April 22, 2011

STAKEHOLDER COMMENTS RECEIVED ON DRAFT FINAL STANDARD:
Green Seal™ Standard for Personal Care and Cosmetic Products, GS-50

In the final stage of developing the Green Seal Standard for Personal Care and Cosmetic Products, GS-50, registered stakeholders were invited to review the Draft Final Standard and submit comments before it was issued as a final standard. Comments from the registered stakeholders were solicited on the Draft Final Standard from March 18, 2011 until April 8, 2011.

Included in this document are the comments received on the Draft Final Standard for Personal Care and Cosmetic Products, GS-50, March 18, 2011, with responses and an explanation on how the issued standard included any corresponding modifications.

By participating in Green Seal's standard setting process, the following organizations that provided comments played an important role in Green Seal's effort to encourage the design, manufacture, and end use of environmentally superior products. Their assistance and involvement is greatly appreciated.

Participating Organizations:
Arylessence, Inc.
The Dow Chemical Company
Herban Lifestyle, LLC
L'Oreal USA

The language from the Draft Final Standard is included, followed by comments, and Green Seal's response to the comments. *Issued Standard language is provided in italics.*

General Comments:

Comment:
We are still in disagreement with the standards request to have data on everything in the formulation down to 0.01% in the undiluted formulation, even if that includes contaminants. Particularly if it is expected that to have data or some form of information on every endpoint outlined in the standard. The fundamental question is what the purpose of requesting all known constituents >0.01% may be. The manufacturer of the product is in any case legally required to assure that the product does not harm human health or the environment. It seems as if Green Seal would merely collect confidential business information which cannot be used for any further purpose as it is protected by secrecy agreements. We propose that the standard focuses on collecting information being directly relevant to its purpose of enhancing sustainability.

Response:
Green Seal requires full disclosure of the product formula for certification. This was clarified in the standard with the addition of the criterion 3.1 Formula Disclosure for Certification. Green Seal uses this information to ensure that the product meets the requirements in the standard. The criteria in the standard go above and beyond compliance to existing regulations, providing additional safeguards for human and environmental health. For example, studies have shown that contamination of personal care products with the carcinogen 1,4-dioxane is common, so Green Seal prohibits the use of the materials that typically deliver this contaminant (i.e., ethoxlyated chemicals). Such protections are important elements of product sustainability in this category since product formula (i.e., reduced toxicity) and packaging are leading environmental considerations for these products. There are several criteria in the standard that require evaluation of all known components, including fragrance components that are sometimes not even fully known by the product manufacturer. This disclosure is conducted under confidentiality agreements, often with the supplier of the raw material. Green Seal has a long track record of maintaining the confidentiality of this information, having been founded in 1989. This experience with certification also has enabled the development of a significant database of existing data on the various end-points included in the criteria in the standard. Due to this experience, the burden of providing information for all of the components in the product is minimized. Over the 20-plus years of running this program, Green Seal has found that full disclosure of the product formula and a thorough review of this formula is necessary and feasible, without compromising a company's confidentiality or resource availability. As a result, the standard will not be changed.

2.4.3 Photostability. Sunscreen products shall be tested for photostability using an objective, scientifically-validated method conducted under controlled and reproducible conditions including sun protection from UVA and UVB radiation

exposure. The sun protection of the product after at least 120 minutes of radiation exposure shall be at least 80% of the sun protection before radiation exposure.

Comment:
This should include explicit references to testing protocols, or must be more specific, especially with regard to the intensity of the radiation used in the test. For example the intensity could be defined by "UVA and UVB radiation exposure equal to that of a clear sky, mid summer day at noon at 30 degrees N latitude" or "that fraction of the radiation of a 5780 K blackbody (the blackbody temperature of the sun) that falls in the UVA and UVB radiation bands." The duration of the sun protection depends on the intensity of the UVA and UVB radiation used in the test, so that intensity needs to be specified if there is a 120 minute performance criteria.

Response:
This testing is relatively new and there isn't an accepted, standardized approach available yet. Until a standardized method is established, Green Seal will accept a range of methods provided that they appropriately address the end point (photostability). However, to ensure that the testing conditions are similar, more specificity on the testing conditions has been added accordingly:

Photostability. Sunscreen products shall be tested for photostability using an objective, scientifically-validated method conducted under controlled and reproducible conditions to measure sun protection from UVA and UVB radiation exposure that is representative of a sunny, mid-summer day at noon at sea level and up to 55° North latitude. The sun protection of the product after at least 120 minutes of radiation exposure shall be at least 80% of the sun protection before radiation exposure.

3.2 Animal Testing. Animal testing of the product or its components in order to meet the provisions in the standard is prohibited.

Non-animal (in-vitro) test results, modeling data, data from structural analogs, and other lines of evidence may also be accepted, provided that the methods are peer-reviewed, applicable, and the manufacturer provides rationale for the particular method. Specific in vitro or modeling methods may be noted in the standard, but additional options may be accepted by the certifying organization.

Further, a mixture need not be tested if existing information demonstrates that each of the applicable components complies with the criterion.

Comment:
Animal Testing - We support the use of alternative methods when available and valid, and use of read across/category approaches. However, this new appears to draft prohibit the generation of animal data to meet the provisions of the Green Seal Standard. It does not specify however if it prohibits new animal studies (conducted after a specific time) or all animal studies for whatever purpose conducted at anytime.

This implies that if you have a new ingredient, you cannot demonstrate that it has or does not have any of the properties that are not permitted since you are not able to test it! Later on in the text it states that you can use animal data on the product or the ingredients in order to characterize the hazards. However the way it is worded seems to indicate that new studies can be conducted on the product or components and this is contradictory to the opening comments on animal testing. In general, this whole section is very confusing and inconsistent.

A specific example cited in the new version states that "Animal testing of the product or its components in order to meet the provisions in the standard is prohibited." The next paragraph then states that non-animal (in vitro) test results, models, etc. MAY ALSO be accepted, implying that test data in animals will be accepted. And later states, that a "mixture need not be tested if existing information demonstrates that each of the applicable component complies with the criterion." How could a mixture or components be tested in the first place if animal testing is prohibited and alternative methods MAY be accepted?

More clarity on what exactly the standard is trying to address here is needed (e.g. what are the possibilities for using data generated for other purposes. Is this acceptable? Would you have to include a statement indicating that the data were generated for another purpose, etc). Consideration should also be given to understanding how restricting animal testing has significant implications for new products.

Response:
Green Seal will accept testing data that has been generated for other purposes, such as for regulatory purposes. There is no cut-off date for testing, since the testing ban only applies to conformance to the criteria in the standard for certification. New ingredient development should utilize the many alternatives to animal testing that can be leveraged to avoid new testing. This includes in vitro methods for most end-points and use of modeling and structural relationship evaluation for other end-points. For existing ingredients, all available data can be used to demonstrate conformance with a criterion. The use of the word "may" was used to state that Green Seal will critically evaluate any submitted data to ensure that it is appropriate and that Green Seal could reject submitted data if found to be insufficiently valid. The references within other criteria to animal tests were intended to be transparent about the types of available data that are of priority. Green Seal understands that such references have made the animal testing ban less clear. As a result, the animal testing criterion and the various criteria with such references will be adjusted in attempt to resolve this confusion, as follows (the skin and eye corrosion criterion is included below to illustrate).

Animal Testing. Animal testing of the product or its components in order to meet the provisions in the standard is prohibited.

To avoid new animal testing, existing data from previous testing will be accepted as evidence of meeting a criterion, preferably following the methods accepted by the Interagency Coordinating Committee on the Validation of Alternative

Methods or the European Centre for the Validation of Alternative Methods, unless indicated otherwise. In addition, non-animal (in-vitro) test results, modeling data, data from structural analogs, and other lines of evidence may be accepted, provided that the methods are peer-reviewed, applicable, and the manufacturer provides rationale for the particular method.

Skin and Eye Corrosion. The undiluted product shall not cause skin corrosion or cause serious eye damage. For purposes of demonstrating compliance with this requirement, data may be evaluated for each of the product's components at 0.01% or more in the undiluted product. If the components at 0.01% or more in the undiluted product are not shown to cause skin corrosion or serious eye damage at the concentrations used, then the product will not be considered to cause skin corrosion or serious eye damage, unless the product is required to be labeled as such. Further, a product is considered to cause skin corrosion or to cause serious eye damage if it has a pH of 2 or less or a pH of 11.5 or greater, unless data prove otherwise.

3.3 Acute Toxicity. The undiluted product shall not be toxic to humans. A product is considered toxic if any of the following criteria apply :

Oral lethal dose (LD50) < 5,000 mg/kg
Inhalation lethal concentration (LC50) < 200 mg/L at 1 hr
(dusts, mists and vapours)
Inhalation lethal concentration (LC50) < 20,000 ppmV at 1 hr
(gases)
Dermal lethal dose (LD50) < 2,000 mg/kg

For purposes of demonstrating compliance with this requirement, existing acute toxicity data for each of the product's components at 0.01% or more in the undiluted product may be used. This data is used to calculate a weighted average that assumes that the toxicity of the individual components is additive. The toxicity values are adjusted by the weight of the components in the product and summed using the following formula:

See standard for formula.

Where,
TP = toxicity of the product
wti = the weight fraction of the component
TV = the toxicity value for each component (LD50)
n = number of components

Inhalation toxicity shall be determined from all components at 0.01% or more in the undiluted product with a vapor pressure greater than 1 mm Hg at 1 atm pressure and 20°C.

Alternatively, toxicity shall be measured on the product as a whole. The toxicity

testing procedures should meet the requirements put forth by the Organization for Economic Co-operation and Development (OECD) Guidelines for Testing of Chemicals, or as noted in 3.2 an appropriate non-animal test. These protocols include Acute Oral Toxicity Test (TG 401, TG 420, TG 423, and TG 425 or 3T3 Neutral Red Uptake cytotoxicity assay), Acute Inhalation Toxicity Test (TG 403), and Acute Dermal Toxicity Test (TG 402).

Comment:
Last paragraph discusses conducting toxicity testing on the product as a whole and following OECD guidelines. This is contradictory to Section 3.2 which states that testing is not allowed in the first place.

Additionally, the requirement to consider all components > 0.01% in the context of acute toxicity is excessive and unnecessary to identify any hazard. It could even lead to unnecessary animal testing on components present at low concentrations which would never result in acute toxicity. We propose to adopt the approach of GHS to regard components present at > 1% as relevant and to base the assessment on >90% of the ingredients (GHS 3.1.3.3 and 3.1.3.6.3.2).

The toxicity values are adjusted by the weight of the components in the product and summed using the following formula:

Where,
TP = toxicity of the product
wti = the weight fraction of the component
TV = the toxicity value for each component (LD50)

The standards need to specify if TV is measured in mol/kg/day or mg/kg/day or some other unit. Relative ranking would change depending on molecular weight.

"Inhalation toxicity shall be determined from all components at 0.01% or more in the undiluted product with a vapor pressure greater than 1 mm Hg at 1 atm pressure and 20°C." This could be clearer and worded to indicate whether the vapor pressure criteria applies to the product, to each pure component in the product, or to the contribution each component makes to the product's total vapor pressure. Could be "Inhalation toxicity shall be determined for each pure component present at 0.01% or more in the undiluted product, if that pure component has a partial pressure greater than 1 mm Hg at the concentration that the component is present in the product and at 1 atm pressure and 20 degrees C."

Response:
The criterion is based on a weighted average of the components present at 0.01% or more. This appropriately addresses the hazard level of the mixture. For example, if a more toxic material is used at a low level and other materials are not toxic, the product may not be considered toxic – the single toxic material doesn't necessarily make the product as a whole toxic. The evaluation of components at 0.01% or more (versus 1%) is consistent with the purpose of this standard, being a leadership sustainability standard for products that are in close contact with the body for all types of individuals, including vulnerable populations. Data is

typically available to evaluate all of these materials. The units are outlined in the thresholds included in the criterion (oral evaluated as mg/kg, etc).

The language of the criterion has been adjusted to be aligned with the animal testing prohibition. In addition, the inhalation toxicity language has been adjusted to be clearer.

Acute Toxicity. The undiluted product shall not be toxic to humans. A product is considered toxic if any of the following criteria apply[1]:

Oral lethal dose (LD_{50})	*$\leq$ 5,000 mg/kg*
Inhalation lethal concentration (LC_{50}) (dusts, mists and vapours)	*$\leq$ 200 mg/L at 1 hr*
Inhalation lethal concentration (LC_{50}) (gases)	*$\leq$ 20,000 ppmV at 1 hr*
Dermal lethal dose (LD_{50})	*$\leq$ 2,000 mg/kg*

For purposes of demonstrating compliance with this requirement, existing acute toxicity data for each of the product's components at 0.01% or more in the undiluted product will be used. This data is used to calculate a weighted average that assumes that the toxicity of the individual components is additive. The toxicity values are adjusted by the weight of the components in the product and summed using the following formula:

$$TP = \left(\sum_{i=1}^{n} \frac{wt_i}{TV_i} \right)^{-1}$$

Where,
TP = toxicity of the product
wt_i = the weight fraction of the component
TV = the toxicity value for each component (LD_{50})
n = number of components

Inhalation toxicity shall be determined from all components at 0.01% or more in the undiluted product, when the component has a vapor pressure greater than 1 mm Hg at 1 atm pressure and 20°C.

