Notice of Modification to the *List of Permitted Colouring Agents* to Extend the Use of Potassium Aluminum Silicate-Based Titanium Dioxide, Potassium Aluminum Silicate-Based Iron Oxide, and Potassium Aluminum Silicate-Based Titanium Dioxide and Iron Oxide as Colouring Agents to Unstandardized Bakery Products, Gelatin Desserts and Standardized Bite Sized Chocolate

Notice of Modification – *Lists of Permitted Food Additives*

Reference Number: [NOM/ADM-0061]

October 7, 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 received a food additive submission seeking approval for the use of mica-based titanium dioxide, mica-based iron oxide and mica-based titanium dioxide, and iron oxide colouring agents for unstandardized bakery products, gelatin desserts and standardized bite sized chocolates at a maximum use level of 0.15%. The mica component of these food additives is muscovite[1], which is naturally-sourced potassium aluminum silicate.

The potassium aluminum silicate-based titanium dioxide is to be used alone or mixed with other permitted colouring agents. The colouring agent itself or the mixture of which it is a part is applied to the surface of the food for decorative purposes.

Potassium aluminum silicate-based titanium dioxide, as well as potassium aluminum silicate-based iron oxide, and potassium aluminum silicate-based titanium dioxide and iron oxide are already permitted for use in Canada as colouring agents for unstandardized confectionery and for chewing gum at a maximum level of use, singly or in combination, of 1.25%, and for unstandardized alcoholic beverages at a maximum level of use of 0.5%, singly or in combination. As these three colours are considered equivalent from a safety perspective, they were all considered as part of the safety evaluation of the proposed new use.

The results of Health Canada's evaluation of available scientific data support the safety of potassium aluminum silicate-based titanium dioxide, as well as potassium aluminum silicate-based iron oxide, and potassium aluminum silicate-based titanium dioxide and iron oxide, when used in the foods and at the maximum level of use requested by the petitioner. Therefore, Health Canada has modified the *List of Permitted Colouring Agents* to extend the use of all three potassium aluminum silicate-based colouring agents by adding the entries to the list as shown in the table below.

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.

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
8.	Sodium Copper Chlorophyllin	(1) Frozen novelties; Ice cream mix; Ice milk mix; Sherbet; **Unstandardized confectionery;** Unstandardized frozen desserts; Unstandardized mixes for frozen dairy products	(1) 300 p.p.m.
10.	Potassium aluminum silicate-based iron oxide	**(3)** **Gelatin desserts; Unstandardized bakery products**	**(3)** **0.15%. If any combination of potassium aluminum silicate-based iron oxide, potassium aluminum silicate-based titanium dioxide or potassium aluminum silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 0.15%.**
		(4) **Colour formulations applied to the surface of bite sized chocolate, bite sized milk chocolate, bite sized sweet chocolate or bite sized white chocolate**	**(4)** **0.15% of the chocolate product as consumed. If any combination of potassium aluminum silicate-based iron oxide, potassium aluminum silicate-based titanium dioxide or potassium aluminum silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 0.15% of the chocolate product as consumed.**
11.	Potassium aluminum silicate-based titanium dioxide	**(3)** **Gelatin desserts; Unstandardized bakery products**	**(3)** **0.15%. If any combination of potassium aluminum silicate-based iron oxide, potassium aluminum silicate-based titanium dioxide or potassium aluminum silicate-based titanium dioxide and iron oxide is used, the total amount not to**

			exceed 0.15%.
		(4) **Colour formulations applied to the surface of bite sized chocolate, bite sized milk chocolate, bite sized sweet chocolate or bite sized white chocolate**	**(4)** **0.15% of the chocolate product as consumed. If any combination of potassium aluminum silicate-based iron oxide, potassium aluminum silicate-based titanium dioxide or potassium aluminum silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 0.15% of the chocolate product as consumed.**
12.	Potassium aluminum silicate-based titanium dioxide and iron oxide	**(3)** **Gelatin desserts; Unstandardized bakery products**	**(3)** **0.15%. If any combination of potassium aluminum silicate-based iron oxide, potassium aluminum silicate-based titanium dioxide or potassium aluminum silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 0.15%.**
		(4) **Colour formulations applied to the surface of bite sized chocolate, bite sized milk chocolate, bite sized sweet chocolate or bite sized white chocolate**	**(4)** **0.15% of the chocolate product as consumed. If any combination of potassium aluminum silicate-based iron oxide, potassium aluminum silicate-based titanium dioxide or potassium aluminum silicate-based titanium dioxide and iron oxide is used, the total amount not to exceed 0.15% of the chocolate product as consumed.**

Corrective Modifications to the *List of Permitted Colouring Agents*

Health Canada has also modified the *List of Permitted Colouring Agents* to make two corrections as follows. First, the term "Confectionery" in column 2 of item 8 of the list has been changed to "unstandardized confectionery" to reflect the intended provision to permit the use of sodium copper chlorophyllin in unstandardized confectionery only and not standardized confectionery such as "Chocolate".

Second, in the French version of the list (*Liste des colorants autorisés*), the name "Dioxyde de titane et d'oxyde de fer sur support de silicate de potassium et d'aluminium" that appears in

column 3 of sub-items 10.(1), 10.(2), 11.(1), 11.(2), 12.(1) and 12.(2) has been changed to "Dioxyde de titane et oxyde de fer sur support de silicate de potassium et d'aluminium" for consistency with the common name of this food additive appearing in item 12 of column 1 of this list.

Rationale

Health Canada's Food Directorate completed a premarket safety assessment of the new uses of potassium aluminum silicate-based colouring agents as set out in the table above. The assessment considered the microbiological, toxicological, nutritional and chemical suitability of these uses of these colouring agents, and found that the requested uses are acceptable from a food safety perspective. Therefore, the Department has enabled the requested uses of potassium aluminum silicate-based colouring agents by modifying the *List of Permitted Colouring Agents* as described in the above 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 potassium aluminum silicate-based colouring agents that were evaluated by Health Canada meet these food-grade specifications.

Implementation and Enforcement

The above modification came into force October 7, 2015, the day it was published in *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 potassium aluminum silicate-based colouring agents. 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 "**potassium aluminum silicate-based colouring agents**" in the subject line of your e-mail.

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