



THE MARK OF ENVIRONMENTAL RESPONSIBILITY

# GS-44

## **GREEN SEAL® STANDARD FOR SOAPS, CLEANSERS, HAND SANITIZERS, AND SHOWER PRODUCTS**

**EDITION 4.3**

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**GREEN SEAL®**

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# GREEN SEAL STANDARD FOR SOAPS, CLEANSERS, HAND SANITIZERS, AND SHOWER PRODUCTS, GS-44

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## FOREWORD

**Edition.** Edition 4.3 was issued on June 23, 2022. It replaces Edition 4.2 from September 10, 2020. Corrections and/or clarifications were last made to this standard on October 29, 2021. Information on changes made to this standard can be found on Green Seal's website.<sup>1</sup>

**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, services, or organizations covered in the scope of the standard. These requirements are subject to revision, and generally cover aspects above and beyond regulatory compliance. This standard neither modifies nor supersedes laws and regulations. Any conformity assessment to this standard requires compliance with all applicable laws and regulations for the manufacturing and marketing of the products.

Provisions for safety have not been included in this standard, since they are supervised by regulatory agencies. Adequate safeguards for personnel and property should be employed for all stages of production, and for all tests that involve safety considerations.

Products, services, or organizations 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 a feature 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 a standard to account for the unanticipated environmental, health, or societal impacts.

Normative references (e.g., other standards) in this standard intend to refer to the most recent edition of the normative reference. Test methods may be required for product evaluation. Unless explicitly stated that a specified method is the only acceptable one, the intent of the standard is that an equivalent test method may be accepted at Green Seal's sole discretion.

Certification to this standard shall be awarded only by Green Seal, or, with Green Seal's explicit written permission, by a third-party certification program conducting on-site audits.

**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.

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<sup>1</sup> Library of Standards Documents, [www.greenseal.org/green-seal-standards/library#section17](http://www.greenseal.org/green-seal-standards/library#section17)

## ACRONYMS AND ABBREVIATIONS

**ACGIH.** American Conference of Governmental Industrial Hygienists  
**AOEC.** Association of Occupational and Environmental Clinics  
**ASTM.** ASTM International, a standard setting organization formerly known as the American Society for Testing and Materials  
**BOD.** Biological Oxygen Demand  
**CFR.** Code of Federal Regulations  
**DFG.** German Deutsche Forschungsgemeinschaft  
**DOC.** Dissolved Organic Carbon  
**EN.** European Standard  
**EPA.** United States Environmental Protection Agency  
**FDA.** United States Food and Drug Administration  
**GHS.** Globally Harmonized System for Classification and Labeling of Chemicals  
**ISO.** International Organization for Standardization  
**LLNA.** Local Lymph Node Assay  
**NOAEL.** No-Observed Adverse Effect Level  
**OECD.** Organization for Economic Co-operation and Development  
**VOC.** Volatile Organic Compound

## GREEN SEAL STANDARD FOR SOAPS, CLEANSERS, AND SHOWER PRODUCTS, GS-44

### 1.0 SCOPE

This standard establishes environmental requirements for hand, hair, and body *soaps* and *cleansers* used and rinsed after use. This includes liquid and solid *soap* and *cleansers*, *shampoo*, *conditioner*, and related *shower products* for baby, child, adult, and *professional-use*. This standard also establishes health and environmental requirements for alcohol-based antiseptic rubs, referred to herein as *hand sanitizers*. This standard does not apply to products used for animal or pet use, those used in commercial or institutional facilities where the products are not intended to be sold to consumers, or products required to be registered under the Federal Insecticide, Fungicide, and Rodenticide Act, such as those making claims as sterilizers, *disinfectants*, or *antimicrobial soaps* and *cleansers*. See Appendix 1 for an example list of products included in this standard.

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 Soaps, Cleansers, and Shower Products.** The product shall perform as well as or better than a conventional, nationally recognized product in its category and at equivalent concentration using an objective, scientifically validated method conducted under controlled and reproducible laboratory conditions. The testing protocol shall include, at a minimum: cleaning ability, lathering/rinsing, and skin or hair condition after use. A standard soil shall be used and conclusions shall be derived from at least six separate samples. All results, a summary of conclusions, and a description of how panelists were chosen shall be submitted.

