

December 16, 2013

The Honourable Rona Ambrose, P.C., M.P.
Health Canada
Brooke Claxton Building, Tunney's Pasture
Postal Locator: 0906C
Ottawa, Ontario K1A 0K9

Transmission: by email

Dear Honourable Ambrose,

Re: NGO response to proposed changes to the Cosmetics Ingredient Hotlist dated October 10, 2013

The Chemical Sensitivities Manitoba (CSM) and Canadian Environmental Law Association (CELA) are providing the following comments in response to the posting dated October 10, 2013.

CELA (www.cela.ca) is a non-profit, public interest organization established in 1970 to use existing laws to protect the environment and to advocate for environmental law reform. It is also a legal aid clinic that provides legal services to citizens or citizens' groups who are unable to afford legal assistance. In addition, CELA also undertakes substantive environmental policy and legislation reform activities in the area of access to justice, pollution and health, water sustainability and land use issues since its inception. Under its environmental health program, CELA has been actively involved in matters that promote the prevention and elimination of toxic chemicals addressed in the *Canadian Environmental Protection Act*, including the categorization process and implementation of the CMP since 2000.

CSM, a volunteer organization, was founded in 1997 by four individuals who saw the need to address the affects of toxic chemicals on human health and the possible link between the onset of chemical sensitivities and chemical exposure and, in particular, chronic low-level exposure. CSM raises awareness of the presence of toxic chemicals in the home and the environment and strongly advocates for the safe substitution of these toxins.

CELA and CSM have submitted comments to previous proposals to amend the Cosmetic Ingredients Hotlist under the Cosmetic Regulations as it pertains to substances assessed through the CMP Industry Challenge. We have also commented, in previous submissions, about our on-going concerns that the government is relying on the use of the Cosmetic Ingredient Hotlist to achieve the prohibition of toxic chemicals in

cosmetic and personal care products. The Cosmetics Ingredient Hotlist is not fully protective of consumers because it remains a non-regulatory instrument and notification requirements to disclose ingredients to Health Canada are conducted as a post market requirement. We urge the government to give serious consideration to these matters in the establishment of fully protective measures for consumers. In light of these concerns, we offer the following comments on specific chemicals.

Proposed additions to the Health Canada's Cosmetics Ingredient Hotlist

➤ Solvent Red 23 - CAS 85-86-9

Assessed through the Government of Canada's Chemicals Management Plan, it was concluded that Solvent Red 23 has potential genotoxic and carcinogenic health effects related to oral exposure. As a result, it is proposed that this substance to be added as a prohibited ingredient in cosmetic products intended for use on or around mucosal membranes due to health concerns and to also reflect its proposed addition to Schedule 1 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999). This substance was originally listed on the Hotlist under the "Coal Tar Dye" entry.

Comments:

- Considering that Solvent Red 23 has potential genotoxic and carcinogenic health effects related to oral exposure, there should be prohibition for its use in facial, bronzing and blush cosmetics. These products are used close to mucosal membranes. The proposed cautionary statements on the label of a cosmetic containing Solvent Red 12 are inadequate. Consumers do not always read the labeling and in particular, may be difficult if it is in fine print. Furthermore, there is an inappropriate assumption that the application of these products in the facial area may not result in the unintentional transfer to mucosal areas as a result of rubbing facial areas with the hands and then the subsequent touching of mucosal areas. The proposed amendments may not be protective in these situations. This concern is further exacerbated if consideration is given to circumstances where children may come into contact with cosmetics containing Solvent Red 23 through regular contacts with adults who use these products.
- There are cosmetic products on the market that are considered safe for use close to mucosal membranes and do not contain Solvent Red 23 but perform the same function as this substance. Therefore, it demonstrates that it is possible to formulate these cosmetics without the use of Solvent Red 23 and still have these products be competitive in the marketplace.
- Consideration should also be given to the fact that the cosmetics using Solvent Red 23 are products that get washed down the drain and into the sewer system with eventual release to the aquatic environments like the Great Lakes. Solvent Red 23, an azo substance that would metabolize into aromatic amines can do harm in the aquatic environment. This should also act as an incentive to prohibit this substance from all cosmetics not only those that are used around the mucosal membranes.

