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Notice of Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*, the *List of Permitted Food Additives with Other Accepted Uses*, the *List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents*, and the *List of Permitted Sequestering Agents* to Extend the Use of Potassium Phosphate, dibasic to the Same Foods and Levels of Use as Sodium Phosphate, dibasic

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0145

April 8, 2020



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 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 extension of use of potassium phosphate, dibasic as a buffering agent, pH stabilizer and adjusting agent, and an emulsifier, stabilizer and texturizer in those same foods and at the same maximum level of use as is already permitted for its sodium analogue, sodium phosphate, dibasic. Those foods are: mustard pickles and relishes, cottage cheese and creamed cottage cheese, evaporated milk, evaporated partly skimmed milk or concentrated partly skimmed milk, evaporated skim milk or concentrated skim milk, and sour cream<sup>1</sup>; glaze for frozen fish and frozen mushrooms<sup>2</sup>; ice cream mix, ice milk mix, and sherbet<sup>3</sup>; and cream<sup>4</sup>. In addition, while potassium phosphate, dibasic is permitted as a yeast food in ale, beer<sup>5</sup>, light beer, malt liquor, porter, stout and unstandardized bakery products<sup>6</sup>, and as a pH agent in unstandardized foods<sup>4</sup>, it is not permitted in the former foods as a pH adjusting agent or in the latter as a sequestering agent, as is currently the case for sodium phosphate, dibasic. Sodium phosphate, dibasic is also permitted in bacterial cultures<sup>4</sup>, while potassium phosphate, dibasic is currently not.

Potassium phosphate, dibasic is already permitted for use in Canada as an emulsifier, gelling, stabilizing or thickening agent in certain types of processed cheeses and flavoured milks; as a pH adjusting agent in unstandardized foods; as a sequestering agent in injection or cover solutions and pumping pickle for certain meat cuts, in meat tenderizers, and in certain other meat products or cuts of meat; and as a yeast food in ale, beer, cider, honey wine, light beer, malt liquor, porter, stout, wine and unstandardized bakery products.

Both potassium phosphate, dibasic and sodium phosphate, dibasic are used for similar technological functions in foods. Potassium phosphate, dibasic can be used as a partial or complete replacement for the sodium analogue.

The results of the Food Directorate's evaluation of available scientific data support the safety of potassium phosphate, dibasic when used as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#), the [List of Permitted Food Additives with Other Accepted Uses](#), the [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#), and the [List of Permitted Sequestering Agents](#) to extend the use of potassium phosphate, dibasic by adding the entries shown below to the lists.

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<sup>1</sup> [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#)

<sup>2</sup> [List of Permitted Food Additives with Other Accepted Uses](#)

<sup>3</sup> [List of Permitted Sequestering Agents](#)

<sup>4</sup> [List of Permitted pH Adjusting Agents; Acid-Reacting Materials and Water Correcting Agents](#)

<sup>5</sup> Despite the modernized beer standard (as published in *Canada Gazette* Part II, vol. 153, no.9), beer, ale, stout, porter and malt liquor can still, until December 13, 2022, be sold in accordance with the standards as they read immediately before the day the *Regulations Amending the Food and Drug Regulations (Beer)* came into force.

<sup>6</sup> [List of Permitted Yeast Foods](#)

## Modifications to the Lists of Permitted Food Additives

Item P.11 be modified by adding entries for new sub items P.11(3) to P.11(7) to Columns 2 and 3 in the [List of Permitted Emulsifying, Gelling, Stabilizing of Thickening Agents](#), as follows:

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
P.11	Potassium Phosphate, dibasic	(3) Mustard pickles; Relishes	(3) Good Manufacturing Practice
		(4) Cottage cheese; Creamed cottage cheese	(4) 0.5% in accordance with the requirements of sections B.08.051 and B.08.052, calculated as sodium phosphate, dibasic
		(5) Evaporated milk; Evaporated partly skimmed milk or concentrated partly skimmed milk; Evaporated skim milk or concentrated skim milk	(5) 0.1% calculated as sodium phosphate, dibasic. If any combination of potassium phosphate, dibasic, sodium phosphate, dibasic, and sodium citrate is used, the total added phosphate salts not to exceed 0.1% calculated as sodium phosphate, dibasic and the total amount not to exceed 0.1%
		(6) Sour cream	(6) 0.05% calculated as sodium phosphate, dibasic. If used in combination with sodium phosphate, dibasic, total added phosphate salts not to exceed 0.05%, calculated as sodium phosphate, dibasic
		(7) Unstandardized Foods	(7) Good Manufacturing Practice

