



THE MARK OF ENVIRONMENTAL RESPONSIBILITY

GS-50

BACKGROUND INFORMATION ON THE PROPOSED GREEN SEAL™ STANDARD FOR PERSONAL CARE AND COSMETIC PRODUCTS

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INTRODUCTION

Green Seal is a non-profit organization whose mission is to use science-based programs to empower consumers, purchasers, and companies to create a more sustainable world. The development of this sustainability standard for personal care and cosmetic products is part of Green Seal's sustainability standards and certification program guided by International Organization for Standardization (ISO) 14020/14024. The Proposed Standard for personal care and cosmetic products takes into account the life cycle of these products and includes multiple attributes to address the life cycle considerations (e.g., raw materials, manufacturing, packaging, use, and end-of-life). This background document provides information about what is included in the Proposed Standard, but the actual content of the Proposed Standard is not included (refer to the GS-50 Proposed Green Seal Standard for Personal Care and Cosmetic Products). The standard is not final. The standard is being proposed to get input from stakeholders to facilitate the development of a draft final standard (and additional stakeholder review). Later, when the standard has completed the stakeholder review and development steps, it will be issued as a final standard and will be available for Green Seal certification.

Green Seal sets sustainability standards, such as this one in development, to reduce, to the extent technologically and economically feasible, the environmental, health, and social impacts throughout the life cycle of products, services, and companies. With sufficient commitment by manufacturers and support from purchasers/consumers, the standard identifies the top 15-20% of the category (current and emerging). Green Seal standards may be used for product development, conformity assessment (e.g., Green Seal certification), purchaser specifications, and public education.

STANDARD SCOPE

The scope of the Proposed Standard includes personal care and cosmetic products that are applied to and intentionally left on the surface of the body or hair. These products typically are used to enhance the appearance, cleanliness, health/well-being, and feel of the skin and hair and provide other personal care and hygiene functions. The product categories covered in the Proposed Standard include skin care, sun care, hair styling, cosmetics, and hygiene products, which typically include lotions, moisturizers, oils, powders, creams, sun block, sun screen, insect repellent, hair spray, hair styling products, makeup, nail polish, bronzers, antiperspirant, and deodorant used for adults, babies, children, and pets. This would include consumer retail products as well as institutional and professional products.

Products applied to the surface of the body or hair that are intended to be rinsed off immediately after use are excluded from the Proposed Standard since those are covered in other Green Seal standards (GS-41, GS-44). Products that are intended to impart a lasting color or texture change to hair, such as hair dyes, hair relaxers, and permanent curl solutions are not included in the Proposed Standard. Products that are intended to be ingested or used in the mouth, like oral care products, are not included in the Proposed Standard. Products injected below the surface of the skin, like tattoo inks, are not included in the Proposed Standard.

The United States Food and Drug Administration (FDA) regulates the products covered in the Proposed Standard. An exception is insect repellent active ingredients, which are regulated by the United States Environmental Protection Agency (EPA). FDA classifies the products covered in the scope of this standards as cosmetics because they are intended for beautifying, promoting attractiveness, or altering the appearance of the body/hair. Further, these products may also be classified as drugs if they intend to cure, treat, mitigate or prevent disease or that affect the structure or function of the human body, and are further regulated by the FDA (including sunscreen and antiperspirant). The Proposed Standard intends to neither modify nor supersede any applicable laws and regulations. Compliance is required for all applicable laws and regulations for the manufacturing and marketing of products. Generally, the requirements included in the Proposed Standard cover aspects above and beyond compliance issues.

Moisturizers and Skin Care Products

Moisturizing products typically function by slowing water loss from skin by either drawing in moisture from the environment and keeping it near the skin or by forming a barrier on the surface of the skin. These products are typically emulsions with a pH around 5-7. They are comprised of water, emollients, humectants, emulsifiers, viscosity agents, preservatives, fragrance, and pH regulators. Many of these and other skin care products also contain unique active ingredients that deliver an intended product function (e.g., anti-wrinkle, acne treatment, sunscreen). The viscosity of the emulsion varies, resulting in lotions, creams, and ointments. The products are commonly made in batch mixing/heating processes up to 180°F.

Hair Styling and Hair Spray Products

Hair styling and hair spray products function by either fixing hair into a position or to facilitate styling of the hair. This is typically done with polymeric or resinous compositions that are sticky and film-forming. Hair styling products are typically solutions, ointments, and gels with an acidic pH. These products are commonly made in batch mixing processing.

Makeup

Makeup is comprised of products for the eyes, face, eye lashes, nails, lips, and body. These products are used to deliver color to the body. As a result, there is a high level of colorant components in these products (e.g. iron oxides, mica, titanium dioxide). Makeup products typically contain colorants, waxes/oils, humectants, emulsifiers, and preservatives. Sometimes makeup contains sunscreen components or other active ingredients (like skin care products). Lip products may also have flavoring agents, including artificial sweeteners. Sunless tanners are typically comprised of dihydroxyacetone as the active ingredient to darken the skin. This is achieved by reacting with amino acids in the skin's surface. Nail products are film-forming products that are high in volatile content due to their function of being a liquid that dries hard. The volatiles are typically ethyl acetate, butyl acetate, and isopropyl alcohol. Nail product also can contain carcinogens like toluene and formaldehyde. Makeup products typically come in creams, powders, liquids, gels, and solids. Makeup products may require more heat during production to melt the fat components used in them (around 190°F) or more shear (both of which require more energy), followed by a homogenization step.

Antiperspirant and Deodorant

Deodorant products are used to reduce the body odor caused by perspiration. Antiperspirant products usually include deodorant functionality, but also reduce the production of sweat by the body. These products typically are comprised of moisturizers, emulsifiers, solvents, preservatives, fragrances, and active/antimicrobial materials. They usually come in the form of creams, roll-on solutions, solids, and sprays. The products are commonly made in batch mixing/heating processes up to 185°F followed by a homogenization step. The common active ingredients are aluminum-containing compounds (a list of approved active ingredients and usage levels is provided by the FDA¹). For example, aluminum chlorohydrate is typically in products at 20-25%.

Insect Repellent

Insect repellent is applied to the skin, hair, and clothing and is intended to help reduce exposure to insects and corresponding bites, namely from mosquitoes and ticks. The active ingredients are regulated by the EPA, through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), to ensure that they are effective. According to EPA, "all pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment," which includes insect repellent². When an active ingredient is approved by EPA, it is "registered." There are exceptions allowed for "minimum risk pesticides" that meet specific

1 Federal Register. 2003. 68 34273-34293 (June 9); 21 CFR 350.605.

2 EPA. 1993. Flower and Vegetable Oils R.E.D. Facts. Accessed 6-3-10.
<http://www.epa.gov/oppsrrd1/REDs/factsheets/4097fact.pdf>

requirements for active ingredients³. Examples of commonly used active ingredients are DEET (N,N-diethyl-m-toluamide) used typically at 4-100%⁴, picaridin (2-(2-hydroxyethyl)-1-piperidinecarboxylic acid 1-methylpropyl ester, KBR 3023 or Bayrepel) used typically at 5-10%⁵, oil of citronella (considered a minimum risk pesticide), and p-menthan 3,8-diol (PMD, or from oil of lemon eucalyptus) used typically around 25%. These active ingredients may be included in product preparations with other ingredients, sometimes including sunscreen ingredients, in sprays, lotions, and sticks.

Sunscreen

Sunscreens are topical products intended to reduce the amount of ultraviolet radiation that is absorbed by the skin. These sun products typically include several active ingredients that act against ultraviolet A rays/radiation (UVA) and UVB rays. UVA are the so-called “aging rays” which, due to their longer wavelength (320 nm - 400 nm), permeate more deeply into the skin. UVB rays are the “burning rays” that cause redness and sunburn; these rays are of higher-energy due to their shorter wavelength (290 nm - 320 nm), and affect only the surface of the skin. Sunscreen products include active ingredients that are either inorganic compounds that reflect UV radiation or organic chemicals that absorb the radiation and filter it before it can penetrate the skin. The FDA has approved active agents for sunscreen formulas (see Appendix A)⁶. These products are typically suspensions with a neutral pH. The viscosity of the emulsion varies, resulting in lotions, creams, and sprays. The products are commonly made in batch mixing/heating processes up to 180°F.

