

December 23, 2009

The Honourable Leona Aglukkaq, P.C., M.P.
Minister of Health
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The Honourable Jim Prentice, P.C., M.P.
Minister of the Environment
Environment Canada
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Transmission by email

Dear Minister Aglukkaq and Minister Prentice:

Re: Response to List of Prohibited and Restricted Cosmetic Ingredients (The Cosmetic Ingredient Hotlist) and Proposed Changes to the Cosmetic Ingredient Hotlist posted as of October 23, 2009

The Canadian Environmental Law Association and Chemicals Sensitivities Manitoba are responding to the consultation “Proposed Changes to the Cosmetic Ingredient Hotlist” posted as of October 23, 2009. Below we have provided our brief comments and recommendations on the chemicals proposed for listing to the Cosmetic Ingredient Hotlist.

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 pollution and 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.

Chemical Sensitivities Manitoba (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.

Throughout the implementation of the Chemicals Management Plan, our organizations have submitted substantial comments and recommendations to the government of Canada on the use of the Cosmetic Ingredients Hotlist as the tool to restrict and prohibit chemicals considered toxic under CEPA. We have urged the government to establish regulatory goals for elimination for all

CEPA toxic chemicals, applying the use of prohibition and phase out action plans for these chemicals. It is our view that action on the 13 chemicals or groups of chemicals listed in the consultation document (see table below) should be targeted for goals of elimination, including their use in cosmetic products.

We have concerns that the government's approach to manage the use of these chemicals is relying on non regulatory tools such as the Cosmetic Ingredient Hotlist. Our organizations propose that the government use its full authority to regulate these chemicals using regulatory tools to prohibit these chemicals. While we support the intent in the Cosmetic Ingredient Hotlist to prohibit the current and future use of chemicals in cosmetics, it also permits the continued usage of a range of toxic chemicals through restrictions. We have significant concerns that the Hotlist lacks the necessary regulatory framework to ensure the adequate protection of human health from toxic chemicals on the Hotlist.

Our concerns include:

- The list outlines chemicals targeted for prohibition and those targeted for restriction. The list is quite confusing to users such as the general public who are one of the intended audiences. For those who are not well acquainted with the list, there will be confusion about which chemicals are targeted for prohibition and which have restrictions, since the two categories are not explicitly listed separately.
- Application of restrictions for chemicals identified with specific health impacts such as carcinogens or reproductive and developmental toxicity is not a preventative approach. This approach may continue to result in additional environmental and health impacts downstream through disposal methods of cosmetic products containing toxic chemicals.
- The list does not provide sufficient additional consideration for those chemicals that may result in unique vulnerabilities to subpopulations such as children, pregnant women, workers, aboriginal communities, people with chemical sensitivities and people of low income.
- It is unclear whether manufacturers or importers abide by the limits on the Hotlist.
- The list does not require exporters of cosmetic products to comply with the requirements of the Hotlist. This is a significant flaw, not only of the Hotlist but of the management regime for toxic chemicals in Canada. The use of CEPA toxic chemicals should not be permitted for products intended for the export market.
- There are no public reporting requirements to assess the effectiveness of the post marketing notification process for the Cosmetic Ingredient Hotlist. To date, the public is not provided with a report that outlines how many offences have been made under the Hotlist and how the government has resolved such offences. The presence of public reporting may be a useful trigger for producing better products.
- There is no clear understanding of the fines or penalties for companies that fail to comply with the Hotlist.¹

¹ See: Canadian Environmental Law Association and Lowell Center for Sustainable Production, "The Challenge of Substances of Emerging Concern in the Great Lakes Basin: A review of chemicals policies and programs in Canada and the United States," A report prepared for the International Joint Commission Multi-Board Work Group on Chemicals of Emerging Concern in the Great Lakes Basin, June 2, 2009.

At present, the government relies on a post-market notification process to assess the compliance to the Hotlist. However, this process lacks adequate public accountability and the timeframe for notification of “10 days within introduction to the market” is limited for substantial review of data submitted by industry. Alternatively, the government should make changes in the framework through amendments to the Cosmetic Regulations. The amendments should include:

- enhancing the accountability of industry on the safety of their products, which may be done by revising the notification timeframe towards a pre-notification process rather than a post notification, expanding the timeframe to complete this process; and
- creating a dedicated prohibition list under the Regulation. The chemicals listed for prohibition under the Cosmetic Ingredient Hotlist should be adopted for this section of the Cosmetic Regulations.

Currently, the Cosmetic Regulations² include requirements for targeted chemicals, for example, coal tar dye or base, mercury, and chloroform and even estrogens. This last category lacks definition in the regulation but should not be interpreted as limiting. Estrogens may include chemicals that are carcinogens, reproductive and developmental toxicants and endocrine disruptors. A special list of chemicals for prohibition should be added to the Regulations to ensure complete prohibition of the use, sale, import, manufacture, production and export of these chemicals. We propose that this amendment to the Cosmetic Regulations include all chemicals proposed in the consultation document.

