



Yoshiko Noda
Mitsubishi Chemical Corporation
1-1, Marunouchi 1-chome, Chiyoda-ku
Tokyo 100-8251
JAPAN

Re: GRAS Notice No. GRN 001287

Dear Yoshiko Noda:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001287. We received Mitsubishi Chemical Corporation (MCC)'s notice on June 17, 2025, and filed it on September 26, 2025. MCC submitted amendments to the notice on January 18 2026, and January 30, 2026, clarifying the manufacturing process, specifications, dietary exposure, literature search, and safety information.

The subject of the notice is sucrose oligoesters (SOE) for use as an emulsifier or stabilizer in whipping and whipped cream products and non-dairy whipped toppings at a level up to 0.5% by weight. The notice informs us of MCC's view that these uses of SOE are GRAS through scientific procedures.

Our use of the term, "sucrose oligoesters" or "SOE," in this letter is not our recommendation of those terms as an appropriate common or usual name for declaring the substance in accordance with FDA's labeling requirements. Under 21 CFR 101.4, each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for non-standardized foods. Issues associated with labeling and the common or usual name of a food ingredient are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Nutrition Center of Excellence. The Office of Pre-Market Additive Safety did not consult with ONFL regarding the appropriate common or usual name for "sucrose oligoesters."

MCC describes SOE as a white to red-brown powder, flake, soft solid, or stiff gel, or a colorless to red-brown viscous liquid. SOE contains a mixture of sucrose fatty acid esters with an average degree of esterification ranging from four to seven. MCC states that the identity of SOE is the same as that specified in 21 CFR 172.869.

MCC states that SOE is manufactured by inter-esterification of sucrose with methyl esters of fatty acids, derived from edible vegetable or hydrogenated edible vegetable oils and fats, in the presence of solvents, as specified in 21 CFR 172.869. After the esterification process, the crude reaction product is dissolved in a solvent, purified by extraction with water, and dehydrated to yield SOE. The dehydrated form of SOE can be

cooled and flaked, or cooled, flaked, and pulverized to yield other forms of SOE. MCC states that mixed tocopherols (0.01%) are added as an antioxidant to some SOE products, especially those containing unsaturated fatty acid esters. MCC states that SOE is manufactured according to current good manufacturing practices, and that all raw materials and processing aids are food-grade and are used in accordance with applicable U.S. regulations or are GRAS for their intended uses.

MCC provides specifications for SOE, which include the minimum content of sucrose esters ($\geq 90\%$), tetra-, penta-, hexa-, and hepta-esters ($\geq 50\%$), and limits on mono-, di-, and tri-esters ($\leq 45\%$), octa-esters ($\leq 40\%$), free sucrose ($\leq 0.5\%$), residue on ignition ($\leq 0.7\%$), acid value (≤ 4), methanol (≤ 10 mg/kg), dimethyl sulfoxide (≤ 2 mg/kg), isobutyl alcohol (≤ 2 mg/kg), lead (≤ 0.1 mg/kg), arsenic (≤ 0.1 mg/kg), mercury (≤ 0.1 mg/kg), cadmium (≤ 0.1 mg/kg), and microorganisms. MCC provides results from the analyses of three non-consecutive batches of SOE that does not contain mixed tocopherols and three non-consecutive batches of SOE containing mixed tocopherols to demonstrate that SOE can be manufactured to meet the specifications. MCC states that SOE without mixed tocopherols is stable for 24 months, whereas SOE containing mixed tocopherols is stable for 12 months when stored unopened in a cool, dark and well-ventilated space at a temperature below 35 °C.

MCC estimates an eaters-only cumulative dietary exposure to SOE from the intended uses and uses currently approved under 21 CFR 172.869¹ to be 386 mg/person(p)/d (6.2 mg/kg body weight (bw)/d) at the mean and 860 mg/p/d (13.3 mg/kg bw/d) at the 90th percentile for the U.S. population aged 2 years or older using food consumption data from the 2017-2018 National Health and Nutrition Examination Survey (NHANES).