LIFE CYCLE OVERVIEW

The life cycle of the range of products included in the scope of the Proposed Standard includes the raw materials used in the product formulas and packaging, manufacturing of the product and package, distribution of the raw materials and finished product, product use, and the end-of-life of the product and package. The leading concerns for personal care and cosmetic products are product formulas with toxic and hazardous materials (due to the nature that these products are directly applied to the body and left on) and the amount and type of packaging used.

PRODUCT PERFORMANCE REQUIREMENTS

Product effectiveness is an important component of the marketability of the product and is an essential requirement for ecolabel programs, such as Green Seal's. However, for most of the products in the Proposed Standard there are no standardized methods, such as ASTM or ISO methods used to evaluate the performance effectiveness of the products. As a result, to demonstrate effectiveness (based on the primary product function/s and condition of the body or hair after use) products shall perform as good as or better than a competitive product, using a controlled and repeatable procedure. All results, a summary of conclusions, and a description of how panelists were chosen, if applicable, shall be submitted.

A recent study conducted by Consumer Reports showed that efficacy claims about cosmetic products may be overstated⁷. While the FDA may not require premarket approval for efficacy claims for cosmetic products, there must be substantiation available to prove such claims are factual and not misleading.

3 EPA. 2009. Minimum Risk Pesticides. Accessed 6-3-10. http://www.epa.gov/opbppd1/biopesticides/regtools/25b_list.htm

4 EPA. 1998. DEET R.E.D Facts. Accessed 6-3-10. <http://www.epa.gov/oppsrrd1/REDs/factsheets/0002fact.pdf>

5 EPA. 2005. Picaridin New Pesticide Fact Sheet. Accessed 6-3-10. <http://www.epa.gov/opprd001/factsheets/picaridin.pdf>

6 CFR. 2009. Sunscreen Products for Over-the-Counter Human Use. 21 CFR 352

7 Consumers Reports. 2010. Anti-wrinkle face serums: tests show inflated claims and limited results. Accessed 5-3-10. <http://www.consumerreports.org/health/healthy-living/beauty-personal-care/skincare/wrinkle-serum-5-10/overview/wrinkle-serum-ov.htm>

This will be clarified in the Proposed Standard by requiring all products to have efficacy testing to demonstrate efficacy claims.

Antiperspirant is classified as a drug by the FDA. There is an over-the-counter (OTC) Final Monograph on Antiperspirant Products that addresses effectiveness of the products, among other issues such as labeling and actives allowed¹. As a result, a product labeled as an antiperspirant must demonstrate its performance using the Subpart D - Guidelines for Effectiveness Testing in the Final Monograph (since the Proposed Standard requires compliance to laws and regulations).

Insect repellent performance is required and evaluated through the registration process of the EPA, under the authority of FIFRA. As a result, registration will be required for insect repellents as a demonstration of performance. There are some insect repellents that are exempt from EPA registration, and thus could be on the market without an effective performance evaluation. For those products, including the “minimum risk pesticides”, they must demonstrate that they meet the performance requirements outlined by the EPA for insect repellents included in the OPPTS 810.3700 Insect Repellents for Human Skin and Outdoor Premises⁸.

Sunscreen products are required to have a sun protection factor (SPF) rating (regulated by FDA). However, the SPF rating provides only a portion of the efficacy expected by consumers by providing only UVB protection but not protection against other UV rays. It has been estimated that only 70% of products on the market include broad spectrum UV protection (UVA and UVB)⁹. According to the Environmental Working Group UVA radiation is the greater concern, than UVB, since it “hastens the progression of skin cancer, suppresses the immune system, and ages the skin over time⁹.” The FDA has proposed a means to address this gap in 2007¹⁰, but this has yet to be adopted. Further, the proposed regulation does not include a minimum efficacy for UVA protection. The European Commission has published a recommendation that is being taken up in the marketplace to address this gap¹¹. It requires that the minimum UVA protection be 1/3 of the labeled SPF. It also includes a minimum critical wavelength of 370 nm. This aims to ensure broad protection. The European Commission recommendation regarding UVA (1/3 of SPF) and a critical wavelength (at least 370 nm) will be adopted in the Proposed Standard. As a result of the 1/3 SPF requirement, there will be a minimum SPF requirement of 15 that aligns with Skin Cancer Foundation recommendation of using SPF's of at least 15¹². Another performance consideration is that sunscreen products begin to lose their efficacy after UV radiation exposure. As a result, these products need to be reapplied for continued effectiveness¹³ and in some cases need to contain stabilizers to retain appropriate levels of effectiveness¹⁴. It has also been found that this photodegradation of efficacy is greater for UVA protection¹⁵. As a result, the Proposed Standard will include a requirement for

8 EPA. 2000. OPPTS 810.3700. Insect repellents for human skin and outdoor premises. Accessed 6-3-10. <http://www.epa.gov/scipoly/sap/meetings/2000/april/insectguid.pdf>

9 Environmental Working Group. 2009. Sunscreen Investigation. Accessed 5-13-10. <http://www.ewg.org/cosmetics/report/sunscreen09/investigation/summary-of-findings>

10 Federal Register. 2007. 72 (165), August 27. Accessed 5-13-10. <http://edocket.access.gpo.gov/2007/pdf/07-4131.pdf>

11 European Commission. 2006. Sunscreen Products. Accessed 5-10-10. <http://ec.europa.eu/enterprise/sectors/cosmetics/cosmetic-products/sunscreen-products/>

12 Skin Cancer Foundation. 2007. The SCFs Guide to Sunscreens Accessed 6-17-10. <http://www.skincancer.org/the-scfs-guide-to-sunscreens.html>

13 Diffey, B.L. 2001. When Should Sunscreen be Reapplied? Journal of the American Academy of Dermatology. 45(6): 882-5.

14 Gaspar LR, Campos P. 2006. Evaluation of the photostability of different UV filter combinations in a sunscreen. International Journal of Pharmaceutics 307(2): 123-28.

15 Gonzalez H, et al. 2007. Photostability of commercial sunscreens upon sun exposure and irradiation by ultraviolet lamps. BMC Dermatol 7(1).

testing for photodegradation across UVA and UVB radiation exposure. Products with insufficient stability will not be acceptable – determined by degradation greater than 20% over 120 minutes. There are a range of methods available for this determination, and will be accepted. FDA regulates claims about water resistance for sunscreen and requires performance tests to prove claims (21 CFR 352.76)¹⁶. The Proposed Standard will not require water resistance, but products making such claims shall be in compliance with FDA regulations.

PRODUCT-SPECIFIC SUSTAINABILITY REQUIREMENTS

The leading regulator authority on these products is the FDA. However, the Food, Drug, and Cosmetic (FD&C) Act does not authorize FDA to approve cosmetic products or ingredients, with the exception of color additives that are not coal-tar hair dyes. As a result, personal care and cosmetic products are not subject to pre-market approval by FDA. Drugs, unlike cosmetics, are subject to a review and approval process by FDA before their release to the public. The Alliance for a Clean and Healthy Maine estimated that the average adult American uses nine personal care products everyday, resulting in 126 different chemicals being used¹⁷. Life cycle research shows that there are significant health considerations for personal care and cosmetic products since these products come into direct contact with the body and hair for long periods at a time. With the limited regulatory oversight and high level of use of these products directly on the body, the Proposed Standard will include a number of health and environmental requirements to reduce the use of hazardous materials. In addition, there will be an attempt to harmonize the health and environmental requirements with the European Union, and other countries like Canada, that are typically more stringent than the United States. As a result, the products will need to be in compliance with the ingredient/composition requirements of the European Commission Directive 76/768/EEC, 27 July 1976 on the Approximation of the Laws of the Member States relating to Cosmetic Products (also known as the Cosmetic Directive)¹⁸. This includes, but is not limited to the colorants (Annex IV), preservatives (Annex VI), and UV filters (Annex VII) that are allowed, prohibition of components (Annex II), and corresponding opinions from the European Commission Scientific Committee for Consumer Safety (formerly known as the Scientific Committee for Consumer Products; SCCS/SCCP)¹⁹. The SCCS/SCCP has clarified some of the contents of the Cosmetic Directive as data becomes available. For example, the SCCS/SCCP has reviewed nanoparticles of titanium dioxide and zinc oxide. While sufficient data has become available to permit the use of titanium dioxide in nanosize, zinc oxide is not permitted for use in nanosize (but is allowed for use greater than 100 micrometers)²⁰. Further, the Globally Harmonized System for Classifying Chemicals (GHS) provides a common means of communicating hazard information. As a result, the Proposed Standard includes GHS references throughout, including the testing methods, hazard category, phrase, and number.

