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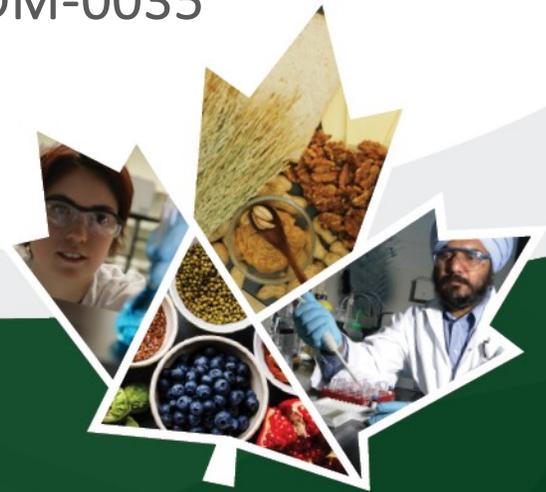
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Health Canada's Proposal to Enable the Use of Potassium Polyaspartate to Inhibit Crystal Formation in Wine

Notice of Proposal – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0035

July 24, 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 potassium polyaspartate to inhibit the formation of crystals in wine at a maximum level of use of 0.01%. Tartaric acid is one of three main acids found in grapes alongside malic, and citric acids, and is arguably the most important acid in wine due to the prominent role it plays in maintaining the chemical stability of the wine, the wine's colour and influencing the taste of the finished product.

Tartaric acid's solubility in wine is temperature-dependent and may bind with the naturally occurring potassium in the wine to form potassium bitartrate crystals. Though their appearance may be a bit off-putting, potassium bitartrate crystals are harmless. The purpose of adding potassium polyaspartate to wine is to inhibit the formation of potassium bitartrate crystals.

The Food Directorate concluded that information related to the safety and efficacy of potassium polysorbate supports its use in the food of interest. Therefore, Health Canada proposes to enable this use of potassium polyaspartate by adding the entry shown in the table below to the [List of Permitted Food Additives with Other Accepted Uses](#).

Proposed Modification to the *List of Permitted Food Additives with Other Accepted Uses*

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Purpose of use	Column 4 Maximum Level of Use and Other Conditions
P.4.4	Potassium Polyaspartate	Wine	To inhibit crystal formation	0.01%

Rationale

Health Canada's Food Directorate completed a premarket safety and efficacy assessment of the requested uses of potassium polyaspartate. The assessment considered information related to allergenicity, chemistry, microbiology, nutrition, toxicology and efficacy.

Potassium polyaspartate is produced from L-aspartic acid and potassium hydroxide, and spray-dried to produce a light powder. There are no reports of allergic reactions related to potassium polyaspartate. This substance is non-toxic in animal tests and its use in wine as proposed does not pose any microbiological or nutritional safety concerns.

The results of the premarket assessment support the safety of potassium polyaspartate to inhibit the formation of crystals in wine as set out in the table above. Health Canada is therefore proposing to enable the use of this food additive as shown in the table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as potassium polyaspartate 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 version of *Food Chemicals Codex* (FCC) 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. The JECFA established specifications for polyaspartate in June 2019.¹ These will eventually be added to the *Combined Compendium of Food Additive Specifications*.

Implementation and Enforcement

The proposed change will be effective the day on which it is published in the [List of Permitted Food Additives with Other Accepted Uses](#). This will be announced via a Notice of Modification that will be published on the [Government of 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 "**Potassium polyaspartate (NOP-0035)**" in the subject line of your e-mail. Health Canada is able to consider information received by **October 6, 2020**, 75 days from the date of this posting.

¹ FAO and WHO. 2020. Compendium of Food Additive Specifications. Joint FAO/WHO Expert Committee on Food Additives (JECFA), 87th Meeting June 2019. FAO JECFA Monographs 23. Rome. <https://doi.org/10.4060/ca7513en>

