



Marisa Rihner  
Exponent  
1150 Connecticut Avenue NW  
Suite 1100  
Washington, DC 20036

Re: GRAS Notice No. GRN 000740

Dear Ms. Rihner:

The Food and Drug Administration (FDA, we) completed our evaluation of the supplement that you submitted on behalf of Lanxess Corporation regarding additional uses for the subject of GRN 000740.<sup>1</sup> We received the supplement on May 31, 2024. The supplement addresses additional uses for the subject of GRN 000740. Lanxess submitted amendments to the supplement on April 4, 2025, July 23, 2025, and August 25, 2025, regarding the identify, manufacturing process, intended use, specifications, and toxicity studies.

We previously responded to GRN 000740 on May 17, 2018. We stated that we had no questions at that time regarding Lanxess's conclusion that long-chain glycolipids from *Dacryopinax spathularia* (glycolipids preparation) is GRAS for use as an antimicrobial agent in select non-alcoholic beverages at use levels ranging from 2 to 100 mg/kg (Table 1). Subsequently, on August 25, 2023, FDA responded to a supplement to GRN 000740 from Lanxess, received October 15, 2020, stating that we had no questions at that time regarding Lanxess' conclusion that glycolipids preparation is GRAS for use as an antimicrobial agent on cheese (all types) and dry-cured sausage (including sausage casings prior to filling and dry-curing) at levels resulting in no more than 500 mg/kg and 100 mg/kg, respectively, in the finished food (Table 1).

In the supplement dated May 31, 2024, Lanxess informs us of its view that glycolipids preparation is GRAS, through scientific procedures, for use as an antimicrobial agent in various food categories as described in Table 1. Lanxess provides data and information to support the efficacy and application of glycolipids preparation as an antimicrobial agent on pomegranate arils and in alcoholic and non-alcoholic wine; non-alcoholic beer; alcoholic and non-alcoholic beer mix beverages; hard seltzers; flavored syrups for beverages; and liquid dietary supplements.

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<sup>1</sup> GRN 000740 was submitted by IMD Natural Solutions GmbH, now known as Lanxess Corporation.

**Table 1. Food categories and maximum use levels for glycolipids preparation.**

<b>Food Category</b>	<b>Maximum Use Levels (mg/kg)<sup>a</sup></b>
<b>GRN 000740</b>	
Carbonated soft drinks (diet and regular soft drinks)	25
Fruit drinks (Fruit juice drinks, non-alcoholic mixers, fruit flavored drink, coconut water, fruit nectars)	80
“Energy” drinks	50
Sports drinks	50
Enhanced water	25
Tea, Ready-To-Drink (RTD)	50
Juice (fruit and vegetable juice)	100
<b>GRN 000740 Supplement dated October 15, 2020</b>	
Cheese, all types	500
Dry cured sausages (including sausage casings prior to filling and dry-curing)	100
<b>GRN 000740 Supplement dated May 31, 2024</b>	
Light beer, malt beverages, and cereal beverages (including flavored beer, malt beverages, and cereal beverages); including dealcoholized forms	50
Wine and wine specialty products (including juice used for wine making); including dealcoholized forms	30 <sup>a</sup>
Distilled spirit specialty beverages ( <i>e.g.</i> , cocktails <15% ABV); including dealcoholized forms	30
Coffee, RTD (excludes brewed coffee)	50
Liquid dietary supplements ( <i>i.e.</i> , shots containing fruit juice, vitamins and minerals)	800
Flavor syrups (for beverages)	60
Pomegranate, raw	100

<sup>a</sup> level in finished food.

Our use of the term “glycolipids preparation” 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 section 101.4 in Title 21 of the Code of Federal Regulations (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 Nutrition Center of Excellence (NCE) in the Human Foods Program (HFP). The Office of Pre-Market Additive Safety did not consult with ONFL regarding the appropriate common or usual

name for “glycolipids preparation.”

In the supplement, Lanxess states that the identity and method of manufacture of glycolipids preparation are the same as described in the supplement for GRN 000740 dated October 15, 2020. Lanxess updated the heavy metal specifications for lead ( $<0.7$  mg/kg), cadmium ( $\leq 0.1$  mg/kg), and mercury ( $\leq 0.1$  mg/kg). The remainder of the specifications are unchanged from those in the October 15, 2020 supplement to GRN 000740.

Lanxess estimates the cumulative dietary exposure to glycolipids preparation from the existing and intended uses using food consumption data from the 2017-2020 National Health and Nutrition Examination Survey (NHANES). Lanxess estimates the eaters-only cumulative dietary exposure to glycolipids preparation to be 47.5 mg/person (p)/d (0.77 mg/kg body weight (bw)/d) at the mean and 96.4 mg/p/d (1.67 mg/kg bw/d) at the 90<sup>th</sup> percentile for the total U.S. population.<sup>2</sup>

Lanxess states that an updated search of the published literature through February 2024 was performed and did not result in any relevant new safety data or any new information that would raise safety concerns regarding the proposed new uses of glycolipids preparation.

Based on the totality of the data and information, Lanxess concludes that glycolipids preparation is GRAS for its intended use.

### **Standards of Identity**

In the supplement to GRN 000740, Lanxess states its intention to use glycolipids preparation 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 Lanxess’ supplement concluding that glycolipids preparation 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 glycolipids preparation. Accordingly, our response should not be construed to be a

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<sup>2</sup> FDA estimated the mean and 90<sup>th</sup> percentile eaters-only cumulative dietary exposures to glycolipid preparation for the U.S. population aged 2 years and older to be 47.5 mg/p/d (0.76 mg/kg bw/d) and 97.6 mg/p/d (1.63 mg/kg bw/d), respectively, using food consumption data from the 2017-2020 NHANES.

statement that foods containing glycolipids preparation, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

## Conclusions

Based on the information that Lanxess provided, as well as other information available to FDA, we have no questions at this time regarding Lanxess's conclusion that glycolipids preparation is GRAS under its intended conditions of use. This letter is not an affirmation that glycolipids preparation 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 000740 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

**Susan J.  
Carlson -S**

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