Reregistration Eligibility Decision for Aliphatic Alcohols

March 2007

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508P)

EPA 738-R-07-004

Reregistration Eligibility Decision for Aliphatic Alcohols

Reregistration Eligibility Decision (RED) for Aliphatic Alcohols

List D

Case No. 4004

Approved by: _____

Date: _____

Debra Edwards, PhD., Director
Special Review and Reregistration Division

TABLE OF CONTENTS

Abstract v
I. Introduction 1
II. Chemical Overview 1
A. Regulatory History 1
B. Chemical Identification 2
III. Summary of Aliphatic Alcohols Risk Assessments 4
A. Human Health Risk Assessment 4
B. Environmental Risk Assessment 6
1. Environmental Fate and Transport 7
2. Ecological Risk Assessment 8
IV. Risk Management, Reregistration, and Tolerance Reassessment Decision 14
A. Determination of Reregistration Eligibility 14
B. Public Comment Period 15
C. Regulatory Position 15
1. Regulatory Rationale 15
2. Endocrine Disruptor Effects 16
3. Endangered Species 16
D. Labeling Requirements 17
V. What Registrants Need to Do 17
A. Manufacturing Use Products 18
1. Additional Generic Data Requirements 18
2. Labeling for Manufacturing-Use Products 18
B. End-Use Products 18
1. Additional Product-Specific Data Requirements 18
2. Labeling for End-Use Products 18
C. Labeling Changes Summary Table 19

Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
GENEEC	Tier I Surface Water Computer Model (Estimated Aquatic Environmental Concentrations)
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
N/A	Not Applicable
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RQ	Risk Quotient
TGAI	Technical Grade Active Ingredient
UV	Ultraviolet
WPS	Worker Protection Standard

ALIPHATIC ALCOHOLS TEAM

Office of Pesticide Programs:

Health Effects Risk Assessment
Elissa Reaves
Shanna Recore
Yvonne Barnes

Ecological Fate and Effects Risk Assessment
Colleen Flaherty
Silvia Termes

Biological and Economics Analysis Assessment
Jihad Alsadek
Jenna Carter
Art Grube

Registration Division
Tony Kish

Risk Management
Kevin Costello
Tom Moriarty
Kimberly Nesci

Abstract

The Environmental Protection Agency (EPA or the Agency) has completed the human health and environmental risk assessments for the Aliphatic Alcohols case 4004 and is issuing its risk management decision. Currently, case 4004 consists of four active ingredients. Three of these active ingredients, 1-octanol, 1-decanol and a mixture of aliphatic alcohols described as "fatty alcohols," are used as plant growth regulators on tobacco. The fourth, 1-dodecanol (also known as lauryl alcohol), is registered as a Lepidopteran pheromone/sex attractant in pear and apple orchards.

A tolerance reassessment was performed in 2002 for the use of 1-dodecanol as a pheromone. In that assessment of potential human exposure and dietary risk, the Agency concluded, "the tolerance exemption for Lepidopteran pheromones has been reassessed and is in compliance with the FQPA ." Neither a handler nor post-application (reentry) occupational assessment has been conducted for any uses of aliphatic alcohols of case 4004, because no dermal, oral, or inhalation endpoints of toxicological concern have been identified.

The potential for ecological risk from the pheromone use and from the growth-regulator uses is considered in this document. The ecological risk assessment identifies no ecological risks of concern from the use of aliphatic alcohols.

The risk assessments, which are summarized below, are based on the review of the required target database supporting the use patterns of currently registered products. After considering the potential risks identified, EPA has determined that aliphatic alcohol-containing products are eligible for reregistration. That decision is discussed fully in this document.

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. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as 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 risks arising from the currently registered uses of the 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" criterion of FIFRA.

This document summarizes EPA's human health and ecological risk assessments and reregistration eligibility decision (RED) for aliphatic alcohols. The document consists of six sections. Section I contains the regulatory framework for reregistration; Section II provides an overview of the chemical and a profile of its use and usage; Section III gives an overview of the human health and environmental effects risk assessments; Section IV presents the Agency's decision on reregistration eligibility and risk management; and Section V summarizes the label changes necessary to implement the risk mitigation measures outlined in Section IV. Finally, the Appendices list related information, supporting documents, and studies evaluated for the reregistration decision. The risk assessments for aliphatic alcohols and all other supporting documents are available in the Office of Pesticide Programs (OPP) public docket (http://www.regulations.gov) under docket number EPA-HQ-OPP-2007-0134.

II. Chemical Overview

A. Regulatory History

Reregistration case number 4004 consists of straight chain aliphatic alcohols with 6 to 16 carbon atoms in the chain, which has been abbreviated in previous documents as aliphatic alcohols (Cx-Cxx) or (C6-C16). Currently, case 4004 consists of four active ingredients. Three of these active ingredients are used as plant growth regulators on tobacco. These are described as fatty alcohol blend (PC code 079029), 1-octanol (079037) and 1-decanol (079038). The fatty alcohol blend under PC code 079029 is predominantly a mixture of 1-octanol and 1-decanol, although some labels list 0.5% 1-hexanol (C6) and 1.5 % dodecanol (C12) among the active ingredients. The single product listed under PC code 079037, although listed as 1-octanol, is also in fact a mixture of 1-octanol and 1-decanol. The earliest registered label for use of aliphatic alcohols for tobacco sucker control included in the Agency's Pesticide Product Label System (PPLS) was issued to Uniroyal in 1964.

The fourth active ingredient in case 4004, 1-dodecanol (PC code 001509), was first registered for use as a Lepidopteran pheromone/sex attractant in 1993. The potential human health risks from 1-dodecanol were reassessed in 2002 by the Agency's Biopesticides and Pollution Prevention Division (BPPD), as described in the document, *Tolerance Reassessment Decision Regarding Tolerance Exemption for the Biochemical Lepidopteran Pheromones. July*

26, 2002. This RED document describes the potential ecological effects of the use of 1-dodecanol.

