Health Canada Santé Canada

Canada

Consumer Product Safety

Draft Guidance on Heavy Metal Impurities in Cosmetics

The online consultation is now closed. Comments and suggestions received during the public consultation period are being considered in the finalization of this document. The final report will be made available as soon as possible.

Contents

1.0 Purpose/Scope

Many heavy metals are prohibited as ingredients in cosmetic products sold in Canada. Yet impurities exist due to the persistent nature of these substances and the fact that they are found in the natural environment. The purpose of this guidance is to determine and communicate appropriate limits of these impurities in cosmetic products. The focus is on the heavy metals with known significant toxicological properties: lead, arsenic, cadmium, mercury and antimony.

2.0 Background

Heavy metals are found naturally in the environment in rocks, soil and water, and therefore exist in the manufacture of pigments and other raw materials in all industries including the cosmetics industry. Some of these metals have been used as cosmetic ingredients in the past. Examples include the preservative thimerosal (mercury), the progressive hair dye lead acetate and a number of tattoo pigments such as red cinnabar (mercuric sulfide).

The Government of Canada has implemented numerous measures to reduce the amount of heavy metals to which Canadians are exposed, including prohibiting their use in cosmetics. Lead, arsenic, cadmium, mercury, antimony and chromium are heavy metal ingredients prohibited in cosmetics sold in Canada. Accordingly, these elements, or compounds containing these elements, cannot be intentionally added to cosmetic products, and are listed as prohibited ingredients on the Cosmetic Ingredient Hotlist.

As the issue of heavy metals as deliberate cosmetic ingredients has been addressed, attention turns to the presence of these substances as impurities. The metals of primary toxicological concern in cosmetics are lead, arsenic, cadmium, mercury and antimony. The toxicity of these substances is outlined below, as well as established impurity limits for certain types of products.

2.1 Exposure

Heavy metals are naturally occurring, are present in the environment and can make their way in trace quantities into raw materials. These substances end up in the products we consume and use every day. Dermal exposure is expected to be the most significant route for cosmetic products

since the majority of cosmetics are applied to the skin. Dermal absorption of heavy metals is fairly minimal, with absorption of individual elements influenced by a number of factors including physical-chemical properties of the mixtures (1). Oral exposure can occur for cosmetics used in and around the mouth, as well as from hand-to-mouth contact after exposure to cosmetics containing heavy metal impurities. Inhalation exposure is typically considered to be negligible.

2.2 Heavy Metals

The toxicological properties of lead, arsenic, cadmium, mercury and antimony are described below. The impurity limits listed under each metal are for discussion purposes only. These limits encompass a variety of products with exposure scenarios that may differ significantly from cosmetics and it would not necessarily be appropriate for cosmetics to have a similar heavy metal impurity limit. Acceptable impurity limits for cosmetic products, as determined by Health Canada, are listed in Section 4.0 of this document.

2.2.1 *Lead*

Lead exerts adverse effects on numerous organs and systems including the central nervous system (CNS), the kidneys and on the hematopoietic (blood forming) system. Exposure to lead is typically greater in children, who are also more susceptible to the effects of lead than adults. Children are particularly at risk for the subtle adverse effects of chronic low-dose lead exposure, as are pregnant women/fetuses. Children absorb about 50% of ingested lead (6). The identification of causal relationships between exposure and effects is complicated by the delay between the time of lead exposure and the onset of effects (2, 8). Dermal absorption of inorganic lead has been demonstrated in animals and human subjects, however, few studies have provided quantitative estimates of dermal absorption and the contribution of the dermal intake to lead body burden (4). Absorption of lead through the skin has only been measured accurately for organic lead compounds (8). Exposure to lead from cosmetics previously occurred from use of progressive hair dye preparations containing lead acetate (8), however, lead acetate is now prohibited for such use in Canada.

The Drinking Water Guidelines in Canada limit the lead content to a Maximum Acceptable Concentration (MAC) of 0.010 milligrams per litre (0.010 ppm) of water (10). Acceptable oral intake of lead impurities include 0.1 ppm (US FDA for candy) to 10 ppm (USP for nutritional supplements). The World Health Organization (WHO) has established 25 micrograms of lead per kilogram of body weight per week as a provisional tolerable weekly intake (PTWI) for children. Health Canada's Natural Health Products Directorate (NHPD) limits lead in products applied to the skin to 10 ppm (NHPD Compendium of Monographs).