MCC discusses published data and information on the safe use of SOE in foods that has been discussed in previous GRNs or sourced from a literature search through December 2025. MCC discusses toxicological studies on SOE, including a 28-day range-finding study, a 12-month oral toxicity study, and a two-year combined chronic toxicity and carcinogenicity study in rats. MCC notes that the pivotal two-year carcinogenicity study reported no effects up to a dietary concentration of 5% SOE, corresponding to 2,120 mg/kg bw/d for male rats, the highest dose tested. MCC notes that previous GRAS notices on sucrose fatty acid esters (SFAE) (GRNs 000129, 000248, 000421, 000514, and 001123)² are supportive of safety, as both SOE and SFAE are sucrose esters, with SOE containing a higher percentage of lipophilic esters than SFAE. In turn, MCC discusses a two-generation developmental and reproductive toxicity study on a sucrose polyester mixture, and a combined 12-month oral toxicity and carcinogenicity study, and two human tolerability studies on SFAE, as supportive evidence of safety of SOE.

¹ SOE is a food additive approved for use as an emulsifier or stabilizer in chocolate and in butter-substitute spreads at a level not to exceed 2% (21 CFR 172.869). Standards of identity exist for sweet, white, and milk chocolate, that permit the use of emulsifiers at levels up to 1%, 1.5%, and 1%, respectively (21 CFR part 163). MCC applied those use levels to the standardized chocolate products when estimating the cumulative dietary exposure to SOE.

²The subjects of GRNs 000129, 000248, 000421, 000514, and 001123 are various forms of sucrose fatty acid esters. We evaluated these notices and responded in letters dated November 7, 2003, October 24, 2008, August 10, 2012, December 3, 2014, and November 3, 2023, respectively, stating that we had no questions at the time regarding the notifiers' GRAS conclusions.

MCC discusses the absorption, distribution, metabolism, and excretion of SOE and states that it is hydrolyzed in the gastrointestinal tract and excreted intact or as incompletely hydrolyzed sucrose esters, primarily in the feces. MCC also notes that other conclusions on SOE and SFAE from the Joint FAO/WHO Expert Committee on Food Additives and the European Food Safety Authority are supportive of their GRAS conclusion.

Based on the totality of the data and information, MCC concludes that SOE is GRAS under its intended conditions of use.

Standards of Identity

In the notice, MCC states its intention to use SOE in several food categories, including in a food category for which standards of identity exist, located in Title 21 of the CFR. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Potential Requirement for a Color Additive Petition

There is no GRAS provision for color additives. In the notice, MCC describes SOE as a white to red-brown powder, flake, soft solid, or stiff gel, or a colorless to red-brown viscous liquid. As such, the use of SOE in food products may constitute a color additive use under section 201(t)(1) of the FD&C Act and FDA's implementing regulations in 21 CFR Part 70. Under section 201(t)(1) and 21 CFR 70.3(f), a color additive is a material that is a dye, pigment, or other substance made by a synthetic process or similar artifice, or is extracted, isolated, or otherwise derived from a vegetable, animal, mineral, or other source. Under 21 CFR 70.3(g), a material that otherwise meets the definition of a color additive can be exempt from that definition if it is used (or is intended to be used) solely for a purpose or purposes other than coloring. Our response to GRN 001287 is not an approval for use as a color additive nor is it a finding of the Secretary of the Department of Health and Human Services within the meaning of section 721(b)(4) of the FD&C Act. Questions about color additives should be directed to the Division of Food Ingredients in the Office of Pre-Market Additive Safety.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of MCC's notice concluding that SOE are GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing SOE. Accordingly, our response should not be construed to be a statement that foods containing SOE, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that MCC provided, as well as other information available to FDA, we have no questions at this time regarding MCC's conclusion that SOE are GRAS under its intended conditions of use. This letter is not an affirmation that SOE are GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 001287 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

Digitally signed by Susan J. Carlson -S
Date: 2026.03.23 11:11:17 -0400'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Pre-Market Additive Safety
Office of Food Chemical Safety, Dietary
Supplements, and Innovation
Human Foods Program