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and Toxic Substances  
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May 2007

# Reregistration Eligibility Decision for Antimycin A

US EPA ARCHIVE DOCUMENT

**REREGISTRATION ELIGIBILITY**

**DECISION**

**for**

**Antimycin A**

List D  
Case No. 4121

Approved by:



Peter Caulkins

Acting Director, Special Review and  
Reregistration Division

5/16/07  
Date

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## Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC <sub>50</sub>	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD <sub>50</sub>	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
PIS	Primary Irritation Score
ppb	Parts Per Billion ( $\mu\text{g/L}$ ; micrograms per liter)
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

## I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984, and amended again by the Food Quality Protection Act of 1996 (FQPA) and the Pesticide Registration Improvement Act of 2003 (PRIA) to set time frames for the issuance of Reregistration Eligibility Decisions. FIFRA calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all data submitted to the U.S. Environmental Protection Agency (EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of a pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

The Agency made its reregistration eligibility determination for antimycin A based on the required data, the current guidelines for conducting acceptable studies to generate such data, and published scientific literature. The Agency has found that currently registered piscicidal (fish-kill) uses of antimycin A are eligible for reregistration provided the requirements for reregistration identified in this reregistration eligibility decision (RED) are implemented.

This document consists of six sections: Section I contains the regulatory framework for reregistration reassessment; Section II provides an overview of the chemical, including a profile of its use and usage; Section III gives an overview of the human health and ecological risk assessments; Section IV presents the Agency's reregistration eligibility and risk management decisions; Section V summarizes label changes necessary to implement the risk mitigation measures outlined in Section IV; and Section VI includes the appendices, related supporting documents, and Data Call-In (DCI) information. The revised risk assessment documents and related addenda are not included in this document, but are available in the Public Docket at <http://www.regulations.gov> in docket number EPA-HQ-OPP-2006-1002.

## II. Chemical Overview

Antimycin A, or 3-methylbutanoic acid 3[[3-(formylamino)-2-hydroxybenzoyl]amino]-8-hexyl-2,6-dimethyl-4,9-dioxo-1,5-dioxonan-7-yl ester, is a Restricted Use Pesticide registered by EPA for piscicidal (fish kill) uses. Derived as a fermentation product from *Streptomyces* mold, the chemical is applied directly to water to renovate recreational fish populations and to remove scaled fish from catfish fingerling and food-fish production ponds. Over the past decade antimycin A has been used by Federal and state agencies to restore threatened/endangered (listed) fish to their native habitats. Although once explored as a potential cancer treatment, there is no known use of antimycin A in human medicine.

## A. Regulatory History

Antimycin A was discovered in 1945 and was first registered as a fish toxicant in 1960. There is one registered product that contains antimycin A (Fintrol-® Concentrate, EPA Registration Number 39096-2, Aquabiotics Corp.). This product is classified as a Restricted Use Pesticide (RUP) due to aquatic toxicity and the need for highly specialized applicator training.

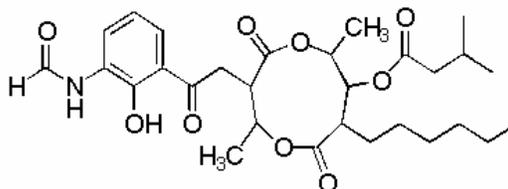
Data call-ins were issued in 1993 and several required toxicology studies were submitted. The technical registrant submitted waiver requests for the remaining requirements and the Agency granted these requests based on low usage.

## B. Chemical Identification and Nomenclature

PC Code: 006314

Common name: Antimycin A

Chemical structure:



Molecular Formula:  $C_{28}H_{40}N_2O_9$

IUPAC name: 3-methylbutanoic acid 3[[3-(formylamino)-2-hydroxybenzoyl]amino]-8-hexyl-2,6-dimethyl-4,9-dioxo-1,5-dioxonan-7-yl ester

Chemical Class: Nitrosalicylanilide

CAS# 1397-94-0

## C. Use Profile

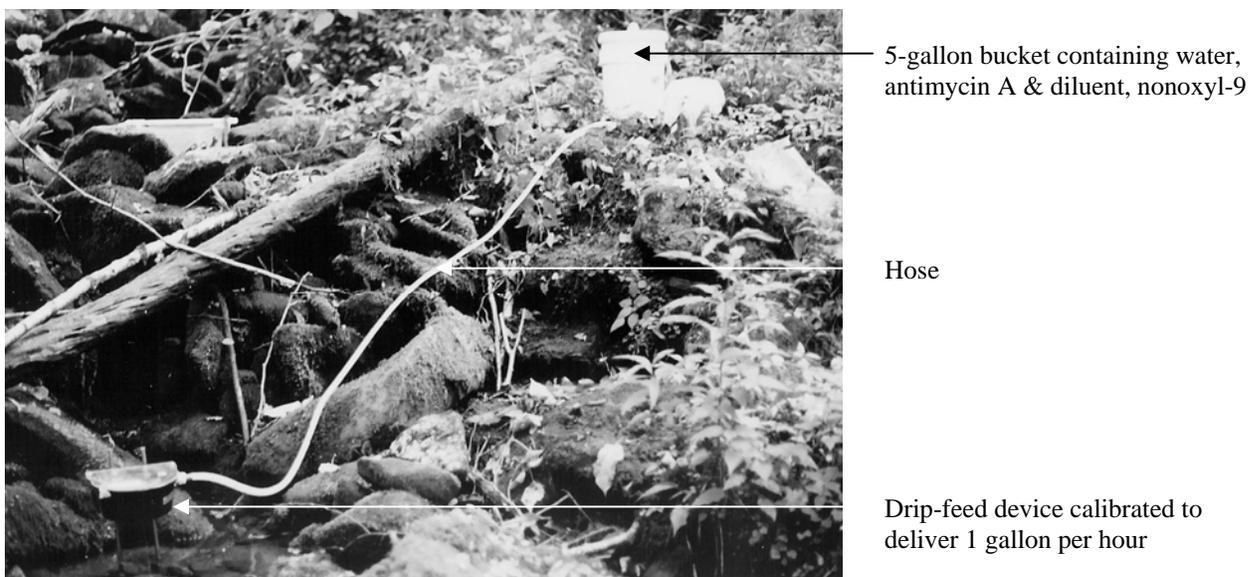
Antimycin A has two broad uses as a piscicide: fish management program use and aquaculture use. Environmental factors such as water body size, pH, temperature, and, in lotic environments, flow rate and gradient affect the amount of antimycin A and number of application sites/stations that must be used to achieve the desired concentration. For example, antimycin A is more effective in warm water; thus, less antimycin A may be required during the summer months than the winter months for the same treatment site, assuming other factors remain constant.

