
# GS-41

## GREEN SEAL® STANDARD FOR
# HAND CLEANERS AND HAND SANITIZERS FOR INDUSTRIAL AND INSTITUTIONAL USE

**Edition 2.3**
**September 10, 2020**

Green Seal, Inc. • 1001 Connecticut Ave. NW, Ste 827 • Washington, DC USA 20036-5525
(202) 872-6400 • FAX (202) 872-4324 • greenseal.org

## GREEN SEAL

Green Seal is a nonprofit organization whose mission is to use science-based programs to empower consumers, purchasers, and companies to create a more sustainable world. Green Seal sets leadership standards that aim to reduce, to the extent technologically and economically feasible, the environmental, health, and social impacts throughout the lifecycle of products, services, and companies. The standards may be used for conformity assessment, purchaser specifications, and public education.

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

Green Seal
1001 Connecticut Avenue, NW, Suite 827
Washington, DC 20036-5525
(202) 872-6400 • FAX (202) 872-4324
greenseal@greenseal.org
greenseal.org

# GREEN SEAL STANDARD FOR HAND CLEANERS AND HAND SANITIZERS FOR INDUSTRIAL AND INSTITUTIONAL USE, GS-41

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## FOREWORD

**Edition.** Edition 2.3 was issued on September 10, 2020 and replaces Edition 2.2 from September 8, 2017. Information on the revision of Edition 2.2 can be found on Green Seal's website.

**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.

## ACRONYMS AND ABBREVIATIONS

**ASTM.** ASTM International a standard setting organization formerly known as the American Society for Testing and Materials
**CARB.** California Air Resources Board
**EPA.** United States Environmental Protection Agency
**FDA.** United States Food and Drug Administration
**ISO.** International Organization for Standardization
**NIOSH.** National Institute for Occupational Safety and Health
**OECD.** Organization for Economic Co-operation and Development
**VOC.** Volatile Organic Compound

# GREEN SEAL STANDARD FOR HAND CLEANERS AND HAND SANITIZERS FOR INDUSTRIAL AND INSTITUTIONAL USE, GS-41

## 1.0 SCOPE

This standard establishes environmental requirements for *institutional hand cleaners* (GS-41 A), *industrial heavy-duty hand cleaners* (GS-41 B), and alcohol-based antiseptic rubs, referred to herein as *hand sanitizers* (GS-41 C). For purposes of this standard, *industrial heavy-duty hand cleaners* are defined as those products advertised for heavy-duty use to remove oil, grease, ink or other hard to remove soils in garages, print shops, and other industrial settings. *Institutional hand cleaners* are defined as those products advertised for routine, nonspecialized hand cleaning in office buildings, schools, retail and other public buildings. The standard does not include hand cleaners in households, food preparation operations, or medical facilities. 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 Hand Cleaners.** Using a fixed, repeatable procedure, the product shall demonstrate efficacy against a nationally- recognized or market-leading product of its type, showing equivalent or better performance. The testing protocol shall include, at a minimum: cleaning ability, lathering/rinsing, and skin 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 are chosen shall be submitted.

**2.2 Hand Sanitizers.**

**In Vitro Testing.** The product shall demonstrate at least a 3-log reduction (99.9 percent) of a test organism within 30 seconds, as determined by a Minimum Inhibitory Concentration / Minimum Bactericidal Concentration (MIC/MBC) test. 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.[1]

Testing must be carried out in compliance with Current Good Manufacturing Practice for Finished Pharmaceuticals (CRF Title 21, Chapter 1, Subchapter C, Part 211).

