
0.05 (Aerial)	0.02	0.0035	0.0125	0.0025

**B. Ecological Effects Characterization**

In screening-level ecological risk assessments, the effects characterization section describes the types of effects on aquatic and terrestrial organisms, which result from pesticide exposure. This characterization is based on registrant-submitted studies that describe information regarding acute and chronic effects toxicity for various aquatic and terrestrial animals and plants.

**Appendix B** summarizes the results of the registrant-submitted toxicity studies on clethodim used to characterize effects for this risk assessment.

The toxicity testing reported in this section is not an exhaustive survey of all species of birds, mammals, or aquatic organisms. Only a few surrogate species for both freshwater fish and birds are used to represent all freshwater fish (2000+) and bird (680+) species in the United States. For mammals, acute studies are usually limited to the Norway Rat or the House Mouse. Testing for reptiles and amphibians are not required. The risk assessment assumes that conclusions drawn from avian toxicity studies are applicable to reptiles. Similarly, conclusions drawn from studies conducted with fish are assumed applicable to amphibians.

In general, categories of acute toxicity ranging from “practically nontoxic” to “very highly toxic” have been established for aquatic organisms (based on LC<sub>50</sub> values), terrestrial mammals (based on LD<sub>50</sub> values), avian species (based on LC<sub>50</sub> values), and non-target insects (based on LD<sub>50</sub> values for honey bees).

**1. Aquatic Effects Characterization**

Summarized below in Table 9 are the most sensitive toxicity values to be used to calculate risk to aquatic animals, aquatic plants, and algae based on their maximum estimated exposure to clethodim. A more detailed summary of the aquatic toxicity data available is given in **Appendix B**.



**Table 9 Selected Clethodim Toxicity Values for Assessing Risk to Aquatic Organisms**

Study Type	Species	Exposure Duration	Toxicity Value	Reference (Study Classification)
<b>Freshwater Fish</b>				
Acute	Rainbow trout	96 hours	15 mg a.i./L (LC <sub>50</sub> )	409745-28 (Acceptable)
Chronic	N/A	N/A	N/A	N/A
<b>Freshwater Invertebrates</b>				
Acute	Water flea	48 hours	5.7 mg/L a.i. (LC <sub>50</sub> )	4 1685 1-01 (Acceptable)
Chronic	N/A	N/A	N/A	N/A
<b>Estuarine/Marine Fish</b>				
Acute	N/A	N/A	N/A	N/A
Chronic	N/A	N/A	N/A	N/A
<b>Estuarine/Marine Invertebrates</b>				
Acute	N/A	N/A	N/A	N/A
Chronic	N/A	N/A	N/A	N/A
<b>Aquatic Plants</b>				
Vascular	Duckweed	14 days	1.1 mg a.i. /L (EC <sub>50</sub> ) 0.30 mg/L (NOAEC)	420297-01 (Acceptable)
Algae	Freshwater diatom	120 hours	11 mg a.i./L (EC <sub>50</sub> ) 3.1 mg a.i./L (NOAEC)	42029706 (Acceptable)
Algae	Marine alga	120 hours	8.6 mg a.i./L (EC <sub>50</sub> ) 5.4 mg a.i./L (NOAEC)	420297-04 (Acceptable)
<b>Beneficial Insects</b>				
Acute Contact	Honey Bee	48 hours	> 100 ug/bee	410302-05

**2. Terrestrial Effects Characterization**

The acute and chronic toxicity reference values (TRVs) associated with exposure of terrestrial species to clethodim are summarized in Table 10. A more detailed summary of the terrestrial toxicity data available is given in Appendix B.

**Table 10 Selected Clethodim Toxicity Values for Assessing Risk to Terrestrial Organisms**

Study Type	Species	Exposure Duration	Toxicity Value	Reference (Study Classification)
<b>Mammals</b>				
Acute (Dose-based)	Rat	Single oral dose	1,360 mg a.i./kg-bw (LD <sub>50</sub> )	409745-07 (Acceptable)
Chronic (Dietary-based)	Rat	2-Generation reproduction study	500 ppm a.i (NOAEC)	410301-20 (Acceptable)
<b>Birds</b>				
Acute (Dose-based)	Bobwhite quail	Single oral dose	>2000 mg/kg-bw (LD <sub>50</sub> )	409745-25 (Acceptable)
Acute (Dietary-based)	Bobwhite quail	5-Day dietary	>4,270 ppm (LC <sub>50</sub> )	409745-26 (Acceptable)
Chronic (Dietary-based)	Bobwhite quail ( <i>Colinus virginianus</i> )	Avian reproduction study	150 ppm (NOAEC)	410302-06 * (Supplemental)
<b>Plants - seedling emergence</b>				
Monocot	Oat, rye grass, corn, onion	Single application	0.004 lbs TEP /acre (NOAEC) 0.0063 lb TEP/acre (EC <sub>25</sub> )	416851-04 (Acceptable)
Dicot	N/A	Single application	> 0.25 lbs/acre	41685102 (Acceptable)
<b>Plants - vegetative vigor</b>				
Monocot	Oat, rye grass, corn, onion	Single application	0.003 lbs TEP/acre (NOAEC) 0.003 lb TEP/acre (EC <sub>25</sub> )	416851-05 (Acceptable)
Dicot	N/A	Single application	> 0.25 lbs TEP/acre	41685103 (Acceptable)

\* Note: The study is classified as supplemental because it was determined to be scientifically sound but does not fulfill the requirements for an avian reproductive test, since a high rate of adult mortality was not adequately explained. Therefore the lowest value (150ppm) NOAEC was used in this analysis.

VIII. RISK CHARACTERIZATION

Risk characterization is the integration of exposure and effects characterization to determine the ecological risk and the likelihood of effects on aquatic life, wildlife, and plants based on varying pesticide-use scenarios. The risk characterization provides estimations and descriptions of the risk; articulates risk assessment assumptions, limitations, and uncertainties; synthesizes an overall conclusion; and provides the risk managers with information to make regulatory decisions. Risk assessment is based on clethodim and total toxic residues (sulfoxide and sulfone).

A. Risk Estimation - Integration of Exposure and Effects Data

Results of the exposure and toxicity effects data are integrated to evaluate the likelihood of adverse ecological effects on non-target species. For the baseline risk assessment of clethodim, the RQ method is used as an index of risk; RQs are compared to the Agency’s LOCs (Section II.E.3). These LOCs (Table 4) are the Agency’s interpretive policy to analyze potential risk to non-target organisms and assess the need to consider regulatory action. These criteria are used to indicate when a pesticide’s directed label use has the potential to cause adverse effects on non-target organisms.

1. Non-Target Terrestrial Animals (Birds, Mammals, and Beneficial Insects)

RQ values calculated for terrestrial animal exposure and the EEC for clethodim residues are provided in Table 11. No acute or chronic LOC is exceeded for birds or mammals. Since clethodim is practically nontoxic to honey bees no unacceptable adverse effect is expected and, no labeling precautions are required.

Table 11 Acute and Chronic RQ Values for Terrestrial Wildlife and Beneficial Insects

Taxa	Exposure Type	Most Sensitive Species	MRID/Study Classification	Toxicity	EEC	Risk Quotient
Birds	Subacute Dietary	Northern bobwhite quail	409745-26 Acceptable	> 4,270 ppm (LC <sub>50</sub> ; Practically nontoxic)	12 ppm <sup>a</sup>	< 0.1 <sup>a</sup>
Birds	Subacute Dietary	Mallard duck	409745-27 Acceptable	> 2000 ppm (LC <sub>50</sub> ; Practically nontoxic)	12 ppm	< 0.1
Birds	Chronic	Bobwhite Quail	410302-06 Supplemental	150 ppm (NOAEL)	12 ppm	< 1

Taxa	Exposure Type	Most Sensitive Species	MRID/Study Classification	Toxicity	EEC	Risk Quotient
Mammals	Acute	Rat	410301-02 Acceptable	> 1,400 mg/kg-bw (LD <sub>50</sub> )	11.44	< 0.1
Mammals	Chronic	Rat	410301-21 Acceptable	2,500 ppm (NOAEL)	12 ppm	< 0.1
Insects	Acute Contact	Honeybee	409745-32 Acceptable	> 100 ug/bee; (LC <sub>50</sub> )	NA <sup>b</sup>	Practically non-toxic

<sup>a</sup> The highest terrestrial EEC residue for clethodim is provided (short grass (12 ppm) after application of 0.05 lb. ai/A

<sup>b</sup> Currently, EFED does not assess risk to insects.