Other aliphatic alcohols are not assessed in this document. The fatty alcohol product included under PC code 079059 is not being supported, and will be voluntarily cancelled. In April 1995, the Agency completed a Reregistration Eligibility Decision (RED) for case number 4003 (C1 - C5), which consists of aliphatic alcohols with only one to five carbons. The active ingredients addressed in that assessment included ethanol (PC code 001501), and isopropanol (PC code 047501).

B. Chemical Identification

The aliphatic alcohols are considered primary alcohols (i.e., the –OH group in the C-1 position). The aliphatic alcohols 1-octanol (PC code 079037) and 1-decanol (PC code 079038) are also known by many other common names, and the fatty alcohol blend (PC code 079029) is a generic term meaning that the compound is obtained by the hydrolysis of fatty acid esters. The registrations under the name fatty alcohol blend (PC code 079029) are considered a mixture of the linear, straight chain chemicals 1-octanol and 1-decanol. Tables 1 - 3 provide the chemical identification for 1-octanol, 1-decanol, and 1-dodecanol, respectively.

Table 1. Chemical Identification of 1-Octanol

Type of Information	Information for this Chemical
IUPAC Name	**1-Octanol**
CAS Reg. No.	111-87-5
Other Names	Octyl alcohol; n-Octan-1-ol; n-Octanol; n-Octyl alcohol; Caprylic alcohol; Heptyl carbinol; Octanol; Alcohol C-8; Capryl alcohol; n-Heptyl carbinol; Octan-1-ol; Prim-n-octyl alcohol; Octanol-(1); Octyl alcohol, normal-primary; Primary octyl alcohol; Hydroxyoctane
Empirical Formula	$C_8H_{18}O$
Molecular Weight Number of Carbons	130.23 The number of carbons is 8
Chemical Structure	

Table 2. Chemical Identification of 1-Decanol

Type of Information	Information for this Chemical
IUPAC Name	**1-Decanol**
CAS Reg. No.	112-30-1
Other Names	Decyl alcohol; n-Decan-1-ol; n-Decanol; n-Decyl alcohol; Alcohol C10; Capric alcohol; Caprinic alcohol; Decanol; Nonylcarbinol; Decylic Alcohol; Decan-1-ol; Decanol-(1); Decyl, n- alcohol 22; Primary decyl alcohol; Nonyl carbinol
Empirical Formula	$C_{10}H_{22}O$
Molecular Weight Number of Carbons	158.28 The number of carbons is 10

Type of Information	Information for this Chemical
Chemical Structure	

Table 3. Chemical Identification of 1-Dodecanol

Type of Information	Information for this Chemical
IUPAC Name	**1-Dodecanol**
CAS Reg. No.	112-53-8
Other Names	Dodecyl alcohol; *n*-Dodecan-1-ol; *n*-Dodecyl alcohol; Alcohol C-12; Dodecanol-1; Lauric Alcohol; Laurinic alcohol; Lauryl alcohol; 1-Dodecyl alcohol; Duodecyl alcohol; *n*-Lauryl alcohol; *n*-Lauric alcohol, primary; Dodecanol; 1-Hydroxydodecane; Hydroxydodecane
Empirical Formula	$C_8H_{18}O$
Molecular Weight Number of Carbons	186.33 The number of carbons is 12
Chemical Structure	

The aliphatic alcohols 1-octanol and 1-decanol are applied as water-based sprays to burley, flue cured and dark tobacco by hand using a back pack sprayer, or to tobacco plants by a boom. The aliphatic alcohols are applied to tobacco at the button or early flower stage and act as chemical pinching agents to control sucker shoots. The aliphatic alcohols dissolve the layer of waxy cuticle on the plant, causing dehydration of the young sucker. Because these aliphatic alcohols are applied solely on tobacco, its use is limited to the tobacco growing states, mainly on the east coast (Connecticut, Pennsylvania, Virginia, North Carolina, South Carolina, Georgia, and Florida), but also in Kentucky and Tennessee. Between 1.5 and 2 million pounds of aliphatic alcohols are applied annually.

Recommended application rates range from approximately 8.5 lbs ai/acre up to approximately 21 lbs active ingredient/acre, at 1 to 3 applications per year. However, 1-octanol and 1-decanol have estimated volatilization half-lives of 3.5 and 1.0 minutes, respectively. Therefore, the amount of the aliphatic alcohol available for runoff or for chronic exposure to terrestrial animals is likely to be lower than the maximum label rates. As described below, the ecological risk assessment took this into account when estimating potential exposure.

The volatility of 1-dodecanol is essential to its use as a pheromone in apple and pear orchards. The pheromone is applied from polyethylene dispenser tubes hung throughout the orchard. The active ingredient, 1-dodecanol (lauryl alcohols; PC code 001509), disperses passively from the tube into the atmosphere over 3-4 months. Once dispersed from its dispensers, 1-dodecanol degrades quickly by photolysis in the air.

The aliphatic alcohols are used in, or can be naturally found in various food items. The Food and Drug Administration permits the use of aliphatic alcohols as a food additive, under certain conditions. The aliphatic alcohols have been found to be natural components of apples and oranges, and have been reported as a component of edible seeds, oils and fermented beverages.

III. Summary of Aliphatic Alcohols Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents, and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for aliphatic alcohols.

While the following risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket, docket number EPA-HQ-OPP-2007-0134, and may also be accessed through the website http://www.regulations.gov/. Hard copies of these documents may be found in the OPP public docket under this same docket number.