[1] Appendix C, List of organisms for consumer and health care in-vitro testing https://www.fda.gov/media/135559/download

## 3.0 PRODUCT-SPECIFIC HEALTH AND ENVIRONMENTAL REQUIREMENTS

***Note:*** *Hand sanitizers* are exempt from certain requirements. See Annex B.

**3.1 Skin Sensitization.** The product shall not be a *skin sensitizer* as tested by Organization for Economic Co-operation and Development (OECD*)* Guidelines for Testing Chemicals, Section 406, Buehler (1994), or Magnusson and Kligman (1969) or other peer-reviewed or standard test methods. The product shall not be considered a *skin sensitizer* under the following scenarios:

- if test data shows that the whole product is not a *skin sensitizer*,
- if test data shows that each *ingredient* present at or above a concentration of 0.1% is not a *skin sensitizer*, or
- if test data shows that any known *skin sensitizers* are non-sensitizing when present at 0.1% or greater in the product.

Note: See separate requirements for *hand sanitizers* in Annex B.

**3.2 Skin Irritation.** The product shall not be a *skin irritant* as tested by OECD Guidelines for Testing Chemicals, Section 404 or other peer-reviewed or standard test methods. The product shall not be considered a *skin irritant* 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.

**Note:** See separate requirements for *hand sanitizers* in Annex B.

**3.3 Antimicrobial Claims.** The product shall make no antibacterial, *disinfecting, antiseptic* or *sanitizing* product claims. *Hand sanitizers* are exempt from this requirement.

**3.4 Prohibited Ingredients.** The product shall not contain the following *ingredients*:

- Phosphates
- *Nitrilotriacetic acid*
- *Ethylene diaminetetra-acetic acid*
- Alkylphenol ethoxylates
- *Halogenated organic solvents*
- Butoxy-ethanol

**3.5 Fragrances.** The product shall declare any fragrances on the product label and on material safety data sheets. Any fragrances used shall have been produced or handled following the code of practice of the International Fragrance Association.

**3.6 Colorants.** Each *colorant* shall meet one of the following:

- Be certified by the U.S. Food and Drug Administration (FDA) and permitted for ingestion
- Be a *natural colorant*
- Not have any of the following heavy metals intentionally added: arsenic, cadmium, cobalt, hexavalent chromium, lead, manganese, mercury, nickel, and selenium

**3.7 Carcinogens.** The product shall not be formulated or manufactured with any *carcinogens*. Ethyl alcohol[2] in *hand sanitizers* is exempt from this prohibition

**3.8 Volatile Organic Compound (VOC) Content.** VOCs include all organic compounds that have a vapor pressure of greater than 0.1 mm mercury at 1 atm pressure and 20º C. "VOC content" means the total weight of VOCs in a product expressed as a percentage of the product weight. *Hand sanitizers* are exempt from this requirement.

For *industrial heavy-duty hand cleaners*, the VOC content shall not exceed the current regulatory limits of the Air Resources Board for the State of California (CARB) for its product category.

For *institutional hand cleaners*, VOCs shall not exceed the lower of the following options:

- 1% by weight.
- The current CARB regulatory limit.

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

- By summing the percent by weight contribution from all volatile organic *ingredients*.
- According to the California Air Resources Board Method 310 (or equivalent), modified to include all *fragrances* and all volatile organic *ingredients*[3].

Current CARB regulatory limits for VOCs[4].

| Product Category | Effective Date | Limit (%) |
|---|---|---|
| *Industrial heavy-duty hand cleaners* or soap | 1/1/2005 (12/31/2013) | 8 (1) |

[2] Ethyl alcohol, CAS No. 64-17-5, EC No. 200-578-6

[3] Evaluation of the VOC content in this standard includes all *fragrances* and VOCs present in the product at 0.01% or more. Evaluation of the VOC content under Method 310 exempts *fragrances* and all volatile organic compounds present below 0.1%.

[4] These limits are a reference to the current CARB regulatory limits and will be updated to reflect any amendments made by CARB in the future.

**3.9 Aquatic Biodegradability.** Each of the individual organic *ingredients* in the *product as used* shall exhibit ready biodegradability in accordance with the OECD definition, except for polymers. For the evaluation of organic *ingredients,* biodegradability shall be measured by one of the following methods:

- ISO 7827, 9439, 10707, 10708, 9408, or 14593
- OECD Methods 301A–F
- 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%
- $CO_2$ evolution, as % of theoretical $CO_2$ > 60%

Per OECD guidance the 10-day window requirement does not apply to structurally-related surfactant homologues.

