

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 172

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N. Hawkins

[Docket No. 98F-0717]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Sucrose Oligoesters

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of sucrose oligoesters (sucrose esters of fatty acids with an average degree of esterification ranging from four to seven) as an emulsifier or stabilizer, at a level not to exceed 2.0 percent, in chocolate and in butter-substitute spreads. This action is in response to a petition filed by Mitsubishi Chemical Corp.

DATES: This rule is effective [*insert date of publication in the Federal Register*]. Submit objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*]. The Director of the Office of the **Federal Register** approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of certain publications in new § 172.869 (21 CFR 172.869), effective [*insert date of publication in the Federal Register*].

ADDRESSES: Submit written objections and requests for a hearing to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3077.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of September 1, 1998 (63 FR 46465), FDA announced that a food additive petition (FAP 8A4610) had been filed by Mitsubishi Chemical Corp., 5-2, Marunouchi 2-chome, Chiyoda-Ku, Tokyo 100, Japan, proposing that the food additive regulations be amended to provide for the safe use of sucrose esters of fatty acids with an average degree of esterification ranging from four to seven, as an emulsifier or stabilizer, at a level not to exceed 2.0 percent, in chocolate and in butter-substitute spreads. The petitioner also proposed to adopt the name SOE as the common or usual name for this additive.

The petitioner derived the name SOE as an acronym for sucrose oligoesters. Mitsubishi requested the name SOE to differentiate this additive from sucrose fatty acid esters (SFAE), listed under § 172.859 (21 CFR 172.859), and olestra, listed under § 172.867 (21 CFR 172.867).

The agency has reviewed the term sucrose oligoesters and finds it to be an acceptable name to identify the petitioned substance. Therefore, the agency agrees that the name sucrose oligoesters may be used as the common or usual name for sucrose esters of fatty acids with an average degree of esterification ranging from four to seven.

The agency has also considered the acronym SOE as an alternate name for this ingredient. The agency has generally allowed an acronym to be used as an alternate name for an ingredient in those cases where the name of the

ingredient is long and only after there has been sufficient exposure to the acronym in conjunction with the established name to allow consumers to recognize the acronym as an alternative to the established name. For the subject petition, the agency believes that neither the food industry nor the consumer is currently familiar with the term SOE. Therefore, the agency is not adopting the acronym SOE as an alternate name for sucrose oligoesters at this time.

Sucrose oligoesters consists of a mixture of sucrose fatty acid esters, containing tetra-, penta-, hexa-, and hepta-esters (representing not less than 50 percent of the total esters), mono-, di- and tri-esters (representing not greater than 45 percent of the total esters), and octa-ester (representing not greater than 40 percent of the total esters). The fatty acid moieties are derived from edible fats and oils, predominantly C8 through C22 fatty acids. The proposed additive, sucrose oligoesters, has a composition that overlaps that of sucrose fatty acid esters, listed under § 172.859, and olestra, listed under § 172.867. However, § 172.859(b)(1) requires that sucrose fatty acid esters contain a minimum of 80 percent of mono-, di-, and tri-esters of sucrose and § 172.867(b)(1) requires that olestra contain a minimum of 97 percent of octa-, hepta-, and hexa-esters of sucrose. The proposed additive is thus mid-range between these two listed food additives in terms of the average number of ester moieties on the sucrose backbone.

In support of the safety of the proposed use of sucrose oligoesters, Mitsubishi submitted a combined chronic and carcinogenicity study with a sucrose fatty acid ester blend of mono- through penta-esters in male and female rats, as well as analytical data on the percentages of mono- through octa-esters in both the proposed additive and the fatty acid ester blend. Mitsubishi also

submitted a metabolism/pharmacokinetic study of ¹⁴C-labeled sucrose fatty acid esters in rats and several study reports and publications previously considered by FDA during its safety reviews of sucrose fatty acid esters and olestra.

