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Canadian Cosmetics Regulations Updates and Proposed Amendments to Hotlist

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***Regulations Amending Certain
Regulations Concerning the
Disclosure of Cosmetics Ingredients
(The proposed Regulations)***

Background information

- Certain fragrance ingredients are known to cause or lead to allergic contact dermatitis when used on the skin. Common symptoms include irritation and rashes.
 - This may affect 1 to 3% of the general population.
- Building on the February 9, 2022 [announcement to introduce the *Strengthening Environmental Protection for a Healthier Canada Act*](#), the Government will address the growing demand for clearer and more detailed information on chemicals in consumer products, including cosmetics. This was also in the 2021 Mandate Letters for the Minister of Health and the Minister of Environment and Climate Change.
 - With regards to cosmetics, Health Canada is proposing amendments to the *Cosmetic Regulations (CR)* under the *Food and Drugs Act* to require the disclosure of certain fragrance ingredients in cosmetics, which will help people in Canada make better decisions regarding the cosmetics they use.

The objectives of the proposed Regulations

- The objectives are to:
 - introduce a requirement to disclose certain fragrance allergens on cosmetic labels;
 - add greater flexibility for the disclosure of ingredients for cosmetics sold in small packages;
 - improve the oversight of cosmetics by clarifying terminology, strengthening the cosmetic notification requirements and enhancing compliance and enforcement tools; and
 - address changes of administrative nature.

Introduce a requirement to disclose fragrance allergens on cosmetic labels

- Currently, the fragrance ingredients can be listed as follows:
 - Individually in the list of ingredients; or
 - The term “parfum” can be included at the end of the list of ingredients.
- The proposed Regulations would require the disclosure of certain fragrance allergens on cosmetic labels within the list of ingredients, when its concentration exceeds 0.001 % in leave-on products or 0.01 % in rinse-off products.
 - It is proposed to align with the European Commission with regard to the format and the list of fragrance allergens that would require disclosure
 - » It is proposed to incorporate by reference the fragrance allergens within Annex III of the *European Union’s Cosmetic Products Regulation* (currently there are 24 fragrance allergens), including the transition period set out in that Annex, to address future updates to substances identified for disclosure.
 - Fragrance allergens would need to be included as ingredients in the Cosmetic Notification (CN).
 - This requirement would come into force two years after the registration of the final Regulations.

Add greater flexibility for disclosure of ingredient for cosmetics available in small packages

- Currently, for small packages that can't meet the legibility requirement, the list of ingredients can appear on a tag, tape or card affixed to the container or package.
- It is proposed to add the option to use a website to disclose the list of ingredients for cosmetics sold in small packages, provided that there is a statement specifying that the list of ingredients appears on that website and includes the location of the website.

Examples of statements:

Pour la liste des ingrédients / For the list of ingredients: www.websitename.ca

Ingrédients /Ingredients: www.websitename.ca

- This amendment would come into force 180 days after the registration of the final Regulations.

Improve regulatory oversight of cosmetics (1)

- Adding or clarifying terminology used in the *Cosmetic Regulations*:
 - (New) Importer: “*means a person that imports a cosmetic into Canada for the purpose of selling it*” .
 - (Update) Manufacturer: “*means a person that, in Canada, sells a cosmetic under the person`s own name or under a trademark, design, trade name or other name or mark owned or controlled by that person, on in the absence of such a person, a person that fabricates or processes a cosmetic in Canada on behalf of another person*” .
 - (New) Leave-on : “*means any cosmetic that is intended to stay in prolonged contact with the skin, hair or mucous membranes*” .
 - (New) Rinse-off : “*means any cosmetic that is intended to be removed after application to the skin, hair or mucous membranes*” .

Improve regulatory oversight of cosmetics (2)

The proposal would strengthen the CN requirements, as follows :

- Require ingredients to be identified using International Nomenclature of Cosmetic Ingredients (INCI) in the CN;
- Require identification of whether the product is leave-on or rinse-off (in the CN);
 - » This would **not** be retroactive. It would be required for new or amended CNs.
- No longer require information about the Canadian distributor in the CN (amendment to paragraph 30(2)(f) of the CR);
- Revise the table of concentration ranges from 7 ranges to 13 ranges.

Modernize the contact information present on the label:

- Currently, the manufacturer name and principal place of business is required on the label.
 - It is proposed to allow that a telephone number, email address, website or any other information for a consumer's questions be indicated on the label.

