

US EPA ARCHIVE DOCUMENT



United States  
Environmental Protection  
Agency

Prevention, Pesticides  
And Toxic Substances  
(7508P)

EPA738-R-07-002  
March 2007

---

# Reregistration Eligibility Decision

# Aliphatic Esters

List D

Case No. 4005

Reregistration Eligibility Decision (RED) Document  
for Aliphatic Esters

Approved by:



Debra Edwards, Ph. D.

Director

Special Review and Reregistration Division

Date:

March 13, 2007

## Table of Contents

Aliphatic Esters Reregistration Eligibility Decision Team.....	4
Glossary of Terms and Abbreviations .....	5
Summary .....	7
I. Introduction .....	7
II. Chemical Overview.....	7
III. Risk Assessment Summary.....	9
A. Human Health Risk Assessment.....	10
B. Ecological Risk Assessment.....	13
IV. Risk Management and Reregistration Decision .....	14
V. What Registrants Need to Do.....	16
Additional Generic Data Requirements .....	16
1. Additional Product-Specific Data Requirements.....	16
2. Labeling for End-Use Products.....	16

## Aliphatic Esters Reregistration Eligibility Decision Team

### Office of Pesticide Programs:

#### Health Effects Risk Assessment

Elissa Reaves, Ph.D.

Shanna Recore

Yvonne Barnes

Alan Nielsen

#### Environmental Fate and Effects Risk Assessment

Mark Corbin

Colleen Flaherty

#### Registration Support

Jim Tompkins

#### Risk Management

Cathryn O'Connell

Tom Myers

## Glossary of Terms and Abbreviations

ai	Active Ingredient
CFR	Code of Federal Regulations
CSF	Confidential Statement of Formula
DCI	Data Call-In
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
G	Granular Formulation
GLN	Guideline Number
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24(c) of FIFRA)

TGAI	Technical Grade Active Ingredient
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

## Summary

The Environmental Protection Agency (referred to as the “EPA” or “the Agency”) has evaluated the risks from the supported uses of the aliphatic esters and has determined that no unreasonable adverse effects will result from exposure to the methyl esters of fatty acids, the only active ingredient in the aliphatic esters case with registered products. Based on the lack of hazard concern, no quantitative human health risk assessment was conducted. However, based on a potential concern of chemical pneumonia for handlers, EPA will require the use of an organic-vapor respirator during mixing, loading, and application of the product and will increase the restricted entry interval (REI) from 4 hours to 12 hours. Due to the limited use outside of greenhouses and the direct application of this chemical to ornamentals in and around greenhouses no unreasonable adverse ecological risks are expected and no ecological risk mitigation is required.

## 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. 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 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.

This document presents the EPA decision regarding the reregistration eligibility of the registered uses of the aliphatic esters. There are 6 active ingredients in the aliphatic esters case; however, 5 of these active ingredients do not have active registered products. These chemicals are not being supported and are not addressed in this reregistration decision. The methyl esters of fatty acids (PC 079034) is the only active ingredient in the case with an active product.

The Agency made its reregistration eligibility determination 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 uses of aliphatic esters are eligible for reregistration provided the mitigation and labeling outlined in this RED are implemented.

## II. Chemical Overview

There are 6 active ingredients in reregistration case 4005 for the aliphatic esters. The active ingredients are presented below in Table 1. This RED evaluates only the

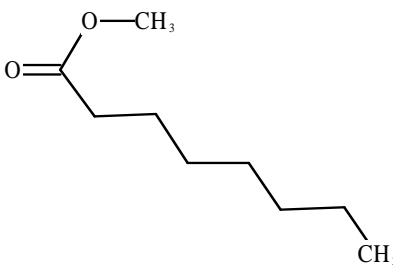


active ingredients in this case with active products; therefore, only the methyl esters of fatty acids (PC Code 079034) were assessed. The other 5 active ingredients in this case have no product registrations and are not being supported for reregistration. These active ingredients would be evaluated only if and when new registration applications were to be submitted for new products.

The first product with methyl esters of fatty acids was registered in January 1968 to the Procter and Gamble Company (EPA Reg # 3573-23). The registration was transferred to the Buckeye Cellulose Corporation in March 1979 (EPA Reg # 42855-1). In March of 1987 the registration was transferred again to Cochran Corporation (EPA Reg # 57582-1). The Cochran Corporation remains the only active registrant. Currently only one active product is registered in this case, Off-Shoot-O (EPA Reg # 57582-1).

Table 1. Active ingredients in case 4005			
Active Ingredient Name	PC Code	CAS	Status
methyl esters of fatty acids	079034	67762-39-4	1 active product (EPA Reg # 57582-1)
amyl acetate	000169	628-63-7	No active products.
ethyl acetate	044003	141-78-6	No active products.
dibutyl succinate	077802	141-03-7	No active products.
1-tetradecanol formate	079069	5451-63-8	No active products.
n-pentyl valerate	100901	2173-56-0	No active products.

