Sucrose Octanoate Esters

Livestock

Identification of Petitioned Substance

Chemical Names:
sucrose octanoate esters

Other Name:
(∀-D-glucopyranosyl-∃-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate

Trade Names:
Avachem Sucrose Octanoate Manufacturing Use Product
Avachem Sucrose Octanoate [40%]

CAS Numbers:
CAS NO. 42922-74-7 (monooctanoate), 58064-47-4 (dioctanoate)

Other Codes:
OPP Chemical Code: 035300

Characterization of Petitioned Substance

<u>Composition of the Substance</u>:

Sucrose octanoate esters (SOEs) belong to the organic chemical family sucrose fatty acid esters (SFAEs).[1] SFAEs are surfactants (or surface active agents**)** that lower the surface tension of a liquid, allowing easier spreading and evaporation. Surfactants are usually organic compounds that contain both hydrophobic (fat-soluble) and hydrophilic (water-soluble) groups (Wikipedia, n. d.). SFAEs have sucrose residues as the hydrophilic group and fatty acid residues as the lipophilic group. SOEs are manufactured from sucrose (table sugar) and an octanoic acid ester commonly found in plants and animals. Sucrose esters, as a class of related compounds, vary depending on the number and locations of esters attached to the sucrose molecules. Sucrose has eight potential places where individual esters may attach (Montello, Inc., n. d.). The substance under review is a mixture of mono-, di-, and triesters.

Sucrose esters were first isolated when researchers investigated the insecticidal properties of the tobacco leaf hairs. This insecticidal property of sucrose esters acts by dissolving the waxy protective coating (cuticle) of target pests, causing them to dry out and die (U.S. EPA, 2002b). SOEs marketed as biopesticides are intended to mimic the pest control properties of *Nicotiana gossei* Domin. (wild tobacco) and other *Nicotiana* species. In addition to the tobacco plant, insecticidal sugar esters have been found in wild tomato and wild potato species and in the petunia plant (Chortyk et al., 1996). Naturally occurring sugar ester biopesticides are present at low concentrations in their host plants; according to the petitioner, the highest-yielding plant, *Nicotiana trigonophylla*, has less than three grams of sucrose esters per kilogram of plant material (Barrington, 2004a).

<u>Properties of the Substance</u>:

Product Chemistry (U.S. EPA, 2002a)	
Color	Amber
Physical State	Liquid
Odor	Faint sweet smell
Melting Point	Exists in liquid state

[1] An ester is a product of the reaction of an acid and an alcohol, notable as sweet smelling organic compounds produced by plants and fruits, such as pineapples and oranges. The most common esters found in nature are fats and vegetable oils. [Source: http://en.wikipedia.org/wiki/Ester]

Boiling Point	Decomposes above 221°F/105°C
Solubility	Forms an emulsion with water
Stability	Stable below 104°F/40°C
Oxidizing or Reduction Action	Does not contain an oxidizing or reducing agent
Flammability/Flame Extension	None; decomposes above 221°F/105°C
Explodability	Not potentially explosive
Miscibility	Not to be diluted using petroleum solvents

<u>Specific Uses of the Substance</u>:

SOE is an EPA-registered biopesticide. As a biopesticide, SOEs are currently used as an insecticide to control certain soft-bodied insects (e.g., mites, aphids, thrips, whiteflies, and psyllids (Puterka, n. d.)). SOEs are permitted by EPA for use as a biopesticide for foliar spray in 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 (U.S. EPA, 2002a).

The control of *Varroa* mites on honeybees is one of the currently petitioned uses for SOEs. An amendment to the petition extends the request to include the other EPA-approved pesticide uses (foliar spray on greenhouse, nursery, and field crops, and *Sciarid* fly control in mushroom-growing media). This review addresses the petitioned use for livestock (i.e., honey bees). The petitioned uses for crops are addressed in a separate report.

<u>Approved Legal Uses of the Substance:</u>

The primary commercial uses of SOEs are as biopesticide and as an emulsifier, texturizer, or protective coating for certain foods.

In foods, sucrose fatty acid esters may be used as emulsifiers, stabilizers, texturizers, and components of protective coatings applied to fresh fruits to retard ripening and spoiling (21CFR172.859, 2004). (See FDA Status Section, below.)

SOEs are also approved for use as a contact-type biochemical insecticide/miticide (EPA Registration Number 70950-2, OPP No. 035300) to control soft-bodied insects (Puterka, n. d.). In particular, EPA has registered SOEs as a biopesticide for foliar spray on greenhouse, nursery, and field crops; for *Sciarid* fly control in mushroom-growing media; and for *Varroa* mite control on honeybees (Barrington, 2004a). (See EPA Status Section, below.)

