



Background Report

**Development of Proposed Criteria
for Alcohol-Based Hand Sanitizers**

July 30, 2020

About Green Seal

Green Seal® is a global nonprofit organization that pioneered the ecolabeling movement with a mission to transform the economy for a healthier, greener world. For 30 years, Green Seal's rigorous standards for health, sustainability and product performance have driven permanent shifts in the marketplace, empowering better purchasing decisions and rewarding industry innovators. With thousands of certified products, services and spaces from the world's leading companies, the Green Seal certification mark is a universal symbol that a product or service meets the highest benchmark of health and environmental leadership.

Our Mission.

To transform the economy for a healthier, greener world.

Our Vision.

A healthy society in balance with nature.

Introduction

This background report summarizes research and technical justifications for Green Seal's Proposed Criteria for Alcohol-Based Hand Sanitizers.

Since entering the US marketplace in the 1980s, hand sanitizers have provided an effective and efficient option for hand hygiene. US and international health organizations have called the use of alcohol-based hand sanitizers the second-best hand hygiene option, after hand washing with soap and water. Hand sanitizers are now critical to public health worldwide, as governments and healthcare groups work to slow the spread of COVID-19.

Given the strong demand for these products, which people may be using an estimated 20 to 50 times per day, Green Seal has developed a health-protective framework for hand sanitizer certification. Green Seal-certified products, with all ingredients reviewed by an independent third party for meeting highly health-protective requirements, are intended to inform and assure consumers and procurement professionals who are seeking healthy, effective products.

Efficacy against Bacteria and Certain Viruses, Including Coronaviruses

COVID-19 is caused by a virus. Although alcohol-based hand sanitizers are frequently marketed as *antibacterial* hand hygiene products, the high concentrations of alcohol in many hand sanitizers have broad-spectrum antimicrobial activity, including the ability to inactivate enveloped coronaviruses.¹

A Common and Vital Purchase

Efficacy, convenience, and the COVID-19 public health emergency have made alcohol-based hand sanitizers ubiquitous: hand sanitizer is provided free at grocery stores, restaurants, public buildings, commercial office spaces, and even outdoor public spaces, such as parks and playgrounds. The use and free provision of hand sanitizer have been codified into certain state, county, and local protocols that now specify placing hand sanitizer dispensers at building entrances.²

Green Seal-Certified Hand Sanitizers: Healthier Ingredients, Reduced Environmental Impact

The production, use, and disposal of hand sanitizers have health and environmental consequences. Consumers and purchasers will benefit from a simpler, meaningful choice that highlights safer, greener products. Green Seal certification for hand sanitizers is intended to provide information and assurance to purchasers and product users, while recognizing the health and environmental leadership of product manufacturers.

Urgent Need for Assurance against Hazardous Hand Sanitizers on the US Market

With the sudden demand for hand sanitizers, new companies have entered this space, some of them offering products containing hazardous ingredients, and supply chains have shifted. Consumers have been warned by the US Food and Drug Administration (FDA) to stay vigilant and beware of hand sanitizers with dangerous formulations.

Three deaths occurred in New Mexico in June 2020, when individuals ingested hand sanitizer illegally formulated with methanol, a highly toxic substance.³ Even product users who correctly applied this product may have suffered from the exposure to methanol, also known as wood alcohol. As of July 2020, the FDA listed 77 commercially available hand sanitizer products that contain hazardous ingredients and should not be purchased.⁴ Green Seal's third-party certification is not the only immediate solution for

1 <https://www.cdc.gov/coronavirus/2019-ncov/hcp/hand-hygiene.html>

2 <https://www.kingcounty.gov/depts/health/covid-19/workplaces/grocery-stores.aspx>

3 <https://www.nytimes.com/2020/06/26/us/3-dead-drinking-hand-sanitizer.html>

4 <https://www.usatoday.com/story/money/2020/07/11/hand-sanitizers-recalled-methanol-risk-avoid-these-kinds/5420188002/>

avoiding hazardous products. However, product certification offers an opportunity for manufacturers to demonstrate an additional layer of oversight and offer superlative formulations that provide protection for health and the environment, above and beyond the standards set in federal and state regulations.