## 2. Non-Target Aquatic Animals (Fish and Invertebrate) and Plants

### a. Aquatic Animals

No toxicity data were available to assess the risk to estuarine/marine fish and invertebrates. Therefore, EFED only evaluated the risk to freshwater fish and invertebrates. Clethodim is slightly toxic to freshwater fish and invertebrates on an acute exposure basis. No toxicity data were available to estimate the chronic risk of clethodim to aquatic animals. Based on estimated peak surface water exposure concentrations for parent clethodim alone and for total residues (clethodim + degradates) obtained from GENEEC, acute risk quotients for freshwater animals are below levels of concern (Table 12).

**Table 12 RQ Values for Aquatic Animals**

Taxa	Exposure Type	Most Sensitive Species	MRID/ Classification	Toxicity Value	EEC (ppm) <sup>1</sup>	RQ
Freshwater Fish	Acute	Rainbow trout	409745-28 Acceptable	15 ppm	0.003	< 0.05 <sup>2</sup>
Freshwater Invertebrates	Acute	<i>Daphnia magna</i>	416851-01 Acceptable	5.7 ppm	0.003	< 0.05

<sup>1</sup> GENEEC2 generated estimated environmental concentration. See Tables 1 and 2.

<sup>2</sup> The LOC for adverse effects is not exceeded.

### b. Aquatic Plants

Risk quotients based on total toxic residues were less than 1 and thus did not exceed any level of concern for aquatic plants (Table 13).

Table 13 RQ Values for Aquatic Plants from Estimated Clethodim Residues in Surface Water

Type of Plant	Most Sensitive Species/MRID	Toxicity <sup>1</sup>		Risk Quotient		
		EC <sub>50</sub> (ppm)	NOAEL (ppm)	EEC (ppm)	Non-listed (EEC/EC <sub>50</sub> )	Endangered (EEC/NOAEL)
Vascular	<i>Lemma gibba</i> 420297-01	1.1	0.30	0.003	< 1	< 1
Non-vascular (algae)	<i>Anabaena flos-aquae</i> MRID 42029705	16.7	5.6	0.003	<1	<1
	<i>Skeletonema costatum</i> MRID 42029704	8.6	5.4	0.003	<1	<1
	<i>Navicula pelliculosa</i> MRID 42029706	11	3.1	0.003	<1	<1

3. Non-Target Terrestrial and Semi-Aquatic Plants

To determine the potential risk of clethodim to terrestrial plants, the EC<sub>25</sub> and NOEL values of the most sensitive species in the seedling emergence study (Table 9) are compared to runoff and drift exposure, and the EC<sub>25</sub> and NOEL values of the most sensitive species (Table 9) in the vegetative vigor study are compared to the drift exposure to calculate the risk quotients. The calculated risk quotients for terrestrial plants indicate that the LOC is exceeded for risk to non-listed and listed monocotyledon plants only (Table 14).

Table 14 RQ Values for Terrestrial and Semi-Aquatic (Riparian-Wetland) Plants from Clethodim Runoff and Spray Drift

	Adjacent Areas RQ = EEC/(Seedling Emergence EC <sub>25</sub> for nonlisted and NOAEL for listed species) EEC = Runoff + Drift		Semi-aquatic areas RQ = EEC/(Seedling Emergence EC <sub>25</sub> for nonlisted and NOAEL for listed species) EEC = Runoff + Drift		Drift RQs RQ = Drift EEC/(Vegetative Vigor EC <sub>25</sub> for nonlisted and NOAEL for listed species)	
	Monocot	Dicot	Monocot	Dicot	Monocot	Dicot
Nonlisted Species						
	0.88	NC *	3.13	NC *	0.83	NC *
Listed Species						
	0.88	NC**	3.13	NC**	0.83	NC**

\* The RQ value for nonlisted dicot species was not calculable because the EC<sub>25</sub> value was > 0 .25 lbs .a.i./acre which was the highest application rate tested, and is also the highest application rate of current registered uses. However, since the EC<sub>25</sub> is higher than the highest application rate for the proposed corn use, the RQ would be less than one.

\*\*The RQ for listed dicot species was not calculable because the NOAEC value was > 0 .25 lbs/acre which was the highest application rate tested, and is also the highest application rate for current registered uses.

## **B. Risk Description**

### **1. Risks to Terrestrial Organisms**

#### ***a. Animals***

There are no acute or chronic LOC exceedances for birds or mammals. Therefore there is no presumption of direct acute or chronic risks to birds and the taxa they are surrogates for (i.e., reptiles and terrestrial-phase amphibians) or mammals from the proposed use of clethodim on corn crops.

#### ***b. Risk to terrestrial plants***

LOC values are exceeded for listed and non-listed monocot plant species inhabiting semi-aquatic areas that receive runoff and spray drift from clethodim use on corn crops. Therefore there is a presumption of direct risks to these species in riparian or wetland areas. However, based on the best available terrestrial plant toxicity data this risk is only applicable to monocot plant species and not to dicot species or to monocots in upland areas. The best available toxicity data indicates that dicots are much less sensitive to clethodim than monocots (Appendix B). Additionally, loading and spray drift to upland areas is expected to be below listed and nonlisted LOC values for both monocots and dicots; therefore, there is no presumption of direct risks to these areas and species.

### **2. Risk to Aquatic Organisms**

#### ***a. Animals***

##### **Acute Risk**

Based on the available data, there is no acute LOC exceedance for non-listed or listed fish or invertebrates for the proposed use at the maximum label application rate of one application of 0.05 lbs. a.i./acre. Thus, EFED predicts that there will be minimal risk of adverse acute effects to fish or aquatic invertebrates. These risk quotient calculations are based only on freshwater fish and invertebrate studies. No marine or estuarine fish or invertebrate toxicity data have been submitted to the Agency.

##### **Chronic Risk**

Currently, no fish or invertebrate chronic toxicity data are available for the Agency to evaluate the chronic toxicity risk of clethodim to fish and invertebrates. However, EFED expects clethodim to pose minimal risk of chronic toxic effects to fish or aquatic invertebrate since clethodim: 1) is only slightly toxic to fish and aquatic invertebrates on an acute basis, 2) is only moderately persistent in aquatic environments, and 3) poses a minimal risk of chronic toxic

effects to birds and mammals (Table 7). Similar compounds in the same herbicide class showed minimal risks and given that clethodim is expected to have greater toxicity than these compounds, minimal risk is expected. Further discussion of similar compounds and their toxicity characteristics may be found in Appendix E.

***b. Risk to aquatic plants and algae***

The RQs indicate that the LOCs are not exceeded for risk to aquatic plants or algae. Thus, EFED predicts that there will be minimal risk of adverse effects to aquatic plants or algae.

**3. Federally Threatened and Endangered (Listed) Species Concerns**

***a. Action Area***

For listed species assessment purposes, the action area is considered to be the area affected directly or indirectly by the Federal action and not merely the immediate area involved in the action. At the initial screening-level, the risk assessment considers broadly described taxonomic groups and so conservatively assumes that listed species within those broad groups are collocated with the pesticide treatment area. This means that terrestrial plants and wildlife are assumed to be located on or adjacent to the treated site and aquatic organisms are assumed to be located in a surface water body adjacent to the treated site. The assessment also assumes that the listed species are located within an assumed area, which has the relatively highest potential exposure to the pesticide, and that exposures are likely to decrease with distance from the treatment area. The Use Characterization of this risk assessment presents the pesticide use sites (corn) that are used to establish initial collocation of species with treatment areas.

If the assumptions associated with the screening-level action area result in RQs that are below the listed species LOCs, a "no effect" determination conclusion is made with respect to listed species in that taxa, and no further refinement of the action area is necessary. Furthermore, RQs below the listed species LOCs for a given taxonomic group indicate no concern for indirect effects upon listed species that depend upon the taxonomic group covered by the RQ as a resource. However, in situations where the screening assumptions lead to RQs in excess of the listed species LOCs for a given taxonomic group, a potential for a "may affect" conclusion exists and may be associated with direct effects on listed species belonging to that taxonomic group or may extend to indirect effects upon listed species that depend upon that taxonomic group as a resource. In such cases, additional information on the biology of listed species, the locations of these species, and the locations of use sites could be considered to determine the extent to which screening assumptions regarding an action area apply to a particular listed organism. These subsequent refinement steps could consider how this information would impact the action area for a particular listed organism and may potentially include areas of exposure that are downwind and downstream of the pesticide use site.