### Fish Management Program Use

As part of a fish management program, antimycin A is used primarily by Federal and state agencies to eliminate invasive or non-native species in an area where threatened or indigenous species would later be restored. The compound is applied to water to achieve

treatment concentrations up to 25 parts per billion (ppb) by a drip-feed device which is part of a drip station (see Figure 1), or by backpack sprayer, boat bailer, or other hand-held sprayer. Drip stations are typically used in streams and rivers inaccessible to boat traffic. Backpack sprayers may be used to supplement drip stations or other application devices in areas with poor water circulation (e.g., stagnant pools that the chemical may not reach through natural stream flow). Backpack sprayers are used in areas where water depth is 1 foot or less. Boat bailers are used in larger water bodies such as ponds and rivers. Deeper water bodies may require the use of a pump mechanism (to ensure adequate mixing throughout the water column) where antimycin A is dispensed through a perforated hose stretching the length of the water column, or is delivered through the boat's propeller wash using a pump mechanism.

Figure 1: Antimycin A Drip Station



Aquaculture Use

In aquaculture (catfish production), antimycin A can be applied at concentrations up to 25 ppb to achieve a “complete kill” or at concentrations up to 10 ppb to achieve a “selective kill.” Complete kills are performed prior to stocking fingerlings to eliminate all fish in the treatment area. Selective kills are performed after stocking fingerlings to eliminate only smaller or more sensitive species that compete for food and resources and may reduce the yields of commercial farmers. Approximately 18 to 36 months elapse before fingerlings weighing <50 grams (g) are harvested as adult catfish weighing >450 g.

Use Profile Summary

Type of Pesticide:	Piscicide.
Summary of Use:	Antimycin A is applied directly to water to manage fish populations in lakes, ponds, reservoirs, rivers, streams, and in

aquaculture. The chemical can be applied at high concentrations to achieve a “complete kill” or, in aquaculture only, at lower concentrations to achieve a “selective kill.” Complete kills are used to eliminate all fish in the treatment area; selective kills are used to eliminate only smaller or more sensitive species.

Target Organisms:	Undesired fish species.
Mode of Action:	Antimycin A uncouples oxidative phosphorylation by blocking the electron transport pathway to Complex III within the mitochondria.
Tolerances:	No tolerance exists for antimycin A.
Use Classification:	The Antimycin A product is classified as a Restricted Use Pesticide due to aquatic toxicity and the need for highly specialized applicator training.
Formulation:	Liquid.
Methods of Application:	Applications are made with a drip-feed device as part of a drip station, backpack sprayer, boat bailer, and sprayer.
Use rates:	The label evaluated in this RED for the sole product containing antimycin A allows the chemical to be applied to achieve treatment concentrations up to 25 parts per billion (ppb) and recommends 7 to 10 ppb for use in aquaculture.
Application Timing:	Antimycin A may be applied at any time of year.
Annual usage:	Available usage data for piscicidal applications indicate that several hundred pounds of antimycin A are applied annually.

### III. Summary of Risk Assessments

This section summarizes EPA’s human health and ecological risk conclusions for antimycin A to help the reader better understand EPA’s risk management decisions. The full risk assessments and related supporting documents are available at <http://www.regulations.gov> in docket number EPA-HQ-OPP-2006-1002. EPA’s human health and ecological risk assessments were updated based on comments received during the 60-day public comment period that closed on March 19, 2007.

Comments were received from Aquabiotics Corp., National Park Service, Food & Water Watch, Trout Unlimited, Wyoming Game and Fish Department, State of Arizona Game and Fish Department, American Fisheries Society Task Force on Fishery Chemicals,

Turner Enterprises, People for the Ethical Treatment of Animals, Colorado Division of Wildlife, Wilderness Watch, and several citizens. In addition to other comments, respondents expressed interest in reviewing the proposed standard operating procedures manual, the necessity of preventing human exposure, concerns with the relatively sparse human health and ecological database, and suggested risk reduction strategies. The Agency's response to comments documents are available in the antimycin A public docket and this RED presents risk management decisions based on public input.

Where possible, EPA relied on maximum labeled application concentrations to estimate exposure in its human health and ecological risk assessments. The antimycin A label evaluated in EPA's assessments allows treatment concentrations up to 25 ppb for difficult-to-control species but does not specify a maximum treatment concentration. Based on communications with stakeholders and users, EPA believes that treatment concentrations of 25 ppb or lower are suitable to control unwanted fish species and that higher concentrations may result in additional and unnecessary risk. As a result of this RED, labels will be amended to specify a maximum treatment concentration of 25 ppb (see Section IV).

**A. Human Health Risk Assessment**

Because relatively few data are available, EPA did not conduct a quantitative human health risk assessment for antimycin A. EPA evaluated the submitted data as well as available open literature and determined that there is adequate information to support a reregistration eligibility decision for the limited piscicidal uses, provided labeling is implemented that will eliminate or virtually eliminate the potential for human exposure.

**1. Toxicity Profile**

Toxicity assessments estimate to what degree a pesticide could cause adverse health effects in humans and the level or dose at which such effects could occur.

**a) Acute Toxicity Profile**

Table 1 presents available information on the acute toxicity for the one registered end-use pesticide product containing antimycin A (Fintrol®, 23% active ingredient). Waiver requests have been granted for the remaining data requirements due to low and specialized use patterns. In cases where data were not available, EPA made reasonable worst-case toxicity assumptions. The Agency may modify its conclusions or assumptions upon submission of additional data.

Table 1. Acute Toxicity Profile of Fintrol®

Guideline Number	Study Title	Source (MRID)	Results	Toxicity Category
870.1100	End-use acute oral [rat]	45937201	LD <sub>50</sub> = 286 mg/kg (M) LD <sub>50</sub> = 361 mg/kg (F) LD <sub>50</sub> = 316 mg/kg (combined)	II

Guideline Number	Study Title	Source (MRID)	Results	Toxicity Category
870.1200	Acute dermal [rat]	46762604	LD <sub>50</sub> >5000 mg/kg	IV
870.1300	Acute inhalation [rat]	46762605	LC <sub>50</sub> = >2.59 mg/L	IV
870.2400	Acute eye irritation [rabbit]	46762603	From 24 hours to 14 days, 1/2 had scattered diffuse areas of opacity	II
870.2500	Acute dermal irritation	46762602	Not a dermal irritant	N/A
870.2600	Skin sensitization	N/A	Not a dermal sensitizer	N/A

LD<sub>50</sub> = Median Lethal Dose; N/A = not applicable

### b) Completeness of Database

The toxicological database for antimycin A is inadequate to conduct a quantitative risk assessment. However, EPA believes that the available submitted data as well as available open literature studies are adequate to support a reregistration eligibility decision, provided labeling is implemented that will eliminate or virtually eliminate the potential for human exposure.

#### 2. Metabolites and Degradates

EPA reviewed the metabolism of antimycin A and concluded that there are degradation products. EPA believes that degradation products would not likely present risks above the Agency's level of concern, provided labeling is implemented that will eliminate or virtually eliminate the potential for human exposure.