Approach to Health and Environmental Criteria

Green Seal's standard development process uses an open, transparent, and systematic approach to developing health and environmental criteria for product categories. Aligned with best practices for standard development, including ISO 14024 and ISEAL's Standards Code, and drawing from life-cycle methodology, including ISO 14040 and US Environmental Protection Agency (EPA) Life Cycle Assessment: Principles and Practices, Green Seal's standard development process is as follows:

Identify impact reduction opportunities.

Green Seal first confirms that a product type or category (e.g., hand sanitizer) is widely available in the North American market and that variations in its raw materials, formulas, production, packaging, use, and disposal may allow for a distinction between conventional products and those which are safer and more sustainable.

Conduct a product life-cycle review.

Green Seal conducts life-cycle mapping and a life-cycle phase impact review. Green Seal identifies the regulatory or market framework that shapes the product life cycle, including regulations and legislation; environmental, health, and consumer advocacy priorities; and health and environmental claims made by product manufacturers.

Engage expert stakeholders.

Green Seal engages stakeholders, including producers, users, and public interest groups. Green Seal conducts informational interviews to gather data, record perspectives, uncover issues that are not studied or publicized, and take into account technical and market guidance.

Implement market surveys and ingredient screenings.

Green Seal gathers information on product efficacy testing, active ingredients, raw materials, additives, contaminants, and packaging. During this phase, Green Seal highlights opportunities to design a healthier product for the user and opportunities to phase out health and environmental hazards from the supply chain. Green Seal screens ingredients against 12 foundational criteria (e.g., prohibitions on carcinogens, mutagens, and reproductive toxins) that make up Green Seal's framework for assessing products.

Design measurable, meaningful requirements for impact reduction.

Green Seal identifies the most critical, feasible, and measurable opportunities for reducing the health and environmental impacts across the product's life cycle. This may include limits on water and energy use in the manufacturing phase, the prohibition of hazardous ingredients with "non-regrettable" substitutes, and requirements for a specified percentage of recovered materials in place of virgin materials.

Collect and publish public comment and public response.

Green Seal publishes Proposed Criteria and encourages stakeholders to submit comments, suggest clarifications, and provide substantive criticism. Green Seal publishes all formally submitted comments, plus responses to each substantive issue identified by commenters.

Issue Final Criteria or Standard and initiate product certifications.

After resolving or addressing all substantive issues, Green Seal issues the Final Criteria or the Final Standard, at which point products are eligible to achieve the Green Seal certification.

Impact Reduction Pathways

Green Seal's Proposed Hand Sanitizer Criteria are designed to protect human health and the environment via three major pathways:

- **Prohibitions on Chronic Health Hazards**
 - Ingredients known to be carcinogens, mutagens, reproductive toxins, endocrine disruptors, and asthmagens are prohibited.

- **Protections for Skin and Eyes**
 - Ingredients that cause eye damage are restricted.
 - Ingredients that are skin irritants are restricted.
 - Ingredients that are skin sensitizers are restricted.

- **Restrictions on Acute Aquatic Hazards**
 - Product must be non-toxic to aquatic life.
 - Product must be biodegradable.
 - Product must not result in chemical bioaccumulation.

The above list reflects the lifecycle impact areas determined to have significant impact reduction opportunities. An overview of the health and environmental impacts across the hand sanitizer product lifecycle can be found on Page 12.

Document Guide

Part I of this report provides a brief review of over-the-counter consumer antiseptic rubs (i.e., hand sanitizers), including a brief discussion of regulations, product function, product composition, common ingredients, and known hazards. The review is restricted to products manufactured and sold in the US market.

Part II of this report summarizes the justifications and intentions for Green Seal's Proposed Criteria for Alcohol-Based Hand Sanitizers.

Instructions for Submitting Public Comments

As of the publication date of this report, Green Seal has opened a Public Comment Process for the Development of Hand Sanitizer Criteria. To submit comments on this background report or the Proposed Criteria, visit [Green Seal's website](#).

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PART I. HAND SANITIZERS OVERVIEW

Scope of Proposed Criteria

Hand sanitizers are a convenient, effective option for maintaining hand hygiene when handwashing is not accessible or convenient. Hand sanitizers are designed to quickly reduce the number of pathogens on human hands. These products are not designed to clean or remove contaminants, however; they are designed for use on unsoiled skin.

Hand sanitizers are regulated in two categories: consumer antiseptic rubs and healthcare antiseptic rubs. Consumer antiseptic rubs, hereafter referred to as “consumer hand sanitizers” or simply “hand sanitizers,” are formulated with one of three active ingredients: ethyl alcohol, isopropyl, or benzalkonium chloride.