Toxicity

To begin with, the Consumer Product Safety Commission (CPSC) has established criteria for hazardous substances. This includes definitions on what a “toxic” and “highly toxic” product are. To follow this guidance, the Proposed Standard requires that the product shall not have toxic characteristics such that it

16 CFR. 2009. Determination if a Product is Water Resistant and Very Water Resistant. 21 CFR 352.76. Accessed 6-24-10.
http://edocket.access.gpo.gov/cfr_2009/aprqttr/pdf/21cfr352.76.pdf

17 Alliance for a Clean and Healthy Maine. That's a Killer Look. Accessed 5-24-10.
<http://www.cleanandhealthyme.org/LinkClick.aspx?fileticket=7uqB2t8lR7U%3D&tabid=36>

18 European Commission. 2008. Cosmetic Directive. Accessed 5-13-10.
<http://ec.europa.eu/enterprise/sectors/cosmetics/documents/directive/>

19 European Commission. SCCP. Accessed 5-13-10.
http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm

20 European Union. SCCP Opinion on Safety of Nanomaterials in Cosmetic Products. Accessed 5-13-10.
http://ec.europa.eu/health/archive/ph_risk/committees/04_sccp/docs/sccp_o_123.pdf

falls under the labeling requirements as a toxic or highly toxic product, as defined by CPSC regulations found at 16 Code of Federal Regulations (CFR) Chapter II, Part 1500.3²¹. For example, this would exclude such products that have an oral LD₅₀ ≤ 5 g/kg (rat); inhalation LC₅₀ ≤ 20,000 ppm (1 hr, rat, vapor) or ≤ 200 mg/L (1 hr, rat, mist or dust)²²; Dermal LD₅₀ ≤ 2 g/kg (rabbit); and contain a known or probable chronic toxicant (e.g., carcinogens, neurotoxins, developmental/reproductive toxins).

Carcinogens, Mutagens, and Reproductive Toxins

The use of ingredients and intentional additives that are suggestive, likely, potential, possible, probable, reasonably anticipated, or known human carcinogens will be prohibited. Green Seal references carcinogen lists with the priority for international and national lists to follow the guidance of ISO 14024. This includes IARC, NTP, EPA, OSHA, and GHS.

Chemicals known to cause reproductive toxicity and include both male and female reproductive toxins and developmental toxins shall be prohibited. California Prop 65 is the most readily available and accepted source for these compounds and shall be cited along with GHS. Further, mutagens will also be prohibited. These will be characterized as chemicals that meets the criteria for category 1 (H340), chemicals known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans, and category 2 (H341), substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans, under the GHS..

These prohibitions apply to ingredients of the product materials used at 0.01%, as well as any intentionally added components. An intentional component is considered to be a deliberately added product component, where it is added for its continued presence in the final product to provide a specific characteristic, appearance, or quality. These prohibitions follow the common, protective approach for these materials in other ecolabel programs. Since reference lists and GHS classification is used, testing is not needed.

Materials used in personal care and cosmetics products that would be prohibited due to their carcinogenicity, mutagenicity, or reproductive toxicity include, but are not limited to, mercury-based preservatives, acrylonitrile, butylated hydroxyanisole, toluene, and formaldehyde.

Titanium dioxide is classified as a “possible carcinogen” in category 2B by IARC when it is of a respirable nature. This substance is commonly used in makeup and sunscreen products and generally considered one of the preferable active sunscreen ingredients. These uses have titanium dioxide in a form that is not generally respirable. As a result, an exception will be permitted to allow for the use of titanium dioxide, but there will be a limitation on the form/kind of packaging allowed for sunscreens to ensure the product isn’t respirable (not allowed in spray pumps or aerosols).

Skin and Eye Irritants and Skin and Respiratory Sensitizers

Damaging, irritating, and sensitizing ingredients used in personal care and cosmetic products affect user safety and comfort. As a result the Proposed Standard will require that the product shall not be corrosive or irritating to the skin or cause serious eye damage. Further, skin and respiratory sensitizers will not be allowed. The GHS includes definitions, testing methods, and classification criteria for these hazards that will be used. Green Seal uses existing data to evaluate for these effects, so testing is typically not required, unless data is not available or indicate a need for testing.

Skin Absorption

Since the nature of these products is to contact the skin, skin absorption potential and then potential for subsequent systemic toxicity needs to be considered. The potential for skin absorption can be estimated for individual ingredients using peer reviewed lists of chemicals with skin absorption potential from

21 CFR.2009. Definitions. 16 CFR 1500.3. Accessed 6-24-10. http://www.access.gpo.gov/nara/cfr/waisidx_09/16cfr1500_09.html

22 Note that the GHS has a lower threshold for this value, 20 mg/L at 1 hr.

credible scientific sources. There is a list from the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values for Chemical Substances (TLV) that includes substances with a high potential for skin absorption (skin notation) and systemic health effects. Another is from the Deutsche Forschungsgemeinschaft (DFG) Maximum Allowable Concentrations (MAK) list for chemicals with a high potential for skin absorption H notation. Both of these lists will be used to limit use of such substances, to less than 1% of the product formula. Further, there will be a limit of use of substances with the same target end-point to less than 1% of the product formula. No testing is needed to meet this requirement.

Asthma

Given the extended and close contact the products in the Proposed Standard have with the body, materials known to cause asthma will be prohibited. The Association of Occupational and Environmental Clinics (AOEC) provides a list of asthmagens (that is not readily available elsewhere). It is periodically updated through a peer-reviewed process, and new chemicals are added and out-dated listings are deleted. It has clear criteria, is accessible online, and oversight is provided by medical professionals with no financial incentive. Thus, it is sufficiently authoritative to address this very import health concern for personal care products. As a result, the Proposed Standard shall use the AOEC list to prohibit materials that are known to cause asthma. Testing is not needed to meet this requirement.

Volatile Organic Compounds and Chronic Inhalation Toxicity

Volatile organic compounds (VOCs) are carbon-based chemicals characterized by boiling points ranging from about 50-260°C and include alcohols, aldehydes, straight chain and cyclic alkanes, aromatic hydrocarbons, halogenated hydrocarbons, terpenes, ketones, and esters. VOCs are common ingredients in personal care products, including essential oils, ethanol, and fragrances. Minimization of VOC exposure has been recognized as a key indoor air quality strategy²³ and outdoor air quality strategy. Poor indoor air quality as a result of VOCs is one of the biggest contributors to asthma and other respiratory ailments in school aged children. As a result, VOC limits and chronic inhalation requirements have been included in the Proposed Standard.

In the product surveys conducted by the Air Resources Board in California (CARB), there was a range of VOC levels in the products covered in the Proposed Standard. Some of the variation was due to product function or delivery form, for which CARB made allowances for in their regulations, and some was due to different ingredient content within product types. Generally, a VOC limit of 1% was found to be achievable for most products (e.g., skin care products and makeup). The product categories that had higher VOC levels included nail products, hair styling products, and hair spray products. The nail products were typically less than 90% VOC, with levels below 75% VOC feasible. Hair styling products have regulatory limits of 55% for hair spray, 6% for aerosols and pumps, and 2% for all other types. CARB has a limit for insect repellents at 65%, but that is based on the products being sold as aerosols. Since aerosol products are not allowed in the Proposed Standard, a lower VOC level of 55% will be required. This has been found to be achievable across the product category with essential oil-based products being about 6% VOC and DEET-based products that include ethyl alcohol from 25-75%.