#### 3. Human Exposure and Risk

In the absence of data demonstrating exposure and risk below the Agency's level of concern, exposure to antimycin A must be virtually eliminated to be eligible for reregistration. Dietary exposure to antimycin A may occur by consuming treated water or fish. Recreational exposure may occur by swimming, wading, fishing, or performing other recreational activities in treated water. Occupational exposure may occur by mixing, loading, applying, or otherwise directly participating in an antimycin A application.

To preclude human exposure, labels must be amended to prohibit harvesting of surviving fish from a selective kill use for 12 months after treatment; require drinking water intakes within the treatment area to be closed until monitoring samples demonstrate antimycin A levels are below the limit of detection (0.015 ppb); prohibit public access to the treatment area during and for 7 days after treatment (i.e., after >99% degradation assuming  $t_{1/2}$  = 12 hours); require outflow from treated areas to be deactivated with potassium permanganate; require additional personal protective equipment (PPE) for handlers. In addition, the registrant must submit a detailed standard operating procedures (SOP) manual (see Section IV).

These measures will be incorporated in the product labeling. Certain label restrictions may be reduced or removed upon submission of acceptable toxicity and exposure studies that demonstrate risk would not exceed the Agency's level of concern.

## **B. Ecological Risk Assessment**

EPA conducted an ecological risk assessment for antimycin A to support the reregistration eligibility decision. EPA evaluated the submitted environmental fate and ecological studies as well as available open literature and determined that the data are adequate to support a reregistration eligibility decision.

### **1. Environmental Fate and Transport**

Although environmental fate data are limited, the primary route of degradation appears to be base hydrolysis. In studies conducted by EPA, antimycin A degraded relatively rapidly ( $t_{1/2} < 12$  hours, pH 1 to 9) under static conditions. Half-lives for antimycin A tended to decrease with increasing pH and under more alkaline conditions (pH 9) the average half-life due to hydrolysis was 3.4 hours. In studies where the test solutions were mechanically mixed rather than static, half-lives at environmentally relevant pH values (pH 5 to 8) ranged from less than 1 hour to 10 hours.

Field data indicating that antimycin A can move considerable distances (1.75 km) are not inconsistent with measured hydrolysis rates since the flow rate of treated stream water in these studies was such the chemical could move over a kilometer in less than 12 hours. However, the hydrolysis data and field data are inconsistent with chemical half-lives estimated using a registrant-submitted aerobic metabolism study. It is uncertain why laboratory data indicate that antimycin A is subject to rapid hydrolysis whereas the aerobic metabolism study indicates otherwise. It is possible that sediment-water systems, such as that used in the aerobic metabolism study, may provide a substrate for antimycin A sorption and that the sediment may shield antimycin A from hydrolytic degradation. However, antimycin A that is bound to sediment is not expected to be bioavailable and any amount of compound that may desorb is expected to degrade rapidly given the short half-life.

Based on model estimates, antimycin A is not expected to be mobile in soil and sediment ( $\log K_{oc} = 3.41$ ) and has a relatively low potential for bioconcentrating in aquatic organisms (bioconcentration factor = 350x). A compound is considered likely to bioconcentrate if the bioconcentration factor (BCF) is  $>1000$ . Models indicate that antimycin A is not likely to persist in the environment and its low vapor pressure ( $2.31 \times 10^{-15}$  mm Hg) and Henry's Law constant ( $2.42 \times 10^{-17}$  atm-m<sup>3</sup> mol<sup>-1</sup>) limit its volatility.

### **2. Ecological Exposure and Risk**

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity information using the risk quotient (RQ) method. RQs are calculated by dividing acute and chronic estimated environmental concentrations (EEC) by ecotoxicity values for

various wildlife and plant species. RQs are then compared to the levels of concern (LOC) presented in Table 2.

Table 2. EPA’s Levels of Concern for Risk Quotients

Risk Presumption	Level of Concern		
	Terrestrial Animals	Aquatic Animals	Plants
<i>Acute Risk</i> - there is potential for acute risk	0.5	0.5	1
<i>Acute Endangered Species</i> - endangered species may be adversely affected <sup>1</sup>	0.1	0.05	1
<i>Chronic Risk</i> - there is potential for chronic risk	1	1	N/A

<sup>1</sup> RQs that exceed EPA’s level of concern for endangered species do not constitute a “may affect finding” under the Endangered Species Act.

When the RQ exceeds the level of concern for a particular category, the Agency presumes a risk of concern. In general, the higher the RQ, the greater the potential risk. Risk characterization provides further information on potential adverse effects and the possible impact of those effects by considering the fate of the chemical and its degradates in the environment, organisms potentially at risk, and the nature of the effects observed.

**a) Aquatic Organisms**

EPA estimated toxicity, exposure, and risk to freshwater fish and invertebrates. Data were not available to evaluate the risk of antimycin A exposure to non-target aquatic plants. To estimate risks to aquatic animals, the Agency considered estimated environmental concentrations (EEC) in surface water bodies based on a treatment concentration of 25 ppb. Table 3 presents a summary of potential ecological risk from exposure to antimycin A.

Table 3. Summary of Potential Risk to Aquatic Organisms

Taxonomic Group <sup>1</sup>	Direct Acute Effects	RQ
Freshwater Fish	Mortality	2,778
Freshwater Invertebrates	Mortality, immobilization	3,125
Saltwater Mollusk	Mortality	0.40

<sup>1</sup> Data were not available for aquatic plants.

Freshwater Fish

As a registered piscicide, antimycin A is expected to kill fish and aquatic invertebrates at the concentrations at which it is applied. Based on the most sensitive species and treatment concentrations of 25 ppb, acute risk levels of concern are exceeded for aquatic animals by several orders of magnitude. Even for the least sensitive fish and aquatic

invertebrates tested, treatment concentrations of 25 ppb would exceed acute risk levels of concern.

Adequate data are not available to quantitatively estimate chronic risk to aquatic or terrestrial animals. However, available data indicate that antimycin A will not persist in the environment; would, in flowing waters, eventually be flushed through the system and would be diluted by untreated tributaries; and is typically only applied to an area once per year. Thus, the likelihood of chronic ecological exposure is low. To ensure chronic exposure does not occur, the Agency will require outflow from treatment areas to be deactivated with potassium permanganate (see Section IV).

Where antimycin A is used to remove scaled fish from aquaculture ponds, treatment concentrations are considerably lower than 25 ppb to ensure that the health/survival of the crop is not impaired. Therefore, the likelihood of either acute or chronic effects in non-target animals from the use of antimycin in aquaculture is low, particularly since the treated water is typically retained within the aquaculture facility. The extent to which treated water is released into adjacent water bodies is uncertain as are the associated risks to non-target aquatic animals. Therefore, to preclude exposure to non-target aquatic animals, outflow of treated water from aquaculture ponds must be deactivated with potassium permanganate (see Section IV). Potassium permanganate is a strong oxidizing agent with a variety of uses including deactivating piscicides such as antimycin A and purifying drinking water for human consumption.

