



# Proposed Criteria for Hand Sanitizers

**PUBLISH DATE: July 22, 2020**

## **Overview**

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Protecting public health amid the COVID-19 pandemic has precipitated stringent new routines in hand hygiene and facility care. Stakeholders in Green Seal’s community, including cleaning product manufacturers, cleaning service providers, and facility managers, have been working diligently in unprecedented conditions to aid the response to the COVID-19 global health emergency.

Green Seal recognizes that hand sanitizers are a critical tool for health protection. Green Seal has developed the Proposed Criteria for Hand Sanitizers to provide clarity, assurance, and simpler purchasing options for building managers, cleaning service providers, institutional purchasers, and consumers who are seeking products that are healthier for human health and protect the environment.

## **Scope of the Proposed Criteria**

The Proposed Criteria for Hand Sanitizers, included herein for public review

- (1) alcohol-based hand sanitizers for household use
- (2) alcohol-based hand sanitizers for professional use

These criteria will be housed in two existing Green Seal standards that cover hand hygiene products:

- Standard for Hand Cleaners for Industrial and Institutional Use ([GS-41](#))
- Standard for Soaps, Cleansers, and Shower Products ([GS-44](#)).

## **Instructions for Submitting Comments**

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The deadline for comments is Wednesday, August 5, 2020.

Submit all comments to [standards@greenseal.org](mailto:standards@greenseal.org), subject line: “Hand Sanitizer Comments.”

### **Contact Information**

For questions about Green Seal’s criteria development process or concepts included within this proposal, please contact Brie Welzer, Standards Program Manager, [bwelzer@greenseal.org](mailto:bwelzer@greenseal.org).

*Green Seal® is the leading U.S. ecolabel, symbolizing transparency, integrity, and proven environmental leadership. We develop life-cycle-based standards and certify products and services that can prove they meet our strict criteria for human health, reduced environmental impacts, and effective performance. Operating as a nonprofit since its founding in 1989, Green Seal has certified thousands of products and services in over 450 categories, and is specified by countless schools, government agencies, businesses and institutions.*

## **Product Eligibility – PROPOSED**

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### **Hand sanitizer products eligible for Green Seal Certification:**

- Consumer antiseptic rubs, as defined by the US Food and Drug Administration
- Alcohol-based hand sanitizers
- Hand sanitizers applied as liquids, including spray products
- Hand sanitizers applied as gels, foams, and lotions

### **Hand sanitizer products ineligible for Green Seal Certification**

- Healthcare antiseptics, as defined by the US Food and Drug Administration
- Benzalkonium chloride-based hand sanitizers
- Hand sanitizers sold as wipes or aerosols

## Product Performance Requirements – PROPOSED

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### **Product Performance.**

**In Vitro Testing.** Hand sanitizers shall demonstrate at least a 3-log reduction (99.9 percent) of the 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.

**In Vivo Testing.** Hand sanitizers shall demonstrate a 2-log reduction of the test organism, as required by the FDA's Tentative Final Monograph (TFM).

Test organisms for both in vitro and in vivo tests shall be representative of bacterial infections occurring in consumer settings.

Testing must be carried out in compliance with Good Laboratory Practices (GLP) (CRF 21, Part 58).

## Non-Toxic Verification Requirements – PROPOSED

### Verification that the Product is Non-Toxic via Ingestion, Inhalation, or Dermal Exposure

**Acute Toxicity.** The product shall not be toxic to humans. A product is considered toxic if any of the following criteria apply<sup>1</sup>:

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

For purposes of demonstrating compliance with this requirement, existing acute toxicity data for each of the product's *ingredients* will be used. This data is used to calculate a weighted average that assumes that the toxicity of the individual *ingredients* is additive. 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<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* in the product, when the *ingredient* has a vapor pressure greater than 1 mm Hg at 1 atm pressure and 20°C.

#### Definition of Ingredient

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

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

## General Human Health Requirements – PROPOSED

### Prohibitions on Ingredients Classified as Carcinogens, Mutagens, or Reproductive Toxins

**Carcinogens, Mutagens, and Reproductive Toxins.** The product shall not contain any *ingredients* that are *carcinogens, mutagens, or reproductive toxins*.

The product shall not contain any *ingredients* known to produce or release *carcinogens, mutagens, or reproductive toxins*.

The product shall not contain any *ingredients* that, according to published uses,<sup>1</sup> are typically added for the purpose of releasing substances into a raw material or the final product, if those substances are *carcinogens*.

<sup>1</sup> Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.

### Definitions

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

**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)).

**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.

**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).

### Prohibitions on Ingredients Classified as Endocrine Disruptors

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

### Definition of Ingredient

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

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## Skin and Eye Protection – PROPOSED

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### Ingredient Restrictions to Prevention of Skin Corrosion and Serious Eye Damage

**Skin and Eye Corrosion.** The product shall not cause *skin corrosion* or cause *serious eye damage*.

For purposes of demonstrating compliance with this requirement, data may be evaluated for each of the product's *ingredients*. If each *ingredient* is not shown to cause *skin corrosion* or *serious eye damage* at the concentrations in the product, then the product will not be considered to cause *skin corrosion* or *serious eye damage*.

Further, a product is considered to cause *skin corrosion* or to cause *serious eye damage* if it has a pH of 2 or less or a pH of 11.5 or greater, unless data prove otherwise.

### Definitions

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

**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*.

**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*.

### Ingredient Restrictions to Prevent Dermal Irritation

**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*.

#### Definition

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

### Ingredient Restrictions to Prevent Dermal Allergic Reactions

**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.

#### Definition

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

## Respiratory Protection – PROPOSED

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### Prohibition on Ingredients known to Cause Asthma

**Ingredients That Cause Asthma.** The product shall not contain any *ingredients* that have been identified as *asthmagens*. An exemption shall be made for triethanolamine (TEA)<sup>1</sup> only for gel hand sanitizers.