2.2.2 *Arsenic*

Arsenic exerts adverse effects on the skin; arsenic has a pronounced affinity for skin and keratinizing structures including the hair and nails. Therefore, symptoms of acute overexposure include a variety of skin eruptions, alopecia and characteristic striation of the nails (2). Arsenic does not act as a sensitizer, due to poor skin penetrating ability of its naturally occurring compounds (2). The health effects of arsenic in humans vary depending on the compound and form. Metallic arsenic is not absorbed by the gastrointestinal tract and does not have any known adverse health effects (9). Carcinogenicity has been observed only in its inorganic form (2). Inorganic arsenic compounds are more acutely toxic than environmentally occurring organic arsenic (eg. dimethylarsinate). Dermal uptake is expected to be very limited. One study (Environmental Assessment and Risk Analysis Element, White Paper Summary, US FDA, January, 2003) predicted that dermal exposure to arsenic may contribute less than 1% of the exposure from ingestion. Children could ingest arsenic-containing cosmetics from hand-to-mouth contact (e.g. by rubbing their hands over the mouth and/or eating after rubbing the face).

The maximum acceptable concentration (MAC) for arsenic in drinking water is 0.010 mg/L (10 µg/L = 10 ppb) in Canada (9) . Acceptable limits of oral ingestion of arsenic impurities include

0.1 ppm in foods (Health Canada) to 3 ppm in nutritional supplements (USP). The US FDA limit for arsenic in certain colourants is <3 ppm (7). The US EPA has established a reference dose of 0.3 ug/kg bw/day for arsenic. The WHO provisional tolerable daily intake (PTDI) for inorganic arsenic is 2 ug/kg bw/day.

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2.2.3 *Cadmium*

Cadmium is classified as a human carcinogen by the National Institute for Occupational Safety and Health (NIOSH) (2). Absorption of cadmium through the skin is low (0.5%) and would be of concern only in situations where concentrated solutions would be in contact with the skin for several hours or longer. Cadmium binds to epidermal keratin when applied topically, thus explaining the limited dermal absorption observed *in vitro* (2). However, significant dermal exposure, as could occur in an occupational setting, can cause irritant dermatitis (2).

The Canadian Drinking Water Guideline maximum acceptable concentration (MAC) for cadmium is 0.005 mg/L (0.5 ppb) (12). Acceptable oral limits of cadmium include 0.09 ug/kg bw/day to 3 ppm (USP for nutritional supplements). The WHO (17) has established a Provisional Tolerable Daily intake for cadmium of 1 ug/kg bw/day.

2.2.4 *Mercury*

The literature on the health effects of mercury is extensive. Most of the literature focusses on effects following inhalation exposure to metallic mercury vapours and oral exposure to inorganic and organic mercury compounds. There is limited information on adverse effects following dermal exposure to ointments and creams that contain inorganic mercury compounds.

Various forms of mercury are toxic. The form of mercury plays a role in how much is absorbed via dermal or oral routes. Organic (methyl) mercury is of greater concern than inorganic mercury, however, all forms of mercury are absorbed through the skin and mucosa (2) and dermal exposure can result in systemic toxicity. For the general population, the major route of mercury exposure is dietary intake (2). Mercury compounds may cause allergic reactions, skin irritation, or adverse effects on the nervous system (3). Clinical symptoms of overexposure to mercury include tremors, weakness, memory loss, dermatitis and impaired kidney function (8), with the form of mercury typically determining the specific symptoms.

Health Canada has established a limit of 0.5 ppm mercury in most commercial fish (11). WHO has established a provisional tolerable daily intake of 2 ug/kg bw/day for total mercury and a provisional tolerable weekly intake of 0.0016 microgram per kilogram bw for methylmercury (17). A limit of 3 ppm has been established for nutritional supplements (USP nutritional supplements). The US FDA limits mercury impurities in some colourants to <1 ppm (7). Thimerosal, a mercury salt, is acceptable for use as a preservative in eye cosmetics in the US, with a limit of 65 ppm mercury.

2.2.5 *Antimony*

Overexposure to antimony (Sb) and its compounds can adversely affect the skin, lungs, cardiovascular system and liver. The more significant antimony compound is sulfides and, to a lesser extent, oxides of Sb(III), and combinations with lead, copper, and silver (13, 14). Because antimony is found naturally in the environment, the general population is exposed to low levels, primarily in food, drinking water, and air (most individuals consume about 5 micrograms of antimony per day). Dermal absorption of antimony has not been well studied. The WHO provisional tolerable daily intake for antimony is 6 ug/kg bw/day (17).

2.2.6 *Other Metals*

Other metals (e.g., selenium, barium and chromium) may be present as impurities in cosmetic products, however the toxicological properties and corresponding risk associated with these substances are considered less significant than for lead, arsenic, cadmium, mercury and antimony. Accordingly, impurity limits in cosmetics have not been developed for these metals.

2.3 *Considerations and approach to impurity limits for cosmetics*

Acceptable limits for heavy metals vary according to the subpopulation of interest (e.g. children are more susceptible to heavy metal toxicity than adults; have greater exposure potential due to hand-to-mouth activity); the amount of product used, and the site of application (e.g. arms vs. lips). Assessment of dermal absorption by a single component in a cosmetic product is complex (5) and depends on factors such as the concentration in the product, the amount of product applied, the length of time left on the skin and the presence of emollients and/or penetration enhancers in the cosmetic product (5). Given this complexity, and the lack of well-conducted dermal absorption studies incorporating these factors, determination of heavy metal limits in cosmetics based on human health risk alone is a challenge.

