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An Aquatic Organism Ecological Risk Assessment for Chlorfenapyr in Cotton

American Cyanamid Company
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I. Executive Summary

An ecological risk assessment for aquatic organisms was carried out for the use of chlorfenapyr in cotton. The assessment employed the terminology and followed the procedures set out in the United States Environmental Protection Agency's (EPA's) Framework for Ecological Risk Assessment (1992). That document states that ecological risk assessment is *"a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors"*. It also notes that an ecological risk assessment may evaluate one or many stressors and ecological components. In the present assessment, a single stressor, chlorfenapyr, is evaluated but multiple ecological components will be considered. The higher tier assessment closely followed the procedures specified in the *Framework*. All components of the Problem Formulation, Analysis, and Risk Characterization phases were carried out.

This higher tier assessment was carried out because the Environmental Fate and Effects Branch (EFED) reviewed the data on chlorfenapyr, performed a Tier 1 assessment, and concluded that chlorfenapyr poses an unacceptable acute risk to aquatic organisms. An important issue to registrants is, if a Tier 1 assessment indicates unacceptable risk, what can be done to provide an acceptable higher tier ecological risk assessment? Cyanamid is unaware of any guidance on how to perform such an assessment. We have elected to follow the formalism of the *Framework* document very closely in the hope that the resulting higher tier assessment will be acceptable.

There is an extensive set of guideline and non-guideline studies available for chlorfenapyr. These studies were supplemented with data and information on the mode of action of chlorfenapyr, the fate and partitioning of chlorfenapyr in the environment, cotton insect pest management, aquatic ecosystems associated with cotton, and the cotton agroecosystem in a spatial context. Risk was evaluated at the local population level, i.e., populations of aquatic organisms present in aquatic ecosystems associated with cotton agroecosytems. The risk to threatened and endangered species was also considered. Highlights of the significant conclusions or outcomes of each of the phases of the assessment follow.

In the **Problem Formulation** phase, the valued ecological entity was identified as aquatic organisms inhabiting aquatic ecosystems associated with cotton fields. The assessment endpoints for individual species were survival, growth and reproduction due to direct effects of chlorfenapyr. Effects on organisms inhabiting both the water and sediment phases of aquatic ecosystems were evaluated. A generalized conceptual model was provided.

The **Analysis** phase of the assessment summarized and synthesized data on ecological effects and exposure. Exposure estimates were made for five distinct regions of the cotton belt using MUSCRAT (Multiple Scenario Risk Assessment Tool; beta version 1.0). The exposure estimates were then refined using data gathered in a Geographic Information Systems (GIS) analysis of water bodies associated with cotton agroecosystems.

In the **Risk Characterization** phase, risk was estimated for freshwater fish and aquatic invertebrates, saltwater fish and aquatic invertebrates, and sediment-dwelling aquatic invertebrates by using a Risk Quotient approach. Model-derived time-weighted estimated environmental concentrations (EECs) in water or sediment were compared with laboratory-derived toxicity values for different species of aquatic organisms. The results of this initial assessment indicated a minimal level of risk. However, the risk was further refined with data gathered from the GIS studies. The results of this analysis indicated that most cotton is grown on relatively flat land, with slopes of less than 1%, which should minimize runoff potential. In addition, the analysis indicated a general lack of water bodies associated with cotton fields; between 91% and 99% of the total cotton acreage was not within 50 meters of any type of water body. Finally, the majority of the water that was within 50 meters of cotton was flowing water, most commonly canals, drainage ditches or intermittent streams. When static water is found in close proximity to cotton, it is predominantly large water bodies, greater than 25 acres in size. Any exposure to water bodies of this size would result in greater dilution than is predicted by exposure models. The results of this assessment have been supported by Section 18 Emergency Exemption monitoring programs in over 1 million areas in nine states where no adverse incidents were uncovered during multiple years of widespread use of chlorfenapyr across the cotton growing states in the U.S..

The results of this ecological risk assessment, conducted in compliance with the procedures established in EPA's Framework for Ecological Risk Assessment indicates that the use of chlorfenapyr on cotton will not result in unreasonable risk to aquatic organisms.

II. Introduction, Definitions and Organization of the Assessment

This is an aquatic organism ecological risk assessment of chlorfenapyr (AC 303630) for the control of Lepidoptera, especially budworm, bollworm, the armyworm complex, and mites, in cotton. It is based on the Environmental Protection Agency's (EPA) *Framework for Ecological Risk Assessment* (USEPA 1992). The *Framework* defines ecological risk assessment as follows: *"... a process that evaluates the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors. A risk does not exist unless (1) the stressor has the inherent ability to cause one or more adverse effects and (2) it co-occurs with or contacts an ecological component (i.e., organisms, populations, communities, or ecosystems) long enough and at sufficient intensity to elicit the identified adverse effect. Ecological risk assessment may evaluate one or many stressors and ecological components."* In the present assessment, a single stressor, chlorfenapyr, is evaluated. Multiple ecological components will be considered.

There are 3 major phases to the ecological risk assessment process as defined by the *Framework*. The first phase, Problem Formulation, includes preliminary characterization of exposure and effects, examination of scientific data and data needs, policy and regulatory issues, and site-specific factors to define the feasibility, scope, and objectives of the risk assessment (USEPA 1992). Successful completion of this phase will result in: assessment endpoints that adequately reflect management goals and the ecosystem they represent; conceptual models that describe key relationships between a stressor and assessment endpoint, and; an analysis plan (USEPA 1996).

The second phase of ecological risk assessment is termed Analysis. It consists of two activities, characterization of exposure and characterization of effects. Characterization of exposure aims to predict or measure the spatial and temporal distribution of a stressor and its co-occurrence or contact with ecological components of concern. Characterization of effects aims to identify and quantify the adverse effects elicited by the stressor, and, if possible, evaluate cause and effect relationships.

The third phase of ecological risk assessment is termed Risk Characterization. In this phase, the results of the exposure and ecological effects analyses are used to evaluate the likelihood of adverse effects occurring. Risk characterization includes a summary of the assumptions used, the scientific uncertainties, and the strengths and weaknesses of the analyses.

Ecological risk assessment is but one part of the regulatory decision-making process. There is a critical need for interaction between the risk assessor and the risk manager. Risk managers (i.e., decision-makers) have a central role in ensuring that the assessment provides relevant information for making decisions on the issues under consideration. This input should occur during the Problem Formulation phase. Also, the output of the ecological risk assessment process is a key product for the decision-makers' deliberations. Depending on the adverse effect and the regulatory context, the risk manager may also weigh the ecological risks against likely benefits; this exercise falls outside the scope of ecological risk assessment. However, because chlorfenapyr will be regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), weighing of its benefits against its risk is permissible.

In standard laboratory tests, chlorfenapyr has exhibited high or very high toxicity to fish and aquatic invertebrates, which has raised concerns about the potential risk the compound may pose to aquatic organisms. These concerns are supported by the standard Tier 1 assessment done for chlorfenapyr by the

Ecological Fate and Effects Division. In this screening level assessment, the main tool used is the Risk Quotient (RQ), the ratio of estimated environmental concentration (EEC) derived by the simplistic Generic Estimated Exposure Concentration (GENEEC) model to toxicity (EC50 or LC50 test results). It was concluded that chlorfenapyr poses unacceptable acute risk to aquatic organisms.

A critical initial objective of the refined assessment is to identify the major factors to be considered that influence or contribute to the assessment and their regulatory context. One very important aspect of that context is the Tier 1 assessment. Specifically, if the Tier 1 assessment indicates unacceptable risk, what can be done to provide EPA with a refined (higher tier) assessment? There appears to be little guidance or agreement on the scope, data requirements, and procedures necessary to produce an acceptable higher tier assessment. Cyanamid proposes that an acceptable higher tier assessment can be generated by closely following the formalism of the ecological risk assessment process as set forth in the *Framework*, and by providing additional data and analyses.

There are 3 main differences between the refined assessment and a standard Tier 1 assessment. First, the former follows the formalism outlined in the United States Environmental Protection Agency's (EPA's) Framework for Ecological Risk Assessment (1992). There will be explicit statements of assessment and measurement endpoints and of uncertainties. Second, it draws on many guideline and non-guideline laboratory tests, as well as a simulated aquatic field test, EPA-validated surface water runoff and aquatic fate modeling, and information on the cotton crop and its environs. Results of monitoring programs conducted by the States under the Section 18 Emergency Exemptions are also considered. One unique feature of the field information is a Geographical Information System (GIS) analysis of aquatic ecosystems associated with cotton. These efforts are designed to greatly improve estimates of exposure as compared to a Tier 1 assessment. In this context, exposure can mean residues entering aquatic ecosystems associated with cotton fields, the measured residues of chlorfenapyr in these aquatic ecosystems over time, or the geographic relationship between cotton fields and aquatic ecosystems.