#### Freshwater Invertebrates

Based on laboratory data, aquatic invertebrates and fish appear to demonstrate comparable sensitivity to antimycin A. However, field studies in high-gradient mountain streams deactivated with potassium permanganate suggest that aquatic invertebrate populations are temporarily affected by antimycin A. Sampling conducted several months to a year after treatment indicate that aquatic invertebrate abundance and diversity were similar to pretreatment levels. Even in first-order streams where antimycin A was not deactivated with potassium permanganate, invertebrate drift and survival did not appear to be significantly affected during or immediately after 8-hr treatments at 10 ppb. Whether these studies are indicative of aquatic invertebrate communities in all antimycin A use areas is uncertain. To address the uncertainty of whether these studies are indicative of aquatic invertebrate communities in general, the standard operating procedures manual required by this RED will include, as part of the required final report, a discussion of the pre- and post-treatment monitoring results for non-target organisms within the treatment area (see Section IV).

#### **b) Terrestrial Organisms**

EPA estimated toxicity, exposure, and risk to avian and mammalian terrestrial organisms. Data were not available to evaluate the risk of antimycin A exposure to non-target insects or terrestrial plants; however, given the ways in which antimycin A is applied, exposure is expected to be minimal. To estimate risks to terrestrial animals, the Agency

considered EECs in surface water bodies based on a treatment concentration of 25 ppb. Table 4 presents a summary of potential ecological risk from exposure to antimycin A. The estimated risks to evaluated terrestrial organisms are below the Agency's level of concern.

Table 4. Summary of Potential Risk to Terrestrial Organisms

<b>Taxonomic Group<sup>1</sup></b>	<b>Direct Acute Effects</b>	<b>RQ<sup>2</sup></b>
Birds	Mortality, sub-lethal	<0.01
Mammals	Mortality	<0.01

<sup>1</sup> Data were not available for insects or terrestrial plants.

<sup>2</sup> Dose-based values.

### Birds

Based on an acute oral toxicity study using formulated product, antimycin A is classified as very highly toxic to water fowl (mallard duck  $LD_{50} = 2.9$  mg/kg body weight) and highly toxic to upland game birds (bobwhite quail  $LD_{50} = 39$  mg/kg body weight). However, since antimycin A is applied directly to water, there is little likelihood that terrestrial forage items for birds will contain antimycin A residues from this use. While it is possible that some piscivorous birds may feed opportunistically on dead or dying fish located on the surface of treated waters, amended labels will recommend that dead fish be collected and buried, rendering the fish less available for consumption (see Section IV). In addition many of the dead fish, given sufficient time, will sink and will not be available for consumption by birds.

### Mammals

Based on an acute oral toxicity study using formulated product, antimycin A is classified as moderately toxic to mammals following acute oral exposure (male rat  $LD_{50} = 286$  mg/kg, female rat  $LD_{50} = 361$  mg/kg). However, antimycin A is not likely to present significant food exposure to wild mammals because treatments are typically conducted in an area no more than once per year and dead fish, given sufficient time, will tend to bloat and sink below the surface of the water where they disintegrate and will not be available for terrestrial animal consumption. Antimycin A is not likely to present significant drinking water exposure to wild mammals because human presence will temporarily drive away wildlife and the compound will rapidly degrade (standing and flowing water), become diluted (flowing water), and, after deactivation with potassium permanganate, move beyond (flowing water) treatment areas.

## **3. Ecological Incidents**

A review of the Ecological Incident Information System database revealed no reported incidents related to the use of antimycin A. However, because an incident has not been formally reported does not necessarily indicate that incidents have not occurred. The relatively low annual usage of antimycin A may partially explain the lack of reported incidents.

#### 4. Endangered Species

The Endangered Species Act required federal agencies to ensure that their actions are not likely to jeopardize listed species or adversely modify designated critical habitat. A primary use of antimycin A is to eliminate invasive or non-native species in designated critical habitat so threatened or indigenous species may later be restored.

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on federally listed endangered and threatened species, and to implement mitigation measures that address these impacts. To assess the potential of registered pesticide uses that may affect any particular species, EPA puts basic toxicity and exposure data developed for the REDs into context for individual listed species and considers ecological parameters, pesticide use information, the geographic relationship between specific pesticide uses and species locations and biological requirements and behavioral aspects of the particular species. When conducted, these analyses take into consideration any regulatory changes recommended in the RED being implemented at that time. A determination that there is a likelihood of potential effects to a listed species may result in limitations on the use of the pesticide, other measures to mitigate any potential effects, and/or consultations with the Fish and Wildlife Service or National Marine Fisheries Service, as necessary. If the Agency determines use of antimycin A “may affect” listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

The ecological assessment that EPA conducted for this RED does not, in itself, constitute a determination as to whether specific species or critical habitat may be harmed by the pesticide. Rather, this assessment serves as a screen to determine the need for any species specific assessment that will evaluate whether exposure may be at levels that could cause harm to specific listed species and their critical habitat. That assessment would refine the screening-level assessment to take into account such things as the geographic area of pesticide use in relation to the listed species, the habits and habitat requirements of the listed species, etc. If the Agency’s specific assessments for antimycin A result in the need to modify use of the pesticide, any geographically specific changes to the pesticide’s registration will be implemented through the process described in the Agency’s Federal Register Notice (54 FR 27984) regarding implementation of the Endangered Species Protection Program.

#### IV. Risk Management and Reregistration Eligibility Decisions

##### A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether pesticides containing the active ingredient are eligible for reregistration. Based on available data, EPA has completed its assessment of the risks associated with the use of pesticides containing the active ingredient antimycin A and has

concluded that it has sufficient information to make a decision as part of the reregistration process under FIFRA, as amended by the Food Quality Protection Act (FQPA).

EPA has determined that currently registered uses of antimycin A will not pose unreasonable risks to humans or the environment if the requirements for reregistration outlined in this document are implemented. Unless labeled and used as specified in this document, antimycin A would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the requirements for reregistration identified in this document, the Agency may take regulatory action to address the potential risk concerns from the use of antimycin A.

## B. Requirements for Reregistration

Piscicidal uses for antimycin A are eligible for reregistration provided that registrant complies with the requirements outlined in this document including the following: (1) implement risk mitigation measures; (2) amend product labels; and (3) submit an up-to-date confidential statement of formula (CSF) for each product.

### 1. Risk Mitigation Measures

Products containing antimycin A are eligible for reregistration provided that the registrant implements the risk mitigation measures presented in Table 5. Specific labeling requirements to implement these measures are presented in Table 6.