Recommendations:

- Health Canada should prohibit Solvent Red 23 in consumer and personal care products in Canada, including hair dyes, face powders, blush and bronzers and not only products intended for use around the mucosal membranes.
- Solvent Red 23 should also be added to Schedule 1 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

➤ **Diethylhexyl Adipate (CAS #103-23-1)**

Diethylhexyl Adipate (CAS #103-23-1) assessed through Batch 11 of the Government of Canada's Chemicals Management Plan was concluded to be harmful to human health. However, there are still uncertainties regarding the acceptable levels of exposure to humans due to dermal absorption. A limit of 6% in leave-on body moisturizers was determined to be adequately protective of human health, based on the use patterns of DEHA in cosmetics.

Comments:

- Based on the use patterns of DEHA in cosmetics, the determination of a 6% limit of DEHA in leave-on body moisturizers being adequately protective of human health appear to be in contradiction of existing uncertainties regarding the acceptable levels of exposure to humans due to dermal absorption. The presence of this uncertainty should provide sufficient rationale to apply a more precautionary approach for the use of this substance in personal care products. As a result, it would be more appropriate for DEHA to be prohibited in products when there is dermal absorption.
- DEHA has the potential for chronic toxicity in aquatic environment. The DEHA assessment concluded that DEHA has the potential to cause ecological harm in Canada.¹ This evidence further demonstrates the need to prohibit the use of this chemical in personal care products. This is matter is of concern for waterbodies such as the Great Lakes – St. Lawrence River Basin, where wastewater treatment plants may not have the adequate technology to reduce the level of DEHA from its wastewater effluent discharge. The current level of knowledge on DEHA indicates that contributions of DEHA from consumer products and industrial emissions have not been adequately determined. This level of uncertainty indicates the importance of prohibiting the discharge of DEHA from all sources.
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¹ Environment Canada and Health Canada. 2011. Proposed Risk Management Approach for Hexanedioic acid, bis(2-ethylhexyl) ester DEHA - Chemical Abstracts Service Registry Number (CAS RN): 103-23-1. On-line: <https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=2AC65068-1>.

Recommendations:

- Health Canada should prohibit the use of DEHA in use all leave-on cosmetic products.
- Monitoring and surveillance programs should include DEHA, particularly in highly industrial regions such as the Great Lakes – St. Lawrence River Basin.

➤ **Resorcinol (CAS #108-46-3)**

Comment:

- The recommendation for resorcinol to be prohibited for use in cosmetics intended for use on the skin is acceptable but should be expanded to apply to the entire body.

Recommendations:

- Resorcinol should be added for prohibition in cosmetic products
- We support prohibiting the use of resorcinol in skin applied cosmetics that can be used anywhere on the body, regardless of the method of application of the product containing resorcinol.

➤ **Methylene Glycol (CAS #463-57-0): Proposed addition to the Hotlist and Formaldehyde (CAS #50-00-0): Proposed amendment to clarify some requirements**

Methylene glycol is a hydration product of formaldehyde and it is currently a focus of prohibition in consumer products in Canada (i.e., not listed on Cosmetics Ingredient Hotlist). However, formaldehyde is listed as a restricted substance in consumer products (i.e., listed on the Cosmetic Ingredient Hotlist). The restrictions, conditions of use, warnings and cautionary statements that are being proposed for methylene glycol are the same as those for formaldehyde – including proposed new additions and existing restrictions.

For formaldehyde, there is also a current proposal to amend the inhalation hazard posed by the release of formaldehyde by heat, and its use in hair straighteners (non-oral products).

Comments:

- The presence of methylene glycol in cosmetics should be considered equivalent to having formaldehyde in a product. Formaldehyde is irritating to the eyes, skin and respiratory tract. Exposure to the substance has been linked to cancer (leukemia) in humans and the International Agency for Research on Cancer (IARC) has classified formaldehyde as a potential human carcinogen.² Apart from the proposal for the

² European Union Scientific Committees Green Facts: Methylene glycol in hair straighteners. 2012. Online: http://ec.europa.eu/health/scientific_committees/docs/citizens_methylene_glycol_en.pdf

labels of nail hardeners to include a mention that formaldehyde/methylene glycol has the potential to cause skin sensitivities, the other health hazards have not been mentioned. Nail finishes that use hardeners, containing up to 5% formaldehyde/methylene glycol, can be still subjected to some forced convection (with heat) which could result in the release of formaldehyde vapors.