Finally, the third major difference between the refined assessment and a Tier 1 assessment relates to reliance on the Risk Quotient (RQ). In the Tier 1 assessments done under FIFRA, the major index used is the RQ. While the term Risk Quotient implies that the RQ is a measure of risk, the RQ does not specifically measure either of the 2 components of risk, i.e., the likelihood or the magnitude of adverse effects. Rather, it is suggested that the RQ is correlated with the magnitude of adverse effects. Nonetheless, the RQ is the measure used by EPA in its assessments and the writers are unaware of any other index that is accepted by EPA for regulatory evaluations. Therefore, in this refined assessment, point estimate RQ's will be calculated based on typical worst case assumptions for various regions of the cotton belt. Due to the limitations of the RQ with regard to both likelihood and magnitude of effects, other weight-of-the-evidence approaches will also be used including, a variety of measurement endpoints and expert judgment, in addition to numerical pass or fail criteria.

The refined assessment focuses on non-threatened, non-endangered aquatic species. However, the additional information that has been gathered on aquatic species common to aquatic ecosystems associated with cotton fields is also germane to threatened and endangered species. As EPA is aware, there is a substantial effort for protecting endangered species underway by an Industry group termed the FIFIRA Endangered Species Task Force (FESTF), which is working with EPA in a cooperative research program to develop and implement measures which will adequately protect threatened and endangered species. American Cyanamid Company is a founding member of that Task force and will help provide EPA with additional information.

III. Problem Formulation – Scoping Phase

A. Stressor Characteristics

1. Biological

Chlorfenapyr (also termed AC 303630) is a member of a novel class of insecticide-miticides called pyrroles. *In vitro* studies have shown that chlorfenapyr can be converted to CL 303268, which targets the mitochondria and that the fatal biochemical effect is due primarily to uncoupling of oxidative phosphorylation (Treacy *et al.* 1994). The proton gradient across mitochondrial membranes is disrupted and the ability of the mitochondria to produce ATP from ADP is impeded. The impediment leads to cell death and may ultimately lead to the death of the organism (Treacy *et al.* 1994).

This mode of action is supported by the following information. First, herbivorous insects generally are known to be able to oxidize xenobiotics (Hung *et al.* 1990). Second, CL 303268 has been identified in tobacco budworm (*Heliothis virescens*) larvae (Treacy *et al.* 1994). Third, Colorado potato beetle (*Leptinotarsa decemlineata*) adults, exposed to the microsomal mono-oxygenase inhibitor piperonyl butoxide, were significantly less sensitive to chlorfenapyr than adults that were not exposed to piperonyl butoxide (R. M. Hollingworth, unpublished). In this particular case, piperonyl butoxide would inhibit oxidative metabolism and the biotransformation of chlorfenapyr to CL 303268. And fourth, CL 303268 has been shown to be a potent uncoupler of oxidative phosphorylation in mouse liver mitochondria. CL 303268 stimulated state-4 respiration and decreased respiratory control in mouse liver mitochondria. Stimulation of state-4 respiration continued until oxygen was depleted. The UC_{50} is the concentration which causes 50% uncoupling of oxidative phosphorylation in the bioassay. The UC_{50} for CL 303268 in this system was 2.4 nM (nanoMolar), whereas the UC_{50} for AC 303630 in the same system was >1000 nM (Treacy *et al.* 1994).

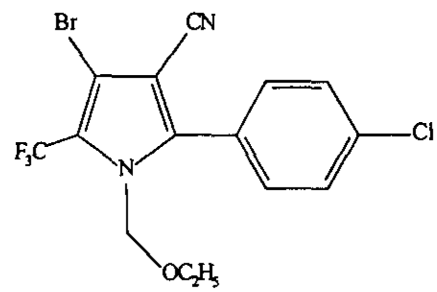
One very important result from the laboratory evaluations was the relative toxicity of the compound by the oral and the dermal routes of exposure. Screening work had shown that the compound is toxic to insects by both routes of exposure (Lovell *et al.* 1990). Treacy *et al.* (1990) evaluated the toxicity of chlorfenapyr to 5th instar tobacco budworm larvae by oral gavage and by topical application. The 48 hour oral LD_{50} was 5.7 µg/gram, whereas the 48 hour dermal LD_{50} was greater than 450 µg/gram. For tobacco budworm larvae, it is not clear if the difference between oral and dermal toxicity is due to biochemical activation of chlorfenapyr to CL 303268 in the hindgut, or to limited absorption through the cuticle, or to some combination of these factors (Treacy *et al.* 1990). The low vapor pressure (4.05×10^{-8} torr at 25°C) of chlorfenapyr strongly suggests that insects will be not be exposed by the inhalation route. The work by Treacy *et al.* (1990) also provides a working level for concentrations in dying insects. This value, 5.7 µg chlorfenapyr/gram insect wet weight, was obtained in tobacco budworm larvae that averaged 212 mg in weight.

Additional detail on the mode of action of chlorfenapyr is provided in **Appendix 1**.

2. Physico-chemical properties

The physical and chemical properties of chlorfenapyr are summarized in Table 1.

Table 1. Physical and chemical characteristics of chlorfenapyr.

Structure	
Chemical name	
IUPAC	4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-pyrrole-3-carbonitrile
CAS	4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile
CAS Number	122453-73-0
Molecular weight	407.6
Molecular formula	$C_{15}H_{11}BrClF_3N_2O$
Water solubility	0.12, 0.13, 0.14, and 0.12 ppm in deionized water, at pH 4, 7, and 10 buffers, respectively
Vapor pressure	4.05 x 10-8 torr at 25°C
K_{ow}	67,670 (Log K_{ow} = 4.83)
Hydrolysis	Stable to hydrolysis over 30 days in pH 5, 7 and 9 buffers
Aqueous photolysis	Half-life 5-7 days in pH , 7 and 9 buffers
Soil photolysis	Half-life 130± 40 days
Aerobic Soil	
Lab	230 days - alluvial clay loam (Japan) 250 days - volcanic ash light clay (Japan) 241 days - clay soil (Texas) 349-415 days - sandy loam (CA, MS, NC,NJ)
Anaerobic Soil	Half-life 670 days - sandy loam (NJ)

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Kd_{ads}	32 - 155
Kd_{des}	67 - 362
K_{oc}	
AC 303630	11,500 (Median)
CL 312094	3060

The dissipation of chlorfenapyr under field conditions is summarized in Table 2.

Table 2. Field dissipation Half-lives;

Soil Type	Location	Half-life (Days)
loamy sand	San Joaquin Valley, Madera, CA	175
sandy loam	San Joaquin Valley, Hickman, CA	241
silt loam	Greenville, MS	251
clay loam	Uvalde, TX	279
sandy soil	Gainesville, FL	418

Chlorfenapyr and CL 312094 (its major metabolite in soil and fish), are strongly adsorbed by soils, with K_{oc}'s of 11500 and 3060, respectively. The large soil/water adsorption coefficients and the low water solubility of chlorfenapyr and CL 312094 indicate that the compounds are immobile in soil and leaching would not be expected to occur. Chlorfenapyr is slowly degraded in soil under aerobic conditions in the laboratory, with half-lives of 230 - 250 days in an alluvial clay loam and a volcanic ash light clay from Japan and 1370 days in a sandy loam from NJ. There was only one major metabolite formed, CL 312094, which accounted for up to 8% of the applied dose in the aerobic soil metabolism study using a sandy loam soil, and up to 25% of the dose in a volcanic ash light clay and an alluvial clay loam from Japan. Chlorfenapyr was slowly degraded in soil under anaerobic conditions in the laboratory, with a half-life of 670 days. As in the aerobic soil studies, the major compound produced is CL 312094. A soil photolysis study showed that chlorfenapyr degrades more rapidly in the presence of light than in an aerobic soil metabolism study. Half-lives on soil exposed to continuous irradiation were estimated to be about 75 days, which would represent approximately 150-225 days in the field. Two compounds, CL 303267 and CL 325195, were formed over 30 days, each of which accounted for only 5% of the applied dose. This indicates that metabolites or degradates will not be a significant source of exposure in the soil. Half-lives in field dissipation studies (175-418 days) are similar to those found in the laboratory studies. The study on the sandy soil in Florida clearly demonstrates that there should be no concerns on the leaching potential for this compound since there was no movement of the compound through the soil profile on a sand (92% sand, 4% silt, 4% clay, 1.5% O.M.) which received 60 inches of rainfall in the year after application, and 95 inches of rainfall over the 540 days of the study.

Three important physico-chemical properties of chlorfenapyr are its very low volatility, its low water solubility, and its tendency to bind to soil. These will be important in defining exposure potential.

