



Dr. James Akingbasote  
Intertek Assuris  
2233 Argentia Rd, Suite 201 W  
Mississauga, Ontario L5N 2x7  
CANADA

Re: GRAS Notice No. GRN 001216

Dear Dr. Akingbasote:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Saputo Dairy UK (Saputo) that we cease our evaluation of GRN 001216, which we filed on November 8, 2024. We received this request on March 25, 2025.

The subject of the notice is galacto-oligosaccharides (GOS) for use as an ingredient in non-exempt infant formula for term infants and formula for children more than 12 months of age at a maximum use level of 7.8 g/L of formula, as consumed. Additional uses for GOS included in the notice are as an ingredient in infant and toddler cereals at levels up to 6.41 g/100 g; juice, puddings, custards, and similar desserts, and yogurt drinks for infants at levels up to 2.72 g/100g; snacks (including cookies, crackers and puffs) for infants at levels up to 14.3 g/100 g; ready-to-serve (RTS) fruit-based food, RTS dinners, and ready-to-feed vegetables for infants and toddlers at levels up to 1.83 g/100 g; baked goods and baking mixes; ready-to-eat breakfast cereals; coffee and tea; milk and cream analogs; ice cream, frozen yogurt and other dairy desserts; puddings, flans, custards, and other milk- or egg-based desserts; bars; pastas; milk, flavored milk, milk drinks and shakes; yogurt and yogurt drinks; milk-based sauces; milk-based nutrition and protein beverages; milk-based and non-milk-based meal replacement beverages; coconut beverages; soft drinks, “energy” drinks, and sports drinks; “enhanced”, flavored, carbonated or fortified waters; fruit juices, drinks, ades, nectars, and smoothies; canned fruits; vegetable juices; snacks; soft and hard candies; fruit fillings; jams, jellies, and preserves; dessert toppings and sweet syrups; and soups and soup mixes at maximum levels ranging from 0.62 g/100g to 40 g/100 g.<sup>1</sup> The notice informs us of Saputo’s view that these uses of GOS are GRAS through scientific procedures.

In an email on March 21, 2025, we communicated with you as Saputo’s representative regarding additional information needed to support a GRAS conclusion. As noted in our email, there is a substantial amount of information that is missing from the notice that is necessary for us to continue our review. This includes recalculating the dietary exposure estimate to incorporate accurate food codes and cumulative use levels, and

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<sup>1</sup> Saputo states that GOS is not intended for use in products under the jurisdiction of the United States Department of Agriculture or in foods for which standards of identity do not permit its addition.

revising the safety narrative to include accurate citations and a discussion on the relevancy of cited publications to the safety conclusion. This information is quite voluminous and, as such, we stated that it would require the notifier to rewrite the notice to include this missing information.

We have ceased our evaluation of the notice at your request on behalf of Saputo. We remind Saputo of a manufacturer's responsibility to ensure the safety and regulatory status of the substances that it markets for use in food or that it uses in food. We also remind Saputo that the use of a substance in food that is not GRAS (and is not otherwise excluded from the definition of a food additive), must have pre-market approval by FDA for its use in food (21 CFR 170.30(g)). More information about the criteria for GRAS is available in our regulations (21 CFR part 170).

Your request on behalf of Saputo does not preclude Saputo from submitting a future GRAS notice with respect to the subject of this notice (21 CFR 170.260(b)). We recommend that Saputo address the issues that we will provide in a separate communication to adequately support a GRAS conclusion. We strongly recommend that Saputo request a pre-submission meeting prior to submitting a revised notice to ensure that they have adequately addressed our concerns. Finally, we remind Saputo of the signed statements and certification (part 1 of a GRAS notice, 21 CFR 170.225) by which Saputo agrees to make all data and information regarding its GRAS conclusion available to FDA upon request.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 001216 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

Susan J. Carlson

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Digitally signed by Susan J.  
Carlson -S  
Date: 2025.04.10 17:33:36 -04'00'

Susan J. Carlson, Ph.D.  
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