### ***b. Taxonomic Groups Potentially at Risk***

The Level I screening assessment process for listed species uses the generic taxonomic group-based process to make inferences on direct effect concerns for listed species. The first iteration of reporting the results of the Level I screening is a listing of pesticide use sites and taxonomic groups for which RQ calculations reveal values that meet or exceed the listed species LOCs. In the majority of cases, the screening-level risk assessment process reports RQ calculations for the following broad taxonomic groupings:

- Birds (also used as surrogate for terrestrial-phase amphibians and reptiles)
- Mammals
- Freshwater fish (also used as a surrogate for aquatic phase amphibians)
- Freshwater invertebrates
- Estuarine and marine fish
- Estuarine and marine invertebrates
- Terrestrial invertebrates
- Terrestrial plants
- Aquatic plants

#### **(1) Discussion of Risk Quotients**

As mentioned above, there are clethodim LOC exceedances for listed monocot terrestrial plants inhabiting areas adjacent to the clethodim use site and in semiaquatic areas that receive drainage from the clethodim use site. These exceedances range from 2.5 to 17.50. The LOC was not exceeded for dicot plants or for monocot plants not exposed to drainage from clethodim sites. Additionally, the proposed use does not exceed the Agency's LOC for direct toxic effects to birds, mammals, aquatic invertebrate, fish, aquatic plants, or algae.

## **4. Implications of Sublethal Effects**

### ***a Indirect Effects Analysis***

The Agency acknowledges that pesticides have the potential to exert indirect effects upon the listed organisms by, for example, perturbing forage or prey availability, altering the extent of nesting habitat, creating gaps in the food chain, etc.

In conducting a screen for indirect effects, direct effect LOCs for each taxonomic group are used to make inferences concerning the potential for indirect effects upon listed species that rely upon non-listed organisms in these taxonomic groups as resources critical to their life cycle.

*Screening-level RQs for monocot terrestrial plants* are above the LOCs. The Agency considers this to be indicative of a potential for adverse effects to those listed species within the action area that rely either on a specific plant species (plant species obligate) or multiple plant species (plant dependent) for some important aspect of their life cycle. The Agency may determine if listed organisms, for which plants were a critical component of their resource needs, are within the



action area. This will be accomplished through a comparison of Service-provided a species profiles and listed species location data. If no listed organisms that are either plant species obligates or plant dependent reside within the action area, a no effect determination on listed species will be made. If plant species obligate or dependent organism resides within the pesticide use area, the Agency will consider temporal and geographical nature of exposure, and the scope of the effects data, to determine if any potential effects can be determined to not likely adversely affect a plant species obligate or dependent listed organism.

EFED concludes that due to terrestrial plant LOC exceedances (using maximum application rates); there may be a concern for indirect effects to the following groups of organisms in the area for the clethodim regulatory action:

- Freshwater fish
- Freshwater amphibians
- Freshwater invertebrates
- Terrestrial invertebrates
- Birds
- Mammals
- Reptiles

For listed species that may potentially be affected directly and/or indirectly by the Federal action, see Appendices F (Locates runs). Table 15 illustrates the indications of whether clethodim poses a risk of direct or indirect effect to the different animal taxa evaluated in the risk assessment.

**Table 15. Direct and Indirect Risk Concerns For Federally Listed as Endangered and/or Threatened Species**

Listed Taxon	Direct Effects	Indirect Effects
Dicot terrestrial and semi-aquatic plants	No	No
Monocot terrestrial plants	No	No
Monocot semi-aquatic plants	Yes (Based on LOC exceedances to monocot terrestrial plants)	No
Birds	No	Yes, (Based on LOC exceedances to monocot semi-aquatic plants)
Freshwater Fish	Unknown	No
Terrestrial-phase amphibians	No	Yes, (Based on LOC exceedances to monocot semi-aquatic plants)
Reptiles	No	Yes, (Based on LOC exceedances to monocot semi-aquatic plants)
Mammals	No	Yes, (Based on LOC exceedances to monocot semi-aquatic plants)
Aquatic non--vascular plants	No	No
Aquatic vascular plants	No	No
Aquatic-phase amphibians	No	No

Listed Taxon	Direct Effects	Indirect Effects
Freshwater crustaceans	No	No
Mollusks	No	No
Marine/estuarine fish	No	No
Marine/estuarine crustaceans	No	No

#### ***b Critical Habitat***

In the evaluation of pesticide effects on designated critical habitat, consideration is given to the physical and biological features (constituent elements) of a critical habitat identified by the U.S. Fish and Wildlife and National Marine Fisheries Services as essential to the conservation of a listed species and which may require special management considerations or protection. The evaluation of impacts for a screening level pesticide risk assessment focuses on the biological features that are constituent elements and is accomplished using the screening-level taxonomic analysis (risk quotients, RQs) and listed species levels of concern (LOCs) that are used to evaluate direct and indirect effects to listed organisms.

The screening-level risk assessment has identified potential concerns for indirect effects on listed species for those organisms dependant upon *monocot terrestrial plants*. In light of the potential for indirect effects, the next step for EPA and the Service(s) is to identify which listed species and critical habitat are potentially implicated. Analytically, the identification of such species and critical habitat can occur in either of two ways. First, the agencies could determine whether the action area overlaps critical habitat or the occupied range of any listed species. If so, EPA would examine whether the pesticide's potential impacts on non-listed species would affect the listed species indirectly or directly affect a constituent element of the critical habitat. Alternatively, the agencies could determine which listed species depend on biological resources or have constituent elements that fall into the taxa that may be directly or indirectly impacted by the pesticide. Then EPA would determine whether use of the pesticide overlaps the critical habitat or the occupied range of those listed species. At present, the information reviewed by EPA does not permit use of either analytical approach to make a definitive identification of species that are potentially impacted indirectly or critical habitats that is potentially impacted directly by the use of the pesticide. EPA and the Service(s) are working together to conduct the necessary analysis.

This screening-level risk assessment for critical habitat provides a listing of potential biological features that, if they are constituent elements of one or more critical habitats, would be of potential concern. These correspond to the taxa identified above as being of potential concern for indirect effects and include the following: freshwater fish and aquatic invertebrates, amphibians, birds, mammals, and reptiles. This list should serve as an initial step in problem formulation for further assessment of critical habitat impacts outlined above, should additional work be necessary.

### ***c. Co-occurrence Analysis***

The goal of the analysis for co-location is to determine whether sites of pesticide use are geographically associated with known locations of listed species. At the screening level, this analysis is accomplished using the LOCATES database. The database uses location information for listed species at the county level and compares it to agricultural census data for crop production at the same county level of resolution. The product is a listing of federally listed species that are located within counties known to produce the crop upon which the pesticide will be used. Because the Level I screening assessment considers both direct and indirect effects across generic taxonomic groupings, it is not possible to exclude any taxonomic group from a LOCATES database run for a screening risk assessment. Given the extent of proposed clethodim usage across the U.S. and the expected large number of listed species that are likely to occur in counties where this pesticide is proposed to be used, a list of endangered/threatened species and crop acreage at the county level for the taxonomic groups and crops of concern is not included in this phase of the risk assessment process.

Appendices F provide a list of endangered/threatened species at the state level for the taxonomic groups of concern. EFED assumes that listed species may be at risk for the states where onion use occurs according to LOCATES, but where clethodim usage is not reported necessarily by BEAD Usage Report. The registrant must provide information on the proximity of federally listed freshwater invertebrates, terrestrial and aquatic plants, birds, mammals, amphibians, crustaceans, reptiles, arachnids, insects, snails, and clams to the clethodim use sites. This requirement may be satisfied in one of three ways: 1) having membership in the FIFRA Endangered Species Task Force (Pesticide Registration [PR] Notice 2000-2); 2) citing FIFRA Endangered Species Task Force data; or 3) independently producing these data, provided the information is of sufficient quality to meet FIFRA requirements. The information will be used by the OPP Endangered Species Protection Program to develop recommendations to avoid adverse effects to listed species.

## **C. Description of Assumptions, Uncertainties, Strengths, Limitations and Data Gaps**

### **1. Data Gaps**

The fate database for clethodim is complete. Based on the available data, there are no acute LOC exceedances for fish or aquatic invertebrates. There are no chronic toxicity data available for the Agency to access chronic risk of clethodim to fish and aquatic invertebrates. Currently, the Agency assumes no chronic risk to fish and invertebrates because clethodim: 1) is only slightly toxic to fish and aquatic invertebrates on an acute basis, 2) are only moderately persistent in aquatic environments, and 3) poses a minimal risk of chronic toxic effects to birds and mammals. However, there is some uncertainty regarding the chronic risk of clethodim to fish and aquatic invertebrate because no aquatic organism chronic toxicity data have been submitted to the Agency. This data will help clarify the uncertainty regarding the chronic risk of clethodim to fish and aquatic invertebrates.