Table 5. Risk Mitigation Measures for Antimycin A

Risk of Concern	Mitigation Measures
Exposure from consuming treated water may pose risks of concern	<ul style="list-style-type: none"> <li>• Flowing water (including outflow from standing water such as lakes and aquaculture ponds) from treatment areas must be deactivated with potassium permanganate.</li> <li>• Drinking water intakes within the treatment area must be closed during treatment and until monitoring samples demonstrate antimycin A levels are below the limit of detection (0.015 ppb).</li> </ul>
Exposure from consuming treated fish may pose risks of concern	<ul style="list-style-type: none"> <li>• Through posting and access area closures, the Certified Applicator or designee under his/her direct supervision must prohibit consumption of dead fish taken from treatment areas.</li> <li>• The registrant must amend labels to specify maximum treatment concentrations of 10 ppb for use as a 'selective kill' in aquaculture.</li> <li>• When antimycin A is applied as a selective kill in aquaculture, the Certified Applicator must inform the owner/operator of the aquaculture site being treated that surviving fish must not be harvested for food or feed for a minimum of 12 months after treatment.<sup>1</sup></li> <li>• When antimycin A is applied as a complete kill in aquaculture, the Certified Applicator must inform the owner/operator of the aquaculture site being treated that the water body must not be restocked for a minimum of 7 days after treatment.</li> </ul>

<p>Exposure from performing recreational activities in treated water may pose risks of concern</p>	<ul style="list-style-type: none"> <li>• Through posting and access area closures, the Certified Applicator or designee under his/her direct supervision must prohibit recreational access (e.g., wading, swimming, boating and fishing) to the treatment area during treatment and for 7 days after treatment.</li> </ul>
<p>Occupational exposure may pose risks of concern</p>	<ul style="list-style-type: none"> <li>• The registrant must amend labels to specify maximum treatment concentrations of 25 parts per billion (ppb).</li> <li>• The registrant must amend labels to require antimycin A applications to be supervised by an on-site Certified Applicator. The on-site Certified Applicator should attend a certification program for piscicide applications.</li> <li>• The registrant must amend labels to require all mixers/loaders and others exposed to the concentrate (e.g., through cleaning equipment) to wear long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks, protective eyewear, a dust/mist respirator, and a chemical-resistant apron.</li> <li>• The registrant must amend labels to require all applicators and other handlers to wear long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks, and protective eyewear.</li> <li>• In addition, applicators using handheld equipment or handheld nozzles must wear a dust/mist respirator and coveralls.</li> <li>• The registrant must amend labels to prohibit handlers from wearing contact lenses while handling this product.</li> </ul>
<p>Ecological risk quotients (RQ) for non-target species exceed OPP's level of concern</p>	<ul style="list-style-type: none"> <li>• The registrant must amend labels to prohibit antimycin A use in estuarine/marine environments.</li> <li>• Through deactivation with potassium permanganate, the Certified Applicator or designee under his/her direct supervision must ensure that antimycin A will not affect areas beyond the treatment area.</li> <li>• The Certified Applicator or designee under his/her direct supervision should collect and bury dead fish.</li> </ul>

<sup>1</sup> The registrant may request that EPA remove or reduce this restriction upon submission of acceptable toxicity and exposure studies that demonstrate risk from consuming fish is below OPP's level of concern

## 2. Product Label Amendments

Manufacturing-Use Products and End-Use Products must be amended to reflect the mitigation measures presented in Table 5 and the label amendments presented in Table 6 and Table 7 (see Section V). As a result of this RED, the registrant will also be required to develop and submit a standard operating procedures (SOP) manual that will be part of the product labeling.

EPA believes that a detailed SOP manual is necessary for antimycin A because the ways in which it is applied are significantly more complex than typical agricultural pesticides. Because so many detailed instructions and procedures must be followed to conduct a safe, effective, and lawful piscicide application, the product label may need to be augmented to capture all of the necessary SOPs.

In addition to other topics and information, the antimycin A SOP manual must contain detailed procedures/instructions for completing potentially complex activities including, but not limited to, the following topics: planning an antimycin A application; applying antimycin A as a complete and selective kill treatment; deactivating antimycin A with potassium permanganate; virtually eliminating human (handler, bystander, dietary, recreational) exposure; minimizing ecological exposure; documenting pre- and post-treatment non-target populations; keeping treatment records; posting and preventing access to treated areas; and facilitating compliance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Clean Water Act (CWA), the National Environmental Policy Act (NEPA), and the Endangered Species Act (ESA).

The SOP manual is currently under development and the registrant will continue to seek input from EPA for developing the draft SOP manual. The manual will be released for public and stakeholder comment prior to finalization. The registrant will be responsible for updating the manual as necessary and also for making it available to antimycin A users as part of the required labeling.

### **3. Confidential Statement of Formula**

Certain inert ingredients or impurities in the end-use product (Fintrol®) may pose risks to human health and the environment. As part of product reregistration, the registrant must submit an updated confidential statement of formula (CSF). The CSF must quantify all inert ingredients and impurities >0.1%. If appropriate, EPA will take additional steps to address risks of concern from inert ingredients and impurities (see 40 CFR 158.155).

#### **C. Regulatory Rationale**

The Agency has determined that antimycin A is eligible for reregistration provided that the registrant implements the mitigation measures in this RED through amended labeling. With amended labeling, EPA believes that antimycin A will not present risks inconsistent with FIFRA and that the benefits of antimycin A to society – including enhanced recreational areas and control of non-native and invasive species – outweigh the remaining risks. A summary of EPA's rationale for reregistering and managing risks associated with antimycin A is presented below.

#### **1. Benefits and Alternatives**

Antimycin A and rotenone (CAS Number 83-79-4, EPA PC Code 071003) are the only two broad spectrum piscicides registered in the United States. Antimycin A and rotenone each appear to have niche uses, although both can be applied in a variety of situations. In general, antimycin A is used to repopulate native, threatened, or endangered trout species in streams, by eliminating nonnative fish species, particularly in high-altitude alpine lakes and streams because it is effective in cold alpine waters and where pH is low. In addition, this piscicide may be used at low concentrations, which makes it easy to transport to isolated or hard to reach mountain streams. Rotenone is most often used in standing water, such as large lakes and reservoirs. It is typically applied to improve or maintain sport

fisheries, to sample fish populations, and to eliminate unwanted species in rearing ponds. The costs of rotenone and antimycin A are similar. For sampling fish populations, alternatives such as electrofishing are available. Electrofishing requires the use of specialized equipment that runs a low-voltage current through the water to temporarily stun fish for easy collection. However, for water bodies requiring partial or complete kill of certain fish species, rotenone and antimycin A are more effective. Dewatering is an effective alternative for complete kill in a water body. In select cases, gill netting, which generally only reduces fish populations, has been used to remove fish from certain mountain lakes in California.

Although some uses of rotenone and antimycin A coincide, they are not direct replacements for each other. Because there are no other broad spectrum piscicides available, the only possible alternatives are non-chemical fish control methods, and none are applicable for all uses of rotenone or antimycin A. In situations where dewatering or electrofishing are potential replacements, it is not clear if these are more cost effective or less detrimental to the environment.