<u>Action of the Substance</u>:

Sucrose octanoate esters act as biopesticides by dissolving the waxy protective coating (cuticle) of target pests (e.g., mites), causing them to dry out and die (Puterka and Severson, 1995).

Status

<u>EPA</u>

In 2002, EPA approved SOEs for use as the active ingredient in the end-use product, Avachem Sucrose Octanoate [40.0%] (U.S. EPA, 2002b) (Avachem Sucrose Octanoate Manufacturing Use Product for formulating into biochemical insecticide/miticide end-use products, EPA Registration Number 70950-1; Avachem Sucrose Octanoate [40.0%] for use as a biochemical insecticide/miticide end-use product, EPA Registration Number 70950-2). EPA's registration review concluded that no FFDCA tolerance level is required for SOE residues in or on any food commodity. EPA arrived at this conclusion as a result of data that demonstrated no toxicity, except from ocular exposure (discussed in Evaluation Question #11, below) (U.S. EPA, 2002a). The approve target pests and use sites include:

(1) Mites and soft-bodied insects on food and non-food crops, including certain ornamentals
(2) Immature forms of certain species of gnats found in media used for growing mushrooms
(3) *Varroa* mites on adult honey bees

The approved application method is spray with ground equipment (U.S. EPA, 2002b).

FDA

Since 1983, the US Food and Drug Administration (FDA) has allowed sucrose fatty acid esters, including SOEs, to be added to certain processed foods (21CFR172.859, 2004). Sucrose fatty acid esters may be used as emulsifiers or as stabilizers in baked goods and baking mixes, in chewing gum, in coffee and tea beverages with added dairy ingredients and/or dairy product analogues, in confections and frostings, in dairy product analogues, in frozen dairy desserts and mixes, and in whipped milk products. They also are used as texturizers in biscuit mixes, in chewing gum, in confections and frostings, and in surimi-based fabricated seafood products. They may also be used components of protective coatings applied to fresh apples, avocados, bananas, banana plantains, limes, melons (honeydew and cantaloupe), papaya, peaches, pears, pineapples, and plums to retard ripening and spoiling. Sucrose fatty acid esters must be used in accordance with current good manufacturing practice and in an amount not to exceed that reasonably required to accomplish the intended effect (21CFR172.5, 2003).

International

SOEs are not specifically listed for the petitioned use or other uses in the following international organic standards:

- Canadian General Standards Board
- CODEX Alimentarius Commission
- European Economic Community (EEC) Council Regulation 2092/91
- International Federation of Organic Agriculture Movements
- Japan Agricultural Standard for Organic Production

However, some organic standards do allow the use of some natural *Nicotiana*-derived products that most likely contain small amounts of sucrose esters, including SOEs, for pest control:

- The Canadian General Standards Board allows the introduction of botanical compounds (e.g., menthol, vegetable oils, essential oils, herbal teas) in honey production. However, such remedies may not be used within thirty days of honey flow or whenever honey supers (additional honey-collecting structures) are on the hive. The use of synthetic antibiotics in honey production is allowed only when the imminent health of the colony is threatened. Before such treatments, a hive must be removed from the foraging area and taken out of organic production to prevent the spread of antibiotics within the apiary. Honey extracted following the use of such antibiotics cannot be certified organic, in accordance with the standard, for the remaining season (Canadian General Standards Board, 1999).

- Codex Alimentarius allows the use of tobacco tea (except pure nicotine) to combat a pest infestation (Codex Alimentarius Commission, 2001).

- The EEC Council Regulation allowed the application of an extract (aqueous solution) from *Nicotiana tabacum* as an insecticide only against aphids in subtropical fruit trees (e.g., oranges, lemons) and tropical crops (e.g., bananas); it can be used only at the start of the vegetation period. This permission expired March 31, 2002 (European Economic Community, 1991).

- The International Federation of Organic Agriculture Movements allows the use of tobacco tea as a crop protectant, but pure nicotine is forbidden (IFOAM, 2002).

