Ms. Mary M. Murphy
Exponent, Inc.
1150 Connecticut Avenue, NW
Suite 1100
Washington, DC 20036

Re: GRAS Notice No. GRN 001116

Dear Ms. Murphy:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001116. We received the notice that you submitted on behalf of AAK USA, Inc. (AAK USA) on September 29, 2022 and filed it on April 5, 2023. AAK USA submitted amendments to the notice on September 15, 2023, and December 12, 2023 which provided clarification on the identity, manufacture, specifications, analytical methodology, safety data, and clarifications on intended use.

The subject of the notice is shea stearin for use as a source of fat in various foods at the maximum use levels specified in Table 1.[1] The notice informs us of AAK USA's view that these uses of shea stearin are GRAS through scientific procedures.

Table 1. Intended food categories and maximum use levels of shea stearin

Food category	Food use	Maximum use level (%)
Plant-based meat and poultry analogues	Burgers/ground meat, and sausages	14
Plant-based dairy alternatives and dairy analogues	Butter Cheese Cream cheese Creamers Frozen desserts Milks Sour cream Yogurt	45 25 20 6 15 3.5 12 3.5
Fillings	Cookies and wafers Confectionary	40 35
Nut and seed products	Nut/seed spreads and butters	45

[1] AAK USA states that shea stearin is not intended to be used in infant formula, products regulated by USDA, and foods where standards of identity don't permit the use.

Food category	Food use	Maximum use level (%)
Fats and oils	Margarines/spreads	35
Bakery	Bars	15
	Biscuits	20
	Cakes	15
	Cookies	20
	Laminated dough products (Danish pastry/croissants)	16
	Muffins	15
	Pie crust	20

Our use of the term, "shea stearin," in this letter is not our recommendation of that term 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 Center for Food Safety and Applied Nutrition (CFSAN). The Office of Food Additive Safety (OFAS) did not consult with ONFL regarding the appropriate common or usual name for "shea stearin."

AAK USA describes shea stearin as an ivory to off-white solid at room temperature obtained from shea butter. Shea stearin is composed of triglycerides, comprised primarily of stearic acid and oleic acid, and smaller amounts of palmitic acid, linoleic acid, and other fatty acids, and unsaponifiable matter including triterpene alcohols, sterols, phenols and tocopherols. AAK USA states that 1,3-distearoyl-2-oleoylglycerol (CAS Registry No. 2846-04-0) accounts for approximately 75% of the total triglycerides in shea stearin.

AAK USA describes the manufacturing process for shea stearin as a standard production method for edible oils. Shea kernels are cleaned, steamed and mechanically extracted by expeller pressing to yield shea oil and shea meal. The shea meal is extracted with hexane to remove the residual shea oil and then combined with the expeller pressed oil. The combined oil fractions (crude shea butter) are treated with sodium hydroxide to remove free fatty acids. Hexane is added to the shea butter to separate the liquid and solid fractions and cooled. The crude shea stearin crystals are separated from the liquid shea olein and subjected to degumming with acetone, bleaching, and deodorization yielding the final shea stearin. AAK USA states that shea stearin is manufactured in accordance with good manufacturing practices using food-grade raw materials and processing aids that are suitable for their intended use and permitted in food manufacturing in the U.S.

AAK USA provides specifications for shea stearin that include peroxide value (≤10 meq/kg), stearic acid (≥50%), oleic acid (≤40%), free fatty acids as oleic acid (≤1%), trans fatty acids (≤1%), unsaponifiable matter (≤3%), lead, mercury, arsenic (each ≤0.1 mg/kg), cadmium (≤0.02 mg/kg), hexane (≤1 mg/kg) and acetone (≤1 mg/kg), as well

as limits for microorganisms, including *Salmonella* serovars (absent in 25 g). AAK USA provides the results from the analyses of three non-consecutive batches to demonstrate that shea stearin can be manufactured to meet these specifications.