The chemical structure and properties are presented below in Tables 2 and 3.

Table 2. Nomenclature for Methyl Esters of Fatty Acids	
Chemical structure	
Common name	Aliphatic Esters, Fatty Acids Methyl Esters (FAME)
Molecular formula	$\text{CH}_3(\text{CH}_2)_n\text{COOCH}_3$
Molecular weight	158.24
IUPAC name (Estimation)	(C <sub>6</sub> -C <sub>12</sub> ) Alkylcarboxylic acid methyl ester
CAS name	Methyl ester, aliphatic
CAS number	67762 - 39 - 4
PC Code	079034

Parameter	Value	Reference
Melting point/range	-20 °C	MRID 417855-01
pH at 20 °C	4.7	MRID 417855-01
Density at 20 °C	7.23 lbs/gal	MRID 417855-01
Water solubility at 20 °C	Zero gm/100 ml	MRID 417855-01
Solvent solubility at 20 °C	Ethanol -- 100 gm/100 ml Petroleum Ether -- 100 gm/ 100 ml	MRID 417855-01
Vapor pressure at 25° C	Less than 1 mm Hg	MRID 417855-01
Dissociation constant, pK <sub>a</sub>	Not Applicable, non-polar	MRID 417855-01
Octanol/water partition coefficient	Estimate Log P = 3.32	EPI™ version 3.12
UV/visible absorption spectrum	Not provided	Data Gap <sup>i</sup>

<sup>i</sup> The UV/visible absorption spectrum data requirement only applies to technical products.

## Use Profile

**Type of Pesticide:** Plant Growth Regulator or Pinching Agent.

**Summary of Use:** May be applied as a foliar spray inside or outside a greenhouse on ornamentals such as azalea, cotoneaster, juniper, ligustrum, rhamnus, and taxus (yew). Most applications are to azaleas inside greenhouses.

The methyl esters of fatty acids are also registered with the Food and Drug Administration (FDA) for use as a direct food additive (21 CFR 172.225) and in animal feed (21 CFR 573.640).

**Formulation Type:** Emulsifiable concentrate.

**Application Methods:** Handgun sprayer, high pressure handwand and low pressure handwand.

**Usage:** Approximately 9,000 pounds of active ingredient are sold per year.

## III. Risk Assessment Summary

The following is a summary of EPA's human health and ecological risk findings and conclusions for the methyl esters of fatty acids, as presented fully in the Health Effects Division document, *Aliphatic Esters: Human Health Chapter of the Reregistration Eligibility Decision (RED) Document* (E. Reaves, et. al.; 6/30/06, D330299), and the Environmental Fate and Effects Division document, *Revised*

*Ecological Risk Assessment for Use in Methyl Esters of Fatty Acids in Greenhouses*, (Corbin, M. and Flaherty, C., 2/8/07, D336252).

## **A. Human Health Risk Assessment**

### *Toxicology*

The available data for the methyl esters of fatty acids are sufficient for hazard assessment. Methyl esters of fatty acids are straight chain and saturated methyl esters of caproic acid (hexanoic acid), caprylic acid (octanoic acid), capric acid (decanoic acid), and lauric acid (dodecanoic acid). Since they are metabolized in a manner similar or identical to other neutral fats which are understood by the Agency, no additional testing is required to understand the metabolism of methyl esters of fatty acids.

Acute toxicity studies show that the methyl esters are slight skin and eye irritants and not toxic from the oral route of exposure (see Table 4). The skin sensitization and acute inhalation studies are considered unacceptable but provide useful information for hazard assessment. The skin sensitization and acute inhalation studies were waived in 1995 because methyl esters of fatty acids metabolize in a similar manner to other neutral fats that are well understood by the Agency. The acute inhalation study raises a concern for chemical pneumonia for handlers especially when used in greenhouses.

A chromosome aberration (bone marrow) test in Chinese hamsters along with a literature source was submitted. The bone marrow test was found to be unacceptable because it did not meet the guideline requirements. However, based on the published literature that indicates that the straight chain methyl esters of fatty acids are structurally related and metabolized in a similar manner to other neutral fats with the production of similar metabolic byproducts, further testing of methyl esters for their genotoxic (mutagenic) effects was deemed unnecessary.

The FDA has approved the methyl esters of higher fatty acids as a food additive when used in animal feed (21 CFR 573.640). Based on the safe history of food additive use and the known metabolism of these compounds, there is no information to suggest a carcinogenic potential of the methyl esters of fatty acids or a concern for toxicity from the oral route of exposure; therefore, a cancer assessment is not needed and was not performed.

Reproductive, developmental, and subchronic toxicity studies are not available. However, based on the metabolism data, there is no information to suggest that the methyl esters of fatty acids would be of toxicological concern or that they would warrant additional animal testing. Based on the available data, there is no evidence to suggest increased susceptibility in infants and children.

