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Notice of Modification to the *List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents* to Enable the Use of Calcium Carbonate as a pH Adjusting Agent in Infant Cereal Products

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0047]

April 01, 2015

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*. 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 MA's 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 calcium carbonate as a pH adjusting agent at use levels up to 2.52% weight/weight (w/w) in infant cereal products.

Calcium carbonate is already permitted for use in Canada as a pH adjusting agent in unstandardized foods as well as in several standardized foods at levels consistent with Good Manufacturing Practice.

The results of Health Canada's evaluation of available scientific data support the safety of calcium carbonate when used in infant cereal products as requested by the petitioner. The toxicological database also supports identifying a maximum level of use that is consistent with Good Manufacturing Practice. Therefore, Health Canada has modified the [List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents](#) to extend the use of calcium carbonate by adding the entry shown below to the List.

Modification to the *List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents*

Item No.	Column 1 Additive	Column 2 Permitted in or upon	Column 3 Maximum Level of Use and Other Conditions
C.2	Calcium Carbonate	(7) Infant cereal products	(7) Good Manufacturing Practice

Rationale

With respect to the maximum level of use for this additive, the ADI for calcium carbonate is "not limited"; generally, the maximum level of use for such additives can be established as "Good Manufacturing Practice" or GMP. This would be consistent with the position taken by Codex and current approved uses in the U.S., EU and Australia and New Zealand.

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Health Canada's Food Directorate completed a pre-market safety assessment of calcium carbonate. The assessment considered toxicological, nutritional and chemical aspects of calcium carbonate when used as requested in the food additive submission.

Based on the results of the safety assessment, Health Canada's Food Directorate considers that the data support the safety of calcium carbonate when used as requested by the petitioner. The Department has therefore enabled the use of calcium carbonate as described in the above table.

Implementation and Enforcement

The above modification came into force **April 01, 2015**, the day it was published in [*List of Permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting 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 permitted food additive including calcium carbonate. 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 "**calcium carbonate**" in the subject line of your e-mail.

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

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