**Alternative Evaluation Options: Substances that Do Not Exhibit Ready Biodegradability.** For organic *ingredients* at 0.01% in the *product as used* that do not exhibit ready biodegradability, one of the following options may be acceptable:

1. The manufacturer may demonstrate biodegradability in sewage treatment plants using the Coupled Units Test found in OECD 303A by demonstrating DOC removal > 90%.
2. The manufacturer may demonstrate that the compound has low aquatic toxicity (acute LC50 ≥ 100 mg/L for algae, daphnia, or fish) and exhibits inherent ultimate biodegradability with biodegradation rates above 70% (measured as BOD, DOC, or COD), per ISO test methods 9887 or 9888 or OECD 302A-C.

**Note:** Testing is not required for any *ingredient* for which sufficient information exists concerning its biodegradability, either in peer-reviewed literature or databases. In the absence of experimental data, Quantitative Structure-Activity Relationship data from EPA's BioWin (EpiSuite) models may be considered.

**3.10 Toxicity to Aquatic Life.** The *product as used* shall not be toxic to aquatic life. A product is considered not toxic to aquatic life if the lowest available and most representative acute $LC_{50}$ data for fish, daphnia, or algae is greater than or equal to 100 mg/L. For purposes of demonstrating compliance with this requirement, data for each of the product's *ingredients* may be used to calculate a weighted average.

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

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

Where,
TP = toxicity of the product
$wt_i$ = the weight fraction of the *ingredient*
TV = the toxicity value for each *ingredient* ($LC_{50}$)
n = number of *ingredients*

The preferred sources of data come from the following appropriate protocols in ISO 7346-2 for fish, OEDC TG 203 for fish, OECD TG 202 for daphnia, or OECD TG 201 for algae.

**3.11 Plastic Packaging.** A plastic *primary package* shall be one of the following:

- A *source-reduced package*
- *Recyclable*
- Contain at least 25% *post-consumer material*
- A *refillable package* with an effective *take-back program*
- An alternative approach that has been independently proven to have a similar life cycle benefit as one of the options listed above

**3.11.1 Plastic Labeling.** The package must be marked with the appropriate Resin Identification Code. *Hand sanitizers* are exempt from this requirement.

**3.12 Non-Plastic Package.** For materials other than plastic, the *primary package* shall be one of the following:

- A *source-reduced package*
- *Recyclable*
- Contain at least 25% *post-consumer material*
- An alternative approach that has been independently proven to have a similar life-cycle benefit as one of the options listed.

**Note:** *Bag in box* packaging is acceptable if the bag and the box each meet the relevant requirements in Section 3.11 and 3.12.

**3.13 Heavy Metal Restrictions.** The heavy metals lead, mercury, cadmium, and hexavalent chromium shall not be *intentionally introduced* to the *primary package*. 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 *post-consumer material*.

**3.14 Other Restrictions.** Phthalates, bisphenol A, and chlorinated packaging material are prohibited from being *intentionally introduced* to a plastic *primary package*. An exception is allowed for *primary packages* that would not have added phthalates, bisphenol A, or chlorinated packaging material but for the addition of post-consumer material.

**3.15 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 CERTIFICATION AND LABELING REQUIREMENTS

**4.1 Instructions for Use.** 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.

**4.2 Certification Mark.** The Green Seal® Certification Mark may appear on the product, packaging, secondary documents, and promotional materials, only in conjunction with the certified product. Use of the Mark must be in accordance with *Rules Governing the Use of the Green Seal Certification Mark*[5].

The Green Seal Certification Mark 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.

Green Seal must review all uses of the Certification Mark prior to printing or publishing.

**4.3 Use With Other Claims.** The Green Seal Certification Mark shall not appear in conjunction with any human health or environmental claims, unless verified and approved in writing by Green Seal.

**4.4 Statement of Basis for Certification.** Wherever the Green Seal Certification Mark appears, it shall be accompanied by a description of the basis for certification. The description shall be in a location, style, and typeface that are easily readable.