- *Tolerance Reassessment Decision Regarding Tolerance Exemption for the Biochemical Lepidopteran Pheromones. July 26, 2002;*
- Human Health Risk Assessment: *Aliphatic Alcohols: Human Health Chapter of the Reregistration Eligibility Decision (RED) Document. Reregistration Case Number 4004. June 30, 2006;*
- Ecological Risk Assessment: *Reregistration Eligibility Decision, Reregistration Case 4004: Aliphatic Alcohols C-8, C-10 and C-12. September 8, 2006.*
- *Aliphatic Alcohols (1-octanol; 1-decanol): Tier 2 Aquatic Exposure Model (PRZM and EXAMS) Estimates and Risk Characterization. November 28, 2006;*
- *Aliphatic Alcohols (1-octanol; 1-decanol): Addendum to PRZM and EXAMS refinement of environmental concentrations in surface water (DPBarcode D334066; 11/28/2006). Recalculation of EECs considering volatilization from soil as a dissipation route; Recalculation of Risk Quotients. December 11, 2006;*
- *Aliphatic Alcohols (1-octanol; 1-decanol) Addendum to Ecological Risk Assessment in Support of RED: Reconsideration of Ecological Toxicity Data Gaps in Light of Surface Water EEC Refinements. February 9, 2007.*

A. Human Health Risk Assessment

The Agency has conducted a risk assessment of the tobacco plant growth inhibitor use of the aliphatic alcohols. The Agency's screening level assessment was conducted using data submitted by the registrants and published in the open literature. A summary of the Agency's human health risk assessment is presented below. More detailed information associated with the risks posed by the tobacco plant growth inhibitor use of the aliphatic alcohols can be found in the human health risk assessment, *Aliphatic Alcohols: Human Health Chapter of the Reregistration Eligibility Decision (RED) Document. Reregistration Case Number 4004*, which is available in the public docket.

The potential human health risks from 1-dodecanol were assessed in 2002 by the Agency's Biopesticides and Pollution Prevention Division (BPPD), as described in the document, *Tolerance Reassessment Decision Regarding Tolerance Exemption for the Biochemical*

Lepidopteran Pheromones. July 26, 2002. The tolerance exemption for Lepidopteran pheromones, including 1-dodecanol, was determined to be in compliance with FQPA.

Toxicity Summary for Aliphatic Alcohols

The data base of submitted toxicity studies and published literature is sufficient to assess the uses of the aliphatic alcohols. The available toxicity data base for the aliphatic alcohols consists of acute toxicity, irritation, and sensitization studies. In addition, there are developmental rat (oral and inhalation) toxicity studies and a 90-day rat (dermal) study. The available mutagenicity studies include the Ames, micronucleus, and gene mutation assays.

Currently, there is no known mode of toxicological action for the aliphatic alcohols. Based on the low hazard concern via the oral, dermal, and inhalation routes of exposure, a quantitative risk assessment for the aliphatic alcohols is not appropriate. Therefore, the Agency conducted a qualitative assessment.

Toxicity Profile

Available acute toxicity studies indicate the aliphatic alcohols are of low oral and dermal toxicity. Acute inhalation studies with the rat resulted in estimates of the median lethal dose (LD_{50}) above the limit concentration of 2 mg/L. However, eye irritation studies resulted in severe and sometimes non-reversible eye irritation. Dermal irritation studies revealed slight to moderate irritation in rabbits, and the aliphatic alcohols generally did not produce sensitization in tests with guinea pigs.

There are few subchronic or chronic toxicity data available for the aliphatic alcohols; however, the available developmental toxicity studies revealed no adverse effects in fetal and maternal parameters. The available genotoxicity and mutagenicity studies were negative. There is currently no long-term rodent toxicity information regarding the carcinogenic potential for the aliphatic alcohols. While neurotoxicity information is currently not available, there were no clinical signs in any of the acute, subchronic, or developmental toxicity studies to suggest the aliphatic alcohols elicit a neurotoxic effect. Based on the available data, there is no evidence that warrants determining any dietary, oral, dermal, or inhalation endpoints to quantify sub-chronic or chronic toxicity.

Finally, there is no evidence to suggest that the aliphatic alcohols cause increased susceptibility in infants and children. Therefore, based on the results of the available studies, no endpoints of toxicological concern have been identified for human health risk assessment purposes. Table 4 summarizes the available toxicity data for the aliphatic alcohols.

Table 4. Acute Toxicity Data for the Aliphatic Alcohols

Guideline No.	Study Type	PC Code	MRID	Results	Toxicity Category
870.1100 81-1	Acute oral [rat]	079038 1-Decanol	44460401 46004601	LD_{50} > 2000 mg/kg (other studies report no deaths at 2000 mg/kg, one study showed LD_{50}	III

Guideline No.	Study Type	PC Code	MRID	Results	Toxicity Category
			45507901 0060309 0064859	=5000 mg/kg)	
870.1200 81-2	Acute dermal [rat]	079038 1-Decanol	44460402 46004602 45507902	LD_{50} reported as > 2000 mg/kg; (other studies reported LD_{50}> 4000 mg/kg and one study showed LD_{50} = 5000 mg/kg	III
870.1300 81-3	Acute inhalation [rat]	079038 1-Decanol	44460403 46004603 45517901	LD_{50}> 3.35 mg/L (other studies showed LD_{50}>5.07 mg/L and LD_{50}>7.08 mg/L)	IV
870.2400 81-4	Acute eye irritation [rabbit]	079038 1-Decanol	44460404 44578801 46004604 45517902	Most severe effect reported as corneal opacity in all treated eye at 7 days. Conjunctive irritation until 7 and 14 days. Irreversible vascularisation in one eye until day 21	I-III
870.2400 81-4	Acute eye irritation [rabbit]	079029 Fatty Alcohols	44340701	All 6 rabbits showed moderate to severe irritation. Opacity up to 7 days. Slight iritis with conjunctival redness to day 6, slight chemosis to day 7 and slight to severe discharge to day 8.	II-III
870.2500 81-5	Acute dermal irritation [rabbit]	079038 1-Decanol	44407601 44460405 46004605 45517903	In one study, erythema, eschar formation and edema was evident at 72 hrs. Test substance reported as mild irritant.	III-IV
870.2600 81-6	Skin sensitization [guinea pig]	079038 1-Decanol	44407602 44460406 46004606 45507903	Three studies reported 1-decanol is not a skin sensitizer.	NA
870.2600 81-6	Skin sensitization [guinea pig]	079029 Fatty Alcohols	43386201	All animals survived. No adverse effect on body weight. Not a dermal sensitizer.	NA

