(b) * * *

(2) * * *

(ii) The progress which has been made toward registration of the proposed use, if a repeated specific or public health exemption is sought. It shall be presumed that if a complete application for registration of a use, which has been under a specific or public health exemption for any 3 previous years, or any 5 previous years if the use is supported for registration by the IR-4 program, has not been submitted, reasonable progress towards registration has not been made.

■ 7. Section 166.30 is amended by revising paragraph (a)(1), removing paragraph (b), and redesignating paragraph (c) as paragraph (b).

§ 166.30 Notice of Agency decision.

(a) * * *

(1) *Incomplete applications.* The Agency may discontinue the processing of any application that does not address all of the requirements of § 166.20 until such time the additional information is submitted by the applicant.

* * * * *

■ 8. Section 166.32 is amended by revising the introductory text of paragraph (b) to read as follows:

§ 166.32 Reporting and recordkeeping requirements for specific, quarantine, and public health exemptions.

* * * * *

(b) *Interim and final reports.* A final report summarizing the results of pesticide use under any specific, quarantine, or public health exemption must be submitted to the Agency within 6 months from the expiration of the exemption unless otherwise specified by the Agency. For quarantine exemptions granted for longer than 1 year, interim reports must be submitted annually. When an application for renewal of the exemption is submitted before the expiration of the exemption or before submission of the final report, an interim report must be submitted with the application. The information in interim and final reports shall include all of the following:

* * * * *

■ 9. Section 166.40 is amended by revising paragraph (a), removing the period at the end of paragraph (b) and adding a semi-colon and the word ''and'' at the end of paragraph (b), and adding paragraph (c) to read as follows:

§ 166.40 Authorization.

* * * * *

(a) An unpredictable emergency condition exists;

* * * * *

(c) EPA has provided verbal confirmation that, for food uses, a tolerance or exemption from the requirement of a tolerance can be established in a timely manner, responsive to the projected timeframe of use of the chemical and harvest of the commodity, and that, for any use, the Agency has no other objection.

■ 10. Section 166.43 is amended by revising paragraphs (a)(1) and (b) to read as follows:

§ 166.43 Notice to EPA and registrants or basic manufacturers.

(a) * * *

(1) The State or Federal Agency issuing the crisis exemption must notify the Administrator in advance of utilization of the crisis provisions.

* * * * *

(b) *Contents of notice.* Information required to be provided in notices shall include all of the following:

(1) The name of the product and active ingredient authorized for use, along with the common name and CAS number if available, including a copy of the EPA registered label and use directions appropriate to the authorized use;

(2) The site on which the pesticide is to be used or is being used;

(3) The use pattern;

(4) The date on which the pesticide use is to begin and the date when the use will end;

(5) An estimate of the level of residues of the pesticide expected to result from use under the crisis exemption;

(6) Earliest anticipated harvest date of the treated commodity;

(7) Description of the emergency situation; and

(8) Any other pertinent information available at the time.

§ 166.47 [Removed]

■ 11. Section 166.47 is removed.

■ 12. Section 166.49 is amended by revising paragraph (a) to read as follows:

§ 166.49 Public notice of crisis exemptions.

(a) *Periodic notices.* At least quarterly, the Administrator shall issue a notice in the **Federal Register** announcing issuance of crisis exemptions. The notice shall contain all of the following:

(1) The name of the applicant;

(2) The pesticide authorized for use;

(3) The crop or site to be treated; and

(4) The name, address, and telephone number of a person in the Agency who can provide further information.

* * * * *

[FR Doc. 06–743 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2005–0515; FRL–7757–2]

Sorbitol Octanoate; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical sorbitol octanoate on all food commodities when applied/used in accordance with label directions. AVA Chemical Ventures, L. L. C. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sorbitol octanoate.

DATES: This regulation is effective January 27, 2006. Objections and requests for hearings must be received on or before March 28, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number EPA–HQ–OPP–2005–0515. All documents in the docket are listed on the www.regulations.gov website. (EDOCKET, EPA's electronic public docket and comment system was replaced on November 25, 2005, by an enhanced federal-wide electronic docket management and comment system located at *http://www.regulations.gov/*. Follow the online instructions.) Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Denise Greenway, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8263; e-mail address: *greenway.denise@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document and Other Related Information?

