Notice of Modification to the List of Permitted Food Additives with Other Generally Accepted Uses to Enable the Use of Silicon Dioxide as a Colour Stabilizer in Colouring Agent Formulations

Notice of Modification – Lists of Permitted Food Additives

Reference Number: [NOM/ADM-0041]

October 28, 2014
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 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 silica (silicon dioxide) as a colour stabilizer in a number of permitted colouring agents.

Silicon dioxide is already a permitted food additive in Canada. Item S.1 in the List of Permitted Anticaking Agents provides for the use of silicon dioxide as an anticaking agent in unstandardized dry mixes and foods sold in tablet form at levels consistent with Good Manufacturing Practice (GMP). Silicon dioxide is also permitted as an anticaking agent for use in salt, icing sugar and certain spices and seasonings at levels ranging from 0.5% to 2.0% depending on the food. Item S.1.01 in the List of Permitted Food Additives with Other Generally Accepted Uses provides for the use of silicon dioxide as a suspending agent in edible vegetable oil-based cookware coating emulsions at a maximum level of use of 2.0% of the preparation.

There are no food additive provisions for the use of silicon dioxide to stabilize colouring agents, either in the Lists of Permitted Food Additives or in the standards in Division 6 of the Food and Drug Regulations that set out specifications for colouring agents.

The results of Health Canada’s evaluation of available scientific data support the safety and efficacy of silicon dioxide as a colour stabilizer in colouring agent formulations. Therefore, Health Canada has modified the List of Permitted Food Additives with Other Generally Accepted Uses to extend the use of silicon dioxide by adding the entry shown below to the list. The colouring agent formulations referred to in this new entry apply to a combination of any permitted colouring agent from the List of Permitted Colouring Agents and the silicon dioxide that is used to stabilize the colour.
Modification to the *List of Permitted Food Additives with Other Generally Accepted Uses*

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Column 1 Additive</th>
<th>Column 2 Permitted in or upon</th>
<th>Column 3 Purpose of Use</th>
<th>Column 4 Maximum Level of Use and Other Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>S.1.01</td>
<td>Silicon Dioxide</td>
<td>(2) Colouring agent formulations</td>
<td>(2) Colour stabilizer</td>
<td>(2) Good Manufacturing Practice</td>
</tr>
</tbody>
</table>

**Rationale**

Health Canada’s Food Directorate completed a pre-market safety and efficacy assessment of silicon dioxide as a colour stabilizer in colouring agent formulations. The assessment considered the toxicological and technical aspects of the proposal.

Based on the results of the safety assessment, Health Canada’s Food Directorate considers that the data support the safety of silicon dioxide when used under the conditions of use set out in the table above. The Department has therefore enabled the use of silicon dioxide as described in the above table.

**Other Relevant Information**

Health Canada routinely consults the Canadian Food Inspection Agency (CFIA) and the food industry when the Department is evaluating new food additive uses that could impact foods for which there are compositional standards set out in federal regulations. Several expert groups within the CFIA, and industry associations that represent a number of sectors of the food industry that could be impacted by changes to provisions for food colouring agents, were consulted about the use of silicon dioxide as a colour stabilizer in colouring agent formulations.

None of the groups that responded objected to the proposed use of silicon dioxide. Silicon dioxide used in foods sold in Canada must meet the food-grade specifications for this additive set out in the most recent edition of the *Food Chemicals Codex*. The FCC is a compendium of standards for purity and identity of food ingredients, including food additives, which is published by the United States Pharmacopeial Convention.

**Implementation and Enforcement**

The above modification came into force October 28, 2014, the day it was published in the *List of Permitted 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 permitted food additive, including silicon dioxide. Anyone wishing to submit new scientific information on the use of this food 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 "silicon dioxide in colouring agent formulations" in the subject line of your e-mail.

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