US Environmental Protection Agency
Office of Pesticide Programs

BIOPESTICIDES REGISTRATION ACTION DOCUMENT

Octanoate Esters

Sucrose Octanoate Esters (PC Code 035300)

Sorbitol Octanoate (PC Code 035400)

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U.S. Environmental Protection Agency
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BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

Office of Pesticide Programs:

Biopesticides and Pollution Prevention Division

Biochemical Pesticides Branch

Sheryl K. Reilly, Ph.D.	Biologist, Branch Chief
Denise Greenway	Biologist, Regulatory Action Leader
Todd Peterson, Ph.D.	Biologist, Regulatory Action Leader
Linda Hollis	Microbiologist, Team Leader
Russell S. Jones, Ph.D.	Senior Biologist, Health Effects/Nontarget Organisms
Roy Sjoblad, Ph.D.	Biologist, Health Effects/Nontarget Organisms
Freshteh Toghrol, Ph.D.	Chemist, Senior Scientist

II. Executive Summary

This Biopesticides Registration Action Document (BRAD) was originally published in 2002 for a single active ingredient, Sucrose Octanoate Esters. With the addition of a new octanoate active ingredient (Sorbitol Octanoate), the BRAD is now revised and entitled Octanoate Esters. This edition of the BRAD now covers two active ingredients, Sucrose Octanoate Esters and Sorbitol Octanoate.

A. IDENTITY

The sucrose octanoate esters technical grade active ingredient (TGAI)/manufacturing-use product (MUP), AAvachem Sucrose Octanoate Manufacturing Use Product@ (EPA Registration Number 70950-1), registration was cancelled on July 21, 2005. It consisted of 85.43% sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate], made from a caprylic fatty acid ester derived from an edible oil or fat, and sucrose, a sugar which is a regular part of the diet of humans and animals. The end-use product (EP), AAvachem Sucrose Octanoate [40.0%]@ (EPA Registration Number 70950-2), contains 40.0% sucrose octanoate esters.

The sorbitol octanoate TGAI/MUP, AAvachem Sorbitol Octanoate Manufacturing Use Product@ (EPA File Symbol 70950-U) and the EP, AAvachem Sorbitol Octanoate [90.0%]@ (EPA File Symbol 70950-G) both contain 90.0% sorbitol octanoate as the active ingredient. Sorbitol octanoate [D-Glucitol, octanoate] is not a naturally occurring compound, but is derived as a sugar ester synthesized via the condensation of a sorbitol (a naturally-occurring sugar alcohol) with octanoic acid (a naturally occurring fatty acid). The active ingredient is an oily liquid that is miscible in water, forming a stable emulsion when shaken.

B. USE/USAGE

AAvachem Sucrose Octanoate [40.0%]@ is applied as a spray for use on a) various crops to control soft-bodied insects and mites, b) mushroom growing media to control sciarid flies, and c) adult honey bees to control *Varroa* mites. The use is classified as a food crop application.

AAvachem Sorbitol Octanoate [90.0%]@ is to be used for spray treatments in greenhouses and on nursery and field crops to control or suppress soft-bodied pests (insects and mites).

C. RISK ASSESSMENT

No unreasonable adverse effects on humans or the environment are anticipated from aggregate exposure to: 1) AAvachem Sucrose Octanoate Manufacturing Use Product@ (now cancelled) or AAvachem Sucrose Octanoate [40.0%]@, or 2) AAvachem Sorbitol Octanoate Manufacturing Use Product@ or AAvachem Sorbitol Octanoate [90.0%]@. This includes all anticipated exposures for which there is reliable information.

1. Human Health Risk Assessment

a. Toxicological Endpoints

No toxicological endpoints are expected. Mammalian toxicology information from the open scientific literature and data were submitted to adequately satisfy data requirements to support registration.

Sucrose Octanoate Esters: Submitted information and data for the TGAI/MUP and the EP indicate Toxicity Category IV for acute oral, acute dermal, and acute inhalation toxicity; and for primary dermal irritation. Neither the TGAI/MUP (product registration now cancelled), nor the EP, is a dermal sensitizer. The data reported for primary eye irritation studies show that the test substance was moderately to severely irritating, and is thus Toxicity Category II when the EP is tested and Toxicity Category I when the TGAI/MUP is used.

Sorbitol Octanoate: Submitted information and data for the TGAI/MUP and the EP indicate Toxicity Category IV for acute oral, acute dermal, and acute inhalation toxicity; and for primary dermal irritation. Neither the TGAI/MUP, nor the EP, is a dermal sensitizer. The data reported for primary eye irritation show that the test substance was severely irritating and is Toxicity Category II for both the TGAI/MUP and the EP.

b. Human Exposure

While exposure to the general population is expected to be low, worker exposure will occur. Appropriate protective wear and precautionary label language will mitigate vulnerability to the worker.

c. Risk Assessment

The Biopesticides and Pollution Prevention Division (BPPD) has not identified any subchronic, chronic, immune, endocrine, dietary or nondietary exposure issues with respect to octanoate esters as relates to children or the general U.S. population. Ocular risk to applicators is mitigated providing the label directions are followed. No toxicological endpoints are expected, and there is limited exposure of the general public to octanoate esters products when used according to the label instructions. The Agency has considered octanoate esters in light of relevant safety factors in the Food Quality Protection Act (FQPA) of 1996 and under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and determined there will be no unreasonable adverse effects from the use of these products.

2. Ecological Risk Assessment

a. Ecological Toxicity Endpoints

Data waivers were requested and granted for ecological testing requirements because no toxic endpoints are expected for octanoate esters, based on submitted mammalian data and information from the open scientific literature. An acute contact honey bee toxicity study demonstrated that sucrose octanoate esters are practically non-toxic to honey bees ($LD_{50} > 80$ µg/bee).

b. Ecological Exposure

The active ingredients do not persist in the environment and biodegrade quickly. Sucrose octanoate degrades within approximately five days at approximately 20-27EC, in both aerobic and anaerobic conditions. Sorbitol octanoate biodegrades with an apparent post-application half-life of approximately 7 to 10 days.

c. Risk Assessment

Risk to other organisms is expected to be minimal due to the low chances of exposure to the environment. The Agency posits octanoate esters products, used according to label directions, will not result in significant adverse effects to wildlife or other organisms.

D. DATA GAPS / LABELING

There are no data gaps. Certain precautionary labeling is required for octanoate esters products to mitigate risks associated with ocular exposure (results of primary eye irritation testing placed the active ingredients sucrose octanoate and sorbitol octanoate in Toxicity Categories I and II, respectively; see Labeling Rationale for details).