In addition to using EDOCKET (*http://www.epa.gov/edocket/*), you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

In the **Federal Register** of September 29, 2004 (69 FR 58166) (FRL–7679–1), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2E6389) by AVA Chemical Ventures, L. L. C., 80 Rochester Avenue, Suite 214, Portsmouth, NH, 03801. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of sorbitol octanoate. This notice included a summary of the petition prepared by the petitioner AVA Chemical Ventures, L. L. C. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of the FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider ''available information concerning the cumulative effects of a particular pesticide's residues'' and ''other substances that have a common mechanism of toxicity.''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Sorbitol octanoate is a fatty acid ester made from sorbitol and caprylic acid. Caprylic acid, also known as octanoic acid, is a common fatty acid in plants that is derived from edible oils or fats. It also is produced in small quantities in the human body and is marketed as a human dietary supplement (Ref. 1). Sorbitol, a food grade sweetener with about half the sweetness of sucrose, is a hexahydric alcohol and occurs naturally in fruits such as apples, plums, pears, cherries, dates, peaches, and apricots (Ref. 2). Both sorbitol and octanoic acid are on the Agency's List 4 Inerts of Minimal Concern. Sorbitol is cleared for food use in unlimited quantities as an antidusting agent (40 CFR 180.910). While sorbitol octanoate is the subject of this final rule, the raw materials from which it is made are common in crops eaten regularly by humans and animals.

Furthermore, sorbitol octanoate is chemically and toxicologically similar to certain groups of compounds, namely certain sorbitan esters and certain sucrose octanoate esters that have been FDA-approved since 1983 when used as direct additives in food, as emulsifiers in certain processed foods, and as post-harvest protective coatings for certain fruits (21 CFR 172.836, 172.838, 172.840, 172.842 and 172.859). In 1995, FDA expanded the range of foods in which sucrose octanoate esters (SOEs) are permitted (August 29, 1995, 60 FR 44756). Sorbitol octanoate and SOEs both are fatty acid esters, and both are made by reacting sugars with octanoic acid (i.e., both are non-ionic surfactants manufactured by esterifying C_8 fatty acid with a sugar: sorbitol in the case of sorbitol octanoate and sucrose in the case of SOEs). Sorbitol octanoate and SOEs have similar solubility in water, similar degrees of stability, and require a similar concentration to achieve droplet spread. FDA-approved sorbitan esters are different from sorbitol octanoate only in that sorbitol has one more water molecule than sorbitan. Therefore, the toxicological data associated with SOEs and sorbitan esters can be used to support an exemption from the requirement of a tolerance for sorbitol octanoate.

The applicant collected and summarized the toxicological data associated with the cited FDA food-use approvals for SOEs which included sorbitan esters (as they are chemically similar), and submitted this information in support of an earlier tolerance exemption request (64 FR 49010, September 9, 1999) for SOEs (Ref. 3). In turn, the Agency reviewed and accepted both the summaries and the underlying data in granting the tolerance exemption for SOEs (67 FR 60146, September 25, 2002). Because of the substantial similarity between the two active

ingredients (i.e., sorbitol octanoate and SOEs), the Agency allowed the applicant to ''bridge'' to that previously-submitted data/information to support the tolerance exemption requested for sorbitol octanoate.

Toxicity information/data submitted in support of this tolerance exemption are referenced below. Toxicity data requirements that relate to or aggregate with human dietary risk were addressed by requests for data waivers, which were based on publically available information/data that were previously submitted by the applicant, and reviewed and accepted by the Agency, in support of the tolerance exemption that the Agency granted for the chemically-similar SOEs (Refs. 3, 4, and 6). In addition, the Agency found relevant data from additional public sources, including EPA's National Toxicology Program, which contributed to the Agency's review (Ref. 1). All of this information/data, which, in combination, was equivalent to what would normally be provided by guideline studies, and therefore would likely have been adequate to meet each toxicology requirement had they been submitted as such pursuant to 40 CFR 152.90(b)(4), was deemed adequate to support the waiver requests. Sorbitan esters and sucrose fatty acid esters, which are used as food emulsifiers and as post-harvest fruit protectants, have been found to be of no particular toxic concern in studies used to support their safety to the FDA. Sorbitol octanoate is different from the FDA-approved sorbitan esters in that octanoate is the sole fatty acid component and sorbitan anhydrides are derived from sorbitol by removal of one molecule of water. Therefore, results from studies on sorbitan esters can be used to support lack of toxicity concern with sorbitol octanoate. 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 EPA's List 4 inert ingredients, and thus are of minimal concern. Sucrose octanoate has previously been registered by EPA (EPA Reg. No. 70950–2). The rationales for waiver requests for all required mammalian toxicological studies are acceptable. More detailed analyses of these data and information can be found in specific Agency reviews of the studies and technical literature (Refs. 1, 6, 7, 8 and 9).

