



Stella Si
Anchor Center for Certification
No. 1295 Chuan Qiao Road, Building 2, Suite 302
Pudong, Shanghai, 201206
CHINA

Re: GRAS Notice No. GRN 001308

Dear Stella Si:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001308. We received the notice that you submitted on behalf of Kluyveromyces Yeast Technology (Hainan) Co., Ltd. (KYT) on November 18, 2025, and filed it on March 4, 2026. KYT submitted amendments to the notice on June 16, 2026, June 21, 2026, June 23, 2026, July 15, 2026, and July 19, 2026, that clarified the manufacturing process, specifications, intended use, dietary exposure, microbiological controls, and aspects of the safety narrative.

The subject of the notice is β -glucan produced by *Kluyveromyces marxianus* CGMCC 26703 (β -glucan) for use as an ingredient in foods at the maximum use levels as specified in Table 1, excluding uses in infant formula and products under the jurisdiction of United States Department of Agriculture. The notice informs us of KYT's view that these uses of β -glucan are GRAS through scientific procedures.

Table 1. Proposed uses for β -glucan.

Food category	Food uses	Maximum use level (mg/100 g)
Baked goods	Cookies	667
Beverages and beverage bases	Meal replacement beverages (non-milk based)	83
Cereals and cereal products	Nutritional bars (breakfast, granola, and protein)	500
Dairy product analogs	Soy milk	83
	Plant-based yogurt	89
Milk and milk products	Meal replacement beverages	83
	Cultured dairy beverages	83
	Yogurt	89

	Yogurt beverages	83
Plant protein products	Soy protein bars	500
Processed fruit and fruit juices	Fruit beverages (drinks, juices, and smoothies)	83
Soft candy	Chocolate confections	500
Soup and soup mixes	Soups	82

KYT provides information on the identity and composition of β -glucan and describes it as a light yellow to yellowish-brown powder. KYT states that β -glucan is a polysaccharide containing $\geq 70\%$ β -glucans, with a structure consisting predominantly of a β -(1,3)-linked glucan backbone with β -(1,6)-linked glucan branches and has a molecular weight of 20-4000 kDa.

KYT describes the method of manufacture of β -glucan produced by *K. marxianus* CGMCC 26703, a non-pathogenic and non-toxigenic organism that has been isolated from a traditional yogurt sample in Nagqu, Tibet, China. KYT states that *K. marxianus* CGMCC 26703 is deposited in the China General Microbiological Culture Collection Center with the depository number CGMCC 26703. β -Glucan is manufactured by controlled batch-fed fermentation of *K. marxianus* CGMCC 26703 at 30°C. The resulting culture is centrifugated to separate the biomass from the medium and the cellular material is washed, resuspended in water, and subjected to enzymatic cell wall hydrolysis using papain and a neutral protease. Following heat treatment to inactivate the enzymes, the yeast cell wall material is collected using centrifugation. Subsequently, β -glucan is extracted via a series of dissolution, heat treatment at basic and acidic conditions, and centrifugation steps. The concentrated β -glucan is then spray-dried into a powder. KYT states that β -glucan is manufactured in accordance with current good manufacturing practices and that all raw materials and processing aids are food grade and are approved for their respective uses in accordance with an appropriate U.S. regulation, are GRAS for their intended use, or are the subject of an effective food contact notification. KYT states that no components of the culture medium are allergens or are derived from allergenic sources.

KYT provides specifications for β -glucan that include total carbohydrates ($\geq 85\%$), β -glucans ($\geq 70\%$), and limits for moisture ($\leq 6\%$), protein ($\leq 3.5\%$), fat ($\leq 10\%$), ash ($\leq 3\%$), heavy metals, including lead (≤ 0.1 mg/kg), cereulide (≤ 0.1 μ g/kg), and microorganisms, including *Cronobacter* spp. (not detected in 25 g) and *Listeria monocytogenes* (not detected in 25 g). KYT provides the results from the analyses of three non-consecutive batches to demonstrate that β -glucan can be manufactured to meet the specifications. KYT states that β -glucan has a shelf-life of 12-24 months at ambient conditions (20-25 °C, 60% relative humidity) based on results from an accelerated stability study.

KYT provides the estimated dietary exposure to β -glucan based on the intended uses. Using food consumption data from the 2021-2023 National Health and Nutrition Examination Survey (NHANES), KYT estimates the eaters-only dietary exposure to β -glucan from the intended uses to be 333 mg/person (p)/d at the mean and 675 mg/p/d

at the 90th percentile for the total U.S. population¹. KYT states that the intended uses will be substitutional for other β -glucans produced by microbial fermentation and therefore, there will be no increase in the cumulative dietary exposure to β -glucan from the intended uses.

KYT states that it relies on the Dietary Reference Intake levels for total dietary fiber as established by the Institute of Medicine (IOM) to evaluate *K. marxianus* yeast-derived β -glucan dietary exposure levels. The IOM report states that the adequate intake of dietary fiber is in the range of 30 to 38 g/p/d and 21 to 26 g/p/d for adult males and females, respectively, and that IOM has not established an upper intake limit for dietary fiber.² KYT cites a long history of dietary exposure to β -glucans derived from yeast sources, and a limited digestibility and absorption of yeast-derived β -glucans. Based on an updated literature search through June 2026, KYT considers the findings of animal studies and human clinical tolerance studies that administered yeast- and mushroom-derived β -glucan as corroborative evidence in its safety determination on the intended use level of β -glucan. KYT concludes that dietary exposure to *K. marxianus* derived β -glucan is not at a level of concern.

Based on the totality of the data and information, KYT concludes that β -glucan is GRAS under the intended conditions of use.

Standards of Identity

In the notice, KYT states its intention to use β -glucan 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, & Cosmetic (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 β -glucan 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 Nutrition Center of Excellence. The Office of Pre-Market Additive Safety did not consult with ONFL on this issue or evaluate any information in terms of labeling. Questions related to food labeling should be directed to ONFL.

¹ FDA estimated the dietary exposure to β -glucan from the intended uses using food consumption data from the 2021-2023 NHANES to be 335 mg/p/d at the mean and 677 mg/p/d at the 90th percentile for the U.S. population aged 2 years and older.

² The Office of Pre-Market Additive Safety does not determine whether the ingredient in the GRAS notification meets the FDA's regulatory definition of dietary fiber. Dietary fiber is defined in 21 CFR 101.9(c)(6)(i) and is under the purview of the Office of Nutrition and Food Labeling (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 our evaluation of KYT's notice concluding that β -glucan 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 β -glucan. Accordingly, our response should not be construed to be a statement that foods containing β -glucan, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that KYT provided, as well as other information available to FDA, we have no questions at this time regarding KYT's conclusion that β -glucan is GRAS under its intended conditions of use. This letter is not an affirmation that β -glucan 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 001308 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

SUSAN J.

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Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Pre-Market Additive Safety

Office of Food Chemical Safety, Dietary
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