Table 4: Toxicity Data for Methyl Esters of Fatty Acids					
Guideline No.	Study Type	PC Code	MRID	Results	Toxicity Category
870.1100 81-1	Acute oral [rat]	079034	43334501	Methyl Esters (99.6%) LD50>5000 mg/kg	IV
870.1200 81-2	Acute dermal [rabbit]	079034	43334502	Methyl Esters (99.6%) LD50>2000 mg/kg	III
870.1300 81-3	Acute inhalation [rat] UNACCEPTABLE	079034	43334505	Unacceptable but data waived. New study would not add to knowledge (Kocialski Memorandum 7/5/95)	III
870.1400 81-4	Eye Irritation [rabbit]	079034	43334503	Methyl Esters (99.6%) Slight Irritant. Redness and discharge at 1 hour only. No involvement of the cornea or the iris at any time.	III
870.2500. 81-5	Acute dermal irritation [rabbit]	079034	43334504	Methyl Esters (99.6%) Slight irritant. Slight to well defined erythema observed thru 72 hours and 4 days.	IV
870.2600 81-6	Skin sensitization UNACCEPTABLE	079034	43334505	Data Waived (Kocialski Memorandum 7/5/95). Original conclusion is that this formulation is not a sensitizer.	NA
870.5385 84-2	Bone Marrow Chromosome Aberration	079034	43334507	Unacceptable/Nonguideline Data Waived (Kocialski Memorandum 7/5/95)	NA

*Dietary Exposure and Risk*

Based on the lack of hazard concern and the metabolic profile of the methyl esters of fatty acids, toxicological endpoints have not been identified for risk assessment purposes and there are no food uses; therefore, a quantitative dietary (food and water) risk assessment is not necessary and was not performed.

Additionally, the methyl esters of fatty acids have no pesticide tolerances under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) because their uses are not likely to result in residues in food. Accordingly, these pesticides are not subject to the aggregate risk assessment requirements in FFDCA section 408.

### *Residential Exposure and Risk*

Since the methyl esters of fatty acids are chemical pinching agents for use on woody ornamentals in occupational settings, and there are no residential uses of methyl esters of fatty acids, a residential exposure assessment is not needed and has not been performed.

### *Aggregate Exposure and Risk*

An aggregate exposure assessment considers the different pathways (food, water, occupational, and residential) through which exposure to the methyl esters of fatty acids may occur. An aggregate assessment for the methyl esters of fatty acids is not necessary to assess risks to human health. This is based on the fact that there are no pesticide food uses, there are no residential uses, there is low oral hazard concern from the safe history of use with the FDA, and no endpoints were identified for acute or chronic exposures through the dermal or inhalation routes of exposure.

### *Occupational Exposure and Risk*

There is potential for exposure to occupational mixers, loaders, and applicators of methyl esters of fatty acids formulations; however, based on the lack of hazard concern and the metabolic profile of the methyl esters of fatty acids, toxicological endpoints have not been identified for risk assessment purposes. Therefore, an occupational exposure assessment has not been performed.

Available dermal studies (acute dermal toxicity and dermal irritation) indicate that the methyl esters of fatty acids are of low systemic toxicity via the dermal route and are only slightly irritating. Also, an acute inhalation study was submitted in response to the Phase 4 Data Call-In. This study was reviewed and determined to be unacceptable (Kocialski Memorandum, D207640, 7/5/95). However, the results of this acute inhalation study raise the possibility of chemical pneumonitis to handlers, from exposure to the methyl esters of fatty acids due to the high volatility of the active ingredient. The vapor pressure is less than 1 millimeters of mercury at 25 degrees Celsius. Specifically, the review indicates: "a concern with regard to the use of this product in greenhouses." For the reduction of risk of pneumonitis from inhalation exposure, the memo recommended that: a) the label require the use of an organic-vapor respirator during use of the product or b) a new acute inhalation study be conducted over the same time period and number of days as originally conducted by the registrant with histopathology conducted on the lungs. As a result of this RED, labels must be amended to include organic vapor respirators, unless new data demonstrate they are not needed.

Based on the hazard profile for dermal exposure to methyl esters of fatty acids, no post-application dermal risk was assessed. For uses within the scope of the Worker Protection Standard for Agricultural Pesticides (40 CFR 170), a restricted entry interval (REI) must be established. The REI is based on the category assigned to the acute dermal toxicity, skin irritation potential, and eye irritation potential of the active ingredient. For

the one registered product containing methyl esters of fatty acids, Off-Shoot-O, Registration No. 57582-1, the current REI is 4 hours. EPA permits registrants to reduce the Worker Protection Standard (WPS) restricted entry intervals (REIs) from 12 to 4 hours for certain low risk pesticides. Considering evidence of chemical pneumonia from the existing inhalation study, the Agency no longer concludes that the conditions warranting a 4 hour REI exist. Therefore, a 12 hour REI is required unless and until a new acute inhalation study is conducted over the same time period and number of days as originally conducted by the registrant with histopathology conducted on the lungs.