1. *Acute oral toxicity waiver (OPPTS 870.1100) MRID 444158–03, and amendment number 1.* Acute oral and dietary toxicity data, previously evaluated in three publications by the Food and Agriculture Organization (FAO) of the United Nations World Health Organization (WHO), were submitted in support of this data waiver request (Refs. 3 and 4). The data contained in these reports demonstrated that sorbitan esters and sucrose octanoate esters had extremely low oral toxicity (in laboratory studies), even at concentrations substantially higher than are found in human food.

In studies with rats and humans, it was demonstrated that sorbitan esters and sucrose octanoate esters were rapidly hydrolyzed and absorbed by the body. Sorbitol octanoate is different from the sorbitan esters approved by FDA for direct addition to food for human consumption in the degree to which water is removed during the manufacturing process and the specific fatty acid that is used to make the esters. Sorbitan is a generic name for anhydrides (cyclic ether tetrahydric alcohols) derived from sorbitol by removal of one molecule of water. Octanoic acid is used to make sorbitol octanoate, but the sorbitan esters are made with mixtures of several longer-chain fatty acids. Sorbitan monopalmitate in the diet of rats; sorbitan monostearate in the diet of rats; sorbitan tristearate administered to rats by gavage; and sorbitan monopalmitate, sorbitan monostearate, and sorbitan tristearate in rats (maximum oral dose) caused no toxic symptoms/mortality. The acute oral LD_{50}s for monoleate and sorbitan monolaurate in rats were 39.8 and 37.5 grams/kilogram (g/kg), respectively. An estimate of acceptable daily intake in man of 0-25 milligrams/kilogram (mg/kg) was set by the Expert Committee on Food Additives. Sorbitol octanoate hydrolyzed rapidly to sorbitol and octanoic acid. The LD_{50}s for sorbitol in mice/rats dosed intravenously or orally ranged from 7,100 to 25,700 mg/kg, respectively. The oral LD_{50}s for octanoic acid were 1,283 mg/kg (one study, male rats) and 10,080 mg/kg (another study, male and female rats), amounts far greater than humans would encounter via the oral exposure route from pesticidal use of sorbitol octanoate. Sorbitol (21 CFR 184.1835) and ocatanoic acid (21 CFR 184.1025) are classified as GRAS by the FDA and are in EPA's List 4 - Inerts of Minimal Concern. Because sorbitol octanoate is chemically similar to SOEs, for which an exemption from tolerance already is established, and octanoic acid is a sorbitol octanoate constituent/degradate of no toxicological concern, the information/data described above support waiver from the data requirements for acute oral toxicity studies (classification: acceptable; Toxicity Category IV for the manufacturing-use product and end-use product).

2. *Acute dermal toxicity waiver (OPPTS 870.1200) MRID 444158–03 and amendment number 1.* A data waiver was granted for this guideline study based on the strength of the supporting information/data submitted by the registrant in connection with the tolerance exemption granted for SOEs, which as noted above are chemically and toxicologically similar to sorbitol octanoate. Also, dermal toxicity data on the sorbitan esters is relevant to sorbitol octanoate. The only difference between the sorbitan esters used in cosmetics and sorbitol octanoate is in the degree to which water is removed during the manufacturing process. Sorbitan fatty acid esters were generally minimal to mild skin irritants in animals and humans. In addition, publically available sources list the rabbit dermal LD_{50} for octanoic acid (a sorbitol octanoate constituent/degradate of no toxicological concern) as > 5,000 mg/kg (Ref. 1), an amount far greater than humans would encounter via the dermal exposure route from pesticidal use of sorbitol octanoate and which places it in the Toxicity Category of no concern (IV) (classification: acceptable; Toxicity Category IV for the manufacturing-use product and end-use product).

