



William J. Rowe
GRAS Associates, LLC
27499 Riverview Center Blvd.
Suite 212
Bonita Springs, FL 34134

Re: GRAS Notice No. GRN 000850

Dear Mr. Rowe:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000850. We received the notice that you submitted on behalf of BUNGE Loders Croklaan BV (BUNGE) on March 13, 2019 and filed it on May 29, 2018. BUNGE submitted amendments to the notice on January 5, 2020 and March 3, 2020, confirming that the analytical methods in the notice are validated for the described uses, and confirming the correct taxonomy for the shea tree and the CAS Registry number identifying the subject of the notice.

The subject of the notice is olein from shea tree nut extract (shea olein) at use levels from 1.5 to 60% by weight, for use as a replacement for animal and vegetable fats rich in palmitic, myristic, and lauric acids, in baked goods and baking mixes, breakfast cereals, condiments and relishes, gravies and sauces, confections and frostings, fats and oils, desserts, nuts and nut products, snack foods, soft candy, and soup and soup mixes.¹ The notice informs us of BUNGE's view that this use of shea olein is GRAS through scientific procedures.

Our use of the terms "olein from shea tree nut extract" or "shea olein" in this letter is not our recommendation of this 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. The Office of Food Additive Safety (OFAS) did not consult with ONFL regarding the appropriate common or usual name for "olein from shea tree nut extract or shea olein."

BUNGE provides information about the identity and composition of shea olein. BUNGE describes shea olein as a viscous pale yellow liquid at room temperature and provides

¹ Excluding foods under the jurisdiction of the United States Department of Agriculture.

CAS No. 93348-61-9 for the substance. BUNGE states that shea olein is predominantly 92% (w/w) triglycerides and 8% (w/w) unsaponifiable matter. BUNGE notes that oleic acid accounts for 54% of the total fatty acids in shea olein, followed by stearic acid at 30%; this is based on the level of total Fatty Acid Methyl Esters (FAME).

BUNGE describes the manufacturing process of shea olein. BUNGE states that shea olein is produced from shea butter or from the nuts of the shea tree (*Vitellaria paradoxa*) that is indigenous to sub-Saharan Africa and northern Ghana. Crude shea butter is extracted from crushed, boiled, and physically pressed shea tree nuts. The pressed cake is further washed and pressed with hexane to extract any remaining oil. Crude shea butter is then de-gummed with acetone and any hydrated gums present are removed by centrifugation. The de-gummed shea butter is further fractionated with acetone to separate the olein and the stearin fractions. The olein fraction is then refined, neutralized, deodorized, and bleached. BUNGE states that shea olein is produced in accordance with current good manufacturing practice.

BUNGE provides the following specifications for shea olein: color (≤ 7)², odor and taste (neutral), peroxide value (PV, ≤ 10 mEq/kg), free fatty acid as oleic acid ($\leq 1.0\%$), unsaponifiable matter ($\leq 9\%$), oleic acid ($\geq 44\%$), stearic acid ($\leq 44\%$), trans fatty acids ($\leq 1\%$), iron (≤ 2.5 mg/kg), copper (≤ 0.1 mg/kg), lead (≤ 0.1 mg/kg), and arsenic (≤ 0.1 mg/kg). BUNGE provides results from analyses of three non-consecutive batches to demonstrate that shea olein can be produced to meet the stated specifications. BUNGE states that shea olein meets the criteria specified in the CODEX STAN 19-1981.³ BUNGE also provides a summary of the typical fatty acid composition of shea olein. BUNGE provides data to demonstrate the storage stability of shea olein for up nine months at ambient temperature.

BUNGE provides an estimate of the dietary exposure to shea olein based on the intended uses using data from 2013-2014 National Health and Nutrition Examination Surveys (NHANES). BUNGE states that the mean and 90th percentile estimated dietary exposures for ages 2+ are 15.24 g/person (p)/day (d) (0.26 g/kg bw/d) and 30.33 g/p/d (0.56 g/kg bw/d), respectively. BUNGE also provides an exposure estimate for phytosterols present in shea olein of 2.8 g/p/d (40 mg/kg bw/d) based on the 90th percentile estimated exposure for shea olein. BUNGE states that use of shea olein is self-limiting due to taste and technological issues.

BUNGE notes that the absorption, distribution, metabolism, and excretion of triglycerides, the principle components of shea olein, are well understood. BUNGE summarizes the published studies of the absorption and excretion of shea olein sterols (unsaponifiables) in rats and in a small group of men. In both rats and humans, a majority of the 4,4-dimethylsterols (4,4-DMS), the most abundant sterol fraction in the unsaponifiable matter, are excreted unchanged.