For occupational uses of methyl esters of fatty acid-containing products, dermal, eye and respiratory irritation effects are addressed through precautionary labeling requirements for use of Personal Protective Equipment (PPE). For the one registration for methyl esters of fatty acids, the PPE required on the label is long sleeved shirts, long pants, and shoes plus socks. In addition, the label must require the use of an organic-vapor respirator during application of the product to protect from chemical pneumonia from inhalation exposure.

## **B. Ecological Risk Assessment**

The Agency has considered the ecological risks associated with the use of methyl esters of fatty acids. Ornamentals such as cotoneaster, juniper, ligustrum, rhamnus, and taxus (yew) are included on the methyl esters of fatty acids label and could be grown inside or outside of greenhouses. According to usage information azaleas grown inside greenhouses are the primary application site. Up to 10% of the total amount, or roughly 1,000 pounds of active ingredient, were estimated to be applied to ornamentals outside of greenhouses. A screening level (Tier I) risk assessment was completed to evaluate the potential risk to aquatic and terrestrial organisms using an application rate calculated from use information, label instructions, and adjusted to consider the directed spray method of application to ornamentals inside and outside greenhouses (1.914 lbs a.i./A). The application rate was translated from a per plant rate into a per acre rate because this is the format that the screening model requires.

Aquatic exposure modeling using GENEEC2 provided an acute peak 1-in-10 year estimated environmental concentration (EEC) of 42  $\mu\text{g/l}$ . Comparing the aquatic EEC of 42  $\mu\text{g/l}$  to the most sensitive acute toxicity endpoint available, the daphnid  $\text{EC}_{50}$  of 1.7 mg a.i./L, yields a risk quotient (RQ) of 0.02, which is below the level of concern (LOC) of 0.5 for aquatic species and also below the endangered species LOC of 0.05. From this assessment, the acute risks to aquatic species are presumed to be minimal.

Terrestrial dietary exposures for methyl esters of fatty acids were estimated using the Tier-1 model, T-REX Version 1.2.3. Assuming a single application of 1.914 lbs a.i./A, the upper-bound residues on food items, such as vegetation and insects, range from approximately 29 to 459 ppm. Acute risks to mammals appear to be minimal, given the rat acute oral  $\text{LD}_{50}$  is greater than 5000 mg/kg. No acute or chronic avian toxicity data are available. Based on this screening level assessment acute risks to aquatic organisms and terrestrial mammals are presumed to be minimal.

#### IV. Risk Management and Reregistration Decision

The Agency has determined that the methyl esters of fatty acids are eligible for reregistration provided that the risk mitigation measures and label amendments specified in this RED are implemented. The following is a summary of the rationale for managing risks associated with the use of the methyl esters of fatty acids.

Summary of risk mitigation measures:

- Increase the REI from 4 to 12 hours.
- Add an organic-vapor respirator for all mixers, loaders, and applicators.

##### *Human Health Risks*

No dermal, oral, or inhalation endpoints of toxicological concern were identified for methyl esters of fatty acids; therefore, no quantitative human health risk assessment was performed. However, based on an acute inhalation toxicity study there is a potential concern of chemical pneumonia for occupational handlers especially when used in enclosed areas like greenhouses. To reduce the potential risk of pneumonia from inhalation exposure, EPA will require the use of an organic-vapor respirator during mixing, loading, and application.

The current REI for methyl esters of fatty acids is 4 hours. Based on the concern for chemical pneumonia, the REI will be increased to 12 hours unless and until acceptable data as identified in this determination are submitted and support a lower REI.

##### *Ecological Risks*

From the screening level ecological risk assessment, the potential acute risks to aquatic and terrestrial organisms assessed are below all levels of concern including endangered species levels of concern. Based on the low toxicity for the species included in the screening level assessment, the limited use of the methyl esters of fatty acids outside of greenhouses, and the directed application of this chemical to ornamentals in and around greenhouses, the acute and chronic risks to other aquatic and terrestrial species not assessed are expected to be minimal.

There is no data to assess risk to birds, but based on data on other salts of fatty acids that indicate that this group of compounds are practically non toxic to birds, and that the methyl esters of fatty acids as approved flavoring agents in human food under 21 CFR 172 and can be used in animal feeds are per 21 CFR 573, no additional avian data is required at this time. From the results of this screening level assessment, adverse ecological effects are not expected and no ecological risk mitigation is required.

## 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 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 the methyl esters of fatty acids “may affect” listed species or their designated critical habitat, EPA will employ the provisions in the Services regulations (50 CFR Part 402).

Based upon the screening-level assessment conducted on the methyl esters of fatty acids, 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 mammals, or freshwater fish and invertebrates. Acute toxicity data were not available to assess potential risks to birds, aquatic or terrestrial plants, or estuarine/marine fish and invertebrates, and chronic toxicity data were not available for any taxon. The low acute risk to freshwater animals suggests that chronic risk to freshwater animals from methyl esters of fatty acids may be unlikely. Similarly, since risk to freshwater animals is likely to be minimal, the Agency does not anticipate risk to estuarine/marine animals. Given the method of application and the minimal outdoor use of methyl esters of fatty acids, risks to birds and non-target plants may be minimal. Nevertheless, due to the lack of toxicity data, the Agency cannot preclude acute risks to birds, aquatic and terrestrial plants, estuarine/marine fish and invertebrates, or chronic risk to any taxon (*i.e.*, freshwater animals, estuarine/marine animals, birds, mammals).