3. *Acute inhalation toxicity waiver (OPPTS 870.1300) MRID 444158–03 and Amendment number 1.* A data waiver was granted for this guideline study based on the strength of the supporting information/data submitted by the registrant in connection with the tolerance exemption granted for SOEs, which as noted above are chemically and toxicologically similar to sorbitol octanoate (Refs. 1,3,4 and 6). No adverse effects have been reported by researchers working with sorbitol octanoate, and the compound is not volatile. The sorbitol octanoate constituents sorbitol and octanoic acid are classified as Generally Recognized as Safe (GRAS) by the FDA and are among EPA's List 4 Inerts of Minimal Concern. The chemically-similar sorbitan fatty acid esters are waxy solids or viscous liquids which cannot be inhaled (classification: acceptable; Toxicity Category IV for the manufacturing-use product and end-use product).

4. *Hypersensitivity study waiver (OPPTS 870.2600) MRID 455973–01.* No hypersensitivity incidents have been reported for laboratory workers regularly exposed to sorbitol octanoate for up to 7 years. Neither have there been reports of hypersensitivity from

those working with the chemically-similar sucrose octanoate. A waiver for conduct of a dermal sensitization study for sorbitol octanoate thus can be supported. In addition, the registrant is obliged under the Federal Insecticide,Fungicide, and Rodenticide Act (FIFRA) section 6(a)(2) to notify the Agency in the event of such incidents (classification: acceptable).

5. *Genotoxicity and mutagenicity waiver (OPPTS 870.5300, 870.5195) MRID 444158–03 and amendment number 1.* No guideline studies were submitted, but it was determined that none are required because acceptable information/data were submitted from the open technical literature to scientifically justify a waiver of the data requirements for genotoxicity and mutagenicity. This information/data demonstrate that SOEs and sorbitol octanoate (because of their chemical and toxicological similarities) are not genotoxic and/or mutagenic, nor is the active ingredient structurally and/or chemically similar to known mutagens or known classes of mutagens (Refs. 3, 4 and 6). In addition, a study reported by EPA's National Toxicology Program shows octanoic acid, a sorbitol octanoate constituent/degradate of no toxicological concern, to be negative for genotoxicity/mutagenicity (Ref. 1) (classification: acceptable).

6. *Other data requirements waived.* Immune response and all remaining Tier I biochemical toxicology data requirements that relate to or aggregate with human dietary risk were waived (see OPPTS 880.3800 through 870.4200, MRID 444158–03 and amendment number 1) due to the low toxicity of the chemically similar SOEs, as reported in the open technical literature (Refs. 3, 4, 5, 6 and 7). In addition, octanoic acid, a sorbitol octanoate constituent/degradate of no toxicological concern, is considered a nonteratogenic compound even at the very high dose rate of 18.75 millimoles/kg (Ref. 1).

IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* An Acceptable Daily Intake (ADI) of SOEs for humans was estimated by FAO/WHO to be up to 16 mg/kg body weight/day, which is equivalent to 1.28 kg of SOEs per day for a 176 lb person (Refs. 3, 4, and 6). There are no reasonably foreseeable circumstances in which the residue levels of SOEs or the chemically- and toxicologically-similar compound sorbitol octanoate would ever approach this amount. Sorbitol octanoate hydrolyzes into its constituents (sorbitol and octanoic acid) shortly after application and then biodegrades. In studies with rats and humans, it was demonstrated that SOEs were rapidly hydrolyzed and absorbed by the body (Ref. 6). Because sorbitol octanoate is made from sorbitol (present in certain fruits) and caprylic acid (derived from edible oils and fats), there is a great likelihood of exposure in the normal human diet to both SOEs (derived from sugar and edible tallow or edible vegetable oils) and sorbitol octanoate, and their components for most, if not all, individuals, including infants and children. Sorbitol and octanoic acid are common components of the human diet. Thus, sorbitol octanoate may be considered a normal part of the human diet. To date, there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions in humans resulting from exposure to either SOEs (which for years have been FDA-approved food emulsifiers) or the chemically-similar sorbitol octanoate. Even if there is a significant increase in dietary exposure to sorbitol octanoate due to its use as a pesticide, the acute toxicity information from the National Toxicology Program and the information submitted by the registrant demonstrating extremely low mammalian toxicity (Toxicity Category IV) for SOEs (which, again, are chemically similar to sorbitol octanoate) indicate that any possible risk associated with acute exposures by the oral, dermal and inhalation routes to sorbitol octanoate would be low to non-existent. Further, any increased exposure due to the proposed products would be negligible because the active ingredient sorbitol octanoate will rapidly hydrolyze into its constituent components (sorbitol and octanoic acid), which subsequently will be rapidly metabolized by soil bacteria, thus limiting the general public's contact with treated plants or food products.

