



THE MARK OF ENVIRONMENTAL RESPONSIBILITY

## **GS-50**

**PROPOSED GREEN SEAL™ STANDARD FOR  
PERSONAL CARE AND  
COSMETIC PRODUCTS**

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## **GREEN SEAL™**

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## 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  
**CFC.** Chlorofluorocarbon  
**CFR.** Code of Federal Regulations  
**CO<sub>2</sub>.** Carbon dioxide  
**DFG.** German Deutsche Forschungsgemeinschaft  
**DNA.** Deoxyribonucleic acid  
**DOC.** Dissolved organic carbon  
**EPA.** United States Environmental Protection Agency  
**FD&C.** Food, Drug, and Cosmetic  
**FDA.** The United States Food and Drug Administration  
**GHS.** Globally Harmonized System for 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.** National Toxicology Agency  
**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  
**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

## PROPOSED 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, moisturizers, oils, powders, creams, hair spray, hair styling products, sunscreen, nail polish, insect repellent, makeup, antiperspirant, and deodorant. The products are intended for use by adults, babies, children, and animals in residential homes or for institutional and professional use. See Appendix A for an example list of products included in this standard.

This standard excludes fragrance products (see definition herein), 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)<sup>1</sup>.

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.

### 2.0 DEFINITIONS

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

**2.2 Allergen.** Allergenic substances listed by the European Commission Directive 76/768/EEC, 27 July 1976 on the Approximation of the Laws of the Member States relating to Cosmetic Products (also known as the Cosmetic Directive) in Annex III and those listed by the United States Food and Drug Administration (FDA) (including food allergens Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II)).

**2.3 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.

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<sup>1</sup> Personal care products that are rinsed off are covered under the Green Seal Standard for Soaps, Cleansers, and Shower Products, GS-44.

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

**2.5 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.

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

**2.7 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 but is considered a component of the package. 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.

**2.8 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.

**2.9 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.

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

**2.11 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.

**2.12 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 Agency

(NTP Groups 1 and 2), United States Environmental Protection Agency Integrated Risk Information System (EPA 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 Code of Federal Regulations (CFR) 1910.1003(a)(1)), or under the Globally Harmonized System for Classification and Labeling of Chemicals (GHS Hazard Categories 1 (H350, may cause cancer) and 2(H351, suspected of causing cancer)).

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

**2.14 Component.** A deliberate addition to the product, where it is added for its continued presence in the final product to provide a specific characteristic, appearance, or quality. Naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered intentional components if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 CFR Part 141.

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

**2.16 Contaminant.** A substance in the product that was not added for its functionality, but is known to be present. Naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered contaminants if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 CFR Part 141

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

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

**2.19 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)].

**2.20 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.

**2.21 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.

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

**2.23 Haber's Rule.** For a given toxic gas, the concentration of the gas multiplied by the duration of exposure equals a constant ( $C \times t = k$ ); for example, doubling the concentration will halve the time for a given toxic effect.

**2.24 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.

**2.25 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.

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

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

**2.28 Ingredient.** Any component of a product that is intentionally added or known to be a contaminant that comprises at least 0.01% by weight of the product.

**2.29 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.

**2.30 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.

**2.31 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.

**2.32 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 ingredients, both active and inert, are demonstrably safe for the intended use.

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

**2.34 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.

**2.35 Nanoscale Component.** Components that are roughly 1 to 100 nanometers in size in at least one dimension. This size typically enables novel applications that a larger-sized version of the component could not achieve.

**2.36 Natural Components.** Components that come from materials found in nature including mineral, forestry, agricultural, or biological materials; do not contain transgenic hybrid organisms (inserted deoxyribonucleic acid (DNA) that originated in a different species); have been processed without irradiation; and are not chemically altered.

**2.37 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 B).

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

**2.39 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.

**2.40 Organic Components.** Components certified as organic (by meeting the United States Department of Agriculture (USDA) organic standards) by a USDA-accredited certifying agent.