## **2. Related to Exposure for All Taxa**

This screening-level risk assessment relies on labeled statements of the maximum rate of clethodim application, the maximum number of applications, and the shortest interval between applications (when applicable). Together, these assumptions constitute a maximum use scenario and can overestimate risk. However, the maximum use scenario must be considered because it is a reflection of the allowable use of clethodim.

## **3. Related to Exposure for Aquatic Species**

### ***a. Lack of Averaging Time for Exposure***

For an acute risk assessment, there is no averaging time for exposure. An instantaneous peak concentration, with a 1 in 10 year return frequency, is assumed. The use of the instantaneous peak assumes that instantaneous exposure is of sufficient duration to elicit acute effects comparable to those observed over more protracted exposure periods tested in the laboratory, typically 48 to 96 hours. In the absence of data regarding time-to-toxic event analyses and latent responses to instantaneous exposure, the degree to which risk is overestimated cannot be quantified. However, since no aquatic LOCs were exceeded, this is not an issue.

### ***b. Routes of exposure***

Screening-level risk assessments of pesticide application for aquatic organisms consider exposure through the gills. Other potential routes of exposure, not considered in this assessment, are discussed below:

### ***c. Dietary consumption***

The screening assessment does not consider the ingestion pathway. Due to the physical and chemical properties of clethodim, bioaccumulation is not expected to be an issue.

## **4. Exposure for Terrestrial Species**

### ***a. The Likelihood of Wildlife Presence at Time of Application***

Birds and mammals may utilize outdoor areas and animal premise areas that have been treated with clethodim therefore may be exposed.

### ***b. Significance of Wildlife Utilization of Treatment Areas***

Characterizing risk to non-target wildlife from the use of Clethodim on the areas, for which it is registered, requires a clear understanding of the many limitations of identifying exactly what species are most likely to use treated areas and for what purpose. The simple fact is wildlife utilization of animal premise areas and general outdoor areas is highly variable and difficult to predict and, as such, there is a great deal of uncertainty surrounding this issue when conducting an ecological hazard evaluation.

### ***c. Routes of Exposure***

The risk assessment findings of acute risk to terrestrial animals are based on risk assessments where ingestion of contaminated food is considered as the primary route of exposure. The risk assessment did not consider the other possible routes of exposure, e.g., dermal, preening, and respiratory pathways. Other routes of exposure, not considered in this assessment, are discussed below:

#### **(1). Incidental soil ingestion exposure**

This risk assessment does not consider incidental soil ingestion. Available data suggests that up to 15% of the diet can consist of incidentally ingested soil depending on the species and feeding strategy (Beyer et al., 1994).

#### **(2) Inhalation exposure**

This risk assessment does not consider respiratory pathways.

#### **(3) Dermal Exposure**

The screening assessment does not consider dermal exposure, except as it is indirectly included in calculations of RQs based on lethal doses per unit of pesticide treated area. Dermal exposure may occur through two potential sources: (1) incidental contact with contaminated vegetation, or (2) contact with contaminated water or soil.

The available measured data related to wildlife dermal contact with pesticides are extremely limited. The Agency is actively pursuing modeling techniques to account for dermal exposure via incidental contact with vegetation.

#### **(4) Drinking Water Exposure**

Drinking water exposure to a pesticide active ingredient may be the result of consumption of surface water or consumption of the pesticide in dew or other water on the surface of the treated area. For pesticide active ingredients with a potential to dissolve in runoff, puddles on the

treated area may contain the chemical. However, the likelihood of exposure to Clethodim via drinking water is not quantified in the exposure modeling.

#### (5) Incidental Pesticide Releases Associated with Use

This risk assessment is based on the assumption that the entire treatment area is subject to Clethodim application at the rates specified on the label. In reality, there is the potential for uneven application of the pesticide through such plausible incidents as changes in calibration of application equipment, spillage, and localized releases.

### **5. Related to Effects Assessment**

#### ***a. Age class and sensitivity of effects thresholds***

It is generally recognized that test organism age may have a significant impact on the observed sensitivity to a toxicant. The screening risk assessment acute toxicity data for fish are collected on juvenile fish between 0.1 and 5 grams. Aquatic invertebrate acute testing is performed on recommended immature age classes (e.g., first instar for daphnids, second instar for amphipods, stoneflies and mayflies, and third instar for midges). Similarly, acute dietary testing with birds is also performed on juveniles, with mallard being 5-10 days old and quail 10-14 days old.

Testing of juveniles may overestimate toxicity at older age classes for pesticidal active ingredients because younger age classes may not have the enzymatic systems associated with detoxifying xenobiotics. The screening risk assessment has no current provisions for a generally applied method that accounts for this uncertainty. In so far as the available toxicity data may provide ranges of sensitivity information with respect to age class, the risk assessment uses the most sensitive life-stage information as the conservative screening endpoint.

#### ***b. Use of the Most Sensitive Species Tested***

Although the screening-level risk assessment relies on a selected toxicity endpoint from the most sensitive species tested, it does not necessarily mean that the selected toxicity endpoints reflect sensitivity of the most sensitive species existing in a given environment. The relative position of the most sensitive species tested in the distribution of all possible species is a function of the overall variability among species to a particular chemical. In the case of listed species, there is uncertainty regarding the relationship of the listed species' sensitivity and the most sensitive species tested.

The Agency is not limited to a base set of surrogate toxicity information in establishing risk assessment conclusions. The Agency also considers toxicity data on non-standard test species when available.

## **6. Associated with Acute and Chronic LOCs**

The risk characterization section of the assessment document includes an evaluation of the potential for individual effects at an exposure level equivalent to the LOC. This evaluation is based on the median lethal dose estimate and dose/response relationship established for the effects study corresponding to each taxonomic group for which the LOCs are exceeded.

# Appendix A

## Environmental Fate Studies

### §161-1 Hydrolysis (MRID 409745-20; Acceptable)

Propyl-labeled [ $^{14}\text{C}$ ] clethodim incubated in the dark at 25 °C in sterilized aqueous buffers degraded with half-lives of 26 days at pH 5 (reviewer-calculated) and approximately 300 days at pH 7 and 9. Allyl-labeled [ $^{14}\text{C}$ ] clethodim degraded with half-lives of 42 days at pH 5 and 360 days at pH 7. The major degradates were clethodim oxazole and 1-chloropropen-3-ol.

### §161-2 Aqueous Photolysis (MRID 410301-33 and MRID 410301-34; Acceptable)

Photolysis first-order half-lives of [allyl-2- $^{14}\text{C}$ ] clethodim (approximately 10 ppm) in sterile buffer solutions at pH 5, 7, and 9 were 1.39, 4.05, and 5.43 days, respectively, when exposed to natural sunlight at  $25 \pm 1^\circ\text{C}$  (MRID 410301-33). Sulfoxidation and elimination of the chloroallyl side chain were two major initial photolytic reactions. The initial photoproducts were clethodim sulfoxide, imine, imine sulfoxide, chloroallyl alcohol and 3-chloropropenal which were then further photolyzed to form carbon dioxide and 1,2-dimethoxyethane(DME) sulfoxide; most of the photoproducts were rapidly formed and then degraded.

Photolysis first-order half-lives of [4, 6-ring  $^{14}\text{C}$ ]-clethodim (approximately 10 ppm) in sterile buffer solutions at pH 5, 7, and 9 were 1.5, 6.4, and 9.3 days, respectively, when exposed to natural sunlight at  $25 \pm 1^\circ\text{C}$  (MRID 410301-34). Sulfoxidation and elimination of the chloroallyl side chain were two major initial photolytic reactions. The initial photoproducts were clethodim sulfoxide and imine, which were then further photolyzed to form imine sulfoxide and DME sulfoxide; most of the photoproducts were rapidly formed and then degraded, except DME sulfoxide.

In both of these studies, the authors made the same conclusion: the results imply that clethodim would be degraded faster under natural conditions since photosensitizers are known to be present in natural waters.

### §161-3 Soil Photolysis (MRID 410301-35; Acceptable)

The surface of a sandy loam (Crevasse, from Greenville, Mississippi) was treated with ring-labeled [ $^{14}\text{C}$ ] clethodim at a rate equivalent to 0.25 lb/A and then exposed to natural sunlight under outdoor conditions for 0, 1, 2, 3, 4, and 7 days. Less than 6.8% of parent remained after 7 days. Little or no volatile material, organic or carbon dioxide ( $\text{CO}_2$ ), was produced. The single major product was clethodim sulfoxide. All products were



detected in both light and dark flasks. Least square analysis of the data gave half-lives of 1.87 and 1.96 days for the dark samples, and 1.53 and 1.82 days for the light samples in the two runs. The study author felt that since the dark and light-exposed flasks yielded statistically identical results, it could be concluded that the degradates detected were metabolites, rather than photoproducts, and that soil metabolism predominated under the experimental conditions. The reviewer concluded that the metabolism of clethodim is so rapid that photolysis on soil will not be a major pathway of degradation.