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3. General Information on Use Pattern

Chlorfenapyr will be used primarily to control the budworm, bollworm, and armyworm complex in cotton across the Cotton Belt, and to control mites and other minor worm pests in AZ and CA. The proposed labels are provided in **Appendix 2.** In the majority of the Cotton Belt (i.e., the Delta, the Southeast, NM, and TX), applications would begin about July 1, for budworm and bollworm. From August 16 to boll maturation, applications would be made for budworm, bollworm and the armyworm complex. In AZ and CA, applications for early season mite control could start as early as May 1. Applications for mid-season mite control would be possible starting June 15. Applications for the armyworm complex could begin by July 1 and continue until boll maturation. In all areas of the Cotton Belt, the budworm, bollworm, and armyworm moths must find and colonize the fields, and this colonization depends on many factors which are difficult to predict. Although it may be necessary to treat for budworm and bollworm several times during the season, the current label allows 2 applications, with a typical minimum interval of 7 days between applications, and an absolute minimum interval of 5 days. It is difficult to predict which fields will need treatment, and whether a field will be treated once or twice with chlorfenapyr. These circumstances are due to pest management recommendations for managing resistance and to the nature of insect infestations in cotton.

B. Ecological Effects

As mentioned in the Introduction, there is a large data base of guideline and non-guideline studies with chlorfenapyr in the laboratory and in the field. Information on the toxicity of chlorfenapyr to organisms that inhabit both the water column and the sediment phase of aquatic systems have been evaluated and will be used in the risk assessment. The potential for chlorfenapyr to cause mortality, growth inhibition and reproductive effects in aquatic organisms will be included in the evaluation, as well as the potential to bioaccumulate and biomagnify in the environment. The potential to cause secondary effects due to reductions in food sources will also be assessed.

C. Ecosystems Potentially at Risk

Meaningful definitions of ecosystems are elusive, mainly because it is difficult to establish spatial and temporal scales. In this assessment, the term ecosystem will therefore be replaced by aquatic ecosystems (i.e., natural assemblages of organisms present in permanent water bodies) associated with a cotton fields. This would include organisms inhabiting ponds, lakes, rivers, streams or estuaries. A cotton field is defined as an agricultural field that is capable of supporting commercial cotton production.

D. Assessment Endpoints

Assessment endpoints are explicit expressions of the actual environmental value that is to be protected (EPA 1992). There are several criteria for selecting assessment endpoints. These criteria include: ecological relevance; susceptibility to the stressor, and; their relationship to management goals. Also, it would be ideal if assessment endpoints could be measured directly and thereby also serve as measurement endpoints (EPA 1996). Such a direct relationship would reduce the uncertainty in the assessment.

Each assessment endpoint must contain 2 elements: the valued ecological entity and the characteristic of that entity which is potentially at risk and which is important to protect (EPA 1996). For this assessment, the valued ecological entity is the aquatic ecosystems associated with the cotton fields defined above. Only organisms inhabiting those aquatic ecosystems that are associated with cotton fields are potentially at risk.

E. Measurement Endpoints

Measurement endpoints are measurable responses to a stressor that are related to the valued characteristics identified by the assessment endpoints (EPA 1992). There are several considerations for selecting measurement endpoints. These considerations include: relevance to the assessment endpoint; consideration of indirect effects; sensitivity and response time; signal-to-noise ratio; consistency with assessment endpoint exposure scenarios; diagnostic ability, and; practicality (EPA 1992).

It is important to note some general observations about the approach taken in deciding upon measurement endpoints for this assessment. Few of them are measured in the standard testing battery required by the current Pesticide Assessment Guidelines. Nor are some of these assessment endpoints readily estimated from the standard tests. Therefore, it will be necessary to rely on a suite of measurement endpoints and a weight-of-the-evidence approach rather than relying on a single index or measurement. A disadvantage of this approach is that it requires expert judgment and will not necessarily provide single numbers that indicate risk or lack of risk.

F. Conceptual Model

The conceptual model allows for the development of working hypotheses about how the stressor might affect components of the aquatic ecosystem (NRC, 1986). The principal route of exposure to aquatic organisms is via contact with waterborne residues or residues associated with aquatic sediment. Another potential exposure route is through the food web. However, results of a fish bioaccumulation study with chlorfenapyr indicate that the compound is rapidly metabolized in biological systems. Therefore, the likelihood of chlorfenapyr causing effects on aquatic organisms through its movement through the aquatic food web is minimal.

Adverse effects on aquatic ecosystems due to secondary effects (e.g., reduction in a food source that would adversely affect a higher trophic level) were also assessed. However, this is unlikely to occur due to the fact that the toxic potency of chlorfenapyr to various aquatic animals is similar, and therefore, effects on lower trophic levels (e.g., aquatic invertebrates) would not likely occur in the absence of effects on higher trophic levels (e.g., insectivorous or planktivorous fish).

The likelihood of direct applications to water bodies is extremely small given the proposed label restriction for applications of the product to cotton (i.e., 150-foot buffer by aerial application and 25-foot by ground application, requirement of a vegetative buffer strip between cotton fields and sensitive water bodies, etc). Therefore, the principal route of entry into an aquatic system will be due to surface runoff during rain events. Because of the low water solubility and high soil biding properties of the compound, the majority of the residues that can enter an aquatic ecosystem will do so adsorbed to eroded soil. Therefore, only very heavy rainstorms, which can transport significant levels of soil into aquatic systems, will result in exposure to these systems.

This ecological risk assessment will review all available information concerning these exposure pathways and will compare exposure concentrations derived from higher tier surface runoff and aquatic fate modeling with toxicity data from the laboratory and the field to assess risk to aquatic organisms.

IV. Analysis

A. Characterization of Ecological Effects

The following is a synopsis of ecological effects data for chlorfenapyr. A complete summary of all of the laboratory studies can be found in **Appendix 3,** while a summary of individual studies, including an aquatic microcosm study, can be found in **Appendix 4.**

Acute Toxicity to Fish
The results of standard laboratory acute toxicity studies with fish are summarized in the following table.

Species	96 Hour LC50 (µg/L)	96 Hour NOEC (µg/L)
Bluegill Sunfish	11.6	5.0
Channel Catfish	12.3	7.2
Rainbow Trout	7.4	2.6
Sheepshead Minnow	60.4	30.7

In standard laboratory studies, chlorfenapyr is classified as very highly toxic to the four species studied. The most sensitive species was rainbow trout, with an LC50 of 7.4 µg/L (parts per billion). The only toxic effect observed in all studies was mortality.

Chronic Toxicity to Fish
The results of standard laboratory chronic toxicity (early life-stage (ELS) and life-cycle (LC)) studies with fish are summarized in the following table.

Species / Test	LOEC (µg/L)	NOEC (µg/L)	MATC (µg/L)
Rainbow Trout ELS	7.6	3.7	5.7
Sheepshead Minnow ELS	18.7	8.7	12.7
Fathead Minnow LC	13.3	5.9	8.9
Sheepshead Minnow LC	1.9	1.0	1.4

Results of early-life-stage and life-cycle chronic toxicity studies with fish demonstrate that chronic toxicity effect levels in the long-term studies are similar to levels causing acute effects. In general, the most sensitive endpoint in the long-term studies was post-hatch survival. Although there were some growth reduction observed in the sheepshead minnow life-cycle study, there were no effects on egg hatching or reproduction in any of the long-term studies. These results indicate that fish survival is the most sensitive toxic endpoint to chorfenapyr and the risk assessment for fish can be based exclusively on acute toxicity.

Bioaccumulation in Fish
The results of a standard fish (i.e., bluegill sunfish) bioaccumulation study with chlorfenapyr indicate that chlorfenapyr was taken up rapidly by bluegills, with a maximum whole-fish bioconcentration factor (BCF) of 2136 determined in the study based on total chlorfenapyr derived radioactivity. However, it was apparent that the test organism was extensively metabolizing chlorfenapyr to its desbromo metabolite,

CL 312094. At steady-state, this metabolite accounted for 89 to 95% of the total radioactive residues in the fish tissue. When bioaccumulation was adjusted to account for this transformation, the maximum BFC was 114. When the fish were placed in clean water, residues were rapidly eliminated by the bluegill. The half-life for depuration was 3-4 days.

These results indicate that chlorfenapyr has a low potential for both bioaccumulation in aquatic organisms, and biomagnification through the food web.

Acute Toxicity to Aquatic Invertebrates
The results of standard laboratory acute toxicity studies with aquatic invertebrates are summarized in the following table.

Species	96 Hour LC50/ EC50 (µg/L)	96 Hour NOEC (µg/L)
Daphnia magna	6.1	2.5
Mysid Shrimp	2.0	0.32
Eastern Oyster	9.3	5.5

In standard laboratory studies, chlorfenapyr is classified as very highly toxic to the three species studied. The most sensitive species was the marine invertebrate, the mysid, with an LC50 of 2.0 µg/L. In the *Daphnia* and mysid studies, the only toxic effect observed was mortality. In the oyster study, effect on shell growth was the toxic endpoint evaluated.

Chronic Toxicity to Aquatic Invertebrates
The results of standard laboratory chronic toxicity (life-cycle toxicity, LC) studies with aquatic invertebrates are summarized in the following table.

Species / Test	LOEC (µg/L)	NOEC (µg/L)	MATC (µg/L)
Daphnia magna LC	7.7	3.6	5.2
Mysid Shrimp LC	0.39	0.17	0.28

Results of life-cycle chronic toxicity studies demonstrate that chronic toxicity effect levels in the long-term studies are similar to levels which cause acute effects. The most sensitive endpoint in both long-term studies was survival of the first generation organisms; there were no effects on growth or reproduction in either of the long-term studies. These results indicate that survival is the most sensitive toxic endpoint of aquatic invertebrates to chlorfenapyr and the risk assessment for aquatic invertebrates can be based primarily on acute toxicity.