II. Overview

E. ACTIVE INGREDIENT OVERVIEW

Common Name:	Sucrose octanoate esters	Sorbitol octanoate
Chemical Name:	Sucrose octanoate esters [(α-D-glucopyranosyl, β-D-fructofuranosyl-octanoate), mono, di-, and triesters of sucrose octanoate]	Sorbitol octanoate [D-Glucitol, octanoate]
CAS Numbers:	42922-74-7 and 58064-47-4	108175-15-1
Trade and Other Names:	Avachem Sucrose Octanoate Manufacturing Use Product (cancelled), Avachem Sucrose Octanoate [40.0%]	Avachem Sorbitol Octanoate Manufacturing Use Product, Avachem Sorbitol Octanoate [90.0%]
OPP Chemical Code:	035300	035400
Basic Manufacturer:	Manufactured for: AVA Chemical Ventures, L.L.C. 80 Rochester Avenue Suite 214 Portsmouth, NH 03801	

B. USE PROFILE

Proposed uses and application methods for octanoate esters include the following:

	Sucrose octanoate esters	Sorbitol octanoate
Type of Pesticide:	Biochemical insecticide/miticide	Biochemical insecticide/miticide

Use Sites:	Field, greenhouse, and nursery use on any type of agricultural commodity (including certain non-food ornamentals); as well as on mushroom growing media and on adult honey bees.	Field, greenhouse, and nursery use on any type of agricultural commodity (including certain non-food ornamentals).
Formulation Types:	Liquid	Liquid
Method and Rates of Application:	Most conventional ground spray application equipment may be used. Shake or stir before use, adding the appropriate quantity to water, with agitation. Maintain gentle agitation during application. The proposed label specifies application rates a) between 0.8% and 1.0% volume/volume (v/v) for foliarly applied spray, b) between 1.25% and 2.50% v/v for mushroom growing media, and c) of 0.625% v/v for application to honey bees.	Apply by ground spray equipment (e.g. ground boom, air blast). Shake or stir before use, adding the appropriate quantity to water, with agitation. Maintain gentle agitation during application. The proposed label specifies application rates of 0.5% volume/volume (v/v) for all use sites.
Use Practice Limitations:	Do not allow workers into treated areas for 48 hours following application.	Do not allow workers into treated areas for 24 hours following application.
Timing:	Application to foliage or adult honey bees should be initiated as soon as the target pest is observed. Mushroom growing media applications are to be made prior to spawning.	Initiate applications as soon as pest pressure is observed. Repeat applications, as necessary, at intervals of 7 - 10 days.

C. ESTIMATED USAGE

Sucrose Octanoate Esters: The sucrose octanoate esters MUP (now cancelled) and EP were both granted section 3(c)(5) registration on September 16, 2002. Although the Experimental Use Permit (EUP) issued in 2000 allowed the application 25 gallons of active ingredient over 50 acres in the state of California, no sucrose octanoate esters were actually applied under the experimental program (due to the unexpected unavailability of the test plot acreage). The EUP issued in 2002 allowed the application of 33 gallons of active ingredient over 100 acres in the state of California.

Sorbitol Octanoate: None used yet since this is the first registration of this new active ingredient.

D. DATA REQUIREMENTS

BPPD reviewed data requirements for granting this registration under Section 3(c)(5) of FIFRA. Mammalian toxicology and ecological effects data requirements for octanoate esters were fulfilled. Product analysis data requirements are adequately satisfied.

E. REGULATORY HISTORY

Sucrose Octanoate Esters:
On February 23, 1999, EPA received an application from AVA Chemical Ventures, L.L.C. for two new products with the new active ingredient, sucrose octanoate. A notice of receipt of the application for registration of sucrose octanoate (C_8 fatty acid mono-, di- and triesters of sucrose octanoate and sucrose dioctanoate) (α-D-glucopyranoside, β-D-fructofuranosyl, monooctanoate and dioctanoate) was published in the Federal Register on August 11, 1999 (64 FR 43701) with a 30-day comment period. No comments were received following this publication.

Note that the Agency and the registrant agreed to represent the active ingredient name as sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] on the product labels and Confidential Statements of Formula and the tolerance exemption expression. This name is synonymous with the name used in the Federal Register notice of receipt of August 11, 1999 (64 FR 43701).

On September 9, 1999, EPA published a Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals (sucrose fatty acid esters) in or on Food (8E4926, 64 FR 49010) with a 30-day comment period. No comments were received.

The EPA determined that the designation Asucrose fatty acid esters@ is too broad, in that it could include other compounds not intended by the registrant, and for which the Agency has not reviewed relevant data. The data and information submitted by the registrant in support of the petition cover an exemption from the requirement of a tolerance for sucrose octanoate esters, which have been identified as the specific type of sucrose fatty acid esters that act as the active ingredient in the registrant=s pending products. EPA=s general policy is to establish a tolerance or exemption from the requirement of a tolerance for the actual active ingredient contained in the registrant=s products. Because the active ingredient for which the registrant actually is petitioning is technically defined as sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate], all discussions in this document (and the tolerance exemption expression established in the associated Final Rule for this active ingredient) refer only to Asucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate]. Hereinafter EPA uses the term Asucrose octanoate esters@ to mean sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate].

On August 14, 2000, EPA received an application from the United States Department of Agriculture=s Agricultural Research Service (USDA/ARS) for an Experimental Use Permit (EUP) covering the use of sucrose octanoate esters to evaluate control of the glassy-winged sharp shooter on non-bearing grape vines. On September 15, 2000, the Agency granted the EUP (65 FR 76259) to use 25 gallons/year of the biochemical active ingredient sucrose octanoate esters on 50 acres in the state of California.

On April 24, 2002, EPA received an application from AVA Chemical Ventures, L.L.C., on the behalf of the USDA/ARS, for a new Experimental Use Permit (EUP) covering the use of sucrose octanoate esters to evaluate control of the glassy-winged sharp shooter on non-bearing/post harvest citrus in addition to non-bearing grape vines. On May 31, 2002, the Agency granted the EUP (67 FR 43598) to use 33 gallons/year of the biochemical active ingredient sucrose octanoate esters on 100 acres in the state of California.

On September 25, 2002, EPA published a final rule (67 FR 60146) which established at 40 CFR '180.1222 an exemption from the requirement of a tolerance for residues of sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] in or on all food commodities.

On December 4, 2002, EPA published a Notice of Registration Approval (67 FR 72172) announcing the September 16, 2002 section 3(c)(5) registration of the two applications for pesticide products [EPA Registration Numbers 70950-1(now canceled) and 70950-2] containing an active ingredient not included in any previously registered products.

Sorbitol Octanoate:
On December 5, 2001, EPA received an application from AVA Chemical Ventures, L.L.C. for two new products with the new active ingredient, sorbitol octanoate. A notice of receipt of the application for registration of sorbitol octanoate was published in the Federal Register on September 29, 2004 (69 FR 58164) with a 30-day comment period. No comments were received following this publication.

On September 29, 2004, EPA published a Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical (sorbitol octanoate) in or on Food (2E6389, 69 FR 58166) with a 30-day comment period. No comments were received.