#### 2.2 Hand Sanitizers.

**In Vitro Testing.** *Hand Sanitizers* shall demonstrate at least a 3-log reduction (99.9 percent) of the test organism within 30 seconds. Acceptable methods for in vitro testing include ASTM E2783 and ASTM E2315.

A test organism shall be representative of microorganisms that commonly exist in consumer or healthcare settings.<sup>2</sup>

### 3.0 PRODUCT-SPECIFIC HEALTH AND ENVIRONMENTAL REQUIREMENTS

**Note:** *Hand sanitizers* are exempt from certain requirements. See Appendix 3.

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<sup>2</sup> FDA Briefing Document (2020), Appendix C, List of organisms for consumer and health care in-vitro testing <https://www.fda.gov/media/135559/download>

**3.1 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> ) | ≤ 20 mg/L at 1 hr |
| Dermal lethal dose (LD <sub>50</sub> )              | ≤ 2,000 mg/kg     |

Toxicity shall be measured on the product as a whole. Alternatively, a mixture need not be tested if existing toxicity information demonstrates that each of the *ingredients* complies. 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).

Testing is not required for any *ingredient* for which sufficient information exists.

To demonstrate compliance with this requirement. It is assumed 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*

For inhalation toxicity, it is determined from all *ingredients* with a vapor pressure greater than 1 mm Hg at standard conditions (1 atm and 20-25°C).

Refer to Annex B for potential alternate thresholds for products as *powders/solids/non-aqueous liquids*.

**3.2 Carcinogens, Mutagens, and Reproductive Toxins.** The *undiluted product* shall not contain any *ingredients* or *components* that are *carcinogens*, *mutagens*, or *reproductive toxins*. The product shall not contain any *ingredients* or *components* known to produce or release *carcinogens*, *mutagens*, or *reproductive toxins*. Ethyl alcohol<sup>3</sup> in *hand sanitizers* is exempt from this prohibition.

The product shall not contain any *ingredients* that, according to published uses,<sup>4</sup> are typically added for the purpose of releasing substances into a raw material or the final product, if those substances are *carcinogens*.

<sup>3</sup> Ethyl alcohol, CAS No. 64-17-5, EC No. 200-578-6

<sup>4</sup> Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.



**3.3 Per- and Polyfluorinated Alkyl Substances (PFAS).** The *undiluted product* shall not contain any *ingredients* or *components* that are *Per- and Polyfluorinated Alkyl Substances (PFAS)*.

**3.4 Skin and Eye Irritation.** The *undiluted product* shall not cause skin irritation, *skin corrosion*, or *serious eye damage* as defined by the Globally Harmonized System for Classification and Labeling of Chemicals (GHS). Further, a product is considered to cause skin irritation, *skin corrosion*, or *serious eye damage* if it has a pH of 2 or less or a pH of 11.5 or greater, unless proven otherwise.

The product shall not cause skin irritation as tested by OECD Guidelines for Testing Chemicals, Section 404 or other peer-reviewed or standard test methods. The product shall not be considered to cause skin irritation 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.

Further, a product shall be evaluated for *skin corrosion* and *serious eye damage* following the testing and evaluation strategy described in the GHS. Green Seal prefers that 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 be used. Green Seal will also accept the results of other peer-reviewed or standard *in vitro* or *in vivo* test methods demonstrating that the product mixture does not cause *skin corrosion* or *serious eye damage*. Testing is not required for any *ingredient* for which sufficient information exists.

Refer to Annex B for potential alternate thresholds for products as *powders/solids/non-aqueous liquids*.

**3.5 Skin Sensitization.** The *undiluted product* shall not be a *skin sensitizer*, as tested by the Local Lymph Node Assay (LLNA) or following the U.S. Environmental Protection Agency (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.

**3.6 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 carrying a skin notation, or substances that are listed on the German Deutsche Forschungsgemeinschaft (DFG) Maximum Allowable Concentrations 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.

*Hand sanitizers* are exempt from this requirement.

**3.7 Components that Cause Asthma.** The *undiluted product* shall not contain any *components* that have been identified as *asthmagens*. Triethanolamine<sup>5</sup> is exempt for gel *hand sanitizers*.