TABLE 1: Summary of CEPA toxic chemicals for addition to the Cosmetic Ingredient Hotlist

BATCH 1 CHEMICALS	BATCH 2 CHEMICALS
Hydroquinone (123-31-9)	Epichlorohydrin (Oxirane, (chloromethyl)) (106-89-8)
Methyloxirane monomer (propylene oxide) (75-56-9)	4,4'-Isopropylidenediphenol (Bisphenol A) (80-05-7)
Naphthalene (91-20-3)	Isoprene monomer (1,3-Butadiene, 2-methyl) (78-79-5)
Toluene Diisocyanates (TDIs) including, 2,4-diisocyanato-1-methyl-benzene (2,4-toluene diisocyanate) (584-84-9); 2,6-diisocyanato-1-methyl-benzene (2,6 toluene diisocyanate) (91-08-7); and 1,3-diisocyanatomethyl-benzene (mixed isomers of toluene diisocyanate) (26471-62-5)	HC Blue No. 4 (158571-57-4)
	HC Blue No. 5 (68478-64-8, 158571-58-5)
	Alcohols, C13-15, reaction products with N-[3-(dimethoxymethylsilyl)-2-methylpropyl]- 1,2-ethanediamine, glycidol and hydroxyterminated di-Me siloxanes (237753-63-8)
	Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, hydroxy- and methoxy-terminated, polymers with polyethylene-polypropylene glycol bis(2-methyl-2-

² Government of Canada. Cosmetic Regulations C.R.C., C. 869.

	propen-1-yl) ether (921936-12-1)
	Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, hydroxy-terminated, polymers with hydrogen terminated di-Me siloxanes and polyethylene glycol bis(2-methyl-2-propen-1-yl) ether (929218-99-5)
	Siloxanes and Silicones, 3-[(2-aminoethyl)amino]-2-methylpropyl Me, di-Me, reaction products with N,N,N-trimethyloxiranemethanaminium chloride (495403-02-6)

Recommendation #1: We support the intent of government to aim for a prohibition of toxic chemicals used in cosmetic products.

Recommendation #2: We urge the government to amend the Cosmetic Regulations under the *Food and Drug Act* to enhance the accountability of industry in providing data to demonstrate the safety of chemicals used in cosmetic products. We also recommend the government to require a mandatory pre notification process and to create a section in the regulation that lists all toxic chemicals used in cosmetic products aimed for sale, use, manufacture, import and export that will be prohibited. The use of the current Cosmetic Ingredient Hotlist, a non-regulatory tool, to manage chemicals is inadequate to achieve these objectives.

Recommendation #3: Require public reporting on the effectiveness of the pre-notification process and compliance with the prohibition list of toxic chemicals.

Recommendation #4: All 13 toxic chemicals proposed for addition to the Cosmetic Ingredient Hotlist (see Table 1) should be listed for prohibition in the Cosmetic Regulation as this is considered the appropriate regulatory measure. This would require the addition of a new section to the regulation.

The following are brief comments and recommendations to support the above recommendations.

TABLE 2: Proposed CEPA toxic chemicals for addition to the Cosmetic Ingredient Hotlist – Comments and Recommendations

Chemical Name (CAS number)	Government Proposal	Comments	Recommendation
BATCH 1			
Hydroquinone (123-31-9)	1) Restricted to hair dye products and nail products 2) Permitted at concentrations equal to or less than 0.3% as an oxidizing colouring agent for hair dyes. The inner and outer labels of hair dye	The proposed restrictions focus on hair and nail products only. Therefore, the proposed restrictions do not effectively protect consumers despite findings that hydroquinone is a carcinogen. The Hotlist lists hydroquinone as prohibited for use on skin or mucous membrane. However, the proposed restrictions will not	Recommendation: Based on its carcinogenicity, hydroquinone should not be permitted for use in any cosmetic products, regardless of concentration. See above recommendation #4.

