



Kristin Spoden
Unilever
700 Sylvan Avenue
Englewood Cliffs, NJ 07632

Re: GRAS Notice No. GRN 001105

Dear Ms. Spoden:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001105. We received Unilever's notice on September 21, 2022, and filed it on January 23, 2023. Unilever submitted amendments to the notice on April 20, 2023, April 28, 2023, and May 8, 2023, clarifying intended uses, specifications, and estimates of dietary exposure and providing additional information on the narrative.

The subject of the notice is polyglycerol polyricinoleic acid (PGPR) for use as an emulsifier at levels up to 0.5% in chocolate and chocolate-type products based on vegetable fats other than cocoa butter, and at levels up to 0.8% in mayonnaise and spreads. The notice informs us of Unilever's view that these uses of PGPR are GRAS through scientific procedures.

Our use of the term, "PGPR," 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 nonstandardized 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 did not consult with ONFL regarding the appropriate common or usual name for "PGPR."

Unilever provides information on the identity of PGPR and describes it as a clear, light brown viscous liquid formed by the esterification of polyglycerol with condensed castor oil fatty acids. Unilever notes that PGPR is insoluble in water and alcohol but soluble in ether, hydrocarbons, and halogenated hydrocarbons. Unilever states that the chemical name for PGPR is 1,2,3-propanetriol, homopolymer, (9Z,12R)-12-hydroxy-9-octadecenoate, with a molecular formula of $C_{18}H_{34}O_3 \cdot x (C_3H_8O_3)_n$ and a CAS registry number of 68936-89-0.

Unilever describes the manufacturing process for PGPR as a four-step process. First, castor oil is hydrolyzed with water and steamed at 2.8 MPa without a catalyst to produce

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glycerol free castor oil fatty acids comprised of 80 - 90% ricinoleic acid, 3 - 8% oleic acid, 3 - 7% linoleic acid, and 0 - 2% stearic acid. The castor oil fatty acids are then condensed by heating at 205 - 210 °C under vacuum and CO₂ atmosphere for approximately 8 hours until an acid value of 35 - 40 mg KOH/g is reached. The polyglycerol is prepared by polymerization of either: (a) glycerol using a strong base as a catalyst, (b) glycidol, or (c) epichlorohydrin, followed by hydrolysis to yield linear polyglycerols. The final stage involves the esterification of the condensed castor oil fatty acids with polyglycerol. This is carried out using the same conditions as for the fatty acid condensation. The reaction is allowed to proceed until an acid value of ≤ 6 mg KOH/g is achieved. Unilever states that PGPR is manufactured in accordance with current good manufacturing practices and that all starting materials and processing aids are used in accordance with applicable U.S. regulations or were concluded to be GRAS for their intended uses.

Unilever provides specifications for PGPR that include hydroxyl value (80-100 mg KOH/g), iodine value (72-103), refractive index (1.463-1.467), saponification value (170-210 mg KOH/g), acid value (≤ 6 mg KOH/g), polyglycerol content (≥ 75% of di- and tri-glycerols and ≤ 10% hepta- or higher glycerols), total arsenic (≤ 0.1 mg/kg), cadmium (≤ 0.1 mg/kg), lead (≤ 0.1 mg/kg), and mercury (≤ 0.1 mg/kg). Unilever provides the results from the analyses of three non-consecutive batches to demonstrate that PGPR can be manufactured to meet the specifications. Unilever states that PGPR conforms to the specifications for PGPR in the 12th Edition of the Food Chemicals Codex.

Using food consumption data from the 2015-2018 National Health and Nutrition Examination Survey (NHANES), Unilever estimates the eaters-only dietary exposure to PGPR from the proposed uses to be 104 mg/p/d (1.55 mg/kg bw/d) at the mean and 228 mg/p/d (3.37 mg/kg bw/d) at the 90th percentile for the U.S. population aged 2 years and older. In addition, Unilever estimates an eaters-only cumulative dietary exposure to PGPR from all current and proposed uses of PGPR to be 7.98 mg/kg bw/d at the 90th percentile for the U.S. population aged 2 years and older.

Unilever reports the published data supporting the safe use of PGPR in foods, and discusses that previous GRAS notices (GRNs 000009, 000179, 000266, 000270, and 000466)¹ have also reviewed the safety of PGPR. These data include, but were not limited to, a reproductive toxicity study and two-year combined chronic toxicity and carcinogenicity study, both in rats. Unilever notes that there were no adverse effects at the highest dose tested in the reproductive toxicity study. Unilever reviews the published two-year combined chronic toxicity and carcinogenicity study that reports no adverse effects² of 5% PGPR in the diet³. Unilever discusses a published absorption,

¹ PGPR was the subject of GRNs 000009, 000179, 000266, 000270, and 000466. We evaluated these notices and responded in letters dated April 2, 1999, January 20, 2006, June 15, 2009, and September 25, 2013, respectively, stating that we had no questions at those times regarding the notifiers' GRAS conclusions.

² Unilever notes that treatment-related effects reported in this study were non-adverse adaptive increases in liver and kidney weights.

³ 5% PGPR is approximately equivalent to 2,500 mg/kg bw/d.

distribution, metabolism, and excretion study indicating that PGPR is extensively digested into polyglycerols and fatty acids⁴, is not stored or accumulated in tissue, and is ultimately excreted either in the urine as mono-, di-, and tri-glycerols or in the feces as hexa-, penta-, and higher-polyglycerols. Unilever performs an updated literature search through April 2023 and reports no new safety data that would contradict the current GRAS conclusion.

Based on the available data and information summarized above, Unilever concludes that PGPR is GRAS for the intended uses.

Standards of Identity

In the notice, Unilever states its intention to use PGPR 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.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (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 Unilever's notice concluding that PGPR 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 PGPR. Accordingly, our response should not be construed to be a statement that foods containing PGPR, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions


Based on the information that Unilever provided, as well as other information available to FDA, we have no questions at this time regarding Unilever's conclusion that PGPR is GRAS under its intended conditions of use. This letter is not an affirmation that PGPR 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.

⁴ Unilever concludes that ricinoleic acid, the monomer fatty acid of PGPR, is readily metabolized through common physiological pathways of fatty acid metabolism, is well-tolerated, and is not a safety concern from the intended uses.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 001105 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

 Digitally signed by Susan
J. Carlson -S
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Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

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Center for Food Safety

and Applied Nutrition