Notice of Modification to the List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents and the List of Permitted Food Additives with Other Generally Accepted Uses to Enable the Use of Lactylated Mono- and Di-glycerides as an Emulsifying Agent and Sodium Stearoyl-2-Lactylate as a Whipping Agent, respectively, in Whipped Yogurt

Notice of Modification – Lists of Permitted Food Additives

Reference Number: [NOM/ADM-0085]

Santé

Canada

January 4, 2017















Notice of Modification to the List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents and the List of Permitted Food Additives with Other Generally Accepted Uses to Enable the Use of Lactylated Mono- and Di-glycerides as an Emulsifying Agent and Sodium Stearoyl-2-Lactylate as a Whipping Agent, respectively, in Whipped Yogurt.

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*. 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 Health Canada's 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 received a food additive submission seeking approval for the use of lactylated mono- and di-glycerides and sodium stearoyl-2-lactylate in the manufacture of whipped yogurt. These additives are mixed into the yogurt, prior to aeration, to help create the mousse texture of the whipped yogurt. The requested maximum level of use for each additive, on the basis of the finished whipped yogurt, is 0.5% and 0.05%, respectively.

Both additives already have permitted uses in Canada. Lactylated mono- and di-glycerides are permitted as an emulsifying agent in unstandardized foods, a food category that includes whipped yogurt. However, the current maximum level of use is lower than the concentration that the petitioner indicates is required in whipped yogurt. Sodium stearoyl-2-lactylate is permitted as a whipping agent in certain standardized egg products and in oil toppings or topping mixes, but there are no provisions that would allow its use in whipped yogurt.

The results of Health Canada's evaluation of available scientific data support the safety of the requested use of lactylated mono- and di-glycerides and sodium stearoyl-2-lactylate in whipped yogurt. Therefore, Health Canada has modified the <u>List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents</u> and the <u>List of Permitted Food Additives with Other Generally Accepted Uses</u> by adding the entries shown below to the lists.

Modifications to the *List of Permitted Food Additives*

The following entry has been added to the <u>List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents</u>:

| Item | Column 1 | Column 2 | Column 3 Maximum Level of Use and Other Conditions |
|------|--|-----------------------|--|
| No. | Additive | Permitted in or upon | |
| L.1 | Lactylated Mono- and Di-glycerides | (3) Whipped yogurt | (3) 0.5% |

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The following entry has been added to the <u>List of Permitted Food Additives with Other Generally Accepted Uses:</u>

| 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 |
|-------------|------------------------------------|-------------------------------------|----------------------------|--|
| S.9A | Sodium Stearoyl-2- Lactylate | (5) Whipped yogurt | (5) Whipping agent | (5) 0.05% |

Justification

Health Canada's Food Directorate assessed the safety of lactylated mono- and di-glycerides and sodium stearoyl-2-lactylate for their requested use in whipped yogurt. The assessment focused on the toxicological and nutritional aspects of this use of these additives. No food safety concerns were identified. Therefore, Health Canada has enabled their requested use by modifying the <u>List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents</u> and the <u>List of Permitted Food Additives with Other Generally Accepted Uses</u> as described above.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as lactylated mono- and diglycerides and sodium stearoyl-2-lactylate, which do not have specifications set out in the Regulations, meet the food-grade specifications set out in the most recent edition of the *Food Chemicals Codex* (FCC). The FCC is a compendium of standards for purity and identity for food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

Implementation and Enforcement

The above modifications came into force January 4, 2017, the day they were published in the <u>List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents</u> and the <u>List of Permitted</u>
Food Additives with Other Generally 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 any new scientific information on the safety in use of any food additive, including lactylated mono- and di-glycerides and sodium Notice of Modification to the List of Permitted Emulsifying, Gelling, Stabilizing or Thickening Agents and the List of Permitted Food Additives with Other Generally Accepted Uses to Enable the Use of Lactylated Mono- and Di-glycerides as an Emulsifying Agent and Sodium Stearoyl-2-Lactylate as a Whipping Agent, respectively, in Whipped Yogurt.

stearoyl-2-lactylate. Anyone wishing to submit new scientific information on the use of these additives 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 "lactylated mono- and di-glycerides" and/or "sodium stearoyl-2-lactylate" in the subject line of your e-mail.

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