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Health Canada's Proposal to Enable the Use of Three New Colouring Agents: Potassium Aluminium Silicate-Based Iron Oxide; Potassium Aluminium Silicate-Based Titanium Dioxide; and Potassium Aluminium Silicate-Based Titanium Dioxide and Iron Oxide in Certain Unstandardized Foods

Notice of Proposal – *Lists of Permitted Food Additives*

January 26, 2015

Bureau of Chemical Safety
Food Directorate
Health Products and Food Branch





Canada

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 has received a food additive submission seeking approval for the use of mica-based iron oxide, mica-based titanium dioxide, and mica-based titanium dioxide and iron oxide as colouring agents in unstandardized confectionery and chewing gum at a maximum level of use of 1.25%, and in unstandardized alcoholic beverages at a maximum level of use of 0.5%. The mica component of these food additives is muscovite[1] which is naturally-sourced potassium aluminum silicate.

The results of Health Canada's evaluation of available scientific data support the safety and efficacy of the aforementioned mica-based colouring agents for this purpose. Therefore, it is the intention of Health Canada to modify the *List of Permitted Colouring Agents* by adding the following entries to the list.

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
10	Potassium aluminium silicate-based iron oxide	(1) Chewing gum; Unstandardized confectionery	(1) 1.25%. If any combination of potassium aluminium silicate-based iron oxide, potassium aluminium silicate-based titanium dioxide or potassium aluminium silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 1.25%.

[1] Muscovite is the most common form of mica and is a hydrated silicate of potassium and aluminum, i.e., potassium aluminum silicate. Mica is a general term applied to a group of complex mineral aluminosilicates which may also contain potassium, magnesium, iron, sodium, fluorine and/or lithium.

		(2) Unstandardized alcoholic beverages	(2) 0.5%. If any combination of potassium aluminium silicate-based iron oxide, potassium aluminium silicate-based titanium dioxide or potassium aluminium silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 0.5%.
11	Potassium aluminium silicate-based titanium dioxide	(1) Chewing gum; Unstandardized confectionery	(1) 1.25%. If any combination of potassium aluminium silicate-based iron oxide, potassium aluminium silicate-based titanium dioxide or potassium aluminium silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 1.25%.
		(2) Unstandardized alcoholic beverages	(2) 0.5%. If any combination of potassium aluminium silicate-based iron oxide, potassium aluminium silicate-based titanium dioxide or potassium aluminium silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 0.5%.
12	Potassium aluminium silicate-based titanium dioxide and iron oxide	(1) Chewing gum; Unstandardized confectionery	(1) 1.25%. If any combination of potassium aluminium silicate-based iron oxide, potassium aluminium silicate-based titanium dioxide or potassium aluminium silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 1.25%.

		(2) Unstandardized alcoholic beverages	(2) 0.5%. If any combination of potassium aluminium silicate-based iron oxide, potassium aluminium silicate-based titanium dioxide or potassium aluminium silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 0.5%.

Rationale

Health Canada's Food Directorate has completed a pre-market safety and efficacy assessment of mica-based colouring agents when used as described in the table above. The assessment considered toxicological, chemical, microbiological, and nutritional aspects of the proposal.

The mica-based colouring agents are formed by depositing titanium and/or iron salts onto the mineral muscovite mica, followed by heating to produce a substance consisting of the colours titanium dioxide and/or iron oxide coated on the muscovite form of the mineral mica. Mica-based colouring agents are not mixtures of titanium dioxide and/or iron oxide and mica, but rather composite substances composed either of mica and titanium dioxide (mica/TiO_2; muscovite mica-based titanium dioxide), mica and iron oxide (mica/Fe_2O_3; muscovite mica-based iron oxide), or mica with both titanium dioxide and iron oxide (mica/TiO_2/Fe_2O_3; muscovite mica-based titanium dioxide and iron oxide), in different ratios.

The mica component acts as a substrate for the titanium dioxide and/or iron oxide, leading to a pearlescent colour effect. The pearlescence effect is created by particles reflecting some light and allowing a portion of the available light to penetrate into deeper platelet particles where reflection also occurs. The reflection at both the surface and underlying particles simultaneously creates a luster effect or pearlescence.

The mica-based colouring agents can be produced with a variety of different pearlescent effects depending upon the mica platelet particle size and the amount of titanium dioxide and/or iron oxide deposited on the mica. Sequential precipitation of iron oxide and titanium dioxide on the mica platelets is also used to create a spectrum of colour shades which include shades of silver, red or gold.

The mica-based colouring agents were reported as being stable in various conditions, including gastric and intestinal fluids. Study results showed that the pigments were practically insoluble in

these fluids. It was concluded that the mica-based colouring agents would contribute a negligible amount of potassium and/or iron to dietary intake of these elements.

The thermal conditions during food processing and storage are considered not to influence the stability of the mica-based colours, as they are rather mild, compared to the thermal conditions under which the colours were produced (calcination at 900°C). The chemical conditions during food processing and storage are also not considered to influence the stability of the mica-based pigments. This is consistent with the results of tests on the solubility of these colours in gastric and intestinal fluids.

The available evidence supports the conclusion that mica-based colouring agents are not bioavailable and that they are not toxic, even at very high doses in acute, subchronic and carcinogenicity studies in experimental animals.

No microbiological or nutritional safety concerns have been identified for the proposed use of mica-based colouring agents.

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

Other Relevant Information

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has published food-grade specifications for potassium aluminum silicate-based pearlescent pigments, Type I (i.e., mica-based titanium dioxide), potassium aluminium silicate-based pearlescent pigments, Type II (i.e., mica-based iron oxide), and potassium aluminium silicate-based pearlescent pigments Type III (i.e., mica-based titanium dioxide and iron oxide). The muscovite mica-based colouring agents that were evaluated by Health Canada meet these food-grade specifications.

In the European Union, potassium aluminium silicate is permitted for use as a carrier for the colours titanium dioxide and iron oxide. Both colours are permitted for use in a wide variety of foods.

In the United States, the mica-based colouring agents are referred to as "mica-based pearlescent pigments"[2] and they may be used as a colour additive at a maximum level of 1.25% in cereals, confections, gelatin desserts, hard and soft candies (including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum.

[2] Defined in the U.S.A. *Code of Federal Regulations* as an additive formed by depositing titanium salts onto muscovite mica followed by heating to produce titanium dioxide on mica.

Mica-based colouring agents are not listed in the *Codex General Standard for Food Additives* (GSFA) and they are not currently permitted for use as colours in Australia or New Zealand.

Implementation and Enforcement

The proposed changes will be effective the day on which they are published in the *List of Permitted Colouring Agents*. This will be announced via a Notice of Modification which will be published on the Food and Nutrition - Public Involvement and Partnerships section of 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.

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 "**mica-based colouring agents**" in the subject line of your e-mail. Health Canada is able to consider information received by **April 10, 2015**, 75 days from the date of this posting.