



Health
Canada

Healthy Environments
and Consumer Safety
Branch

Santé
Canada

Direction générale,
Santé environnementale et
sécurité des consommateurs

Your file Votre référence
10-122300 - 962

Our file Notre référence

October 18, 2010

dpraznik@cctfa.ca

Dear Mr. Praznik,

Thank you for your letter dated September 10, 2010 in which you outline several substances of concern to a number of non-governmental organizations.

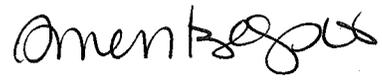
Health Canada monitors cosmetics for their safety and regularly reviews new scientific and regulatory information on cosmetic ingredients as it becomes available. Furthermore, many of these substances were identified for priority review under the Government of Canada's Chemicals Management Plan, which assesses potential effects on human and environmental health. In their assessment, Health Canada scientists take a weight of evidence approach. If there are concerns that an ingredient poses a risk as used in cosmetics, the Department will take action to mitigate any risks to consumers.

Appropriate risk management action on ingredients of concern to Health Canada depends on the nature of the risk, and ranges from restrictions (e.g. setting maximum ingredient limits; special instructions or precautions on the labelling) to complete prohibition of the substance, all of which are communicated to stakeholders through the Cosmetic Ingredient Hotlist at www.healthcanada.gc.ca/hotlist. The Hotlist is an administrative tool to help manufacturers satisfy the cosmetic safety provisions of section 16 of the *Food and Drugs Act*, which states that no person shall sell a cosmetic product that has in it any substance that may injure the health of the user when the cosmetic is used according to its customary method. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the *Food and Drugs Act*, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

For ease of reference, I have provided in the appendix Health Canada's position on the ingredients outlined in your letter, based on the current scientific knowledge of the ingredient and weight of evidence. If you are not already, I encourage you and your members to subscribe to the "Cosmetics @ Health Canada" listserve to receive updates on cosmetics, particularly updates to the Cosmetic Ingredient Hotlist.

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Sincerely,

A handwritten signature in black ink, appearing to read "Amentzelopoulos".

Athana Mentzelopoulos
Director General

Attachment: Appendix A

c.c.: kljubisic@cctfa.ca

October 2010 Health Canada Status on Cosmetic Ingredients of Interest

Below is the current state of knowledge on a dozen ingredient categories that have been the subject of interest in recent months. Please note that the information may change with new information. Any new decisions on the status of ingredients will be communicated through the Cosmetic Ingredient Hotlist at www.healthcanada.gc.ca/hotlist.

1. BHA and BHT

BHA (butylated hydroxyanisole) and BHT (butylated hydroxytoluene) are used as preservatives in many foods, cosmetic products and drugs. In cosmetics, these ingredients are found mainly in shampoos, deodorants, body lotions and make-up, usually at a concentration of 0.1% or less. BHA and BHT help maintain the quality and safety of products and extend shelf life.

BHA was fully evaluated under the Government of Canada's Chemicals Management Plan, and was found to not present a risk at current levels of exposure. In 2002, the U.S. Cosmetic Ingredient Review Expert Panel (with the support of the U.S. Food and Drug Administration) reviewed BHT in cosmetic products and found that BHT is safe as currently used in cosmetics.

2. Coal Tar Dyes

Coal tar dyes are colour ingredients that were originally made from chemicals extracted from coal tar. When the ingredients used to make the dyes were extracted, distillation process was not 100% effective, often leaving harmful impurities in the final product.

Although the coal tar dyes in use today are no longer made from coal tar, the name has stuck. Coal tar dyes are now made synthetically or derived from petrochemicals. These ingredients have a high level of quality and purity, as they undergo a refining process to remove any unacceptable impurities. Some coal tar dyes, like para-phenylenediamine (also known as PPD) and others used in oxidative hair dyes, still pose a health risk because they are known sensitizers, causing allergic reactions upon repeat exposure.