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

**3.9 Volatile Organic Compound Content.** The *undiluted product* shall contain no more than 1% of volatile organic compound (VOC) content, in order to avoid significant contribution to the production of photochemical smog, tropospheric ozone, or poor indoor-air quality.

The VOC content shall be determined in one of the following ways:

- By summing the percent by weight contribution from all organic *components* of the product that have a vapor pressure of greater than 0.1 mm mercury at 1 atm pressure and 20° C.
- According to the California Air Resources Board Method 310 (or equivalent), modified to include all *fragrances* and all organic *components*<sup>6</sup>.

*Hand sanitizers* are exempt from this requirement.

**3.10 Chronic Inhalation Toxicity.** The *product as used* shall not contain *ingredients* with a vapor pressure above 1 mm mercury at ambient conditions (1 atm pressure and 20-25° 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.
- 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 LOAEL can be used with a ten-fold safety factor (i.e., LOAEL/10).

<sup>5</sup> Triethanolamine (TEA), CAS Number 102-71-6, EC Number: 203-049-8

<sup>6</sup> Evaluation of total VOCs in this standard includes all *fragrances* and all organic compounds present in the product at 0.01% or more. Evaluation of total VOCs under Method 310 exempts *fragrances* and all organic compounds present below 0.1%.

*Hand sanitizers* are exempt from this requirement.

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

Acute LC<sub>50</sub> for algae, daphnia, or fish  $\geq 100$  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, and OECD test guidance 202 for daphnia.

Alternatively, the product shall not be toxic to aquatic life defined as IC<sub>50</sub>>1000 mg/L as measured by whole formulation short-term sensitive toxicity test performed on the bacteria *Photobacterium phosphoreum*. Aquatic toxicity shall be measured by one of the following test methods: *Biological Test Method: Toxicity Test Using Luminescent Bacteria (Photobacterium phosphoreum)*, Report EPS 1/RM/24, November 1992, Environment Canada, ASTM International (ASTM) D5660-96 or ISO 11348.

**3.12 Bioaccumulating Compounds.** The *product as used* shall not contain any *ingredients* that bioaccumulate or that form degradation products that bioaccumulate. A chemical is considered to bioaccumulate when it has a 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, 3.12, it may be considered to not bioaccumulate. Testing is not required for any *ingredient* for which sufficient information exists. If no test results are available, a chemical with a log octanol/water partition coefficient log Kow > 3 may be considered to bioaccumulate.

**3.13 Aquatic Biodegradability.** Each of the individual organic *ingredients* in the *product 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)  $> 60\%$
- BOD, as % of Theoretical Oxygen Demand (ThOD)  $> 60\%$
- CO<sub>2</sub> evolution, as % of theoretical CO<sub>2</sub>  $> 60\%$

Per OECD guidance the 10-day window requirement does not apply to structurally-related surfactant homologues. For organic *ingredients* 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* or *naturally-derived components* that do not exhibit ready biodegradability if it does not have acute aquatic toxicity <100 mg/L (according to 3.10), does not have a chronic toxicity <100 mg/L (tested according to OECD 210, 211, or 201), is not bioaccumulating (3.11), and exhibits biodegradation rates above 70% (measured as BOD, DOC, or COD), per ISO test methods 9887 or 9888; or OECD 302A, B, or C.

Testing is not required for any *ingredient* for which sufficient information exists concerning its biodegradability, either in peer-reviewed literature or databases.

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

**3.15 Prohibited Components.** The *undiluted product* shall not contain the following *components*:

- 2-butoxyethanol
- Alkylphenol ethoxylates
- Butylated hydroxytoluene
- Ethoxylated chemicals
- Ethylene diaminetetra-acetic acid or any of its salts
- Formaldehyde donors
- Heavy metals including, lead, hexavalent chromium, or selenium both in the elemental form or compounds
- *Halogenated organic solvents*
- Methylidibromo glutaronitrile
- Monoethanolamine, Diethanolamine, and Triethanolamine alone or in compounds. Note: Triethanolamine<sup>7</sup> is exempt in gel *hand sanitizers*.
- Nitro-musks
- Parabens
- Phthalates
- Polycyclic musks

**3.16 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 5.2 and 5.5).

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<sup>7</sup> Triethanolamine (TEA), CAS Number 102-71-6, EC Number: 203-049-8

**3.17 Preservatives.** The use of preservatives for purposes other than preservation of the product is not allowed. Documentation must be provided to demonstrate the dosage necessary to preserve the product.