Because there are niche uses and no direct replacements available for all piscicidal uses of antimycin A, EPA concludes that continued registration, subject to the requirements of this RED, would provide benefit to society in controlling invasive or unwanted fish species.

## **2. Human Health Risk**

Adequate data were not available to conduct quantitative assessments to estimate dietary, recreational, and occupational risk. In the absence of data demonstrating risk below the Agency's level of concern, to be eligible for reregistration, labeling must be adopted that will virtually eliminate exposure to antimycin A. Certain restrictions may be reduced or removed upon submission of acceptable toxicity and exposure studies that demonstrate risk would not exceed the Agency's level of concern.

### **a) Consuming Treated Water**

Because the toxicological effects of antimycin A on humans cannot be estimated, the Agency made the conservative assumption that exposure from consuming treated water may pose risks of concern. To mitigate the potential risks, flowing water (including outflow from standing water such as lakes and aquaculture ponds) from treatment areas must be deactivated with potassium permanganate and, when drinking water intakes are present within the treatment area, the intakes must be closed during treatment and until monitoring samples demonstrate antimycin A levels are below the limit of detection (0.015 ppb). Deactivation with potassium permanganate – a strong oxidizing agent that is also used to purify drinking water – and, where required, closure of drinking water intakes within the treatment area will ensure that antimycin A does not move beyond the intended treatment area and inadvertently contaminate drinking water.

Upon submission of acceptable data, the registrant may request that the Agency remove the monitoring requirement. Although not required at this time, the registrant or other entity may choose to submit data to confirm that no exposure to antimycin A will occur in situations where water is either treated with potassium permanganate for deactivation purposes or is subject to an oxidative drinking water treatment regimen.

#### **b) Consuming Treated Fish**

Because the toxicological effects of antimycin A on humans cannot be estimated, the Agency made the conservative assumption that exposure from consuming treated fish may pose risks of concern. Humans could potentially consume treated fish from a fish management program use (complete kill) or an aquaculture use (complete or selective kill).

##### Fish Management Program Use

To mitigate the potential risks from the fish management program use, consumption of dead fish taken from treatment areas will be prohibited through posting and access area closures. Coupled with the low likelihood that humans would scavenge for and consume dead fish, the Agency believes posting a prohibition on consuming dead fish will preclude human exposure to antimycin A.

##### Aquaculture Use

To mitigate the potential risks from the complete kill use in aquaculture, the Certified Applicator must inform the owner/operator of the aquaculture site being treated that the water body must not be restocked for a minimum of 7 days after treatment.

Depending on environmental conditions, the expected half-life of antimycin A ranges from several minutes to approximately 12 hours. Based on the conservative estimate that antimycin A will have a half-life of 12 hours, the Agency estimates that at least 99% of the compound will have degraded after 7 days. The Agency believes a 7-day prohibition on restocking will prevent residues in fish and, thus, preclude human exposure.

To mitigate the potential risks from the selective kill use in aquaculture, the Certified Applicator must inform the owner/operator of the aquaculture site being treated that surviving fish must not be harvested for food or feed for a minimum of 12 months after treatment.

When data are not available to estimate residues of pesticides in agricultural food or feed crops, the Agency typically requires a 12-month pre-harvest interval and classifies the use as a non-food use. Unless adequate data are available to indicate the contrary, EPA considers 12 months to be sufficient time to allow residues to dissipate below levels that may pose a risk to human health.

Based on PBT Profiler modeling, antimycin A does not appear to bioconcentrate in fish (bioconcentration factor = 350X). A compound is considered likely to bioconcentrate if

the bioconcentration factor (BCF) is >1000. In general, chemicals that have the potential to bioconcentrate also have the potential to bioaccumulate. Since a BCF in fish can be readily measured in the laboratory and bioaccumulation is much more complicated to determine, the BCF is frequently used to predict the importance of bioaccumulation. Because of antimycin A's relatively low BCF, the chemical is not considered likely to bioaccumulate in aquatic food chains.

Repeat applications or long-term exposure could potentially result in increased likelihood of bioconcentration; however, antimycin A is applied only once to catfish fingerlings and, under static conditions, the half-life of antimycin A in water is relatively short ( $t_{1/2} < 12$  hours, pH 1 to 9). Therefore, long-term or repeat exposure to antimycin A is not expected to occur.

Based on the chemical's low likelihood to bioconcentrate and the fact that fish would only be exposed one time and for a short duration (<12 hours), the Agency believes the default 12-month harvesting restriction will preclude human exposure to antimycin A in surviving fish from a selective kill use in aquaculture. Because there is no reasonable expectation of antimycin A residues, a tolerance is not required for antimycin A residues in harvested fish used for food or feed.

#### **c) Performing Recreational Activities**

Because the toxicological effects of antimycin A on humans cannot be estimated, the Agency made the conservative assumption that exposure from performing recreational activities in treated water may pose risks of concern. To mitigate the potential risks, through posting and access area closures, the Certified Applicator or designee under his/her direct supervision must prohibit recreational access (e.g., wading, swimming, boating and fishing) to the treatment area during treatment and for 7 days after treatment. Depending on environmental conditions, the expected half-life of antimycin A ranges from several minutes to approximately 12 hours. Based on the conservative estimate that antimycin A will have a half-life of 12 hours, the Agency estimates that at least 99% of the compound will have degraded after 7 days. Coupled with the relatively low exposure expected from performing recreational activities, the Agency believes a 7-day prohibition on recreational access will preclude human exposure to antimycin A.

#### **d) Performing Occupational Activities**

Because the toxicological effects of antimycin A on humans cannot be estimated, the Agency made the conservative assumption that exposure from performing occupational activities may pose risks of concern. To mitigate the potential risks, the registrant must amend labels to specify maximum treatment concentrations of 25 ppb; require antimycin A applications to be supervised by an on-site Certified Applicator; require all mixers/loaders and others exposed to the concentrate through cleaning equipment to wear long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks, protective eyewear, a dust/mist respirator, and a chemical-resistant apron; require all applicators and other handlers to wear long-sleeved shirt and long pants, chemical-resistant gloves, shoes plus socks, and protective

eyewear (in addition, applicators using handheld equipment or handheld nozzles must wear a dust/mist respirator and coveralls); and prohibit handlers from wearing contact lenses while handling this product. The Agency believes the specification of a maximum treatment concentration and the additional required PPE will virtually eliminate occupational human exposure to antimycin A.

### **3. Ecological Risk**

EPA conducted an ecological risk assessment for antimycin A to support the reregistration eligibility decision and concluded that ecological risk estimates exceed OPP's level of concern. To mitigate ecological risk, the Agency is requiring the registrant to amend labels to prohibit antimycin A use in estuarine/marine environments; require deactivation with potassium permanganate to ensure that antimycin A will not affect areas beyond the treatment area; and encourage users to collect and bury dead fish. The Agency believes that these measures will reduce the potential ecological risk posed by continued use of antimycin A.