Unless otherwise approved in writing by Green Seal, the description shall read as follows, unless an alternate version is approved in writing by Green Seal:

For products certified under GS-41 A:

> This product meets Green Seal® Standard GS-41A based on effective performance and protective limits on VOCs and human & environmental toxicity. GreenSeal.org.

For products certified under GS-41 B:

[5] Available by request.

> This product meets Green Seal® Standard GS-41B based on effective performance and protective limits on VOCs and human & environmental toxicity. GreenSeal.org.

For *hand sanitizers* under GS-41C:

> This product is certified to the Green Seal® Standard GS-41C based on effective performance and protective limits on human & environmental toxicity, skin/eye irritation, and minimized/recycled packaging. GreenSeal.org.

## ANNEX A – DEFINITIONS (Normative)

Note that the defined terms are italicized throughout the standard.

**Antimicrobial.** Substances which can kill or inhibit the growth of microorganisms.

**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.

**Bag in box.** A flexible bag held inside a rigid outside container (box) that is not removed prior to use of the bag.

**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 substance 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). For *hand sanitizers*, *carcinogens* shall also be identified via the following lists and classifications: 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)).

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

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

**Endocrine Disruptors.** Chemicals 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.

**Ethylene Diaminetetra-Acetic Acid.** Ethylene diaminetetra-acetic acid (also known as ethylene dinitrilotetraacetic acid, EDTA) or any of its salts.

**Halogenated Organic Solvent.** Any 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."

**Industrial Heavy-Duty Hand Cleaner.** A product advertised for heavy-duty use to remove oil, grease, ink or other hard to remove soils in industrial settings.

**Ingredient.** Any constituent that comprises at least 0.01% by weight of a product, whether it is intentionally added or present as a contaminant.

**Institutional Hand Cleaner.** A product advertised for routine, non-specialized hand cleaning in office buildings, schools, retail and other public buildings.

**Intentionally Introduced.** The use of substances for their desired or deliberate presence in the *primary package* for the purpose of providing a specific characteristic or quality. It does not refer to the use of substances as processing aids or the use of an intermediate that imparts certain chemical or physical changes during manufacturing, as long as the substance or intermediate is present in the *primary package* at concentrations below 100 ppm.

**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.

**Natural Ingredient.** An *ingredient* 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.

**Natural Colorant.** *A colorant* that comes from biological products, forestry, or agricultural materials (including plant, animal, and marine materials), or minerals.

**Naturally Derived Ingredient.** An *ingredient* that is partially chemically altered without petroleum and has been minimally processed such that it remains biodegradable and non-toxic.

**Nitrilotriacetic Acid.** Nitrilotriacetic acid or any of its salts.

**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).** Synthetic chemicals comprised of carbon-fluorine bonds, which are known to be persistent, known to bioaccumulate, and to be hazardous to aquatic life and human health. For Green Seal certification, PFAS are identified via the US EPA's CompTox database.[6]

**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.

[66] https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster

**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 hand soap or *hand sanitizer* shall be used and 0.9 ml of foam soap shall be used.

**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.

**Refillable Package.** A package that is routinely returned to and refilled by the product manufacturer at least five times with the original product held by the package, and demonstrated in practice. For the purpose of this standard, the product manufacturer or the product manufacturer's agent may refill a package.

**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).

**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*.

**Skin Irritant.** The substance causes erythema or edema of the skin graded at 2 or more as defined by OECD 404.

**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 causes an immunologically mediated cutaneous reaction, also known as allergic contact dermatitis.

**Source-Reduced Package.** A package that has at least 20% less material (by weight) compared to containers commonly used for that product type. For bag-in-the-box type packages, the box is included in the weight if the box is used during product use or in product merchandising.

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

## ANNEX B – 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 which is Specially Denatured Alcohol (SDA). Documentation must also demonstrate a purity that meets or exceeds USP certification levels.

- Isopropyl alcohol-based *hand sanitizers* shall be at least 70 percent isopropyl alcohol.