3.4 Skin and Eye Corrosion and Irritation. The *undiluted product* shall not cause *skin corrosion* or cause *serious eye damage.* Further, a product is considered to cause *skin corrosion* or to cause *serious eye damage* if it has a pH of 2 or less or a pH of 11.5 or greater, unless existing or test data prove otherwise.

A product shall be evaluated for *skin corrosion* and *serious eye damage* following the testing and evaluation strategy described in the *GHS*, preferably using an in vitro test validated by the Interagency Coordinating Committee on the Validation of Alternative Methods or the European Centre for the Validation of Alternative

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[1] Products meeting the requirements in 3.3 will not fall into hazard categories 1 through 5 for acute oral and dermal toxicity and will not fall into hazard categories 1 through 4 for acute inhalation toxicity under the Globally Harmonized System for the Classification and Labeling of Chemicals (*GHS*) when the whole product is evaluated using the weighted average approach described below.

Methods. The results of other peer-reviewed or standard in vitro or in vivo test methods demonstrating that the product mixture is not corrosive will also be accepted. Testing is not required for any *components* at 0.01% or more in the *undiluted product* for which sufficient information exists.

Comment:
Skin and Eye Corrosion and Irritation – last sentence in the paragraph of each sub-section states that testing is not required when sufficient information exists. This is also contradictory to Section 3.2. Similar comment as on acute toxicity – a corrosive component present at 0.02% in a cosmetic would not trigger the cosmetic to be irritating or corrosive. The provisions of the draft standard may even trigger unnecessary animal testing. We propose to adopt the cut-off criteria of GHS for skin and eye corrosion and irritation.

Response:
Corrosion and irritation of materials is dependent on the concentration in the product and this appropriately addresses the hazard level of the mixture. For example, if a corrosive material is used at a low level (where it is not corrosive); the product may not be corrosive. The evaluation of components at 0.01% or more (versus 1%) is consistent with the purpose of this standard, being a leadership sustainability standard for products that are in close contact with the body for all types of individuals, including vulnerable populations, and data is typically available for this review. So, the GHS cut-off will not be used. The language of the criterion has been adjusted to be clearer about this and also be aligned with the animal testing prohibition.

Skin and Eye Corrosion. The undiluted product shall not cause skin corrosion or cause serious eye damage. For purposes of demonstrating compliance with this requirement, data may be evaluated for each of the product's components at 0.01% or more in the undiluted product. If the components at 0.01% or more in the undiluted product are not shown to cause skin corrosion or serious eye damage at the concentrations used, then the product will not be considered to cause skin corrosion or serious eye damage, unless the product is required to be labeled as such. Further, a product is considered to cause skin corrosion or to cause serious eye damage if it has a pH of 2 or less or a pH of 11.5 or greater, unless data prove otherwise.

3.5 Carcinogens and Reproductive Toxins. The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The product shall not contain any components known to produce or release carcinogens or reproductive toxins. An exception shall be made for titanium dioxide and essential vitamins and minerals.

Comment:
The new version of the standard introduces numerous exemptions for vitamins and minerals and specific constituents however no concentration limits are given for them –

i.e. you cannot have a reprotoxin in the formulation, but vitamins and minerals are exempt – so I can have 100% vitamin A because it is a vitamin?

Response:
Green Seal has included exceptions for essential vitamins and minerals since they are required for human health. Since the essential vitamins and minerals have established upper limits, these will be included in this exception. It is worth noting that there remains a prohibition of retinoids in sunscreen products due to photosensitivity issues. The updated criterion is as follows:

Carcinogens and Reproductive Toxins. The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The product shall not contain any components known to produce or release carcinogens or reproductive toxins. An exception shall be made for titanium dioxide. An exception shall also be made for essential vitamins and minerals, which shall not exceed the lowest tolerable upper limit in the product.

Tolerable Upper Limit. The highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population, as established by the Food and Nutrition Board, Institute of Medicine, National Academies.

Comment:
Carcinogens and Reproductive Toxins – We do wonder if cosmetic products with the GreenSeal cannot contain e.g. ethanol? There are other examples where the general exclusion of substances being designated as carcinogens or reproductive toxicants on different lists does not make any sense. This is due to the fact that those lists are based on criteria which are not necessarily useful for the GreenSeal standard. It could for example be the more sustainable solution to use bio-ethanol as solvent rather than iso-propanol in certain products. The standard should define own criteria based on the possible risk to the consumer.

Comment:
The statement should be qualified by route of exposure, for example: "The undiluted product shall not contain any components that are carcinogens or reproductive toxins via a route of exposure reasonably anticipated for the product." This qualification would allow, for example, titanium dioxide in a liquid product such as a sunscreen, since titanium dioxide is only classified as carcinogenic via inhalation. This qualification would also eliminate the need for a titanium dioxide exception.

Response:
Green Seal's standard addresses human and environmental health. As a result, prohibition of materials classified as carcinogens is aligned with the purposes of the standard. Green Seal considers a material carcinogenic based on the way it is listed by the referenced sources. For example, ethanol is a carcinogen "for alcoholic beverages" (not personal care products) by IARC. Titanium dioxide is used extensively in personal care products and is considered a preferable sunscreen active ingredient by many. Green Seal choose to include an explicit

exemption for titanium dioxide to allow for its use in these products along with protections such as not allowing sunscreens to be sold in powder or spray form. As a result, the criterion will not be changed.

3.6 Mutagens and Neurotoxins Toxins. The undiluted product shall not contain any components that have been identified as mutagens or neurotoxins toxins. An exception shall be made for essential vitamins and minerals.

Comment:
The new version of the standard introduces numerous exemptions for vitamins and minerals and specific constituents however no concentration limits are given for them – Since manganese is essential, does this mean you can have lots of manganese under this exemption even though high doses are neurotoxic?

Response:
Green Seal has included exceptions for essential vitamins and minerals since they are required for human health. Since the essential vitamins and minerals have established upper limits, these will be included in this exception. It is worth noting that there remains a prohibition of retinoids in sunscreen products due to photosensitivity issues. The updated criterion is as follows:

Mutagens and Neurotoxins/Systemic Toxins. The undiluted product shall not contain any components that have been identified as mutagens or neurotoxins/systemic toxins. An exception shall be made for essential vitamins and minerals, which shall not exceed the lowest tolerable upper limit in the product.

Tolerable Upper Limit. The highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population, as established by the Food and Nutrition Board, Institute of Medicine, National Academies.

3.7 Endocrine Disruptors. The undiluted product shall not contain any components that are on the EPA List of Chemicals for Tier 1 Screening that have been shown to disrupt hormones (e.g., have estrogen- or androgen-mediated effects), tested according to the EPA Series 890 - Endocrine Disruptor Screening Program Test Guidelines.

Comment:
The EPA List of Chemicals for Tier 1 Screening that have been shown to disrupt hormones is a good start, but there should be a more comprehensive list.

Specifically, there is growing concern that Bisphenol A and parabens (e.g., methyl, butyl, propyl, etc.) have endocrine disrupting effects in animals and humans. The European Commission is currently investigating this. This should be cause enough for concern about allowing these substances in Green Seal products. See pages 64-65 of the European

Commission's report on Endocrine Disruptors
http://ec.europa.eu/environment/endocrine/documents/bkh_report.pdf#page=76

Substances strongly suspected of hormone disruption, as outlined in the European Commission's report, should be taken into consideration.

Response:
Parabens had already been prohibited, through section 3.18. Bisphenol A is typically used in packaging and was prohibited for use in packaging (section 5.6). Bisphenol A will be added to the prohibited component list as well.

3.8 Components That Cause Asthma. The undiluted product shall not contain any components that have been identified as asthmagens. An exception shall be made for zinc oxide.

Comment:
Components that cause Asthma – AOEC list of asthmagens also includes ginseng, chamomile, tea, rosehips, sunflower, and freesia (among others), all very commonly used components in many of the personal care products covered in this standard. Henna, also listed as an asthmagen, is used as a self-tanner in natural products. It is recommended that Green Seal more closely evaluate the use of the AOEC list of asthmagens as a criterion for this standard as its use will decrease the number of ingredients generally recognized as safe, many of which are considered natural, for use in these products.

Comment:
This statement should be qualified by route of exposure, such as "The undiluted product shall not contain any components that have been identified as asthmagens via a route of exposure reasonably anticipated for the product." It does not make sense to prohibit, for example, a natural extract which may be an asthmagen by your definition, in a dermally-applied liquid product.

Response:
The standard prohibits materials that cause asthma through sensitization. So, henna, freesia, sunflower, and rosehips (among others) are not prohibited through this criterion. Further, the material form listed by the reference list (for asthma, cancer, etc) is what is prohibited. A common example is that IARC lists ethanol as a carcinogen in alcoholic beverages and since the standard is not for alcoholic beverages, ethanol is not prohibited. This same consideration is applied to asthmagens. However, while it may seem intuitive that only volatile or airborne materials cause asthma, there are materials that have caused asthma through dermal exposure. So, it would be inappropriate to limit the asthmagen prohibition across-the-board to only those materials that can be inhaled. Thus, Green Seal will continue to use reference lists and their support materials to apply the appropriate prohibitions, and the criterion will not be changed.

3.9 Respiratory Sensitization. The undiluted product shall not contain any components that have been identified as respiratory sensitizers.

Comment:
Section 3.5 – 3.9 Prohibits inclusion of any components identified as Carcinogens, Reproductive Toxins, Mutagens, Neurotoxins, Endocrine Disruptors, Asthmagens, and Respiratory Sensitizers - however no criteria or authoritative listing bodies (e.g., IARC) are identified as the source.

Response:
To make it more clear when a term has a corresponding definition in the standard, the term was italicized. The definition included the authoritative bodies used by Green Seal. For example, there was a definition for the term carcinogens that outlined the following: Substances listed as a known, probable, reasonably anticipated, or possible human carcinogen by the International Agency for Research on Cancer (IARC Groups 1, 2A, and 2B), National Toxicology Agency (NTP Groups 1 and 2), EPA Integrated Risk Information System (IRIS weight-of-evidence classifications A, B1, B2, C, carcinogenic, known/likely human carcinogen, likely to be carcinogenic to humans, and suggestive evidence of carcinogenicity or carcinogen potential), by the Occupational Safety and Health Administration (OSHA as carcinogens under 29 CFR 1910.1003(a)(1)), or under the *GHS* (hazard categories 1 (H350, may cause cancer) and 2 (H351, suspected of causing cancer)).

3.10 Skin Sensitization. The undiluted product shall not be a skin sensitizer. Acceptable data may be for the product or each of its components at 0.01% or more in the undiluted product. Testing and evaluation should follow the GHS, preferably using an in vitro test validated by the Interagency Coordinating Committee on the Validation of Alternative Methods or the European Centre for the Validation of Alternative Methods or the Local Lymph Node Assay (LLNA) or follow EPA test guidelines for skin sensitization (OECD Guideline 429, OPPTS 870.2600). Testing is not required for when sufficient information exists.

Comment:
Sensitization – same as above. The Sensitisation section still specifies the use of the LLNA even though there are other methods available and valid that should be included in the standard. Additionally, the LLNA is not the most reliable test for surfactants and published information on this point is forthcoming in the public literature. This section does not specify what to do if some minor component were a sensitizer, but it were present at a concentration not evoking any risk of sensititzation. To avoid unnecessary animal testing of finished cosmetic products, state of the art risk assessments based on the components should be permitted to be used to exclude any risk of sensitization.

Response:
Sensitization is dependent on the concentration in the product and this appropriately addresses the hazard level of the mixture. For example, if a

sensitizer is used at a low level (where it have proven to not be a sensitizer), the product may not be a sensitizer. The language of the criterion has been adjusted to be clearer on this and to also be aligned with the animal testing prohibition.

Skin Sensitization. The undiluted product shall not be a skin sensitizer. For purposes of demonstrating compliance with this requirement, data may be evaluated for each of the product's components at 0.01% or more in the undiluted product. If the components at 0.01% or more in the undiluted product are not shown to be skin sensitizers at the concentrations used, then the product will not be considered to be a skin sensitizer.