F. CLASSIFICATION

Sucrose Octanoate Esters: On January 14, 1997, the Biochemical Classification Committee determined that the insecticide/miticide sucrose octanoate esters are functionally identical and structurally similar to naturally occurring sucrose fatty acid esters, and so are eligible for testing using the biochemical reduced data requirements. Following review of the full data set submitted in support of the registration applications, which demonstrated a non-toxic, indirect mode of action for the active ingredient, the committee on July 2, 2002, amended the report by granting the Abiochemical pesticide@ designation to sucrose octanoate esters (Ref. 1).

Sorbitol Octanoate: On February 28, 2001, the Biochemical Classification Committee determined that the insecticide polyol esters (C_8/ C_{10} fatty acid esters of sorbitol) are very similar to sucrose octanoate esters (currently classified as a biochemical) and have a non-toxic mode of action. Sorbitol octanoate was designated as a biochemical.

G. FOOD CLEARANCES/TOLERANCES

Sucrose Octanoate Esters: On September 25, 2002, EPA published a final rule (67 FR 60146) which established at 40 CFR '180.1222 an exemption from the requirement of a tolerance for residues of sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] in or on all food commodities. There are no Codex tolerances for sucrose octanoate esters.

Sorbitol Octanoate: On September 29, 2004, EPA published a Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical (sorbitol octanoate) in or on Food (2E6389, 69 FR 58166) with a 30-day comment period. No comments were received. A final rule establishing an exemption from the requirement of a tolerance is being published in association with this document. There are no Codex tolerances for sorbitol octanoate

III. Science Assessment

A. PHYSICAL/CHEMICAL PROPERTIES ASSESSMENT

All product chemistry data requirements for the octanoate esters technical grade/manufacturing-use products and the end-use products are met.

1. Product Identity and Mode of Action

a. Product Identity:

Sucrose Octanoate: The technical grade active ingredient/manufacturing-use product, AAvachem Sucrose Octanoate Manufacturing Use Product@ (cancelled), consisted of 85.43% sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] and the end-use product, AAvachem Sucrose Octanoate [40.0%],@ 40% sucrose octanoate esters.

Sorbitol Octanoate: The technical grade active ingredient/manufacturing-use product, AAvachem Sorbitol Octanoate Manufacturing Use Product@ and end use product, AAvachem Sorbitol Octanoate [90.0%]@ both consist of 90.0% sorbitol octanoate esters [D-Glucitol, octanoate].

b. Mode of Action:

Sucrose Octanoate: The mode of action is physical and non-toxic; the surfactant effect of sucrose octanoate esters de-waxes the cuticle of the target pest, causing it to dessicate.

Sorbitol Octanoate: The mode of action is a physical, surfactant effect that results in rapid suffocation and/or dewaxes the cuticle of the target pests, subsequently causing dessication via loss of body fluids. There are no neurological and/or physiological interactions with the target pest.

2. Physical And Chemical Properties Assessment

The physical and chemical characteristics of all products (TGAI/MUP and EP) were submitted to support registration. They are summarized in Table 1.

Table 1. Product chemistry data requirements.

Product Chemistry	Sucrose Octanoate Esters TGAI/MUP (MRID 444880-01, as amended by 451974-01, 451974-02, 454103-01 and, 454103-02)	Sucrose Octanoate Esters EP	Sorbitol Octanoate TGAI/MUP and EP (MRIDs 455974-01 and 455974-02 (and its amendment))
151B-10 (880.1100): Product identity	Avachem Sucrose Octanoate Manufacturing Use Product, the technical product, consists of 85.43% sucrose octanoate esters and 14.57% other ingredients	Avachem Sucrose Octanoate [40.0%], the end-use product, contains 40% sucrose octanoate esters	Avachem Sorbitol Octanoate Manufacturing Use Product and Avachem Sorbitol Octanoate [90.0%], the end-use product, both contain 90.0% sorbitol octanoate
151B-11 (880.1620): Formulation process	An acceptable description of the manufacturing process was submitted.	The product is formulated via a simple mixing process without any chemical reactions.	An acceptable description of the manufacturing processes was submitted.
151B-12 (880.1400): Discussion of formulation of unintentional impurities	Acceptable nominal concentrations and certified limits were reported for the manufacturing impurities.	No impurities of toxicologic concern are formed during the formulation process.	No impurities of toxicologic concern are formed during the formulation processes.
151B-13 (880.1700): Preliminary analysis	Data obtained from the five-batch analysis demonstrate that the analytical method is precise and accurate.	No five-batch preliminary analysis data were submitted, but none are required since the end-use product is not manufactured via an integrated system, and because the TGAI/MUP was registered simultaneously with the EP.	Data obtained from the TGAI/MUP five-batch analysis demonstrate that the analytical method is adequate and without deficiency. No five-batch preliminary analysis data were submitted for the EP, but none are required since the EP is 100% MUP
880.1750: Certified limits	The certified limits for the active ingredient and other impurities are acceptable.	Acceptable nominal concentrations and certified limits were reported for the other (inert) ingredient in the formulation.	The certified limits for the active ingredient and other impurities are acceptable.

Product Chemistry	Sucrose Octanoate Esters TGAI/MUP (MRID 444880-01, as amended by 451974-01, 451974-02, 454103-01 and, 454103-02)	Sucrose Octanoate Esters EP	Sorbitol Octanoate TGAI/MUP and EP (MRIDs 455974-01 and 455974-02 (and its amendment))
880.1800: Enforcement analytical method	The analytical method is high performance liquid chromatography (HPLC).	An acceptable liquid chromatography (HPLC) analytical method was submitted.	The analytical methods are high performance liquid chromatography (HPLC) and gas chromatography (GC)
Physical/Chemical Properties	**Sucrose Octanoate Esters TGAI/MUP (MRID 444158-02, as amended by MRIDs 446101-02, 447634-01, and 451974-02)**	**Sucrose Octanoate Esters EP**	**Sorbitol Octanoate TGAI/MUP and EP**
880.6302: Color	Amber	Amber	Amber
880.6303: Physical State	Liquid	Liquid	Liquid
880.6304: Odor	Faint sweet smell	Faint sweet smell	Faint sweet smell
880.7200: Melting Point	NA, not a solid	Not required per 40 CFR ' 158.190	NA, not a solid
880.7220: Boiling Point	Decomposes above 105EC	Not required per 40 CFR ' 158.190	Decomposes above 105EC
880.7300: Density, Bulk Density, or Specific Gravity	8.75 to 9.50 lbs/gal	8.50 to 9.00 lbs/gal	9.30 to 9.90 lb/gal
880.7840: Solubility	Forms an emulsion with water	Not required per 40 CFR ' 158.190	Forms an emulsion with water
880.7050: Vapor Pressure	<5 mm Hg	Not required per 40 CFR ' 158.190	<5 mm Hg
880.7370: Dissociation constant	Not Applicable	Not Applicable	Not Applicable
880.7550: Octanol/water partition coefficient	Unknown	Not required per 40 CFR ' 158.190	Not Applicable