**3.18 Colorants.** [Reserved]

**3.19 Nanoscale Components.** [Reserved]

**3.20 Optical Brighteners.** The *undiluted product* shall not contain any *ingredients* that are *optical brighteners*.

*Hand sanitizers* are exempt from this requirement.

**3.21 Animal Testing.** To avoid new animal testing, previous test results will be accepted as evidence of meeting a criterion. When existing data are not available, the preferred methods for new testing include methods that replace, reduce, or refine animal use, particularly those recommended 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, other 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 and applicable. Specific in vitro or modeling methods may be noted in the standard, but additional options may be accepted by the certification program.

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

## 4.0 PACKAGING REQUIREMENTS

### 4.1 Primary Package.

**4.1.1 Source Reduction in Primary Package.** The *primary package* shall be a *source-reduced package* or *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.

**4.1.2 Concentrated Product Packaging.** *Concentrates* are prohibited from being packaged in ready-to-use forms, including but not limited to pump-dispenser bottles.

**4.1.3 Heavy Metal Restrictions.** Heavy metals, including lead, mercury, cadmium, and hexavalent chromium, shall not be *intentionally introduced*. Further, the sum of the concentration levels of these metals present shall not exceed 100 parts per million by weight (0.01%); an exception is allowed for refillable packages or packages 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 or packaging *component* is not desired or deliberate, if the final packaging or packaging *component* complies with the incidental concentration restrictions of 100 ppm.

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

**4.1.5 Hand Sanitizer Wipes Per Package.** *Hand sanitizers* sold as wipes shall not be individually packaged or individually wrapped. The *primary package* for *hand sanitizers* sold as wipes must contain at least 20 wipes.

**4.2 Secondary Package.** A *secondary package* shall only be used for *concentrates*. An exception may be made for packaging of multiple units when up to one of the units is a ready-to-use form, including but not limited to pump-dispenser bottles, and total packaging (*primary plus secondary package*) is a reduction in packaging material use.

*Hand sanitizers* are exempt from this requirement.

## 5.0 USER INFORMATION AND PRODUCT LABEL REQUIREMENTS

**5.1 Antimicrobial Claims.** The product shall make no antibacterial, disinfecting, *antiseptic*, or sanitizing product claims.

*Hand sanitizers* are exempt from this requirement.

**5.2 Ingredient Line.** The product shall list the product *components* using the naming convention of the International Nomenclature of Cosmetic Ingredients 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*.

*Hand sanitizers* are exempt from this requirement.

**5.3 Organic Claims.** Organic claims must be supported with documentation that they meet the U.S. Department of Agriculture National Organic Program or meet the NSF International 305 standard.

**5.4 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*. An exception is permitted for lye used to produce *soap*.

- "Natural" or "Biobased" products shall contain 95% *natural, naturally-derived, or biobased components*, respectively.
- Claims on specific product *ingredients* being "natural" or "biobased" may be permitted if it is a *natural or biobased ingredient*.

**5.5 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 ingredients*. *Hand sanitizers* are exempt from these requirements but are required, per Fragrances (3.16), to declare within the ingredient line if a *fragrance* has been added.

*Hand sanitizers* are exempt from this requirement.

**5.6 Consumer Communication.** The product ingredient line (5.2) shall be made available to consumers in an easily accessible means besides the product package, such as the company website.

*Hand sanitizers* are exempt from this requirement.

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

*Hand sanitizers* are exempt from this requirement.

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

**5.8.1 Resin Identification Code.** If plastic, the packaging must be clearly marked with the appropriate Society of the Plastics Industry symbol to identify the type of plastic for recycling and appropriate qualification of recyclability as referenced in 4.1.1 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."

*Hand sanitizers* are exempt from this requirement.

**Note: Additional Product Label Requirements**

For products sold as *powders/solids/non-aqueous liquids*, refer to Annex B.