Toxicity to Sediment-Dwelling Invertebrates
The toxicity of chlorfenapyr to two sediment-dwelling invertebrate species has been evaluated in two different exposure systems. In a study conducted according to EPA guidelines with the freshwater amphipod, *Hyallella azteca*, the toxicity of sediment associated chlorfenapyr was evaluated. In this study, chlorfenapyr was mixed into the test sediment and the concentrations in the sediment that caused toxicity were determined during 10 days of exposure. In this study, the 10-day LC50 was 20.6 mg/kg

of sediment (parts per million), while the NOEC was 10.9 mg/kg. In this study, mortality was the primary toxic effect; there were no adverse effects on growth.

In the second study, which was a chronic study conducted according to German BBA test guidelines with larvae of the midge, *Chironomus riparius*, a different exposure system was used. In this study, the test substance was added to the surface of the overlaying water of a water-sediment system containing first-instar midge larvae, thus simulating exposure by drift to an aquatic system. The results of the study were based on initial water concentrations of chlorfenapyr. The 28-day LC50 was determined to be 49.9 μg/L, while the NOEC and MATC values were 18.8 and 26.5 μg/L, respectively. The LC50 concentration corresponds to an application rate of approximately 0.8 lbs ai/acre directly to a 6-foot deep water body. The most sensitive endpoint of toxicity in this study was survival; there were no effects on growth or time to emergence (i.e., development rate).

A third sediment organism toxicity study with chlorfenapyr is currently being conducted with the saltwater amphipod, *Leptochirus plumulosus* according to EPA guidelines to assess the toxicity of sediment associated chlorfenapyr. Preliminary results indicate that the sensitivity of this species will be in the same concentration range as *Hyalella azteca*. The final report for this study should be available during early 1998, and will submitted to EPA to supplement the data package to support chlorfenapyr registration on cotton.

Aquatic Toxicity of Chlorfenapyr Metabolites and Degradates

The toxicity of metabolites and soil degradates of chlorfenapyr was evaluated in standard laboratory studies with bluegill sunfish and *Daphnia magna*. Compounds evaluated were CL 312094, *the principal metabolite found in the bluegill bioaccumulation study* and a major soil degradate of chlorfenapyr, and two other known soil degradates, CL 303267 and CL 325195. The results of these studies are summarized in the following table.

Species / Test	LC50 / EC50	NOEC
Bluegill LC50 - CL 312094	928 μg/L	242 μg/L
Daphnia EC50 - CL 312094	560 μg/L	360 μg/L
Bluegill LC50 - CL 303267	70 μg/L	36 μg/L
Daphnia EC50 - CL 303267	107 μg/L	79 μg/L
Bluegill LC50 - CL 325195	2,100 μg/L	1,000 μg/L
Daphnia EC50 - CL 325195	1,700 μg/L	610 μg/L

Results of these studies indicate that CL 312094 and CL 325195 are highly toxic to *Daphnia* and bluegill, while CL 303267 is highly toxic to *Daphnia* and very highly toxic to bluegill. However, all three compounds are significantly less toxic to these organisms than chlorfenapyr. The degradates range from 6 to 181 times less toxic to bluegill and from 18 to 278 times less toxic to *Daphnia*. These results indicate that chlorfenapyr degrades to less toxic compounds in the environment.

Aquatic Field Study

In order to refine the assessment of hazard of chlorfenapyr to aquatic organisms, a pilot microcosm study has been conducted with the 3SC formulation of chlorfenapyr (i.e., PIRATE). In this study, simulated aquatic ecosystems containing natural pond water and sediment with natural assemblages of zooplankton, phytoplankton, and benthic invertebrates were stocked with juvenile bluegill. Treatments to the systems simulated exposures to simulate spray drift, surface runoff and a combination of drift and runoff to exaggerated concentrations. The pattern of bluegill mortality and effects on zooplankton populations demonstrated that suspended solids and sediment significantly reduce the bioavailability and hazard to bluegill and aquatic invertebrates. The results also demonstrated that chlorfenapyr is more hazardous when entering an aquatic system by spray drift as opposed to surface runoff. In this study, the NOEC for effects on fish and invertebrates in the water column was 15 µg/L by spray drift, while the NOEC by runoff was at least 30 µg/L, the highest concentration tested. The 15 µg/L by spray drift concentration represents 5% drift of 0.4 lbs. ai/acre to a 6-inch deep water body, or direct overspray of 0.3 lbs. ai/acre to a 6-foot deep water body. The results of the study demonstrate that the components of a natural ecosystem will attenuate the toxicity of chlorfenapyr to aquatic organisms and measures should be employed to prevent significant levels of spray drift to aquatic systems.

B. Characterization of Environmental Exposure

1. Simulated Exposure Modeling

The potential concentrations of chlorfenapyr in pond water and sediments were modeled in five regions of the U.S. using MUSCRAT (beta version 1.0). The regions were : Region 4 (AL, GA, KY, NC, SC, TN, VA); Region 5 (FL), Region 6 (AR, LA, MO, MS, OK); Region 7 (TX) and Region 11 (AZ, CA). MUSCRAT (Multiple Scenario Risk Assessment Tool) is a software tool which : (1) develops a set of input parameters for PRZM (version 3) and EXAMS (version 2) based on the crop of interest and the locations where the product will be used; (2) using PRZM, calculates on a daily basis for 36 years at up to 25 sites in each region the amount of the product which will run-off a field and be present in run-off water and attached to sediment; (3) using EXAMS, calculates the daily concentrations of the chemical in a farm pond; and (4) processes the results to determine the daily concentrations and several time weighted average concentrations.

The soil properties, cropping patterns and climatic conditions were selected by the MUSCRAT processor based on publicly available databases which had been evaluated by the NRCS (Natural Resource Conservation Service, formerly the SCS) as having the potential to grow cotton. The pesticide specific properties which were input into PRZM to determine the concentrations in run-off are summarized below.

PRZM Input Values

Two different application timings for PIRATE were used as input values to assess chlorfenapyr exposure resulting from either early or late season cotton spray programs in the Mid-South region of the U.S.. Calculations for the early season sprays were based on two weekly applications at rates of 0.3 and 0.2 lb ai/acre applied on July 7 and July

15, respectively. For the late season scenario, these two weekly applications were delayed until August 15 and August 21. A different spray schedule was used for ALERT applications to western cotton in Region 11, namely, 0.2 lb ai/acre applied on June 15 followed by a second application of 0.3 lb ai/acre on July 15. All cases assumed ground applications made to foliage in which the crop canopy was growing in a linear mode and 1% reached water bodies by spray drift. Additionally, exposure from aerial applications assuming 5% drift was computed for Region 6 (Delta). However, the results showed that ground applications produced higher aquatic concentrations than aerial applications, since 95% of the material was delivered to the field when the product was applied by ground, versus 75% by air.

The half-life of chlorfenapyr in the top horizon of soil was 433 days at the 95% C.I. for the six field studies (MRID #43492851). The field half-life values were used rather than the aerobic soil metabolism half-lives since it has been shown that both aerobic soil metabolism and photolysis play significant roles in the degradation of chlorfenapyr. An additional set of simulations was conducted using an aerobic half-life of 1370 days and an average field half-life of 280 days. These results indicated that the worst-case concentrations in water changed by less than 1 ppb. The soil/water adsorption coefficient (Koc) is 11500.

EXAMS Input Values

Except for a modification in the default value for the amount of chlorfenapyr which would remain on the sediment after the initial desorbtion from the sediment into the water column (default = 50%; a very conservative estimate of 90% was used), only a few simple physical properties and biotic degradation half-lives for water and sediment were used.

The following EXAMS input parameters were used:

Molecular Weight :407.6
Water Solubility : 0.12 mg/L
Vapor Pressure : 0.1 x 10^{-7} torr
Adsorption Coefficient (Koc) : 11500
Biological Degradation in Water Half-life : 100 days
Biological Degradation in Sediment Half-life :250 days

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The maximum water and sediment concentrations of chlorfenapyr for the 5 regions modeled are summarized in the following table.