Product Chemistry	Sucrose Octanoate Esters TGAI/MUP (MRID 444880-01, as amended by 451974-01, 451974-02, 454103-01 and, 454103-02)	Sucrose Octanoate Esters EP	Sorbitol Octanoate TGAI/MUP and EP (MRIDs 455974-01 and 455974-02 (and its amendment))
880.7000: pH	Not Applicable	7.0	7.0-7.3
880.6313: Stability	Stable below 40EC	Not required per 40 CFR '158.190	Stable below 40EC
880.6314: Oxidizing or Reduction Action	Not Applicable, does not contain an oxidizing or reducing agent	Not Applicable, does not contain an oxidizing or reducing agent	Not Applicable
880.6315: Flammability/Flame Extension	None; decomposes above 105EC	Not Applicable, does not contain a combustible liquid	Decomposes above 105EC
880.6316: Explodability	Not Applicable, is not potentially explosive	Not Applicable, is not potentially explosive	Non-explosive
880.6317: Storage Stability	Not Applicable	At least 1year at 40EC based on shelf-life tests	At least 1year at 40EC based on shelf-life tests
880.7100: Viscosity	Not required per 40 CFR '158.190	500 to 2000 CP at 25EC	500 to 10,000 cP at 25EC
880.6319: Miscibility	Not Applicable, is not to be diluted with petroleum solvents	Totally miscible in water	Miscible in water
880.6320: Corrosion Characteristics	Not Applicable	Non-corrosive to metals, plastics and glass	Non-corrosive to metals, plastics and glass
880.6321: Dielectric Breakdown Voltage	Not required per 40 CFR '158.190	Not Applicable, is not to be used around electrical equipment	Not Applicable

B. HUMAN HEALTH ASSESSMENT

Information and data submitted to support registration of the octanoate esters technical grade/manufacturing-use and end-use products adequately satisfy the food and non-food use requirements set forth in 40 CFR '158.690 (c) for biochemical pesticides.

In general, for example with regard to sorbitol octanoate, the TGAI is not a naturally occurring substance, but is a sugar ester synthesized via the condensation of a sorbitol (a naturally-occurring sugar alcohol) with octanoic acid (a naturally-occurring fatty acid). Sorbitol octanoate is chemically similar to certain sorbitan esters and other sugar fatty acid esters that have been approved by FDA for direct food use as food emulsifiers and postharvest protective fruit coatings (see 21 CFR '172.836; 172,838; 172.840; and 172.842). Sorbitan esters are different from sorbitol octanoate only in that sorbitol has one more water molecule than sorbitan. Sorbitol octanoate is chemically similar to the active ingredient sucrose octanoate esters (found in EPA Registration Number 70950-2),and its effects on target pests are virtually identical (Ref. 9). Furthermore, sorbitol is a naturally-occurring carbohydrate found in apples, plums, pears, cherries, dates, peaches, apricots, and other fruits (Ref. 9). Octanoic acid (caprylic acid) is a naturally-occurring fatty acid found in plants, coconut oil, meat, and milk (Ref. 9). Sorbitol and octanoic acid are on EPA's List 4 Inerts of Minimal Concern. Sorbitol is cleared for food use in unlimited quantities as an anti-dusting agent under 40 CFR '180.910.

Excepting ocular exposure, the overall toxicological risk from human exposure to octanoate esters is negligible.

1. Toxicology Assessment

Adequate mammalian toxicology information and data are available and support registration of the products containing octanoate esters as the active ingredient. For sucrose octanoate esters, new studies were contracted by the registrant for primary eye irritation and primary dermal irritation. For sorbitol octanoate, new studies were contracted by the registrant for primary eye irritation only. Data waivers were requested and granted for all other toxicity data requirements (Ref. 10). Publically available information/data were submitted, in lieu of studies, as part of the scientific justification necessary to support the data waiver requests (Refs. 2, 3, 6). In addition, the Agency has found additional relevant data from additional public sources, including the National Toxicology Program (NTP), which have been of value to the Agency=s review (Ref. 4). The submitted information/data, in combination, were found equivalent to what would normally be provided by guideline studies, and therefore are adequate to meet each toxicology requirement pursuant to 40 CFR '152.90 (b)(4). More detailed analyses of these data and information can be found in specific Agency reviews of the studies and technical literature (Refs. 4, 5, 7 and 10).

a. Acute Toxicity

The registrant submitted acceptable data and information from the open technical literature (Refs. 2 and 3) to justify the data waiver requests and satisfy the requirement for acute toxicity studies. Based on the submitted information/data and additional relevant data found by the Agency from public sources, including the NTP (Ref. 4), BPPD categorized both the manufacturing-use and end-use octanoate esters products as Toxicity Category IV for acute oral toxicity, acute dermal toxicity and acute inhalation toxicity. On the strength of reports showing no hypersensitivity responses or incidents among workers regularly exposed for up to seven years to octanoate esters, BPPD has determined that octanoate esters are not a sensitizer, and has waived the hypersensitivity study (Ref. 5 and MRID 455973-01).

Sucrose Octanoate Esters: Following ocular instillation of 0.1 mL of undiluted manufacturing-use product into the eyes of rabbits, moderate to severe eye irritation and mild corneal opacity was observed in the treated eyes of all

rabbits at 24 hours post-dosing and persisted in one rabbit to 21 days post-dosing. Mild iritis was exhibited in three rabbits at 24-hours post-dosing and persisted in one rabbit to 72 hours. This classifies Avachem Sucrose Octanoate Manufacturing Use Product as Toxicity Category I. Following ocular instillation of 0.1 mL of undiluted end-use product into the eyes of rabbits, moderate to severe eye irritation was observed in the treated eyes of all six rabbits at 72 hours post-dosing, was mild at seven days, and cleared by 14 days. Mild corneal opacity was observed in all six rabbits at 24 hours, and persisted to seven days in one rabbit, then cleared by 14 days post-dosing. Mild iritis persisted in four rabbits to 72 hours, then cleared. This classifies Avachem Sucrose Octanoate [40.0%] as Toxicity Category II.

Sorbitol Octanoate: The manufacturing use product (MUP) caused corneal opacity in six of six rabbits tested at 24 hours after dosing with the MUP at 0.1 ml/eye. Corneal opacity resolved by day 14 after dosing. Eyes of all six rabbits also showed conjunctival irritation, and five of six rabbits showed iritis at one hour post-dosing. These signs also resolved by day 14. Sorbitol octanoate MUP is severely irritating to the eye and is Toxicity Category II (MRID 455974-03).