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 freshwater animals, estuarine marine animals, birds, mammals, and aquatic and terrestrial plants cannot be precluded, indirect effects to listed species which rely on these taxa can also not be dismissed.



## V. What Registrants Need to Do

The Agency has determined that the products containing methyl esters of fatty acids (PC 079034) are eligible for reregistration provided that the mitigation measures and label changes identified in this RED are implemented. Registrants will need to amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table 5. The Agency intends to issue a Data Call-In (DCI) requiring product specific data. For product-specific data, the registrant will have eight months to submit data and amended labels.

### Manufacturing Use Products

#### Additional Generic Data Requirements

The generic database supporting the reregistration of the methyl esters of fatty acids for the eligible uses has been reviewed and determined to be complete. No additional data are required.

### 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 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 5.

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

<b>Table 5: Summary of Labeling Changes for the Methyl Esters of Fatty Acids</b>		
<b>Description</b>	<b>Amended Labeling Language</b>	<b>Placement on Label</b>
Manufacturing-Use Products		
Required on all MUPs	“Only for formulation into a plant growth regulator for the following use(s) [fill blank only with those uses that are being supported by MP registrants].”	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.	<p>“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).”</p> <p>“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).”</p>	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 Pollutant 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. Do not contaminate water when disposing of equipment wash-waters.”	Directions for Use
End Use Products Intended for Occupational Use		
PPE Requirements Established by the RED <sup>1</sup> for liquid (including	<p>“Personal Protective Equipment (PPE)”</p> <p>“All mixers, loaders, applications and other handlers must wear:</p>	Immediately following/below Precautionary Statements:

<p>emulsifiable concentrate) formulations</p>	<p>&gt; Long-sleeved shirt and long pants,          &gt; Shoes plus socks, and          &gt; A NIOSH-approved respirator with          -- an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or          -- a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or          -- an organic-vapor cartridge or canister with any N*, R or P or He prefilter.”</p> <p><i>* Note to Registrant:</i> Drop the “N” type prefilter from the respirator statement, if the pesticide product contains, or is used with, oil.</p>	<p>Hazards to Humans and Domestic Animals</p>
<p>User Safety Requirements</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>	<p>Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements</p>
<p>User Safety Recommendations</p>	<p>“User Safety Recommendations</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: Hazards to Humans and Domestic Animals immediately following Engineering Controls</p> <p>(Must be placed in a box.)</p>

	* Remove the gloves statement if the end use product does not require gloves based on the product acute toxicity tests.	
Environmental Hazards	“Keep out of lakes, ponds, or streams. Do not contaminate water by cleaning of equipment or disposal of wastes.”	Precautionary Statements immediately following the User Safety Recommendations
Restricted-Entry Interval for products with directions for use within scope of the Worker Protection Standard for Agricultural Pesticides (WPS)	“Do not enter or allow worker entry into treated areas during the restricted entry interval (REI) of 12 hours.”	Directions for Use, Under Agricultural Use Requirements Box
Early Entry Personal Protective Equipment for products with directions for use within the scope of the WPS	“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 plants, soil, or water, is: * coveralls, * shoes plus socks, * chemical-resistant gloves made of any waterproof material.”	Direction for Use Agricultural Use Requirements box
General Application Restrictions	“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 directly above the Agricultural Use Box.

<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.

## **Appendices**

**Appendix A: Use Patterns Subject to Reregistration of Aliphatic Esters**

<b>Active ingredient</b>	<b>Commodity</b>	<b>Site</b>	<b>Application</b>	<b>Formulation</b>	<b>Application Equipment</b>	<b>Directions for Use</b>
Methyl esters of Fatty Acids (PC 079034)	Ornamentals: azalea, cotoneaster, juniper, ligustrum, rhamnus, taxus (yew)	Inside and outside greenhouses	Spray until the growing tips are covered.	Emulsifiable Concentrate	Handgun sprayers High and Low pressure handwands	Do not re-spray plants; one spray application per pinch. Do not re-spray plants within 24 hours.

## Appendix B. Table of Generic Data Requirements and Studies Used to Make the Reregistration Decision

### GUIDE TO APPENDIX B

Appendix B contains a listing of data requirements which support the reregistration for active ingredients within the dodine case covered by this RED. It contains generic data requirements that apply dodine in all products, including data requirements for which a “typical formulation” is the test substance.