B. Environmental Risk Assessment

The Agency has conducted a screening-level risk assessment of the tobacco plant growth inhibitor and pheromone uses of the aliphatic alcohols. The Agency's screening level assessment was conducted using data submitted by the registrants in conjunction with acceptable

ecotoxicity data from the open literature. Anticipated exposure pathways to non-target species include oral exposure, and inhalation of aliphatic alcohol products.

A summary of the Agency's ecological risk assessment is presented below. More detailed information associated with the ecological risks posed by use of the aliphatic alcohols can be found in the environmental risk assessment, *Reregistration Eligibility Decision for the Aliphatic Alcohols*, dated September 8, 2006, which is available in the public docket.

1. Environmental Fate and Transport

Because environmental fate data are not available, physical and chemical properties for the aliphatic alcohols were estimated by Quantitative Structure-Activity Relationships (QSAR) using EPISuite v3.21 (Estimation Programs Interface for Windows (EPIWIN)). The estimated properties of 1-octanol, 1-decanol and 1-dodecanol differ somewhat, due to the different lengths (i.e. number of carbons) in their straight, saturated carbon chains. As suggested by their common names, 1-octanol has 8 carbons in its chain, 1-decanol has 10 carbons, and 1-dodecanol has 12 carbons.

In spite of these small differences, the expected behavior of these aliphatic alcohols in the environment is generally similar. The major route of dissipation in the field for these chemicals is likely to be volatilization. The volatility half-lives for 1-octanol and 1-decanol were estimated using the Dow Method described in the *Handbook of Chemical Property Estimation Methods* by Lyman, Reehl and Rosenblatt. The half-lives for volatility from soil for 1-octanol and 1-decanol were estimated to be 3.5 minutes and 1 minute, respectively. 1-dodecanol would likely volatilize even more quickly, but the half-life was not estimated, since volatility from pheromone traps is the known route of dissipation.

There is some uncertainty about the rate of volatility of 1-octanol and 1-decanol from plant surfaces, since aliphatic alcohols are hydrophobic and, therefore, have affinity for the waxy surfaces of plants. However, these volatility half-lives suggest that the aliphatic alcohols will not be available long to expose non-target terrestrial animals, nor to be transported to surface water bodies in runoff. Residues of 1-dodecanol are not expected on plants or in soil, since they are dispersed in the air from pheromone traps, and then degraded by photolysis. The ecological risk assessment concluded that except for terrestrial insects, which are the target for the pheromone use of 1-dodecanol, "environmental exposures resulting from this use are likely negligible." The risk assessment for this use was therefore qualitative.

Additional estimation of environmental fate parameters obtained from EPISuite provides a basic set of data to perform a screening-level environmental risk assessment. The model indicates that aliphatic alcohols have a moderate tendency to bind to soils. The portion of applied chemical that binds to the soil, rather than volatilizing, will be subject to biodegradation, with estimated half-lives for 1-octanol and 1-decanol of 2.3 days. The portion of applied chemical that does volatilize is estimated to degrade in the air by reaction with hydroxyl radicals with half-lives of about 10 hours.

As mentioned above, dissipation via volatilization will greatly reduce the amount of aliphatic alcohols reaching surface-water bodies, and aliphatic alcohols will volatilize from water as well as soil. However, the fraction that does reach surface water will not be degraded by hydrolysis. These alcohols have the potential to bioaccumulate in fish, but the rates of uptake, metabolism, and depuration, as well as the nature of metabolites, are not known. However, the magnitude of the bioconcentration factors (BCF) suggests a low potential to bioconcentrate.

EPISuite does not provide information on the rates of formation/decline of product, the nature and relative amounts of transformation products, and their distribution in soil/sediment-water-air. Therefore, the specific nature and persistence of potential biotransformation products (primary biodegradation) are not known. However, the ultimate biotransformation products of the aliphatic alcohols are water and carbon dioxide.

2. Ecological Risk Assessment

The Agency uses a pesticide's use profile, exposure data, and toxicity information to determine risk estimates to non-target terrestrial and aquatic organisms. Estimated environmental concentrations (EECs) are used to calculate risk quotients (RQs). EECs are based on the maximum application rate(s) which would potentially yield the greatest exposure. An RQ is derived by dividing the EEC by a single estimate of toxicity. The Agency then compares an RQ to its Level of Concern (LOC) to determine if exposure to the aliphatic alcohols could potentially pose a risk to non-target organisms (RQs that exceed the LOC indicate potential risk). Table 5 outlines LOCs, and the Agency's corresponding risk presumptions.