BUNGE describes published 13-week oral toxicity studies in Wistar rats administered

² Lovibond color value red (5.25" cell), ISO 27608.

³ CXS 19-1981, "Standard for edible fats and oils not covered by individual standards," Amended in 2019.

diets containing 20% shea olein, palm oil, or soybean oil. BUNGE reports that an increase in body weight gain (~5%) was noted in male rats that were fed palm oil and soybean oil diets in comparison to those fed with shea olein. A small but statistically significant reduction in heart weight (~6%) was observed in female rats fed diets containing shea olein when compared to other treated groups. The authors did not consider any of these findings to be adverse because there were no associated histopathological changes in the heart. BUNGE summarizes two published dietary studies in rats on the reproductive toxicity of shea olein during pre-mating, mating, pregnancy, and offspring weaning. Rats were fed diets containing 7 or 15% (w/w) unhardened shea olein or hardened (hydrogenated) shea olein or sheanut oil, palm oil, cocoa butter, or toffee powder for up to 20 weeks. A dietary level of 7 or 15% is approximately equivalent to 3.5 or 7.5 g/kg bw/d of shea olein. Based on the results of both studies, the authors concluded that no evidence of reproductive toxicity was seen for both unhardened and hardened shea olein at levels equating to approximately 7.5 g/kg bw/d. BUNGE describes a carcinogenicity study in Wistar rats that were administered shea olein, sheanut oil, or palm oil at a dietary level of 15% (w/w) for 104 weeks. The authors concluded that in comparison to other test oils, shea olein was well tolerated and did not produce any toxicologically relevant adverse effects or evidence of significant tumorigenic potential.

BUNGE summarizes three published human studies using spreads enriched with sheanut oil sterols that were comparable to the sterol fraction of shea olein. The notifier states that no adverse effects were reported for doses up to 3.3 g/d except for a small reduction in β -carotene absorption in the study with 3.3 g/day sheanut oil sterols. In addition, two published human efficacy studies on products containing 70-75% sheanut oil-derived 4,4-DMS did not mention any adverse effects at levels up to 2.25 g/d. BUNGE concludes that all these studies support the safety of shea olein and the unsaponifiable material of sheanut oil-derived sterols.

BUNGE notes that the Joint FAO/WHO expert Committee on Food Additives (JECFA) established a group acceptable daily intake of 0-40 mg/kg bw/d for desmethyl phytosterols, phytostanols, and their esters from various plant sources.

To corroborate its safety, BUNGE states that shea olein is neither mutagenic nor genotoxic based on the results of the unpublished *in vitro* genotoxicity studies. BUNGE also states that the unsaponifiable matter of shea olein is not genotoxic based on unpublished but publicly available information in a premarket new dietary ingredient notification (NDIN) submitted to FDA⁴ that included an acute toxicity study, an Ames assay, and an *in vivo* mouse micronucleus assay.

BUNGE states that there is no indication of an allergenic risk to consumers, including individuals with peanut or tree nut allergies.

BUNGE includes the report of a panel of individuals (BUNGE's GRAS panel). Based on

⁴ BSP Pharma A/S (2004) NDI 179, SheaNature - Original NDIN. Available at: <https://www.regulations.gov/document?D=FDA-2004-S-0571-0033> (Accessed: July 18, 2018).

its review, BUNGE's GRAS panel concluded that shea olein is safe under the conditions of its intended use.

Based on the totality of the data and information described above, BUNGE concludes that shea olein is GRAS for its intended use in food.

Standards of Identity

In the notice, BUNGE states its intention to use shea olein in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. 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 olein 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 ONFL in the Center for Food Safety and Applied Nutrition. 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 eight foods or food groups (i.e., milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) or a food ingredient that contains protein derived from one of those foods. Shea olein derived from shea tree nuts may require labeling under the FD&C Act because it may contain protein 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 OFAS. Questions related to food labeling in general should be directed to the ONFL in the Center for Food Safety and Applied Nutrition.

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 BUNGE’s notice concluding that shea olein 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 olein from shea tree extract. Accordingly, our response should not be construed to be a statement that foods containing olein from shea tree extract, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).


Conclusions

Based on the information that BUNGE provided, as well as other information available to FDA, we have no questions at this time regarding BUNGE’s conclusion that shea olein is GRAS under its intended conditions of use. This letter is not an affirmation that shea olein 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 000850 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

 Digitally signed by Susan J.
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