**§162-1 Aerobic Soil Metabolism (MRID 409745-22 and MRID 413768-01 (a revision of MRID 409745-21); Acceptable)**

Propyl-labeled [ $^{14}\text{C}$ ] clethodim incubated at 25 °C at an initial concentration of 10.3-10.7 ppm in a sandy loam soil (1% organic matter, pH 7.1) degraded with a half-life of approximately 2.6 days (registrant-calculated) (MRID 409745-22). Labeled [ $^{14}\text{C}$ ] clethodim decreased from 99.8% of the applied at day 0 to 46% at 3 days and 2.8% at 14 days; 0.4% of the [ $^{14}\text{C}$ ] clethodim applied to the soil remained undegraded at 380 days. The major degradate at the end of the 380 day incubation period was  $\text{CO}_2$  which represented 54.4% of the applied radioactivity. Clethodim sulfoxide, which was initially the major nonvolatile degradate, peaked at 60.7-64.6% of the applied at 7 days post treatment, decreased to 12.8-16.5% at 62 days, and was  $\leq 0.3\%$  at 120-380 days. Clethodim sulfone (nonvolatile), which was formed from the oxidation of the sulfoxide, peaked at 10.1-11.7% of the applied at 62 days post-treatment, declined to 3.7-5.0% at 90 days post-treatment, and was  $< 0.6\%$  at 180-380 days post-treatment. Other nonvolatile degradates identified during the study were: clethodim oxazole sulfone (9.3-10.4% at 180-380 days); clethodim oxazole sulfoxide (5.9-6.1% at 90 days); clethodim oxazole (2.0-2.1% at 3 days); and clethodim imine sulfoxide (1.0-1.1% at 14-30 days).

(Ring-4,6- $^{14}\text{C}$ ) clethodim or (allyl-2- $^{14}\text{C}$ ) clethodim incubated at 25 °C at initial concentrations of 10 ppm in a sandy loam soil (0.9% organic matter, pH 7.5) degraded with half-lives of approximately one day. The major degradate at the end of the 4 month incubation period was  $\text{CO}_2$ , which represented 57% of the ring-labeled and 45% of the allyl-labeled applied radioactivity. Clethodim sulfoxide, which was initially the major degradate, peaked at 62-72% of the applied radioactivity at 3-7 days post-treatment and then declined (half-life approximately 30 days) to 0.2-0.5% of applied at 121 days post-treatment. Clethodim sulfone, which was formed from the oxidation of the sulfoxide, peaked at 15% of applied at 30 days post-treatment and then declined to 5-7% of applied at 121 days post-treatment. Other degradates identified during the studies were: clethodim oxazole sulfone (9% at 125 days); clethodim oxazole sulfoxide (4% at 125 days); and clethodim imine sulfoxide (2% at 7-14 days).

**§162-2 Anaerobic Soil Metabolism (MRID 410301-36; Unacceptable )**

The reviewer of this study concluded it “did not address the intent of the data requirement, which is to establish the behavior of the compound in flooded soil.” and that

it could not “be repaired by additional information, and therefore a new study is required.”

The reviewer comments that “The useful information which can be gained from the current study” is: 1) "anaerobic" metabolism on dry soil appears to take a distinctly different pathway from that under aerobic conditions; 2) principal degradates at 31 days were clethodim imine (43.5% of applied) and clethodim imine sulfate (14.3% of applied), and do not include CO<sub>2</sub>; and 3) degradates formed by anaerobic means may persist, as indicated by 63 day values. Clethodim imine represented 33.0% of applied material, and the imine sulfate was 11.2%.”

**§163-1 Mobility - Leaching and Adsorption/Desorption (MRID 409745-23; Acceptable)**

[<sup>14</sup>C] clethodim and its degradates, clethodim sulfoxide, clethodim sulfone, and celthodim oxazole sulfone degradates appeared to have high mobility based on batch equilibrium adsorption/desorption experiments conducted using five soils. These degradates and clethodim were weakly adsorbed onto 2 sandy loam soils (OM = 1.0% and 0.4%, pH = 5.8 and 7.0), a clay loam (OM = 2.8% , pH = 8.1), a sandy clay loam (OM = 0.6%, pH = 7.0), and a sandy soil (OM = 1.3% and pH = 7.8). The following ranges of Freundlich K<sub>ads</sub> values were reported for clethodim and its degradates after equilibration with the 5 test soils at 25°C: clethodim (0.08-1.6; see **Table B-1**), clethodim sulfoxide (< 0.2; see **Table B-2**), clethodim sulfone (< 0.1; see **Table B-3**), and clethodim oxazole sulfone (0.3-7.0; see **Table B-4**). The following ranges of Freundlich 1/n values were reported: clethodim (0.5-1.9), clethodim sulfoxide (0.5 on one soil, no measurable adsorption on other 4 soils), clethodim sulfone (1.3 on one soil, no measurable adsorption on 4 other soils), and clethodim oxazole sulfone (0.8-1.1).

Table B-1. Freundlich Constants for Clethodim in Five Soil Types.					
Soil Type	K <sub>ads</sub>	1/n <sub>ads</sub>	Mobility Classification	K <sub>des</sub>	1/n <sub>des</sub>
1.0% loamy sand (pH 5.8)	1.57	0.49-1.90 for all soils	Very Mobile	4.15	0.83-1.77 for all soils
0.4% loamy sand (pH 7.0)	0.15			380 <sup>a</sup>	
0.6% sandy clay loam (pH 7.0)	0.46			1.40-22.60	
1.3% sand (pH 7.8)	0.51				
2.8% clay loam (pH 8.1)	0.08				
<sup>a</sup> Reviewer concluded this value resulted from a computational error					

Table B-2. Freundlich Constants for the Clethodim Degradate Clethodim Sulfoxide in Five Soil Types.					
Soil Type	K <sub>ads</sub>	1/n <sub>ads</sub>	Mobility Classification	K <sub>des</sub>	1/n <sub>des</sub>
1.0% loamy sand (pH 5.8)	0.22	0.47	Very Mobile	1.06	0.66
0.4% loamy sand (pH 7.0)	K <sub>ads</sub> <0.2 for all other soils. Desorption values could not be reliably calculated because the amount of clethodim absorbed was too low.				
0.6% sandy clay loam (pH 7.0)					
1.3% sand (pH 7.8)					
2.8% clay loam (pH 8.1)					

Table B-3. Freundlich Constants for the Clethodim Degradate Clethodim Sulfone in Five Soil Types					
Soil Type	K <sub>ads</sub>	1/n <sub>ads</sub>	Mobility Classification	K <sub>des</sub>	1/n <sub>des</sub>
1.0% loamy sand (pH 5.8)	0.11	1.27	Very Mobile	1.37	0.86
0.4% loamy sand (pH 7.0)	K <sub>ads</sub> <0.1 for all other soils. Desorption values could not be reliably calculated because the amount of clethodim absorbed was too low.				
0.6% sandy clay loam (pH 7.0)					
1.3% sand (pH 7.8)					
2.8% clay loam (pH 8.1)					

Table B-4. Freundlich Constants for the Clethodim Degradate Clethodim Oxazole Sulfone in Five Soil Types					
Soil Type	K <sub>ads</sub>	1/n <sub>ads</sub> <sup>a</sup>	Mobility Classification	K <sub>des</sub>	1/n <sub>des</sub> <sup>a</sup>
1.0% loamy sand (pH 5.8)	0.29		Very Mobile	0.72	
0.4% loamy sand (pH 7.0)	1.79			3.30	
0.6% sandy clay loam (pH 7.0)	1.60			5.69-25.30	
1.3% sand (pH 7.8)	1.02				
2.8% clay loam (pH 8.1)	6.96		Mobile - Very Mobile		
<sup>a</sup> Study reports 1/n values of 0.82-1.09, but does not indicate the type of 1/n.					

## Appendix B

### Description of Ecological Effects Studies

#### i. Toxicity to Birds

##### a. Acute and Subacute

An acute oral toxicity study with either a water fowl or a game bird using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of clethodim to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this test are tabulated below. Clethodim is practically nontoxic to avian species on an acute oral basis. The acute oral toxicity data requirement (§71-1) is fulfilled.