Water Concentrations*

Region	Application	Instantaneous Concentration	96-hour Concentration	21-Day Concentration
4	Early	3.00 µg/L	2.35 µg/L	1.57 µg/L
5	Early	3.03 µg/L	2.30 µg/L	1.67 µg/L
6	Early	3.64 µg/L	2.91 µg/L	1.89 µg/L
7	Early	4.26 µg/L	3.08 µg/L	1.50 µg/L
4	Late	2.52 µg/L	2.10 µg/L	1.34 µg/L
5	Late	2.75 µg/L	2.19 µg/L	1.19 µg/L
6	Late	3.46 µg/L	2.78 µg/L	1.84 µg/L
7	Late	2.85 µg/L	2.06 µg/L	1.08 µg/L
11	0.2 June, 0.3 July	0.96 µg/L	0.74 µg/L	0.45 µg/L

Sediment Concentrations*

Region	Application	Instantaneous Concentration	96-hour Concentration	21-Day Concentration
4	Early	527 µg/kg	526 µg/kg	525 µg/kg
5	Early	461 µg/kg	461 µg/kg	458 µg/kg
6	Early	623 µg/kg	623 µg/kg	619 µg/kg
7	Early	433 µg/kg	433 µg/kg	431 µg/kg
4	Late	464 µg/kg	464 µg/kg	462 µg/kg
5	Late	364 µg/kg	364 µg/kg	361 µg/kg
6	Late	559 µg/kg	559 µg/kg	556 µg/kg
7	Late	323 µg/kg	323 µg/kg	319 µg/kg
11	0.2 lb June, 0.3 lb July	130 µg/kg	129 µg/kg	128 µg/kg

**Values in this table represent the maximum time-weighted water and sediment concentrations of chlorfenapyr in each Region*

Early Application = 0.3 and 0.2 lb ai/acre in July
Late Application = 0.3 and 0.2 lb ai/acre in August

Region 4 = AL, GA, KY, NC, SC, TN, VA
Region 5 = FL
Region 6 = AR, LA, MO, MS, OK
Region 7 = TX
Region 11 = AZ, CA

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As expected, the concentrations in the water and sediment were higher in the early application scenarios for Regions 4, 5, 6, and 7 due to the lower amount of interception by the crop canopy which is not well developed at this time. Therefore, the concentrations based on early applications will be used in the initial Risk Quotient calculation for these Regions.

The maximum 96-hour time-weighted average water concentrations ranged from 0.74 μg/L in Region 11 (Arizona, California) to 3.08 μg/L in Region 7 (Texas), while the maximum 21-day time-weighted average water concentrations ranged from 0.45 μg/L in Region 11 to 1.89 μg/L in Region 6 (Arkansas, Louisiana, Missouri, Mississippi, Oklahoma).

The maximum 96-hour time-weighted average sediment concentrations ranged from 129 μg/kg in Region 11 (Arizona, California) to 623 μg/kg in Region 6 (Arkansas, Louisiana, Missouri, Mississippi, Oklahoma), while the maximum 21-day time-weighted average sediment concentrations ranged from 128 μg/kg in Region 11 to 619 μg/kg in Region 6.

In examining the results of these modeling simulations it is important to keep in mind that in selecting the soils to be used in the analysis, the selection was made from all soils which had been evaluated by the NRCS as having a potential to grow cotton. The values listed in the tables above represent the worst-case value from all of the representative soils in each of the regions. In many cases the concentrations are significantly lower in areas representing approximately 15-20% of the potential areas. This is very significant because many of the soils giving the highest predicted concentrations are from soils with very high slopes, including average slopes up to 15%. Under modern agriculture these types of runoff conditions would not exist due to the need for erosion control. Therefore, the values generated are extremely conservative, especially since it is extremely unlikely that the soil half-lives in each of the 36 years of application would be at the upper 95% confidence interval for field half-lives.

2. Characterization of Cotton Agroecosystems and Surrounding Environs Using Remote Sensing Incorporated into a Geographic Information System (GIS).

There are several important landscape factors that will affect the ability of pesticide to enter a water body at sufficient levels and result in adverse effects to organisms inhabiting those water bodies. These include: 1) proximity of the water body to a treated field, 2) the composition of the buffer zone between the treated field and the water body, 3) the slope of the treated field, 4) the size of the treated field, 5) the size and depth of the water body, and 6) the characteristics of the water body (i.e., whether it is a lotic (moving water) or lentic (static water) system. These important factors are not typically addressed into the simulated exposure models discussed above; generally, somewhat conservative default values are used.

In order to refine the assessment of exposure and risk that chlorfenapyr presents to aquatic ecosystems associated with cotton agroecosystems, a study was conducted using remote sensing to quantify environmental characteristics (e.g., cotton field characteristics, water body characteristics, aquatic buffer characteristics, adjacency of water bodies to cotton) that affect exposure to water bodies. Detailed summaries of the study can be found in **Appendix 5**.

Geographic Information System (GIS) Study

In this study, twenty locations throughout the cotton-growing regions of the United States were selected, of which fifteen, totaling an area of approximately 12,000,000 acres were fully characterized. Only those areas within one mile of agricultural lands (including row-crops and tree crops) and within the political boundaries of the United States were included in the characterization to reduce the potential bias produced in the summary statistics from the inclusion of large, contiguous nonagricultural areas. Satellite imagery was used to determine characteristics of cotton fields, their surrounding habitats, and the juxtaposition of cotton with surface water, both flowing and static. The numbers of cotton fields, the total cotton acreage, the maximum, minimum and mean field sizes, total cotton field perimeter lengths, minimum, maximum, and mean perimeter lengths within each study site are reported. Existing soil type, hydrologic, elevational, and transportation data were combined with the satellite data in a GIS to characterize the cotton fields according to their slope, soil type and the land cover classes within 10 m (33 ft) or 50 m (164 ft).

In addition to landscape data obtained in this study, data on threatened and endangered aquatic species at the sub-county level were obtained for each of the study sites, except for Texas. These data contain specific locations (latitude and longitude) for species that are federally listed as threatened or endangered. The source of these data varies by study site; however, most of the information was derived from the state Natural Heritage programs, state wildlife departments, or the U.S. Fish and Wildlife Services. There were no data available that identified sub-county locations of threatened and endangered species in Texas; therefore, only data on the presence of threatened and endangered species by county were used.

In general, cotton was found to be grown on relatively flat land, with the vast majority of fields (85%) possessing slopes < 1%. At least 96% of the cotton acreage for all study sites was grown on slopes of 2% or less. This will greatly reduce surface run-off potential.

For the majority of the study sites, the average cotton field size ranged from 13 to 78 acres. The only exception was the California site, where the average field size was 259 acres.

In the fifteen sites that were characterized, between 91% and 99% of the total cotton acreage was not within 50 meters of any type of water body. No aquatic habitat was common in close proximity to cotton fields. Of the less than 10% of the cotton acres that were grown within 50 meters of water, 85-99% was flowing water of which 70-99% consisted of canals, drainage ditches, or intermittent streams. In two locations, one in Tennessee and one in Louisiana, rivers and streams comprised the majority of the flowing water bodies, with 38% in Tennessee and 54% in Louisiana. The percentage between flowing and static water was somewhat evenly distributed at 53 and 47%, respectively, in a single location in Georgia. However, it is important to point out that 98% of the cotton in this location is not grown within 50 meters of any water. Therefore, the total amount of static water bodies in this region is still quite small in relation to the amount of cotton grown.

The number of static water bodies (i.e., lakes and ponds) and the acreage of each size class were determined for each study site. In all studies sites, water bodies in the largest water body size class (> 25 acres) accounted for the largest water body acreage, ranging from 28 to 94% of the total water body acreage in a study site. However, water bodies of the smallest water body size class (0.25 to 1.0 acre) made up the greatest single percentage of the total number of water bodies, ranging from 25 to 73% of the total number of water bodies in a study site.

The most common land cover adjacent to cotton fields across all locations is other agriculture, with grass/pasture being the second most common.

An analysis of threatened and endangered species data at the sub-county level indicated no threatened or endangered aquatic species identified in any of the study sites.

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V. Risk Characterization

A. Risk Estimator

Risk to various aquatic organisms will be estimated using U.S. EPA's Quotient Method. Acute Risk Quotients will be calculated by dividing the model-derived 96-hour (acute) Estimated Environmental Concentration (EEC) in water or sediment by the LC50 or EC50 values for the various test species. Chronic Risk Quotients will be calculated by dividing the model-derived 21-day EEC in water or sediment by the MATC values for the various test species. In Regions 4, 5, 6, and 7, the concentrations in the water and sediment were higher in the early application scenarios. Therefore, the concentrations based on early applications will be used to calculate Risk Quotients for these Regions.

The significance of calculated quotient values is made reference to the levels of concern proposed by EPA in the published Rejection Rate Analysis (US EPA, 1994). For acute effects, Risk Quotients of < 0.1 indicate minimal risk, while values that lie between 0.1 and 0.5 indicate potential risk that can be mitigated through restricted use labeling. Acute Risk Quotients of 0.5 or more indicate significant risk. For chronic effects, values greater than 1.0 indicate significant risk.

B. Risk Quotients Based on Maximum Time-Weighted EECs for Region 4 (Alabama, Georgia, Kentucky, North Carolina, South Carolina, Tennessee, and Virginia)

1. Acute Risk Quotients

Acute Risk Quotients for various test species are summarized in the following table. Acute Risk Quotients were calculated using the maximum 96-hour time-weighted EEC in water of 2.35 µg/L.