The mitigation measures presented in this document, in addition to the detailed Antimycin A SOP Manual, will be incorporated in the product labeling. Certain restrictions may be reduced or removed upon submission of acceptable toxicity and exposure studies that demonstrate risk would not exceed the Agency's level of concern.

### **4. Endocrine Screening**

EPA is required under the FFDCFA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there were scientific bases for including, as part of the program, androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. When the appropriate screening and/or testing protocols being considered under the Agency's Endocrine Disruptor Screening Program (EDSP) have been developed and vetted, antimycin A may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

## **V. What Registrants Need to Do**

The Agency has determined that antimycin A is eligible for reregistration provided that the requirements for reregistration identified in this RED are implemented (see Section IV). The registrant will also need to amend product labeling and submit an updated confidential statement of formula for each product.

The database supporting the reregistration of antimycin A for piscicidal uses has been reviewed and determined to be adequate to support a reregistration eligibility decision. Additional data are not required at this time. In the future, the registrant may request that EPA remove or reduce certain restrictions or mitigation measures upon submission of acceptable toxicity and exposure studies that demonstrate risk exposure to antimycin A is below OPP's level of concern and/or that no exposure to antimycin A will occur in situations where water is either treated with potassium permanganate for deactivation purposes or is subject to an oxidative drinking water treatment regimen.

### **A. Manufacturing Use Products**

Currently there is no registered manufacturing use product for antimycin A. If, in the future, manufacturing use products are registered, the registrant must include the label requirements presented in Table 6. The Agency does not intend to issue a generic data call-in for antimycin A at this time.

### **B. End-Use Products**

#### **1. Product-Specific Data Requirements**

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product. The Agency intends to issue a separate product-specific data call-in (PDCI) outlining specific data requirements.

Generally, registrants will have 90 days from receipt of a PDCI to complete and submit response forms or request time extensions and/or waivers with a full written justification. Registrants will have eight months to submit product-specific data.

#### **2. Confidential Statement of Formula**

As part of product reregistration, the registrant must submit an updated confidential statement of formula (CSF) for each antimycin A End-Use product. Each CSF must list all components present at a concentration of 0.1% or more by weight. These components fall into three general categories: active ingredients, inert ingredients, and impurities. Active ingredients are those that have some active role in controlling the pest. Inert ingredients are intentionally added to the product to achieve effects not directly related to controlling the pest (such as water, emulsifiers, preservatives, carriers). Impurities (also known as contaminants) are compounds not intentionally added to the product. Impurities that do not have toxic properties can be lumped together on the CSF as "Other ingredients" only if each is below 0.1% by weight.

### 3. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV. Specific language to incorporate these changes is presented in Table 7. Generally, conditions for the distribution and sale of products bearing old labels/labeling will be established when the label changes are approved. However, specific existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors.

Table 6. Label Changes Summary Table for Antimycin A Manufacturing-Use Products<sup>1</sup>

Description	Amended Labeling Language for Manufacturing Use Products	Placement on Label
For all Manufacturing Use Products	<p>“Only for formulation into a piscicide (fish kill) for the following use(s) [<i>MUP registrant, insert those uses that are being supported by the RED</i>].”</p> <p>“Only for formulation into products that are classified as Restricted Use.”</p>	Directions for Use
Additional Uses	<p>“This product may be used to formulate products for any additional use(s) not listed on the MUP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).”</p>	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	<p>“This product is extremely toxic to fish and other aquatic organisms.”</p> <p>“Do not contaminate water, food, or feed by storage or disposal.”</p> <p>“Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority.”</p>	Precautionary Statements

<sup>1</sup> Currently there is no registered manufacturing use product for antimycin A.

Table 7. Label Changes Summary Table for Antimycin A End-Use Products Intended for Occupational and Residential Use

Description	Amended Labeling Language for End-Use Products	Placement on Label
RUP	<p>“Restricted Use Pesticide”</p> <p>“Due to toxicity to fish and other aquatic organisms and the need for specialized applicator training.”</p> <p>“For retail sale to and use by only Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator’s certification.”</p>	<p>This statement must appear at the very top of the label's front panel [see 40 CFR 156.10(j)(2)(i) for more information]. No other wording or symbols may appear above the RUP statement.</p>
SOP Manual	<p>“THIS PRODUCT MUST BE ACCOMPANIED BY AN EPA-APPROVED PRODUCT LABEL AND THE EPA-APPROVED ‘ANTIMYCIN A STANDARD OPERATING PROCEDURES MANUAL.’ THE ANTIMYCIN A STANDARD OPERATING PROCEDURES (SOP) MANUAL IS LABELING. READ AND UNDERSTAND THE ENTIRE LABELING AND SOP MANUAL PRIOR TO USE. ALL PARTS OF THE LABELING AND SOP MANUAL ARE EQUALLY IMPORTANT FOR SAFE AND EFFECTIVE USE OF THIS PRODUCT.”</p>	<p>Immediately below the RUP statement on the label and on the cover page of the Antimycin A SOP Manual.</p>

Description	Amended Labeling Language for End-Use Products	Placement on Label
<p>PPE Requirements Established by the RED<sup>1</sup> for all Formulations</p>	<p>“Personal Protective Equipment (PPE)”</p> <p>“Some materials that are chemical-resistant to this product are” [<i>EUP registrant, insert correct chemical-resistant material</i>]. “If you want more options, follow the instructions for category” [<i>EUP registrant, insert A, B, C, D, E, F, G, or H</i>] “on an EPA chemical-resistance category selection chart.”</p> <p>“All mixers/loaders and others exposed to the concentrate through cleaning equipment or spills must wear:</p> <ul style="list-style-type: none"> <li>* long-sleeved shirt and long pants,</li> <li>* chemical-resistant gloves,</li> <li>* shoes plus socks,</li> <li>* protective eyewear,</li> <li>* a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, R, P, or HE filter, and</li> <li>* a chemical-resistant apron.”</li> </ul> <p>“All applicators and other handlers must wear:</p> <ul style="list-style-type: none"> <li>* long-sleeved shirt and long pants,</li> <li>* chemical-resistant gloves,</li> <li>* shoes plus socks, and</li> <li>* protective eyewear.”</li> </ul> <p>“In addition, applicators using handheld equipment or handheld nozzles must wear:</p> <ul style="list-style-type: none"> <li>* a dust/mist filtering respirator (MSHA/NIOSH approval number prefix TC-21C), or a NIOSH approved respirator with any N, R, P, or HE filter, and</li> <li>* coveralls</li> </ul> <p>Exception: if the applicator is exposed to splashing water or walking in water that is being treated, chest waders must be worn instead of coveralls.”</p>	<p>Precautionary Statements under the heading “Hazards to Humans and Domestic Animals”</p>