- 2.41 Organic Compound.** A substance that contains a carbon atom.
- 2.42 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 Category 1 (H420), hazardous to the ozone layer, under GHS.
- 2.43 Package.** This includes the applicator, primary package, and any secondary package used for the product. It does not include case or shipping material.
- 2.44 Photostability.** The ability of a product to retain its initial level of efficacy after ultraviolet A and B (UVA and UVB) radiation exposure.
- 2.45 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.
- 2.46 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.
- 2.47 Primary Product Function.** The main use/s for which the product category is intended to be used. See Appendix C for an example list of primary product functions of products included in this standard.
- 2.48 Product As Used.** The amount of product needed, as directed by the product label or other applicable manufacturer instructions, for use. If dilution with water is needed for use, this shall be done in unheated tap water.
- 2.49 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.
- 2.50 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.

**2.51 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.

**2.52 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 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 GHS.

**2.53 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 criteria for category 1 (H334) under the GHS.

**2.54 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.

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

**2.56 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.

**2.57 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.

**2.58 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.

**2.59 Skin Irritation.** The production of reversible damage to the skin following the application of a test substance for up to 4 hours.

- 2.60 Skin Sensitizer.** A substance that will lead to an allergic response following skin contact.
- 2.61 Source-Reduced Package.** A package that has at least 20% less material (by weight) compared to containers commonly used for that product type.
- 2.62 Sunscreen.** Products that intend to protect the body from UV radiation by absorbing, scattering, or reflecting radiation.
- 2.63 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.
- 2.64 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.
- 2.65 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.
- 2.66 Toxic Release Inventory Persistent, Bioaccumulative, and Toxic (TRI PBT) Chemicals.** The chemicals listed by the EPA on the Toxic Release Inventory as Persistent, Bioaccumulative, and Toxic (PBT) Chemicals.
- 2.67 Undiluted Product.** The most concentrated form of the product produced by the manufacturer for distribution outside its facility.

### 3.0 PRODUCT-SPECIFIC PERFORMANCE REQUIREMENTS

- 3.1 Product Performance.** The product shall perform as well as or better than a conventional, nationally-recognized product in its category that provides a similar function with similar use directions using an objective, scientifically-validated method conducted under controlled and reproducible conditions. The testing protocol shall include, at a minimum, the primary product function/s (see Appendix C for examples) and the body or hair condition after use. Conclusions shall be derived from at least six separate samples, including how panelists were chosen (if applicable).

**3.2 Antiperspirant.** The product shall demonstrate at least a 20% reduction in sweat according to the FDA Guidelines for Effectiveness Testing of Over-the-Counter (OTC) Antiperspirant Drug Products and meet 3.1 herein for additional primary product functions.

**3.3 Insect Repellent.** The product shall include active components that are registered with the EPA for use as an insect repellent on skin or clothing. Note that EPA may specify use levels or packaging types for registered components. Alternatively, minimum risk pesticide-based products shall demonstrate that they meet the guidance in the EPA OPPTS 810.3700 Insect Repellents for Human Skin and Outdoor Premise.

**3.4 Sunscreen.**

**3.4.1 Sun Protection Factor (SPF).** Sunscreen products shall meet the regulatory requirements in 21 CFR 352 for sunscreens including SPF and achieve a rating of 15 or higher.

**3.4.2 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 UVA protection achieving at least 1/3 of the SPF and for critical wavelength achieving at least 370 nm.

**3.4.3 Photostability.** Sunscreen products shall be tested for photostability using an objective, scientifically-validated method conducted under controlled and reproducible conditions including UVA and UVB radiation exposure. The photostability of the product after at least 120 minutes of radiation exposure shall be at least 80% of the product before radiation exposure.

**4.0 PRODUCT-SPECIFIC SUSTAINABILITY REQUIREMENTS**

**4.1 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 (LD <sub>50</sub> )  | ≤ 5,000 mg/kg          |
| Inhalation lethal concentration (LC <sub>50</sub> )<br>(dusts, mists and vapours) | ≤ 200 mg/L at 1 hr     |
| Inhalation lethal concentration (LC <sub>50</sub> )<br>(gases)                    | ≤ 20,000 ppmV at 4 hrs |
| Dermal lethal dose (LD <sub>50</sub> )  | ≤ 2,000 mg/kg          |

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. These protocols include Acute Oral Toxicity Test (TG 401), Acute Inhalation Toxicity Test (TG 403), and Acute Dermal Toxicity Test (TG 402). Products meeting the above requirements will not fall into hazard categories 1 through 5<sup>2</sup> for acute oral and dermal toxicity and will not fall into hazard categories 1 through 4<sup>3</sup> for acute inhalation toxicity under the GHS when the whole product is evaluated using the weighted average approach described below.