Sucrose Octanoate Esters: Following dermal application of 0.5 mL of undiluted manufacturing-use product to the skin of rabbits, five rabbits exhibited very slight erythema and one exhibited well-defined erythema at one hour post-treatment. Very slight erythema persisted on four rabbits to 24 hours, then cleared. No edema was observed on any rabbit. Following dermal application of 0.5 mL of undiluted end-use product to the skin of rabbits, very slight erythema was exhibited by six rabbits at 0.5 hour post-treatment and five rabbits exhibited very slight to slight edema. All symptoms cleared by 24 hours. The results from these two studies place both the manufacturing-use and end-use sucrose octanoate esters products in Toxicity Category IV for primary dermal irritation. Based on the submitted information for hypersensitivity, sucrose octanoate esters is not a dermal sensitizer. Agency reviews are available in the docket (Ref. 5).

b. Genotoxicity and Mutagenicity

No guideline studies were submitted, but the Agency determined none are required because the registrant submitted published information from the open, technical literature to scientifically justify waivers for these studies (Refs. 2 and 3). The submitted data/information demonstrate that octanoate esters are not genotoxic and/or mutagenic, nor structurally and/or chemically similar to known mutagens or known classes of mutagens (Ref. 5). A study reported by the NTP shows a sucrose octanoate esters and sorbitol octanoate constituent, octanoic acid, to be negative for genotoxicity/mutagenicity (Ref. 4).

c. Other Subdivision M Toxicity Data Requirements

Due to the low toxicity of sucrose octanoate esters (as demonstrated in the cited open technical literature (Refs. 2, 3, 5, 6 and 7), the Agency granted waivers from all Subdivision M toxicity data requirements, including the immune response, 90-day feeding and teratogenicity studies. In addition, a sucrose octanoate esters and sorbitol octanoate constituent, octanoic acid, is considered a nonteratogenetic compound even at the very high dose rate of 18.75 mmoles/kg (Ref. 4).

Data Waivers (Refs. 2, 3 and 6) were requested for the following studies:

Acute oral toxicity (OPPTS 870.1100)
Acute dermal toxicity (OPPTS 870.1200)
Acute inhalation (OPPTS 870.1300)
Hypersensitivity study (OPPTS 870.2600)
Studies to detect genotoxicity (OPPTS 870.5300)

Immune response (OPPTS 880.3800)
Mammalian mutagenicity tests (OPPTS 870.5195)
90-Day Feeding (OPPTS 870.3100)
Teratogenicity (OPPTS 870.3700)

The registrant=s rationale to support the waivers is that considerable sucrose octanoate esters safety data are available (Refs. 2, 3 and 6). The active ingredient sucrose octanoate esters, derived from edible vegetable oils, edible tallow or hydrogenated edible tallow, has been FDA-approved for use as emulsifiers in certain processed foods and as post-harvest protective coatings for certain fruits since 1983. In 1995, FDA expanded the range of foods in which sucrose octanoate esters are permitted, to include use in emulsifiers, stabilizers, and texturizers in chewing gum, confections, and frostings; texturizers in surimi-based fabricated seafood products; and emulsifiers in coffee and tea beverages with added dairy ingredients and/or dairy product analogs (60 FR 44755). Sucrose octanoate esters= constituent sugars and fatty acids are normal parts of the human diet, and the Agency knows of no instance where they have been associated with any toxic effects related to the consumption of food. Due to this knowledge of sucrose octanoate esters= presence in the human diet (Ref. 4), the summarized safety data (Ref. 2), the NTP data (Ref. 4), and the recent primary eye and primary dermal irritation testing, EPA believes sucrose octanoate esters are unlikely to be carcinogenic or have other long-term toxic effects. See also memos from R. S. Jones to D. Greenway, February 14, 2000 (Ref. 5) and D. Greenway to R. S. Jones, August 7, 2002 (Ref. 7).

Sorbitol octanoate also rapidly hydrolyzes to sorbitol and octanoic acid, both of which are common human dietary components of no toxicological concern. Both sorbitol and octanoic acid are included in the Agency=s List 4 inert ingredients, and thus are of minimal concern.

Mammalian toxicity data for sucrose octanoate esters and sorbitol octanoate are summarized in Tables 2A and 2B, respectively.

Table 2A. Sucrose Octanoate Esters - Toxicity data requirements

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
152-10, 870.1100	Acute oral toxicity in rats and mice	Data waiver granted (see text for details) Toxicity Category IV (MUP and EP)	444158-03 and Amendment No. 1
152-11, 870.1200	Acute dermal toxicity	Data waiver granted (see text for details) Toxicity Category IV (MUP and EP)	444158-03 and Amendment No. 1, and 444158-04
152-12, 870.1300	Acute inhalation toxicity	Data waiver granted (see text for details) Toxicity Category IV (MUP and EP)	None; not a likely pathway of exposure
152-13, 870.2400	Primary eye irritation in rabbits	Toxicity Category I (MUP) Toxicity Category II (EP)	446101-05 446101-06
152-14, 870.2500	Primary dermal irritation in rabbits	Toxicity Category IV (MUP) Toxicity Category IV (EP)	446101-03 446101-04
152-15, 870.2600	Dermal sensitization	Data waiver granted (see text for details) Not a sensitizer	444158-04
152-17, 870.5300	Studies to detect genotoxicity	Data waiver granted (see text for details)	NA
152-18, 870.8700	Cellular immune response	Data waiver granted (see text for details)	NA
152-19, 870.5195	Mammalian mutagenicity test	Data waiver granted (see text for details)	NA

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
152-20, 870.3100	90-Day Feeding	Data waiver granted (see text for details)	NA
152-23, 870.3700	Teratogenicity	Data waiver granted (see text for details)	NA

Table 2B. Sorbitol Octanoate - Toxicity data requirements

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
152-10, 870.1100	Acute oral toxicity in rats and mice	Data waiver granted (see text for details) Toxicity Category IV	Not Applicable
152-11, 870.1200	Acute dermal toxicity	Data waiver granted (see text for details) Toxicity Category IV	Not Applicable
152-12, 870.1300	Acute inhalation toxicity	Data waiver granted (see text for details) Toxicity Category IV	Not Applicable
152-13, 870.2400	Primary eye irritation in rabbits	Toxicity Category II (MUP)	455974-03
152-14, 870.2500	Primary dermal irritation in rabbits	Data waiver granted (see text for details) Toxicity Category IV	Not Applicable
152-15, 870.2600	Dermal sensitization	Data waiver granted (see text for details) Not a sensitizer	455973-01
152-17, 870.5300	Studies to detect genotoxicity	Data waiver granted (see text for details)	Not Applicable
152-18,	Cellular immune	Data waiver granted	

GUIDELINE NO.	STUDY	RESULTS	MRID NO.
870.8700	response	(see text for details)	Not Applicable
152-19, 870.5195	Mammalian mutagenicity test	Data waiver granted (see text for details)	Not Applicable
152-20, 870.3100	90-Day Feeding	Data waiver granted (see text for details)	Not Applicable
152-23, 870.3700	Teratogenicity	Data waiver granted (see text for details)	Not Applicable

d. Effects on the Endocrine System

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) Amay have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate.@ Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was 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 the Program include evaluations of potential effects in wildlife. For pesticide chemicals, 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).

Based on the weight of the evidence of available data, no endocrine system-related effects have been identified for octanoate esters.

2. Dose Response Assessment

No toxicological endpoints are expected.

