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Notice of Modification to the *List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents* to Enable the Use of Citric Acid Esters of Mono- and Diglycerides (CITREM) as an Emulsifier in Whole Protein-Based Infant Formulas for Special Dietary Purposes

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0153

September 18, 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 citric acid esters of mono- and diglycerides (CITREM) as an emulsifier in whole protein-based infant formulas for special dietary or medical uses at a maximum level of 0.155% as consumed. Based on information provided in the submission, the intended use of CITREM is captured by the term 'whole-protein based infant formula for special dietary purposes'. Whole protein-based infant formulas for special dietary purposes have modified fat profiles. They are typically used to manage the diets of infants with certain allergies or disease-related malnutrition and failure to thrive.

CITREM is already permitted for use in Canada as an emulsifying agent in infant formulas based on crystalline amino acids or protein hydrolysates, or both, at the same maximum level as the one requested by the petitioner.

The results of the Food Directorate's evaluation of available scientific data support the safety of CITREM 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 CITREM to whole protein-based infant formula for special dietary purposes by revising sub-item (1) for Item C.18 of the list as shown below.

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
C.18	Citric Acid Esters of Mono- and Di-glycerides	(1) Infant formula based on crystalline amino acids or protein hydrolysates, or both; Whole protein-based infant formula for special dietary purposes	(1) 0.155% as consumed

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of CITREM for use as an emulsifying agent. The assessment concluded that information related to allergenicity, chemistry, nutrition,

and toxicology supports the safety of CITREM for its requested use. Therefore, the Department has enabled the requested use of CITREM by revising sub-item (1) for Item C.18 of 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 CITREM 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 **September 18, 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 CITREM. 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 "**CITREM (NOM-0153)**" in the subject line of your e-mail.

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

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