

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

Re: GRAS Notice No. GRN 001225

Dear Ms. Rihner:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001225. We received the notice that you submitted on behalf of Suntory Global Spirits (Suntory) on October 16, 2024, and filed it on December 19, 2024. Suntory submitted amendments to the notice on March 14, 2025, and April 10, 2025, providing additional information about the composition, manufacturing process, analytical data, specifications, dietary exposure, and safety narrative.

The subject of the notice is sakura (*Prunus speciosa*) leaf distillate (sakura leaf distillate) for use as a flavoring agent in alcoholic ($\geq 0.5\%$ alcohol by volume (ABV) and dealcoholized ($< 0.5\%$ ABV) distilled spirits at a level up to 20% by volume and in alcoholic and dealcoholized ready-to-drink distilled spirit-based cocktails at a level up to 5% by volume. The notice informs us of Suntory's view that these uses of sakura leaf distillate are GRAS through scientific procedures.

Our use of the term, "sakura leaf distillate," 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 Nutrition Center of Excellence. The Office of Pre-Market Additive Safety did not consult with ONFL regarding the appropriate common or usual name for "sakura leaf distillate."

Suntory provides information about the identity and composition of sakura leaf distillate, describing it as an aqueous ethanol-based solution derived from the leaves of *P. speciosa* trees. Suntory states that sakura leaf distillate is a colorless liquid containing sakura leaf derivatives, ethanol, and water. Suntory provides a table describing the composition of sakura leaf distillate.

Suntory describes the method of manufacture for sakura leaf distillate. The sakura leaves are hand-sorted to remove any other materials, rinsed with water, and the clean leaves are either used fresh or flash frozen, vacuum sealed and stored in a freezer. The fresh or frozen leaves are mixed with grain-neutral spirit (GNS; ethanol) and water, and the slurry is steeped at room temperature for three weeks. Citric acid may also be added for pH adjustment. The slurry is filtered using a 5 mm mesh screen to remove the leaves, and the filtrate is vacuum distilled to obtain the final sakura leaf distillate. Suntory states that sakura leaf distillate is manufactured using current good manufacturing practices and all raw materials and processing aids are food-grade and are used in accordance with applicable U.S. regulations, are GRAS for their intended uses, or are the subject of an effective food contact notification.

Suntory provides specifications for sakura leaf distillate that include total solids (<0.6 g/100 L), total sakura leaf derivatives (0.01-0.02% w/v), and ABV (32-33% w/v), as well as limits for lead (<0.01 mg/kg), arsenic (<0.005 mg/kg), cadmium (<0.001 mg/kg), mercury (<0.001 mg/kg), and microorganisms. Suntory provides the results from the analyses of three non-consecutive batches of sakura leaf distillate to demonstrate that the ingredient can be manufactured to meet the specifications. Based on accelerated stability studies, Suntory concludes that sakura leaf distillate is stable for at least six months when stored at room temperature.

Suntory estimates the dietary exposure to sakura leaf distillate based on the intended uses and food consumption data from the 2017-2020 National Health and Nutrition Examination Survey (NHANES). Suntory estimates the mean and 90th percentile eaters-only dietary exposure to sakura leaf distillate for the U.S. population aged 21 years and older to be 18.2 g/person (p)/d (0.21 g/kg body weight (bw)/d) and 38.9 g/p/d (0.46 g/kg bw/d), respectively.

Suntory assesses the safety of sakura leaf distillate based on a review of available information from authoritative sources on the individual chemical components of the ingredient. This includes considering existing regulations or guidance on dietary exposure to certain chemical components or identifying established safety reference values for other chemical components to ensure the safety of the dietary exposure to sakura leaf distillate at the intended use levels in alcoholic and dealcoholized distilled spirit beverages. Suntory concludes that the dietary exposure to the chemical components in sakura leaf distillate are not at levels of concern and are commonly found in plants that humans consume. In further support of safety, Suntory describes the history of consumption of the leaves of the *P. speciosa* tree. For instance, they are incorporated into food items such as desserts in Japan. Additionally, sakura leaf distillate is listed as a flavor in Japan.

Based on the totality of the data and information, Suntory concludes that sakura leaf distillate is GRAS for its intended use.

Section 301(II) 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 Suntory's notice concluding that sakura leaf distillate 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 sakura leaf distillate. Accordingly, our response should not be construed to be a statement that foods containing sakura leaf distillate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Suntory provided, as well as other information available to FDA, we have no questions at this time regarding Suntory's conclusion that sakura leaf distillate is GRAS under its intended conditions of use. This letter is not an affirmation that sakura leaf distillate 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 001225 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
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