Avian Acute Oral Toxicity					
Species	% a.i.	LD <sub>50</sub> (mg/kg-bw a.i.)	Toxicity Category	MRID No.	Study Classification
Bobwhite quail	82	> 2000	Practically nontoxic	409745-25	Acceptable

Two subacute dietary studies one with a waterfowl and one with a game bird using the TGAI are required to establish the acute dietary toxicity of clethodim to birds. The preferred test species are a mallard duck and bobwhite quail. Results of these tests are tabulated below. Since the avian 5-day subacute LC<sub>50</sub> is > 3978 ppm a.i., clethodim is classified as practically nontoxic to avian species on a subacute dietary basis. The subacute dietary data requirement (§71-2) is fulfilled.

Avian Subacute Dietary Toxicity					
Species	% a.i.	5-day LC <sub>50</sub> (ppm a.i.)	Toxicity Category	MRID No.	Study Classification <sup>1</sup>
Bobwhite Quail	82	> 4270	Practically nontoxic	409745-26	Acceptable
Mallard Duck	82	> 3978	Practically nontoxic	409745-27	Acceptable

##### b. Reproductive Toxicity

Two avian reproduction studies, a Mallard Duck and a Bobwhite Quail study, testing clethodim were submitted to the Agency; the results of the studies are summarized in the following table. The Mallard Duck study was reviewed and classified as acceptable for use in determining risk from clethodim. The Bobwhite Quail study was classified as supplemental because it was determined to be scientifically sound but does not fulfill the requirements for an avian reproductive test, since a high rate of adult mortality was not adequately explained. Therefore the lowest NOEAC value of 150ppm was used for

analysis. The high rate of mortality in adults and chicks contributes to a level of variation high enough to prevent statistical accuracy. The reproductive data requirement (§71-2) is not fulfilled.

Avian Reproductive Toxicity						
Species/ Exposure Duration	% a.i.	Test Type	Toxicity Value (ppm)	Affected Endpoints	MRID No/ Author / Year.	Study Classification
Mallard Duck / Chronic Exposure	83.3	Reproductive Toxicity	NOAEC = 833 (highest concentration tested)	No effects on adult growth and survival or reproduction or growth and survival of chicks	410302-05	Acceptable
Bobwhite quail	83.3	Reproductive Toxicity	NOAEC = 150	LOAEC: Reduced embryo viability and 14-day-old survivors of eggs set	410302-06	Supplemental

**ii. Toxicity to Mammals, Acute and Chronic**

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values submitted by registrants to the Agency's Health Effects Division (HED) substitute for wild mammal testing. A single acute oral dose study and a two-generation reproduction study with rats were available; these toxicity results are summarized in the table below.

Mammalian Acute and Chronic Toxicity						
Species	% a.i.	Test Type	Toxicity Value	Affected Endpoints	MRID No/ Author / Year.	
Rat	TGAI	Acute Test	LD <sub>50</sub> = 1360 mg/kg-bw (males)	Mortality	409745-07	
Rat	TGAI	2 Generation Chronic Test	NOAEC = 500 ppm	LOAEC: Based on decreased body weight and food consumption in parental organisms. No reproductive effects at up to 2500 ppm.	410301-20	

Based on the result of the acute exposure study, clethodim is classified as slightly toxic to mammals with an acute oral LD<sub>50</sub> in male rats of 1360 mg/kg-bw (MRID 409745-07).

**iii. Toxicity to Insects**

A honey bee acute contact study using the TGAI is required for clethodim because its proposed uses may result in honey bee exposure. Results of this test are summarized in

the table below. The results indicate that clethodim is practically non-toxic to bees on an acute contact basis. The honey bee acute contact data requirement (§141-1) is fulfilled.

Non-target Insect Acute Contact Toxicity					
Species	% a.i.	LD <sub>50</sub> (ug/bee)	Toxicity Category	MRID No. Author/Year	Study Classification
Bee	88	> 100	Practically nontoxic	416851-07	Acceptable

iv. Toxicity to Freshwater Aquatic Animals

a. Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of clethodim to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). A Rainbow trout and Bluegill Sunfish study following acute test guidelines were submitted; the studies were reviewed and classified as acceptable for use in calculating risk. Summaries of the results of these tests are tabulated below.

Freshwater Fish Acute Toxicity					
Species	% a.i.	96-hour LC <sub>50</sub> (a.i. ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout	83.3	15	Slightly Toxic	409745-28	Acceptable
Bluegill sunfish	83.3	> 33	Slightly to potentially practically nontoxic *	409745-29	Acceptable

\* Note: The 96-h LC<sub>50</sub> was demonstrated to be higher than the highest concentration tested which was 33 ppm.

Since the acute 96-h LC<sub>50</sub> for freshwater fish ranges from 15 - > 33 ppm a.i., clethodim toxicity to freshwater fish, based on this data, ranges from slightly toxic to potentially practically nontoxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled.

b. Fish, Chronic toxicity.

Currently no chronic fish toxicity data testing clethodim is available. However, given the physical and chemical properties of this compound, chronic toxicity to fish is not expected to be an issue.

c. Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test is required to establish the toxicity of clethodim to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

Freshwater Invertebrate Acute Toxicity					
Species	% a.i.	48-hour EC <sub>50</sub> (ppm a.i.)	Toxicity Category	MRID No. Author/Year	Study Classification

**Freshwater Invertebrate Acute Toxicity**

<i>Daphnia magna</i>	25.6	5.7	Moderately toxic	41685101	Acceptable
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Since the EC<sub>50</sub> falls in the range 1-10 ppm, clethodim is moderately toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled.

**d. Freshwater Invertebrate, Chronic**

Currently, no invertebrate chronic toxicity studies testing clethodim have been submitted to the Agency.

**v. Toxicity to Estuarine and Marine Animals**

**a. Estuarine and Marine Fish, Acute**

Currently, no estuarine and marine fish acute toxicity studies have been submitted to the Agency.

**b. Estuarine and Marine Fish, Chronic**

Currently, no estuarine and marine fish chronic toxicity studies have been submitted to the Agency.

**c. Estuarine and Marine Invertebrates, Acute**

Currently, no estuarine and marine invertebrate toxicity studies have been submitted to the Agency.

**d. Estuarine and Marine Invertebrate, Chronic**

Currently, no estuarine and marine invertebrate chronic toxicity studies have been submitted to the Agency.

**vi. Toxicity to Plants**

**a. Terrestrial Plants**

Terrestrial plant testing is required for clethodim because it is an herbicide with non-residential terrestrial use patterns, and it may be applied via ground broadcast spray which may result in spray drift or runoff that may pose hazards to non-listed or listed plant species. The required testing consists of seedling emergence and vegetative vigor tests with ten crop species. Six of the species must be dicotyledonous and represent at least four families. One of these species must be soybean (*Glycine max*) and a second must be a root crop. The remaining four species must be monocotyledonous and represent at least two families. One of these species must be corn (*Zea mays*). Tier I tests (§122-1) may be conducted to measure the response of plants, relative to a control, at a test level that is equal to the highest use rate (expressed as lbs a.i./A) or three times the EEC for non-target areas. Tier II tests (§123-1) are required for any test species that shows a reduction in response equal to or greater than 25% in the Tier I tests.

Tier II tests measure the response of plants, relative to a control, and five or more test concentrations. A seedling emergence study and a vegetative vigor phytotoxicity study with clethodim formulation containing 82.4% of clethodim as the active ingredient have been submitted to the Agency (MRID 41613611). Both studies have been classified as acceptable for use in EFED's ecological risk assessment of clethodim. The results of the studies are tabulated below.

<b>Effects of Clethodim Formulation (82.4% Clethodim) on the Tier II Vegetative Vigor of Non-target Terrestrial Plants MRID 41685105</b>		
<b>Species</b>	<b>EC25 (lbs a.i./acre)</b>	<b>NOEL</b>
Corn (monocot)	N.R.	0.003
Corn (monocot)	0.006	0.006
Ryegrass (monocot)	0.003	0.003
Oat (monocot)	0.011	0.013
<b>Effects of Clethodim Formulation (82.4% Clethodim) on the Tier II Seedling Emergence of Non-target Terrestrial Plants MRID 41685104</b>		
<b>Species</b>	<b>EC25 (lbs a.i./acre)</b>	<b>NOEL</b>
Corn	0.009	0.0125
Oat	0.004	0.0063

Note: Tier I vegetative vigor and seedling emergence tests demonstrates that dicot species tested demonstrated no adverse effects from clethodim at the highest use proposed rate of 0.25 lbs./acre

#### **b. Aquatic Plants**

Aquatic plant testing (Tier II) is required for clethodim because it potentially may move off-site by runoff and by aerial spray drift. The minimal species tested should include the following: *Kirchneria subcapitata* (formerly *Selenastrum capricornutum*), *Lemna gibba*, *Skeletonema costatum*, *Anabaena flos-aquae*, and a freshwater diatom. Tier II testing with all of these species have been submitted. Except for the *Lemna gibba* test, all results are considered acceptable for use in estimating risk from clethodim exposure. Results of Tier II toxicity testing on the material are tabulated below.

