Notice of Modification to the List of Permitted Colouring Agents to Enable the Use of **Ground Limestone in Unstandardized** Confectionery

Notice of Modification – Lists of Permitted Food Additives

Reference Number: NOM/ADM-0129

Santé

Canada

March 20, 2019















Notice of Modification to the *List of Permitted Colouring Agents* to Enable the Use of Ground Limestone in Unstandardized Confectionery

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* (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 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 ground limestone as a colouring agent in hard and soft candies and in inks for writing on various confections. The proposed maximum levels of use are 1% by weight in confectionery and 0.05% by weight in the final inked confections. The confections of interest are unstandardized foods.

The results of the Food Directorate's evaluation of available scientific data support the safety and efficacy of ground limestone when used as requested by the petitioner. Since this is a food additive that was not previously permitted for use in Canada, Health Canada published a *Notice of Health Canada's Proposal to Enable the Use of Ground Limestone as a Colouring Agent in Unstandardized Confectionery* [NOP/ADP-0029] on October 4, 2018, which was open to the public for comment for 75 days. No new scientific information was submitted to the Department as a result of this publication. Since the conclusions of the evaluation remain as described in the publication, Health Canada has enabled the requested uses of ground limestone by adding the entry shown in the table below to the *List of Permitted Colouring Agents*.

Modification to the List of Permitted Colouring Agents

Item	Column 1	Column 2	Column 3 Maximum Level of Use and Other Conditions
No.	Additive	Permitted in or Upon	
14.	Ground Limestone	Unstandardized Confectionery	Good Manufacturing Practice

Rationale

Health Canada's Food Directorate completed a premarket safety and efficacy assessment of the requested uses of ground limestone. The assessment concluded that information related to chemistry, microbiology, nutrition, toxicology, and allergenicity supports the safety of ground limestone for its requested uses. Therefore, the Department has enabled the requested uses of

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ground limestone by adding to the List of Permitted Colouring Agents the new item number and its corresponding entries as shown in the above table.

Other Relevant Information

The Food and Drug Regulations require that food additives 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. In the case of limestone, its food-grade specifications can be found in the *Food Chemicals Codex*.

Notification – Summary of Comments

No comments were received in response to Health Canada's Proposal to Enable the Use of Ground Limestone as a Colouring Agent in Unstandardized Confectionery, published on October 4, 2018.

Implementation and Enforcement

The above modification came into force March 20, 2019, the day it was published in the *List of* Permitted Colouring 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 ground limestone. 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 "Ground Limestone (NOM-0129)" in the subject line of your e-mail.

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