3.13.1 Total VOC Content. The *undiluted product* shall contain no more than current VOC regulatory limits of the Air Resources Board for the State of California (CARB) or the following VOC content (% by weight), whichever is more stringent:

Products	VOC Content (% by weight)
Astringent/toner	**35%**
Hair spray*, *hair shine*, and *insect repellent	**55%**
Hair styling products* not sold in *pump spray packaging	**2%**
Hair styling products* sold in *pump spray packaging	**5%**
Nail polish	**75%**
All other products	**1%**

The VOC content shall be determined either by summing the percent by weight contribution from all *components* of the product that have a vapor pressure of greater than 0.1 mm mercury at 1 atm pressure and 20°C or by the CARB Method 310 modified to not allow the exemption for *fragrances* specified under Method 310.

3.13.2 High and Medium Volatility Organic Compound Content. *Antiperspirant* and *deodorant undiluted products* shall meet current regulatory limits for *high and medium VOCs* of CARB or the following, whichever is more stringent, including not containing *components* that are *high and medium VOCs*. An exception shall be made for ethanol and colorant *components* and *fragrance* up to a combined level of 2% of product.

Comment:
Acetone is exempted from counting as VOC in the CARB antiperspirant and deodorant regulation and should be exempted in GS-50 as well.

VOCs are regulated because they participate in forming ground level ozone, a potential inhalation hazard. They are not regulated because they are "toxic". The presence of a VOC in indoor air cannot automatically be assumed to be harmful. Prohibiting compounds such as acetone in personal care and cosmetic products simply because it is a VOC can not be justified. Manufacturers take great care to ensure that uses of their cosmetics and personal care products do not result in consequential exposures.

Response:
VOCs indoors have been associated with health concerns. For example, terpenes react with ozone in the air to produce hydroxy radicals and formaldehyde that are detrimental to health by causing respiratory issues or chronic illness[2]. As a result, Green Seal's approach with VOC content limits includes indoor air and human health considerations, not just outdoor air considerations. The VOC content limits do not exclude the use of specific VOCs, like acetone - as long as a VOC can meet the other criteria in the standard and does not exceed the VOC limit, it can be used. The only specific VOCs that are prohibited are high and medium volatility organic compounds in antiperspirant and deodorant, as guided by CARB. The criterion will be updated to reflect the CARB more appropriately accordingly.

High and Medium Volatility Organic Compound Content. Antiperspirant and deodorant undiluted products shall meet the CARB Regulation for Reducing Volatile Organic Compound Emissions from Antiperspirants and Deodorants, specifically those regulations pertaining to high and medium VOCs and including the exceptions provided in the regulations.

3.14 Toxicity to Aquatic Life. The product as rinsed-off shall not be toxic to aquatic life. A substance is considered not toxic to aquatic life if it meets one or more of the following criteria :

Acute LC50 for algae, daphnia, or fish ≥100 mg/L

For purposes of demonstrating compliance with this requirement, aquatic toxicity testing is not required if sufficient aquatic toxicity data exist for each of the product's components at 0.01% or more in the product as rinsed-off, using a weighted average approach (as in section 3.3). Aquatic toxicity tests shall follow the appropriate protocols in International Organization for Standardization (ISO) 7346-2 for fish, OECD test guidance 203 for fish, OECD test guidance 201 for algae, or OECD test guidance 202 for daphnia.

Comment:
According to the standard as written, if a product has an LC50 of < 100 mg/L for two of the three species and > 100 mg/L for the third, it would pass. The standard should be more clearly written to require testing in algae and one of the other two species, and all results should be > 100 mg/L.

Also given the variability in testing procedures, the results should be expressed as +/- 25 mg/L.

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[2] Nazaroff, E., et al. 2009. Indoor Air Chemistry: Cleaning Agents, Ozone and Toxic Air Contaminants Final Report: Contract No. 01-336 for California Air Resources Board and the California Environmental Protection Agency: California Air Resources Board Research Division.

Response:
Testing variability will not be included since this isn't typical for such thresholds, for example GHS does not include such ranges. Given the lack of data for all species, one species is sufficient to demonstrate compliance to this criterion, though all of the available data (including algae) would be reviewed and if it were toxic for one it would be considered toxic. This has been clarified as follows:

Toxicity to Aquatic Life. The product as rinsed-off shall not be toxic to aquatic life. A product is considered not toxic to aquatic life if[3]*:*

Acute LC_{50} for fish, daphnia, and/or algae ≥100 mg/L

For purposes of demonstrating compliance with this requirement, data for each of the product's components at 0.01% or more in the product as rinsed-off can be used to calculate a weighted average (as in section 3.3). The preferred sources of data come from the following appropriate protocols in International Organization for Standardization (ISO) 7346-2 for fish, OEDC Test Guidance (TG) 203 for fish, OECD TG 202 for daphnia, or OECD TG 201 for algae.

3.16 Bioaccumulating Compounds. The product as rinsed-off shall not contain any components at 0.01% or more that bioaccumulate or that is known to form degradation products that bioaccumulate. A chemical is considered to bioaccumulate when it has a bioconcentration factor (BCF) ? 500 (or log Kow ?4) as determined by ASTM International (ASTM) E-1022-94 Standard Guide for Conducting Bioconcentration test with Fishes and Saltwater Bivalve Mollusks or OECD 305 Bioconcentration: Flow-through Fish Test. Additionally, the product as rinsed-off shall not be classified as H410 (Very toxic to aquatic life with long lasting effects, Hazard Category 1), H411 (Toxic to aquatic life with long lasting effects, Hazard category 2), H412 (Harmful to aquatic life with long lasting effects, Hazard category 3) or H413 (May cause long lasting harmful effects to aquatic life, Hazard Category 4) under the GHS. If the chemical meets the requirement for biodegradability, 3.15 herein, it may be considered to not bioaccumulate. Testing is not required when sufficient information exists.

Comment:
Add "If a chemical meets the requirement for biodegradability as described under section 3.15, it may be considered nonbioaccumulating."

Response:
This language had already been included in the criterion. It followed the language about chronic aquatic toxicity, which has now been removed and placed in a separate criterion as follows:

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[3] Products meeting the above will not fall into in categories 1, 2 or 3 for acute (short-term) hazards to the aquatic environment (H400, 401, and 402) under the *GHS.*

Criterion:
Chronic Aquatic Toxicity. The product as rinsed-off shall not contain any components at 0.01% or more that have chronic aquatic toxicity. The preferred sources of data are from the OECD TG 210 for fish, OECD TG 211 for daphnia, and OECD TG 201 for algae. If adequate chronic aquatic toxicity data is not available, the guidance in GHS shall be followed for classification of the chemical.

Definition:
Chronic Aquatic Toxicity. Substances that cause long-lasting adverse effects to aquatic organisms and classified in hazard categories 1 through 4 for long-term hazards to the aquatic environment (H410 through H413) under the GHS.

3.18 Prohibited Components. The undiluted product shall not contain any of the following components:

- **2-butoxyethanol**
- **Alkylphenol ethoxylates**
- **Benzophenone and its derivatives**
- **Butylated hydroxytoluene**
- **Ethoxylated chemicals**
- **Ethylene-diamine-tetra acetic acid or any of its salts**
- **Formaldehyde donors**
- **Halogenated organic solvents**
- **Hazardous air pollutants**
- **Heavy metals including, lead, hexavalent chromium, or selenium both in the elemental form or compounds**
- **Methyldibromo glutaronitrile**
- **Mercury-containing compounds**
- **Mineral oils**
- **Monoethanolamine, Diethanolamine, and Triethanolamine alone or in compounds**
- **Nitrilotriacetic acid**
- **Nitro-musks**
- **Optical brighteners**
- **Parabens**
- **Paraffin wax**
- **Petrolatum**
- **Phthalates**
- **Polycyclic musks**
- **Toxic Release Inventory Persistent, Bioaccumulative, and Toxic (TRI PBT) Chemicals**
- **Triclosan**

Comment:
We object to the use of a specific list of restricted substances – there is absolutely no justification for the inclusion of any of them. If standard intends to restrict substances

then it should outline sound arguments that are based on the criteria already outlined in the standard. If the criteria set in the standard for defining an acceptable ingredient are sufficiently robust, then a specific restricted substance list is not needed.

Comment:
3.18 – Prohibited Components – The new version does not take into account any of the comments previously submited on why some compounds on the list should not be there (e.g., APEs, Parabens etc). We again note our objection to the use of a specific list of restricted substances – there is absolutely no justification for the inclusion of any of them. If standard intends to restrict substances then it should outline sound arguments that are based on the criteria already outlined in the standard. If the criteria set in the standard for defining an acceptable ingredient are sufficiently robust, then a specific restricted substance list is not needed.

Response:
Green Seal's life cycle based approach is to minimize the use of more harmful ingredients or classes of ingredients rather than to determine at what levels they may be used safely or with an acceptable amount of risk at each stage of the life cycle. This is consistent with other ecolabel programs. The specific list of prohibited components is included in the standard since there are some hazardous materials that are not limited by the other criteria in the standard. 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 so there is limited data available for all of the chemicals used in personal care products using these tests. Since the standard outlines the criteria, not background information, rationale for the chemical on the list is not included in the standard. Green Seal provided rationale for the chemicals on the list in a background document provided with the Proposed Standard (available on the project web site).

Comment:
The "prohibited ingredient" "Hazardous Air Pollutants" requires further clarification. Different federal and state agencies have differing lists of "hazardous" air pollutants. If this is to be considered a true prohibition a list of the materials of concern needs to be supplied to the formulators who will be working to comply with this standard.

Response:
To make it clear when a term has a corresponding definition in the standard, the term was italicized. There was a definition for the term hazardous air pollutants that outlined the following (in addition, Green Seal provides links to referenced lists on its web site (the link to HAPs is included): Hazardous Air Pollutant (HAP). A substance listed by the EPA in the Clean Air Act Section 112(b) (1) as a hazardous air pollutant.

Comment:
Note that some of the terms used for 'restricted substances' describe whole classes of chemistries comprising single substances of very different toxicological profiles. The term 'heavy metals' is even undefined and should be avoided.

Response:
Heavy metals that are prohibited from this criterion are specifically listed.

Comment:
A more pragmatic approach to components that cause respiratory sensitization should be applied for the use of mono-, di-, and triethanolamine (MEA, DEA, TEA). As noted in the response to comments, it is the listing on the AOEC list that prohibits these ingredients.

Response:
MEA, DEA, and TEA are not only asthmagens, but also are known to form nitrosamines (i.e., carcinogens) in products, among other issues, and thus will continue to be prohibited.

Comment:
Please provide the rationale behind the ban of ethoxylated chemicals.

Response:
Materials that are known to be contaminated with toxic substances were prohibited. It is known that ethoxylated chemicals are commonly contaminated with 1,4-dioxane. Testing of personal care and cosmetic products has found that about one-third of products were contaminated with 1,4-dioxane[4]. 1,4-dioxane is a possible carcinogen on the IARC list (and would be prohibited if it were directly added to the product. As a result, ethoxylated chemicals will continue to be prohibited.

Comment:
A specific case in point is – the chelant EDTA. The main issue with EDTA is that it is not readily biodegrable. This raised concern in the EU relating to the possibility of that it could accumulate in the environment and possibly make heavy metals more bioavailable. Looking at the aquatic biodegradation section of the criteria, it exempts chelating agents from the need to be biodegradable, then in the restricted substances list it lists EDTA – so what exactly is the rational in this instance? More transparency is needed here.

Response:
EDTA is a strong chelator and as a result is associated with detrimental environmental impacts – such as mobilizing heavy metals in water ways. Phosphorus, also a strong chelator with detrimental environmental impacts, eutrophication, is limited in the standard as well. The biodegradability exclusion for chelators would apply to other types of chelators. EDTA will continue to be prohibited.

[4] 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

3.24 Color Components. Color components are prohibited. An exception shall be made for makeup, nail polish, and sunless tanning products.

Comment:
Color Components – Color components should not be considered "unnecessary functionally". For example color components in sunscreen aid the person who is applying the lotion in ensuring that all exposed skin is protected which in turn, enhances the effectiveness of the product in protecting against exposure that can increase a person's risk of skin cancer. Suggest that this statement be removed from the standard.

Comment:
Please define "color components." Are these all ingredients which impart color to a product? If so this is unworkable, many ingredients in cosmetic products impart color but have other functions as well. In addition, it makes no sense to prohibit "color components" only in specific categories of products and allow them in others such as makeup. Whatever rationale you used to prohibit color components in one category applies to other categories as well. Finally, since all cosmetic colorants must be approved by FDA based on their safety profile, the rationale for banning them in any category is not clear.

