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Health Canada's Proposal to Enable the Use of Ground Limestone as a Colouring Agent in Unstandardized Confectionery

Notice of Proposal – *Lists of Permitted Food Additives*

Reference Number: **NOP/ADP-0029**

October 4, 2018

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 received a food additive submission seeking approval for the use of ground limestone as a colouring agent in hard and soft candies and in edible inks for writing on certain confectioneries. The proposed maximum levels of use are 1% by weight in the confectionery (i.e., the hard and soft candies) and 0.05% by weight in the final inked confectionery. The confectioneries of interest are considered to be unstandardized foods.

Ground limestone consists primarily of calcium carbonate, but can contain other minerals. While calcium carbonate is already permitted for use as a colouring agent for the same uses that are requested for ground limestone, Health Canada considers ground limestone to be distinct from calcium carbonate since the two substances have separate food-grade specifications.¹ Ground limestone does not currently have any permitted uses as a food additive (i.e., it is a "new" food additive in Canada). It may, however, be added to flour as a source of calcium.²

The results of Health Canada's evaluation of the scientific information support the safety and efficacy of ground limestone when used in the foods requested by the petitioner at a level consistent with Good Manufacturing Practice. Therefore, Health Canada proposes to enable this use of ground limestone by adding an entry for ground limestone to column 1 of item no. 14 of the [List of Permitted Colouring Agents](#) as shown in the table below. This listing accommodates its use in edible inks on confectionery as the ink is considered part of the confectionery once applied.

Proposed Modification to the *List of Permitted Colouring Agents*

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

¹ For example, the *Food Chemicals Codex* (11th edition, first supplement) specifies that the minimum calcium content, on the dried basis, of ground limestone is 94.0% and of calcium carbonate is 98.0%.

² See section B.13.001(f) of the *Food and Drug Regulations*.

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Rationale

The Food Directorate completed a premarket safety and efficacy assessment of the requested use of ground limestone. The assessment considered the information related to the toxicological, nutritional, chemical and technical aspects of ground limestone for its requested use.

The primary constituent of ground limestone is calcium carbonate, which dissociates into calcium ions and carbonate ions in the acidic environment of the human stomach.

Calcium and carbonate are normal constituents of the human body. Calcium in particular is an essential nutrient. After intestinal absorption, calcium enters normal metabolic pathways and is stored by the body, for example in bones, with excess calcium being excreted in urine and feces. Carbonate ions are also absorbed and are excreted as carbon dioxide and do not accumulate in the body.

The proposed use of ground limestone would not contribute a significant amount of calcium to the diet, and there are no food safety concerns with the additional intake of carbonate from the proposed use of ground limestone.

The results of the premarket safety assessment support the safety of ground limestone for use as a colouring agent as set out in the table above. Health Canada is therefore proposing to enable this use of ground limestone as shown in the table.

Other Relevant Information

The *Food and Drug Regulations* require that food additives such as ground limestone 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 proposed change will be effective the day on which it is published in the [List of Permitted Colouring Agents](#). This will be announced via a Notice of Modification that will be published on the [Government of 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.

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Contact Information

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

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If communicating by e-mail, please use the words "**Ground Limestone (NOP-0029)**" in the subject line of your e-mail. Health Canada is able to consider information received by **December 17, 2018**, 75 days from the date of this posting.