3. Dietary Exposure and Risk Characterization

a. Dietary

ii. Food

Sucrose octaonate esters: Because sucrose octanoate esters are the mono-, di- and tri-esters of sucrose with fatty acids and are derived from sucrose and edible tallow or edible vegetable oils,

there is a great likelihood of exposure to sucrose octanoate esters= components for most, if not all individuals, including infants and children. Thus, sucrose octanoate esters may be considered a normal part of the human diet. Because the sucrose octanoate esters= constituent sucrose (table sugar, to which humans and animals are regularly exposed) is the primary photosynthetic product of all higher plants, and the constituent octanoic acid (caprylic acid) is a common fatty acid in plants, any residues of sucrose octanoate esters on treated plants would be indistinguishable from background levels of the compounds (Ref. 4). Toxicological endpoints are not expected; therefore, risk from the consumption of residues is not expected for the general population, including infants and children. An acceptable daily intake (ADI) of sucrose octanoate esters for humans was estimated to be up to16 mg/kg body weight/day, which is equivalent to 2.82 lb (1.28 kg) of sucrose octanoate esters per day for a 176 lb person. In studies with rats ands humans, it was demonstrated that sucrose octanoate esters were rapidly hydrolyzed and absorbed by the body (Ref. 5). To date, there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions in humans resulting from exposure to sucrose octanoate esters. Even if there is a significant increase in exposure to sucrose octanoate esters due to its use as a pesticide, the acute toxicity information and data submitted by the registrant demonstrating extremely low mammalian toxicity (Toxicity Category IV) indicate that risk associated with acute exposures by the oral, dermal and inhalation routes would be low to non-existent.

Sorbitol octanoate: Sorbitol octanoate rapidly hydrolyzes to sorbitol and octanoic acid, naturally-occurring compounds both of which are common human dietary components of no toxicological concern. Sorbitol octanoate is chemically similar to certain sorbitan esters and other sugar fatty acid esters that have been approved by FDA for direct food use as food emulsifiers and postharvest protective fruit coatings (see 21 CFR 172.836; 172,838; 172.840; and 172.842). Sorbitan esters are different from sorbitol octanoate only in that sorbitol has one more water molecule than sorbitan. Sorbitol octanoate is chemically similar to sucrose octanoate (EPA Registration Number 70950-2) and its effects on target pests are virtually identical (Puterka et al., 2003). Furthermore, sorbitol is a naturally-occurring carbohydrate found in apples, plums, pears, cherries, dates, peaches, apricots, and other fruits (Lawson, 1997). Octanoic acid (caprylic acid) is a naturally-occurring fatty acid found in plants, coconut oil, meat, and milk (Hall, 1995; Rogge et al., 1991; Tatsuka et al., 1993). Both sorbitol and octanoic acid are included in the Agency=s List 4 inert ingredients, and thus are of minimal concern. Sorbitol is cleared for food use in unlimited quantities as an anti-dusting agent under 40 CFR '180.910.

iii. Drinking Water

No drinking water exposure is expected, as sucrose octanoate esters are not soluble in water, do not persist in the environment and biodegrade within approximately five days at approximately 20-27EC, in both aerobic and anaerobic conditions (Ref. 5). Because sucrose octanoate esters have extremely low toxicity, have been approved for food use by FDA, and are present as direct food additives in many foods, should exposure through drinking water occur, no risk is anticipated.

No drinking water exposure is expected; and as noted above, sorbitol octanoate rapidly hydrolyzes to sorbitol and octanoic acid, naturally-occurring compounds (found in foods) both of which are common human dietary components of no toxicological concern.

b. Other Non-occupational Exposure

The potential for non-dietary exposure to octanoate esters residues for the general population, including infants and children, is unlikely because potential use sites are commercial, agricultural, and large-scale horticultural. Octanoate esters= constituent sugars and fatty acids are normal parts of the human diet. While there exists a great likelihood of prior exposure for most, if not all, individuals, any increased exposure due to the proposed products would be negligible.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

Significant additional human exposure to octanoate esters is not expected in residential, school and day care areas since uses are limited to commercial, agricultural and large-scale horticultural settings.

a. Occupational Exposure

Agricultural use of octanoate esters is subject to the Worker Protection Standard (WPS), requiring Personal Protective Equipment (PPE), *i.e.*, a long-sleeved shirt, long pants, shoes plus socks, and protective eyewear; and a product-specific 24 or 48 hour Restricted Entry Interval (REI).

b. Residential, School and Day Care Exposure and Risk Characterization

Because toxicological endpoints are not expected, risk from the consumption of residues is not expected for populations, including infants and children, in residential, school and day care settings.

5. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database, unless EPA determines that a different margin of exposure will be protective for infants and children. Margins of exposure are often referred to as uncertainty or safety factors. In this instance, based on all the available information, the Agency concludes that octanoate esters are practically non-toxic to mammals, including infants and children. Thus, there are no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply. Sucrose octanoate esters= and sorbitol octanoate=s chemical components are found naturally in many foods already consumed by infants and children. And, as no toxic endpoints are expected, any hazard is impossible to determine (other than ocular). As a result, EPA has not used a margin of exposure approach to assess the safety of octanoate esters.

6. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure to octanoate esters by field workers and applicators may occur via oral and dermal routes. These risks are measured via the acute toxicity studies and information submitted to support registration. The oral toxicity information and data for octanoate esters showed no toxicity (Toxicity Category IV); the risks anticipated from oral exposure are considered minimal. Because the inhalation route is not a likely pathway of exposure, and based on octanoate esters safety data from the open, technical literature, the risks anticipated for this route of exposure are also considered minimal (Toxicity Category IV).

BPPD concluded that the submitted acute dermal toxicity information indicated no toxicity (Toxicity Category IV). Study results also demonstrated no significant dermal irritation (Toxicity Category IV). Furthermore, BPPD has concluded that sucrose octanoate esters and sorbitol octanoate are not skin sensitizers. Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via oral, dermal and inhalation exposure are a compilation of three low risk exposure scenarios and are negligible, when appropriate protective clothing is used.

Aggregate exposure to sucrose octanoate esters and sorbitol octanoate by the consumer would include other sources in addition to the limited amount on treated agricultural/horticultural products. The octanoate esters= constituent sugars and fatty acids are normal parts of the human diet. While there exists a great likelihood of prior exposure for most, if not all, individuals, any increased exposure due to the proposed products would be negligible.

7. Cumulative Effects

Except through ocular exposure, octanoate esters are not toxic and it is not anticipated there would be cumulative effects from common mechanisms of toxicity. Risks to eyes can be prevented by the use of required protective eyewear (goggles or face shield).

8. Risk Characterization

The Agency has considered octanoate esters in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U. S. population in general, and to infants and children in particular, will result from the use of Avachem Sucrose Octanoate [40.0%] or Avachem Sorbitol Octanoate [90.0%] when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Effects Hazard Assessment

The end-use products Avachem Sucrose Octanoate [40.0%] and Avachem Sorbitol Octanoate [90.0%] are intended for agricultural and large-scale horticultural use. When applied according to the proposed label directions, no direct exposure of birds or aquatic organisms to octanoate esters is expected to occur.