The Cosmetic Ingredient Hotlist lists the prohibitions, restrictions and requirements for coal tar dyes. Coal tar dyes are very different from actual "coal tar", which is not permitted in cosmetics. Most coal tar dyes are safe for use in cosmetics, however those coal tar dyes that have been found to be unsafe are prohibited. Many coal tar dyes are not permitted in the area of the eye.

Those used in permanent and semi-permanent hair dyes must have cautionary statements on the inner and outer labels to warn consumers that the ingredients may cause skin irritation in certain individuals, and that a patch test should be done before use.

The Government of Canada is currently reviewing many colourants under the Chemicals Management Plan. If any of these ingredients are found to be unsafe, Health Canada will add them to the Hotlist as a substance intended to be prohibited or restricted.

3. Diethanolamine (DEA) and other ethanolamines

DEA is not allowed in cosmetics in Canada. This is because DEA and similar compounds like diisopropanolamine (DIPA) can form harmful nitrosamines that may be linked to cancer. DEA and DIPA, along with any ingredients that can cause the formation of nitrosamines, are completely prohibited in cosmetics in Canada as noted in the Cosmetic Ingredient Hotlist.

Cocamide DEA, Cocamide DIPA and other fatty acid ethanolamines are permitted for use in cosmetics as they do not have the same characteristics as DEA on its own. However, the Hotlist prohibits their use in combination with nitrosamine-forming agents, in addition to other limitations.

Scientific reviews have concluded that other ethanolamines like triethanolamine (TEA) and monoethanolamine (MEA) are safe for use in cosmetics designed for brief use followed by thorough rinsing from the surface of the skin. In products intended for prolonged contact with the skin, the concentration of ethanolamines should not exceed 5%.

4. Dibutyl Phthalate and other phthalates

Phthalates are used in cosmetics as plasticizers (to keep nail polish supple, for example), perfume solvents, fixatives and antifoam ingredients. Many scientific reviews in Canada, the U.S. and the E.U. have shown that the phthalates most commonly used in cosmetics (DBP—dibutyl phthalate and to a lesser extent, DEP—diethyl phthalate) are safe at the levels at which they are currently used in cosmetics. Available studies looked at the typical routes of exposure through normal use of cosmetics (skin absorption and inhalation).

- In 2005, the United States Cosmetic Ingredient Review Expert Panel reaffirmed its original safety assessment, stating that DBP and DEP are “safe as used” in cosmetics.
- In 2007, the Scientific Committee on Consumer Products (the European Union’s top scientific body) evaluated the human health risks of DEP in cosmetics and found it safe at current levels of use.
- The European Chemicals Bureau completed an in-depth risk assessment on DEP in 2004. In addition to a thorough evaluation of toxicity, the Bureau assessed exposure to DBP from cosmetics, focussing on nail polish in particular. The risk assessment found that there was no need for further risk reduction measures for consumers.
- Health Canada has conducted risk assessments on DBP, which it deemed “not CEPA toxic” on the first Priority Substances List. In addition, DBP will be re-assessed within the medium priorities of Canada’s Chemical Management plan (CMP).

- In 2004, Koo et. al. estimated exposure (inhalation and dermal) to phthalates in cosmetics and concluded that estimated exposure is relatively small.
- Health Canada added diethylhexyl phthalate (DEHP) to the Cosmetic Ingredient Hotlist, prohibiting its use in cosmetics in Canada. DEHP was assessed by the Government of Canada under the Chemicals Management Plan, and was deemed to be “toxic” under the *Canadian Environmental Protection Act*. While the phthalate DEHP has not been reported in any cosmetics registered with Health Canada, it is used in other countries as a cosmetic ingredient.

5. Formaldehyde and Formaldehyde-releasing preservatives

Formaldehyde is used in small amounts in hair and skin cosmetics as a preservative to maintain the integrity of the product and prevent growth of microorganisms. Formaldehyde-releasing ingredients slowly release very small amounts of formaldehyde to act as a preservative for the product. Formaldehyde use has declined in recent years.

