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Notice of Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents* to Enable the Use of Polysorbate 80 as an Emulsifying Agent in Wheat-based Ready-to-Eat Cereals

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0148

June 15, 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 polysorbate 80 as an emulsifying agent in wheat-based ready-to-eat cereals. The requested maximum level of use is 0.05%.

Polysorbate 80 is already permitted for use in Canada as an emulsifier in a number of foods, including rice-based ready-to-eat cereals at a maximum level of 0.1%.

The results of the Food Directorate's evaluation of available scientific data support the safety of polysorbate 80 when used as requested by the petitioner. Therefore, Health Canada has modified the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#) to extend the use of polysorbate 80 by adding the entry shown below to the List.

Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents*

Item No.	Column 1 Additive	Column 2 Permitted in or Upon	Column 3 Maximum Level of Use and Other Conditions
P.2	Polyoxyethylene (20) Sorbitan Monooleate (Polysorbate 80)	(24) Wheat-based ready-to-eat cereals	(24) 0.05%

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of polysorbate 80 for use as an emulsifying agent in wheat-based ready-to-eat cereals. The assessment concluded that information related to allergenicity, chemistry, microbiology, nutrition, and toxicology supports the safety of polysorbate 80 for its requested uses. Therefore, the Department has enabled the requested use of polysorbate 80 by adding it to the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents](#) as shown in the above table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as polysorbate 80 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.

Implementation and Enforcement

The above modification came into force **June 15, 2020**, the day it was published in the [List of Permitted Emulsifying, Gelling, Stabilizing or Thickening 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.

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 polysorbate 80, that could impact the approved use of the additive. 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 "**Polysorbate 80 (NOM-0148)**" in the subject line of your e-mail.

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

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