Sucrose Octanoate Esters: Acceptable information/data were submitted from the open technical literature to support the data requirements for avian acute oral toxicity, avian dietary toxicity, freshwater fish LC_{50}, freshwater invertebrate LC_{50}, and non-target plants. Based on the data, the Agency concludes that it is unlikely that any toxic effects will occur in birds, freshwater fish, freshwater aquatic invertebrates, and/or non-target plants when the product containing sucrose octanoate esters is used according to label directions (Ref. 5).

A request for a waiver from the non-target insect studies requirement was adequately supported by a) an acute contact honey bee toxicity study from which the Agency determined that the active ingredient may be classified as practically non-toxic to honey bees (LD_{50} is > 80 Φg active ingredient/bee, Ref. 8), and b) three supplemental non-target insect studies obtained from the open technical literature which indicate that sucrose octanoate esters are relatively non-toxic to certain non-target, beneficial, insects (Ref. 5).

Sorbitol Octanoate: Waivers were requested for sorbitol octanoate based on evidence that it degrades in the environment to sorbitol and octanoic acid, which already are natural components of plants. Further, sorbitol and octanoic acid are Agency List 4 inerts and thus are of minimal concern. Field trials with sorbitol octanoate have not shown any phytotoxicity.

As a result of BPPD=s assessment of the information and data described above, organism/ecological effects studies were waived for the particular uses of Avachem Sucrose Octanoate [40.0%] and Avachem Sorbitol Octanoate [90.0%]. However, standard precautionary label statements under AEnvironmental Hazards@ are presented on the label.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II, (40 CFR Section 158.690(d)(2)(vii through xv)) was not triggered because the Tier I studies were waived. Risk is minimal due to the lack of exposure, low toxicity, use pattern, and application methods.

3. Ecological Exposure and Risk Characterization

Octanoate esters do not persist in the environment. Sucrose octanoate esters biodegrade within approximately five days at approximately 20-27EC, in both aerobic and anaerobic conditions. The approximate half-life for sorbitol octanaote is seven to ten days post-application in the field. Minimal potential for exposure exists to insects, fish and other non-target wildlife as a result of Avachem Sucrose Octanoate [40.0%] or Avachem Sorbitol Octanoate [90.0%] use.

D. EFFICACY DATA

No efficacy data are required, because no public health uses are involved. However, acceptable product performance data were submitted for sucrose octanoate esters, demonstrating activity against aphids, pear pyslla and whitefly. Product performance data for sorbitol octanoate demonstrated a range of activities against pear psylla nymphs, tobacco aphid, tobacco hornworm, and the two-spotted spider mite.

IV. Risk Management Decision

A. DETERMINATION OF ELIGIBILITY FOR REGISTRATION

Section 3(c)(5) of FIFRA provides for the registration of new active ingredients if it is determined that (A) its composition is such as to warrant the proposed claims for it; (B) its labeling and other materials required to be submitted comply with the requirements of FIFRA; (C) it will perform its intended function without unreasonable adverse effects on the environment and (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

To satisfy criterion AA@ above, the fatty acid composition of octanoate esters accounts for the surfactant-type physical mode of action against the target pests, and is not expected to cause unreasonable adverse effects when used according to label instructions. Criterion AB@ is satisfied by the product -specific current labels and by the data presented in this document. It is believed that octanoate esters (sucrose octanoate esters and sorbitol octanoate) will not cause any unreasonable adverse effects, and will act as a pesticide to control soft-bodied insects, satisfying Criterion AC.@ Criterion AD@ is satisfied by the data/information submitted and the products= low toxicity when used according to the label directions.

Therefore, octanoate esters (sucrose octanoate esters and sorbitol octanoate)are eligible for registration. The uses are listed in Table 4, Appendix A.

B. REGULATORY POSITION

1. Unconditional Registration

All data requirements have been fulfilled and/or waived by the Agency and the Biopesticides and Pollution Prevention Division recommends unconditional registration of products which contain octanoate esters as their sole active ingredient.

2. Tolerances for Food Uses and/or Exemptions

Sucrose Octanaote Esters: EPA received a pesticide petition (8E4926) from AVA Chemical Ventures, L.L.C., proposing [pursuant to section 408(b)(2)(D) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346], to amend 40 CFR Part 180 by establishing an exemption from the requirement of a tolerance for the biochemical pesticide, sucrose fatty acid esters, in or on all food commodities.

EPA determined the designation Asucrose fatty acid esters@ to be too broad. The active ingredient for which the registrant actually petitioned is technically defined as sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate]. Per

section II. E. of this document, the tolerance exemption expression established in the associated Final Rule for this new active ingredient will be for Asucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate].@

Sorbitol Octanoate: EPA received a pesticide petition (2E6389) from AVA Chemical Ventures, L.L.C., proposing [pursuant to section 408(b)(2)(D) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346], to amend 40 CFR Part 180 by establishing an exemption from the requirement of a tolerance for the biochemical pesticide, sorbitol octanoate, in or on all food commodities.

3. CODEX Harmonization

There are no CODEX Maximum Residue Levels (MRLs)established for residues of sucrose octanoate esters or sorbitol octanoate.

4. Nonfood Re/Registrations

There are no non-food issues at this time. The non-food uses are listed in Appendix A, Table 4.

5. Risk Mitigation

There exits a risk from ocular exposure. Risks to workers are mitigated by label language requiring protective clothing, and a product-specific 24 or 48 hour re-entry interval.

6. Endangered Species Statement

Sucrose Octanaote Esters: Given the species-specific action of this biochemical pesticide, the intended use pattern, the results of toxicity and exposure data from the public scientific literature and data submitted by the applicant, the Agency has determined that this action will have no effect on currently listed endangered and threatened species.

Sorbitol Octanoate: The Agency has determined there will be No Adverse Effect (NAE) on endangered species or other non-target organisms following the use of Avachem Sorbitol Octanoate [90.0%] containing sorbitol octanoate as its active ingredient. There is no evidence of toxicity to any non-target organisms or effects on critical habitat based on data obtained from a review of the available literature. Exposure to non-target organisms is mitigated by the rapid degradation of the active ingredient in the environment. The constituent molecules, sorbitol and octanoic acid, are simple molecules that are common in the environment and rapidly metabolized by animal systems.

C. LABELING RATIONALE

The Agency=s position is that the labeling of Avachem Sucrose Octanoate [40.0%] and Avachem Sorbitol Octanoate [90.0%], as well as that of the technical grade active ingredient/manufacturing-use products, Avachem Sucrose Octanoate Manufacturing Use Product (85.43%)(cancelled) and Avachem Sorbitol Octanoate Manufacturing Use Product (90.00%), complies with current pesticide labeling requirements.

