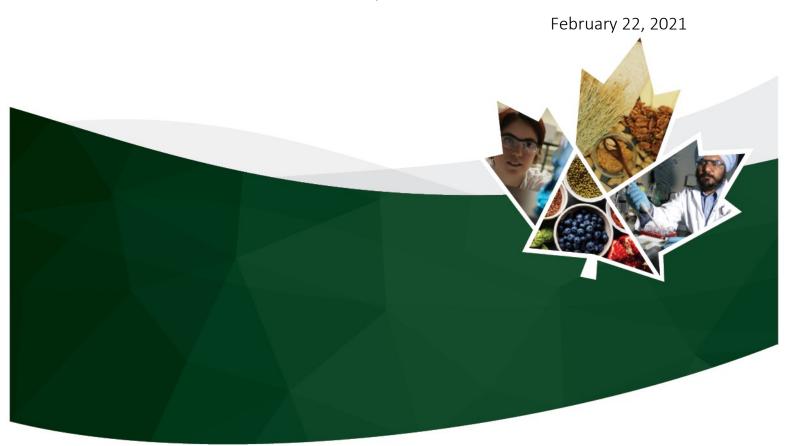
Notice of Modification to the *List of Permitted Food Additives with Other Accepted Uses* to Enable the Use of Potassium Polyaspartate in Wine

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0162





Summary

Food additives are regulated in Canada under <u>Marketing Authorizations</u> (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 <u>Lists of Permitted Food Additives</u> 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 bitartrate crystals in wine. The requested maximum level of use is 0.01%.

The results of the Food Directorate's evaluation of available scientific data support the safety and efficacy of potassium polyaspartate for use to inhibit crystal formation in wine. Since this is a food additive that was not previously permitted for use in Canada, <u>Health Canada's Proposal to Enable the Use of Potassium Polyaspartate to Inhibit Crystal Formation in Wine</u> was published on July 24, 2020, which was open to the public for comment for 75 days. No comments were submitted to the Department as a result of this Proposal. Since the conclusions of the evaluation remain as described in the proposal, Health Canada has enabled the requested use of potassium polyaspartate by adding the entry shown in the table below to the <u>List of Permitted Food Additives with Other Accepted Uses</u>.

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%

Corrective Modification

A minor modification was required to place two additives in alphabetical order in the English version of the <u>List of Permitted Food Additives with Other Accepted Uses</u>. The entry for potassium stearate was moved from immediately preceding the entry for potassium pyrophosphate, tetrabasic to immediately following it. The item numbers for the two additives were switched accordingly (i.e. the item number for potassium pyrophosphate, tetrabasic was changed from P.5.1 to P.5 and the item number for potassium stearate was changed from P.5 to P.5.1). The same modification was made to the French version of the List. In addition, a minor typographical error was corrected in the header of column 4 of the French version of the List ("autre" was replaced by "autres") and the number of significant figures for the level of use shown in column 4 of subitem no. P.5.1(2) of the French version of the List was revised to align with the English version of the List ("2 %" was replaced by "2,0 %").

Rationale

Health Canada's Food Directorate completed a premarket safety and efficacy assessment of potassium polyaspartate for use as an inhibitor of crystal formation in wine. The assessment did not identify any food safety concerns with this use of this additive with respect to allergenicity, chemistry, microbiology, nutrition, or toxicology. Therefore, the Department has enabled the requested use of potassium polyaspartate by adding to the List of Permitted Food Additives with Other Accepted Uses the new entry shown in the above 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 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, 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.

Notification – Summary of Comments and Health Canada's Responses

No comments were received in response to Health Canada's Proposal to Enable the Use of Potassium Polyaspartate to Inhibit Crystal Formation in Wine, published on July 24, 2020.

Implementation and Enforcement

The above modification came into force **February 22, 2021**, the day it was published in the <u>List of Permitted</u> Food Additives with Other Accepted Uses.

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 potassium polyaspartate. Anyone wishing to submit new scientific information on the use of this additive or to submit inquiries on this modification may do so in writing, by regular mail or electronically. If you wish to contact the Food Directorate electronically, please use the words "potassium polyaspartate (NOM-0162)" in the subject line of your e-mail.

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