U.S. FOOD & DRUG ADMINISTRATION

Human Foods Program

Anthony T. Pavel
Keller and Heckman LLP
1001 G St, NW Suite 500W
Washington, D.C. 20001

Re: GRAS Notice No. GRN 000763

Dear Mr. Pavel:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement to GRN 000763 that you submitted on behalf of Agropur, Inc (Agropur). We received the supplement on January 9, 2026. The supplement addresses the addition of infant formula as an intended use, as well as changes to the specifications. Agropur submitted clarifying information on July 13, 2026, and October 1, 2026, that clarified the intended use, specifications, and aspects of the safety narrative.

We previously responded to GRN 000763 on December 10, 2018. We stated that we had no questions at that time regarding Agropur's conclusion that α-lactalbumin (ALA) is GRAS for use as a protein source and/or texturizer in powdered meal replacement or meal supplement beverages (at levels up to 20% w/w powder), sports beverages (at levels up to 20% w/w), meal replacement or snack bars (at levels up to 25% w/w), and milk products (including dairy beverages, at levels up to 10% w/w), intended only for use in these foods where permitted by applicable standards of identity.

In the supplement dated January 9, 2026, Agropur informs us of its view that ALA is GRAS, through scientific procedures, for use as an ingredient in non-exempt infant formula for term infants at a maximum level of 3.4 g/L of infant formula, as consumed.[1]

In the supplement, Agropur provides information on the identity and manufacturing process for ALA and states that the identity is the same and it is produced using the same method as described in GRN 000763; however, Agropur provides updated specifications for ALA. The specifications from GRN 000763 are unchanged except for adding limits for heavy metals, cereulide, *Cronobacter sakazakii*, and *Bacillus cereus*. The specifications for ALA include protein content (≥ 95% on a dry basis; ≥ 90% on an as-is basis), ALA as a percentage of protein (≥ 90%), ash (≤ 3.5%), moisture (≤ 6%), lactose (≤ 0.2%), fat (≤ 0.5%), pH (6.0 - 7.5), scorched particles (≤ 15 mg/25 g), arsenic (< 0.1 mg/kg), cadmium (< 0.05 mg/kg), chromium (< 0.2 mg/kg), lead (< 0.05 mg/kg), mercury (< 0.01 mg/kg), cereulide (< 0.5 µg/kg), and microorganisms,

[1] Agropur states that while they intend to use ALA in cow milk-based infant formula only, this ingredient could potentially be used in sheep- and goat-milk based formula as well. We did not evaluate the use of ALA in sheep- or goat-milk based infant formula, and this supplement does not cover those uses.

including *B. cereus* (≤ 50 colony forming units/g), *Salmonella* serovars (absent in 375 g), *Listeria monocytogenes* (absent in 25 g), and *C. sakazakii* (absent in 300 g). Agropur provides the results from five non-consecutive batch analyses[2] to demonstrate that ALA can be consistently produced to meet these specifications.

Agropur estimates the dietary exposure to ALA from the intended use in non-exempt infant formula for term infants based on published estimates of the highest energy intake per kg body weight (bw) per day (d) for infants (ages 14–27 d), the caloric content of typical infant formula for term infants (67.6 kcal/100 mL), and the maximum intended use level of 3.4 g/L. Agropur estimates the 90th percentile dietary exposure to the subject of the supplement to be 0.70 g/kg bw/d and to the ALA protein[3] to be 0.57 g/kg bw/d. Agropur states that the dietary exposure to the ALA protein is the same as described in GRN 000809,[4] and that there would be no change to the dietary exposure to ALA from the intended use.

Agropur performed an updated literature review in July 2026, and discusses newer publications relevant to ALA safety, including multiple oral feeding studies in healthy term infants that did not report any adverse effects. Agropur states that upon review of these publications, ALA continues to be safe as discussed originally in GRN 000763 and additionally in GRN 000809, and that the intended use in this supplement for non-exempt infant formula for term infants is safe.

Based on the totality of the data and information, Agropur concludes that ALA is GRAS for its intended use.

Standards of Identity

In the notice, Agropur states its intention to use ALA in several food categories, including foods 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 Labeling Issues

Under section 403(a) of the Federal Food, Drug, & Cosmetic (FD&C) Act, a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). If products containing ALA

[2] In the July 13, 2026, amendment, Agropur provides the results of testing for cereulide in four non-consecutive batches of ALA demonstrating that cereulide content is below the limit of quantitation (<0.2 µg/kg).
[3] Agropur states that the ingredient contains a minimum of 81% ALA protein on an as-is basis.
[4] Fractionated whey protein concentrate containing 41% ALA was the subject of GRN 000809. We evaluated this notice and responded in a letter dated May 6, 2019, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Nutrition Center of Excellence (NCE). The Office of Pre-Market Additive Safety did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Allergen Labeling

The FD&C Act requires that the label of a food that is or contains an ingredient that contains a "major food allergen" declare the allergen's presence (section 403(w)). The FD&C Act defines a "major food allergen" as one of nine foods or food groups (i.e., milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, soybeans, and sesame) or a food ingredient that contains protein derived from one of those foods. ALA requires labeling under the FD&C Act because it contains protein derived from milk.

Intended Use in Infant Formulas

Under section 412 of the FD&C Act, a manufacturer of a new infant formula must make a submission to FDA providing required assurances about the formula at least 90 days before the formula is marketed. Our response to Agropur's GRAS notice does not alleviate the responsibility of any infant formula manufacturer that intends to market an infant formula containing ALA to make the submission required by section 412. Infant formulas are the purview of the Office of Critical Foods in NCE.

Section 301(ll) of the 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 Agropur's supplement concluding that ALA is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing ALA. Accordingly, our response should not be construed to be a statement that foods containing ALA, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Agropur provided, as well as other information available to FDA, we have no questions at this time regarding Agropur's conclusion that ALA is GRAS under its intended conditions of use. This letter is not an affirmation that ALA is 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 the supplement to GRN 000763 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J. CARLSON -S

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