For purposes of demonstrating compliance with this requirement, acute toxicity testing is not required if sufficient acute toxicity data exist for each of the product's ingredients to demonstrate that the product mixture complies, using a weighted average approach that assumes that the toxicity of the individual ingredients is additive. The toxicity values are adjusted by the weight of the ingredient 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<sub>i</sub> = the weight fraction of the ingredient

TV = the toxicity value for each ingredient (LD<sub>50</sub>)

n = number of ingredients

Inhalation toxicity shall be determined from all ingredients with a vapor pressure greater than 1 mm Hg at 1 atm pressure and 20°C.

## 4.2 Skin and Eye Corrosion and Irritation.

**4.2.1 Skin and Eye Corrosion.** The *undiluted* product shall not be corrosive to the skin or cause serious eye damage as defined by the GHS. The product, or each of its ingredients, shall not fall into Hazard Categories 1A, 1B or 1C for Skin Corrosion/Irritation (H314, "Causes severe skin burns and eye damage") and shall not fall into Hazard Category 1 for Serious Eye Damage/Eye Irritation (H318, "Causes Serious Eye Damage") by the GHS.

Additionally, a product is considered corrosive or irritating to the skin 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.

<sup>2</sup> Testing in animals in Category 5 ranges (2,000-5,000 mg/kg body weight) is discouraged and should only be considered when there is a strong likelihood that the results would have a direct relevance to the protection of human health.

<sup>3</sup> The OECD Task Force on Harmonization of Classification and Labeling (HCL) did not include numerical values for inhalation toxicity Category 5, May be harmful if inhaled, but instead specified doses "equivalent to the range of 2000-5000 mg/kg bodyweight by the oral or dermal route.

A product shall be evaluated for skin corrosion and 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 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 ingredient for which sufficient information exists.

**4.2.2 Skin Irritation.** The *undiluted* product shall not be irritating to the skin. The product shall not be considered a skin irritant or fall into category 2 or 3 for skin irritation/mild skin irritation (H315 and H316) by the GHS, under the following scenarios:

- if test data shows that the whole-product is not a skin irritant,
- if test data shows that each ingredient present at or above a concentration of 5% is not a skin irritant, or
- if test data shows that any known skin irritants are non irritating when present at 5% or greater in the product.

A product shall be evaluated for skin irritation 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 Methods. The results of other peer-reviewed or standard *in vitro* or *in vivo* test methods demonstrating that the product mixture is not irritating will also be accepted. Testing is not required for any ingredient for which sufficient information exists.

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

**4.4 Mutagens and Neurotoxins.** The *undiluted* product shall not contain any ingredients or components that have been identified as mutagens or neurotoxins.

**4.5 Endocrine Disruptors.** The *undiluted* product shall not contain any ingredients or components that are on the EPA Final List of Chemicals for Initial Tier 1 Screening or the European Commission Endocrine Disruptor Priority List 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.

**4.6 Components That Cause Asthma.** The *undiluted* product shall not contain any ingredients or components that have been identified as asthmagens.

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

**4.8 Skin Sensitization.** The *undiluted* product shall not be a skin sensitizer, as tested by the Local Lymph Node Assay (LLNA) or following EPA test guidelines for skin sensitization (OECD Guideline 429, OPPTS 870.2600). The results of other standard test methods, such as the guinea pig maximization test (OECD Guideline 406) or the Buehler test (OECD 406), will be accepted as proof that the product in its most concentrated form is not a skin sensitizer when data from LLNA tests are not available. Any new product or ingredient testing should use the LLNA. Testing is not required for any ingredient for which sufficient information exists. Products meeting the above requirement will not fall into Category 1 for Skin Sensitization under the GHS.

**4.9 Skin Absorption.** The *undiluted* product shall not contain ingredients, 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 Deutsche Forschungsgemeinschaft (DFG) maximum allowable concentrations (MAK) list with a skin absorption H notation. Further, the product shall not contain ingredients that sum to 1% in the formula that are listed on ACGIH or DFG with the same target organ.