Response:
Green Seal's life cycle-based standards support cleaner production and green chemistry which, among other things, aim to reduce the use of unnecessary materials (of any kind, not just colors). Since colors are unnecessary functionally for many of the products in this standard the life cycle costs associated with not using them would be avoided through this prohibition. The criterion allows for the use of colors permitted by the FDA for products where the color has a functional purpose (e.g., make-up). The term color component was defined in the standard to be: Color Component. A product component that is included primarily to deliver color to the product or user. As a result, materials that may deliver color, but are used in the product primarily for another reason are permitted. Sunscreen, for example, includes titanium dioxide primarily for sun protection but it also delivers color and helps the user see where the product is being applied. Titanium dioxide is not prohibited for such a use. As a result, the criterion will not be changed.

3.25 Nanoscale Components. The use of nanoscale components shall only be permitted when the European Commission Scientific Committee on Consumer Safety (formerly known as the Scientific Committee for Consumer Products) provides an opinion that allows for their safe use for products included in the scope of this standard. If the opinion allows for the safe use of nanoscale components, then the product label shall indicate that the component is "nanoscale" or "nanoparticle" on the ingredient line.

Comment:
Nanoscale Components –Green Seal's reliance on the European Commission Scientific Committee on Consumer Safety is inappropriate. The process to form said opinion was done according to EU processes which were not open to U.S. stakeholders so that they could provide their available data and information and which have no accessible records to document the data an decision making process actually used to form the opinion. As such, the completeness and reliability of the Committee's judgment and the applicability to U.S. products cannot be judged due to the lack of transparency. Therefore, reference to non-U.S. positions should be deleted. Furthermore, the suggestion to postpone the use of nano-scale components until such a time as the SCCS publishes an opinion on the safe use of nanomaterials included within the scope of this standard is misleading and superfluous. Since the European Commission Regulation on cosmetic products (EC) No 1223/2009 not only provides a clear legal definition of a nano-material but contains provisions allowing the safe use of nano-materials in cosmetic products (Art.16).

Response:
It is acknowledged that some US companies may not participate in the EU process for review of nanoscale components. However, there is no active process in the US to review the safety of nanoscale components. The data gaps in safety of these materials are too significant to warrant allowing their use without a thorough safety review. The EU requires pre-market review of safety and issues corresponding opinions on the safety of the materials. It is worth noting that this criterion applies only to insoluble or biopersistent materials. The primary materials used in cosmetics that fall in this category are titanium dioxide and zinc oxide. Given that the EU has issued opinions already and is continually reviewing these nano materials it is relevant to continue to look to that work. If other efforts (in the US or collaborative efforts) progress, the criterion may be revised. As a result, the criterion will not be changed.

4.1 Good Manufacturing Practices (GMPs). GMPs shall be followed by law (e.g., drug products) and for all other products (e.g., non-drug products) including, but not limited to, practices for the building and facility, equipment, personnel, raw materials, production, laboratory, labeling, records, and complaints.

Comment:
Good Manufacturing Practices (GMPs) –Good Manufacturing Practices (GMP) are standard guidelines and are part of Quality Assurance. They ensure product development is carried out using safe quality processes avoiding product contamination, ensure product composition consistency and that products meet specific requirements for identity, quality, and purity. Specifically, cosmetic ingredients are typically manufactured under in facilities that have a certified quality management system in place or a management system based on ISO 9000. There is currently no legal requirement in the USA to manufacture personal care products or ingredients to GMP. It is unclear from the standard what criteria would be used to audit a facility or indeed how this could be achieved in the case of overseas manufacturers. The attributes for evaluating a facility

need to be vetted by stakeholders if the standard is ever to be considered to be a transparent standard

Response:
Green Seal's on-site audit reviews quality procedures. This has traditionally been part of the certification process without an explicit criterion in the standard. The criterion was added to the standard since the standard is often used for educational purposes and as a benchmark for companies and quality procedures should be incorporated. Green Seal does not require that the quality procedures are certificated through a program like ISO, but requires that sufficient quality procedures are in place. This typically includes such things as ensuring that there is documentation describing production methods and materials used, that records are maintained to show that products are made in accordance with documented methods and materials, and that products inspected, tested, or otherwise evaluated to ensure proper performance, among other considerations. The specific items required for Green Seal certification will be communicated to applicants during the certification process, as with all other criteria. The definition for GMP will be updated as follows:

Good Manufacturing Practices (GMP). Incorporation of quality practices and procedures, such as those included in the FDA's Inspection Operations Manual, to minimize the risk of adulterated or misbranded products.

4.2 Energy, Water, Air, and Waste. The following information shall be reported for the manufacturing processes included in the converting of the raw materials into the finished product (excluding the production of raw materials and package – it is a gate-to-gate report) on an annual basis or when any changes are made to the processes, with alternate reporting units acceptable upon approval by the certifying body:

Energy millions of British thermal unit (BTU)/ton of product
Water gallons/ton of product
Air Emissions regulated air pollutant tons/ton of product
Waste Water gallons/ton of product
Solid Waste dry ton/ton of product

Comment:
Energy, Water, Air, and Waste – Formulators may make multiple products in the same facility and not know the contribution of each product to the total units reported.

Comment:
This seems particularly onerous – the annual reporting of energy, air, water etc. The restrictions on staffing etc. Further consideration should be given to the value of including these requirements within the standard itself or whether they should be presented recommendations.

Response:
The criterion noted that alternate reporting units may be accepted. This could include total facility numbers, extrapolations from total facility numbers (e.g., a fraction of the total facility based on the production volume of the product within that facility), or other approaches. This provides flexibility to allow for existing business approaches, rather than creating new demands on resources. Responsible organizations should be able to track their use of such resources and generation of waste. As a result, the criterion will not be changed.

5.5 Heavy Metal Restrictions. Heavy metals, including lead, mercury, cadmium, and hexavalent chromium, shall not be intentionally introduced in packaging and applicators. Further, the sum of the concentration levels of these metals present shall not exceed 100 ppm by weight (0.01%); an exception is allowed for refillable packages or packages/applicators that would not exceed this maximum level but for the addition of recovered materials. Further, intentional introduction does not include the use of one of the metals as a processing aid or intermediate to impart certain chemical or physical changes during manufacturing, where the incidental retention of a residual of that metal in the final packaging/applicator or packaging/applicator component is not desired or deliberate, if the final packaging/applicator or packaging/applicator component complies with the incidental concentration restrictions of 100 ppm.

Comment:
Heavy Metal Restrictions (for packaging) – please see the previous comment that the term heavy metals is undefined. Depending on the applied definition, even glass would have >100 ppm content in heavy metals. This section should be reconsidered carefully to account for raw materials, additives and catalysts applied in the manufacture of sustainable packaging materials.

Response:
The criterion states which heavy metals are included. The criterion also states that the heavy metal limitation is applied to intentional addition of them and allows for processing aids (e.g., catalysts), provided that they are not intended to be present in the final package. As a result, the criterion will not be changed.

5.6 Other Restrictions. Phthalates, bisphenol A, and chlorinated packaging and applicator material are prohibited from being intentionally introduced; an exception is allowed for packages and applicators that would not have these added compounds but for the addition of recovered material.

Comment:
Other Restrictions – Green Seal's reliance on Health Canada's assessment of Bisphenol A is inappropriate. As noted in Health Canada's statement (October 18, 2008), "bisphenol A exposure to newborns and infants is below levels that cause effects: and that the "general public need not be concerned". Therefore, the reference should be deleted.

Response:
Its worth noting that Canada has declared that bisphenol A is harmful and is taking measures to cut its use (e.g., bans in baby bottles). Regardless, Green Seal's standards are intended to address issues above and beyond regulatory compliance. With the evidence for concern (due to endocrine disruption issues) and since there are practical alternatives for the use of bisphenol A, the precautionary approach will be taken and it will not be allowed. As a result, Green Seal will continue to prohibit the use of Bisphenol A in packaging.

6.5 Natural and Biobased Claims. Only the following natural and biobased, or related, claims are allowed when the product meets the following criteria:

•"100 percent Natural", "All Natural", "100 percent Biobased", or "All Biobased" shall only contain natural or biobased components, respectively, excluding water and with no petroleum, silicone, or synthetic components.
•"Natural" or "Biobased" products shall contain 95% natural, naturally-derived, or biobased components, respectively, excluding water and with no petroleum, silicone, or synthetic components.
•Claims on specific product components being "natural" or "biobased" may be permitted if it is a natural or biobased component.

Comment:
Natural and Biobased Claims - "100 percent natural" and "Natural" shall contain only natural or biobased components, excluding water with no petroleum, silicone or synthetic components. Why would water be excluded? And as pointed out in our last comments is not petroleum a natural product? Please address this apparent disparity in the standard.

Response:
Water is excluded from the calculation to apply an even comparison across products addressed in this standard. Some product types may have significant amounts of added water and others have no added water. By excluding water from the calculation makes sure the claim has a harmonized meaning across these products and satisfies consumer expectations. This approach is consistent with other programs that address this issue and is consistent with the approach for organic claims (i.e. the USDA NOP).

Petroleum, while derived from nature, is not renewable within the lifespan of humans and thus is traditionally not considered natural. Excluding petroleum from natural definition is consistent with other programs addressing this issue. As a result, the criterion will not be changed.

6.6 Fragrance and Allergen Labeling. The product label shall declare, separate from the ingredient line, if a fragrance has been added or if no fragrance has been added and if the product contains any allergen components.

Comment:
For consistency, Greenseal should require labeling only if the "added" allergen meets or exceeds the EU Cosmetic Labeling levels.

Comment:
Fragrance and Allergen Labelling – It may be legally difficult for a manufacturer to state that a product does not contain any 'allergen'. We suggest to delete "and if the product contains any allergen components." And insert "In case that the product contains any 'allergen' as listed by the European Commission Directive76/768/EEC, 27 July 1976 on the Approximation of the Laws of the Member States relating to Cosmetic Products (also known as the Cosmetic Directive) in Annex III or those listed by the FDA (including food allergens Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II), the product label shall include a statement " Contains …. (INCI name of substance)."

Response:
The term allergen was defined in the standard to state which materials would be considered allergens. The criterion stipulating labeling of allergens has been adjusted to be more clear that the labeling is for added allergens as follows:

Fragrance and Allergen Labeling. The product label shall declare, separate from the ingredient line, if a fragrance has been added or if no fragrance has been added and shall also indicate any allergen components in the product (e.g., Contains allergen [allergen's INCI name]).

6.11 Statement of Basis for Certification. Whenever the product claims to be certified to this standard, it shall be based on a third party certification program with an on-site auditing program, and shall state, unless otherwise approved in writing by Green Seal:

This product meets the Green Seal™ Standard for Personal Care and Cosmetic Products, GS-50, based on its reduced environmental and human health toxicity and efficient use of packaging material.

Comment:
Statement of Basis for Certification – Last sentence was changed (presumably based on our comments) from "This product meets the Green Seal Standard...based on its reduced environmental and human health toxicity and efficient use of packaging material." Reduced environmental and human health toxicity compared to what? Does this imply that if the Green Seal approved product was tested in animals (which it can't be according to the standard...) against another non-Green Seal product that it would have a more favourable toxicity profile. In reality there is probably not much basis for this assumption. It is a comparison against an unknown entity. If this was a comparison between water and product ingredients, the phrase would be false. We recommend Green Seal consult the US Federal Trade Commission (FTC) "Green Guides" for further guidance.
This statement, and the overall standard in general, still does not take into account the

exposure potential or overall risk of the product but is simply based on the hazard profile of individual (and possibly very low level) components of a product. We ask Green Seal to consider incorporating elements of exposure potential into its overall statement of basis for certification.

Response:
The statement has added more specificity as follows:

This product meets the Green Seal™ Standard for Personal Care and Cosmetic Products, GS-50, based on the use of ingredients that are not irritating to the skin and avoiding ingredients that are toxic or harmful to humans and the environment.

ANNEX A: Definitions of Terms

Comment:
Annex A, Definitions of terms
Carcinogens: Please note that GHS does not list any substances. Please replace 'National Toxicology Agency' by 'National Toxicity Program'

Response:
The GHS reference in the standard was further clarified with the following: Globally Harmonized System for the Classification and Labeling of Chemicals (GHS). The GHS established hazard classes and means for classifying substances; substance classification based on these hazard classes has been listed by the ECHA and the ex-ECB, or is disclosed on a SDS.

As a result, it is accurate and will not be changed. The NTP reference has been updated as follows:

Carcinogens. Substances listed as a known, probable, reasonably anticipated, or possible human carcinogen by the International Agency for Research on Cancer (IARC Groups 1, 2A, and 2B), National Toxicity Program (NTP Groups 1 and 2), EPA Integrated Risk Information System (IRIS weight-of-evidence classifications A, B1, B2, C, carcinogenic, known/likely human carcinogen, likely to be carcinogenic to humans, and suggestive evidence of carcinogenicity or carcinogen potential), by the Occupational Safety and Health Administration (OSHA as carcinogens under 29 CFR 1910.1003(a)(1)), or under the GHS (hazard categories 1 (H350, may cause cancer) and 2 (H351, suspected of causing cancer)).