Table 5. Agency Level of Concerns and Risk Presumptions

Risk Presumption	LOC Terrestrial Animals	LOC Aquatic Animals	LOC Plants
Acute Risk – there is a potential for acute risk	0.5	0.5	1
Acute Endangered Species – endangered species may be adversely affected	0.1	0.05	1
Chronic Risk – there is potential for chronic risk	1	1	N/A

a. Exposure to Aquatic Organisms

The Agency ran a number of exposure modeling simulations to derive expected environmental concentrations of aliphatic alcohols in surface water. The Agency first ran the Tier I GENEEC model, which resulted in exceedences of the endangered species level of concern (LOC) for freshwater fish and estuarine/marine invertebrates for some application scenarios. However, these simulations did not consider the volatilization of aliphatic alcohols from soil, and each thereby overestimated potential exposure.

Although GENEEC is not designed to consider volatility from soil directly, the Agency used an indirect method to consider volatility with the GENEEC model and to refine the aquatic exposure assessment. As described above, the volatility half-lives for the aliphatic alcohols were

estimated using the Dow Method described in the *Handbook of Chemical Property Estimation Methods* (Lyman, et al., 1982). The half-lives for volatility from soil for 1-octanol and 1-decanol were estimated to be 3.5 minutes and 1 minute, respectively. Such short volatility half-lives mean that little pesticide will remain by the time a runoff event occurred, unless rainfall began immediately after application.

To simulate this scenario using GENEEC, the Agency determined the amount of 1-octanol or 1-decanol that would remain in the field 3 to 4 minutes after application at the maximum rates allowed on the label. GENEEC was then run in the standard fashion, but with this "effective application rate." Even though this was done using estimated volatility half-lives on the order of a couple of minutes, the resulting EECs are still considered upper-bound. GENEEC does not simulate a rainfall event until two days after application; if rainfall does not occur until two days after actual application of 1-octanol or 1-decanol, there could be very little product remaining to be subject to transport in runoff. For this reason, the simulations considered only a single application, although aliphatic alcohols can be used more than once within a single growing season.

b. Toxicity to Aquatic Organisms

Registrant-submitted data and open literature studies suggest that the aliphatic alcohols are "slightly" to "moderately" toxic to freshwater fish. Although the data base is not complete for all compounds in the aliphatic alcohol registration case, there are adequate data to assess the acute risk to freshwater fish. Although there are no registrant-submitted acute toxicity data available for estuarine/marine fish, data from the open literature provided the information to assess the acute risks of aliphatic alcohols to these organisms. The relevant study from the open literature indicates that 1-octanol is "slightly" toxic, and 1-decanol is "moderately" toxic to estuarine/marine fish.

No chronic toxicity guideline studies exist for any of the aliphatic alcohols. However, chronic data for freshwater fish from the open literature on 1-octanol provide an endpoint which the Agency used to calculate RQs. Chronic toxicity data for aquatic invertebrates on the aliphatic alcohols were also drawn from the open literature. The Agency used a chronic no observed adverse effect concentration (NOAEC) of 1 mg/L for reproductive effects for 1-octanol. The Agency notes that chronic toxicity data on 1-decanol for aquatic invertebrates would reduce the uncertainty posed by the lack of these data. A summary of all toxicity endpoints is presented below in Table 6.

Table 6. Toxicity Reference Values Used to Calculate RQs for Aliphatic Alcohols

Taxonomic Group	Assessment Endpoint	1-Octanol	1-Decanol
		Species/ Toxicity Endpoint	Species/ Toxicity Endpoint
Freshwater Fish	Survival	Fathead minnow Acute LC_{50} = 12.2 mg/L	Fathead minnow Acute LC_{50} = 2.3 mg/L
	Reproduction, Growth	Fathead minnow NOAEC = 0.75 mg/L	No data available

Taxonomic Group	Assessment Endpoint	1-Octanol	1-Decanol
		Species/ Toxicity Endpoint	Species/ Toxicity Endpoint
Freshwater Invertebrates	Survival	Water flea Acute EC_{50} = 4.16 mg/L	Water flea Acute EC_{50} = 6.5 mg/L
	Reproduction, Growth	Water flea Chronic NOAEC = 1 mg/L	No data available
Estuarine/marine Fish	Survival	Bleak LC_{50} = 15 mg/L	Bleak LC_{50} = 7.2 mg/L
	Reproduction, Growth	No data available	No data available
Estuarine/marine Invertebrates	Survival	Harpacticoid copepod LC_{50} = 58 mg/L	Harpacticoid copepod LC_{50} = 4 mg/L
	Reproduction, Growth	No data available	No data available
Aquatic Plants	Survival, Growth	*Scenedesmus subspicatus* EC_{50} = 6.5 mg/L; EC_{10} = 2.8 mg/L	No data available

LC_{50} - Median Lethal Concentration, statistically derived single concentration that can be expected to cause death in 50% of the test animals; EC_{50} - Median Effect Concentration, statistically derived single concentration that can be expected to cause an adverse effect in 50% of the test animals or plants; EC_{10} - statistically derived single concentration that can be expected to cause an adverse effect in 10% of the test animals or plants; NOAEC - no observed adverse effect concentration.

c. Risk to Aquatic Organisms

Based on the refined surface water EECs and the available ecotoxicity data for 1-octanol and 1-decanol, RQs for aquatic animals do not exceed acute LOCs. In addition, although chronic toxicity data are available for 1-octanol, but not 1-decanol, aliphatic alcohols do not appear to pose a chronic risk to freshwater aquatic animals. No chronic toxicity data are available for estuarine/marine fish and invertebrates. In spite of these data gaps, the Agency does not anticipate chronic risk to estuarine marine fish and invertebrates. As described above, little 1-octanol or 1-decanol would likely be available for transport in runoff if a significant rain event did not occur within a few hours of application. Estimated RQs for 1-decanol and 1-octanol are summarized in Tables 7 – 10 below.