The data table is organized in the following formats:

1. Data requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR 158. The reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidance, which is available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. (703) 487-4650.
2. Use Pattern (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns.
  - A. Terrestrial food
  - B. Terrestrial feed
  - C. Terrestrial non-food
  - D. Aquatic food
  - E. Aquatic non-food outdoor
  - F. Aquatic non-food industrial
  - G. Aquatic non-food residential
  - H. Greenhouse food
  - I. Greenhouse non-food
  - J. Forestry
  - K. Residential
  - L. Indoor food
  - M. Indoor non-food
  - N. Indoor medical
  - O. Indoor residential
3. Bibliographic Citation (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a “GS” number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.

Data Requirement			Use Patterns	Citations
New Guideline Number	Old Guideline Number	Description		
<b>PRODUCT CHEMISTRY</b>				
830.1550	61-1	Product Identity and Composition	All	41785501
830.1600	61-2A	Description of materials used to produce the product	All	41785501
830.1620	61-2B	Description of production process	All	41785501
830.1670	61-2B	Formation of Impurities	All	41785501
830.1750	62-0	Certification of Limits	All	41785501
830.1800	62-3	Analytical Method	All	41785501
830.7000	63-12	pH	All	41785501
830.7200	63-5	Melting Point	All	41785501
830.7300	63-7	Density	All	41785501
830.7370	63-10	Dissociation Constants in Water	All	41785501
830.7550	63-11	Partition coefficient, shake flask method	All	41785501
830.7840	63-8	Solubility	All	41785501
830.7950	63-9	Vapor Pressure	All	41785501
<b>ECOLOGICAL EFFECTS</b>				
850.1075	72-1A	Fish Toxicity Bluegill	A, B, D	43246701
850.1010	72-2A	Freshwater Invertebrate Toxicity	A, B, D	43465501
<b>TOXICOLOGY</b>				
870.1100	81-1	Acute Oral Toxicity - Rat	All	43334501
870.1200	81-2	Acute Dermal Toxicity – Rabbit/Rat	All	43334502
870.1300	81-3	Acute Inhalation Toxicity – Rat	All	43334505
870.1400	81-4	Primary Eye Irritation - Rabbit	All	43334503
870.2500	81-5	Primary Skin Irritation	All	43334504
870.2600	81-6	Dermal Sensitization	All	43334505
870.5385		Mammalian Bone Marrow Chromosomal Aberration Test	A, B, D	43334507
<b>ENVIRONMENTAL FATE</b>				
835.4100	162-1	Aerobic Soil Metabolism	A, B, D	42198001
835.4300	162-4	Aerobic Aquatic Metabolism	A, B, D	42198001



## Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, EPA-HQ-OPP-2007-0235.

It is open Monday through Friday, excluding legal holidays, from 8:30 am to 4 pm.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: [www.epa.gov/pesticides/reregistration](http://www.epa.gov/pesticides/reregistration)

These documents include:

### HED Document:

Aliphatic Esters: Human Health Chapter of the Reregistration Eligibility Decision (RED) Document. Reaves, E., Recore, S., and Barnes, Y., D330299, 6/30/2006.

### EFED Document:

Revised Ecological Risk Assessment for Use in Methyl Esters of Fatty Acids in Greenhouses. Corbin, M., and Flaherty, C., D336252, 2/8/2007.