## 6.0 TRADEMARK USE REQUIREMENTS

**6.1 Trademark Use.** Any use of the Green Seal® Certification Mark or Green Seal name, e.g., on the product, product label, packaging, secondary documents, or

promotional materials, must be in accordance with Green Seal's Trademark Use Guidelines.<sup>8</sup>

**6.2 Misleading Claims.** Green Seal trademarks shall not be used in conjunction with any modifying terms, phrases, or graphic images that might mislead consumers as to the extent or nature of the certification.

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<sup>8</sup> [www.greenseal.org/trademark-use-guidelines](http://www.greenseal.org/trademark-use-guidelines)



## ANNEX A – DEFINITIONS (Normative)

Note that the defined terms are italicized throughout the standard.

**Allergen.** Allergenic substances listed by the European Commission in the Cosmetic Directive and those listed by the U.S. Food and Drug Administration (including food allergens).

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

**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.

**Asthmagen.** A substance 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.

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

**Carcinogen.** A chemical listed as a known, probable, reasonably anticipated, or possible human carcinogen by the International Agency for Research on Cancer (Groups 1, 2A, and 2B), National Toxicology Agency (Groups 1 and 2), EPA Integrated Risk Information System (weight-of-evidence classifications A, B1, B2, C, carcinogenic, likely to be carcinogenic, and suggestive evidence of carcinogenicity or carcinogen potential), or by Occupational Safety and Health Administration (as carcinogens under 29 Code of Federal Regulations (CFR) 1910.1003(a)(1)).

**Child-Resistant Packaging.** Child-resistant packaging, as defined by the Poison Prevention Packaging Act, is packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time, and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time. Code of Federal Regulations, Title 16, Part 1700 and Title 40, Part 157.

**Cleanser.** A product intended to clean the body or hair that has detergent properties that are not necessarily due to alkali-fatty acid compounds and may contain synthetic detergents.

**Colorant.** A product *component*, such as a dye or pigment, whose only function is to change the product’s color.

**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.

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

**Conditioner.** A product that is intended to alter the texture or appearance of hair or scalp, used after *shampoo* and rinsed off after use. This can include products called rinses but does not include leave-in products.

**Contaminant.** A product constituent that was not added for its functionality but is known to be present.

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

**Endocrine Disruptor.** A chemical identified by the U.S. Environmental Protection Agency (EPA) List of Chemicals for Tier 1 Screening due to their ability to disrupt hormones (e.g., have estrogen-or androgen-mediated effects), as tested according to the EPA Series 890 -Endocrine Disruptor Screening Program Test Guidelines.

**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.

**Halogenated Organic Solvent.** An organic solvent containing halogens, including fluorine, chlorine, bromine, and iodine.

**Hand Sanitizer.** A product intended to be applied topically to intact human hands to slow or stop the growth of pathogenic microorganisms. These products are regulated by the US FDA under the term “consumer antiseptic rubs” and “healthcare antiseptic rubs.”

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

**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.

**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.

**Mutagen.** A chemical that meets the criteria for category 1, chemicals known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans, under GHS Chemicals Which Cause Mutations in Germ Cells.

**Nanoscale Component.** A *component* that is roughly 1 to 100 nanometers in size, enabling novel applications that a larger-sized version of the *component* could not achieve.

**Natural Component.** A *component* that comes from materials and found in nature including mineral, forestry, agricultural, or biological materials; do not contain transgenic hybrid organisms; have been processed without irradiation; and are not chemically altered.

**Naturally Derived Component.** A *component* that is partially chemically altered without petroleum *components* and has been minimally processed such that it is not altered to such an extent that it is are no longer biodegradable and non-toxic (examples of potentially acceptable processes are included in Appendix B).

**Optical Brightener.** An additive 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.

**Ozone-Depleting Compound.** A compound with an ozone-depletion potential greater than 0.01 (CFC 11=1) according to the EPA list of Class I and Class II Ozone-Depleting Substances.

**Per and Polyfluorinated Alkyl Substances (PFAS).** A class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom. This includes but is not limited to PFAS identified via the US EPA's CompTox database PFAS Master List.<sup>9</sup>

**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.

**Powders/Solids/Non-Aqueous Liquids.** Products that cannot be formulated with additional water due to the form of the product, including, but not limited to: powdered detergents, solid bar soaps, detergents in tablet form, detergents as extruded or cast solids, non-aqueous liquid products in a dissolvable shell.

