



Health
Canada

Santé
Canada

Your health and
safety... our priority.

Votre santé et votre
sécurité... notre priorité.

Health Canada's Proposal to Enable the Use of a New Food Additive, Sodium Hydrogen Malate, as a Coating for Unstandardized Flavouring Preparations Used in Chewing Gum, Dry Beverage Mixes, Gelatin Dessert Powders and Unstandardized Confectionery

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: [NOP/AVP-0013]

March 4, 2016

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch



Canada

Health Canada's Proposal to Enable the Use of a New Food Additive, Sodium Hydrogen Malate, as a Coating for Unstandardized Flavouring Preparations Used in Chewing Gum, Dry Beverage Mixes, Gelatin Dessert Powders and Unstandardized Confectionery

Summary

Food additives are regulated in Canada under [Marketing Authorizations](#) (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 [Lists of Permitted Food Additives](#) 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 pre-market 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 sodium hydrogen malate in an unstandardized flavouring preparation to be used in chewing gum, dry beverage mixes, unstandardized confectionery and gelatin dessert powders. The maximum level of use requested on the basis of the finished food, is 1.5% in the first three food categories and 0.5% in gelatin dessert powders. The technical function of the sodium hydrogen malate is as a coating agent for the flavouring substance.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of sodium hydrogen malate when used as requested by the petitioner. Therefore, it is the intention of Health Canada to modify the [List of Permitted Food Additives with Other Generally Accepted Uses](#) by adding the following item to the list.

Proposed Modification to the *List of Permitted Food Additives with Other Generally 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
S.6.01	Sodium Hydrogen Malate	(1) Unstandardized flavouring preparations to be used in or upon chewing gum, dry beverage mixes or unstandardized confectionery (2) Unstandardized flavouring preparations to be used in or upon gelatin dessert powders	(1) Coating (2) Coating	(1) 1.5% in the finished product (2) 0.5% in the finished product

Rationale

Health Canada's Food Directorate has completed its pre-market safety and efficacy assessment of sodium hydrogen malate. The assessment considered toxicological, chemical and technical aspects of sodium hydrogen malate when used as described above. The potential contribution of sodium from the proposed use was also evaluated from a nutritional perspective. No food safety concerns were identified.

The sodium hydrogen malate is used as a coating for such flavouring substances as organic acid which may be used to impart a tart, sour taste to food. The sodium hydrogen malate creates a barrier between the flavouring and the food to which the flavouring is added, reducing the migration of the flavouring into the food matrix. When the food is consumed, the flavour is released as the sodium hydrogen malate dissolves in saliva. The dissolved sodium hydrogen malate itself also contributes to the flavour profile of the food.

Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of sodium hydrogen malate when used under the conditions of use set out in the table above. The Department is therefore proposing to enable the use of sodium hydrogen malate as described in the above table.

Other Relevant Information

Sodium hydrogen DL-malate (INS 350(i)) is listed in Table III of the Codex General Standard for Food Additives (GSFA). It may be used in a number of foods under the conditions of good manufacturing practice, including confectionery, chewing gum, water-based flavoured drinks, and fruit-flavoured gelatin.

No information on permitted food uses, if any, for sodium hydrogen malate in the United States has been identified. However, malic acid¹ is identified as a direct food substance that has been affirmed as Generally Recognized as Safe (GRAS) as per Section 184.1069, Title 21 (*Food and Drugs*) of the U.S. *Code of Federal Regulations*.

In the European Union, sodium malates (E 350), which includes sodium hydrogen malate (E 350(i)), are authorized for use at a maximum level of *quantum satis* in various food categories including chewing gum, certain confectionery and certain desserts, and flavoured drinks.

Australia and New Zealand permit sodium malates (INS No. 350), which includes sodium hydrogen malate (350(i)), in various food categories including sugar confectionery (which includes chewing gum) and water based flavoured drinks in accordance with good manufacturing practice.

¹ Sodium hydrogen malate is a salt of malic acid.

Health Canada's Proposal to Enable the Use of a New Food Additive, Sodium Hydrogen Malate, as a Coating for Unstandardized Flavouring Preparations Used in Chewing Gum, Dry Beverage Mixes, Gelatin Dessert Powders and Unstandardized Confectionery

The Canadian *Food and Drug Regulations* require that food additives such as sodium hydrogen malate, 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 U.S. Pharmacopeial Convention.

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the *List of Permitted Food Additives with Other Generally Accepted Uses*. This will be announced via a Notice of Modification which will be published on [Health Canada's Website](#).

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

Corrective Modifications to the *Liste des additifs alimentaires ayant d'autres utilisations généralement acceptées*

In the French list, the term “coating” was variously translated using one of the four following terms: couverture, enrober, badigeonner, and enrobage. A corrective modification will be made to items A.1, M.3(3), M.7(2), P.1A(1), P.1A(2), P.2(2) in column 3 of the *Liste des additifs alimentaires ayant d'autres utilisations généralement acceptées* in order to consistently use the single term « enrobage » for the English term “coating”.

Contact Information

For additional information or to submit comments related to this proposal, please contact:

[Bureau of Chemical Safety, Food Directorate](#)
251 Sir Frederick Banting Driveway
Tunney's Pasture, PL: 2202C
Ottawa, Ontario K1A 0L2
E-mail: bcs-bipc@hc-sc.gc.ca

If communicating by e-mail, please use the words “**Sodium Hydrogen Malate**” in the subject line of your e-mail. Health Canada is able to consider information received by **May 17, 2016**, 75 days from the date of this posting.