

DATES: This rule is effective August 20, 2003. Submit objections and requests for a hearing by September 19, 2003. 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 August 20, 2003.

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/comments>.

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-