	<p>products containing hydroquinone must carry a cautionary statement, in English and French, to the effect: "Contains hydroquinone."; "Do not use to dye eyelashes or eyebrows."; "Rinse eyes immediately if the product comes into contact with eyes."</p> <p>3) Permitted at concentration equal to or less than 0.02% in nail products (after mixing for use). The inner and outer labels of nail products containing hydroquinone must carry a cautionary statement, in English and French, to the effect: "Avoid skin contact."; "Read directions carefully before using."</p>	<p>address imported products such as skin lightening products that may contain hydroquinone. This may highlight the weakness in the current enforcement of the Hotlist.</p> <p>Further no additional restrictions are provided to protect vulnerable populations such as children, workers, pregnant women, aboriginal communities, people of low income and people with chemical sensitivities.</p> <p>Labelling requirements should be expanded to include health impacts of chemicals, including carcinogens, reproductive and developmental toxicants, neurodevelopmental toxicants and endocrine disruptions. While it is important to outline direction for use of products, the burden for protection as it relates to exposure, is still placed heavily on consumers rather than manufacturers of products. Consumers may not be aware of the health impacts associated with this chemical.</p>	
Methyloxirane monomer (propylene oxide) (75-56-9)	Prohibition	Since this chemical is a carcinogen, the intent for prohibiting propylene oxide in all cosmetic products without restrictions is supported.	See above recommendation #4.
Naphthalene (91-20-3)	Prohibition	Since this chemical is a carcinogen, the intent for prohibiting naphthalene in all cosmetic products without restrictions is supported.	See above recommendation #4.
Toluene Diisocyanates (TDIs) including, 2,4-diisocyanato-1-methyl-benzene (2,4-toluene diisocyanate) (584-84-9); 2,6-diisocyanato-1-methyl-benzene (2,6 toluene diisocyanate) (91-08-7); and 1,3-diisocyanatomethyl-benzene (mixed isomers of toluene diisocyanate) (26471-62-5)	Prohibition	Since this chemical is found to be a carcinogen, the intent for prohibiting TDIs in all cosmetic products without restriction is supported.	See above recommendation # 4.

BATCH 2			
Epichlorohydrin (Oxirane, (chloromethyl)) (106-89-8)	Prohibition	Since this chemical is found to be a carcinogen, the intent for prohibiting Epichlorohydrin in all cosmetic products without restrictions is supported.	See above recommendation #4.
4,4'-Isopropylidenediphenol (Bisphenol A) (80-05-7)	Prohibition	Based on evidence to demonstrate that BPA has endocrine disruption potential, the intent for prohibiting Bisphenol A in all cosmetic products without restriction is supported.	See above recommendation #4.
Isoprene monomer (1,3-Butadiene, 2-methyl) (78-79-5)	Prohibition	Since this chemical is found to be a carcinogen, the intent for prohibiting Isoprene monomer (1,3-Butadiene, 2-methyl) (78-79-5) in all cosmetic products without restrictions is supported.	See above recommendation #4.
HC Blue No. 4 (158571-57-4)	Prohibition	The intent for prohibiting Epichlorohydrin with HC Blue No.4 in all cosmetic products without restriction is supported.	See above recommendation #4.
HC Blue No. 5 (68478-64-8, 158571-58-5)	Prohibition	The intent for prohibiting Epichlorohydrin and HC Blue No. 5 in all cosmetic products without restriction is supported.	See above recommendation #4.
Alcohols, C13-15 , reaction products with N-[3-(dimethoxymethylsilyl)-2-methylpropyl]-1,2-ethanediamine, glycidol and hydroxyterminated di-Me siloxanes (237753-63-8)	A person that proposes a significant new activity for this substance shall provide the Minister of the Environment, at least 90 days prior to the commencement of the proposed significant new activity, information as per Order 2007-87-10-01 published January 9, 2008, Amending the Domestic Substances List under the <i>Canadian Environmental Protection Act's New Substances Notification Regulations (Chemicals and Polymers)</i> .	Siloxanes assessed under the Chemicals Management Plan were high production volume chemicals and found to be persistent, bioaccumulative and inherently toxic. Therefore, siloxanes as well as other siloxanes listed in this table should be targeted for prohibition rather than an application of restriction such as the SNAC. The use of the Significant New Activity is inadequate as it does not necessarily promote a prohibition or reduction of this chemical from current uses in cosmetic products. Additional provisions should be made to require prohibition of current and future use of these chemicals in all cosmetic products.	Recommendation: We do not support the application of a SNAC on Alcohols, C13-15 , reaction products with N-[3-(dimethoxymethylsilyl)-2-methylpropyl]-1,2-ethanediamine, glycidol and hydroxyterminated di-Me siloxanes (237753-63-8). A complete prohibition should be applied. See above recommendation #4.
Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, hydroxy- and methoxy-	A person that proposes a significant new activity for this	Siloxanes assessed under the Chemicals Management Plan were high production volume chemicals	Recommendation: We do not support the application of a SNAC to Siloxanes and

