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Notice of Modification to the *List of Permitted Sweeteners* to Enable the Use of Steviol Glycosides from *Saccharomyces cerevisiae* CD15380 and CD15407 in a Variety of Foods

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: NOM/ADM-0132

May 14, 2019

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

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Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (MAs) issued by the Minister of Health and the *Food and Drug Regulations* (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 the Canada.ca 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's Food Directorate received a food additive submission seeking approval for the use of steviol glycosides from 2 genetically modified strains of *Saccharomyces cerevisiae*, *S. cerevisiae* CD15380 and *S. cerevisiae* CD15407, in all foods where steviol glycosides from *Stevia rebaudiana* Bertoni is permitted and at the same maximum levels of use.

Steviol glycosides¹ from *Stevia rebaudiana* Bertoni is already permitted for use in Canada as a sweetener in a variety of standardized and unstandardized foods.

The results of the Food Directorate's evaluation of available scientific data support the safety of steviol glycosides from *S. cerevisiae* CD15380 and *S. cerevisiae* CD15407 when used as set out in the table below. Therefore, Health Canada has modified the [List of Permitted Sweeteners](#) to enable the use of steviol glycosides from *S. cerevisiae* CD15380 and *S. cerevisiae* CD15407 by adding the name of these sources in column 1 of item no. S.1.2 as shown below in the list.

Modification to the *List of Permitted Sweeteners*

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
S.1.2	Steviol glycosides from: <i>Stevia rebaudiana</i> Bertoni;	(1) Table-top sweeteners	(1) Good Manufacturing Practice
	<i>Saccharomyces cerevisiae</i> CD15380; <i>Saccharomyces cerevisiae</i> CD15407
		(10) Canned (naming the fruit); Unstandardized canned fruit	(10) 0.012% (calculated as steviol equivalents)

¹ When referring to the name of the additive the term "steviol glycosides" is used in the singular.

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Rationale

Health Canada's Food Directorate completed a premarket safety assessment of the requested uses of steviol glycosides from *Saccharomyces cerevisiae* CD15380 and CD15407. The assessment concluded that information related to chemistry, microbiology, molecular biology, nutrition and toxicology supports the safety of steviol glycosides for its requested uses. Therefore, the Department has enabled the requested steviol glycosides from *S. cerevisiae* CD15380 and CD15407 by modifying the [List of Permitted Sweeteners](#) as shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as steviol glycosides that do not have specifications set out in Part B of the Regulations meet the most recent specifications set out in the *Food Chemicals Codex* or the *Combined Compendium of Food Additive Specifications*. The *Food Chemicals Codex* is a compendium of standards for purity and identity for food ingredients, including food additives, published by the United States Pharmacopeial Convention. The *Combined Compendium of Food Additive Specifications*, which contains specifications prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), is published by the Food and Agriculture Organization of the United Nations. Specifications for steviol glycosides from *S. cerevisiae* CD15380 and CD15407 were not set out in either of these sources at the time of publication of this Notice of Modification. Until such time that a specification is established within the FCC or by JECFA, steviol glycosides from *S. cerevisiae* CD15380 and CD15407 that meets the manufacturer's in-house specifications² as presented to Health Canada are considered acceptable.

Implementation and Enforcement

The above modification came into force **May 14, 2019**, the day it was published in the [List of Permitted Sweeteners](#).

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

Health Canada's Food Directorate is committed to reviewing any new scientific information on the safety in use of any food additive, including steviol glycosides from *Saccharomyces*

² The petitioner indicated that all raw materials, food processing aids and equipment used in the production of the steviol glycosides are food-grade quality, and methods used to purify the product are consistent with those outlined in the Chemical and Technical Assessment (CTA) published by FAO/JECFA for steviol glycosides from *S. rebaudiana*.

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cerevisiae. Anyone wishing to submit new scientific information on the use of this additive or to submit any inquiries may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words “**Steviol glycosides from *S. cerevisiae* (NOM-0132)**” in the subject line of your e-mail.

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

251 Sir Frederick Banting Driveway

Tunney's Pasture, PL: 2202C

Ottawa, Ontario K1A 0L2

E-mail: hc.bcs-bipc.sc@canada.ca