CARB also has regulatory VOC limits for deodorants and antiperspirants including a level of 0% for high volatility organic compounds, i.e., any organic compound that exerts a vapor pressure greater than 80 mm Hg when measured at 20°C, and medium volatility organic compounds, i.e., any organic compound that exerts a vapor pressure greater than 2 mm Hg and less than or equal to 80 mm Hg when measured at 20 C²⁴. There are exceptions allowed for compounds with more than 10 carbon molecules, ethanol,

23 Franke, Deborah L., Eugene C. Cole, Leese, K.E., Foarde, K.K., Berry, M.A. 1997. "Cleaning for Improved Indoor Air Quality: an Initial Assessment of Effectiveness." *Indoor Air* 7 (1), 41–54.

24 CARB. 2008. Regulation for Reducing Volatile Organic Compound Emissions from Antiperspirants and Deodorants. Accessed 6-24-10. <http://www.arb.ca.gov/consprod/regs/2008/apdo.pdf>

and colorants and fragrance up to a combined level of 2% of product. These limits are consistent in other countries such as Canada²⁵.

This criterion specifies the California Air Resources Board method 310 for determining the acceptable levels of VOC content allowed in the various product classes. This method is established and well known. Existing exemptions for fragrances and low vapor pressure components of a product allowed under CARB 310 are not allowed under the Proposed Standard, thus the designated thresholds for each product class consider all VOC content detected under the test method. Further, calculation of the VOC content may be done if all the component data is available (based on components with a vapor pressure of 0.1 mmHg or more).

In addition to the VOC limits, the product will need to demonstrate that it does not contribute to chronic inhalation concerns. This will be done by either demonstrating that each volatile ingredient is not classified as a chronic inhalation hazard (typically by using existing data) or by having the whole product tested for emissions using a chamber test.

Aquatic Safety

Personal care and cosmetic products and their components can end up in the environment and waterways throughout the life cycle including at manufacturing or after product use (e.g., when the consumer washes the product off or disposes the package). These products contain parabens, EDTA, triclosan, and other compounds known to be poorly biodegradable and potentially harmful to aquatic life. As a result, there will be requirements for aquatic toxicity, biodegradation, bioaccumulation, and eutrophication (i.e., phosphorus content). Natural components, such as iron oxides, that are not toxic to aquatic life will not need to be evaluated for biodegradability and bioaccumulation. This is in alignment with ecolabel programs in other countries (e.g., European Flower). In addition, the EPA Toxic Release Inventory chemicals identified as Persistent, Bioaccumulative, and Toxic (PBT) will be prohibited²⁶.

Prohibited Compounds

There are several hazardous compounds that may not be prohibited as a result of the other criteria in the Proposed Standard but may warrant exclusion in a more sustainable product. Further, there may not be a means to prohibit the compounds based on their end point. For example, there are several known endocrine disruptors used in these products. However, until recently there has not been an accepted testing procedure for such activity. In 2010, the EPA published the final guidelines for endocrine disruptor screening testing²⁷. The final guidelines are part of a series of test guidelines that have been developed by the Office of Chemical Safety and Pollution Prevention (OCSPP) for use in the testing of pesticides and toxic substances. However, there is limited data available for all of the chemicals used in personal care products using these tests. As a result, the Proposed Standard will propose the use of the test guidelines for chemicals that have been identified as priority chemicals by the EPA²⁸ and EU²⁹. In addition, known endocrine disruptors will be specifically prohibited. By far the largest group of chemicals with endocrine disruptor effects are phthalates including, but not limited to dibutylphthalate, diethylhexylphthalate, butyl benzyl phthalate, and bis-(2-etoxyethyl) phthalate. The Netherlands Organization (TNO) conducted a market survey in the Netherlands and found that phthalates were in 49

25 Government of Canada. 2008. Volatile Organic Compound (VOC) Concentration Limits for Certain Products Regulations. Canada Gazette. 142 (17). Accessed 6-24-10. <http://canadagazette.gc.ca/rp-pr/p1/2008/2008-04-26/html/req3-eng.html>

26 EPA. 2010. TRI Chemicals. Accessed 6-24-10. <http://www.epa.gov/tri/trichemicals/index.htm>

27 EPA. 2010. OCSPP Harmonized Test Guidelines. Accessed 6-16-10. http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series890.htm

28 EPA. 2009. Final List of Chemicals for Initial Tier 1 Screening. Accessed 6-16-10. <http://www.epa.gov/scipoly/oscpdo/pubs/prioritysetting/finalist.html>

29 EU. 2008. What is Being Done. Accessed 6-16-10. http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm

out of 55 cosmetic products, with diethyl phthalate the most common³⁰. A similar study in the United States had the same results (72% of all products tested had phthalates), with dibutyl phthalate found in 7% of deodorant, fragrance, and hair spray products tested³¹. As a result, the group of phthalate materials will be prohibited.

Another group of compounds used in these products with endocrine disruptor activity are parabens, such as methylparaben, ethylparaben, propylparaben, butylparaben, isobutylparaben, isopropylparaben, and benzylparaben. These compounds are commonly used as preservatives in personal care products. According to the National Institutes of Health³², parabens bind with to estrogen receptors and regulate estrogen-responsive reporter gene expression in experimental cell systems. The estrogenic activities of the parabens increase as the length and branching of the alkyl ester increase. The ER relative binding activity of parabens is in the following approximate order: 2-ethylhexyl > heptyl > benzyl > butyl > propyl = ethyl > methyl. Parabens also can cause skin irritation and contact dermatitis in individuals with paraben allergies, a small percentage of the population³³. As a result, the class of parabens will be prohibited.

There are several materials that are prohibited due to their carcinogenicity or developmental toxicity. However, given their widespread use in personal care products they will be explicitly listed as prohibited materials. These include 2-butoxyethanol (EPA IRIS classification C), mercury-containing preservatives (Prop 65 developmental toxin), and formaldehyde donors. For example, formaldehyde is carcinogenic to humans (IARC classification 1) and would be a prohibited ingredient according to the carcinogen criterion proposed. However, there are commonly used preservative ingredients that are known to release formaldehyde over time (Bronopol; DMDM-hydantoin; Tris Nitro, 2-bromo-2-nitropropane-1,3-diol; 5-bromo-5-nitro-1,3-dioxane; diazolidinyl urea; imidazolidinyl urea; sodium hydroxy methyl glycinate). To further limit the content of known carcinogens, these formaldehyde-donor compounds were added to the list of other prohibited materials.

Materials that are known to be contaminated with toxic substances will be prohibited. For example, it is known that ethoxylated chemicals can be contaminated with 1,4-dioxane. Testing of personal care and cosmetic products found that about one-third of products were contaminated with 1,4-dioxane¹⁷. 1,4-dioxane is a possible carcinogen on the IARC list (and would be prohibited if it were directly added to the product under the Proposed Standard). Ethoxylated alcohols include polyethylene glycols, polyethylene, polyoxyethylene, or sodium laureth sulfate, are used in products included in the Proposed Standard. As a result, ethoxylated chemicals will be prohibited. Diethanolamine (DEA) is on the TLV list with a skin notation, a hazardous air pollutant, and an asthmagen. However, it is included in the list of prohibited compounds since it, along with triethanolamine (TEA) and monoethanolamine (MEA), may cause the formation of cancer-causing nitrosamines in products. It is thought that the specific nitrosamine formed is known as N-nitrosodiethanolamine or NDELA. Most nitrosamines, including those formed from DEA or TEA, are carcinogenic. Further, the National Toxicology Program (NTP) completed a study in 1998 that found an association between the topical application of diethanolamine (DEA) and some DEA-related ingredients and cancer in laboratory animals³⁴. For the DEA-related ingredients, the NTP study suggests that the carcinogenic response is linked to possible residual levels of DEA. As a result, these compounds are prohibited. Mineral oil (paraffinic oils, naphthenic oils, aromatic oils) and petrolatum are known to be contaminated with polycyclic aromatic hydrocarbons (probable carcinogens according to NTP). These compounds will be prohibited.