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: **Is the petitioned substance formulated or manufactured by a chemical process? (From 7 U.S.C. § 6502 (21))**

SOEs are manufactured in an eight-step process that uses as raw materials a sugar, a fatty acid, and an alcohol, and relies on a number of catalysts and solvents. The process is patented because of its unique solvent recovery and reuse properties (Patent #5,756,716) and is described below:

> "First, a fatty acid and methyl or ethyl alcohol is reacted in the presence of sulfuric acid catalyst to produce a fatty acid ester and water. The sulfuric acid catalyst is neutralized with a metal carbonate to make a metal sulfate, with the fatty acid ester being separated from the metal sulfate, the alcohol, and the water. The recovered fatty acid ester is reacted in the presence of a metal carbonate catalyst with sugar dissolved in dimethyl sulfoxide to produce the sugar ester product and alcohol. The dimethyl sulfoxide is separated from the reaction mixture by vacuum distillation, and then water is added to emulsify the sugar ester product and unreacted fatty acid ester. The unreacted sugar and the metal carbonate are dissolved in the water. Next, the emulsified sugar ester product and unreacted fatty acid ester is separated from the water containing dissolved unreacted sugar and metal carbonate by breaking the emulsion of the sugar ester product and unreacted fatty acid ester. The sugar ester product is purified by dissolving the unreacted fatty acid ester in ethyl acetate, and substantially all the dimethyl sulfoxide, alcohol, and ethyl acetate is recovered for reuse in the process. Finally, substantially all the unreacted sugar in a concentrated useful form is recovered." (U.S. Patent and Trade Office, 1998)

According to the commercial manufacturer of SOEs, it is not possible to extract the naturally occurring sugar esters in sufficient quantity to be commercially viable (AVA Chemical Ventures, 2002).

Evaluation Question #2: Is the petitioned substance formulated or manufactured by a process that chemically changes the substance extracted from naturally occurring plant, animal, or mineral sources? (From 7 U.S.C. § 6502 (21).)

As described above, commercially used SOEs are manufactured by a multi-step chemical process that requires a number of catalysts and solvents. The raw materials (sugar, fatty acids, alcohol) for the process can be extracted from naturally occurring sources. However, the petitioner does not specify whether natural sources of raw materials would be used to manufacture SOEs for the petitioned use. The petitioner does not specify whether the various reagents used in the manufacturing process (sulfuric acid, potassium carbonate, dimethyl sulfoxide) would be from natural or synthetic sources, but it is more likely that synthetic reagents would be used. During the process, these raw materials undergo several reactions that substantially change their chemical composition, and produce the material under review, SOEs.

Evaluation Question #3: Is the petitioned substance created by naturally occurring biological processes? (From 7 U.S.C. § 6502 (21).)

SOEs occur naturally in some plants, as a result of normal plant metabolic functions. The exact process that occurs in nature has not been documented, but it is not the same as the commercial manufacturing process, which entails the use of sulfuric acid and metal carbonate catalysis, filtration, transesterification, refluxing, vacuum and fractional distillation, decanting, and centrifugation.

Evaluation Question #4: Is there environmental contamination during the petitioned substance's manufacture, use, misuse, or disposal? (From 7 U.S.C. § 6518 (m) (3).)

Manufacturing: The petitioner has selected a patented commercial manufacturing process that recovers and reuses much of the solvents used, and has no liquid waste streams and minimal air emissions (U.S. Patent and Trade Office, 1998).

Approved Usage: Using SOEs as a pesticide to control parasitic *Varroa* mites on honeybees is one of several approved agricultural/horticultural applications. When applied according to EPA-approved label directions for *Varroa* control, no direct exposure of birds or aquatic organisms to SOE is expected (U.S. EPA, 2002a). EPA concluded that it was not necessary for the petitioner to submit environmental fate and groundwater data, because the risk is expected to be minimal due to the lack of exposure, low toxicity, use pattern, and application methods for all approved uses. However, the label includes the following precautionary statement against applying SOEs directly to:

> "water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Nor should SOEs contaminate water when cleaning equipment or disposing of equipment wash waters. In addition , spray should not be allowed to drift from the application site and contact people, structures people occupy at any time and the associated property, parks and recreational areas, non-target crops, aquatic and wetland areas, woodlands, pastures, rangelands or animals. SOEs should be applied only when wind speed is not more than 10 mph, and for sprays, the largest size droplets possible should be applied." (Barrington, 2004a [Avachem Sucrose Octanoate label])

In addition, SOEs biodegrade within approximately five days at approximately 68-80.6°F/20-27°C, in both aerobic and anaerobic conditions, so minimal potential for exposure exists to insects, fish, and other non-target wildlife as a result of SOE use (U.S. EPA, 2002a).

Misuse: The precautionary statement listed above implies a potential for adverse effects resulting from misuse of the product.

Disposal: The EPA-approved label requires disposal of SOEs on site or at an approved waste disposal facility to mitigate any secondary contamination.