Table 7. Acute and Chronic RQs for Freshwater Fish

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	60-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	LC_{50} = 2300 NOAEC – nd	0.02	13	nd
1-Octanol	4.4, 1 application	140	LC_{50} = 12200 NOAEC = 750	0.01	29	<1

Table 8. Acute and Chronic RQs for Estuarine/Marine Fish

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	60-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	LC_{50} = 7200 NOAEC – nd	<0.01	13	nd
1-Octanol	4.4, 1 application	140	LC_{50} = 15000 NOAEC – nd	<0.01	29	nd

Table 9. Acute and Chronic RQs for Freshwater Invertebrates

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	21-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	EC_{50} = 6500 NOAEC – nd	<0.01	29	nd
1-Octanol	4.4, 1 application	140	EC_{50} = 4160 NOAEC = 1000	0.03	70	<1

Table 10. Acute and Chronic RQs for Estuarine/Marine Invertebrates

Chemical	Effective Application Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ	21-Max Average EEC (µg/L)	Chronic RQ
1-Decanol	1.95, 1 application	57	EC_{50} = 4000 NOAEC – nd	0.01	29	nd
1-Octanol	4.4, 1 application	140	EC_{50} = 58000 NOAEC – nd	<0.01	70	nd

nd = no data

Aquatic plant toxicity data from open literature were only available for 1-octanol. Based on these data, the acute RQs for aquatic plants do not exceed the Agency's acute and endangered species LOCs (both 1.0) (Table 11). However, there is some uncertainty in this risk conclusion, given that the NOAEC for 1-octanol is unknown, and no aquatic phytotoxicity data are available for 1-decanol. The NOAEC is used to calculate an RQ to evaluate potential risk to endangered species. Because the NOAEC was not established, the EC_{10} for 1-octanol was used. Since the LOC for endangered aquatic plants is 1.0, and the RQ derived using the EC_{10} is 0.05, the NOAEC would have to be at least 20 times lower than the EC_{10} for the Agency to have an endangered species concern for aquatic plants.

Based on the analysis of the volatility of the aliphatic alcohols, aquatic exposures resulting from the labeled use of 1-decanol and 1-octanol are unlikely to reach concentrations that exceed the Agency's LOC. As a result, the value of additional aquatic plant studies for the aliphatic alcohols is low.

Table 11. Risk to Aquatic Plants

Chemical	Rate (lbs a.i./acre)	Peak EEC (µg/L)	Toxicity Value (µg/L)	Acute RQ
1-Octanol	4.4, 1 application	140	EC_{50} = 6500 EC_{10} = 2800	0.02 0.05
1-Decanol	1.95, 1 application	57	No data	--

d. Exposure, Toxicity and Risk to Terrestrial Organisms

Birds

Available toxicity data indicate that the aliphatic alcohols are categorized as "practically non-toxic" to birds on acute oral and dietary bases. Acute risks to birds were not quantified, because no discreet median lethal doses or concentrations were established in the acute oral and dietary studies. An acute dietary study from the open literature reported a dietary LC_{50} for bantam chickens of 201,000 ppm (100% 1-decanol). This level is more than 20 times greater than the highest predicted dietary exposure level (~10,000 ppm). Therefore, the Agency concludes that the aliphatic alcohols do not pose an acute risk to birds.

No avian chronic toxicity studies were available for any of the aliphatic alcohols and, therefore, the Agency cannot directly assess the potential chronic risk to avian species. However, since 1) the aliphatic alcohols are not acutely toxic to birds at doses many times higher than expected exposure, 2) the volatility of the aliphatic alcohols makes chronic exposure unlikely, with EECs dropping more than an order of magnitude within 30 minutes, 3) the aliphatic alcohols assessed are listed as food additives and are "Generally Recognized as Safe" (GRAS) by the U.S. Food and Drug Administration[1], and 4) a mammalian chronic toxicity study indicates the aliphatic alcohols are not chronically toxic to mammals, the Agency does not expect a chronic risk to birds, and will not require chronic avian toxicity studies at this time.

Mammals

Acute oral mammalian toxicity data indicate that the aliphatic alcohols are "practically non-toxic" to mammals on an acute oral basis. Four studies performed with laboratory rats did not result in LC_{50} endpoints with which RQs could be calculated. The Agency concludes that aliphatic alcohols do not pose an acute dietary risk to mammals.

In the single chronic mammalian developmental toxicity study, which used a 1-decanol/1-octanol blend, no chronic effects were observed in laboratory rats, even at the maximum tested dose of 957 mg/kg bw/day. It is unknown if the predicted exposures approach the level at which effects may occur since no LOAEC was identified in the chronic study. However, the Agency does not anticipate chronic risk to mammals, considering the volatility of the aliphatic alcohols, and the acceptance of these chemicals as food additives, as described above.

Terrestrial Insects

Available toxicity data indicate that aliphatic alcohols are "practically non-toxic" to honey bees (acute contact $LD_{50} > 25$ µg/bee). However, given that aliphatic alcohols can be used as Lepidopteran sex inhibitors, there is a potential for sublethal (e.g., reproductive) effects on non-target Lepidopterans, such as butterflies. This potential effect cannot be quantified at this time.

[1] http://vm.cfsan.fda.gov/~dms/eafus.html

Terrestrial Plants

Tier-I terrestrial plant seedling emergence study data suggest a fatty alcohol blend (1-decanol and 1-octanol) is not toxic to most plants at the maximum rate tested (18.03 lbs ai/A). An EC_{25} could not be established for tested species, although lesser effects were observed in cucumbers, carrots and tomatoes. Therefore, the Agency did not calculate RQs based on seedling emergence effects.