Comment:
Component: Please define the term 'contaminant'

Response:
The term contaminant was defined with the component definition as follows, and thus does not need additional clarification: a contaminant that was not deliberately

added but is known to be present above 0.01% (100 parts per million), by weight, in the product

Comment:
Halogenated Organic Solvents: We suggest to delete astatine, which has a half life of 8h and is an extremely rare naturally occurring element, ca. 30g in the entire earth crust. It is a halogen, but will never be used in a commercial halogenated solvent.

Response:
This change has been made.

Halogenated Organic Solvents. Organic solvents containing halogens, including fluorine, chlorine, bromine, and iodine.

Comment:
Neurotoxin: the definition lacks a description of the effect or target organ itself – surely e.g. a liver toxicant is not intended to be regarded as neurotoxin.

Response:
This definition had included all target organs and as a result the term has been updated to include systemic toxins to be more accurate, as follows:

Neurotoxin/Systemic Toxin. A substance designated as producing a specific target organ toxicity arising from either single exposure or repeated exposure and thus meets the criteria for hazard categories 1 or 2 (H370, H371, H372, H373) under the GHS.

Comment:
Organic compound: organic cyanides exist – why would they be exempt?

Response:
The biodegradability exemption for organic compounds did not provide that they do not have to biodegrade, but that they must inherently be biodegradable and not be toxic during that process: An exception shall be made for *organic compounds* that do not exhibit ready biodegradability, if the compound has low aquatic toxicity (acute LC50 ≥ 100 mg/L for algae, daphnia, or fish) and exhibits inherent biodegradability per ISO test methods 9887 or 9888 or OECD 302A-C.

It is worth noting that naturally occurring substances have to meet all the criteria in the standard. Cyanide, for example, is very acutely toxic (and also absorbed through the skin and is a HAP).

Comment:
Skin sensitizer: replace ‘will’ by ‘may’

Response:
This definition is consistent with the GHS definition for this term and will not be changed as a result.

Comment:
High and Medium Volatility Organic Compounds (VOCs): The criteria "that contains 10 or less carbon atoms" should be eliminated or justified. An 11 carbon compound that meets the vapor pressure criteria should be classified with a ten carbon compound that meets the vp criteria. The definition f MVOC and HVOC in the CARB antiperspirant and deodorant regulation dose not include the 10 carbon criteria.

Response:
The definition has been updated to be consistent with CARBs definition since that is the basis for the criterion.

High and Medium Volatility Organic Compounds (VOCs). An organic compound that exerts a vapor pressure greater than 2 mm mercury at 1 atm pressure and 20ºC.

The marked up version of the issued standard follows.

GS-50

GREEN SEAL™ STANDARD FOR

PERSONAL CARE AND COSMETIC PRODUCTS

Note: Additions made to the Draft Final Standard are noted in red font in this version of the standard.

April 22, 2011

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GREEN SEAL™

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. Green Seal sets leadership standards that aim to reduce, to the extent technologically and economically feasible, the environmental, health, and social impacts throughout the life-cycle of products, services, and companies. The standards may be used for conformity assessment, purchaser specifications, and public education.

Green Seal offers certification of products, services, and companies in conformance with its standards. For additional information on Green Seal or any of its programs, contact:

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GREEN SEAL™ STANDARD FOR PERSONAL CARE AND COSMETIC PRODUCTS, GS-50

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FOREWORD

General. The final issued standard was developed in an open and transparent process with stakeholder input that included producers, users, and general interests.

The requirements in the standard are based on an assessment of the environmental, health, or social impacts associated with the products covered in the scope of the standard. The requirements included in the standard are subject to revision. Provisions for safety have not been included in this standard. This standard neither modifies nor supersedes laws and regulations. Compliance with this standard is not a substitute for, and does not assure, compliance with any applicable law or regulations. This standard (and any corresponding conformity assessment) presumes compliance with all applicable laws and regulations.

Products that are substantially similar to those covered by this standard in terms of function and life cycle considerations may be evaluated against the intent of the requirements of this standard, accounting for relevant differences between the intended scope of the standard and the actual product, service, or organization to be evaluated.

This standard may not anticipate features of the product that may significantly, and undesirably, increase its impact on the environment, health, or society. In such a situation, Green Seal will ordinarily amend its standards to account for the unanticipated environmental, health, and societal impacts.

Normative references (e.g., other standards) in this standard intend to refer to the most recent edition of the normative reference.

Edition. This version is First Edition of the standard.

Disclaimer of Liability. Green Seal™, as the developer of this standard, shall not incur any obligations or liability for any loss or damages, including, without limitation, indirect, consequential, special, or incidental damages arising out of or in connection with the interpretation or adoption of, reliance upon, or any other use of this standard by any party. Green Seal makes no express or implied warranty of merchantability or fitness for a particular purpose, nor any other express or implied warranty with respect to this standard.

Tests may be required by the standard that involve safety considerations. Adequate safeguards for personnel and property should be employed in conducting such tests.

ACRONYMS AND ABBREVIATIONS

ACGIH. American Conference of Governmental Industrial Hygienists
ANSI. American National Standards Institute
AOEC. Association of Occupational and Environmental Clinics
ASTM. ASTM International, a standard setting organization formerly known as the American Society for Testing and Materials
BCF. Bioconcentration Factor
BOD. Biochemical oxygen demand, also known as Biological Oxygen Demand
BTU. British thermal unit
CAS. Chemical Abstracts Service
CFC. Chlorofluorocarbon
CFR. Code of Federal Regulations
CO2. Carbon dioxide
DFG. German Deutche Forschungsgemeinschaft
DNA. Deoxyribonucleic acid
DOC. Dissolved organic carbon
ECHA. European Chemicals Agency
EPA. United States Environmental Protection Agency
Ex-ECB. ex-European Chemicals Bureau
FD&C. Food, Drug, and Cosmetic
FDA. The United States Food and Drug Administration
GHS. Globally Harmonized System for the Classification and Labeling of Chemicals
GMP. Good Manufacturing Practices
IARC. International Agency for Research on Cancer
IRIS. Integrated Risk Information System
INCI. International Nomenclature of Cosmetic Ingredients
ISO. International Organization for Standardization
LLNA. Local Lymph Node Assay
LOAEL. Lowest-Observed Adverse Effect Level
MAK. Maximum Allowable Concentrations
NOAEL. No-Observed Adverse Effect Level
NSF. NSF International
NTP. United States Department of Health and Human Services, Public Health Service, National Toxicology Program
OECD. Organization for Economic Co-operation and Development
OPPTS. Office of Prevention, Pesticides and Toxic Substances
OSHA. Occupational Safety and Health Administration
OTC. Over The Counter
PPM. Parts per million
SDS. Safety Data Sheet
SPF. Sun Protection Factor
ThOD. Theoretical oxygen demand
TLV. Threshold Limit Value

TRI PBT. EPA Toxic Release Inventory Persistent, Bioaccumulative, and Toxic (TRI PBT) Chemicals.
USDA. The United States Department of Agriculture
UVA. Ultraviolet A rays/radiation
UVB. Ultraviolet B rays/radiation
VOC. Volatile Organic Compound

GREEN SEAL™ STANDARD FOR PERSONAL CARE AND COSMETIC PRODUCTS, GS-50

1.0 SCOPE

This standard establishes environmental, health, and social requirements for products that are intended to enhance the appearance, cleanliness, health/well-being, and feel of the body and hair and may provide other personal care and hygiene functions. These products are left on the body and hair and include, but are not limited to: *lotions*, *hair spray*, *hair styling products*, *sunscreen*, *nail polish, insect repellant*, *makeup*, *antiperspirant*, and *deodorant*. The products are intended for use by adults, babies, and children for personal use or for institutional and professional use. See Appendix 1 for an example list of products included in this standard.

This standard excludes *fragrance products* (e.g., perfumes, colognes, body sprays), tattoo products, hair dye and hair permanent or relaxer products, oral hygiene products (e.g., mouthwash, toothpaste), or products intended to be rinsed off (e.g., soap, shampoo)[5].

This standard neither modifies nor supersedes laws and regulations. Compliance is required for all applicable laws and regulations for the manufacturing and marketing of products. Generally, the requirements included in this standard cover aspects above and beyond compliance issues.

Words and phrases described in the standard that appear in *italics* have a corresponding definition located in the definition section of the standard, Annex A.

2.0 PRODUCT-SPECIFIC PERFORMANCE REQUIREMENTS

2.1 Product Performance. The product shall demonstrate satisfactory performance for the *primary product characteristics* (see Appendix 2 for examples) following the Guidelines for Performance Testing in Annex B.

2.2 Antiperspirant. The *antiperspirant* product shall demonstrate at least a 20% reduction in sweat according to the United States Food and Drug Administration (FDA) Guidelines for Effectiveness Testing of Over-the-Counter (OTC) Antiperspirant Drug Products and meet 2.1 herein for additional *primary product characteristics*.

2.3 Insect Repellent. The product shall include *active components* that are registered with the United States Environmental Protection Agency (EPA) for use as an *insect repellent* on skin or clothing. Note that EPA may specify use levels

[5] Personal care products that are rinsed off are covered under the Green Seal Standard for Soaps, Cleansers, and Shower Products, GS-44.

or *packaging* types for registered *components*. Alternatively, *minimum risk pesticide*-based products shall demonstrate that they meet the guidance in the EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS) 810.3700 Insect Repellents for Human Skin and Outdoor Premise.

2.4 Sunscreen.

2.4.1 Sun Protection Factor (SPF). *Sunscreen* products shall achieve an SPF rating of 15 or higher tested according to 21 Code of Federal Regulations (CFR) 352 for *sunscreens*.

2.4.2 Broad Spectrum. *Sunscreen* products shall be tested according to the European Commission Recommendation of 22 September 2006 on the Efficacy of Sunscreen Products and the Claims Made Relating Thereto for *ultraviolet A (UVA)* protection achieving at least 1/3 of the SPF and at least 370 nm for the critical wavelength.

2.4.3 Photostability. *Sunscreen* products shall be tested for *photostability* using an objective, scientifically-validated method conducted under controlled and reproducible conditions to measure sun protection from *UVA* and *UVB* radiation exposure that is representative of a sunny, mid-summer day at noon at sea level and up to 55º North latitude. The sun protection of the product after at least 120 minutes of radiation exposure shall be at least 80% of the sun protection before radiation exposure.

3.0 PRODUCT-SPECIFIC SUSTAINABILITY REQUIREMENTS

3.1 Formula Disclosure for Certification. For certification to this standard, all of the formula *components* shall be disclosed to the certifying body including the chemical name, the Chemical Abstracts Service (CAS) registry number, and the levels (% by weight) of each *component* in the formula.

3.2 Animal Testing. Animal testing of the product or its *components* in order to meet the provisions in the standard is prohibited.

To avoid new animal testing, existing data from previous testing will be accepted as evidence of meeting a criterion, preferably following the methods accepted by the Interagency Coordinating Committee on the Validation of Alternative Methods or the European Centre for the Validation of Alternative Methods, unless indicated otherwise. In addition, non-animal (in-vitro) test results, modeling data, data from structural analogs, and other lines of evidence may be accepted, provided that the methods are peer-reviewed, applicable, and the manufacturer provides rationale for the particular method.

3.3 Acute Toxicity. The *undiluted product* shall not be toxic to humans. A product is considered toxic if any of the following criteria apply[6]:

Oral lethal dose (LD_{50})	≤ 5,000 mg/kg
Inhalation lethal concentration (LC_{50}) (dusts, mists and vapours)	≤ 200 mg/L at 1 hr
Inhalation lethal concentration (LC_{50}) (gases)	≤ 20,000 ppmV at 1 hr
Dermal lethal dose (LD_{50})	≤ 2,000 mg/kg

For purposes of demonstrating compliance with this requirement, existing acute toxicity data for each of the product's *components* at 0.01% or more in the *undiluted product* will be used. This data is used to calculate a weighted average that assumes that the toxicity of the individual *components* is additive. The toxicity values are adjusted by the weight of the *components* in the product and summed using the following formula:

$$TP = \left(\sum_{i=1}^{n} \frac{wt_i}{TV_i} \right)^{-1}$$

Where,
TP = toxicity of the product
wt_i = the weight fraction of the *component*
TV = the toxicity value for each *component* (LD_{50})
n = number of *components*

Inhalation toxicity shall be determined from all *components* at 0.01% or more in the *undiluted product,* when the *component* has a vapor pressure greater than 1 mm Hg at 1 atm pressure and 20°C.