Evaluation Question #5: Is the petitioned substance harmful to the environment? (From 7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i).)

EPA evaluated potential environmental risks associated with sucrose fatty acid esters in the *Biopesticides Registration Action Document* (U.S. EPA, 2002a). EPA concluded that it expected no risks to the environment from the use of SOE as a biopesticide because:

(1) The esters biodegrade rapidly and therefore do not persist in the environment.

(2) The esters are not toxic to mammals or other non-target organisms.

(3) Organisms are already exposed because these sucrose esters are found in plants.

(4) The tiny amounts used in pesticide products are not expected to substantially increase the amount of these esters in the environment (U.S. EPA, 2002b).

Evaluation Question #6*:* Is there potential for the petitioned substance to cause detrimental chemical interaction with other substances used in organic crop or livestock production? (From 7 U.S.C. § 6518 (m) (1).)

As stated in Evaluation Question #4, SOEs do not persist in the environment and biodegrade within approximately five days at approximately 68-80.6°F/20-27°C, in both aerobic and anaerobic conditions (U.S. EPA, 2002a). Within a beehive, where the preferred temperature is ~95°F/35°C, biodegradation should proceed more rapidly (Shimek, 2000). This minimizes the opportunity for SOEs to chemically interact with other agricultural substances within a beehive or in the surrounding agricultural environment. Prior to biodegradation, it is possible for SOEs to act as an unwanted surfactant with detrimental effects, but no information sources reviewed for this report described or evaluated potential adverse impacts of this nature.

Evaluation Question #7: Are there adverse biological or chemical interactions in the agro-ecosystem by using the petitioned substance? (From 7 U.S.C. § 6518 (m) (5).)

SOEs have been demonstrated to be practically non-toxic to honey bees (*Apis mellifera* L) (LD_{50} > 80 ug/bee) (U.S. EPA, 2002a) and the following beneficial insects, all of which are important predators of homopteran pests: Lady Beetles (*Harmonia* spp., *Curinus coeruleus* Mulsant, *Cycloneda sanguinea* L., *Olla v-nigrum* Mulsant), Green Lacewing (*Chrysopidae rufilabris*), Red Scale Parasoid (*Aphytis melinus* De Bach), Insidious Flower Bug (*Orius insidiosus* Say) (Michaud and McKenzie, 2004). If SOEs escape from the beehive and enter the agro-ecosystem at large, they may come in contact with crop plants. However, the petitioner reports that SOEs have been tested on a range of crops, including almond, apple, pear, citrus, cotton, grape, peach, lettuce, tomato, mint, cabbage, melon, and several ornamental crops, including rose and poinsettia, and no phytotoxicity has been reported (Barrington, 2004a). In addition, SOEs biodegrade quickly (U.S. EPA, 2002a), which reduces the potential for adverse biochemical or chemical interactions.

Evaluation Question #8: Are there detrimental physiological effects on soil organisms, crops, or livestock by using the petitioned substance? (From 7 U.S.C. § 6518 (m) (5).)

Michaud and McKenzie (2004) found that SOEs are not poisonous to bees or certain other beneficial insects (See Evaluation Question #7). However, available information sources do not address the potential for SOEs to cause detrimental physiological effects on soil organisms or other insects not studied by Michaud and McKenzie.

EPA concluded, based on published data, that it is unlikely that any toxic effects will occur in birds, freshwater fish, freshwater aquatic invertebrates, and/or non-target plants, when SOEs are used according to label directions (U.S. EPA, 2002a). In addition, as noted by the petitioner, SOEs occur naturally (at low concentrations) in certain crop and non-agricultural plants (Barrington, 2004a) and is a normal part of animal diets (U.S. EPA, 2002a). This suggests that crop and livestock exposure will have no detrimental physiological effects.

Other organic honeybee pest control substances can have an effect on the flavor of honey (ATTRA, 2003); although SOEs have a noticeable color and flavor and are in use in non-organic apiculture, no tests have been conducted to determine whether honey is tainted by use of SOEs in apiculture (Mussen, 2004).

Evaluation Question #9: Is there a toxic or other adverse action of the petitioned substance or its breakdown products? (From 7 U.S.C. § 6518 (m) (2).)

Breakdown products of SOEs include sucrose, fatty acids, carbon dioxide, and water, all of which are non-toxic (Wayman, 1971).

Evaluation Question #10: Is there undesirable persistence or concentration of the petitioned substance or its breakdown products in the environment? (From 7 U.S.C. § 6518 (m) (2).)

SOEs are rapidly biodegradable, and do not persist or accumulate in the environment (U.S. EPA, 2002a).