2. *Drinking water exposure.* No drinking water exposure is expected. Sorbitol octanoate is not applied directly to water, does not persist in the environment and biodegrades following application/use. Even if sorbitol octanoate residues were to enter drinking water, we do not expect any significant risk since sorbitol octanoate will rapidly hydroloyze into its consituent components (sorbitol and octanoic acid), which then would biodegrade prior to consumption by microorganisms before the general public would contact drinking water containing residues of sorbitol octanoate.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure to sorbitol octanoate residues for the general population, including infants and children, is unlikely because the uses are limited to applications to horticultural and agricultural crops. The sorbitol octanoate constituents sorbitol and octanoic acid are normal parts of the human diet. Sorbitol octanoate toxicity from a dietary exposure standpoint has been determined to be extremely low. Therefore, while there exists a great likelihood of prior exposure for most, if not all, individuals to both sorbitol octanoate and SOEs, any increased non-occupational exposure due to the proposed products would be negligible because the active ingredient sorbitol octanoate will rapidly hydrolyze into its constituent components (sorbitol and octanoic acid) which will be rapidly metabolized by soil bacteria, thus limiting the general public's contact with treated plants or food products via the dermal or inhalation routes.

V. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' These considerations include the possible cumulative effects of such residues on infants and children.

Except through ocular exposure, which is only expected in the occupational setting and can be prevented by the use of protective eyewear, neither sorbitol octanoate nor SOEs are toxic, and it is not anticipated that there would be cumulative effects from common mechanisms of toxicity. EPA does not have, at this time, available data to suggest whether sorbitol octanoate has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity

finding as to sorbitol octanoate and any other substances and sorbitol octanoate does not appear to produce a toxic metabolite produced by other substances. For the purpose of this tolerance action, therefore, EPA has not assumed that sorbitol octanoate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's web site at *http://www.epa.gov/pesticides/cumulative.*

VI. Determination of Safety for U.S Population, Infants and Children

1. *U.S. population.* The Agency has determined that there is a reasonable certainty that no harm will result from aggregate exposure to residues of sorbitol octanoate to the U.S. population. This includes all anticipated dietary exposures and other non-occupational exposures for which there is reliable information. The Agency arrived at this conclusion based on the extremely low levels of mammalian dietary toxicity associated with SOEs and, by extension, sorbitol octanoate due to the fact it is nearly identical chemically. Accordingly, it is unlikely that any toxic effects will result from exposure to sorbitol octanoate via the oral, dermal or inhalation pathways when the registered sorbitol octanoate products are used according to proposed label directions (Ref. 6). Based upon the data submitted in connection with SOEs and, by extension, the chemically-similar compound sorbitol octanoate, the amount of sorbitol octanoate applied to food crops is many orders of magnitude lower than the concentrations of sorbitol octanoate needed to cause toxicological effects. Because the worst case scenario exposure is far below the level of any dietary toxicity known for SOEs or sorbitol octanoate, or their components and degradates, EPA has determined that residues will not pose a dietary risk under reasonably foreseeable circumstances and that granting a tolerance exemption is appropriate.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure for infants and children in the case of threshold effects unless the Agency determines, based on reliable data, that a different margin is safe. Margins of exposure are referred to as uncertainty or safety factors, and are used to account for potential prenatal and postnatal toxicity and any lack of completeness in the data base. Based on all the reliable available information the Agency reviewed on SOEs and, by extension, sorbitol octanoate due to the fact that it is nearly identical chemically, the Agency concludes that sorbitol octanoate is practically non-toxic to mammals from a dietary standpoint, including infants and children. Thus, there are no threshold effects of concern and an additional margin of safety is not necessary to protect infants and children.

VII. Other Considerations

A. Endocrine Disruptors

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) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no 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 wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, sorbitol octanoate may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption. Based on available data, no endocrine system-related effects have been identified with consumption of sorbitol octanoate. To date, there is no evidence to suggest that sorbitol octanoate affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

B. Analytical Method(s)

The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including low toxicity and low exposure from the pesticidal use of sorbitol octanoate. For the same reasons, the Agency concludes that an analytical method is not required for enforcement purposes for sorbitol octanoate.

C. Codex Maximum Residue Level

There are no CODEX maximum residue levels for sorbitol octanoate.