3.4 Skin and Eye Corrosion and Irritation.

3.4.1 Skin and Eye Corrosion. The *undiluted product* shall not cause *skin corrosion* or cause *serious eye damage.* For purposes of demonstrating compliance with this requirement, data may be evaluated for each of the product's *components* at 0.01% or more in the *undiluted product*. If the *components* at 0.01% or more in the *undiluted product* are not shown to cause *skin corrosion* or *serious eye damage* at the concentrations used, then the product will not be considered to cause *skin corrosion* or *serious eye damage*, unless the product is required to be labeled as such. Further, a product is considered to cause *skin corrosion* or to cause *serious eye damage* if it has a pH of 2 or less or a pH of 11.5 or greater, unless data prove otherwise.

[6] Products meeting the requirements in 3.3 will not fall into hazard categories 1 through 5 for acute oral and dermal toxicity and will not fall into hazard categories 1 through 4 for acute inhalation toxicity under the Globally Harmonized System for the Classification and Labeling of Chemicals (*GHS*) when the whole product is evaluated using the weighted average approach described.

3.4.2 Skin Irritation. The *undiluted product* shall not cause *skin irritation*. For purposes of demonstrating compliance with this requirement, data may be evaluated for each of the product's *components* at 5% or more in the *undiluted product*. If the *components* at 5% or more in the *undiluted product* are not shown to cause *skin irritation* at the concentrations used, then the product will not be considered to cause *skin irritation*.

3.5 Carcinogens and Reproductive Toxins. The *undiluted product* shall not contain any *components* that are *carcinogens* or *reproductive toxins*. The product shall not contain any *components* known to produce or release *carcinogens* or *reproductive toxins*. An exception shall be made for titanium dioxide. An exception shall also be made for essential vitamins and minerals, which shall not exceed the lowest *tolerable upper limit* in the product.

3.6 Mutagens and Neurotoxins/Systemic Toxins. The *undiluted product* shall not contain any *components* that have been identified as *mutagens* or *neurotoxins/systemic toxins*. An exception shall be made for essential vitamins and minerals, which shall not exceed the lowest *tolerable upper limit* in the product.

3.7 Endocrine Disruptors. The *undiluted product* shall not contain any *components* that are on the EPA List of Chemicals for Tier 1 Screening that have been shown to disrupt hormones (e.g., have estrogen- or androgen-mediated effects), tested according to the EPA Series 890 - Endocrine Disruptor Screening Program Test Guidelines.

3.8 Components That Cause Asthma. The *undiluted product* shall not contain any *components* that have been identified as *asthmagens*. An exception shall be made for zinc oxide.

3.9 Respiratory Sensitization. The *undiluted product* shall not contain any *components* that have been identified as *respiratory sensitizers*.

3.10 Skin Sensitization. The *undiluted product* shall not be a *skin sensitizer*. For purposes of demonstrating compliance with this requirement, data may be evaluated for each of the product's *components* at 0.01% or more in the *undiluted product*. If the *components* at 0.01% or more in the *undiluted product* are not shown to be *skin sensitizers* at the concentrations used, then the product will not be considered to be a *skin sensitizer*.

3.11 Skin Absorption. The *undiluted product* shall not contain *components* present at greater than or equal to 1% in the product, that are listed on the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit value (TLV) carrying a skin notation, or substances that are listed on the German Deutche Forschungsgemeinschaft (DFG) maximum allowable

concentrations (MAK) list with a skin absorption H notation. Further, the product shall not contain *components* at 0.01% or more in the *undiluted product* that sum to 1% in the formula that are listed on ACGIH or DFG with the same target organ.

3.12 Ozone Depleting Compounds. The *undiluted product* shall not contain any *components* that are *ozone-depleting compounds*.

3.13 Volatile Organic Compound (VOC) Content.

3.13.1 Total VOC Content. The *undiluted product* shall contain no more than current VOC regulatory limits of the Air Resources Board for the State of California (CARB) or the following VOC content (% by weight), whichever is more stringent:

Products	VOC Content (% by weight)
Astringent/toner	35%
Hair spray, *hair shine*, and *insect repellent*	55%
Hair styling products not sold in *pump spray packaging*	2%
Hair styling products sold in *pump spray packaging*	5%
Nail polish	75%
All other products	1%

The VOC content shall be determined either by summing the percent by weight contribution from all *components* of the product that have a vapor pressure of greater than 0.1 mm mercury at 1 atm pressure and 20ºC or by the CARB Method 310 modified to not include the exemption for *fragrances* specified under Method 310.

3.13.2 High and Medium Volatility Organic Compound Content. *Antiperspirant* and *deodorant undiluted products* shall meet the CARB Regulation for Reducing Volatile Organic Compound Emissions from Antiperspirants and Deodorants, specifically those regulations pertaining to *high and medium VOCs* and including the exceptions provided in the regulations.

3.14 Toxicity to Aquatic Life. The *product as rinsed-off* shall not be toxic to aquatic life. A product is considered not toxic to aquatic life if[7]:

Acute LC_{50} for fish, daphnia, and/or algae ≥100 mg/L

[7] Products meeting the above will not fall into in categories 1, 2 or 3 for acute (short-term) hazards to the aquatic environment (H400, 401, and 402) under the *GHS*.

For purposes of demonstrating compliance with this requirement, data for each of the product's *components* at 0.01% or more in the *product as rinsed-off* can be used to calculate a weighted average (as in section 3.3). The preferred sources of data come from the following appropriate protocols in International Organization for Standardization (ISO) 7346-2 for fish, OEDC Test Guidance (TG) 203 for fish, OECD TG 202 for daphnia, or OECD TG 201 for algae.

3.15 Aquatic Biodegradability. Each of the individual *organic compounds* at 0.01% or more in the *product as rinsed-off* shall exhibit ready biodegradability in accordance with the OECD definition, expect for polymers, chelating agents, and colorants. Biodegradability shall be measured according to any of the following methods: ISO 7827, 9439, 10707, 10708, 9408, 14593; OECD Methods 301A – F; or OECD 310. Specifically, within a 28-day test, the *organic compounds* shall meet one of the following criteria within 10 days of the time when biodegradation first reaches 10%:

- Removal of Dissolved Organic Carbon (DOC) > 70%
- Biochemical Oxygen Demand (BOD) > 60%
- % of BOD of Theoretical Oxygen Demand (ThOD) > 60%
- % CO2 evolution of theoretical > 60%

Testing is not required when sufficient information exists. Per OECD guidance the 10-day window requirement does not apply to structurally-related surfactant homologues. For *organic compounds* at 0.01% or more in the *product as used* that do not exhibit ready biodegradability in these tests the manufacturer may demonstrate biodegradability in sewage treatment plants using the Coupled Units Test found in OECD 303A by demonstrating DOC removal > 90%.

An exception shall be made for *organic compounds* that do not exhibit ready biodegradability, if the compound has low aquatic toxicity (acute LC50 ≥ 100 mg/L for algae, daphnia, and/or fish) and exhibits inherent biodegradability per ISO test methods 9887 or 9888 or OECD 302A-C.

3.16 Bioaccumulating Compounds. The *product as rinsed-off* shall not contain any *components* at 0.01% or more that bioaccumulate or that are known to form degradation products that bioaccumulate. A chemical is considered to bioaccumulate when it has a bioconcentration factor (BCF) ≥ 500 (or log K_{ow} ≥4). The preferred source of data is from OECD TG 305 (for BCF). If the chemical meets the requirement for biodegradability, 3.15 herein, it may be considered to not bioaccumulate.

3.17 Chronic Aquatic Toxicity. The *product as rinsed-off* shall not contain any components at 0.01% or more that have *chronic aquatic toxicity*. The preferred sources of data are from OECD TG 210 for fish, OECD TG 211 for daphnia, or OECD TG 201 for algae. If adequate *chronic aquatic toxicity* data is

not available, the guidance in *GHS* shall be followed for classification of the chemical.

3.18 Eutrophication. The *undiluted product* shall not contain phosphorus at more than 0.2% by weight.

3.19 Prohibited Components. The *undiluted product* shall not contain any of the following *components*:

- 2-butoxyethanol
- Alkylphenol ethoxylates
- Benzophenone and its derivatives
- Bisphenol A
- Butylated hydroxytoluene
- Ethoxylated chemicals
- Ethylene-diamine-tetra-acetic acid or any of its salts
- Formaldehyde donors
- *Halogenated organic solvents*
- *Hazardous air pollutants*
- Heavy metals including, lead, hexavalent chromium, or selenium both in the elemental form or compounds
- Methyldibromo glutaronitrile
- Mercury-containing compounds
- Mineral oils
- Monoethanolamine, Diethanolamine, and Triethanolamine alone or in compounds
- Nitrilotriacetic acid
- Nitro-musks
- *Optical brighteners*
- Parabens
- Paraffin wax
- Petrolatum
- Phthalates
- Polycyclic musks
- Toxic Release Inventory Persistent, Bioaccumulative, and Toxic (TRI PBT) Chemicals
- Triclosan

3.20 Makeup and Nail Polish Lead Contamination Limits. The lead content of *undiluted makeup* and *nail polish products* shall not exceed 0.05 parts per million (ppm).

3.21 Sunscreen.

3.21.1 Enhanced Sensitivity to UV. *Sunscreen* products shall not contain *components* that are known to enhance the skin's sensitivity to UV radiation including, but not limited to, *alpha hydroxy acids* and *retinoids*.

3.21.2 Product Form. *Sunscreen* products shall not be sold as powders or in *pump spray packages*.

3.22 Insect Repellent. *Insect repellent* shall not be combined into *sunscreen* products (or vice versa).

3.23 Fragrances. All *fragrance components* shall have been produced and handled following the code of practice of the International Fragrance Association (IFRA).

3.24 Biocides. The use of *biocides* for purposes other than preservation of the product is not allowed. Documentation and testing results shall be provided to demonstrate the dosage necessary to preserve the product. An exception shall be made for *deodorant* and *antiperspirant* products such that they are permitted to include *biocides* for purposes other than preservation.

3.25 Color Components. *Color components* are prohibited. An exception shall be made for *makeup*, *nail polish*, and *sunless tanning products*.

3.26 Nanoscale Components. The use of *nanoscale components* shall only be permitted when the European Commission Scientific Committee on Consumer Safety (formerly known as the Scientific Committee for Consumer Products) provides an opinion that allows for their safe use for products included in the scope of this standard. If the opinion allows for the safe use of *nanoscale components*, then the product label shall indicate that the *component* is "nanoscale" or "nanoparticle" on the ingredient line.

4.0 MANUFACTURING SUSTAINABILITY REQUIREMENTS

4.1 Good Manufacturing Practices (GMPs). *GMP*s shall be followed including, but not limited to, practices for the building and facility, equipment, personnel, raw materials, production, laboratory, labeling, records, and complaints.

4.2 Energy, Water, Air, and Waste. The following information shall be reported for the manufacturing processes included in the converting of the raw materials into the finished product (excluding the production of raw materials and package – it is a gate-to-gate report) on an annual basis or when any changes are made to the processes, with alternate reporting units acceptable upon approval by the certifying body:

Report	Units
Energy	millions of British thermal unit (BTU)/ton of product
Water	gallons/ton of product
Air Emissions	regulated air pollutant tons/ton of product
Waste Water	gallons/ton of product
Solid Waste	dry ton/ton of product

4.3 Distribution. To the extent feasible, the distance and mode of transportation of raw materials (including packaging) and finished products shall be documented.

4.4 Social Responsibility. Documentation shall be provided that product production meets the following social responsibility requirements:

4.4.1 Freedom of Association and Collective Bargaining. Workers shall have the right to join or form trade unions of their own choosing and their right to bargain collectively shall be recognized and respected. An exception shall be made for inmate workers.

4.4.2 Freedom of Labor. There shall not be forced or bonded labor or use of *child labor*.

4.4.3 Freedom from Discrimination. There shall not be discrimination in terms of race, color, sex, religion, age, disability, gender, marital status, sexual orientation, union membership, political opinion, national extraction or social origin such that it affects the opportunity or treatment in employment and there shall be no support or tolerance of corporal punishment, physical or verbal coercion, sexual or other harassment, intimidation or exploitation.

4.4.4 Occupational Health and Safety. A safe and hygienic workplace environment shall be provided with access to potable water. Adequate steps shall be taken to minimize the hazards of the workplace and workers shall receive health and safety training to prevent accidents and injury.

4.4.5 Conditions of Employment. Workers shall work under fair conditions of employment. Wages, working hours and overtime shall meet at a minimum the national legal or industry benchmark standard and regular employment shall be provided.