Formaldehyde is produced commercially but also occurs naturally in fruits and some foods. As well, it is formed endogenously in humans as a normal result of metabolism. At higher doses, however, formaldehyde is anticipated to be a human carcinogen when inhaled over long periods of time.

The Cosmetic Ingredient Hotlist only allows formaldehyde to be used in small concentrations. Cosmetics containing formaldehyde must carry cautionary labels and directions for safe use. Because formaldehyde may cause sensitivity in some individuals, the amount allowed in cosmetics cannot be more than 0.2% in skin and hair products or 0.1% in oral products. These are the lowest possible amounts that still have an effective anti-microbial effect. Formaldehyde is not allowed in aerosol cosmetics.

Based on its restricted use in cosmetics at the recommended concentrations, this ingredient does not pose a health risk as used in cosmetics. Canadian restrictions are similar to those in the European Union and the United States.

6. Fragrance/Parfum Ingredients

Health Canada reviews fragrance ingredients like all other cosmetic ingredients. If a fragrance ingredient is found to be unsafe for use in cosmetics, the ingredient is prohibited or restricted and added to the Cosmetic Ingredient Hotlist.

Canada uses the international naming convention for cosmetics, called "International Nomenclature for Cosmetic Ingredients" (INCI). Under this naming convention, components of a fragrance can be listed as individual ingredients or can be listed under the term "parfum" (in the E.U. and Canada) or "fragrance" (in the U.S.).

The fragrance industry is by and large self-regulating. Most global fragrance suppliers are members of the International Fragrance Association (IFRA). IFRA develops and implements a Code of Practice and safety standards used worldwide to protect the consumer and the environment.

IFRA's standards for use and restrictions on fragrance ingredients are based on safety assessments by the Research Institute for Fragrance Materials (RIFM). RIFM is an independent non-profit institute that evaluates safety data on fragrance ingredients. RIFM's Panel of Experts is made up of toxicologists, pharmacologists and dermatologists who have no commercial ties to the fragrance industry. RIFM publishes its findings and conclusions in a peer-reviewed and accredited scientific journal.

7. Parabens

Parabens are used as preservatives in many cosmetic and personal care products, including make-up, moisturizers, hair care products and shaving products. They are generally used at concentrations of 0.3% or less.

All commercially used parabens are synthetically produced, although some parabens also occur naturally as preservatives in certain fruits (for example, blueberries and carrots).

Parabens have been found to weakly mimic estrogens in animal studies. While this raises a concern because of the link between the hormone estrogen and breast cancer, there are many questions and conflicting scientific studies about the effects of low level estrogen in humans. For example, a 2004 British study that reported finding parabens in breast tumours has proved invalid and the U.S. Cosmetic Ingredient Review Expert Panel concluded that parabens are "safe as used" in cosmetics.

Currently, there is no evidence to suggest a causal link between parabens and breast cancer. Health Canada will continue to monitor and review any new scientific data on parabens.

Please see the United States Food and Drug Administration (U.S. FDA) statement on parabens, with which Health Canada agrees: <http://www.fda.gov/cosmetics/productandingredientsafety/selectedcosmeticingredients/ucm128042.htm>

8. PEG compounds

PEG, or poly(ethylene glycol) compounds are used to make non-ionic surfactants (surfactants allow for easier spreading of cosmetics, among other purposes). There are hundreds of different types of PEG compounds used in cosmetics. PEGs have low oral and dermal toxicity. The U.S. Cosmetic Ingredient Review Expert Panel found that cosmetics containing PEGs should not be used on compromised skin, but there was no evidence of problems with healthy, intact skin.

Currently, there are no restrictions or prohibitions on cosmetic PEG compounds in Canada, the European Union or the United States.