30 TNO (2004): "Ftalaten en muskverbindingen in cosmetics". TNO Milieu, Energie en Procesinnovatie. Report no R 2004/607.

31 EWG. 2008. Not Too Pretty. Accessed 3-10-10. http://www.ewg.org/files/nottoopretty_final.pdf

32 National Institutes of Health (NIH). 2004. Butylparaben [CAS No. 94-26-8] Final Review of Toxicological Literature. June 2004.

33 Nagel J.E., et al. 1977. Paraben allergy. JAMA. April 11 1977; 237(15):1594-5.

34 FDA. 2006. Diethanolamine and Cosmetic Products. Accessed 4-12-10. <http://www.cfsan.fda.gov/~dms/cos-dea.html>

Human toxicological and epidemiologic data on oxybenzone (i.e., Benzophenone-3) suggest it to be the most common source photo allergies³⁵. Oxybenzone animal studies have demonstrated a range of effects including hormone disruption³⁶. An April 2008 study published in Environmental Health Perspectives revealed that, when exposed to benzophenone, cinnamate, or camphor-based sunscreens, coral developed viral infections that led to bleaching³⁷. Given the widespread use of the benzophenone chemical class and that it is significantly absorbed through the skin³⁸, it will be prohibited. Cinnamate and camphor derivatives, in addition to potentially contributing to coral bleaching, have been shown to have hormone disruption activity³⁹. However, these sunscreen ingredients do not appear to be absorbed through the skin in significant concentrations⁴⁰. Thus, they will not be prohibited. However, there will be limits on the form sunscreen products can be in – not allowing for powders or sprays.

SCCS/SCCP evaluated the data on methylidibromo glutaronitrile (1,2-Dibromo-2,4-dicyanobutanone), a preservative commonly used in personal care products, and concluded that its use should be limited due to its demonstrated contact allergy effects⁴¹. The SCCS/SCCP also stated that triclosan should not be used for leave on products, thus they will be prohibited⁴².

The following chemicals are prohibited specifically due to their aquatic hazards. Musks, nitro-musks and polycyclic musks are prohibited because of their bioaccumulation and aquatic effects. Phosphates are prohibited due to their contribution to eutrophication effects. Nitrotriacetic acid (NTA) and ethylene diaminetetra-acetic acid (EDTA) are poorly degradable and are suspected of remobilizing heavy metals in e.g. riverbeds. NTA is also a suspected carcinogen. There have been issues with the biodegradation, effects on microflora and fish, and skin sensitization or irritation of traditional, fluorescent, optical brighteners. Alkylphenol ethoxylates (APEs) degrade into nonylphenol and other products which are known to persist and bioaccumulate in waterways and aquatic life and act as endocrine disrupters.

Hazardous air pollutants (HAPs) cause or may cause cancer or other serious health effects, such as reproductive effects or birth defects, or adverse environmental and ecological effects. As a result, the EPA regulates these substances⁴³. There are some that are included in personal care products such as ethylene glycol, phenol, phthalic anhydride, and hydroquinone (used as a skin lightener). As a result, HAPs will be prohibited.

35 Scheuer, E. and E. Warshaw. 2006. Sunscreen Allergy: Epidemiology, Characteristics and Allergens. *Dermatitis*. 17(1):3-11

36 Calafat, et al. 2008. Concentrations of the Sunscreen Agent Benzophenone-3 in Residents of the United States: National Health and Nutrition Examination Survey 2003–2004. *Environmental Health Perspectives*. 116 (7). Accessed 4-12-10. <http://ehp03.niehs.nih.gov/article/etchArticle.action?articleURI=info:doi/10.1289/ehp.11269>

37 Danovaro, R., et al. 2008. Sunscreens Cause Coral Bleaching by Promoting Viral Infections. *Environmental Health Perspectives*. 116 (4).

38 Jiang, et al. 1999. Absorption of sunscreens across human skin: an evaluation of commercial products for children and adults. *Br J Clin Pharmacol*. 48(4):635-7. Accessed 5-27-10. <http://www3.interscience.wiley.com/cgi-bin/fulltext/119092761/PDFSTART>

39 Schlumpf M, Schmid P, Durrer S, Conscience M, Maerkel K, Henseler M, et al. 2004. Endocrine activity and developmental toxicity of cosmetic UV filters--an update. *Toxicology* 205(1-2): 113-22.

40 Environmental Working Group. 2010. Nanomaterials and hormone disruptors in sunscreens. Accessed 5-27-10. <http://www.ewg.org/2010sunscreens/full-report/nanomaterials-and-hormone-disruptors-in-sunscreens/>

41 Scientific Committee on Consumer Products (SCCP) 2005. Opinion on Methylidibromo glutaronitrile. Accessed 4-12-10. http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_060.pdf

42 European Commission. SCCP Opinion on Triclosan. Accessed 5-13-10. http://ec.europa.eu/health/archive/ph_risk/committees/04_sccp/docs/sccp_o_166.pdf

43 EPA. 2009. About Air Toxics. Accessed 6-24-10. <http://www.epa.gov/ttn/atw/allabout.html>

According to the EPA⁴⁴, “Stratospheric ozone is a naturally-occurring gas that filters the sun’s ultraviolet (UV) radiation. A diminished ozone layer allows more radiation to reach the Earth’s surface. For people, overexposure to UV rays can lead to skin cancer, cataracts, and weakened immune systems.” Ozone depleting substances have been identified in the global initiative, the Montreal Protocol. These are regulated by the EPA and classified as Class I and Class II, and also classified by GHS as Category 1. These will be prohibited.

The primary active ingredients for antiperspirant are aluminum-based. There has been question about aluminum’s safety, especially related to causing Alzheimer’s disease (and to some extent to breast cancer, but aluminum is not listed as a carcinogen by any of the authorities on cancer). A preliminary study showed “a trend toward a higher risk [of Alzheimer’s] with increasing frequency of use” of antiperspirant⁴⁵. One of the key questions related to this concern is the extent of dermal (or even nasal-olfactory) absorption of aluminum and subsequent transport and uptake into the brain with antiperspirant use⁴⁶. This seems to be unanswered. Since spray and aerosol products can be inhaled or swallowed, these materials can then be transported throughout the body. As a result, antiperspirant and deodorant will not be allowed to be in spray or aerosol packages. A recent review on the risk factors for Alzheimer’s was completed in Canada⁴⁷. They found that there was no statistically significant association with antiperspirant use and Alzheimer’s. As a result, at this time there will be not be a prohibition for aluminum-containing antiperspirants.

Sunscreen

There are substances that have been demonstrated to enhance the skin’s sensitivity to UV radiation. This has been shown to cause increased damage to the skin with sun exposure that may lead to skin cancer. Alpha hydroxy acids and retinoids are among these. Animal studies have shown little-to-no effect^{48,49}, while human studies have demonstrated enhanced photodamage^{50,51}. Recent research suggests that retinoids may potentially have additional phototoxicity concerns, such as photodegradation products of concern^{52,53}. These substances are found in personal care products since they have cosmetic (and drug) functions to enhance the appearance of skin (e.g., reducing wrinkles, reducing acne, and even reducing the appearance of sun damage). When products are used with these substances, sun

44 EPA. 2010. Brief Questions and Answers on Ozone Depletion. Accessed 6-24-10. http://www.epa.gov/ozone/science/q_a.html

45 Borenstein Graves, A. et al. 1990. The association between aluminum-containing products and Alzheimer’s disease. *Journal of Clinical Epidemiology*. 43 (1): 35-44.

46 Exley, C. 1998. Does antiperspirant use increase the risk of aluminium-related disease, including Alzheimer’s disease? *Mol Med Today*. 4(3):107-109.

