



Health
Canada

Santé
Canada

Notice of Modification to the *List of Permitted Food Enzymes* to Enable the Use of Pectin Lyase from *Aspergillus niger* Rung373 in Various Standardized and Unstandardized Foods

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM-0154

September 23, 2020



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 pectin lyase (a type of pectinase) from *Aspergillus niger* Rung373 as a food enzyme in apricot nectar; peach nectar; pear nectar; cider; coffee; concentrated (naming the fruit) juice; distillers' mash; natural flavour and colour extractives; single-strength fruit juices; skins of fruits destined for jam, marmalade, and candied fruit production; tea leaves for the production of tea solids; unstandardized fruit and vegetable products; unstandardized pomace; unstandardized purées; vegetable stock for use in soups; and wine. The food enzyme is intended to be used at a level consistent with Good Manufacturing Practice.

Several of the specific types of foods that the petitioner requested are included in broader food categories as per the food additive list below. Consequently, the use of pectin lyase from *A. niger* Rung373 is permitted in these specific foods even though they are not identified as such in the [List of Permitted Food Enzymes](#):

- (1) The enzyme is not intended to be added directly to concentrated (naming the fruit) juice¹ but is permitted to be present in it when the enzyme is used in manufacturing the single-strength fruit juice from which the concentrated juice is prepared. Therefore, there is only an entry for "Single-strength fruit juices" in the table below;
- (2) The enzyme is permitted for use in "skins of citrus fruits destined for jam, marmalade and candied fruit production", "vegetable stock for use in soups", "unstandardized pomace" and "unstandardized purées" by virtue of being permitted in "Unstandardized fruit and vegetable products" as shown in the table below.

Based on the information provided in the submission and in accordance with the Food Directorate's [Policy for Differentiating Food Additives and Processing Aids](#),² the Food Directorate has determined that the use of pectin lyase from *A. niger* Rung373 in coffee processing is a processing aid use of this enzyme rather than a food additive use. Consequently, a modification to the *List of Permitted Food Enzymes* is not required for this enzyme to be used in this application.

Pectinase from other sources is already permitted for use in Canada as a food enzyme in the foods that were added to the *List of Permitted Food Enzymes* for pectin lyase from *A. niger* Rung373, except apricot nectar,

¹ There is a standard of composition for Concentrated (naming the fruit) juice as per section [B.11.130](#) of the Regulations.

² Information about food processing aids is available in the [Policy for Differentiating Food Additives and Processing Aids](#).

peach nectar and pear nectar. However, *A. niger* Rung373 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 pectin lyase from *A. niger* Rung373 for the uses set out in the table below. Therefore, Health Canada has modified the [List of Permitted Food Enzymes](#) to extend the use of pectinase (specifically, the pectinase “pectin lyase”) by adding a new entry “(i) pectin lyase” to column 1 for Item No. P.3 and adding the following entries in columns 2, 3 and 4 shown below to the new entry (i) of Item No. P.3 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
P.3	Pectinase (i) Pectin lyase	<i>Aspergillus niger</i> Rung373	(1) Apricot nectar; Peach nectar; Pear nectar	(1) Good Manufacturing Practice
			(2) Cider; Wine	(2) Good Manufacturing Practice
			(3) Distillers’ Mash	(3) Good Manufacturing Practice
			(4) Natural flavour and colour extractives	(4) Good Manufacturing Practice
			(5) Single-strength fruit juices	(5) Good Manufacturing Practice
			(6) Tea leaves for the production of tea solids	(6) Good Manufacturing Practice
			(7) Unstandardized fruit and vegetable products	(7) Good Manufacturing Practice

Rationale

Health Canada’s Food Directorate completed a premarket safety assessment of pectin lyase from *A. niger* Rung373 for use as a food enzyme. The assessment concluded that information related to allergenicity, chemistry, microbiology, molecular biology, nutrition, and toxicology supports the safety of pectin lyase from *A. niger* Rung373 for its uses shown in the table above. Therefore, the Department has enabled these uses of

pectin lyase from *A. niger* Rung373 by adding the new entries shown in the above table to the [List of Permitted Food Enzymes](#).

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as pectin lyase from *A. niger* Rung373 that do not have food-grade specifications set out in Part B of the Regulations meet the food-grade specifications 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. 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) and published by the Food and Agriculture Organization of the United Nations.

Implementation and Enforcement

The above modification came into force **September 23, 2020**, 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 any new scientific information on the safety in use of any food additive, including pectin lyase from *A. niger* Rung373. 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 "**Pectin Lyase (NOM-0154)**" 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: hc.bcs-bipc.sc@canada.ca