As discussed in more detail in section II of this document, the agency focused its safety evaluation on the exposure and the metabolic fates of the tetra-, penta-, and hexa-ester components of sucrose oligoesters because FDA considered the other esters more fully in the earlier decisions. The agency's safety determinations for the mono-, di-, and tri-ester components (sucrose fatty acid esters (60 FR 44755, August 29, 1995)) and for the hepta- and octa-ester components (olestra (61 FR 3118, January 30, 1996)) remain unchanged.

II. Evaluation of Safety

In order to establish, with reasonable certainty, that this new food additive is not harmful under its intended conditions of use, FDA considered the probable human dietary exposure to the additive, the available toxicological data on the additive, and the manufacturing process for this additive.

A. Estimated Daily Intake for Sucrose Oligoesters and its Component Esters

The petitioner provided information on both typical use levels and maximum use levels. Absent specific information on typical use levels, FDA bases its estimation of exposure to an additive on the maximum possible use levels of the additive. FDA believes that typical use levels are more appropriate for consideration of lifetime exposure because a consumer is unlikely to consistently choose only those products with the maximum levels of the additive. Furthermore, the maximum level allowed may be higher than what is used in most foods. Consistent with good manufacturing practices, products formulated with the additive will contain the additive at a level no greater

than that needed to accomplish the intended technical effect. The petitioner has provided information which indicates that the typical use level of the additive in food products is 0.5 percent. Therefore, in estimating probable daily intake for sucrose oligoesters, the agency used 0.5 percent as the level in foods consumed over a lifetime of exposure.

The agency has estimated that the mean lifetime-averaged daily intake of sucrose oligoesters would be approximately 45 milligrams per person per day (mg/p/day). FDA also estimated that an individual at the 90th percentile of consumption of food that would contain the additive would have an exposure approximately two times the mean intake or 98 mg/p/day (Ref. 1).

Because the additive is a mixture and because the relevant safety studies were conducted on mixtures with a variety of compositions, FDA also examined the potential exposure to the component esters of sucrose oligoesters. The agency evaluated data from approximately 50 batches of the additive. Based on these data, the average percentages of the mono- through octa-esters in the additive were calculated. These averages were used in estimating exposure to the sucrose ester components of sucrose oligoesters for the consumer at the 90th percentile. FDA estimates exposure to these component esters to be 1.5 mg/p/day for the mono-ester, 4.2 mg/p/day for the di-ester, 10 mg/p/day for the tri-ester (or 16 mg/p/day for the mono-, di-, and tri-esters combined), 14 mg/p/day for the tetra-ester, 19 mg/p/day for the penta-ester, 23 mg/p/day for the hexa-ester, 20 mg/p/day for the hepta-ester, and 9 mg/p/day for the octa-ester (Ref. 1).

B. Evaluation of Safety Studies

As mentioned in section II.A of this document, sucrose oligoesters consist of a mixture of mono- to octa-esters, with most of the esters ranging from four

to seven fatty acids. The agency considered the nature of the petitioned substance, its constituents and metabolites, the currently approved uses of sucrose fatty acid esters and olestra, available related toxicological data, and exposure estimates for the individual sucrose fatty acid esters. Based on the totality of this information, the agency finds that the previous safety assessments for the mono-, di-, and tri-ester components and the hepta- and octa-ester components of sucrose oligoesters made during reviews for SFAE (sucrose fatty acid esters (60 FR 44755)) and olestra (olestra (61 FR 3118)), respectively, are applicable for the petitioned use of this additive (Ref. 2).

As stated previously, the estimated exposure to the combined mono-, di-, and tri-ester components of sucrose oligoesters from the proposed use is 16 mg/p/day. The agency finds that this estimated daily intake to these three sucrose esters from the proposed use of sucrose oligoesters and all approved uses of SFAE is less than the acceptable daily intake (ADI) level that was established for SFAE (Ref. 3).