Concentration ranges

Item	Concentration range	Corresponding number
1	More than 80%, up to 100%	1 ^a
2	More than 65%, but not more than 80%	2 ^a
3	More than 50%, but not more than 65%	3 ^a
4	More than 40%, but not more than 50%	4 ^a
5	More than 30%, but not more than 40%	5 ^a
6	More than 20%, but not more than 30%	6 ^a
7	More than 10%, but not more than 20%	7 ^a
8	More than 3%, but not more than 10%	8
9	More than 1%, but not more than 3%	9
10	More than 0.3%, but not more than 1%	10
11	More than 0.1%, but not more than 0.3%	11
12	More than 0.001%, but not more than 0.1%	12 ^a
13	More than 0%, but not more than 0.001%	13 ^a

“a” indicates a new concentration range being proposed

Improve regulatory oversight of cosmetics (3)

- The proposed Regulations would enhance Health Canada's compliance and enforcement tools. The proposed amendments would:
 - Clarify that the sale of a cosmetic is prohibited unless a CN is submitted to Health Canada within 10 days of the first sale (see amendment described in section 15.3(1));
 - Clarify that if the information requested is not provided after 10 days of the request, the Minister would have the authority to request a stop sale of the product;
 - Clarify that the discontinuation of the sale for a product is considered of a change to the CN and requires a revised notification;
 - Add the ability to request evidence of safety from the importer (in addition to the manufacturer) (section 29).

Other Amendments:

- Amendments of administrative nature are as follows:
 - Definitions were updated to reflect current drafting conventions;
 - Update the publisher and edition of the INCI Dictionary;
 - Update the Schedule for outdated ingredient names;
 - Update the format of the Schedule to facilitate its understanding:
 - ❖ English version:
 - The heading of column 1, “EU Trivial Name” ⇒ “EU Technical Name”;
 - The heading of column 2, “English Equivalent” ⇒ “INCI Name”;
 - ❖ French version:
 - The heading of column 1, “Nom trivial attribué par l’UE” ⇒ “Nom technique attribué par l’UE”;
 - The heading of column 3, “Équivalent anglais” ⇒ “Appellation INCI”;
 - Clarify that for ingredients included in the schedule, all three terms listed for the same ingredient, e.g. “Water / Eau / Aqua” can be used on the label.

Consequential amendments to the *Cannabis Regulations*

- Updates are made to ensure terminology for the labelling of cannabis topicals remains consistent with the terminology to be used for cosmetics
- As a result of the change to the columns headings in the Schedule, consequential amendments to the *Cannabis Regulations* are proposed, as follows:
 - Subsection 130(1) is amended to reflect the change made to the heading of column 1 in the Schedule
 - Subparagraph 132.17(1)(c)(iv) is amended to reflect the changes made to the headings of column 1 and column 2 in the Schedule

Coming into force provisions

- Amendments related to disclosure of fragrance allergens would come into force two years after the registration of the final Regulations
- All other amendments would come into force 180 days after the registration of the final Regulations

How to submit comments

- Use commenting box available on the [Canada Gazette Webpage](#)
 - allows you to comment by section or overall, in the General Comments section.
- Once satisfied with your comments, you can submit them directly through the Canada Gazette Webpage;
- Before submitting you will have to accept the system's Terms and Conditions and Privacy Notice.

- Health Canada will review comments to ensure that the content complies with Government of Canada rules (privacy, hate speech, foul language etc.).
- After the end of the consultation period, all approved comments will be posted in the section "Closed Consultation with published comments" of the Canada Gazette Webpage.

Updates to the Cosmetic Ingredient Hotlist

Cosmetic Ingredient Hotlist

The latest update to the Hotlist was published on August 26, 2022.

<https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restricted-ingredients/hotlist.html>

2020 Final Hotlist Update

- **Ethylhexyl Ethylhexanoate**
 - Added to the list of restricted substances with limits for certain product types.
- **Azelaic acid and its salts**
 - Added to the list of restricted substances with maximum permitted concentration of 14%.
- **Retinoic acid and its salts**
 - Amended to add salts to entry on list of prohibited substances for clarity.
- **Eucalyptus oil**
 - Amended to better mitigate the risk of unintentional ingestion, particularly in pediatric populations.
 - Introduced cautionary label statements for products in non-solid forms with concentrations greater than 0.022%.

2020 Final Hotlist Update

- **Peroxide and peroxide-generating compounds**
 - Amended to clarify Evidence of Safety requirements to align with Technical Guidance.
- **p-Hydroxyanisole**
 - Amended to expand the permitted nail product categories to include products for consumer use, and increase the maximum concentration permitted for these products.

2020 Hotlist Update – Deferred entries

- **Alpha-hydroxy acids**

- Proposed revisions are outlined in the 2022 Notice to Stakeholders.