## Appendix D. Citations Considered to be Part of the Data Base Supporting the Reregistration Eligibility Decision

MRID	Citation Reference
62728	Procter & Gamble (19??) Procter & Gamble Tobacco Sucker Control Agent No. 120. ? : Procter & Gamble. (Also~In~unpublished submission received Jun 4, 1968 under 3573-18; CDL:229498-A)
120754	Procter & Gamble Co. (1967) Technical Information Support for the Registration of Off-Shoot-T Tobacco Sucker Control Agent. (Un- published study received Oct 3, 1967 under 3573-18; CDL: 007260-B)
120755	Procter & Gamble Co. (1967) ?Efficacy of Chemical Pruning Agents on Tobacco and Other Crops . (Compilation; unpublished study received Oct 3, 1967 under 3573-23; CDL:007261-A)
120756	Procter & Gamble Co. (1967) Technical Information Support for the Registration of Off-Shoot-O Chemical Pinching Agent for Ornamentals. (Unpublished study received Oct 3, 1967 under 3573-23; CDL:007261-B)
120757	Conklin, E. (1967) First Quarterly Report on the Progress of the Experimental Program for Off-Shoot, Chemical Pruning Agent for Ornamentals. (Unpublished study received Oct 26, 1967 under 3573-23; submitted by Procter & Gamble Co., Cincinnati, OH; CDL:007262-A)
120758	Procter & Gamble Co. (1959?) Toxicity Data: ?Tobacco Sucker Control Agent No. 120 . (Unpublished study received Mar 7, 1967 under 3573-EX-1; CDL:127013-A)
120760	Procter & Gamble Co. (1967) ?Efficacy of Chemical Sucker Control Agents on Tobacco . (Compilation; unpublished study received Mar 7, 1967 under 3573-EX-1; CDL:127013-C)
41785500	Cochran Corp. (1991) Submission of Data To Support Reregistration of "Off-Shoot-O," Chemical Pinching Agent for Ornamentals: Product Chemistry Study. Transmittal of 1 study.
41785501	Hathaway, H. (1991) Reregistration of "Off-Shoot-O," Chemical Pinching Agent for Ornamentals Active: Methyl esters of Fatty Acid (C6-C12). Unpublished study prepared by Cochran Corp. 14 p.
42198000	Cochran Corp. (1992) Submission of environmental fate data in support of reregistratrion of Off-Shoot-O, chemical pinching agent for ornamentals. Transmittal of 1 study.
42198001	Christensen, K. (1992) A Literature Review of Biodegradability and Adsorption/Leachability of Fatty Acids and Fatty Acid Esters. Unpublished study prepared by Springborn Labs., Inc. 13 p.
43185400	Cochran Corp. (1994) Submission of Product Chemistry Data for Off-Shoot-O in Support of Reregistration. Transmittal of 1 study.
43185401	Hathaway, H. (1994) Octanol/Water Partition Coefficient Work to Upgrade MRID 41785501 Submission to Guideline Acceptability by Providing a Value in Accordance with 45FR77350, 11-21-80: (Methyl Esters of Fatty Acids). Unpublished study prepared by Cochran Corp. Lab. 5 p.
43246700	Cochran Corp. (1994) Submission of toxicology data in support of reregistration of methyl esters of fatty acids. Transmittal of 1 study.
43246701	McGeehan, R.; Carlock, L. (1994) Methyl Esters of Fatty Acids: Freshwater Fish Toxicity with Bluegill Sunfish, <i>Lepomis macrochirus Rafinesque</i> : Lab Project Number: 11506/25/63. Unpublished study prepared by Union Carbide Environmental Services Toxicity Lab. 25 p.

- 43334500 Cochran Corp. (1994) Submission of toxicity data in support of data call-in for reregistration of Methyl Esters of Fatty Acids. Transmittal of 7 studies.
- 43334501 Jackson, D.; Ogilvie, S. (1994) Methyl Esters of Fatty Acids (C6-C12): Acute Oral Toxicity (Limit) Test in Rats: Lab Project Number: 555719: 94017/COCH: 10481. Unpublished study prepared by Inveresk Research International. 77 p.
- 43334502 Jackson, D.; Ogilvie, S. (1994) Methyl Esters of Fatty Acids (C6-C12): Acute Dermal Toxicity (Limit) Test in Rabbits: Lab Project Number: 555703: 94018/COCH: 10482. Unpublished study prepared by Inveresk Research International. 37 p.
- 43334503 Jackson, D.; Ogilvie, S. (1994) Methyl Esters of Fatty Acids (C6-C12): Primary Eye Irritation Test in Rabbits: Lab Project Number: 555698: 94019/COCH: 10484. Unpublished study prepared by Inveresk Research International. 39 p.
- 43334504 Jackson, D.; Ogilvie, S. (1994) Methyl Esters of Fatty Acids (C6-C12): Primary Skin Irritation Test in Rabbits: Lab Project Number: 555682: 94020/COCH: 10483. Unpublished study prepared by Inveresk Research International. 37 p.
- 43334505 McGeehan, R.; Kemman, R. (1994) Literature Review on Methyl Esters of Fatty Acids. Unpublished study prepared by Compliance Services International. 180 p.
- 43334506 Palmer, S.; Beavers, J. (1994) Methyl Esters of Fatty Acids: An Acute Contact Toxicity Study with the Honey Bee: Final Report: Lab Project Number: 392/101. Unpublished study prepared by Wildlife International Ltd. 15 p.
- 43334507 Carlock, L.; McGeehan, R. (1994) Methyl Esters of Fatty Acids: Chromosome Aberration (Bone Marrow) Test in Chinese Hamsters. Unpublished study prepared by Compliance Services International. 19 p.
- 43465500 Cochran Corporation (1994) Submission of Toxicity Data in Support of the Reregistration of Methyl Esters of Fatty Acids. Transmittal of 1 Study.
- 43465501 Davis, J.; Kernaghan, N. (1994) Methyl Esters of Fatty Acids: Acute Toxicity to the Water Flea, *Daphnia magna*, Under Static Conditions: Lab Project Numbers: J9402004B: 94016-COCH: J9402004A. Unpublished study prepared by Toxikon Environmental Sciences. 89 p.
- 43474700 Cochran Corp. (1994) Submission of Hazard to Non-target Plants Data in Support of Reregistration of Fatty Acids. Transmittal of 1 Study.
- 43474701 Kranzfelder, J. (1994) Methyl Esters of Fatty Acids ("Off-Shoot-O"): Seed Germination/Seedling Emergence: Lab Project Number: J9402004C: 94021-COCH. Unpublished study prepared by Toxikon Environmental Sciences. 108 p.
- 94029000 Cochran Corporation (1990) Reregistration Phase 3 Response: Methyl esters of fatty acids (100% C8 - C12).
- 94029999 Cochran Corporation (1990) Reregistration Phase 3 Response: Methyl esters of fatty acids (100% C8 - C12). Correspondence and Supporting Material.