1. Human Health Hazard

a. Worker Protection Standard

This end-use products come under the provisions of the Worker Protection Standards (WPS). PPE (long-sleeved shirt and long pants, shoes plus socks, and protective eyewear) and REI (product-specific 24 or 48-hour) required.

b. Non-Worker Protection Standard

There are no non-WPS human health hazard issues.

c. Precautionary Labeling

The Agency has examined the toxicological data base for Avachem Sucrose Octanoate Manufacturing Use Product (cancelled), Avachem Sucrose Octanoate [40.0%], Avachem Sorbitol Octanoate Manufacturing Use Product and Avachem Sorbitol Octanoate [90.0%] and concluded that the proposed precautionary labeling (*i.e.*, Signal Word, First Aid and other label statements) adequately mitigates any risks associated with the proposed uses.

Technical Product Precautionary Labeling: For Avachem Sucrose Octanoate Manufacturing Use Product (cancelled)B ADANGER.@ For Avachem Sorbitol Octanoate Manufacturing Use Product B AWARNING.@

Hazards to Humans and Domestic Animals:

Sucrose Octanoate Esters: DANGER: CORROSIVE. Causes irreversible eye damage. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Sorbitol Octanoate: WARNING: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (gogglers or face shield). Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
-Call a poison control center or doctor for treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to do so by the poison control center or doctor.
-Do not give anything by mouth to an unconscious person.

End-Use Product Precautionary Labeling:

For Avachem Sucrose Octanoate [40.0%] B AWARNING@
For Avachem Sorbitol Octanoate [90.0%] -- AWARNING@

Hazards to Humans and Domestic Animals:

For Avachem Sucrose Octanoate [40.0%]: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

For Avachem Sorbitol Octanoate [90.0%]: Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wear protective eyewear (goggles or face shield). Wash thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse.

First Aid:

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.
-Call a poison control center or doctor for treatment advice.

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to do so by the poison control center or doctor.
-Do not give anything by mouth to an unconscious person.

2. Environmental Hazards Labeling

End-Use Product Environmental Hazards Labeling: Although octanoate esters are considered non-toxic to the environment, the environmental hazards statement is nevertheless required on the end-use products= label.

3. Application Rate

The Agency's position is that the labeling for the pesticide products containing octanoate esters complies with current pesticide labeling requirements.

Sucrose Octanoate Esters: The Agency has not stipulated a maximum number of applications for the active ingredient. The label specifies application rates a) between 0.8% and 1.0% volume/volume (v/v) for foliarly applied spray, b) between 1.25% and 2.50% v/v for mushroom growing media, and c) of 0.625% v/v for application to honey bees. The diluent is water. For foliar uses, the finished spray solution may be applied at seven to ten day intervals, up to and including the day of harvest. Mushroom growing media (casing and/or compost) is to be treated prior to spawning. Applications to adult honey bees may be repeated three times per infestation (the limit stipulated by the applicant), at seven to ten day intervals.

Sorbitol Octanoate: The proposed label specifies application by ground spray equipment (e.g. ground boom, air blast). Shake or stir before use, adding the appropriate quantity to water, with agitation. Maintain gentle agitation

during application. The proposed label specifies an application rate of 0.5% volume/volume (v/v) for all use sites. Initiate applications as soon as pest pressure is observed. Repeat applications, as necessary, at intervals of 7 to 10 days.

D. LABELING

(1) Product name: **Avachem Sucrose Octanoate Manufacturing Use Product** (cancelled)

Active Ingredient:
Sucrose Octanoate Esters (α-D-Glucopyranosyl,β-D-fructofuranosyl-octanoate),
mono, di-, and triesters of sucrose octanoate..... . . . . .85.43%
Other Ingredients:. 14.57%

Total 100.00%

Signal word is "DANGER." Ocular exposure risk precautions are appropriate.

The product shall contain the following information:
- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (DANGER)

(2) Product name: **Avachem Sucrose Octanoate [40.0%]**

Active Ingredient:
Sucrose Octanoate Esters (α-D-Glucopyranosyl,β-D-fructofuranosyl-octanoate),
mono, di-, and triesters of sucrose octanoate..... . . . . .40.0%
Other Ingredient:. 60.0%

Total 100.00%

Signal word is "WARNING." Ocular exposure risk precautions are appropriate.

The product shall contain the following information:
- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (WARNING)

(3) Product name: **Avachem Sorbitol Octanoate Manufacturing Use Product**

Active Ingredient:
Sorbitol Octanoate..... . . . . . .90.00%
Other Ingredients:. 10.00%

Total 100.00%

Signal word is "WARNING." Ocular exposure risk precautions are appropriate.

The product shall contain the following information:
- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (WARNING)

(4) Product name: **Avachem Sorbitol Octanoate [90.0%]**

Active Ingredient:
Sorbitol Octanoate..... . . . . .90.0%
Other Ingredients:. 10.0%

Total 100.00%

Signal word is "WARNING." Ocular exposure risk precautions are appropriate.

The product shall contain the following information:
- Product Name
- Ingredient Statement
- Registration Number
- Signal Word (WARNING)

V. Actions Required by Registrants

There are no data requirements, label changes or other responses necessary for the reregistration of the end-use products since they are being registered after November 1984 and are, therefore, not subject to reregistration. There are also no existing stocks provisions at this time.

VI. Appendix A

Table 4 lists the use sites for the sucrose octanoate esters end-use product. The label is also attached.

Table 4. End-Use Product Name, Use Sites, Registration/Reregistration

Avachem Sucrose Octanoate [40.0%] Use Sites: Field Crops (including certain non-food ornamentals), Mushroom Growing Media, Adult Honey Bees	Official date registered: **September 16, 2002**

Table 5 lists the use sites for the sorbitol octanoate end-use product. The label for it and the manufacturing-use product are also attached.

Table 5. End-Use Product Name, Use Sites, Registration/Reregistration

Avachem Sorbitol Octanoate [90.0%] Use Sites: Field, greenhouse, and nursery use on any type of agricultural commodity (including certain non-food ornamentals).	Official date registered:

VII. References

A. References for Sucrose Octanoate

1. USEPA; Amendment of the January 14, 1997, Classification Committee decision on sucrose fatty acid esters. R. S. Jones, July 2, 2002.

2. Barrington, T. and C. L. Hartman. Sucrose Fatty Acid Esters-Safety Data in Support of Petition Proposing a Temporary (sic) Exemption From the Requirement of a Tolerance for Use in All Food Commodities (MRID 444158-03), October 2, 1997.

3. Barrington, T. and W. L. Biehn. Sucrose Fatty Acid Esters-Safety Data in Support of Petition Proposing an Exemption From the Requirement of a Tolerance for Use in All Food Commodities, Amendment No. 1 to MRID 444158-03, July 13, 1998

4. USEPA; Brief Summary of Toxicity Information to Support Registration/Tolerance Exemptions for Sucrose Octanoate. R. S. Jones to D. Greenway; August 8, 2002.

5. USEPA; Science review in support of registration of sucrose octanoate esters. R. S. Jones to D. Greenway, February 14, 2000.

6. Barrington, A., Waiver Request; July 12, 2002.

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