Species	LC50/EC50	EEC	Risk Quotient
Bluegill sunfish	11.6 µg/L	2.35 µg/L	0.20
Channel catfish	12.3 µg/L	2.35 µg/L	0.19
Rainbow trout	7.4 µg/L	2.35 µg/L	0.31
Sheepshead minnow	60.4 µg/L	2.35 µg/L	0.04
Daphnia magna	6.1 µg/L	2.35 µg/L	0.39
Mysid shrimp	2.0 µg/L	2.35 µg/L	1.18
Eastern oyster	9.3 µg/L	2.35 µg/L	0.25
Chironomus riparious	49.9 µg/L	2.35 µg/L	0.05

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2. Chronic Risk Quotients

Chronic Risk Quotients for various test species are summarized in the following table. Chronic Risk Quotients were calculated using the maximum 21-day time-weighted EEC in water of 1.57 μg/L.

Species/Test	MATC	EEC	Risk Quotient
Rainbow trout/ELS	5.7 μg/L	1.57 μg/L	0.28
Sheepshead minnow/ELS	12.7 μg/L	1.57 μg/L	0.12
***Daphnia*/Life-Cycle**	5.2 μg/L	1.57 μg/L	0.30
Mysid/Life-Cycle	0.28 μg/L	1.57 μg/L	5.61
Fathead minnow/LC	8.9 μg/L	1.57 μg/L	0.18
Sheepshead minnow /LC	1.4 μg/L	1.57 μg/L	1.12
Chironomus riprious	26.5 μg/L	1.57 μg/L	0.06

3. Risk Quotients for Sediment Dwelling Organisms

Risk Quotients for sediment-dwelling species are summarized in the following table. The Risk Quotient for *Hyalella* was calculated using 96-hour time-weighted EECs in sediment (526 μg/kg), while the Risk Quotient for *Chironomus* was calculated using the maximum 21-day time-weighted EEC in water (1.57 μg/L).

Species	LC50	EEC	Risk Quotient
Hyalella azteca	20.6 mg/kg	526 μg/kg	0.03
Chironomus riprious	49.9 μg/L	1.57 μg/L	0.03

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C. Risk Quotients Based on Maximum Time-Weighted EECs for Region 5 (Florida)

1. Acute Risk Quotients

Acute Risk Quotients for various test species are summarized in the following table. Acute Risk Quotients were calculated using the maximum 96-hour time-weighted EEC in water of 2.30 µg/L.

Species	LC50/EC50	EEC	Risk Quotient
Bluegill sunfish	11.6 µg/L	2.30 µg/L	0.20
Channel catfish	12.3 µg/L	2.30 µg/L	0.19
Rainbow trout	7.4 µg/L	2.30 µg/L	0.31
Sheepshead minnow	60.4 µg/L	2.30 µg/L	0.04
Daphnia magna	6.1 µg/L	2.30 µg/L	0.38
Mysid shrimp	2.0 µg/L	2.30 µg/L	1.15
Eastern oyster	9.3 µg/L	2.30 µg/L	0.24
Chironomus riprious	49.9 µg/L	2.30 µg/L	0.05

2. Chronic Risk Quotients

Chronic Risk Quotients for various test species are summarized in the following table. Chronic Risk Quotients were calculated using the maximum 21-day time-weighted EEC in water of 1.67 µg/L.

Species/Test	MATC	EEC	Risk Quotient
Rainbow trout/ELS	5.7 µg/L	1.67 µg/L	0.29
Sheepshead minnow /ELS	12.7 µg/L	1.67 µg/L	0.13
***Daphnia*/Life-Cycle**	5.2 µg/L	1.67 µg/L	0.32
Mysid/Life-Cycle	0.28 µg/L	1.67 µg/L	5.96
Fathead minnow/LC	8.9 µg/L	1.67 µg/L	0.19
Sheepshead minnow /LC	1.4 µg/L	1.67 µg/L	1.19
Chironomus riprious	26.5 µg/L	1.67 µg/L	0.06

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3. Risk Quotients for Sediment Dwelling Organisms

Risk Quotients for sediment-dwelling species are summarized in the following table. The Risk Quotient for *Hyalella* was calculated using 96-hour time-weighted EECs in sediment (461 µg/kg), while the Risk Quotient for *Chironomus* was calculated using the maximum 21-day time-weighted EEC in water (1.67 µg/L).

Species	LC50	EEC	Risk Quotient
Hyalella azteca	20.6 mg/kg	461 µg/kg	0.02
Chironomus riprious	49.9 µg/L	1.67 µg/L	0.03

D. Risk Quotients Based on Maximum Time-Weighted EECs for Region 6 (Arkansas, Louisiana, Missouri, Mississippi, and Oklahoma)

1. Acute Risk Quotients

Acute Risk Quotients for various test species are summarized in the following table. Acute Risk Quotients were calculated using the maximum 96-hour time-weighted EEC in water of 2.91 µg/L.

Species	LC50/EC50	EEC	Risk Quotient
Bluegill sunfish	11.6 µg/L	2.91 µg/L	0.25
Channel catfish	12.3 µg/L	2.91 µg/L	0.23
Rainbow trout	7.4 µg/L	2.91 µg/L	0.39
Sheepshead minnow	60.4 µg/L	2.91 µg/L	0.05
Daphnia magna	6.1 µg/L	2.91 µg/L	0.48
Mysid shrimp	2.0 µg/L	2.91 µg/L	1.46
Eastern oyster	9.3 µg/L	2.91 µg/L	0.31
Chironomus riprious	49.9 µg/L	2.91 µg/L	0.06

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2. Chronic Risk Quotients

Chronic Risk Quotients for various test species are summarized in the following table. Chronic Risk Quotients were calculated using the maximum 21-day time-weighted EEC in water of 1.89 μg/L.

Species/Test	MATC	EEC	Risk Quotient
Rainbow trout/ELS	5.7 μg/L	1.89 μg/L	0.33
Sheepshead minnow /ELS	12.7 μg/L	1.89 μg/L	0.15
***Daphnia*/Life-Cycle**	5.2 μg/L	1.89 μg/L	0.36
Mysid/Life-Cycle	0.28 μg/L	1.89 μg/L	6.75
Fathead minnow/LC	8.9 μg/L	1.89 μg/L	0.21
Sheepshead minnow /LC	1.4 μg/L	1.89 μg/L	1.35
Chironomus riprious	26.5 μg/L	1.89 μg/L	0.07

3. Risk Quotients for Sediment Dwelling Organisms

Risk Quotients for sediment-dwelling species are summarized in the following table. The Risk Quotient for *Hyalella* was calculated using 96-hour time-weighted EECs in sediment (623 μg/kg), while the Risk Quotient for *Chironomus* was calculated using the maximum 21-day time-weighted EEC in water (1.89 μg/L).

Species	LC50	EEC	Risk Quotient
Hyalella azteca	20.6 mg/kg	623 μg/kg	0.03
Chironomus riprious	49.9 μg/L	1.89 μg/L	0.04

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E. Risk Quotients Based on Maximum Time-Weighted EECs for Region 7 (Texas)

1. Acute Risk Quotients

Acute Risk Quotients for various test species are summarized in the following table. Acute Risk Quotients were calculated using the maximum 96-hour time-weighted EEC in water of 3.08 μg/L.

Species	LC50/EC50	EEC	Risk Quotient
Bluegill sunfish	11.6 μg/L	3.08 μg/L	0.27
Channel catfish	12.3 μg/L	3.08 μg/L	0.25
Rainbow trout	7.4 μg/L	3.08 μg/L	0.41
Sheepshead minnow	60.4 μg/L	3.08 μg/L	0.05
Daphnia magna	6.1 μg/L	3.08 μg/L	0.50
Mysid shrimp	2.0 μg/L	3.08 μg/L	1.54
Eastern oyster	9.3 μg/L	3.08 μg/L	0.33
Chironomus riprious	49.9 μg/L	3.08 μg/L	0.06

2. Chronic Risk Quotients

Chronic Risk Quotients for various test species are summarized in the following table. Chronic Risk Quotients were calculated using the maximum 21-day time-weighted EEC in water of 1.50 μg/L.

Species/Test	MATC	EEC	Risk Quotient
Rainbow trout/ELS	5.7 μg/L	1.50 μg/L	0.26
Sheepshead minnow /ELS	12.7 μg/L	1.50 μg/L	0.12
***Daphnia*/Life-Cycle**	5.2 μg/L	1.50 μg/L	0.29
Mysid/Life-Cycle	0.28 μg/L	1.50 μg/L	5.36
Fathead minnow/LC	8.9 μg/L	1.50 μg/L	0.17
Sheepshead minnow /LC	1.4 μg/L	1.50 μg/L	1.07
Chironomus riprious	26.5 μg/L	1.50 μg/L	0.06

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3. Risk Quotients for Sediment Dwelling Organisms

Risk Quotients for sediment-dwelling species are summarized in the following table. The Risk Quotient for *Hyalella* was calculated using 96-hour time-weighted EECs in sediment (433 μg/kg), while the Risk Quotient for *Chironomus* was calculated using the maximum 21-day time-weighted EEC in water (1.50 μg/L).