**Appendix E. List of Available Related Documents and Electronically Available Forms**

Pesticide Registration Forms are available via the Agency’s website at <http://www.epa.gov/opprd001/forms/>.

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

**Instructions**

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed).
2. The completed form(s) should be submitted in hard copy in accord with the existing policy.
3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing ‘Confidential Business Information’ or ‘Sensitive Information.’

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at [williams.nicole@epa.gov](mailto:williams.nicole@epa.gov).

The following Agency Pesticide Registration Forms are currently available via the Internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	<a href="http://www.epa.gov/opprd001/forms/8570-1.pdf">http://www.epa.gov/opprd001/forms/8570-1.pdf</a>
8570-4	Confidential Statement of Formula	<a href="http://www.epa.gov/opprd001/forms/8570-4.pdf">http://www.epa.gov/opprd001/forms/8570-4.pdf</a>
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	<a href="http://www.epa.gov/opprd001/forms/8570-5.pdf">http://www.epa.gov/opprd001/forms/8570-5.pdf</a>
8570-17	Application for an Experimental Use Permit	<a href="http://www.epa.gov/opprd001/forms/8570-17.pdf">http://www.epa.gov/opprd001/forms/8570-17.pdf</a>
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	<a href="http://www.epa.gov/opprd001/forms/8570-25.pdf">http://www.epa.gov/opprd001/forms/8570-25.pdf</a>
8570-27	Formulator’s Exemption Statement	<a href="http://www.epa.gov/opprd001/forms/8570-27.pdf">http://www.epa.gov/opprd001/forms/8570-27.pdf</a>
8570-28	Certification of Compliance with Data Gap Procedures	<a href="http://www.epa.gov/opprd001/forms/8570-28.pdf">http://www.epa.gov/opprd001/forms/8570-28.pdf</a>
8570-30	Pesticide Registration Maintenance Fee Filing	<a href="http://www.epa.gov/opprd001/forms/8570-30.pdf">http://www.epa.gov/opprd001/forms/8570-30.pdf</a>
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	<a href="http://www.epa.gov/opprd001/forms/8570-32.pdf">http://www.epa.gov/opprd001/forms/8570-32.pdf</a>
8570-34	Certification with Respect to Citations of Data (PR Notice 98-5)	<a href="http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf</a>
8570-35	Data Matrix (PR Notice 98-5)	<a href="http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf">http://www.epa.gov/oppmsd1/PR_Notices/pr98-5.pdf</a>
8570-36	Summary of the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf</a>
8570-37	Self-Certification Statement for the Physical/Chemical Properties (PR Notice 98-1)	<a href="http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf">http://www.epa.gov/oppmsd1/PR_Notices/pr98-1.pdf</a>

**Pesticide Registration Kit** <http://www.epa.gov/pesticides/registrationkit/>

Dear Registrant:

For your convenience, we have assembled an online registration kit which contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.
2. Pesticide Registration (PR) Notices
  - a. 83-3 Label Improvement Program--Storage and Disposal Statements
  - b. 84-1 Clarification of Label Improvement Program
  - c. 86-5 Standard Format for Data Submitted under FIFRA
  - d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)
  - e. 87-6 Inert Ingredients in Pesticide Products Policy Statement
  - f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement
  - g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments
  - h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

Other PR Notices can be found at <http://www.epa.gov/opppmsd1/PR Notices>

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader).
  - a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment
  - b. EPA Form No. 8570-4, Confidential Statement of Formula
  - c. EPA Form No. 8570-27, Formulator's Exemption Statement
  - d. EPA Form No. 8570-34, Certification with Respect to Citations of Data
  - e. EPA Form No. 8570-35, Data Matrix
4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader).
  - a. Registration Division Personnel Contact List
  - b. Biopesticides and Pollution Prevention Division (BPPD) Contacts
  - c. Antimicrobials Division Organizational Structure/Contact List
  - d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)
  - e. 40 CFR §156, Labeling Requirements for Pesticides and Devices (PDF format)
  - f. 40 CFR §158, Data Requirements for Registration (PDF format)
  - g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' website.
2. The booklet "General Information on Applying for Registration of Pesticides in the United States," PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

National Technical Information Service (NTIS)  
5285 Port Royal Road  
Springfield, VA 22161-0002

The telephone number for NTIS is (703) 605-6000.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their website.
4. The National Pesticide Information Center (NPIC) can provide information on active ingredients, uses, toxicology and chemistry of pesticides. You can contact NPIC by telephone at (800) 858-7378 or through their website at <http://www.ncis.orst.edu>.

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

- Date of receipt;
- EPA identifying number; and
- Product Manager assignment.

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying file symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a chemical abstract system (CAS) number if one has been assigned.