Final Criteria for Hand Sanitizers

September 10, 2020

Overview

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 Health and Environmental Protection 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.

(1) alcohol-based hand sanitizers for use in household, commercial, and institutional settings

(2) alcohol-based hand sanitizers for use in healthcare settings

These criteria are now included within two 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).

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Product Eligibility – FINAL

Hand sanitizer products eligible for Green Seal certification:

- Consumer antiseptic rubs and healthcare antiseptic rubs as defined by the US Food and Drug Administration (FDA)
- 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

- Benzalkonium chloride-based hand sanitizers
- Hand sanitizers sold as wipes or aerosols

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Product Performance Requirements

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.

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 (CFR Title 21, Chapter I, 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

Definition of Hand Sanitizer

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 terms “consumer antiseptic rubs” and “healthcare antiseptic rubs.”

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Non-Toxic Verification Requirements

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:

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

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_i = the weight fraction of the *ingredient*
TV = the toxicity value for each *ingredient* (LD_{50})
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.

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General Human Health Requirements

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*.

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).

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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

Ingredient Restrictions to Prevent 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*.

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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.

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Respiratory Protection

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)[1] only for gel hand sanitizers.

[1] 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).

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Aquatic Life Protection Requirements

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_{50} 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_{50}>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, expect for polymers, chelating agents, and colorants.

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

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BOD, as % of Theoretical Oxygen Demand (ThOD)	> 60%
CO_2 evolution, as % of theoretical CO_2	> 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 LC50 ≥ 100 mg/L for algae, daphnia, and/or fish) and exhibits inherent biodegradability per ISO test methods 9887 or 9888 or OECD 302A-C.

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_{ow} ≥4). The preferred source of data is from OECD TG 305 (for BCF). If the chemical meets the requirement for biodegradability, 3.15 herein, it may be considered to not bioaccumulate.

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.

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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
- Methyldibromo 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.

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Fragrances and Animal Testing Requirements

Quality of Fragrances and Prevention of 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.

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Packaging Requirements

Verification of Minimized / Recycled Content Packaging Produced

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.

Packaging Ingredient Restrictions

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.

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Additional Hand Sanitizer Requirements

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

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.

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 ingredients*, respectively, with no synthetic, petroleum, silicone, or artificial ingredients.
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> "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*.

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.

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 *hand sanitizers*:

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

Definitions

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

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.

Naturally Derived Ingredient. An *ingredient* that is partially chemically altered without petroleum *components* and has been minimally processed such that it is not altered to the extent that it remains biodegradable and non-toxic.

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Additional Hand Sanitizer Requirements

Verification of Compliance with Federal Regulations for Consumer Antiseptics

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

Ethyl alcohol-based hand sanitizers shall be at least 60 percent ethyl alcohol, Specially Denatured Alcohol (SDA), and the ethyl alcohol shall be USP certified or demonstrated to have a purity that meets USP specifications for levels of contaminants.

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

Manufacturing Disclosure Requirements. The following information shall be disclosed: Establishment Registration Number; Labeler code; and National Drug Code (NDC) of the finished product.