AAK USA estimates the dietary exposure to shea stearin from the intended uses using food consumption data from the 2015-2018 National Health and Nutrition Examination Survey (NHANES). AAK USA estimates the eaters-only dietary exposure to shea stearin to be 25 g/person (p)/d (0.4 g/kg body weight (bw)/d) at the mean and 48 g/p/d (0.8 g/kg bw/d) at the 90th percentile for the U.S. population aged 2 years and older. AAK USA states that the intended uses of shea stearin are substitutional for other vegetable and animal fats with a comparable fatty acid profile and therefore, the cumulative dietary exposure to fat or specific fatty acids is not expected to change.

AAK USA discusses the data and information supporting the safety of shea stearin. Since shea stearin is composed of triglycerides and a small fraction of unsaponifiable matter, AAK USA states that the safety of shea stearin was evaluated based upon the safety of dietary fats, in general, and the specific components in shea stearin, namely triglycerides and unsaponifiable matter. Shea stearin is a fat, and AAK USA notes that it follows the normal metabolic pathway of other dietary fats. Additionally, as a macronutrient, fat as a triglyceride has been demonstrated as safe in the diet. AAK USA also states that the dietary exposure to saturated fat from the intended uses of shea stearin is within the range of dietary exposure to saturated fat in the current U.S. diet.

To support the safety of the unsaponifiable matter in shea stearin, AAK USA compares the subject of this notice to the subject of GRN 000850,[2] the test article in published safety studies, and shea butter. AAK USA states that the same sterols/triterpenes present in shea stearin are present in other shea-derived materials and in similar normalized percent distributions. Thus, given the compositional similarities of the unsaponifiable matter in these shea-derived materials, AAK USA concludes that metabolic, pre-clinical, and clinical studies using these materials can be used to assess the fate of sterols/triterpenes in shea stearin. AAK USA incorporates into the notice, and provides summaries of published data from GRN 000850, including metabolic fate and toxicity studies (i.e., subchronic, carcinogenicity and reproductive) using shea olein as the test article. No adverse effects were attributed to shea olein. AAK USA concludes these studies provide evidence of safety of the unsaponifiable matter, as sterols/triterpenes, up to 480 mg/kg bw/d in the carcinogenicity study and up to 1120 mg/kg bw/d of unsaponifiable matter as sterols/triterpenes in the 13-week subchronic study. AAK USA also concludes that these studies support the overall safety of shea stearin at up to 20% of the diet (equivalent to 7.5 to 15 g/kg bw/d). AAK USA discusses unpublished genotoxicity studies using the subject of this notice and incorporates into the notice unpublished genotoxicity data on other shea-derived materials from GRN 000850. AAK USA concludes that shea stearin is not mutagenic, clastogenic, and/or aneugenic.

[2] Olein from shea tree nut extract was the subject of GRN 000850. We evaluated GRN 000850 and responded in a letter dated March 20, 2020, stating that we had no questions at that time regarding the notifier's GRAS conclusion.

To further support the safety of the unsaponifiable matter, AAK USA discusses a clinical study in healthy men consuming sheanut oil extract and incorporates into the notice additional clinical studies from GRN 000850. No adverse effects were observed at doses of shea sterols/triterpenes ranging from 1.6 to 3.2 g/d. AAK USA notes that the estimated dietary exposure to sterols/triterpenes from the intended uses of shea stearin is below the levels consumed in the clinical studies.

Based on the totality of the data and information described above, AAK USA concludes that shea stearin is GRAS for its intended use.

Standards of Identity

In the notice, AAK USA states its intention to use shea stearin 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, and Cosmetic Act (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 shea stearin 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 ONFL in the CFSAN. The OFAS 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. Shea stearin derived from shea tree nuts may require labeling under the FD&C Act because it may contain protein derived from shea tree nuts. Questions about petitions or notifications for exemptions from the food allergen labeling requirements should be directed to the Division of Food Ingredients in the OFAS. Questions related to food labeling in general should be directed to the ONFL in the CFSAN.

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 AAK USA's notice concluding that shea stearin 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 shea stearin. Accordingly, our response should not be construed to be a statement that foods containing shea stearin, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that AAK USA provided, as well as other information available to FDA, we have no questions at this time regarding AAK USA's conclusion that shea stearin is GRAS under its intended conditions of use. This letter is not an affirmation that shea stearin 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 GRN 001116 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2023.12.14 18:05:09 -05'00'

Susan J. Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
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