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

**4.11 Volatile Organic Compound (VOC) Content.**

**4.11.1 Total VOC Content.** The *undiluted* product shall contain no more than 1% of VOC content for all products except for the following:

- Hair spray and insect repellent, with no more than 55% of VOC content
- Hair styling products not sold in pump spray packaging, with no more than 2% of VOC content
- Hair styling products sold in pump spray packaging, with no more than 5% of VOC content
- Nail polish products, with no more than 75% of VOC content

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 California Air Resources Board Method 310 modified to not allow the exemption for fragrances specified under Method 310.

**4.11.2 High and Medium Volatility Organic Compound Content.**

Antiperspirant and deodorant *undiluted* product shall not contain components that are high and medium volatility organic compounds, including any organic compound that contain less than 10 carbon atoms per molecule and that exerts a vapor pressure greater than 2 mm mercury at 1 atm pressure and 20°C. An exception shall be made for ethanol and colorant components and fragrance up to a combined level of 2% of product.

**4.12 Chronic Inhalation Toxicity.** The product shall meet either 4.12.1 or 4.12.2.

**4.12.1** The product *as used* shall not contain ingredients with a vapor pressure above 1 mm mercury at 1 atm pressure and 20° C that cause chronic inhalation toxicity as evidenced by either of the following:

- Listed by the European Chemicals Bureau as R48/23: Danger of serious damage to health by prolonged exposure through inhalation.
- Categorized under the GHS in Category 1 Specific organ toxicity, repeated inhalation exposure (H372). Substances that have produced significant toxicity in humans or that, on the basis of evidence from studies in experimental animals can be presumed to have the potential to produce significant toxicity in humans following repeated exposure via inhalation. Based on the criteria set forth in the GHS, significant toxic effects observed in a 90-day repeated dose study conducted in experimental animals and seen to occur at or below the following values warrant classification in category 1:

| <b>Route of Exposure</b>           | <b>Units</b>  | <b>Guidance values<br/>(dose/concentration)</b> |
|------------------------------------|---------------|---|
| Inhalation (rat) gas               | ppmV/6h/d     | ≤50   |
| Inhalation (rat)<br>vapour         | mg/liter/6h/d | ≤0.2  |
| Inhalation (rat)<br>dust/mist/fume | mg/liter/6h/d | ≤0.02   |

- Classified as producing significant toxic effects in mammals from repeated inhalation exposure at or below 1.0 mg/L as a vapor according to OECD Harmonized Integrated Classification System for Human Health and Environmental Hazards of Chemical Substances and Mixtures. For the purposes of this standard, significant toxic effects in mammals from repeated inhalation exposure at or below 1.0

mg/L as a vapor shall be established by a No-Observed Adverse Effect Level (NOAEL), based on a test duration of 90 days at 6 hours per day; values from other exposure regimes shall be estimated (extrapolated) per the principles of Haber’s rule. In lieu of a NOAEL, the Lowest-Observed Adverse Effect Level (LOAEL) can be used with a ten-fold safety factor (i.e., LOAEL/10).

**4.12.2.** The product *as used* shall meet the inhalation criteria and as tested according to the method used for the GREENGUARD Children and Schools Certification for Cleaners and Cleaning Maintenance Products and Systems, which includes office, school, and restroom models (also called the GREENGUARD Standard Method for Measuring and Evaluating Chemical Emissions from Cleaners and Cleaning Maintenance Systems Using Dynamic Environmental Chambers).

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

Acute LC<sub>50</sub> 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 ingredients to demonstrate that the product mixture complies, using a weighted average approach (as in section 4.1). 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. 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.

**4.14 Aquatic Biodegradability.** Each of the individual organic compounds in the product at 0.01% or more *as used* shall exhibit ready biodegradability in accordance with the OECD definition. 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 ingredient 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%
- % CO<sub>2</sub> evolution of theoretical > 60%

Per OECD guidance the 10-day window requirement does not apply to structurally-related surfactant homologues. For organic compounds 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 natural components that does not exhibit ready biodegradability if it does not have acute aquatic toxicity <100 mg/L (according to 4.13 herein).