Green Seal’s Proposed Criteria is relevant only for alcohol-based hand sanitizers.

Healthcare antiseptic rubs and benzalkonium chloride–based consumer antiseptics are outside the scope of this report and are not covered by Green Seal’s Proposed Criteria for Hand Sanitizers.

Hand Hygiene

Practicing good hand hygiene is considered an effective method for reducing the spread of respiratory and diarrheal infections in a diverse range of settings.⁵ One study notes that teaching effective hand washing in a community led to a reduction in respiratory illnesses by 16 to 21 percent.⁶ National and international guidance addressing the COVID-19 pandemic consistently prescribes meticulous hand hygiene as a critical tool for reducing the spread of the virus.

Studies have presented evidence showing that the application of hand sanitizers is correlated with reduced rates of illness in households, K-12 schools, and university residential facilities.⁷

Effective hand hygiene via the application of hand sanitizers requires applying the appropriate amount of the product (at least 3 ml),⁸ rubbing hands together for at least 20 seconds, and covering all hand surfaces.

Product Profile

The hand sanitizer products in the North American market have the following formulations.

Active Ingredients

- Ethyl alcohol (C₂H₆O), 60 to 72 percent, with the most common formulations at 62 percent
- Isopropyl alcohol (C₃H₈O), 70 percent
- Benzalkonium chloride

Ethyl Alcohol and Isopropyl Alcohol

- Ethyl alcohol is the most common active ingredient for hand sanitizers.
- Isopropyl alcohol is an acceptable active ingredient for hand sanitizers, according to the FDA, but formulations with this active ingredient appear to be rare. Isopropyl alcohol antiseptics are commonly marketed as first-aid products rather than as hand hygiene products.

⁵ <https://www.cdc.gov/healthywater/hygiene/hand/handwashing.html>; <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3291447/>

⁶ <https://pubmed.ncbi.nlm.nih.gov/18556606/>; <https://pubmed.ncbi.nlm.nih.gov/16553905/>

⁷ <https://pubmed.ncbi.nlm.nih.gov/14608304/>

⁸ <https://www.acsh.org/news/2017/01/10/you-arent-using-enough-hand-sanitizer-10717>

Inactive Ingredients

- Water, which acts as a carrier for the ingredients
- Emollients, humectants, and other skin conditioners
- Gelling agents (in gel products), polyacrylates
- Fragrances
- Stabilizers or preservatives
- Ultraviolet (UV) light blockers
- pH buffers

Product Forms

- Gel products are most common in both retail and professional markets⁹
- Liquid sprays are common for retail small-bottle products.
- Foam products are available in the professional market.
- Wipes, aerosols, and concentrates are less common.

US Federal Regulations

Products sold as hand sanitizers in the United States are classified as a drug, defined as a “substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.”¹⁰ The safety, efficacy, and security of drugs in the United States are regulated by the FDA. Specifically, hand sanitizers sold for consumer use are considered “consumer antiseptic rubs” and are over-the-counter (OTC) drugs that can be purchased without a prescription from a physician.

The FDA has two pathways by which an OTC drug can come into the market: 1) it may be reviewed as a “new drug,” or 2) it complies with the applicable drug monograph.¹¹ OTC drug monographs are rulebooks that set conditions of each therapeutic drug category and cover “acceptable ingredients, uses (indications), doses, formulations, labeling, and testing.”¹² Any drug that is compliant with the rules set forth in a monograph can be marketed without having to receive individual FDA evaluation and approval.

OTC Drug Monograph for Hand Sanitizers

The specific requirements for hand sanitizers sold as consumer antiseptic rubs fall under the Monograph for Topical Antimicrobial Drug Products for Over-the-Counter Human Use (Consumer Antiseptic Rubs).¹³ The Consumer Antiseptics OTC Monograph outlines specific requirements for allowed active ingredients, labeling requirements, and claims guidance.

Allowed Active Ingredients

The most recent ruling of the OTC Monograph defers judgment on the three allowed active ingredients for consumer antiseptic rubs—benzalkonium chloride, ethyl alcohol, and isopropyl alcohol.¹⁴ As a result, any manufacturer that follows the current ruling and uses one of the above three actives at the specified concentrations may begin to manufacture and market its product without any review from the FDA. Any hand sanitizer that does not follow these requirements is considered a new drug and must follow an alternative application pathway to be approved for sale.