#### **Non-target Aquatic Plant Toxicity (Tier II)**

<b>Species</b>	<b>ai%</b>	<b>EC<sub>50</sub></b>	<b>NOAEC (ppm a.i.)</b>	<b>Study Category</b>	<b>MRID</b>
Green algae ( <i>Selenastrum capricornutum</i> )	83.3	> 11.4	> 11.4	Acceptable	416851-06
Green algae ( <i>Selenastrum capricornutum</i> )	100	19.5	11.1	Acceptable	420297-03
Marine diatom ( <i>Skeletonema costatum</i> )	100	8.6	5.4	Acceptable	420297-04
Duckweed ( <i>Lemna gibba</i> )	100	42.5	1.1	Supplemental	420297-02
Freshwater diatom ( <i>Navicula pelliculosa</i> )	100	11	3.1	Acceptable	420297-06
Duckweed ( <i>Lemna gibba</i> )	82.4	1.1	0.30	Acceptable	420297-01
Bluegreen algae ( <i>Anabaena flos-aquae</i> )	100	16.7	5.6	Acceptable	420297-05



# Appendix C

## Aquatic Exposure Modeling (GENEEC Output)

RUN No. 1 FOR clethodim ON corn \* INPUT VALUES \*

RATE (#/AC)	No.APPS & ONE (MULT)	SOIL INTERVAL	SOLUBIL Koc (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY (FT)	INCRP (IN)
.050( .050)	1 1	5.0	49.9	AERL_B(13.0)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
35.40	2	N/A	6.40-	793.60	70.80 65.00

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
2.90	2.88	2.74	2.45	2.26

# Terrestrial Animal Exposure Model Analysis and Risk Quotient Calculations (TREM)

The application rate and avian and mammalian toxicity input page for the TREX program, with clethodim inputs shown. The program calculates residues on dietary items using the Kenaga nomograph and is used to determine the clethodim estimated terrestrial organism dose-based and dietary-based exposure values and RQ values..

[illegible]

TREX output of dose-based and dietary-based clethodim EEC values for birds that potentially feed on grasses, broadleaf plants, fruits, seeds, or insects, and dose-based and dietary-based RQs are provided in the following table. Dose-based estimates were

calculated for birds ranging from 20 grams to 1000 grams, sizes expected to feed on such dietary items in agricultural fields.

	Avian Chronic and Food / Weights		
	small 20 g	mid 100 g	large 1000 g
	13.67	7.79	3.49
	6.26	3.57	1.60
	7.69	4.38	1.96
	0.85	0.49	0.22

	Avian Acute (EC)		
		100 g	1000 g
	0.01	0.00	0.00
	0.00	0.00	0.00
	0.01	0.00	0.00
	0.00	0.00	0.00

	ECs	
	Acute	Chronic
	0.00	0.08
	0.00	0.04
	0.00	0.05
	0.00	0.01

TREX output of dose-based and dietary-based clethodim EEC values for mammals that potentially feed on grasses, broadleaf plants, fruits, seeds, or insects, and dose-based and dietary-based RQs are provided in the following table. Dose-based estimates were calculated for mammals ranging from 15 grams to 1000 grams, sizes expected to feed on such dietary items in agricultural fields.

	Mammal Acute and Food / Weights					
	Grasses / Broadleaf Plants			Fruits / Seeds / Insects		
	15 g	100 g	1000 g	15 g	100 g	1000 g
	11.44	7.91	1.83			
	5.24	3.62	0.84			
	6.44	4.45	1.03			
	0.72	0.49	0.11	0.16	0.11	0.03

	Acute		Chronic		RQs (dietary)	
	Acute	Chronic	Acute	Chronic	Acute	Chronic
	0.00	0.01	0.00	0.01	0.00	0.00
	0.00	0.00	0.00	0.00	0.00	0.00
	0.00	0.01	0.00	0.01	0.00	0.00
	0.00	0.00	0.00	0.00	0.00	0.00
	0.00	0.00	0.00	0.00	0.00	0.00

	RQs	
	Acute	Chronic
	#DIV/0!	0.00
	#DIV/0!	0.00
	#DIV/0!	0.00
	#DIV/0!	0.00

# Terrestrial Plant Exposure Model Analysis (TERPLANT)

The following illustrates the input and output for the TERPLANT modeling analysis used to determine the clethodim estimated non-target terrestrial plants exposure values and risk quotient calculations for risk of clethodim to nontarget terrestrial animal. Aerial application scenario was used because it assumed the greatest drift.

## TERPLANT Model Inputs for Clethodim (Aerial Application).

Nonlisted Nontarget plant species Inputs	
Application Rate (lb a.i./acre) for each use	0.05
Runoff Fraction Value	0.02
Minimum Incorporation Depth (cm)	0
Seedling Emergence Monocot EC <sub>25</sub> (lb a.i./acre)	0.004
Seed Emergence Dicot EC <sub>25</sub> (lb a.i./acre)	> 0.25d
Vegetative Vigor Monocot EC <sub>25</sub> (lb a.i./acre)	0.003
Vegetative Vigor Dicot EC <sub>25</sub> (lb a.i./acre)	> 0.25
Listed plant species inputs	
Application Rate (lb a.i./acre) for each use	0.05
Runoff Fraction Value	0.02
Minimum Incorporation Depth (cm)	0
Seedling Emergence Monocot EC <sub>05</sub> or NOAEC (lb a.i./acre)	0.004
Seedling Emergence Dicot EC <sub>05</sub> or NOAEC (lb a.i./acre)	> highest application rate tested
Vegetative Vigor Monocot EC <sub>05</sub> or NOAEC (lbs a.i./acre)	0.003
Vegetative Vigor Dicot EC <sub>05</sub> or NOAEC (lb a.i./acre)	> highest application rate tested

Table 1. Chemical Identity.	
Chemical Name	clethodim
PC code	121011
Use	corn
Application Method	spray
Application Form	liquid
Solubility in Water (ppm)	49.9

Table 2. Input parameters used to derive EECs.			
Input Parameter	Symbol	Value	Units
Application Rate	A	0.05	y
Incorporation	I	1	none
Runoff Fraction	R	0.02	none
Drift Fraction	D	0.05	none

Table 3. EECs for clethodim. Units in y.		
Description	Equation	EEC
Runoff to dry areas	(A/I)*R	0.001
Runoff to semi-aquatic areas	(A/I)*R*10	0.01
Spray drift	A*D	0.0025
Total for dry areas	((A/I)*R)+(A*D)	0.0035
Total for semi-aquatic areas	((A/I)*R*10)+(A*D)	0.0125

Table 4. Plant survival and growth data used for RQ derivation. Units are in y.				
Plant type	Seedling Emergence		Vegetative Vigor	
	EC25	NOAEC	EC25	NOAEC
Monocot	0.004	0.004	0.003	0.003
Dicot	0.25	0.25	0.25	0.25

Table 5. RQ values for plants in dry and semi-aquatic areas exposed to clethodim through runoff and/or spray drift.*				
Plant Type	Listed Status	Dry	Semi-Aquatic	Spray Drift
Monocot	non-listed	0.88	3.13	0.83
Monocot	listed	0.88	3.13	0.83
Dicot	non-listed	<0.1	<0.1	<0.1
Dicot	listed	<0.1	<0.1	<0.1