Small amounts of 1,4 dioxane, a by-product of ethoxylation, may be found in PEG ingredients. Exposure to high levels of 1,4 dioxane (not be confused with the chemical "dioxin") is linked to kidney and liver damage, and to cancer in some laboratory animals. The potential presence of dioxane in this material is well known, and can be controlled through purification steps. **Dioxane exposure via**

cosmetic products was evaluated in Canada's Chemical Management Plan (CMP) and found to be safe. Health Canada advises industry to follow the recommendations set out by the U.S. FDA. If a product was found to have unacceptable levels of this impurity, Health Canada would take action to remove the product from sale.

9. Petrolatum

Petrolatum is used widely in cosmetics as a moisturizer as well as in over-the-counter drugs as a skin protectant. Its safety has been thoroughly reviewed by the U.S. FDA and Health Canada for these purposes. Food, drug and cosmetic petrolatum products are made from highly refined petrolatum at pharmaceutical or cosmetic grade. In the E.U., petrolatum is acceptable in cosmetics if the full refining history is known.

In Canada, if an ingredient is susceptible to impurities, the manufacturer must make sure the ingredients and products are of good quality and safe when used as directed. Manufacturers must be sure that they follow good manufacturing practices and use acceptable quality materials (e.g. cosmetic or pharmaceutical grade). At this time, there have been no reports of unacceptable impurities (like polycyclic aromatic hydrocarbons) in petrolatum found in products regulated by Health Canada.

10. Siloxanes

Cyclomethicone and siloxanes are used in cosmetics to soften, smooth and moisten. Siloxanes are found in the vast majority of haircare and skin conditioning products on the market. Ingredient labelling for cosmetics is mandatory in Canada. You can identify siloxanes in cosmetics by looking for the term "siloxane" or "cyclomethicone" in the ingredient list.

Siloxanes were evaluated for risks to human and environmental health under the Chemicals Management Plan. A careful analysis of exposure through cosmetic products showed that the substances D4, D5 and D6 do not present a risk to human health.

11. Sodium Lauryl Sulfate (SLS)

Sodium Lauryl Sulfate (SLS) is most often used as a cleansing and foaming agent in rinse-off products like shampoos, bath products, shaving creams and skin cleansers. It is also sometimes found in other cosmetics like creams and lotions.

At high levels, SLS can cause skin or eye irritation in some individuals, which is why it is important to follow label instructions when using a cosmetic product. In skin absorption studies, it was found that there was little or no skin penetration with high levels of SLS. However, many baby products do not contain SLS in order to create a milder formula with less potential for skin irritation.

The U.S. Cosmetic Ingredient Review Expert Panel reviewed the safety of SLS in 1983 and again in 2004. They found that SLS is safe in rinse-off products like soaps and shampoos. In products intended for prolonged contact with skin, concentrations should not exceed 1 percent. This ingredient is considered

acceptable in cosmetics by the E.U. and the U.S. FDA. At this time, there is no evidence to show that SLS causes an undue safety risk to consumers when used as directed in cosmetics.

12. Triclosan

Triclosan is used in cosmetics as a preservative to prevent or slow down microbial growth and protect products from spoilage. This ingredient is also used in over-the-counter drugs and other consumer products.

Currently, triclosan is allowed in cosmetics at a concentration of up to 0.03% in mouthwashes and 0.3% in other cosmetic products like soaps (see the Cosmetic Ingredient Hotlist for more about triclosan limits).

These cosmetic limits are consistent with those of the European Union, which allows triclosan in cosmetic products at 0.3% as a preservative.

The Government of Canada identified triclosan as a priority for assessment as part of its Chemicals Management Plan. Scientists at both Health Canada and Environment Canada are currently studying risks to human health and the environment. They are also working with their counterparts in the United States and monitoring new data and scientific reports on the effects of triclosan in other countries. Should unacceptable risks be identified, the Government of Canada will act quickly to protect the health and environment of Canadians.