**4.15 Bioaccumulating Compounds.** The product *as used* shall not contain any ingredients that bioaccumulates or that forms degradation products that bioaccumulates. A chemical is considered to bioaccumulate when it has a bioconcentration Factor (BCF) greater than 100 (or log BCF >2) as determined by ASTM E-1022-94(2007) Standard Guide for Conducting Bioconcentration test with Fishes and Saltwater Bivalve Mollusks or OECD 305 Bioconcentration: Flow-through Fish Test. If the chemical meets the requirement for biodegradability, 4.14 herein, it may be considered to not bioaccumulate. Testing is not required for any ingredient for which sufficient information exists.

Additionally, the product *as used* 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.

An exception shall be made for natural components that does not exhibit ready biodegradability if it does not have acute aquatic toxicity <100 mg/L (according to 4.13 herein).

**4.16 European Commission Cosmetic Directive.** The product shall be in compliance with the ingredient/composition requirements of the European Commission Directive 76/768/EEC, 27 July 1976 on the Approximation of the Laws of the Member States relating to Cosmetic Products (also known as the Cosmetic Directive). This includes, but is not limited to the colorants (Annex IV)), preservatives (Annex VI), and UV filters (Annex VII) that are allowed, prohibition of components (Annex II), and opinions from the European Commission Scientific Committee on Consumer Safety (formerly known as the Scientific Committee for Consumer Products). Note that the US regulations and other criteria in this standard may be stricter, and thus would take precedence.

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

- 2-butoxyethanol
- Alkylphenol ethoxylates
- Benzophenones and its derivatives
- Butylated hydroxytoluene

- Ethoxylated chemicals
- Ethylene diaminetetra-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
- Methylidibromo glutaronitrile
- Mercury-containing compounds
- Mineral oils
- Monoethanolamine, Diethanolamine, and Triethanolamine alone or in compounds
- Nitrilotriacetic acid
- Nitro-musks
- Optical brighteners
- Parabens
- Paraffin wax
- Petrolatum
- Phosphorus-containing chemicals
- Phthalates
- Polycyclic musks
- TRI PBT chemicals
- Triclosan

#### **4.18 Makeup and Nail Polish Heavy Metal Limits.**

**4.18.1 Lead Limits.** The *undiluted* makeup and nail polish products shall be tested for lead content and shall not exceed 0.05 parts per million (ppm).

**4.18.2 Other Heavy Metal Limits.** The *undiluted* makeup and nail polish products shall be tested for the following heavy metals and not exceed the following limits:

- Arsenic: 0.5 ppm
- Cadmium: 0.1 ppm
- Mercury: 0.2 ppm
- Antimony: 0.5 ppm

#### **4.19 Sunscreen.**

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

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

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

**4.21 Fragrances.** All fragrance components shall be disclosed to the certifying body. Any fragrances used shall have been produced and handled following the code of practice of the International Fragrance Association. The product shall declare any fragrances on the product label in the ingredient line (see 7.6 herein).

**4.22 Biocides.** The use of biocides for purposes other than preservation of the product is not allowed. Documentation, testing results, must 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.

**4.23 Color Components.** Color components are prohibited. An exception shall be made for makeup, nail polish, and sunless tanning products using color components permitted by the FDA for such use and meet the criteria herein.

**4.24 Nanoscale Components.** The use of insoluble nanoscale components shall only be permitted when the European Commission 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.

**4.25 Animal Testing.** To discourage animal testing, the results of past peer reviewed or standard tests demonstrating compliance with a criterion will be accepted. A mixture need not be tested if existing information demonstrates that each of the ingredients complies with a criterion. Additionally, non-animal (in-vitro) test results, modeling data, or data from structural analogs may be accepted, provided that the methods are peer-reviewed, applicable, and the manufacturer provides rationale for the particular method.

## 5.0 MANUFACTURING SUSTAINABILITY REQUIREMENTS

**5.1 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.

**5.2 Energy, Water, 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) on an annual basis or when any changes are made to the processes:

- Energy: millions of British thermal unit (BTU)/ ton of final product
- Water: gallons/ton of final product
- Waste water: gallons/ton of final product
- Solid waste: dry ton/ton of final product

**5.3 Distribution.** To the extent feasible, the distance and mode of transportation of raw materials (including packaging) and finished products shall be documented. If the distance and mode of transport of all raw materials (including packaging) is not known, this shall be documented with improved data precision each year until it is complete.

