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Health Canada's Notice of Modification to the *List of Permitted Food Additives with Other Accepted Uses* to Enable the Use of Polysorbate 80 in Bacterial Cultures Intended for Use in Various Infant Foods and Nutritional Supplement Powders

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: **NOM/ADM-0138**

August 13, 2019

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada 

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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 (polyoxyethylene (20) sorbitan monooleate) to improve the survival rate of bacterial cells in bacterial cultures during the spray-drying process. The resulting bacterial culture powder is not consumed directly, but rather is intended to be added as an ingredient to: 1) infant formula powder, 2) dried infant cereal, and 3) powdered nutritional supplements for toddlers (1 to 3 years of age). The amount of polysorbate 80 carried over from the bacterial culture ingredient to these three categories of food would be no more than 3 ppm, 6 ppm, and 3 ppm respectively.

Polysorbate 80 is already permitted for use in Canada as an emulsifying, gelling, stabilizing or thickening agent in a variety of foods.

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. There are no safety concerns with the consumption of polysorbate 80 from spray-dried bacterial cultures in nutritional supplements if consumed by older children and adults because the consumption from nutritional supplements would remain negligible compared to total dietary intake. In addition, there is no specific definition for "toddler" in the *Food and Drugs Act* or the Regulations. The Food Directorate has modified the listing for use in nutritional supplements to be applicable to the general population. Therefore, Health Canada has modified the [List of Permitted Food Additives with Other Accepted Uses](#) by adding the entry shown below to the list.

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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.2C	Polyoxyethylene (20) Sorbitan Monooleate (Polysorbate 80)	Spray-dried bacterial culture preparations for use in dried infant cereal products, infant formula powders, or nutritional supplement powders	To improve viability of spray-dried bacterial cultures	Good manufacturing practice; not to exceed 6 p.p.m. in dried infant cereal products; 3 p.p.m. in infant formula powders; or 3 p.p.m. in nutritional supplement powders

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of polysorbate 80 to improve the survival rate of bacterial cells during spray-drying. The assessment concluded that information related to chemistry, molecular biology, nutrition, and toxicology supports the safety of polysorbate 80 for its requested uses. Therefore, the Department has enabled the requested uses of polysorbate 80 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 polysorbate 80 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 **August 13, 2019**, the day it was published in the [*List of Permitted 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.

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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. 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-0138)**" in the subject line of your e-mail.

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