Evaluation Question #11: Is there any harmful effect on human health by using the petitioned substance? (From 7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4).)

EPA has not identified any subchronic, chronic, immune, endocrine, dietary, or nondietary exposure issues for SOEs in children or the general U.S. population (U.S. EPA, 2002a). In fact, EPA estimated that the SOE acceptable daily intake (ADI) for humans is equivalent to 2.82 lb of SOEs per day for a 176 lb person (U.S. EPA, 2002a).

However, rabbits subject to ocular and dermal exposure to undiluted manufacturing-use SOEs showed irritation that usually resolved in14 days and 24 hours, respectively. EPA concluded that these reactions are unlikely when SOEs are used according to label directions, which include precautions regarding ocular exposure risks (U.S. EPA, 2002a).

<u>Evaluation Question #12:</u> Is there a wholly natural product which could be substituted for the petitioned substance? (From 7 U.S.C. § 6517 (c) (1) (A) (ii).)

There are some natural products under investigation for *Varroa* control, such as fungal pathogens, lactic acid (ATTRA, 2003), essential oils (e. g., thyme, wintergreen, spearmint, rosemary, peppermint) (Amrine et al., 1996b, 1996a)), oxalic acid, and neem oil, but they have not gained industry recognition for organic apicultural use (ATTRA, 2003) and some may affect honey flavor (ATTRA, 2003).[2] No information is available about these substances relative performance, and it is unknown whether they meet or exceed the health and environmental safety and efficacy of SOEs in eliminating *Varroa* mites from honeybee hives. Another substance that may equal the synthetic SOE product under review is naturally occurring SOE that has been extracted from plant leaves. According to the petitioner, this nonsynthetic product, while likely to be equally effective and safe, has not been approved for organic use and would be considerably more expensive than the synthetic version (Barrington, 2004a).

<u>Evaluation Question #13:</u> Are there other already allowed substances that could be substituted for the petitioned substance? (From 7 U.S.C. § 6518 (m) (6).)

Synthetic forms of naturally occurring substances such as folic, formic, and lactic acid have been used for *Varroa* control, but have not been approved for organic apiculture (NOSB Apiculture Task Force, 2001). The safety and efficacy of these substances relative to SOEs are unknown.

The petitioner reports some relative effectiveness data that compare SOEs to some natural industry-recognized classes of materials (and products) that have insecticidal uses similar to those of SOE (see Table 1) (Barrington, 2004c). These data are derived from one non-peer reviewed study of the substances' effectiveness for mealybug control with organic pineapples. The study also reports some environmental safety limitations, such as threats to wildlife from the alternative substances. This study found that no other product performs better than SOEs as an insecticide for mealybugs (Taniguchi, 2003). However, the study did not evaluate the use of SOEs as a miticide on honeybees.

Table 1. Potential Alternative Insecticides

Material Group	Comments
Neem extract and derivatives	Nonsynthetic; some products not labeled for mite control; potential bee hazard
Non-synthetic oils	Nonsynthetic; at least one product labeled for mite control
Petroleum-based oils	Synthetic; toxic to fish
Pyrethrum	Nonsynthetic; products not labeled for mite control; toxic to fish; potential honeybee toxicity
Soap	Synthetic; potential phytotoxicity

Sources: Barrington (2004a) and OMRI (2004)

<u>Evaluation Question #14:</u> Are there alternative practices that would make the use of the petitioned substance unnecessary? (From 7 U.S.C. § 6518 (m) (6).)

ATTRA reports on several bio-technical measures for *Varroa* control that are being investigated, such as spraying the bottom board of the hive to trap mites or replacing it with a mesh screen (ATTRA, 2003) or

[2] Industry-recognized uses of these materials is as follows: Neem oil accepted with restrictions for external parasite use in livestock production; EPA registered or exempt essential oils accepted with restrictions; and lactic acid accepted only as a feed additive and supplement (OMRI, 2004). These materials have not gained industry recognition specifically for apicultural use.

slats (Le Pabic, 2003). Other possible techniques under investigation are the use of smoker fuel to knock mites off bees (ATTRA, 2003), the use of food-grade mineral oil (FGMO) in conjunction with slatted bottom boards (Rodriguez, 2005), varying starter cell size (ATTRA, 2003) and brood comb type (Calis et al., n.d.), and developing *Varroa*-tolerant strains of honeybees (ATTRA, 2003). All show some potential for *Varroa* treatment, but, as yet, most have not been tested in the United States, and none have been approved for control in organic apiculture s (ATTRA, 2003).

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