As further stated previously, the estimated exposure to the hepta-ester from the proposed use of sucrose oligoesters is 20 mg/p/day and the estimated exposure to the octa-ester is 9 mg/p/day. Exposure to the hepta- and octa-esters from the proposed use of sucrose oligoesters would be insignificant in comparison to the current estimated exposure from olestra (20 mg/p/day v. 1,400 mg/p/day for the hepta-ester, and 9 mg/p/day v. 7,000 mg/p/day for the octa-ester) (Ref. 1 and 61 FR 3118).

In its review of the safety of the tetra-, penta-, and hexa-esters of sucrose oligoesters, the agency considered the estimated exposures to these ester components and other relevant information on sucrose fatty acid esters, including pharmacokinetic studies. In particular, the agency considered an

absorption study of ^{14}C -labeled sucrose polyester consisting of approximately 81 percent hexa- and lower esters (predominately hexa- and penta-esters) in rats that was submitted with the Olestra petition (FAP 7A3997). This study demonstrated that only a small percentage (i.e. not more than 1.5 percent) of the administered radiolabeled esters was absorbed and that the majority of the absorbed radioactivity was found in expired air and urine. Additionally, interim necropsies performed during the absorption study demonstrated that the amount of radioactivity detected in tissues decreased rapidly over time and therefore did not bioaccumulate. Because any increase in exposure to the penta- and hexa-esters from the petitioned use of sucrose oligoesters would be very small, and considering the totality of evidence showing no toxicity from these esters, FDA has no safety concerns from the potential intake of penta- and hexa-ester components of sucrose oligoesters from this use (Refs. 4 and 5).

In its review of the safety of exposure to the tetra-ester component of the subject additive, the agency considered a metabolism study of ^{14}C -labeled sucrose esters of stearic acid in rats and a combined chronic oral toxicity/carcinogenicity study of sucrose esters of fatty acids in rats. Based on the comparison of an estimated ADI for the tetra-ester of 110 mg/p/day from the oral toxicity study with a highly conservative exposure estimate for the tetra ester of 26 mg/p/day¹, the agency has no safety concerns regarding the potential intake of sucrose tetra-ester in sucrose oligoesters from the petitioned use (Refs. 1, 2, and 5).

¹Highly conservative estimates of exposures to the component esters of the subject additive have been obtained by adding intakes for 90th percentile eaters-only from the proposed use of SOE and the regulated uses of SFAE and olestra.

C. Specifications

In addition to specifications to ensure the identity of sucrose oligoesters, the agency considered specifications for residual levels of solvents and methanol. The additive is produced by interesterification of sucrose with methyl esters of fatty acids derived from edible fats and oils using the solvents dimethyl sulfoxide, isobutyl alcohol, or other appropriate solvents. To ensure removal of residual solvents and methanol from the methyl esters, the petitioner proposed specification limits for residual levels of dimethyl sulfoxide, isobutyl alcohol, and methanol. FDA has considered the manufacturing process for this additive and has determined that these specifications need to be included in the regulation.

III. Conclusion

Based on the totality of available information regarding the subject sucrose esters and the absence of any observed toxicity, FDA concludes that this additive is safe for its proposed use. Therefore, the agency concludes that the food additive regulations should be amended as set forth in this document. Because the foods described in new § 172.869(c) include foods subject to standards of identity, the agency notes that the additive may not be used in a standardized food unless permitted by the standard of identity. To ensure that only a food grade product is used in food, the additive must meet the specifications set forth in this document. The agency further concludes that the name sucrose oligoesters is acceptable for use as the common or usual name for the additive.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety

and Applied Nutrition by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Effects

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8A4610 (63 FR 46465). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Paperwork Reduction Act 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from DiNovi, Division of Biotechnology and GRAS Notice Review, to Peiperl, Division of Petition Review, June 2, 2003.
2. Memorandum from Young, Division of Food Contact Substance Notification Review, to Peiperl, Division of Petition Review, March 8, 2002.
3. Memorandum from Bleiberg, Division of Health Effects Evaluation, to Anderson, Division of Product Policy, November 4, 1993.
4. Memorandum from Young, Division of Food Contact Substance Notification Review, to Peiperl, Division of Petition Review, July 18, 2002.