Species	LC50	EEC	Risk Quotient
Hyalella azteca	20.6 mg/kg	433 μg/kg	0.02
Chironomus riprious	49.9 μg/L	1.50 μg/L	0.03

F. Risk Quotients Based on Maximum Time-Weighted EECs for Region 11 (Arizona and California)

1. Acute Risk Quotients

Acute Risk Quotients for various test species are summarized in the following table. Acute Risk Quotients were calculated using the maximum 96-hour time-weighted EEC in water of 0.74 μg/L.

Species	LC50/EC50	EEC	Risk Quotient
Bluegill sunfish	11.6 μg/L	0.74 μg/L	0.06
Channel catfish	12.3 μg/L	0.74 μg/L	0.06
Rainbow trout	7.4 μg/L	0.74 μg/L	0.10
Sheepshead minnow	60.4 μg/L	0.74 μg/L	0.01
Daphnia magna	6.1 μg/L	0.74 μg/L	0.12
Mysid shrimp	2.0 μg/L	0.74 μg/L	0.37
Eastern oyster	9.3 μg/L	0.74 μg/L	0.08
Chironomus riprious	49.9 μg/L	0.74 μg/L	0.01

2. Chronic Risk Quotients

Chronic Risk Quotients for various test species are summarized in the following table. Chronic Risk Quotients were calculated using the maximum 21-day time-weighted EEC in water of 0.45 μg/L.

Species/Test	MATC	EEC	Risk Quotient
Rainbow trout/ELS	5.7 μg/L	0.45 μg/L	0.08
Sheepshead minnow /ELS	12.7 μg/L	0.45 μg/L	0.04
***Daphnia*/Life-Cycle**	5.2 μg/L	0.45 μg/L	0.09
Mysid/Life-Cycle	0.28 μg/L	0.45 μg/L	1.61
Fathead minnow/LC	8.9 μg/L	0.45 μg/L	0.05
Sheepshead minnow /LC	1.4 μg/L	0.45 μg/L	0.32
Chironomus riprious	26.5 μg/L	0.45 μg/L	0.02

3. Risk Quotients for Sediment Dwelling Organisms

Risk Quotients for sediment-dwelling species are summarized in the following table. The Risk Quotient for *Hyalella* was calculated using 96-hour time-weighted EECs in sediment (129 μg/kg), while the Risk Quotient for *Chironomus* was calculated using the maximum 21-day time-weighted EEC in water (0.45 μg/L).

Species	LC50	EEC	Risk Quotient
Hyalella azteca	20.6 mg/kg	129 μg/kg	0.01
Chironomus riprious	49.9 μg/L	0.45 μg/L	0.01

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VI. Risk Description

A. Risk Characterization Process

Risks to aquatic organisms have been determined using the quotient method (Urban and Cook, 1986). The significance of calculated quotient values is made reference to the levels of concern proposed by EPA in the published Rejection Rate Analysis (US EPA, 1994).

For acute effects, Risk Quotients of < 0.1 indicate minimal risk, while values that lie between 0.1 and 0.5 indicate potential risk that can be mitigated through restricted use labeling. Acute Risk Quotients of 0.5 or more indicate significant risk. For chronic effects, values greater than 1.0 indicate significant risk.

B. Acute Risk

1. Freshwater Fish

Calculated Risk Quotients for the most sensitive species of freshwater fish, the rainbow trout, range from 0.10 in Region 11 (Arizona and California) to 0.41 in Region 7 (Texas). The values are all below EPA's level of concern (0.5) for significant acute risk (US EPA, 1994). Therefore, the proposed use of chlorfenapyr on cotton will not present a significant acute risk to freshwater fish.

2. Freshwater Invertebrates

Calculated Risk Quotients for the most sensitive species of freshwater invertebrates, *Daphnia magna*, range from 0.12 in Region 11 (Arizona and California) to 0.50 in Region 7 (Texas). The values are all less than or equal to EPA's level of concern (0.5) for significant acute risk (US EPA, 1994). Therefore, the proposed use of chlorfenapyr on cotton will not present a significant acute risk to freshwater invertebrates.

3. Marine Fish

Calculated Risk Quotients for the most sensitive species of marine fish, the sheepshead minnow, range from 0.01 in Region 11 (Arizona and California) to 0.05 in Regions 6 (Arkansas, Louisiana, Missouri, Mississippi, and Oklahoma) and 7 (Texas). The values are all below EPA's level of concern (0.1) for no risk (US EPA, 1994). Therefore, the proposed use of chlorfenapyr on cotton will not present an acute risk to marine fish.

4. Marine Invertebrates

Calculated Risk Quotients for the most sensitive species of marine invertebrates, the mysid, range from 0.37 in Region 11 (Arizona and California) to 1.54 in Region 7 (Texas). Although some of the values are above EPA's level of concern (0.5) for significant acute risk (US EPA, 1994), there are some additional factors that need to be considered; 1) Little, if any cotton is planted in close proximity to saltwater (see results from the definitive GIS study); and 2) The exposure models used in this assessment assume spray drift and surface runoff into a stagnant water body (e.g., farm pond) with no outlet. However, all estuarine and marine waters are subject to tidal flushing twice daily. The tidal action will result in tremendous circulation and dilution of any residues that might reach saltwater. Therefore, the proposed use of chlorfenapyr on cotton will not present a significant acute risk to freshwater invertebrates because exposure will be severely limited.

C. Chronic Risk

1. Freshwater Fish

Calculated Risk Quotients using the most sensitive species of freshwater fish, the rainbow trout (based on early-life stage toxicity), range from 0.08 in Region 11 (Arizona and California) to 0.33 in Region 6 (Arkansas, Louisiana, Missouri, Mississippi, and Oklahoma). The values are all well below EPA's level of concern (1.0) for significant chronic risk (US EPA, 1994). The fact that the chronic Risk Quotients for fish are lower than the acute Risk Quotients confirms the low chronicity of chlorfenapyr. Therefore, the proposed use of chlorfenapyr on cotton will not present a significant chronic risk to freshwater fish.

2. Freshwater Invertebrates

Calculated Risk Quotients for the most sensitive species of freshwater invertebrates, *Daphnia magna*, range from 0.09 in Region 11 (Arizona and California) to 0.36 in Region 6 (Arkansas, Louisiana, Missouri, Mississippi, and Oklahoma). The values are all well below EPA's level of concern (1.0) for significant chronic risk (US EPA, 1994). The fact that the chronic Risk Quotients for freshwater invertebrates are lower than the acute Risk Quotients confirms the low chronicity of chlorfenapyr. Therefore, the proposed use of chlorfenapyr on cotton will not present a significant chronic risk to freshwater invertebrates.

3. Marine Fish

Calculated Risk Quotients using the most sensitive species of marine fish, the sheepshead minnow (based on the full life-cycle toxicity study), range from 0.32 in Region 11 (Arizona and California) to 1.35 in Region 6 (Arkansas, Louisiana, Missouri, Mississippi, and Oklahoma). Many of the values are above EPA's level of concern (1.0) for significant chronic risk (US EPA, 1994). However, this Risk Quotients were derived by comparing a 21-day maximum EEC in water with a toxicity value determined in a 187-day, continuous exposure toxicity test. Therefore, the calculated Risk Quotient is conservatively high. In addition, there are some additional factors that need to be considered; 1) Little, if any cotton is planted in close proximity to saltwater (see results from the definitive GIS study); and 2) The exposure models used in this assessment assume spray drift and surface runoff into a stagnant water body (e.g., farm pond) with no outlet. However, all estuarine and marine waters are subject to tidal flushing twice daily. The tidal action will result in tremendous circulation and dilution of any residues that might reach saltwater. Therefore, the proposed use of chlorfenapyr on cotton will not present a significant chronic risk to marine fish because exposure will be severely limited.

4. Marine Invertebrates

Calculated Risk Quotients for the most sensitive species of marine invertebrates, the mysid, range from 1.61 in Region 11 (Arizona and California) to 6.75 in Region 6 (Arkansas, Louisiana, Missouri, Mississippi, and Oklahoma). Although the values are all above EPA's level of concern (1.0) for significant chronic risk (US EPA, 1994), there are additional factors that need to be considered; 1) Little, if any cotton is planted in close proximity to saltwater (see results from the definitive GIS study); and 2) The exposure models used in this assessment assume spray drift and surface runoff into a stagnant water body (e.g., farm pond) with no outlet. However, all estuarine and marine waters are subject to tidal flushing twice daily. The tidal action will result in tremendous circulation and dilution of any residues that might reach saltwater. Therefore, the proposed use of chlorfenapyr on cotton will not present a significant chronic risk to marine invertebrates because exposure will be severely limited.

D. Risk to Sediment-Dwelling Organisms

Risk to sediment dwelling organisms was calculated using results from two different exposure systems; a system where exposure simulated spray drift into a water body (the *Chironomus* study) and a system where the toxicity of residues in sediment was assessed (the *Hyalella* study). Therefore, risk can be assessed based on both water and sediment exposure scenarios.