There are currently no international standards for impurities in cosmetics. Limits have been established in Germany (15). Rather than taking a risk-based approach, the German limits are based on levels that could be technically avoided. Thus, heavy metal impurities were limited to anything above normal background levels.

The German Federal Government conducted tests to determine background levels of heavy metal contents in toothpastes and other cosmetic products (note that in Canada, most toothpastes are classified as natural health products). Based on their studies, it was determined that heavy metal levels in cosmetic products above the values listed below are considered technically avoidable (15):

Lead:
20 ppm
Arsenic:
5 ppm
Cadmium:
5 ppm
Mercury:
1 ppm
Antimony:
10 ppm

In addition, following a survey of its member companies, the German Industrial Association for Personal Care and Detergents Inc. confirmed that heavy metal contents in toothpastes are at least a decimal power lower than for other cosmetic products (15). Therefore, the Commission for Cosmetic Products at the Federal Ministry of Health in Germany concluded that the following values are the maximum acceptable concentration for toothpastes:

In Germany, a program is in progress to obtain updated values for traces of heavy metals in cosmetics (16).

Lead:
1 ppm
Arsenic:
0.5 ppm
Cadmium:
0.1 ppm
Mercury:
0.2 ppm
Antimony:
0.5 ppm

Health Canada has taken a similar approach in the establishment of heavy metal impurity limits, as the Department has always maintained that impurities in cosmetics should be reduced to the extent that is technically feasible. A review and analysis of the results of heavy metal testing conducted in the Health Canada Product Safety Laboratory on a number of cosmetics sold in Canada lead to the determination of limits in Section 4.0 of this document. Furthermore, comparison of conservative estimates of exposure to Canadians from use of cosmetics and the established tolerable intakes, demonstrated that these levels provide a high level of protection to susceptible subpopulations of consumers (e.g. children).

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3.0 Definitions

GMP - Good Manufacturing Practices

Heavy Metal - any metallic chemical element that has a relatively high density. For the purpose of this guidance, heavy metals will refer to lead, arsenic, cadmium, antimony and mercury and their compounds.

HHE - health hazard evaluation

manufacturer - The *Cosmetic Regulations* define "manufacturer" as a person, a partnership or an unincorporated association that sells, or manufactures and sells, a cosmetic under its own name or under a trade-mark, design, trade name or other name or mark owned or controlled by it.

NHPD - Natural Health Products Directorate

NIOSH - National Institute for Occupational Safety and Health

organic - belonging to the class of chemical compounds having a carbon basis

ppb - parts per billion (1 ppb = 1 ug/kg = 1 ug/liter)

ppm - parts per million (1 ppm = 1 ug/g = 1 mg/kg = 1 mg/liter)

PTDI - provisional tolerable daily intake (PTDI = PTWI ÷ 7)

PTWI - provisional tolerable weekly intake (PTWI = PTDI × 7)

US EPA - United States Environmental Protection Agency

US FDA - United States Food and Drug Administration

USP - United States Pharmacopoeia

WHO - World Health Organization

4.0 Policy Statement

It is acknowledged that heavy metal impurities in cosmetic products are unavoidable due to the ubiquitous nature of these elements, but should be removed wherever technically feasible. Heavy metal concentrations in cosmetic products are seen to be technically avoidable when they exceed the following limits:

Lead: 10 ppm Arsenic: 3 ppm Cadmium: 3 ppm Mercury: 3 ppm Antimony: 5 ppm	These levels are based on background levels found in cosmetic products sampled in Canada and are in line with acceptable levels of impurities in other jurisdictions. In addition, comparison of conservative estimates of exposure to Canadians from use of cosmetics and the established tolerable intakes for these metals demonstrated that these limits provide a high level of protection to susceptible subpopulations of consumers (e.g. children). It is important to note that occurrences of heavy metals above these limits will be evaluated on a case-by-case basis. Products with values above these limits will undergo a Health Hazard Evaluation to

determine the level of risk posed by the product, which will then inform the appropriate enforcement action.

5.0 Responsibilities And Requirements

It is the manufacturer's responsibility to ensure that the finished product contains as few heavy metal impurities as possible so that it does not exceed the limits mentioned above. By law, manufacturers must ensure that products are safe and do not pose a risk to consumers. Health Canada may request information on heavy metal test results for a cosmetic product if a risk is suspected . It is therefore in the manufacturer's best interest to have the information readily available. Health Canada will take action as deemed appropriate for products that contain heavy metals beyond the limits mentioned above. Manufacturers must ensure that their products and the ingredients used in the manufacture of their products are of high quality.

6.0 Effective Date

Draft January 2009

7.0 References

Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section.

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