

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 <sup>14</sup>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 <sup>14</sup>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/day<sup>1</sup>, 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).

#### 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.

<sup>1</sup>Highly 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.

### 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,