EC_{25} values and related no-effect levels were established for two (corn and cucumber) of 10 crop plants tested in a submitted vegetative vigor study. The Agency used these endpoints in the TerrPlant model to calculate RQs (Table 12). All were below the Agency's LOC of 1.

Table 12. Terrestrial Plant Vegetative Vigor RQs from Drift only for Terrestrial Plants*

Class of Terrestrial Plant	Monocot	Dicot
Non-endangered species	0.02	0.01
Endangered species	0.19	0.36
* Based on vegetative vigor monocot NOAEL = 1.12 lbs a.i./A, EC25 = 9.02 lbs a.i./A; dicot NOAEL = 0.58 lbs a.i./A, EC25 = 14.8 lbs a.i./A (MRIDs 42514701, 43379602)		

e. Adverse Ecological Incidents

There are currently no adverse ecological incidents listed in the Ecological Incident Information System (EIIS) that are associated with the aliphatic alcohols.

f. Endangered Species

Based upon the screening-level assessment conducted on aliphatic alcohols, the Agency has not definitively identified exceedences of endangered species LOCs for direct effects to non-target animals or plants. Acute RQs did not exceed endangered species LOCs for birds, mammals, terrestrial plants, freshwater fish and invertebrates, or estuarine/marine fish and invertebrates. Chronic data were not available for birds and estuarine/marine fish and invertebrates. As described above, the Agency believes that the volatility and low toxicity in available acute and chronic toxicity studies for mammals and freshwater animals suggest that chronic risk to birds and estuarine/marine animals is unlikely. However, because the toxicity data are not available, the Agency cannot completely preclude risk to listed birds and estuarine/marine animals at this time. Similarly, since a no-effect level was not determined for aquatic plants, the Agency cannot preclude direct effects on these organisms, although exposure is expected to be negligible.

The Agency considers a potential for not only direct effects, but also adverse indirect effects to listed species that rely on other affected organisms. Because direct effects to aquatic plants cannot be precluded, indirect effects to listed aquatic species which rely on aquatic plants can also not be dismissed. Similarly, indirect effects to terrestrial plants and animals cannot be precluded because of potential reproductive effects of aliphatic alcohols to some terrestrial insects.

Table 13. Potential Listed Species Risks Associated with Direct or Indirect Effects Due to Applications of Aliphatic Alcohols as Shoot Inhibitors on Tobacco.

Listed Taxon	Direct Effects		Indirect Effects to Endangered Species
	Acute	Chronic	
Terrestrial and semi-aquatic plants - monocots	No	N/A	Possible
Terrestrial and semi-aquatic plants - dicots	No	N/A	Possible
Birds	No	No data	Possible
Terrestrial-phase amphibians	No	No data	Possible
Reptiles	No	No data	Possible
Mammals	No	No	Possible
Aquatic non-vascular plants*	Insufficient data	N/A	N/A
Aquatic vascular plants	Insufficient data	N/A	N/A
Freshwater fish	No	No	Possible
Aquatic-phase amphibians	No	No	Possible
Freshwater crustaceans	No	No	Possible
Mollusks	No	N/A	Possible
Marine/estuarine fish	No	No data	Possible
Marine/estuarine crustaceans	No	No data	Possible

* At the present time, no aquatic non-vascular plants are included in Federal listings of threatened and endangered species. The taxonomic group is included here for the purposes of evaluating potential contributions to indirect effects to other taxa and as a record of exceedences should future listings of non-vascular aquatic plants warrant additional evaluation of Federal actions.

Further analysis regarding the overlap of individual species with each use site is required prior to determining the likelihood of potential impact to listed species. At the screening level, this analysis is accomplished using the Location of Crops and Threatened and Endangered Species (LOCATES) data base, which uses location information for listed species at the county level and compares it to agricultural census data for crop production at the same county level of resolution. The ecological risk assessment includes a complete listing of aquatic plants, birds, reptiles, terrestrial-phase amphibians, mammals, and terrestrial invertebrates associated with the States where the aliphatic alcohols are use as a plant growth regulator on tobacco.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing aliphatic alcohols as an active ingredient. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all products containing aliphatic alcohols (C6 – C16).

The Agency has completed its assessment of the human health and ecological risks associated with the use of pesticide products containing aliphatic alcohols (C6 – C16). The Agency has determined that aliphatic alcohol-containing products are eligible for reregistration provided that label amendments are made as outlined in Chapter V. Appendix A summarizes the

uses of aliphatic alcohols (C6 – C16) that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of aliphatic alcohols (C6 – C16), and lists the submitted studies that the Agency found acceptable.

The Agency has identified eye-irritation concerns that warrant specific label language concerning personal protective equipment (PPE) and the length of restricted-entry intervals after application for tobacco uses of the aliphatic alcohols (C6 – C16). If all changes outlined in this document are incorporated into the product labels, the eye-irritation concerns will have been mitigated. Should a registrant fail to implement any of the reregistration requirements identified in this document, the Agency may take regulatory action to address these concerns.

B. Public Comment Period

Because the risks associated with the use of aliphatic alcohols were low and did not warrant mitigation measures, a Phase 3 public comment period on the aliphatic alcohols risk assessments was not conducted. However, a 60-day public comment period will be conducted after the RED is issued, and will be announced in the Federal Register. Comments may be submitted under Docket number EPA-HQ-OPP-2007-0134 at http://www.regulations.gov/. The RED document and technical supporting documents for aliphatic alcohols are also available to the public under docket identification (ID) number EPA-HQ-OPP-2007-0134. In addition, the aliphatic alcohols RED document may be downloaded or viewed through the Agency's website at http://www.epa.gov/pesticides/reregistration/status.htm.