- We are supportive that all aerosol products should not contain formaldehyde or methylene glycol.
- Based on the classification of formaldehyde by IARC, this substance and methylene glycol, should not be used in any cosmetics and personal care products whether they are designed for aerosol, non-aerosol, oral and non-oral applications.
- Formaldehyde as been detected in the surface and groundwater.³ The assessment does not provide estimates to determine the contribution of formaldehyde from consumer products or industrial discharge. It does indicate that formaldehyde may be entering surface water, including in the Great Lakes, from wastewater treatment plants discharges, primarily from industrial sources. Furthermore, formaldehyde may be discharged to groundwater from other sources such as cemeteries.⁴
- Trends show demonstrate companies making commitments to phase out formaldehyde in cosmetic products. Johnson and Johnson has committed to a phase out formaldehyde in adult cosmetic products by the end of 2015.⁵

Recommendation:

- All cosmetics and personal care products should not contain formaldehyde or methylene glycol at any concentration. Health Canada should list formaldehyde or methylene glycol strictly for prohibition from use in all cosmetic products.

³ Government of Canada. 2001. Priority Substances List Assessment Report - Canadian Environmental Protection Act, 1999. Formaldehyde. Online: <http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl2-lsp2/formaldehyde/index-eng.php#a2312>

⁴ Government of Canada. 2001. PRIORITY SUBSTANCES LIST ASSESSMENT REPORT Canadian Environmental Protection Act, 1999. Formaldehyde.. Online: <http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/psl2-lsp2/formaldehyde/index-eng.php#a2312>

⁵ See: Hower, M. 2013. Johnson & Johnson, P&G to Halt Use of Microbeads in Beauty Products Dated August 8th, 2013. Written for Sustainable Life Media. Online; http://www.sustainablebrands.com/news_and_views/behavior_change/johnson-johnson-pg-halt-use-microbeads

A) Proposed amendments to the Health Canada's Cosmetics Ingredient Hotlist

- **Alpha-Hydroxy Acids (AHAs): (CAS #s 77-92-9; 79-14-1; 50-21-5; 6915-15-7; 79-33-4; 5949-29-1; 617-73-2; 90-64-2; 35249-89-9)**

A new protective limit of no more than 30% and a pH of no less than 3.0 for AHA-containing professional cosmetic products have been recommended. For a product with 10% or less of AHAs, a pH of 3.5 or greater is acceptable. For a product containing concentrations of AHAs between 10% and 30% or a pH between 3.0 to 3.5 may be permitted for professional use if the manufacturer provides Health Canada with evidence of the pH, AHA concentrations, directions for use and clinical studies to demonstrate minimal skin irritation.

It is also proposed that skin products containing AHAs at concentrations equal to or greater than 3% shall carry cautionary statements such as: "Use only as directed.", "Avoid contact with the eyes.", "If irritation persists, discontinue use and consult a physician.", "It is recommended that prior to exposure to the sun, users cover areas where AHAs have been applied with sunscreen.", "Contact of the product with the skin must be of limited frequency or duration."

Comments:

- Regardless of the concentration levels of AHAs in a skin product, pH, AHA concentrations, directions for use and clinical studies to demonstrate minimal skin irritation should be required from the manufacturer before the product is permitted to enter the market.
- Taking into consideration the proposed precautionary statements for skin products containing 3% or greater of AHAs, the proposed range of 10-30% concentration of AHA is inadequately protective of human health.
- There are concerns that the 3% AHA concentration in cosmetic products could still pose a significant health risk to consumer safety. The dependence on labeling to provide the necessary protection to human health through the use of precautionary information is not adequate. However, many consumers remain vulnerable since many do not read labels and follow instructions appropriately. By taking the more precautionary approach by limiting the concentration of AHAs in skin products to a maximum of 3% concentration together with providing information to demonstrate that such a concentration does not pose harm to human skin, may be an acceptable approach in the interim. However, the long term goal should be the prohibited use of AHA in cosmetic products.

Recommendations:

- As an interim measure, the maximum concentration of AHAs in a skin preparation should not be greater than 3% if adequate data is submitted to demonstrate no effects on the skin at this concentration. A phase out date for AHA in consumer products should be considered within 5 years to allow time for reformulation of products or identification of safe alternative for use in consumer products.

- The government should require the pH, AHA concentration, use directions and clinical evidence demonstrating minimal skin irritation for every AHA containing product prior to the product goes on the market.

Retinol (CAS #s 68-26-8; 127-47-9; 79-81-2)

Comment:

- Accept the restrictions and the conditions of use for cosmetic products using retinol.

Recommendation:

- We support the proposed restrictions and conditions for the use of retinol in cosmetic and personal care products in Canada.

If you have any questions regarding our comments, please do not hesitate to contact us.

Yours truly,



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