VIII. Conclusions

Based on the toxicology information/data submitted and other information available to the Agency, there is a reasonable certainty that no harm will result from aggregate exposure to residues of sorbitol octanoate to the U.S. population, including infants and children, under reasonably foreseeable circumstances, when the biochemical pesticide is used in accordance with product label directions and good agricultural practices. This includes all anticipated dietary exposures and all other non-occupational exposures for which there is reliable information. The Agency has arrived at this conclusion based on the information/data submitted (and publically available) demonstrating negligible toxicity of the chemically-similar SOEs and sorbitan esters, and of sorbitol octanoate's constituents (sorbitol and octanoic acid). As a result, EPA is establishing an exemption from the tolerance requirements pursuant to FFDCA section 408(c) for residues of sorbitol octanoate in or on all food commodities.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period

for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP-2005–0515 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before March 28, 2006.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 564–6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A.1., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number EPA–HQ–OPP–2005–0515, to: Public Information and Records Integrity Branch, Information Technology and Resources Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. References

1. USEPA. Brief summary of toxicity information to support registration/ tolerance exemptions for sucrose octanoate. R. S. Jones to D. Greenway; August 8, 2002.

2. Lawson, M.E. 1997. Kirk-Othmer's Encyl Chem Tech. 4th Ed. J.I. Kroschwitz (ed). John Wiley & Sons, NY.

3. 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.

4. 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 number 1 to MRID 444158–03; July 13, 1998.

5. Barrington, A. Waiver request; July 12, 2002.

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

7. USEPA. Sucrose octanoate esters; A request for concurrence on a decision to waive the requirement for 90–day feeding study (870.3100) and Developmental Toxicity (Teratogenicity (870.3700) studies, based on the Registrant's correspondence of July 12, 2002. D. Greenway to R. S. Jones; August 7, 2002.

8. USEPA. Secondary Review of Data/ information submitted to support Registration of Sorbitol Octanoate R.D. Sjoblad to D. Greenway; December 29, 2004

9. USEPA. Endangered Species Risk Assessment for Sorbitol Octanoate. R. S. Jones to D. Greenway; September 13, 2005.

XI. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a

substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled*Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801*et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: January 13, 2006.

James Jones,

Director, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.1262 is added to subpart D to read as follows:

§ 180.1262 Sorbitol octanoate; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sorbitol octanoate in or on all food commodities when used in accordance with label directions.

[FR Doc. 06–756 Filed 1–26–06; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1167–F]

RIN 0938–AN02

Medicare Program; Payment for Respiratory Assist Devices With Bi-Level Capability and a Backup Rate

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule clarifies that respiratory assist devices with bi-level capability and a backup rate must be paid as capped rental items of durable medical equipment (DME) under the Medicare program and not paid as items requiring frequent and substantial servicing (FSS), as defined in section 1834(a)(3) of the Social Security Act. Before 1999, respiratory assist devices with bi-level capability (with or without a backup rate feature) were referred to as ''intermittent assist devices with continuous positive airway pressure devices'' under the Medicare program and in the Healthcare Common Procedure Coding System (HCPCS). This final rule responds to public comments received on a proposed rule published in the **Federal Register** on August 22, 2003, and finalizes the policy in that proposed rule. The rule will ensure that respiratory assist devices are consistently and properly paid under Medicare as capped rental items.

DATES: The provisions of this final rule are effective on April 1, 2006.

FOR FURTHER INFORMATION CONTACT: Joel Kaiser, (410) 786–4499.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legislative Authority for Payment for Durable Medical Equipment (DME)

Section 1834(a) of the Social Security Act (the Act) sets forth the payment methodology and requirements for payment for the purchase or rental of new and used durable medical equipment (DME) for Medicare beneficiaries under Medicare Part B (Supplementary Medical Insurance). In accordance with section 1834(a) of the Act, payment for DME is made on a fee schedule basis. Each item of DME that is paid under Medicare Part B is classified into one of the following payment categories:

- Inexpensive or other routinely purchased DME.
- Items requiring frequent and substantial servicing (FSS).
- Customized items.
- Oxygen and oxygen equipment.
- Other covered items (other than DME).
- Other items of DME (capped rental (CR) items).

Each category has its own unique payment rules. With the exception of customized items, for each item of DME that is identified by a code in the Healthcare Common Procedure Coding System (HCPCS), a fee schedule amount is calculated. The Medicare payment amount for a customized item of DME is based on the Medicare carrier's individual consideration of that item.

Section 1834(a) of the Act provides that Medicare payment for DME is equal