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Health Canada's Proposal to Enable the Use of Sucrose Monoesters of Lauric, Palmitic or Stearic Acid as Emulsifiers in Unstandardized Beverages

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/AVP-0019]

June 17, 2016

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations*. Approved food additives and their permitted conditions of use are set out in the [Lists of Permitted Food Additives](#) that are incorporated by reference in the MAs and published on Health Canada's website. A petitioner can request that Health Canada approve a new additive or a new condition of use for an already approved food additive by filing a food additive submission with the Department's Food Directorate. Health Canada uses this premarket approval process to determine whether the scientific data support the safety of food additives when used under specified conditions in foods sold in Canada.

Health Canada received a food additive submission seeking approval for the use of sucrose monoesters of lauric, palmitic or stearic acid as emulsifiers at a maximum level of use of 0.0145%, on an "as consumed" basis, in unstandardized beverages, unstandardized beverage concentrates, and unstandardized beverage mixes.

The results of Health Canada's evaluation of available scientific data support the safety of sucrose monoesters of lauric, palmitic or stearic acid when used as set out in the table below. Therefore, it is the intention of Health Canada to modify the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#) by adding the following entry to the list:

Proposed Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*

Item No.	Column 1 Additive	Column 2 Permitted in or upon	Column 3 Maximum Level of Use and Other Conditions
S.21	Sucrose Monoesters of Lauric, Palmitic or Stearic Acid	Unstandardized beverages; Unstandardized beverage concentrates; Unstandardized beverage mixes	0.0145% in beverages as consumed

Rationale

Health Canada's Food Directorate has completed its pre-market safety assessment of sucrose monoesters of lauric, palmitic or stearic acid. The assessment considered toxicological, chemical and technical aspects of sucrose monoesters of lauric, palmitic or stearic acid when used as emulsifiers in unstandardized beverages.

The sucrose monoesters of lauric, palmitic or stearic acid are used to emulsify flavouring oils and can be used to prepare relatively clear flavoured water-based beverages. Sucrose monoesters of lauric, palmitic or stearic acid are subsets of substances that are found in preparations of sucrose esters of fatty acids—a food additive for which the safety in use as such was previously established by Health Canada and which is already included in the [*List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*](#). As part of the evaluation of the current submission, it was confirmed that the majority of sucrose monoesters of lauric, palmitic or stearic acid is extensively hydrolyzed in the digestive tract into fatty acids and sucrose, both of which are normal constituents of the diet. The small amount that is not hydrolyzed and absorbed intact would be metabolised and excreted or integrated as normal constituents of the body. No toxicological concerns were identified.

Unlike conventional preparations of sucrose esters of fatty acids, sucrose monoesters of fatty acids are manufactured using vinyl esters of fatty acids. Given the difference in manufacturing methods; the existence of separate food-grade specifications (one for sucrose monoesters of lauric, palmitic or stearic acid and one for sucrose esters of fatty acids); and given that the preparations under consideration in this proposal are enriched in sucrose monoester of fatty acid content relative to di- and triesters, an additive entry separate from the one for sucrose esters of fatty acids was considered appropriate.

Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of sucrose monoesters of lauric, palmitic or stearic acid when used under the conditions of use set out in the table above. The Department is therefore proposing to enable the use of sucrose monoesters of lauric, palmitic or stearic acid as described in the above table.

Other Relevant Information

There are food additive provisions for sucrose esters of fatty acids, but not specifically sucrose monoesters of lauric, palmitic or stearic acid, in the Codex *General Standard for Food Additives* (GSFA) or the *Australia New Zealand Food Standards Code*.

In the United States, sucrose monoesters of lauric, palmitic or stearic acid are considered “self-affirmed” GRAS (Generally Recognized as Safe; GRAS Notice No. 248) when used as

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emulsifiers at levels up to 50 mg/L (equivalent to 0.005%) in fruit-flavoured beverages and beverage concentrates (level of use is on an “as-consumed” basis). A GRAS notification was filed with the United States Food and Drug Administration and the agency responded with no further questions regarding the petitioner’s GRAS determination.

Sucrose monoesters of lauric, palmitic or stearic acid, which are included in the European specifications for Sucrose esters of fatty acids, are permitted in certain foods, including flavoured drinks and certain alcoholic beverages.

Implementation and Enforcement

The proposed change will be effective the day on which it is published in the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#). This will be announced via a Notice of Modification which will be published on [Health Canada’s Website](#).

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

Contact Information

For additional information or to submit comments related to this proposal, please contact:

[Bureau of Chemical Safety, Food Directorate](#)

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If communicating by e-mail, please use the words “**sucrose monoesters of lauric, palmitic or stearic acid**” in the subject line of your e-mail. Health Canada is able to consider information received by **August 30, 2016**, 75 days from the date of this posting.