C. Regulatory Position

1. Regulatory Rationale

The Agency has determined that aliphatic alcohols-containing products are eligible for reregistration provided that specified label amendments are made. The following is a summary of the rationale for managing risks associated with the use of aliphatic alcohols.

a. Human Health Risk Management

There are no human health risk concerns for the aliphatic alcohols with the exception of eye irritation for 1-decanol. 1-decanol, which is a component of all active tobacco use formulations of the aliphatic alcohols (C6 – C16), is an acute toxicity category I eye irritant and, therefore, pursuant to the Worker Protection Standards (WPS), products with agricultural uses must require a 48 hour REI and the following PPE for early entry: coveralls, chemical-resistant gloves made of any water proof material, shoes plus socks, and protective eyewear.

b. Ecological Risk Management

The risk assessment identified no exposure scenarios with aliphatic alcohols that pose ecological risks of concern to the Agency, including direct effects on endangered species. Thus,

no mitigation measures to address ecological risks are necessary for the reregistration of aliphatic alcohols.

Moreover, because of the low risks associated with the use of aliphatic alcohols, as summarized in this document, the Agency concludes that spray drift mitigation is not needed as part of the reregistration eligibility determination.

2. Endocrine Disruptor Effects

Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, individual pesticides may be subject to additional screening and/or testing. However, in the available toxicity studies for the aliphatic alcohols, there was no evidence of endocrine disruption.

3. 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. 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 this 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 aliphatic alcohols "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 refines the screening-level assessment to take into account 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 aliphatic alcohols 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.

The Agency has reviewed data and other information for the aliphatic alcohols (C6 – C16) and concludes that this plant growth regulator does not pose a risk of direct acute effects to most species listed under the Endangered Species Act, because EPA's screening-level assessment shows 'no effect' on listed species or their critical habitat (RQ values were below the level of concern for endangered species). There is some uncertainty regarding acute risk to aquatic plants, however. Although the volatility of 1-octanol and 1-decanol suggests that exposure to aquatic plants would be negligible, a no-observed-adverse-effect-level could not be established and, therefore, indirect effects to listed aquatic animals which depend on aquatic plants could not be precluded. Similarly, the Agency believes that the volatility and low toxicity in available acute and chronic toxicity studies for mammals and freshwater animals suggest that chronic risk to birds and estuarine/marine animals is unlikely. However, because the toxicity data are not available, the Agency cannot completely preclude risk to listed birds and estuarine/marine animals at this time.

D. Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing aliphatic alcohols. For the specific labeling statements, refer to Section V of this RED document.

V. What Registrants Need to Do

The Agency has determined that aliphatic alcohols (C6 – C16)-containing products are eligible for reregistration provided that the required label amendments are made. The Agency intends to issue Data Call-In (DCIs) Notices requiring product-specific data. Generally, registrants will have 90 days from receipt of a DCI to complete and submit response forms or request time extension and/or waiver requests with a full written justification. For product-specific data, the registrant will have eight months to submit data. Below are the label amendments that the Agency intends to require for aliphatic alcohols to be eligible for reregistration.

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of aliphatic alcohols for currently registered uses has been reviewed and determined to be substantially complete. However, a few data gaps remain, and these are listed below.

Product Chemistry

830.7050 UV/VIS Spectrum for Pure Active Ingredient (PAI)
830.7950 Vapor Pressure

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing-use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices, and applicable policies. The MUP labeling should bear the labeling contained in Table 14.

B. End-Use Products

1. Additional 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. For any questions regarding the PDCI, please contact Karen Jones at 703-308-8047.

2. Labeling for End-Use Products

To be eligible for reregistration, labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 15. 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.

C. Labeling Changes Summary Table

In order to be eligible for reregistration, amend all product labels to comply with the following table. Table 14 describes how language on the labels should be amended.

Table 14: **Labeling Changes Summary Table for 1-Octanol, 1-Decanol and Fatty Alcohols**

Description	1-Octanol, 1-Decanol and Fatty Alcohols : Required Labeling Language	Placement on Label
Manufacturing-Use Products		
Required on all MUPs	"Only for formulation into a growth regulator for tobacco sucker control."	Directions for Use
One of these statements may be added to a label to allow reformulation of the product for a specific use or all additional uses supported by a formulator or user group.	"This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)." "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."	Directions for Use
Environmental Hazards Statements Required by the RED and Agency Label Policies	"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollution Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA."	Directions for Use

End-Use Products Intended for Occupational Use (WPS and non-WPS)		
Handler PPE Requirements[1] for (insert type of formulation) Note: Separate sections should be used for each formulation type (i.e. liquids, powders, granulars, etc…) unless the required handler PPE is identical for all formulation types.	"Personal Protective Equipment (PPE) Mixers, loaders, applicators, and other handlers must wear: > Long-sleeved shirt and long pants and, > Shoes plus socks"	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"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." "Discard clothing and other absorbent material that have been drenched or heavily contaminated with the product's concentrate. Do not reuse them."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements
User Safety Recommendations	"USER SAFETY RECOMMENDATIONS" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "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."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a

		box.)
Environmental Hazards Statement	"ENVIRONMENTAL HAZARDS" Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water by cleaning of equipment or disposal of wastes."	Precautionary Statements under Environmental Hazards
Restricted-Entry Interval for products with WPS uses	"Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 48 hours."	Directions for Use, Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with WPS uses	"PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as soil or water, is: > coveralls, > shoes plus socks, > chemical-resistant gloves made of any waterproof material, > protective eyewear."	Directions for Use, Agricultural Use Requirements Box
General Application Restrictions for products with WPS or non-WPS uses on the label	"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."	Place in the Direction for Use.

[1] 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. In the case of multiple active ingredients, the more protective PPE must be placed on the product labeling. For guidance on which PPE is considered more protective, see PR Notice 93-7.

Appendix A