**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. Ingredient Prohibitions.** *Hand sanitizers* shall not contain any of the following *ingredients*, in addition to those listed in Criterion 3.4, herein:

Butylated hydroxytoluene
*Endocrine Disruptors*
The heavy metals lead, hexavalent chromium, or selenium, both in the elemental form or compounds
Methyldibromo glutaronitrile
Monoethanolamine (MEA) and Diethanolamine (DEA)
Nitromusks
Parabens
*Per and Polyfluorinated Alkyl Substances (PFAS)*
Phthalates
Polycyclic musks

**D. Additional Health and Environmental Requirements:**

i. Acute Toxicity
ii. Carcinogen Releasers
iii. Mutagens and Reproductive Toxins
iv. Ingredients that Cause Asthma
v. Skin Corrosion
vi. Serious Eye Damage
vii. Ozone Depleting Compounds

**(i) Acute Toxicity.** The product shall not be toxic to humans. A product is considered toxic if any of the following criteria apply:

| | |
|---|---|
| Oral lethal dose ($LD_{50}$) | $\leq$ 5,000 mg/kg |
| Inhalation lethal concentration ($LC_{50}$) | $\leq$ 20 mg/L at 1 hr |
| Dermal lethal dose ($LD_{50}$) | $\leq$ 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
$wt_i$ = the weight fraction of the *ingredient*
TV = the toxicity value for each *ingredient* ($LD_{50}$)
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*.

**(ii) Carcinogen Releasers**. The product shall not contain any *ingredients* known to produce or release *carcinogens*.

**(iii) Mutagens and Reproductive Toxins.** The product shall not contain any *ingredients* that are *mutagens* or *reproductive toxins*.

**(iv) Mutagen and Reproductive Releasers.** The product shall not contain any *ingredients* known to produce or release *mutagens*, or *reproductive toxins.*

**(v) Ingredients that Cause Asthma.** The product shall not contain any *ingredients* that have been identified as *asthmagens*. Triethanolamine (TEA)[7] is exempt for gel *hand sanitizers*.

[7] Triethanolamine (TEA), CAS Number 102-71-6, EC Number: 203-049-8

**(vi) Skin Corrosion and Serious Eye Damage.** A product shall be evaluated for *skin corrosion* and *serious eye damage* following the testing and evaluation strategy described in the Globally Harmonized System for Classification and Labeling of Chemicals (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.

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

For hand sanitizers under this standard, skin irritants are identified under hazard categories 2 or 3 for skin irritation/mild skin irritation (H315 and H316) by the Globally Harmonized System for Classification and Labelling of Chemicals (GHS).

**(viii) Skin Sensitization.** The 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.

**(ix) Ozone Depleting Compounds.** The product shall not contain any *ingredients* that are *ozone-depleting compounds*.

**Claims Requirements for Hand Sanitizers**

**(x) 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.

**(xi) 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 *ingredients*.

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

## APPENDIX 1 – SCOPE (Informative)

Examples of products included in or excluded from the scope of GS-41:

| Products Included in GS-41 | Products Excluded from GS-41 |
|---|---|
| • *A: Institutional hand cleaners*<br>• *B: Industrial heavy-duty hand cleaners*<br>• *C:* Alcohol-based *hand sanitizers* | • General-purpose, restroom, glass and carpet cleaners for industrial and institutional use (included in GS-37)<br>• General-purpose, bathroom, glass, and carpet cleaner products marketed specifically for *household use* (included in GS-8)<br>• Hand cleaning products for household use (covered in GS-44)<br>• Hand cleaning products in food preparation operations or medical facilities.<br>• *Hand sanitizers* formulated with benzalkonium chloride as the active ingredient<br>• *Hand sanitizers* regulated as healthcare antiseptic rubs<br>• *Hand sanitizers* sold as wipes or within aerosol cans<br>• Shampoo, conditioner and related shower products for baby, child, adult, commercial, and professional use (GS-44)<br>• Personal care (GS-50) |