47 Lindsay, J. et al. 2002. Risk Factors for Alzheimer’s Disease: A Prospective Analysis from the Canadian Study of Health and Aging. *American Journal of Epidemiology*. 156 (5): 445-453. Accessed 5-28-10. <http://aje.oxfordjournals.org/cgi/reprint/156/5/445>

48 NTP. 2007. Photocarcinogenesis Study of Glycolic Acid and Salicylic Acid (CAS NOS. 79-14-1 and 69-72-7) In SKH-1 Mice. NIH Publication No. 07-4472.

49 NTP. 2005. Photocarcinogenesis Study of Glycolic Acid and Salicylic Acid (CAS NOS. 79-14-1 and 69-72-7) In SKH-1 Mice. NIH Publication No. 05-4472

50 Kaidbey, K. et al. 2003. Topical glycolic acid enhances photodamage by ultraviolet light. *Photodermatol Photoimmunol Photomed*. 19 (1):21- 27.

51 Tsai, TF, et al. 2000. Effects of glycolic acid on light-induced skin pigmentation in Asian and caucasian subjects. *J Am Acad Dermatol*. 43 (2 Part 1): 238-43.

52 Fu, P.P., et al. 2002. Do Topically Applied Skin Creams Containing Retinyl Palmitate Affect the Photocarcinogenicity of Simulated Solar Light? *Journal of Food and Drug Analysis*. 10 (4): 262-268. Accessed 6-18-10. http://www.fda.gov.tw/files/publish_periodical/10-4-8.PDF

53 EWG. 2010. Letter to FDA Commissioner Re: Pressing Need to Expedite Photocarcinogenicity Assessment for Sunscreen Ingredient Retinyl Palmitate. Accessed 6-18-10. <http://www.ewg.org/files/FDA-NTP%20Vitamin%20A%20in%20Sunscreen.pdf>

avoidance is highly recommended, including the use of sunscreen. However, these substances should not be in sunscreen products since sunscreen products are intended to protect the skin from UV radiation. As a result, these substances will be prohibited from sunscreen products. Additionally, there will be requirements for precautionary language for products that contain alpha hydroxyl acids and retinoids recommending sun protection due to the increased risk of sun damage.

Insect Repellent

There are several effective insect repellent active ingredients. N,N-diethyl-meta-toluamide (aka, DEET) is the most popular, due to its effectiveness in repelling a wide range of insects. Various United States authorities, such as the EPA, the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP), have determined that DEET is safe and effective if used properly. Some studies have found that high exposure to DEET can lead to psychological problems, rashes, dizziness, headache, and nausea, among other symptoms. DEET is absorbed through the skin. DEET is considered "slightly toxic" by the EPA with acute toxicity and ecotoxicity levels such that the amount of DEET in a product would be limited (to approximately to 10-20% of the formula) due to the acute toxicity and ecotoxicity requirements in the Proposed Standard⁴. DEET, as well as other insect repellent actives (e.g., permethrin) is also an irritant and would be further limited to 5% due to the other requirements in the Proposed Standard. It has been found that DEET products meeting this requirement (e.g., 4.75% DEET) are effective for at least 1.5 hours⁵⁴.

The CDC recommends that insect repellent products should not contain sunscreen⁵⁴. This is because the use and reapplication of these products are different; typically insect repellent does not get reapplied as often as other products like sunscreen throughout the day (e.g., the AAP recommends using insect repellent sparingly⁵⁵ and reapplying sunscreen every 1.5 hours⁵⁶). A combination product would lead to over application of and over exposure to insect repellent (that is irritating and slightly toxic), which is cautioned against by the EPA⁵⁷. As a result, insect repellents are not permitted in sunscreen-combination products (or vice versa).

Fragrances

Fragrances are used in personal care products. These ingredients aren't functional for the product's performance, but are used for consumer acceptability. There are many known health and environmental concerns with fragrance ingredients. The International Fragrance Association (IFRA) Guidelines in the Code of Practice aim to limit the use of fragrance ingredients with undesirable effects. However, the IFRA Code is limited to the substances that have been comprehensively evaluated by the Research Institute for Fragrance Materials (RIFM). As a result, the concerning effects of fragrances are addressed in the Proposed Standard (e.g., phthalate prohibition, VOC limits, allergen labeling), not only to limit the use of such fragrance ingredients, but for other components of the product. Note that fragrance products are prohibited.

Biocides and Preservatives

Preservatives/biocides are added to the product to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means. These are considered antimicrobial, antiseptic, disinfectant, or sanitizing agents and are used to maintain the safety, color, and appearance of the products. Preservatives/biocides are often toxic to aquatic life, bioaccumulate, or are poorly biodegradable. Numerous medical groups, including the American Medical

54 CDC. 2010. Insect Repellent Use and Safety. Accessed 6-24-10. http://www.cdc.gov/ncidod/dvbid/westnile/qa/insect_repellent.htm

55 AAP. 2003. Follow Safety Precautions When Using DEET on Children Accessed 6-24-10. <http://www.aap.org/family/wnv-jun03.htm>

56 AAP. 2010. Sunburn: Treatment and Prevention. Accessed 6-24-10. <http://www.healthychildren.org/English/safety-prevention/at-play/pages/Sunburn-Treatment-And-Prevention.aspx>

57 EPA. 2007. The Insect Repellent DEET. Accessed 6-24-10. <http://www.epa.gov/pesticides/factsheets/chemicals/deet.htm>

Association and the CDC have stated that antibacterial soaps are not more effective in preventing disease than ordinary soap and water. Thus, their use in products left on the body is not necessary. Further, there is concern about the use of such components contributing to resistant microorganisms⁵⁸. As a result, the use of such materials for activity beyond preserving the product is prohibited, and they must meet the other criteria of the Proposed Standard including aquatic toxicity, bioaccumulation, and biodegradability (and also be on the Cosmetic Directive Annex VI). Further, antimicrobial products and any claims about antimicrobial functionality are not allowed in the Proposed Standard. An exception will be allowed for deodorant and antiperspirant products.

Colors

The FDA is responsible for regulating color additives used in the United States. Color additives permitted for use are classified as "certifiable" or "exempt from certification"⁵⁹. Color additives that are exempt from FDA certification include pigments derived from natural sources such as vegetables, minerals or animals, and man-made counterparts of natural derivatives. Certifiable color additives are synthetic. The synthetic colors have specifications for purity established by the FDA. This includes limits of heavy metals, due to the common contamination of colors with heavy metals (typically: 20 ppm of lead, 3 ppm of arsenic, and 1 ppm of mercury).

Colorants are not commonly used in personal care products, except for makeup and nail polish. Both of these products have a high colorant content, which may result in high levels of heavy metal contamination. The metals of primary toxicological concern are lead, arsenic, cadmium, mercury and antimony. Lead is the most studied heavy metal. Lead has been found to be a neurotoxin and linked to learning and behavioral disabilities. Lead is a common contaminant in personal care products. A study by the Campaign for Safe Cosmetics found that 61% of lipsticks tested contained detectable levels of lead⁶⁰. As a result, heavy metals are not allowed to be added to products intentionally. However, since heavy metals are often present due to contamination, heavy metal testing will be required for makeup products, as it is required by Health Canada⁶¹ and is proposed in other countries. The allowed levels of heavy metals will be aligned with those found to be feasible for toothpaste (considering background levels in the environmental and testing reliability), with the exception for lead since it has been proven to be able to be less than 0.05 ppm^{62,63}. While there is likely no safe level of lead, zero lead is not a practical limit since there are background levels in the environmental and there are testing limitations. Testing for lead usually has a detection limit associated with it that means levels less than that cannot be quantified. In the study conducted by the Campaign for Safe Cosmetics, the detection limit was 0.02 ppm. In a recent study led by the FDA, the detection limit was 0.04 ppm⁶⁴. Further there is also variability with the method (2% seen in the FDA study). So a limit of 0.05 ppm is feasible.