<sup>1</sup> Triethanolamine (TEA), CAS Number 102-71-6, EC Number: 203-049-8

### Definitions

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

**Asthmagen.** A substance designated as an *asthma* causing agent by the Association of Occupational and Environmental Clinics (AOEC).

## Aquatic Life Protection Requirements – PROPOSED

### Verification that the Product is Non-Toxic to Aquatic Life

**Toxicity to Aquatic Life.** The *product as rinsed off* shall not be toxic to aquatic life. A compound is considered not toxic to aquatic life if it meets the following criteria

Acute LC<sub>50</sub> for fish, daphnia, and/or algae  $\geq 100$  mg/L

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

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.

### Definitions

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

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

### Verification that the Product is Biodegradable

**Aquatic Biodegradability.** Each of the individual organic *ingredients* in the *product as rinsed off* shall exhibit ready biodegradability in accordance with the OECD definition, except for polymers, chelating agents, and colorants.

Biodegradability shall be measured according to any of the following methods: ISO 7827, 9439, 10707, 10708, 9408, 14593; OECD Methods 301A – F; or OECD 310. Specifically, within a 28-day test, the organic *ingredients* 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%

Testing is not required when sufficient information exists. Per OECD guidance the 10-day window requirement does not apply to structurally-related surfactant homologues. For organic *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 organic *ingredients* that do not exhibit ready biodegradability, if the compound has low aquatic toxicity (acute LC<sub>50</sub> ≥ 100 mg/L for algae, daphnia, and/or fish) and exhibits inherent biodegradability per ISO test methods 9887 or 9888 or OECD 302A-C.

### Definitions

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

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

### Prohibition on Ingredients Known to Bioaccumulate

**Bioaccumulating Compounds.** The *product as rinsed off* shall not contain any *ingredients* that bioaccumulate or that are known to form degradation products that bioaccumulate. A chemical is considered to bioaccumulate when it has a bioconcentration factor (BCF) ≥ 500 (or log K<sub>ow</sub> ≥ 4). The preferred source of data is from OECD TG 305 (for BCF). If the chemical meets the requirement for biodegradability, 3.15 herein, it may be considered to not bioaccumulate.

### Definitions

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

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

**Restriction on Phosphorous to Prevent Contribution to Eutrophication**

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

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## Prohibited Ingredients

### Prohibited Ingredient List to Highlight Hazardous Chemicals and Chemical Classes

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

- 2-butoxyethanol (CAS Number: 111-76-2; EC Number: 203-905-0)
- Alkylphenol ethoxylates (including compounds on [Canada.ca List](#))
- Bisphenol A (CAS: 80-05-7; EC: 201-245-8)
- Butylated hydroxytoluene (CAS: 128-37-0; EC:204-881-4)
- Ethylene-diamine-tetra-acetic acid or any of its salts (CAS: 60-00-4; EC: 200-449-4)
- *Halogenated organic solvents*
- The heavy metals lead, hexavalent chromium, or selenium both in the elemental form or compounds
- Methylidibromo glutaronitrile (CAS: 35691-65-7; EC: 252-681-0)
- Monoethanolamine (CAS: 141-43-5; EC: 205-483-3), Diethanolamine (CAS: 111-42-2; EC: 203-868-0), and Triethanolamine (CAS: 102-71-6; EC: 203-049-8).  
**Note:** Triethanolamine is exempted for gel hand sanitizers.
- Musks: Nitro-musks and polycyclic musks (Lists available on request)
- Nitrilotriacetic acid (CAS: 139-13-9; EC: 205-355-7)
- Parabens ([Listed in Peer-Reviewed Studies](#))
- Per- and polyfluoroalkyl substances (PFAS) ([EPA CompTox Chemicals Dashboard](#))
- Phthalates (List available on request)

### Definitions

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

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

## Fragrances and Animal Testing Requirements

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### Requirements to Confirm the Quality of Fragrances and to Prevent Needless Animal Testing

**Fragrances.** All fragrance *ingredients* 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.

**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 *ingredients* complies with the criterion.

#### Definition

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

## Packaging Requirements - PROPOSED

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### Requirements to Verify Minimized or Recycled Content Packaging that was Produced without Hazardous Chemicals

#### Primary Packaging.

**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.

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

**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 *ingredient* is not desired or deliberate, if the final packaging or packaging *ingredient* complies with the incidental concentration restrictions of 100 ppm.

**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.

#### Definition

**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.

## Additional Hand Sanitizer Requirements - PROPOSED

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### Required Disclosures to Verify Product Eligibility and Adherence to Critical Federal Regulations for Consumer Antiseptics

**A. Alcohol Verification.** Hand sanitizers must meet all regulations set by the US Food and Drug Administration. Green Seal shall verify the following:

**Ethyl Alcohol Based Hand Sanitizers.**

- (1) Product shall be at least 60 percent ethyl alcohol.
- (2) Ethyl alcohol must be Specially Denatured Alcohol (SDA).
- (3) Ethyl alcohol must be at least USP grade.

**Isopropyl Alcohol Based Hand Sanitizers.**

- (1) Product must contain at least 70 percent isopropyl alcohol.

**B. Disclosure of Ethanol Impurities in Final Formulation.** The Certificate of Analysis must demonstrate that the ethyl alcohol in the final product meets at least USP impurity levels.

### Manufacturing Disclosure Requirements:

Drug Registration Number  
Establishment Registration Number  
Labeler code