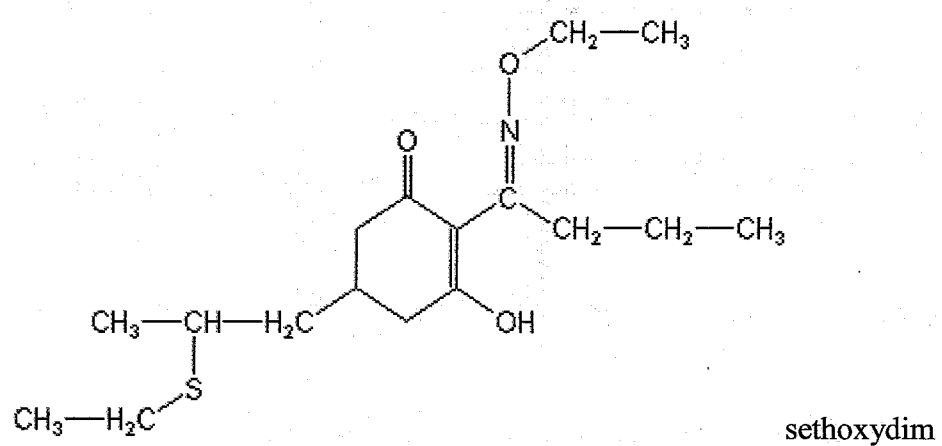
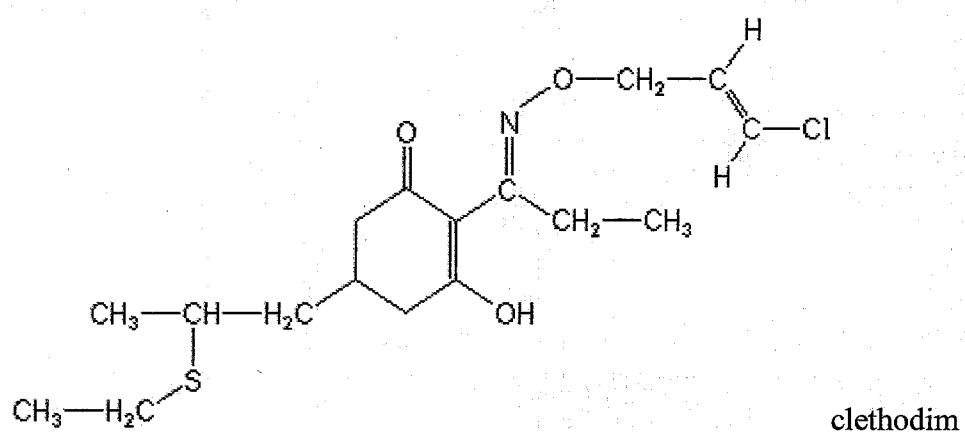
\*If RQ > 1.0, the LOC is exceeded, resulting in potential for risk to that plant group.

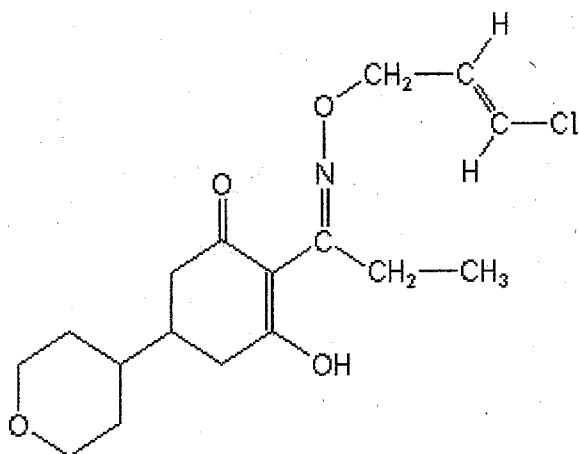
**TERRPLANT Model Risk Quotient Calculations for Clethodim**

Use Rate (lbs /A)	Adjacent Areas RQ = EEC/Seedling Emergence EC <sub>25</sub> (EEC = Runoff + Drift)		Semi-aquatic Areas RQ = EEC/Seedling Emergence EC <sub>25</sub> (EEC = Runoff + Drift)		Drift RQs RQ = Drift EEC/Vegetative Vigor EC <sub>25</sub>	
	Monocot	Dicot	Monocot	Dicot	Monocot	Dicot
Nonlisted Species						
0.05	0.56	<0.1	1.98	<0.1	0.83	<0.1
Listed Species						
0.05	0.88	<0.1	3.13	<0.1	0.83	<0.1

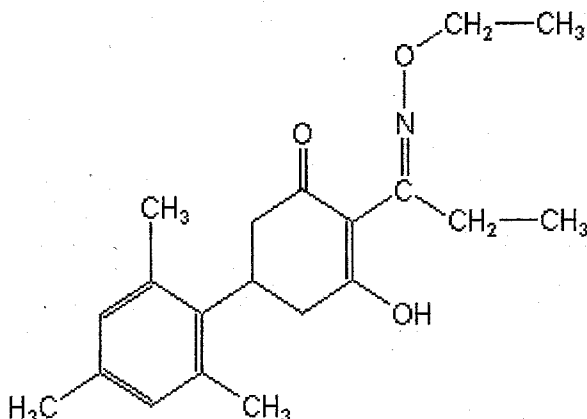
## Appendix E

### Toxicity Values for Other Cyclohexene Oxime Pesticides





tepraloxym



tralkoxydim

### Cyclohexene Oxime Herbicide Acute Toxicity Test Results for Freshwater Fish

Chemical	% a.i.	Species and Weight	Test Type	96-h LC <sub>50</sub> (ppb)	Reference And Study Classification
Sethoxydim	97.3	Bluegill sunfish ( <i>Lepomis macrochirus</i> ) weight = N.R.	S	265,000	72862 Acceptable
Tepaloxym	95	Bluegill sunfish ( <i>Lepomis macrochirus</i> ) weight = 1.62 g	S	77,900 (slope =14.1)	444671-25 Acceptable
Clethodim	83.3	Bluegill sunfish ( <i>Lepomis macrochirus</i> ) weight = 0.53 g	S	>33,000	409745-29 Acceptable
Sethoxydim	97.3	Rainbow trout ( <i>Oncorhynchus mykiss</i> ) weight = N.R.	S	170,000	42815 Acceptable
Tepaloxym	94.95	Rainbow trout ( <i>Oncorhynchus mykiss</i> ) weight = 1.62 g	S	>96,100	444671-24 Acceptable
Clethodim	83.3	Rainbow trout ( <i>Oncorhynchus mykiss</i> ) weight = 0.67 g	S	19,000	409745-28 Acceptable
Tralkoxydim	99	Fathead minnow ( <i>Pimephales promelas</i> ) weight = 0.46 g	S	44,000	453020-03 Acceptable

Test type: S = static

### Cyclohexene Oxime Herbicide Acute Toxicity Test Results for Estuarine/Marine Fish

Chemical	% a.i.	Species and Weight	Test Type	96-h LC <sub>50</sub> (ppb)	Reference And Study Classification
Sethoxydim	97.8	Sheepshead minnow (Cyprinodon variegatus) weight = 0.3 g	S	145,800	423151-01 Acceptable
Tepraloxydim	100	Sheepshead minnow (Cyprinodon variegatus) weight = 0.14 g	SR	123,000	444671-27 Acceptable

Test type: S = static; SR = static renewal

### Cyclohexene Oxime Herbicide Acute Toxicity Test Results for Freshwater Invertebrates

Chemical	% a.i.	Species and Age	Test Type	48-h EC <sub>50</sub> (ppb)	Reference And Study Classification
Sethoxydim	97.3	Water flea ( <i>Daphnia magna</i> ) age = 1st-I	S	78,100	0042816 Acceptable
Tralkoxydim	99	Water flea ( <i>Daphnia magna</i> ) age = <24 hr	S	110,000	45302004 Supplemental
Clethodim	25.6	Water flea ( <i>Daphnia magna</i> ) age = <24 hr	S	20,200	41685101 Acceptable

Test type: S = static

### Cyclohexene Oxime Herbicide Life Cycle Toxicity Test Results for Freshwater Invertebrates

Chemical	% a.i.	Species and Age	Test Type	NOAEC (LOAEC) (ppb)	Reference And Study Classification
Tralkoxydim	97	Water flea ( <i>Daphnia magna</i> ) age = <24 hr	SR	2,100 (4,200)	433397-03 Acceptable

Test type: SR = static renewal

Acute-to-Chronic Ratio for the Water Flea *Daphnia magna*  
 Tralkoxydim Acute 48-hr EC<sub>50</sub>/NOAEC = 110,000/2100 = 52.4

Chemical	% a.i.	Species	Test Type	Toxicity Value (ppb)	Reference And Study Classification
Sethoxydim	94.5	Eastern oyster ( <i>Crassostrea virginica</i> ) Embryo-Larval Test	S	48-h EC <sub>50</sub> >109,000	425374-01 Acceptable
Sethoxydim	97.8	Mysid ( <i>Americamysis bahia</i> ) age = N.R.	S	96-h LC <sub>50</sub> >141,800	423151-02 Acceptable
Tepraloxydim	100	Eastern oyster ( <i>Crassostrea virginica</i> ) Shell Deposition	SR	96-h EC <sub>50</sub> >120,000	444964-01 Acceptable



Tepaloxydim	100	Mysid ( <i>Americamysis bahia</i> ) age = <24 hr	SR	96-h LC <sub>50</sub> >120,000	444964-02 Acceptable
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Test type: SR = static renewal