Based on EECs in water, calculated Risk Quotients for sediment-dwelling organisms range from 0.01 in Region 11 (Arizona and California) to 0.04 in Region 6 (Arkansas, Louisiana, Missouri, Mississippi, and Oklahoma). The values are all well below EPA's level of concern (0.1) for no risk (US EPA, 1994).

Based on EECs in sediment, calculated Risk Quotients for sediment-dwelling organisms range from 0.01 in Region 11 (Arizona and California) to 0.03 in Regions 4 (Alabama, Georgia, Kentucky, North Carolina, South Carolina, Tennessee, and Virginia), 6 (Arkansas, Louisiana, Missouri, Mississippi, and Oklahoma), and 7 (Texas). The values are all well below EPA's level of concern (0.1) for no risk (US EPA, 1994).

Therefore, the proposed use of chlorfenapyr on cotton will not present a risk to sediment-dwelling invertebrates.

E. Potential for Secondary or Indirect Effects

Secondary effects are defined as effects occurring in one group of organisms due to direct effects on another group. An example would be a reduction in aquatic invertebrate populations resulting in adverse effects (e.g., survival, growth) on fish populations that feed on the invertebrates.

The potential for chlorfenapyr to cause secondary effects in aquatic ecosystems has been evaluated, and is considered to be low for the following reasons. The sensitivity of various aquatic animals (i.e., fish, crustaceans, mollusks) to chlorfenapyr is similar. Therefore, it is unlikely that one group of organisms would be impacted without impacting all groups. This was confirmed in the aquatic microcosm study, where fish and aquatic invertebrates were adversely impacted in the same treatment groups, and were both not impacted in others. In addition, there is low probability of chlorfenapyr causing toxicity due to bioaccumulation or biomagnification through the aquatic food web. The results from the fish bioaccumulation study with chlorfenapyr demonstrated that chlorfenapyr is rapidly metabolized in biological systems, and the primary metabolite (desbromo chlorfenapyr) is rapidly eliminated. The results of this study clearly demonstrate a low potential for bioaccumulation and biomagnification.

F. Risk to Endangered Species

Although the major focus of the present assessment is on non-threatened, non-endangered aquatic species, additional information has been gathered on threatened and endangered aquatic species common to aquatic ecosystems associated with cotton fields as a part of the GIS study. This survey indicated no threatened or endangered aquatic species in the sites analyzed. In addition, as EPA is aware, there is a substantial effort for protecting endangered species underway by an Industry group termed the FIFIRA Endangered Species Task Force (FESTF). American Cyanamid Company is a founding member of that Task force and will continue to help provide EPA with additional information on threatened and endangered species as it becomes available.

G. Refinement of Ecological Risk Assessment (Mitigation of Risk)

Although the refined risk assessment that has been conducted using the quotient method has indicated low (i.e., acceptable) risk to aquatic organisms, there are components of the labels for these compounds which will mitigate exposure and risk to aquatic organisms. In addition, there are several important landscape factors that are not addressed in the simulated exposure models (i.e., default values are used), which will further lower the quotients of risk. These include: 1) the proximity of the water body to a treated field, 2) the composition of the buffer zone between the treated field and the water body, 3) the slope of the treated field, 4) the size of the treated field, 5) the size and depth of the water body, and 6) the characteristics of the water body (i.e., whether it is a lotic (moving water) or lentic (static water) system). These factors, which will affect the ability of pesticide to enter a water body at sufficient levels and result in adverse effects to organisms inhabiting those water bodies, were evaluated in the GIS studies that were conducted to support chlorfenapyr use on cotton..

Firstly, the simulated exposure models used in this assessment assumed either 5% drift for aerial applications or 1% by ground application to a water body. However, restrictions on chlorfenapyr labels include mandatory buffer zones between treated fields and water bodies; a 150-foot buffer if the product is applied by air and 25-foot if applied by ground equipment. There are additional restrictions on aerial applications including, controlling spray droplet size, boon length, application height, swath adjustment, wind speed restrictions, applying during period of low relative humidity, and prohibition of applications during temperature inversions. These restrictions will severely limit the amount of material that could drift to water bodies during aerial applications.

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In addition, the surface runoff simulations conducted in this assessment utilized a variety of field slopes, some greater than 10%. In addition, the default assumption for the models is a 10-acre field draining into a 1-acre, static water body. There were several important characteristics of the cotton agroecosystems that were uncovered in the GIS studies that demonstrate that these assumptions are highly conservative. Important characteristics include:

- The majority of the fields (85%) possess slopes of less than 1%, and greater than 96% of the fields have slopes of less than 2%. This severely limits the potential for surface runoff.
- The majority of the cotton acreage is not located near water; in the fifteen sites that were characterized in the GIS study, between 91% and 99% of the total cotton acreage was not within 50 meters of any type of water body.
- Of the cotton grown within 50 meters of water for most of the study sites, between 85 and 99% is associated with flowing water bodies, and between <1 to 15 % with static water bodies. The most common type of water body in most locations were canals, drainage ditches or intermittent streams. Exposure to these types of water bodies would be pulsed exposures with limited duration.
- When static water bodies are found within 50 meters of cotton, the majority of the acreage is associated with relatively large (> 25 acre) water bodies. Therefore, the types of water bodies that are associated with cotton would lead to greater circulation and/or dilution then is predicted by the exposure models.

In summary, when important label restrictions (i.e., mitigation measures) and cotton landscape factors are factored into the risk assessment, one can conclude that exposure of chorfenapyr to sensitive aquatic ecosystems will be limited during its use on cotton. Therefore, the risk of chlorfenapyr to aquatic ecosystems associated with cotton agroecosystems will be minimal.

H. Ecological Monitoring

During 1995, 1996, and 1997, nine states applied for and received Section 18 Emergency Exemptions for the use of chlorfenapyr on cotton. As a condition for use, the states were required to conduct systemic field monitoring during the 1995 and 1996 growing seasons by wildlife management professionals to determine if wildlife kills occurred. These monitoring programs indicated no fish kills due to the use of the product. Since the sensitivity of fish to chlorfenapyr is similar to that of aquatic invertebrates, and chlorfenapyr is primarily acutely toxic to aquatic organisms, fish mortality would be a good indicator of adverse impacts of chlorfenapyr on aquatic ecosystems. Therefore, the lack of any fish kills during the widespread use of the product (applied to over 1 million acres) during multiple years, confirms the low risk of the product to aquatic organisms associated with its use on cotton. These results are not surprising given the favorable Risk Quotients for the majority of aquatic organisms and the dearth of sensitive water bodies associated with cotton fields.

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VII. Conclusions

An aquatic organism ecological risk assessment was carried out for the use of chlorfenapyr in cotton. The assessment employed the terminology and followed the procedures set out in the United States Environmental Protection Agency's (EPA's) Framework for Ecological Risk Assessment (1992). That is, all components of the Problem Formulation, Analysis, and Risk Characterization phases were carried out.

In the Problem Formulation phase, the valued ecological entity was defined as populations of aquatic organisms inhabiting aquatic ecosystems associated with cotton fields. A general conceptual model was provided.

The Analysis phase of the assessment summarized and synthesized data on ecological effects and exposure. Exposure estimates were made for five distinct regions of the cotton belt using MUSCRAT (beta version 1.0) modeling. The exposure estimates were then refined using data gathered in a Geographic Information Systems (GIS) analysis of water bodies associated with cotton agroecosystems.

In the Risk Characterization phase, risk was initially estimated for freshwater fish and aquatic invertebrates, saltwater fish and aquatic invertebrates, and sediment-dwelling aquatic invertebrates by using a Risk Quotient approach. Model-derived time-weighted EECs in water or sediment were compared with laboratory-derived toxicity values for the different laboratory test species. The results of this initial assessment indicated a minimal level of risk. The only species where acceptable Risk Quotients were consistently exceeded was the mysid, a marine invertebrate species. However, there are components of the marine environment (e.g., tidal flushing and increased dilution) which indicate that EECs that were calculated using the computer models are highly conservative for marine species.

The risk to aquatic species was further refined with data gathered in the GIS studies. The results of this analysis indicated that most cotton is grown on relatively flat land, with slopes of less than 1%, which should minimize runoff potential. In addition, the analysis indicated a general lack of water bodies associated with cotton fields; between 91% and 99% of the total cotton acreage was not within 50 meters of any type of water body. Finally, the majority of the water that was within 50 meters of cotton was flowing water, most commonly canals, drainage ditches or intermittent streams. When static water is found in close proximity to cotton, it is predominantly large water bodies greater than 25 acres in size. Any exposure to water bodies of this size would result in greater dilution that is predicted by exposure models which assume exposure to a 1 acre pond. The results of this assessment has been confirmed by Section 18 Emergency Exemption monitoring programs in seven states where no adverse incidents were uncovered during widespread use of chlorfenapyr.

In summary, the results of this refined ecological risk assessment, conducted in compliance with the procedures established in EPA's Framework for Ecological Risk Assessment indicate that the use of chlorfenapyr on cotton will not result in unreasonable risk to aquatic organisms.

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