



Health
Canada

Santé
Canada

Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Lactase from *Kluyveromyces lactis* DS 80496 in Lactose-reducing Enzyme Preparations and in Certain Dairy Foods

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0179

February 2, 2022



Canada

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, a new source 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 β -galactosidase ("lactase"; EC 3.2.1.23) from *Kluyveromyces lactis* DS 80496 in the manufacture of lactose-reducing enzyme preparations and in certain standardized and unstandardized dairy foods (e.g., flavoured milks¹, milk for the production of ice cream, sweetened condensed milk, whey, yogurt, and dulce de leche). The food enzyme is intended to be used at a level consistent with Good Manufacturing Practice².

According to the petitioner, β -galactosidase from *K. lactis* DS 80496 serves to catalyze the breakdown of the milk sugar lactose to its respective monosaccharides, glucose and galactose, and that its use would allow for the production of lactose-reduced and lactose-free dairy products. The petitioner also noted that the use of this enzyme could also increase the sweetness of dairy products as well as improve the texture of certain milk-derived products such as sweetened condensed milks and dulce de leche.

Lactase from other sources is already permitted for use in Canada in the same foods requested by the petitioner. However, the new source organism, *K. lactis* DS 80496, was not a permitted source for any food enzyme in Canada.

The results of the Food Directorate's evaluation of available scientific data support the safety of lactase (β -galactosidase) from *K. lactis* DS 80496 for its requested uses. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to enable the use of lactase from *K. lactis* DS 80496 by adding the name of this source to the entry to Column 2 of item L.1, as shown in the table below (bold font not used in the List).

Modification to the *List of Permitted Food Enzymes*

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
L.1	Lactase	<i>Bacillus licheniformis</i> PP3930; <i>Kluyveromyces lactis</i> DS 80496	(1) Lactose-reducing enzyme preparations	(1) Good Manufacturing Practice
			(2) Milk destined for use in ice cream mix	(2)

¹ The flavoured milks are (naming the flavour) Malted Milk [B.08.022], (naming the flavour) Milk [B.08.016], (naming the flavour) Partly (Partially) Skimmed Milk [B.08.018], (naming the flavour) Partly (Partially) Skimmed Milk with Added Milk Solids [B.08.026], (naming the flavour) Skim Milk [B.08.017], and (naming the flavour) Skim Milk with Added Milk Solids [B.08.023].

² See the definition of "Good Manufacturing Practice" in the [Marketing Authorization for Food Additives That May Be Used as Food Enzymes](#).

Item No.	Column 1 Additive	Column 2 Permitted Source	Column 3 Permitted in or Upon	Column 4 Maximum Level of Use and Other Conditions
				Good Manufacturing Practice
			(3) (naming the flavour) Malted milk; (naming the flavour) Milk; (naming the flavour) Partly skimmed milk; (naming the flavour) Partly skimmed milk with added milk solids; (naming the flavour) Skim milk; (naming the flavour) Skimmed milk with added milk solids	(3) Good Manufacturing Practice

Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of lactase from *K. lactis* DS 80496 for use as a food enzyme in the foods requested by the petitioner. The Department concluded that information related to allergenicity, chemistry, microbiology, molecular biology, nutrition and toxicology supports the safety of lactase from *K. lactis* DS 80496 for its requested uses. Therefore, the Department has enabled the requested uses of lactase from *K. lactis* DS 80496 by adding the name of this new source to Column 2 of item L.1 of the [List of Permitted Food Enzymes](#), as shown in the table above (bold font not used in the List).

Other Relevant Information

Food additives, such as lactase from *K. lactis* DS 80496, are required to meet food-grade specifications set out in Part B of the Regulations, where such specifications exist, or those set out in the most recent edition of 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. Specifications in the *Combined Compendium of Food Additive Specifications* and its associated *General Specifications and Considerations for Enzyme Preparations* are prepared by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), both of which are published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

Lactase from *K. lactis* DS 80496 is being permitted for use in lactose-reducing enzyme preparations, as is already permitted for lactase from numerous other sources. Manufacturers interested in using such a preparation to make a lactose-reduced or lactase-free version of a standardized dairy product that is not

specifically permitted to contain lactase as shown by the List should consult the Canadian Food Inspection Agency's policy on "[Common names for lactose-free dairy products](#)".

The above modification came into force **February 2, 2022** the day it was published in the [List of Permitted Food Enzymes](#).

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 new scientific information on the safety in use of any permitted food additive, including lactase from *K. lactis* DS 80496. Anyone wishing to submit an inquiry or new scientific information on the use of this additive may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "**lactase (NOM-0179)**" 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 0K9

E-mail: bcsc-bipc@hc-sc.gc.ca