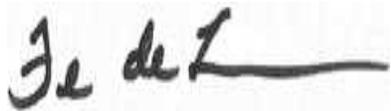
<p>terminated, polymers with polyethylene-polypropylene glycol bis(2-methyl-2-propen-1-yl) ether (921936-12-1)</p>	<p>substance shall provide the Minister of the Environment, at least 90 days prior to the commencement of the proposed significant new activity, information as per Significant New Activity Notice No. EAU-395, published January 12, 2008, under the <i>Canadian Environmental Protection Act's New Substances Notification Regulations (Chemicals and Polymers)</i>.</p>	<p>and found to be persistent, bioaccumulative and inherently toxic. Therefore, siloxanes as well as other siloxanes listed in this table should be targeted for prohibition rather than an application of restriction such as the SNAC.</p> <p>The use of the Significant New Activity is inadequate as it does not necessarily promote a prohibition or reduction of this chemical from current uses in cosmetic products.</p> <p>Additional provisions should be made to require prohibition of current and future use of these chemicals in all cosmetic products.</p>	<p>Silicones, 3-[(2-aminoethyl)amino]propyl Me, di-Me, hydroxy- and methoxy-terminated, polymers with polyethylene-polypropylene glycol bis(2-methyl-2-propen-1-yl) ether (921936-12-1). This will not contribute to an overall approach that will prohibit or reduce the presence of this substance in all cosmetic products nor will it reduce the exposure to the environment and humans. It permits current uses of this chemical in cosmetic products without additional regulatory requirements to industry. A complete prohibition should be applied.</p> <p>Also see recommendation #4.</p>
<p>Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, hydroxy-terminated, polymers with hydrogen terminated di-Me siloxanes and polyethylene glycol bis(2-methyl-2-propen-1-yl) ether (929218-99-5)</p>	<p>A person that proposes a significant new activity for this substance shall provide the Minister of the Environment, at least 90 days prior to the commencement of the proposed significant new activity, information as per Significant New Activity Notice No. EAU-396, published January 12, 2008, under the <i>Canadian Environmental Protection Act's New Substances Notification Regulations (Chemicals and Polymers)</i></p>	<p>Siloxanes assessed under the Chemicals Management Plan were high production volume chemicals and found to be persistent, bioaccumulative and inherently toxic. Therefore, siloxanes as well as other siloxanes listed in this table should be targeted for prohibition rather than an application of restriction such as the SNAC.</p> <p>The use of the Significant New Activity is inadequate as it does not necessarily promote a prohibition or reduction of this chemical from current uses in cosmetic products.</p> <p>Additional provisions should be made to require prohibition of current and future use of these chemicals in all cosmetic products.</p>	<p>Recommendation: We do not support a restrictions to apply SNAC to Siloxanes and Silicones, 3-[(2-aminoethyl)amino]propyl Me, hydroxy-terminated, polymers with hydrogen terminated di-Me siloxanes and polyethylene glycol bis(2-methyl-2-propen-1-yl) ether (929218-99-5). This will not contribute to an overall approach that will prohibit or reduce the presence of this substance in all cosmetic products nor will it reduce the exposure to the environment and humans. It permits current uses of this chemical in cosmetic products without additional regulatory requirements to industry. A complete prohibition should be applied.</p> <p>Also see recommendation #4.</p>
<p>Siloxanes and Silicones, 3-[(2-aminoethyl)amino]-2-methylpropyl Me, di-Me, reaction products with N,N,N-trimethyloxiranemethanaminium chloride (495403-02-6)</p>	<p>A person that proposes a significant new activity for this substance shall provide the Minister of the Environment, at least 90 days prior to the commencement of the proposed significant</p>	<p>Siloxanes assessed under the Chemicals Management Plan were high production volume chemicals and found to be persistent, bioaccumulative and inherently toxic. Therefore, siloxanes as well as other siloxanes listed in this table should be targeted for prohibition rather than an</p>	<p>Recommendation: We do not support a restrictions to apply SNAC to Siloxanes and Silicones, 3-[(2-aminoethyl)amino]-2-methylpropyl Me, di-Me, reaction products with N,N,N-trimethyloxiranemethanaminium chloride (495403-02-6).</p>

	<p>new activity, information as per Significant New Activity Notice No. EAU-135, published November 13, 2004, under the <i>Canadian Environmental Protection Act's New Substances Notification Regulations (Chemicals and Polymers)</i>.</p>	<p>application of restriction such as the SNAC.</p> <p>The use of the Significant New Activity is inadequate as it does not necessarily promote a prohibition or reduction of this chemical from current uses in cosmetic products.</p> <p>Additional provisions should be made to require prohibition of current and future use of these chemicals in all cosmetic products.</p>	<p>This will not contribute to an overall approach that will prohibit or reduce the presence of this substance in all cosmetic products nor will it reduce the exposure to the environment or humans. It permits current uses of this chemical in cosmetic products without additional regulatory requirements to industry.</p> <p>Also see recommendation #4.</p>
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If you have questions about the above recommendations, please do not hesitate to contact us. Our contact information is provided below.

Thank you for your consideration.

Yours truly,



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