5.0 PACKAGING SUSTAINABILITY REQUIREMENTS

5.1 Source Reduction in Packaging. The *primary* and *secondary packaging* shall be at least one of the following:

- *Source-reduced package*
- *Recyclable* and contain at least 25% *post-consumer material* or demonstrate that efforts were made to use the maximum available *post-consumer material* in the *package*
- *Packaging* with an effective *take-back program*
- Contain at least 50% *post-consumer material*
- An alternative approach may be acceptable that has been independently proven to have a similar life cycle benefit as at least two of the above approaches for a substantial majority of communities

5.2 Disposable Wipes. Products may contain disposable towelettes or other disposable wiping materials if they are made from 100% renewable materials including, but not limited to cellulosic materials, and meet the state-of-the-art amount of recovered material content.

5.3 Concentrated Product Packaging. *Concentrates* are prohibited from being *packaged* in ready-to-use forms, including but not limited to *pump spray packages*.

5.4 Aerosol Packaging. Aerosol *packages* are prohibited.

5.5 Pump Spray Packaging. *Pump spray packages* are prohibited for *antiperspirants*, *deodorants*, *sunless tanning products*, and *sunscreen products*.

5.6 Heavy Metal Restrictions. Heavy metals, including lead, mercury, cadmium, and hexavalent chromium, shall not be *intentionally introduced* in *packaging* and *applicators*. Further, the sum of the concentration levels of these metals present shall not exceed 100 ppm by weight (0.01%); an exception is allowed for refillable *packages* or *packages*/*applicators* that would not exceed this maximum level but for the addition of recovered materials. Further, *intentional introduction* does not include the use of one of the metals as a processing aid or intermediate to impart certain chemical or physical changes during manufacturing, where the incidental retention of a residual of that metal in the final *packaging*/*applicator* or *packaging*/*applicator component* is not desired or deliberate, if the final *packaging*/*applicator* or *packaging*/*applicator component* complies with the incidental concentration restrictions of 100 ppm.

5.7 Other Restrictions. Phthalates, bisphenol A, and chlorinated *packaging* and *applicator* material are prohibited from being intentionally introduced; an exception is allowed for *packages* and *applicators* that would not have these added compounds but for the addition of recovered material.

6.0 COMMUNICATION AND LABELING REQUIREMENTS

6.1 Ingredient Line. The label on each package shall list the product ingredients using the naming convention of the International Nomenclature of Cosmetic Ingredients (INCI) in order of predominance. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations of more than 1 %. The general term 'fragrance' may be used for *fragrance components*, however a list of *fragrance components* shall be made available to users in an easily accessible means, such as the company website or through customer service.

6.1.1 Nanoscale Component Labeling. Products that contain *nanoscale components* shall indicate that the *component* is "nanoscale" or "nanoparticle" on the ingredient line.

6.1.2 Consumer Communication. The product ingredient line (6.1 herein) shall be made available to consumers in an easily accessible means besides the label on each *package*, such as the company website.

6.2 Efficacy Labeling.

6.2.1 Antiperspirant Efficacy Labeling. The product shall meet the requirements for a claim made on *antiperspirant* effectiveness (e.g., extra-effective, enhanced duration) according to the FDA Guidelines for Effectiveness Testing of OTC Antiperspirant Drug Products.

6.2.2 Insect Repellent. The label for *insect repellent* products shall indicate the *protection time* as determined by the EPA OPPTS 810.3700 Insect Repellents for Human Skin and Outdoor Premise.

6.2.3 Sunscreen Efficacy Labeling. The label for *sunscreen* products is permitted to claim "broad spectrum" since it meets appropriate performance requirements (2.4.2 herein).

6.3 Antimicrobial Claims. The product shall make no *antimicrobial*, *disinfecting*, *antiseptic*, or *sanitizing* product claims. An exception shall be made for *deodorant* and *antiperspirant* products.

6.4 Organic Claims. Organic claims shall only be based on *certified-organic component* content and shall be supported with documentation that they meet the United States Department of Agriculture (USDA) National Organic Program, programs determined to be equivalent by or have recognition agreements with the USDA National Organic Program, or meet the NSF International (NSF)/American National Standards Institute (ANSI) 305 standard.

6.5 Natural and Biobased Claims. Only the following *natural* and *biobased*, or related, claims are allowed when the product meets the following criteria:

- "100 percent Natural", "All Natural", "100 percent *Biobased*", or "All *Biobased*" shall only contain *natural* or *biobased components*, respectively, excluding water, and with no petroleum, silicone, or *synthetic components*.
- "Natural" or "*Biobased*" products shall contain 95% *natural*, *naturally-derived*, or *biobased components*, respectively, excluding water, and with no petroleum, silicone, or *synthetic components*.
- Claims on specific product *components* being "natural" or "*biobased*" may be permitted if it is a *natural* or *biobased component*.

6.6 Fragrance and Allergen Labeling. The label for each *package* shall declare, separate from the ingredient line, if a *fragrance* has been added or if no *fragrance* has been added and shall also indicate any *allergen components* in the product (e.g., Contains allergen [allergen's INCI name]).

6.7 Use Labeling. The product shall be accompanied by detailed instructions for proper use to maximize product performance and minimize waste.

6.8 Precautionary Statements. Products that contain *components* that are known to enhance the skin's sensitivity to UV radiation including, but not limited to, *alpha hydroxy acids* and *retinoids* shall include a labeling statement about the increased risk of sun damage possible when exposed to sun. Further, statements about protecting the skin from the sun shall be included on the label such as, but not limited to: staying out the sun as much as possible, wearing protective clothing, and using *sunscreen* appropriately, such as the language in the FDA Guidance: Labeling for Cosmetics Containing Alpha Hydroxy Acids.

6.9 Disposal Labeling. The label shall include proper disposal instructions including clear *package* recycling instructions, if applicable.

6.9.1 Plastic Labeling. If plastic, the *packaging* shall be marked with the appropriate Society of the Plastics Industry symbol to identify the type of plastic for recycling. If the symbol is in a conspicuous location, the appropriate qualification of recyclability is required such as "this product may not be recyclable in your area, see if accepted by your local program" or "only a few communities accept this package for recycling, check with your local program."

6.10 Small Packages. *Packages* containing less than one-eighth fluid ounce (or equivalent for other product forms) is exempt from labeling on the label for each *package* the information included in the following provisions herein: 6.1 Ingredient Line; 6.8 Precautionary Statements. However, all of the information from these provisions shall be available to the consumer through other means (e.g., website).

6.11 Statement of Basis for Certification. Whenever the product claims to be certified to this standard, it shall be based on a *third-party certification program* with an on-site auditing program, and shall state, unless otherwise approved in writing by Green Seal:

> This product meets the Green Seal™ Standard for Personal Care and Cosmetic Products, GS-50, based on the use of ingredients that are not irritating to the skin and avoiding ingredients that are toxic or harmful to humans and the environment.

ANNEX A
Normative

Definitions of Terms
(Note: the defined terms are italicized throughout the standard)

Active Component. A *component* in a product that provides, or partly provides, the *primary product characteristic*.

Allergen. Allergenic substances listed by the European Commission Directive76/768/EEC, 27 July 1976 on the Approximation of the Laws of the Member States relating to Cosmetic Products (also known as the Cosmetic Directive) in Annex III and those listed by the FDA (including food allergens Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II).

Alpha Hydroxy Acid. Substances that are organic carboxylic compounds substituted with a hydroxyl group on the adjacent carbon. This includes, but is not limited to, glycolic acid, lactic acid, malic acid, citric acid, and tartaric acid. These may be *natural* or *synthetic*.

Antimicrobial. Substances that are intended to kill or inhibit the growth of microorganisms including *antiseptic*, *disinfectant*, and *sanitizer* substances.

Antiperspirant. A product that is applied topically to the body that reduces the production of perspiration at that site. These products are regulated as *drugs* by the FDA. These products may also function as *deodorants*.

Antiseptic. Substances that are intended to prevent or arrest the growth of microorganisms.

Applicator. An item included in the *packaging* that is intended to be used to apply the product on the body or hair. It is typically, but not necessarily, a separate item in the *package*. This includes, but is not limited to, brushes, sponges, and swabs. This does not include tubes or bottles that can be used to apply the product (e.g., lip products). While the applicator may be part of the *primary package* (e.g., *nail polish*, mascara), for the purposes of this standard it is not considered *primary packaging*. An exception is for pencil-like products (e.g., eye liner), the material in direct contact with the product is considered the applicator and any material used around this is considered either *primary* or *secondary packaging*.

Asthma. Asthma is a chronic inflammatory disorder of the airways that impairs breathing. Asthma affects children and adults, may be intermittent or persistent, and is further classified as mild, moderate, or severe. The chronic inflammation associated with variable airflow obstruction commonly causes difficulty breathing, coughing, wheezing, shortness of breath, and/or chest pain. Symptoms may resolve completely between active

episodes. Symptoms may occur during exposure, immediately after exposure, or up to 24 hours later in a "late phase," frequently interrupting sleep.

Asthmagens. Substances designated as *asthma* causing agents by the Association of Occupational and Environmental Clinics (AOEC), which after review by AOEC have met the AOEC sensitization criteria.

Astringent/Toner. A product applied to the skin for the purpose of cleaning or tightening pores and are not rinsed off of the skin. This category does not include any hand, face, or body cleaner or soap products that are rinsed off of the body**.**

Biobased. The content of a product that is from biological products or renewable materials, forestry, or agricultural materials (including plant, animal, and marine materials).

Biocide. Substances intended 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.

Carcinogens. Substances listed as a known, probable, reasonably anticipated, or possible human carcinogen by the International Agency for Research on Cancer (IARC Groups 1, 2A, and 2B), National Toxicology Program (NTP Groups 1 and 2), EPA Integrated Risk Information System (IRIS weight-of-evidence classifications A, B1, B2, C, carcinogenic, known/likely human carcinogen, likely to be carcinogenic to humans, and suggestive evidence of carcinogenicity or carcinogen potential), by the Occupational Safety and Health Administration (OSHA as carcinogens under 29 CFR 1910.1003(a)(1)), or under the *GHS* (hazard categories 1 (H350, may cause cancer) and 2 (H351, suspected of causing cancer)).

Certified-Organic Components. *Components* certified as organic (by meeting the USDA organic standards) by a USDA-accredited certifying agent or programs determined to be equivalent by or have recognition agreements with the USDA National Organic Program.

Child Labor. The minimum age for admission to employment as outlined in the Convention Concerning Minimum Age for Admission to Employment such as, but limited to, a minimum age not less than 15 or the age of completion of compulsory schooling in the country of production, whichever is older, and for work that is likely to jeopardize health, safety, and morals of young persons the minimum age not less than 18.

Chronic Aquatic Toxicity. Substances that cause long-lasting adverse effects to aquatic organisms and classified in hazard categories 1 through 4 for long-term hazards to the aquatic environment (H410 through H413) under the *GHS*.

Color Component. A product *component* that is included primarily to deliver color to the product or user.

Component. A deliberate addition to the product added at any level or a contaminant that was not deliberately added but is known to be present above 0.01% (100 parts per million), by weight, in the product. Naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered components if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 CFR Part 141.

Concentrate. A product, as sold, that must be diluted with water prior to its intended use.

Deodorant. A product that is applied topically to the body to reduce the body odor caused by the bacterial breakdown of perspiration.

Disinfectant. An *antimicrobial* agent intended to and capable of destroying pathogenic and potentially pathogenic microorganisms on inanimate surfaces.

Drug. The Federal Food, Drug and Cosmetic (FD&C) Act defines drugs, in part, by their intended use, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease" and "articles (other than food) intended to affect the structure or any function of the body of man or other animals" [FD&C Act, sec. 201(g)(1)].

Fragrance. An additive, often (but not limited to) a multi-*component* additive, used for the purpose of imparting or neutralizing a scent in the product.

Fragrance Product. Products with the primary function of imparting and diffusing a fragrant odor, such as, but not limited to, perfumes, colognes, and body sprays. These products are typically highly volatile. For the purposes of this standard, skin care, *deodorant*, and *antiperspirant* products are not considered fragrance products.

Globally Harmonized System for the Classification and Labeling of Chemicals (GHS). The GHS established hazard classes and means for classifying substances; substance classification based on these hazard classes has been listed by the ECHA and the ex-ECB, or is disclosed on a SDS.

Good Manufacturing Practices (GMP). Incorporation of quality practices and procedures, such as those included in the FDA's Inspection Operations Manual, to minimize the risk of adulterated or misbranded products.

Hair Shine Product. A product designed for the primary purpose of creating a shine when applied to the hair.

Hair Styling Product. A product that is designed or labeled for the application to wet, damp, or dry hair to aid in defining, shaping, lifting, styling, and sculpting of the hair. This also includes leave-in volumizers, detanglers, and conditioners that make styling claims.