**Primary Package.** Package material that physically contains and contacts the product, not including the cap or lid. For products that meet the annex requirements for Products as Powders/Solids/Non-Aqueous Liquids, the primary package is the material that holds the individually packaged product units or the entire product.

**Product As Used.** The amount of product directed for use and diluted in 1 liter of tap water. If no dose is suggested, 5 ml of liquid *soap* or *cleansers*, or *hand sanitizers*, shall be used and 0.9 ml of foam *soap* or *cleansers* shall be used, or the equivalent for solid or semi-solid products.

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<sup>9</sup> <https://comptox.epa.gov/dashboard/chemical-lists/PFASMASTER>

**Professional-Use.** Trained or paid workers, such as, but not limited to, hair stylists, that use the products included in the scope of this standard and such products are available for sale to the consumer.

**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 chemical 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).

**Secondary Package.** Package 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. This includes substances identified under Category 1 for Serious Eye Damage/Eye Irritation (H318) under the *GHS*.

**Shampoo.** A *soap* or *cleanser* used to clean the hair and scalp and rinsed off after use. This can include combination shampoo and *conditioner* or shampoo and rinse products.

**Shower Product.** A product that is used on the body or hair with the intention that they are washed off the body. This may include bubble bath, exfoliating scrubs, and other rinse-off products.

**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. This includes substances designated as Category 1A, 1B or 1C for Skin Corrosion/Irritation (H314) under the *GHS*.

**Skin Sensitizer.** A substance that will lead to an allergic response following skin contact.

**Soap.** A product used to clean the body or hair in which most of the nonvolatile matter consists of an alkali salt of fatty acids and whose detergent properties are due to these alkali-fatty acid compounds (21 CFR 701.20).

**Source-Reduced Package.** A package that has at least 50% less material (by weight) compared to containers commonly used for that product type.

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

**ANNEX B – POWDERS/SOLIDS/NON-AQUEOUS LIQUIDS (Normative)**

**Products as Powders/Solids/Non-Aqueous Liquids.** *Powder/solid/non-aqueous liquid* products that meet all of the following requirements may be exempt from the skin and eye corrosion criterion (3.3) and may have an alternate threshold of 300 mg/kg for oral acute mammalian toxicity (3.1) herein.

**A. Packaging Requirements.** The product shall meet the requirements under **either** A(1) Child-Resistant Packaging Requirements **or** A(2) Packaging Durability Requirements.

**(1) Child-Resistant Packaging.** The product shall be packaged in *child-resistant packaging* following the ASTM D3475 classification. *Child-resistant packaging* must be tested per ISO 8317 or European Standard (EN) 862.

**(2) Packaging Durability.** The product shall meet the following requirements to be considered durable.

**i. Drop Test.** The *primary package*, including any lid, shall be durable as demonstrated by passing the following drop test: drop the product from a height of 48 inches with 4 drops scenarios: flat-on-bottom, flat-on-top, flat-on-side, and corner; with passing results including that the packages must not leak, contents must be retained, and no damage to the outer package likely to adversely affect safety must be sustained.

**ii. Spill Resistant.** The *primary package* shall not spill when tipped over, turned upside down or shaken and shall not leak when exposed to water.

**iii. Practically Inaccessible.** The *primary package* shall not allow for easy access/exposure of the product during routine handling of the package, such as while transferring from shipping cartons, during storage, or after opening (e.g. the user still cannot get at the contents, or the contents are protected or wrapped).

**B. Dispensing Exposure Requirements.** Documentation shall be provided to demonstrate that expected dispensing situations will not result in incidental contact exposure to oral consumption/toxicity, skin corrosion, or eye corrosion.

**C. Labeling Requirements.** The product label shall include the following in a conspicuous location:

- The signal word “WARNING” or “CAUTION” on products which cause *skin corrosion*, cause *serious eye damage*, or have an acute mammalian toxicity greater than or equal to 300 mg/kg and less than or equal to 5,000 mg/kg, with the applicable precautionary measures:
  - o May cause skin corrosion, do not get on skin
  - o May cause serious eye damage, do not get in eyes
  - o Harmful if swallowed, do not ingest

- Instruction, when necessary or appropriate, for first-aid treatment
- The statement “KEEP OUT OF REACH OF CHILDREN” or its practical equivalent in capitalized text

**ANNEX C – HAND SANITIZERS (Normative)**

**Hand sanitizers.** *Hand sanitizers* shall meet the requirements and undergo evaluation according to the stipulations below.

