



David Rowe
President
Choco Finesse, LLC
5019 N. Meridian Street
Indianapolis, IN 46208

Re: GRAS Notice No. GRN 000761

Dear Mr. Rowe:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000761. We received Choco Finesse, LLC (Choco Finesse)'s notice on February 22, 2018, and filed it on March 15, 2018.

The subject of the notice is esterified propoxylated glycerol (EPG) for use as a fat replacement in commercial frying of french fries and doughnuts at maximum levels of 8.1% and 10.8% (w/w), respectively. The notice informs us of Choco Finesse's view that these uses of EPG are GRAS through scientific procedures.

Choco Finesse provides information about the identity and composition of EPG. Choco Finesse describes EPG as a white solid that consists of propoxylated glycerol with fatty acid ester moieties that are derived from edible oils. The primary fatty acids in EPG are stearic, oleic, linoleic, arachidic, and behenic acids.

Choco Finesse describes a two-step method of manufacture for EPG. In the first step, food grade glycerol is reacted with propylene oxide with base catalysis to form propoxylated glycerol. In the second step, propoxylated glycerol is esterified using an excess of fatty acids which are derived from edible fats and oils. After the esterification step, the unreacted fatty acids are removed by short-path distillation. Choco Finesse states that a mixture of α -, β -, γ -, and δ -tocopherols are added during the manufacture of EPG.

Choco Finesse provides specifications for EPG that include minimum content of EPG (> 99.5%), a range for total α -, β -, γ -, and δ -tocopherols (775 to 1800 mg/kg), limits for residual propylene oxide (< 1 mg/kg), arsenic (< 0.05 mg/kg), lead (< 0.05 mg/kg), and microorganisms. Choco Finesse provides results from the analysis of three non-consecutive lots to demonstrate that EPG can be made to meet these specifications.

Choco Finesse estimates the dietary exposure to EPG from the intended use in commercial frying applications as a replacement for a certain percentage of total fat.

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Based on the results of analyses conducted to determine the level of EPG absorption in french fries and doughnuts and food consumption data from the National Health and Nutrition Examination Survey (2013-2014), Choco Finesse estimates the mean and 90th percentile dietary exposures to EPG to be 4.0 and 7.6 g/person (p)/day (d) (64 and 130 mg/kg body weight (bw)/d), respectively. Choco Finesse discusses dietary exposure to EPG that was reported in GRN 000583¹ and 000640,² and states that the cumulative exposures to EPG from all intended uses are 11.9 and 25.0 g/p/d (216 and 486 mg/kg bw/d), at the mean and 90th percentile, respectively.

Choco Finesse discusses published and unpublished animal studies and published human studies previously submitted in GRNs 000583 and 000640 to support the safety of EPG. Choco Finesse discusses unpublished absorption, distribution, metabolism, and elimination (ADME) data in rats that show that ingested EPG is poorly absorbed and rapidly metabolized, with the majority of EPG excreted in the feces. Based on the ADME data, EPG did not accumulate in the body following lifetime administration. Choco Finesse summarizes published studies on EPG that showed no subchronic toxicity in rats and micropigs and unpublished studies that showed no subchronic toxicity in mice and beagle dogs. Choco Finesse also discusses unpublished studies on EPG that showed no chronic toxicity in mice, rats, micropigs, and beagle dogs. In addition, Choco Finesse summarizes published studies in rats and rabbits and an unpublished study in rats that showed no adverse effects due to dietary administration of EPG on reproduction and offspring development. Choco Finesse states that although animal studies on EPG have shown some decreases in levels of some fat-soluble vitamins, none of the animals exhibited clinical signs or microscopic evidence of vitamin deficiency requiring vitamin supplementation. Choco Finesse also discusses a published clinical study in which no adverse effects (including decreased fat-soluble vitamin status) were observed over eight weeks with consumption of up to 40 g EPG/d. Choco Finesse includes an update of the literature regarding the safety of EPG through November 2017 and reports that no studies relevant to toxicology were found that would alter its safety conclusion.

To further support its view that EPG is GRAS for the intended use, Choco Finesse summarizes four published genotoxicity studies (including bacterial reverse mutation assay, mouse lymphoma assay, chromosomal aberration assay, and unscheduled DNA synthesis assay) that showed that EPG is non-mutagenic and non-genotoxic.

¹ In GRN 000583, Choco Finesse informed FDA of their view that EPG is GRAS, through scientific procedures, for use as a fat replacer as a component of various confectionery preparations, that is as drizzle, enrobing, inclusions and solid pieces applied to or incorporated into baked goods and baking mixes, frozen dairy desserts and mixes, grain products and pasta, hard candy, soft candy, cough drops, processed fruits, fruit juices, and snack foods. FDA responded in a letter dated December 22, 2015, that the agency had no questions at that time regarding Choco Finesse's conclusion that EPG is GRAS under the intended conditions of use.

² In GRN 000640, Choco Finesse informed FDA of their view that EPG is GRAS, through scientific procedures, for use as a fat replacement in baked goods and baking mixes, frozen dairy desserts and mixes, grain products and pastas, gravies and sauces, nuts and nut products, and soft candy at a maximum level of 21% EPG in finished foods. FDA responded in a letter dated September 21, 2016, that the agency had no questions at that time regarding Choco Finesse's conclusion that EPG is GRAS under the intended conditions of use.

Choco Finesse includes the statement of a panel of individuals (Choco Finesse's GRAS panel). Based on its review, Choco Finesse's GRAS panel concluded that EPG is safe under the conditions of its intended use.

Based on all the available scientific information, Choco Finesse concludes that EPG is GRAS for its intended use in food.

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). The notice raises a potential issue under these labeling provisions. In the notice, Choco Finesse discusses EPG as a fat replacer. If products containing EPG 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 Center for Food Safety and Applied Nutrition. The Office of Food 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.

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 its review of Choco Finesse's notice that EPG is GRAS for the intended use, FDA did not consider whether section 301(ll) or any of its exemptions apply to foods containing EPG. Accordingly, this response should not be construed to be a statement that foods that contain EPG, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Choco Finesse provided, as well as other information available to FDA, we have no questions at this time regarding Choco Finesse's conclusion that EPG is GRAS under its intended conditions of use. This letter is not an affirmation that EPG 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 000761 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,
**Michael A.
Adams -S**

 Digitally signed by Michael A.
Adams -S
Date: 2018.05.25 13:40:41
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Dennis M. Keefe, Ph.D.
Director
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