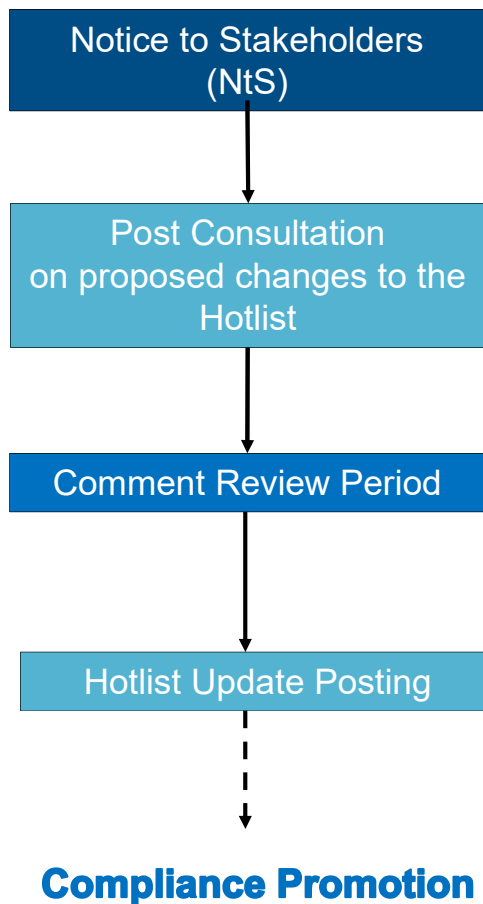
- **Retinoic acid derivatives**

- Further review of information, potential for additional consultation.
- In the interim, the status message for ingredient validation of retinoic acid derivatives on the Cosmetic Notification Form (section 5) will appear as follows:

Status: Restricted

Condition: This ingredient is under review. Any change in ingredient conditions will be communicated as per the Hotlist update process as described on Health Canada's website.

Upcoming: Hotlist Update 2022



November 2022 - NtS

- Notice of NtS posting sent to Cosmetics Mailing List and email address provided by notifiers.

Spring 2023 – Post Consultation (60 days)

- Notice of posting sent to Cosmetics Mailing List and email addresses provided by notifiers.
- **New!** Information sheets on certain ingredients will be piloted.

Spring 2023 – Comment Review

- Health Canada will review any information provided during the consultation and respond to comments received.

Fall 2023 – Final Hotlist Update

- Anticipated Final publication; Notice of posting to be sent to Cosmetics Mailing List and email addresses provided in notifications.
- Notifiers affected by the Hotlist changes will be contacted by Health Canada.

Notice to Stakeholders – November 2022

The [Notice to Stakeholders](#), outlining ingredients under review by CHPSD, was posted November 18, 2022.

Prohibited list:

- ***Proposed additions:***

- **Basic Green 4 (Malachite Green)**
 - » Further to CMP, will be proposed as prohibited due to potential developmental effects
- **Thioglycolic acid esters**
 - » Proposed as prohibited due to risk of skin sensitization

- ***Proposed revisions:***

- **Mixed cresols and derivatives**
 - » Proposed separation of entries due to different risk profiles of each substance
- **Dialkanolamines, secondary**
 - » Proposed expansion of the entry to include salts based on their potential as carcinogenic nitrosamine precursors

Notice to Stakeholders – November 2022

Restricted List:

- ***Proposed additions:***

- **Benzophenone**

- » Further to CMP assessment, proposed restriction due to potential maternal effects including decreased bodyweight

- **p-Chloro-m-cresol**

- » Further to CMP assessment, proposed restriction due to potential effects on adrenal organs

- **Retinal**

- » Proposed restriction due to risk of skin irritation and therapeutic properties

- **Solvent Violet 13**

- » Further to CMP assessment, proposed restriction to protect against possible health effects for certain cosmetic uses

Notice to Stakeholders – November 2022

Restricted List:

- ***Proposed revisions:***

- **Alpha-Hydroxy Acids**

- » Revision to include clarification that PHAs and Bionic acids are captured under this entry

- **Aluminum chlorohydrate and its associated complexes**

- » Revision to clarify that these ingredients are not permitted in aerosol products due to risk of lung effects from inhalation

- **Peroxide and peroxide-generating compounds**

- » Revision to include maximum concentration for hair products, conditions for eyelash and eyebrow products

- **Benzoyl peroxide**

- » Revision to clarify that ingredient may only be used in nail products for professional use due to strong irritation and sensitization potential

- **Hydroquinone**

- » Revision to expand nail product categories to include consumer use applications, and a combined limit when used with p-hydroxyanisole

- **P-Hydroxyanisole**

- » Revision to include a combined limit when used with Hydroquinone

- **Retinol and its esters**

- » Revision to reduce maximum concentration for certain products like body lotions where exposure may exceed Tolerable Upper Intake Levels recommended by Health Canada

- **Talc**

- » Revisions to the entry to reduce exposure to talc from certain cosmetics that may be inhaled or may result in perineal exposure to population with intact ovaries

Contact us

cosmetics@hc-sc.gc.ca

Contact your designated Regional Product Safety Office:

<https://www.canada.ca/en/health-canada/corporate/contact-us/regional-product-safety-offices.html>

or

via telephone 1-866-662-0666

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Questions?