**5.4 Social Responsibility.** Documentation must be provided that the production of the product meets the following social responsibility requirements:

**5.4.1 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.

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

**5.4.3 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.

**5.4.4 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.

**5.4.5 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.

## 6.0 PACKAGING SUSTAINABILITY REQUIREMENTS

**6.1 Source Reduction in Packaging.** The primary and secondary packaging shall be either 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

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

**6.3 Aerosol Packaging.** Aerosol packages are prohibited.

**6.4 Pump Spray Packaging.** Pump spray packages are prohibited for antiperspirants, deodorants, and sunless tanners.

**6.5 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.

**6.6 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.

## 7.0 COMMUNICATION AND LABELING REQUIREMENTS

**7.1 Ingredient Line.** The product shall list the product components using the naming convention of the International Nomenclature of Cosmetic Ingredients (INCI) in order of predominance. The general term 'fragrance' may be used for

fragrance components. The product shall also follow any additional labeling regulations that apply to that product.

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

**7.1.2 Consumer Communication.** The product ingredient line (7.1 herein) shall be made available to consumers in an easily accessible means besides the product package, such as the company website.

**7.2 Efficacy Labeling.** The product shall be tested and only make proven claims about efficacy such that the claims are truthful and not misleading.

**7.2.1 Antiperspirant Efficacy Labeling.** The product shall meet the requirements for the claim made on antiperspirant effectiveness according to the FDA Guidelines for Effectiveness Testing of OTC Antiperspirant Drug Products.

**7.2.2 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.

**7.2.3 Sunscreen Efficacy Labeling.** The label for sunscreen products shall meet regulatory requirements (including, but not limited to, optional claims that are regulated like water resistance) and the label is permitted to claim “broad spectrum” since it meets appropriate performance requirements (3.4.2 herein).

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

**7.4 Organic Claims.** Organic claims shall only be based on organic component content and shall be supported with documentation that they meet the USDA National Organic Program or meet the NSF International (NSF)/ANSI 305 standard.

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

- “100 percent Natural,” “All Natural,” “100 percent Biobased,” or “All Biobased” shall only contain natural or biobased components, respectively, with no synthetic, petroleum, silicone, or artificial components.

- "Natural" or "Biobased" products shall contain 95% natural, naturally-derived, or biobased components, respectively, with no synthetic, petroleum, silicone, or artificial components.
- Claims on specific product ingredients being "natural" or "biobased" may be permitted if it is a natural or biobased component.

**7.6 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.

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

**7.8 Precautionary Statements.** Products that contain ingredients 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 statement on the product label 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.

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

**7.9.1 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 "may be recyclable, see if accepted by your local program" or "only a few communities accept this package for recycling, check with your local program."

**7.10 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 use of substances hazardous to the environment and human health and new packaging material.

## Appendix A

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

### Products included in GS-50

- Aftershave
- Deodorant and antiperspirant
- Cuticle cream, lotion, and oil
- Hair spray
- Hair styling products (balm, gel, mousse,)
- Insect repellents
- Leave on hair conditioner
- Lip products
- Makeup and bronzers
- Massage oil
- Nail polish
- Skin care products (e.g., lotions, moisturizers, creams, oils)
- Sunless tanner
- Sunscreen

### Products excluded from GS-50

- Bubble bath and bath salts (covered in GS-44)
- Exfoliant products (if rinsed off, covered in GS-44)
- Feminine deodorant
- Fragrances/perfume and body spray
- Hair dye
- Hair relaxants
- Nail polish remover
- Oral care products (toothpaste)
- Products intended to be edible
- Shaving cream, gel, and foam (covered in GS-44)
- Soap, cleansers, and toners (covered in GS-44)
- Tattoos

## Appendix B

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)

## Appendix C

Examples of primary product function.

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.

Makeup: Body or hair appearance, last, removability

Moisturizers: Hydration, smoothness/softness

Nail Polish: Quick drying, nail appearance, durability

Sunless Tanner: Suntan appearance

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