58 Aiello et al. 2007 Antibacterial Soap Use: Efficacy and Risks. *Clinical Infectious Diseases* 45:S137-S147.

59 FDA. 2007. Color Additives and Cosmetics. Accessed 5-27-10. <http://www.fda.gov/ForIndustry/ColorAdditives/ColorAdditivesinSpecificProducts/InCosmetics/ucm110032.htm>

60 Campaign for Safe Cosmetics. 2007. A Poison Kiss: the Problem of Lead in Lipstick. Accessed 5-24-10. http://www.safecosmetics.org/downloads/A%20Poison%20Kiss_report.pdf

61 Health Canada. 2009. Draft Guidance on Heavy Metal Impurities in Cosmetics. Accessed 3-12-10. http://www.hc-sc.gc.ca/cps-spc/legislation/consultation/_cosmet/metal-metiaux-consult-eng.php#state

62 FDA. 2009. Lipstick and Lead: Questions and Answers. Accessed 3-12-10. <http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm137224.htm>

63 Campaign for Safe Cosmetics. 2007. A Poison Kiss: The Problem of Lead in Lipstick. Access 3-12-10. http://www.safecosmetics.org/downloads/A%20Poison%20Kiss_report.pdf

64 Hepp, N. et al. 2009. Determination of total lead in lipstick: Development and validation of a microwave-assisted digestion, inductively coupled plasma–mass spectrometric method. *J. Cosmet. Sci.*, 60, 405–414. Accessed 5-2-10. <http://journal.sconline.org/pdf/cc2009open/cc060n04/p00405-p00414.pdf>

The FDA considers dihydroxyacetone (DHA) a color additive⁶⁵. The FDA has approved DHA for external use, but it is not approved for use in the area of the eye, lips, or other mucous membranes⁶⁵. Its use cannot include tanning booths or sprays since it can end up in the eye or other mucous membrane areas not approved. Thus these products will be prohibited to be packaging in spray packages in the Proposed Standard.

Nanoscale Materials

Personal care and cosmetic products use nanoscale materials. For the products covered in the Proposed Standard, the nanoscale materials are typically titanium dioxide⁶⁶. Nanoscale materials are typically defined as materials roughly 1 to 100 nanometers in size in one dimension. However, the Friends of the Earth recently defined nanomaterials to be up to 300 nanometers due to the potential ability of larger molecules to be taken into cells (once already in the body, through injection)^{67,68}. The FDA has not been actively evaluating the safety of nanoscale materials, whereas the European Commission SCCS/SCCP evaluates nanoscale materials for safety (the SCCS/SCCP defines nanoscale materials as those materials having one or more dimension of the order of 100 nanometers or less). The SCCS/SCCP has separated their consideration of nanoscale materials into soluble (and/or biodegradable) and insoluble materials. They have stated that soluble and/or biodegradable materials are assumed to behave as their larger-sized counterparts and thus conventional risk assessment may be sufficient²⁰. As a result, the SCCS/SCCP does not have any reviews in progress (or opinions already issued) for soluble nanoscale materials. However, they have been evaluating insoluble nanoscale materials including titanium dioxide and zinc oxide. At the time of the writing of this document, the SCCS/SCCP determined that nanoscale titanium dioxide was safe for use up to 25%⁶⁹ and they continue to monitor its safety. Their review of zinc oxide determined that there was inadequate data to permit the safe use of nanoscale zinc oxide materials. This may be in part because zinc may have the potential to be absorbed through the skin⁷⁰. The SCCS/SCCP guidance will be used in the Proposed Standard. The SCCS/SCCP continues to review nanoscale materials in cosmetics within a Working Group on Nanomaterials in Cosmetic Products (formed in 2009). Thus, the status of safe use of nanomaterials may change as a result of progress made by the work group.

Animal Testing

Green Seal discourages the use of animal testing to meet the requirements in the Proposed Standard. As a result, the results of past peer reviewed or standard tests demonstrating compliance with a criterion will be accepted. A mixture need not be tested if existing information demonstrates that each of the ingredients complies with a criterion. Additionally, non-animal (in-vitro) test results, modeling data, or data from structural analogs may be accepted, provided that the methods are peer-reviewed, applicable, and the manufacturer provides rationale for the particular method. This is generally consistent with the

65 FDA. 2006. Self Tanners and Bronzers. Accessed 5-27-10.

<http://www.fda.gov/Cosmetics/ProductandIngredientSafety/ProductInformation/ucm134064.htm>

66 Miljostyrelsen. 2007. Survey of Chemical Substances in Consumer Products, No. 81, Survey of nanotechnological consumer products. Accessed 5-10-10.

http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/Udgiv/publications/2007/978-87-7052-536-7/html/helepubl_eng.htm

67 Friends of the Earth. 2010. Nanosunscreens Threaten Your Health. Accessed 6-3-10. <http://www.foe.org/healthy-people/nanosunscreens>

68 Garnett, MC and P Kallinteri. 2006. Nanomedicines and nanotoxicology: some physiological principles. Occupational Medicine. 56:307–311. Accessed 6-3-10. <http://ocmed.oxfordjournals.org/cgi/reprint/56/5/307>

69 European Commission. SCCP Opinion on Titanium Dioxide. Accessed 5-13-10.

http://ec.europa.eu/health/archive/ph_risk/committees/sccp/documents/out135_en.pdf

70 Hall, A. 2010. Zinc from sunscreen absorbed through the skin: study. Accessed 6-3-10.

<http://www.abc.net.au/pm/content/2010/s2830477.htm>

Cosmetic Directive's ban on animal testing. For example, quantitative structure-activity relationship (QSAR) data from EPA's BioWin (EpiSuite) models may be considered for aquatic biodegradability.

MANUFACTURING SUSTAINABILITY

Good Manufacturing Practices (GMPs) shall be followed for product production in order to minimize adulteration or mislabeling. Guidance on GMPs applicable to personal care and cosmetic products is provided by the FDA and includes guidelines on the building and facility, equipment, personnel, raw materials, production, laboratory, labeling, records, and complaints⁷¹. Green Seal realizes that GMPs are required only for drugs (not cosmetic products), however to be consistent Green Seal is requiring this for all products in the scope of the Proposed Standard.

Transportation of raw materials and finished products can also be a large source of pollution. Emissions produced from international merchant fleets involved in global trade are thought to represent a significant contribution to the global anthropogenic emissions such as NO_x, SO₂, CO, CO₂, and VOCs. The environmental costs associated with shipping materials for manufacturing should be taken into consideration, and local sources should be used when possible. If raw materials are being shipped long distances to be manufactured in one locality and then the finished product is shipped back around the world to be sold, the adverse environmental impacts associated with the transportation could offset the environmental benefits associated with the preferable formula and package. One approach to address transportation and related emissions could be to perform a life-cycle assessment (LCA) of a company's carbon footprint. However, preparing an LCA is a complicated process and the results can be quite variable. Therefore, although transportation and related emissions are important in the manufacture of environmentally preferable products, specific criteria have not been included in the Proposed Standard at this time. Rather, reporting of transportation information will be required with the expectation of continuous improvement of documenting this information over time. In addition, Green Seal will require reporting of energy and water use and waste generation during production. There are no thresholds of performance on these areas since this information has yet to be widely available for manufacturers. The aim is that over time this information will be available and leadership performance will become apparent for future versions of the Standard.

In order to ensure that certified products are made in accordance with reasonable social practices, companies may demonstrate compliance with certification under the International Labour Organisation (ILO). In lieu of this certification, manufacturers can demonstrate that they meet the following requirements: freedom of association and collective bargaining, which means that workers are free to elect to join unions and that their bargaining power is respected; freedom of labor, which prohibits bonded and child labor; and freedom from discrimination, which does not allow discrimination based on age, race, sex, political affiliation or social caste that will inhibit opportunities. In addition, freedom from discrimination addresses use or tolerance of corporal punishment or use of physical or verbal abuse or intimidation. Other requirements include occupational health and safety, which establishes minimum safe working conditions and training to minimize injury and accidents as well as conditions of employment that guarantee regular employment, living wages and working hours that are not excessive. This demonstration will need to include: documentation that these requirements are in the company policy; providing a written certification statement signed by a legally responsible officer of the company attesting to said requirements; and a review of site conditions by the certifying auditor.