Hair Spray. A product that is applied to styled hair, and is designed or labeled to provide sufficient rigidity, to hold, retain, and finish the style of the hair for a period of time.

Halogenated Organic Solvents. Organic solvents containing halogens, including fluorine, chlorine, bromine, and iodine.

Hazardous Air Pollutant (HAP). A substance listed by the EPA in the Clean Air Act Section 112(b) (1) as a hazardous air pollutant.

High and Medium Volatility Organic Compounds (VOCs). An *organic compound* that exerts a vapor pressure greater than 2 mm mercury at 1 atm pressure and 20ºC.

Insect Repellent. A product that is intended to be applied to the skin, hair, or clothing to help reduce exposure to insects or prevent insect bites.

Intentional Introduction. The act of deliberately utilizing a material in the formation of a *package* or *packaging component* where its continued presence is desired in the final *package* or *packaging component* to provide a specific characteristic, appearance, or quality.

Lotion. Products that are left on the body to enhance the appearance or feel of the body including, but not limited to: creams, moisturizers, powders, serums, oils, and sprays for use on the face and neck, body, hand, cuticle, foot, and hair.

Makeup. Products that are applied topically and are used to temporarily color and enhance the appearance of facial and body features. Lip balm may be considered makeup if it has colorant *components* intended to temporarily color or enhance the appearance of the lips.

Minimum Risk Pesticide. A special class of pesticides (including *insect repellents*) that are not subject to federal registration requirements through the EPA because they meet specific requirements under section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), including, but not limited to, that the *components*, both active and inert, are demonstrably safe for the intended use.

Mutagen. A substance designated as known to induce, be regarded as if it induces, or which causes concern for humans owing to the possibility that it may induce heritable mutations in the germ cells of humans and thus meets the criteria for hazard categories 1 and 2 (H340 and 341) under the GHS.

Nail Polish. Products that are applied to and form a film on the nail. They are used to color the nails, harden the nails, protect the nails, or nail treatments to address specific nail conditions, such as peeling or brittleness. These products may include top coats and base coats and may also be referred to as lacquers or enamels.

Nanoscale Component. Insoluble or biopersistent *components* that are intentionally manufactured to be roughly 1 to 100 nanometers in size in at least one dimension externally or within the internal structure (i.e., primary particle). This size typically enables novel applications that a larger-sized version of the *component* could not achieve.

Natural Components. *Components* that come from materials found in nature including mineral, forestry, agricultural, or biological materials such as, but not limited to, animal products produced by the animal but not part of the animal; they do not contain petroleum or petroleum-derived compounds; they do not contain transgenic hybrid organisms (inserted deoxyribonucleic acid (DNA) that originated in a different species); they have been processed without irradiation; and they are not chemically altered.

Naturally-Derived Components. *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 (examples of potentially acceptable processes are included in Appendix 3).

Neurotoxin/Systemic Toxin. A substance designated as producing a specific target organ toxicity arising from either single exposure or repeated exposure and thus meets the criteria for hazard categories 1 or 2 (H370, H371, H372, H373) under the *GHS*.

Optical Brighteners. Additives designed to enhance the appearance of colors and whiteness in materials by absorbing ultraviolet radiation and emitting blue radiation. These compounds are also known as fluorescent whitening agents.

Organic Compound. Any member of a large class of chemical compounds whose molecules contain carbon, with the exception of carbides, carbonates, cyanides, diamond and graphite.

Ozone-Depleting Compounds. A compound with an ozone-depletion potential greater than 0.01 (Chlorofluorocarbon - CFC 11=1) according to the EPA list of Class I and Class II Ozone-Depleting Substances or any substances or mixtures falling into hazard category 1 (H420) under the *GHS*.

Package/Packaging. This includes the *applicator*, *primary package*, and any *secondary package* used for the product. It does not include case or shipping material.

Photostability. The ability of a product to retain its initial level of sun protection efficacy after *ultraviolet A and B (UVA and UVB*) radiation exposure.

Post-Consumer Material. Material that would otherwise be destined for solid waste disposal, having completed its intended end-use and product life cycle. Post-consumer material does not include materials and by-products generated from, and commonly reused within, an original manufacturing and fabrication process.

Primary Package. A *package* that is the material physically containing and typically coming into contact with the product. This does not include the cap or lid of a bottle. Product *applicators* are not considered part of the primary *package*.

Primary Product Characteristics. The main function for which the product category is intended for use. See Appendix 2 for an example list of primary product characteristics of products included in this standard.

Product As Rinsed-Off. The dilution of the product for removal from the body at a rate of 5 ml per liter of water, or equivalent measure for another product form (e.g., solid, foam).

Protection Time. The time from application of the *insect repellent* to the time until the first bite or until the repellent no longer reduces bites by 95%, as determined by the EPA Office of Prevention, Pesticides and Toxic Substances (OPPTS) 810.3700 Insect repellents for human skin and outdoor premise. This is the period of time a repellent is expected to remain effective. For ticks and chiggers, this refers to the period between the time of application of the repellent to time of a tick or chigger crawling onto human skin.

Pump Spray. A *package* that dispenses the product through a nozzle after a pump was triggered. It does not require a pressurized propellant to dispense the product.

Recyclable. The *package* can be collected in a substantial majority of communities, separated or recovered from the solid waste stream and used again, or reused in the manufacture or assembly of another *package* or product through an established recycling program.

Reproductive Toxin. A substance listed as a reproductive toxin (including developmental, female, and male toxins) by the State of California under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Code of Regulations, Title 22, Division 2, Subdivision 1, Chapter 3, Sections 1200, et. Seq., also known as Proposition 65) or a substance designated as hazard category 1 (H360), known or presumed reproductive toxicant, category 2 (H362), suspected human reproductive toxicant, or having adverse effects on or via lactation (H362), under the *GHS*.

Respiratory Sensitizer. A substance designated as leading to hypersensitivity of the airways following inhalation of the substance from human evidence or appropriate animal test and thus meets the hazard criteria for category 1 (H334) under the *GHS*.

Retinoids. Vitamin A (all-*trans*-retinol; retinol), its metabolites, analogues, and derivatives. This includes, but is not limited to, retinyl palmitate, retinol, retinaldehyde, and retinoic acid. These may be *natural* or *synthetic*.

Sanitizer. A product intended to reduce the level of microorganisms present to acceptable levels established by federal or provincial health authorities.

Secondary Packaging. *Packaging* used to contain *primary package/s* and typically used for merchandizing. This does not include case or shipping packaging or the *primary package*, cap, or lid.

Serious Eye Damage. The production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application. Identified under hazard category 1 for serious eye damage/eye irritation (H318) by the *GHS*.

Skin Corrosion. The production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia, and scars. Identified under hazard categories 1A, 1B or 1C for skin corrosion/irritation (H314) by the *GHS*.

Skin Irritation/Irritant. The production of reversible damage to the skin following the application of a test substance for up to 4 hours. Identified under hazard categories 2 or 3 for skin irritation/mild skin irritation (H315 and H316) by the *GHS.*

Skin Sensitizer. A substance that will lead to an allergic response following skin contact. Identified under hazard category 1 for skin sensitization (H317) under the *GHS.*

Source-Reduced Package. A *package* that has at least 20% less material (by weight) compared to containers commonly used for that product type.

Sunscreen. Products that intend to protect the body from UV radiation by absorbing, scattering, or reflecting radiation.

Sunless Tanning Product. Products applied to the skin to produce an effect similar in appearance to a traditional suntan without exposure to UV radiation. These products are also known as self-tanning products.

Synthetic Component. *Components* that are created artificially rather than naturally or from *natural components*. For the purposes of this standard*, naturally-derived components* are not considered synthetic *components*.

Take-Back Program. A program sponsored by the original product manufacturer that has been demonstrated to receive at least 50% of sold containers for recycling or reuse.

Third-Party Certification Program. A program without any financial interest or stake in the sales of the product or service being certified, or other conflict of interest. There must be a standard to base the certification upon and the standard must be appropriate and meaningful for its intended purpose. The standard must be publically available and developed with stakeholder input. Certification to the standard must be completed by an

independent party (e.g., not the manufacturer of the product being certified), include site inspections and have a monitoring program to verify ongoing compliance.

Tolerable Upper Limit. The highest level of daily nutrient intake that is likely to pose no risk of adverse health effects to almost all individuals in the general population, as established by the Food and Nutrition Board, Institute of Medicine, National Academies.

Toxic Release Inventory Persistent, Bioaccumulative, and Toxic (TRI PBT) Chemicals. The chemicals listed by the EPA on the Toxic Release Inventory (TRI) as Persistent, Bioaccumulative, and Toxic (PBT) Chemicals.

Undiluted Product. The most concentrated form of the product produced by the manufacturer for distribution outside its facility.

Ultraviolet A (UVA). A type of solar radiation within the region of the electromagnetic spectrum from 320 to 400 nanometers (nm) that penetrate deep within the skin causing damage.

Ultraviolet B (UVB). A type of solar radiation within the region of the electromagnetic spectrum from 290 to 320 nm that cause redness and burning of the skin.

ANNEX B
Normative

Guidelines for Performance Testing

The product shall demonstrate satisfactory performance, which includes at a minimum the *primary product characteristics* (see Appendix 2 for examples). Testing may be completed through one of the following means:

1. A quality test using an objective, scientifically-validated method conducted under controlled and reproducible conditions. This may be conducted by the manufacturer or an external laboratory that has ISO 9001 registration or equivalent quality control verification.

2. A comparative test demonstrating performance equivalent to or better than a market-leading product in its product category. This may be conducted by the manufacturer or an external laboratory that has ISO 9001 registration or equivalent quality control verification.

3. A consumer-based product comparison test. The test shall have a minimum of ten (10) panelists that may be internal or external to the organization, but should maintain a neutral position (i.e., chosen at random). The consumers shall be surveyed about the product's efficacy compared to a market-leading product. A summary of conclusions and a description of how panelists are chosen shall be submitted. The following are some example questions that could be used:

1. How well does the product perform in comparison with the market-leading product with regard to *primary product characteristics*?
2. How does the condition of the hair and/or skin feel after use in comparison with the market-leading product?

APPENDIX 1
Informational

Examples of products included and excluded in the scope of GS-50

Products included in GS-50	Products excluded from GS-50
• Aftershave • *Astringent/toner* • Cleaning wipes that don't require rinsing after use • Cuticle cream, *lotion*, and oil • *Deodorant* and *antiperspirant* • *Hair shine products* • *Hair spray* • *Hair styling products* (e.g., balm, gel, mousse) • *Insect repellents* • Leave-on hair conditioner • Lip products • *Makeup* and bronzers (e.g., foundation, concealer, bronzer, mascara, eyeliner, eye shadow, blush) • Massage oil • *Nail polish* • Skin care products (e.g., *lotions*, moisturizers, creams, oils, serums) • *Sunless tanning products* • *Sunscreen*	• Artificial nails, glues, and removers • Artificial lashes • Bubble bath and bath salts (covered in GS-44) • Exfoliant products (if rinsed off, covered in GS-44) • Feminine deodorant • *Fragrance Products*/perfume and body spray • Hair dye, color, and bleach • Hair relaxants • Hand sanitizers • Nail polish remover • Oral care products (toothpaste) • Products intended to be edible • Shaving cream, gel, and foam (covered in GS-44) • Soap and cleansers(covered in GS-44) • Tattoos

APPENDIX 2
Informational

Examples of *primary product characteristics*.

Antiperspirant: Meet FDA guidelines for standard effectiveness of sweat reduction, malodor reduction

Deodorant: Malodor reduction

Hair Spray: Quick drying, hold power, removability (brushing, shampooing)

Hair Styling Products: Styling power, removability (brushing, shampooing)

Insect Repellent: Meet the EPA guidelines for Insect Repellents for Human Skin and Outdoor Premise.

Lotions: Hydration, smoothness/softness

Makeup: Last, removability

Nail Polish: Quick drying, nail appearance, durability

Sunless Tanning Products: Suntan appearance

Sunscreen: SPF, *UVA* protection, broad UV protection, *photostability*

Refer to the European Cosmetics Association, COLIPA "Guidelines for the Evaluation of the Efficacy of Cosmetic Products", May 2008 for information on test design and data evaluation.

APPENDIX 3
Informational

Examples of Potentially Acceptable Processing Methods of *Naturally-Derived Components* (which must also meet all the requirements in the standard)

- Esterification, Etherification, and Transesterification (to produce esters and ethers like polyglycerols)
- Glucosidation (to produce glucosides)
- Hydrogenation (of fats and oils)
- Hydrolysis and Hydrogenolysis (to produce hydrolyzed proteins, glycerin and fatty acids, and fatty alcohols)
- Other Condensation Reactions like Acylation of proteins and Sulfation of fatty alcohols
- Saponification (to produce soap)