**A. Alcohol Concentration.** Documentation shall be provided to demonstrate the following:

- Ethyl alcohol-based *hand sanitizers* shall be formulated with at least 60 percent ethyl alcohol by volume, which shall be Specially Denatured Alcohol (SDA). Documentation must also demonstrate a purity that meets or exceeds USP grade requirements.
- Isopropyl alcohol-based *hand sanitizers* shall be at least 70 percent isopropyl alcohol by volume.

**B. Manufacturing Disclosure Requirements.** The following documentation shall be provided: Establishment Registration Number; labeler code; and National Drug Code (NDC) of the finished product.

**C. Evaluation level.** *Hand sanitizers* shall be evaluated according to all criteria, herein, based on evaluations of the product as a whole or each of the *ingredients*; chemicals in the product at less than 100 ppm shall not be restricted or prohibited.

**D. Ingredient Prohibitions.**

(1) *Hand sanitizers* shall not contain the following *ingredients*:

(i) *Endocrine Disruptors*



**APPENDIX 1 – SCOPE (Informative)**

Examples of products included in or excluded from the scope of GS-44:

**Products included in GS-44**

- Body wash
- Bubble bath and bath salts
- *Cleansers*
- *Conditioner*
- Exfoliant products (if intended to rinse off)
- Alcohol-based *hand sanitizers* sold as liquids, gels, foams, or lotions
- Face wash
- Makeup remover (if intended to rinse off)
- Moisturizing products (if intended to rinse off)
- *Shampoo*
- Shaving cream, gel, and foam
- *Shower products*
- *Soap*

**Products excluded from GS-44**

- Aftershave (included in GS-50)
- Astringent/toner (included in GS-50)
- Cleaning wipes that don't require rinsing after use (included in GS-50)
- Cuticle cream, lotion, and oil (included in GS-50)
- Deodorant and antiperspirant (included in GS-50)
- Feminine deodorant
- Fragrance Products/perfume and body spray
- Hair shine products (included in GS-50)
- Hair spray (included in GS-50)
- Hair styling products (e.g., balm, gel, mousse) (included in GS-50)

**Products excluded from GS-44, Continued**

- Hair dye, color, and bleach
- Hair relaxant
- Hand cleaning products for industrial and institutional use (covered in GS-41)
- *Hand sanitizers* formulated with benzalkonium chloride as the active ingredient
- *Hand sanitizers* sold within aerosol cans
- Insect repellents (included in GS-50)
- Leave-on hair *conditioner* (included in GS-50)
- Lip products (included in GS-50)
- Makeup and bronzers (e.g., foundation, concealer, bronzer, mascara, eyeliner, eye shadow, blush) (included in GS-50)
- Massage oil (included in GS-50)
- Nail polish remover
- Skin care products (e.g., lotions) (included in GS-50)
- Sunless tanning products (included in GS-50)
- Sunscreen (included in GS-50)

## APPENDIX 2 – PROCESSING METHODS OF NATURALLY-DERIVED COMPONENTS (Informative)

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 3 – EXEMPT CRITERIA FOR HAND SANITIZERS (Informative)**

*Hand sanitizers* are exempt from the following criteria:

**Product-Specific Health and Environmental Requirements**

Skin absorption (3.5)

Volatile Organic Compound Content (3.8)

Chronic Inhalation Toxicity (3.9)

Optical Brighteners (3.19).

**Ingredient-Specific Exemptions**

Ethyl alcohol shall be exempt from the *carcinogens* prohibition (3.2)

Triethanolamine shall be exempt from the *asthmagens* prohibition (3.6)

Triethanolamine is noted as exempt for *hand sanitizers* in the Prohibited Components list (3.14)

**Packaging Requirements**

*Secondary Package* (4.2)

**User Information and Product Labeling Requirements**

Antimicrobial Claims (5.1)

*Allergen* Labeling (5.5)

Consumer Communication (5.6)

Use Labeling (5.7)

Disposal Labeling (5.8)