PACKAGING SUSTAINABILITY REQUIREMENTS

Personal care and cosmetic products are typically packaged in ready-to-use containers. Sometimes an applicator is included (e.g., mascara, nail polish, blush). The packaging options for cosmetic products

71 FDA. 2008. Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist. Accessed 4-19-10.
<http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GoodManufacturingPracticeGMPGuidelinesInspectionChecklist/default.htm>

range from all types of plastic, paper, metal, and glass. The primary package, the material that typically comes into contact with the product may need to be encased in a secondary package for safety protection or to prevent damage to the product or primary package. As a result, the packaging of these products may contribute significantly to their total life cycle impacts. To address this issue, some products contain significant amounts of post-consumer content (up to 100%). Companies have been able to source-reduce the packaging (e.g., lip products with a 33% reduction in waste). Some manufacturers are even providing take-back programs for the packages that aren't readily recyclable (or not recyclable at all)⁷². As a result, reducing the total packaging and material from virgin sources is a key approach for packaging proposed in the Proposed Standard.

Packaging shall not include known toxins such as heavy metals. The Coalition of Northeastern Governors (CONEG) suggested restriction on heavy metals is included in the Proposed Standard, along with prohibition on the use of endocrine disrupters such as Bisphenol A and phthalates in packaging.

COMMUNICATION AND LABELING REQUIREMENTS

According to the FDA, a cosmetic product must be labeled according to cosmetic labeling regulations. OTC drugs must be labeled according to OTC drug regulations, including the "Drug Facts" labeling, as described in 21 CFR 201.63. Combination OTC drug/cosmetic products must have combination OTC drug/cosmetic labeling⁷³. Further, insect repellent must meet the FIFRA regulations as enforced by EPA (which may include registration and labeling of active ingredients).

Green Seal requires that the regulatory labeling rules are followed, including ingredient labeling. Further, the format for ingredient labeling shall be a listing of all components in order of predominance (21 CFR 701.3)⁷⁴, including fragrance materials. For proprietary fragrance materials, the generic term "fragrance" can be used. All other regulatory rules shall apply to the product, for example products characterized as drugs shall follow FDA rules for drug labeling (21 CFR 201).

Organic claims are made on personal care products. Some claims include the United States Department of Agriculture (USDA) seal (and thus meet the USDA regulations), and some do not. The USDA National Organic Program (NOP) is a marketing program housed within the USDA Agricultural Marketing Service. NOP developed national organic standards and established an organic certification program. The definition for organic, developed by the National Organic Standards Board (NOSB) adopted in April 1995, is an "ecological production management system that promotes and enhances biodiversity, biological cycles and soil biological activity. It is based on minimal use of off-farm inputs and on management practices that restore, maintain and enhance ecological harmony." According to the NOP, "regulations require that agricultural products labeled as organic originate from farms or handling operations certified by a State or private entity that has been accredited by USDA⁷⁵." Further, "agricultural products marketed as organic meet consistent, uniform standards⁷⁵." According to an August 23, 2005 memo from Barbara C. Robinson the Deputy Administrator Transportation and Marketing Programs Agricultural Marketing Service on the subject of Certification of agricultural products that meet NOP standards, "There are agricultural products, including personal care products, that, by virtue of their organic agricultural product content, may meet the NOP standards and be labeled as "100 percent organic," "organic" or "made with

72 Greenwala. 2010. Cosmetic "empties" get a makeover thanks to 4 recycling programs. Accessed 4-29-10.

<http://www.greenwala.com/profiles/elizah-leigh/blog/6287-Cosmetics-Empties-Get-a-Makeover-Thanks-To-4-Recycling-Programs>

73 FDA. Is it a cosmetic, drug, or both (or is it a soap). Accessed 2-23-10

<http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm>

74 CFR. Title 21 Section 701.3. Accessed 6-14-10. http://edocket.access.gpo.gov/cfr_2009/aprtr/pdf/21cfr701.3.pdf

75 NOP. 2008. National Organic Program Background Information. Accessed 6-14-10.

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELDEV3004443&acct=nopgeninfo>

organic” pursuant to the NOP regulations...Additionally, products that may be labeled “100 percent organic” or “organic” may also carry the USDA organic seal.” This statement was reinforced in 2008, with a fact sheet on the NOP website⁷⁶. Further, in 2009, the NOSB made a final recommendation for rulemaking on this issue: “assuring consumers that the federal government is policing organic claims on personal care products and allowing for the development of a complete federal organic personal care product program⁷⁷.” As a result, Green Seal will require any product that makes an organic claim to follow the NOP standards and if applicable, may use the USDA organic seal for their claims. Specifically, organic ingredients (production and handling) must be certified by a USDA-accredited certifying agent. Claims about the content of organic ingredients include,

"100 percent organic" must contain only organic components, and may display the USDA Organic seal.

"Organic" products must consist of at least 95 percent organically produced components and may display the USDA Organic seal.

"Made with organic ingredients" contain at least 70 percent organic components and list up to three of the organic components on the principal display panel. The USDA seal cannot be used anywhere on the package.

Further, products that contain less than 70 percent organic ingredients cannot use the term “organic” other than to identify the specific components that are organically produced in the ingredients statement.

Since the NOP doesn't currently regulate organic claims for personal care products, NSF International (NSF) has developed an American National Standard, NSF/ANSI 305 that outlines specific requirements for labeling organic personal care products. The standards outlines that products that meet the “100 percent organic” and the “organic” labeling outlined above by the USDA, shall be certified through the USDA NOP. Products that contain 70% organic ingredients must meet the requirements outlined in NSD/ANSI 305.

Natural claims currently are not regulated. There are a few organizations, some industry led, that have attempted to create definitions for natural including the Natural Products Association, BDIH Natural Guidelines, and the Natural Ingredient Resource Center. The criteria proposed in Green Seal's Proposed Standard are based on these approaches, and the USDA BioPreferred program. First, natural ingredients are those that come from biological, mineral, forestry, or agricultural materials and do not contain genetically modified organisms, have been processed without irradiation, and are not chemically altered. Naturally-derived components that are partially chemically altered without petroleum components and have been minimally processed such that they not be altered to such an extent that they are substantially less biodegradable or more toxic. With this definition of natural and naturally-derived compents, the following claims would then be defined as:

“100 percent Natural” or “All Natural” can only contain natural components with no synthetic components.

"Natural" products can contain 95% of natural components and not include synthetic fragrances, artificial colors or components from petrochemicals.

76 NOP. 2008. Cosmetics, Body Care Products, and Personal Care Products Under the National Organic Program Regulations. Accessed 6-14-10. <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5068442&acct=nopgeninfo>

77 NOSB. 2009. Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP): Subject, Organic Personal Care Accessed 6-14-10. <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081493&acct=nosb>

"Made with/from Natural Ingredients" contains at least 70% natural components and not include synthetic fragrances, artificial colors or components from petrochemicals.

Allergens

The Cosmetic Directive lists fragrance compounds that require labeling due to their known ability to cause allergic reactions (found in Annex III). This will be included in the Proposed Standard, along with labeling of FDA food allergens (e.g., peanut, soy, dairy) as listed in the Food Allergen Labeling and Consumer Protection Act of 2004⁷⁸.

78 FDA. 2004. Food Allergen Labeling and Consumer Protection Act of 2004. Accessed 6-24-10.
<http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/GuidanceComplianceRegulatoryInformation/ucm106187.htm>

Appendix A

FDA Approved Active Ingredients for Sunscreens and Sunblocks

Sunscreen Chemical	UVA or UVB Active
Aminobenzoic Acid	UVB
Avobenzone	UVA
Cinoxate	UVB
Dioxybenzone	UVA, UVB
Ecamsule (Mexoryl SX)	UVA
Ensulizole (Phenylbenzimidazole Sulfonic Acid)	UVB
Homosalate	UVB
Meradimate (Menthyl Anthranilate)	UVA
Octocrylene	UVB
Octinoxate (Octyl Methoxycinnamate)	UVB
Octisalate (Octyl Salicylate)	UVB
Oxybenzone	UVA, UVB
Padimate O	UVB
Sulisobenzene	UVA
Trolamine Salicylate	UVB
Titanium Dioxide	UVA, UVB
Zinc Oxide	UVA, UVB