5. Memorandum from Young, Division of Food Contact Substance Notification

Review, to Peiperl, Division of Petition Review, June 3, 2003.

VII. Objections

Any person who will be adversely affected by this regulation may at any time file with the Division of Dockets Management (see **ADDRESSES**) written or electronic objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to

the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

- 1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

- 2. Section 172.869 is added to subpart I to read as follows:

§ 172.869 Sucrose oligoesters.

Sucrose oligoesters, as identified in this section, may be safely used in accordance with the following conditions:

(a) Sucrose oligoesters consist of mixtures of sucrose fatty acid esters with an average degree of esterification ranging from four to seven. It is produced by interesterification of sucrose with methyl esters of fatty acids derived from edible fats and oils (including hydrogenated fats and oils). The only solvents which may be used in the preparation of sucrose oligoesters are dimethyl sulfoxide, isobutyl alcohol, and those solvents generally recognized as safe in food.

(b) Sucrose oligoesters meet the specifications in the methods listed in the table in this paragraph. The methods cited for determining compliance with each specification are incorporated by reference, in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of the methods may be examined at the Center for Food Safety and Applied Nutrition's Library, room 1C-100, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the Office of the **Federal Register**, 800 North Capitol St. NW., suite 700, Washington, DC. Copies of the methods are available from the sources listed in the table in this paragraph:

Specification	Limit	Method Cited	Source for Obtaining Method
(1) Sucrose esters	Not less than 90%	"Method for Analyzing the Purity of Sucrose Fatty Acid Esters," issued by Mitsubishi Chemical Corp., June 17, 1998.	Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.
(2) Mono-, di-, and tri-esters	Not more than 45%	"Method for Measuring the Ester Distribution of Sucrose Oligoesters," issued by Mitsubishi Chemical Corp., June 17, 1998.	Do.
(3) Tetra-, penta-, hexa-, and hepta-esters.	Not less than 50%	Do.	Do.
(4) Octa-esters	Not more than 40%	Do.	Do.
(5) Free Sucrose	Not more than 0.5%	"Free Sucrose Method," issued by Mitsubishi Chemical Corp., June 17, 1998.	Do.
(6) Acid Value	Not more than 4.0	"Acid Value," Appendix VII, Method I (Commercial Fatty Acids), in the <i>Food Chemicals Codex</i> , 4th ed. (1996), p. 820.	National Academy Press, 2101 Constitution Ave. NW, Washington, DC 20418 (Internet: http://www.nap.edu).
(7) Residue on Ignition	Not more than 0.7%	"Residue on Ignition, Appendix IIC, Method I, in the <i>Food Chemicals Codex</i> , 4th ed. (1996), pp. 751-752, (using a 1-gram sample).	Do.
(8) Residual Methanol	Not more than 10 milligrams/kilogram ..	Method listed in the monograph for "Sucrose Fatty Acid Esters" in the First Supplement to the 4th ed. of the <i>Food Chemicals Codex</i> (1997), pp. 44-45.	Do.
(9) Residual Dimethyl Sulfoxide	Not more than 2.0 milligrams/kilogram	Do.	Do.
(10) Residual Isobutyl Alcohol	Not more than 10 milligrams/kilogram ..	Do.	Do.
(11) Lead	Not more than 1.0 milligram/kilogram ..	"Atomic Absorption Spectrophotometric Graphite Furnace Method," Method I, in the <i>Food Chemicals Codex</i> , 4th ed. (1996), pp. 763-765.	Do.

(c) The additive is used as an emulsifier (as defined in § 170.3(o)(8) of this chapter) or stabilizer (as defined in § 170.3(o)(28) of this chapter) in chocolate and in butter-substitute spreads, at a level not to exceed 2.0 percent; except that the additive may not be used in a standardized food unless permitted by the standard of identity.

Dated: 8/6/03

cf0225

August 6, 2003.

L. Robert Lake

L. Robert Lake,
Director,
Office of Regulations and Policy,
Center for Food Safety and Applied Nutrition.
[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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Dawn P. Hawkins