New item P.4.3 be added to the [List of Permitted Food Additives with Other Accepted Uses](#), as follows:

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.4.3	Potassium Phosphate, dibasic	(1) Glaze for frozen fish	(1) To prevent cracking of glaze	(1) Good Manufacturing Practice
		(2) Frozen mushrooms	(2) To prevent discolouration	(2) Good Manufacturing Practice

Item P.10 be modified by renumbering the existing entry in columns 2 and 3 to sub-item "(1)" and adding a new sub-item "(2)" to Columns 2 and 3 in the [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#), as follows:

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
P.10	Potassium Phosphate, dibasic	(2) Ale; Bacterial culture; Beer; Cream; Light beer; Malt liquor; Porter; Stout	(2) Good Manufacturing Practice

Item P.4 be modified by adding entries for new sub items P.4(9) and P.4(10) to Columns 2 and 3 in the [List of Permitted Sequestering Agents](#), as follows:

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
P.4	Potassium Phosphate, dibasic	(9) Unstandardized foods	(9) Good Manufacturing Practice
		(4) Ice cream mix; Ice milk mix; Sherbet	(4) Good Manufacturing Practice

In addition, the following modifications are required to replace the text in columns 2 and 3 of sub-items S.6(2), S.11(3) and S.11(4) to the [List of Permitted Emulsifying, Gelling, Stabilizing of Thickening Agents](#) as a result of this submission:

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
S.6	Sodium Citrate	(2) Evaporated milk; Evaporated partly skimmed milk or concentrated partly skimmed milk; Evaporated skim milk or concentrated skim milk	(2) 0.1% singly or in combination with potassium phosphate, dibasic or sodium phosphate, dibasic, in accordance with the conditions set out for items P.11 and S.11 in this List
S.11	Sodium Phosphate, dibasic	(3) Evaporated milk; Evaporated partly skimmed milk or concentrated partly skimmed milk; Evaporated skim milk or concentrated skim milk	(3) 0.1%. If any combination of potassium phosphate, dibasic, sodium phosphate, dibasic, and sodium citrate is used, the total added phosphate salts not to exceed 0.1% calculated as sodium phosphate, dibasic and the total amount not to exceed 0.1%
		(4) Sour cream	(4) 0.05%. If used in combination with potassium phosphate, dibasic, total added phosphate salts not to exceed 0.05%, calculated as sodium phosphate, dibasic

## Rationale

Health Canada's Food Directorate completed a premarket safety assessment of potassium phosphate, dibasic for use as a buffering agent, pH stabilizer and adjusting agent, and emulsifier, stabilizer and texturizer. The assessment concluded that information related to chemistry, nutrition, toxicology, and allergenicity supports the safety of potassium phosphate, dibasic for its requested uses. Therefore, the Department has enabled the requested uses of potassium phosphate, dibasic by adding to the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#), the [List of Permitted Food Additives with Other Accepted Uses](#), the [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#), and the [List of Permitted Sequestering Agents](#), the new entries shown in the above five tables.

## Other Relevant Information

Food additives and other ingredients generally must be declared in the list of ingredients on the label of pre-packaged foods sold in Canada. This allows individuals to identify foods that contain this additive if necessary, for example, individuals following a low potassium or low phosphorus diet for health reasons. In addition, companies using these types of food additives are encouraged to voluntarily declare the total amount of potassium and phosphorus, as well as the percentage of the "daily value" for potassium and phosphorus, in the Nutrition Facts table.

On December 14, 2016, Health Canada made changes to the Food and Drug Regulations<sup>7</sup> to require the amount of potassium to always appear in the Nutrition Facts table. Manufacturers have until 2021 to comply with these changes.

The *Food and Drug Regulations* require that food additives such as potassium phosphate, dibasic that do not have food-grade specifications set out in Part B of the Regulations meet the most recent food-grade 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.

## Implementation and Enforcement

The above modification came into force **April 8, 2020**, the day it was published in [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#), the [List of Permitted Food Additives with Other Accepted Uses](#), the [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#), and the [List of Permitted Sequestering Agents](#).

The Canadian Food Inspection Agency is responsible for the enforcement of the *Food and Drugs Act* and its associated regulations with respect to foods.

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<sup>7</sup> [Canada Gazette, Part II, Vol. 150, No 25, December 14, 2016. SOR/DORS/2016-305](#)

## 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 potassium phosphate, dibasic. 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 "**potassium phosphate, dibasic (NOM-0145)**" in the subject line of your e-mail.

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

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