Description	Amended Labeling Language for End-Use Products	Placement on Label
User Safety Requirements	<p>“Do not wear contact lenses while handling this product. Ocular contact with this product can melt a contact lens onto the eye.”</p> <p>“Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.”</p> <p>“Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product’s concentrate. Do not reuse them.”</p>	Precautionary Statements under the heading “Hazards to Humans and Domestic Animals” immediately following/below the PPE requirements
User Safety Recommendations	<p>“User Safety Recommendations”</p> <p>“Certified Applicators applying or supervising the application of this product should attend a training program for piscicide applications.”</p> <p>“Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.”</p> <p>“Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.”</p> <p>“Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.”</p>	<p>Precautionary Statements under the heading “Hazards to Humans and Domestic Animals” immediately following/below the Engineering Controls.</p> <p>(These statements must be placed in a box.)</p>
Environmental Hazards	<p>“Environmental Hazards”</p> <p>“This product is extremely toxic to fish and other aquatic organisms.”</p> <p>“Do not contaminate water by cleaning of equipment or disposal of equipment wash waters.”</p>	Precautionary Statements under the heading “Hazards to Humans and Domestic Animals” immediately following/below User Safety Recommendations

Description	Amended Labeling Language for End-Use Products	Placement on Label
Personal Protective Equipment When Re-entering Treated Areas	<p>“Re-entering the Treatment Area”</p> <p>“For the first 7 days after treatment, handlers re-entering treated water must wear the following PPE:</p> <ul style="list-style-type: none"> <li>* Chest waders over long-sleeved shirt, long pants,</li> <li>* chemical-resistant gloves,</li> <li>* shoes plus socks, and</li> <li>* protective eyewear.”</li> </ul>	Direction for Use under the heading “Re-Entering the Treatment Area”
Complete and Selective kills	<p>“Complete and Selective Kills”</p> <p>“This product may be used to achieve a ‘complete kill’ or a ‘selective kill.’ Complete kills are intended to eliminate all fish in the treatment area whereas selective kills, used only in aquaculture, are intended to eliminate or reduce the number of only certain (more vulnerable) species. Detailed instructions for conducting complete and selective kills are presented in the Antimycin A SOP Manual.”</p>	Directions for Use under the heading “Complete and Selective Kills”

Description	Amended Labeling Language for End-Use Products	Placement on Label
<p>General Application Restrictions for all Formulations</p>	<p>“The Certified Applicator supervising the treatment must remain on-site for the duration of the application.”</p> <p>“The Certified Applicator supervising the treatment must not allow recreational access (e.g., wading, swimming, boating, fishing) within the treatment area while antimycin A is being applied and for 7 days after treatment. See Placarding of Treatment Areas for additional requirements and information.”</p> <p>“For ‘complete kill’ use, do not apply this product in a way that will result in treatment concentrations greater than 25 parts per billion. For ‘selective kill’ use in aquaculture, do not apply this product in a way that will result in treatment concentrations greater than 10 parts per billion.”</p> <p>“Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application.”</p> <p>“Do not apply for with any application method or equipment not specified on this label or in the SOP.”</p> <p>“Do not apply in a manner not specified on this label or the Antimycin A SOP Manual.”</p> <p>"This product must not be applied to estuarine or marine environments."</p> <p>“Where practical, users should collect and bury dead fish.”</p>	<p>Directions for Use</p>

Description	Amended Labeling Language for End-Use Products	Placement on Label
Additional Requirements for Use in Aquaculture	<p>“Additional Requirements for Use in Aquaculture”</p> <p>“When antimycin A is applied as a selective kill in aquaculture, the Certified Applicator supervising the application must inform the owner/operator of the aquaculture site being treated that surviving fish must not be harvested for food or feed for a minimum of 12 months after treatment.”</p> <p>“When antimycin A is applied as a complete kill in aquaculture, the Certified Applicator supervising the application must inform the owner/operator of the aquaculture site being treated that the water body must not be restocked for a minimum of 7 days after treatment.”</p>	Directions for Use under the heading “Additional Requirements for Use in Aquaculture”
Drinking Water Notification Requirements	<p>“Drinking Water Notification”</p> <p>“If drinking water intakes are present within the treatment area, prior to application, the Certified Applicator must provide notification to the party responsible for the public water supply or to individual private water users. Drinking water intakes within the treatment area must be closed during treatment and until monitoring samples demonstrate that antimycin A levels are below the limit of detection (0.015 ppb).”</p> <p>“Detailed instructions for public involvement, notifications, and monitoring are presented in the Antimycin A SOP Manual.”</p>	Directions for Use under the heading “Drinking Water Notification”

Description	Amended Labeling Language for End-Use Products	Placement on Label
<p>Notification Requirements for all applications except aquaculture applications</p>	<p>“Placarding of Treatment Areas, Except Aquaculture Applications”</p> <p>“The Certified Applicator in charge of the application (or someone under his/her supervision) must placard all access areas to the treatment area. Detailed instructions for placarding are presented in the Antimycin A SOP Manual. At a minimum, placards must be placed every 250 feet (including the shoreline of the treated area and up to 250 feet of shoreline past the application site to include immediate public access points) and contain the following information:”</p> <p>“NOTICE: AREA CLOSURE”</p> <ul style="list-style-type: none"> <li>* Skull and crossbones symbol</li> <li>* “DANGER/PELIGRO”</li> <li>* “DO NOT ENTER/NO ENTRE: Pesticide Application”</li> <li>* The name of the product applied</li> <li>* The agency or entity performing the application</li> <li>* The purpose of the application</li> <li>* The start date and time of application</li> <li>* The end date and time of application</li> <li>* The duration of the area closure</li> <li>* “Recreational access (e.g., wading, swimming, boating, fishing) within the treatment area is prohibited while antimycin A is being applied and for 7 days after treatment.”</li> <li>* “In standing water treatment areas (non-flowing water), do not swim or wade in treated water for a minimum of 7 days after the last application.”</li> <li>* “Do not consume dead fish from treated water.”</li> <li>* The name, address, and telephone number of the Certified Applicator in charge of the application</li> </ul> <p>“Signs must remain legible during the entire posting period and must be removed no earlier than 7 days after treatment and no later than 14 days after treatment.”</p>	<p>Directions for Use under the heading “Placarding of Treatment Areas”</p>

Description	Amended Labeling Language for End-Use Products	Placement on Label
Deactivation with Potassium Permanganate	<p>“Deactivation with Potassium Permanganate”</p> <p>“Flowing water (including outflow from standing water) must be deactivated with potassium permanganate to prevent exposure beyond the defined treatment area. Detailed instructions for deactivation with potassium permanganate are presented in the Antimycin A SOP Manual.”</p>	<p>Directions for Use under the heading “Deactivation with Potassium Permanganate (KMnO<sub>4</sub>)”</p>

<sup>1</sup> PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.