⁹ Professional Market, i.e., commercial and institutional procurement; products intended for use in retail facilities, government buildings, and other away-from-home settings.

¹⁰ <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms#D>

¹¹ <https://www.fda.gov/drugs/over-the-counter-otc-drug-monograph-process>

¹² https://www.accessdata.fda.gov/scripts/cder/training/OTC/topic3/topic3/da_01_03_0100.htm

¹³ <https://www.govinfo.gov/content/pkg/FR-2019-04-12/pdf/2019-06791.pdf>

¹⁴ <https://www.govinfo.gov/content/pkg/FR-2019-04-12/pdf/2019-06791.pdf>

FDA Efficacy Guidance

The OTC Monograph does not specify the most appropriate test method for full product formulations, since the focus for the FDA is on the efficacy (and safety) of the active ingredients. However, in responding to comments that mention three ASTM tests, the FDA states that “the test methods ... may be useful to help establish Generally Regarded as Safe and Effective (GRASE) status for the three deferred antiseptic active ingredients for use in consumer antiseptic rub products,” and later specifies that the tests may be appropriately used in part of efficacy criteria (Response 10). Those ASTM tests are ASTM E2755-15, ASTM E1054-08, and ASTM E2783-11. See below for details on these three efficacy test methods for antiseptic rubs.

Although efficacy testing is discussed in the OTC Monograph, it is Green Seal’s understanding that, as with any OTC drug, hand sanitizer manufacturers are not required to submit results of efficacy testing of final formulations.

FDA Good Manufacturing Practices

Prior to selling hand sanitizers, manufacturers must undergo several processes set by the FDA, including registering as “domestic or foreign establishments that manufacture, repack, or re-label drug products in the United States,”¹⁵ and they must comply with Current Good Manufacturing Practices (cGMPs)¹⁶ that apply to manufacturers that create finished pharmaceuticals.¹⁷ cGMP requirements range from standards for facility equipment¹⁸ to stability and active ingredient identity testing.¹⁹ cGMPs ensure the “identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations.”²⁰

The FDA does not require data submission of adherence to these practices before allowing a consumer antiseptic rub to be marketed. However, these practices can be reviewed as part of an FDA compliance audit of manufacturing facilities that make hand sanitizers.

Ethanol Requirements for Purity and Denaturants

Under FDA regulations (21 CFR 229), drugs must comply with compendial standards (FDA Section 502(g)), and for the case of ethanol purity, the USP Monograph. This standard defines purity levels and sets maximum levels for specific hazardous impurities, including acetaldehyde and benzene.

Additionally, the US federal government requires that ethanol not intended for consumption include a “denaturant,” a chemical that makes it bitter and unfit for drinking.

FDA’s June 1 Guidance on Ethanol, in Response to COVID Supply Chain Disruptions

Because of the COVID-19 pandemic, global demand for hand sanitizers has increased. Hand sanitizers that have ethanol as the active ingredient are usually required to use at least USP-grade alcohol, which ensures a limited concentration of specifically identified impurities.

The increase in demand for hand sanitizer has led to a severe shortage of high-grade ethanol. Suppliers of food-grade ethanol, including distilleries, began to respond by providing alternative ethanol.

15 <https://www.fda.gov/industry/fda-basics-industry/registration-and-listing>

16 <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>

17 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211>

18 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211&showFR=1&subpartNode=21:4.0.1.1.11.4>

19 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211&showFR=1&subpartNode=21:4.0.1.1.11.9>

20 <https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps>

On June 1, 2020, the FDA released temporary guidance that allowed manufacturers of alcohol and compounders of hand sanitizer products to produce ethanol by unregistered manufacturing facilities as long as they followed FDA guidelines. The temporary guidance sets temporary acceptable limits on impurities greater than what is specified for USP ethanol.

Product Function: Antimicrobial Activity

Efficacy against Both Bacteria and Certain Viruses

Alcohol-based hand sanitizers have broad-spectrum antimicrobial activity, including the ability to inactivate enveloped coronaviruses.²¹ According to the National Institutes of Health, “Ethyl alcohol, at concentrations of 60%–80%, is a potent viricidal agent inactivating all the lipophilic viruses (e.g., influenza, herpes and vaccinia virus) and many hydrophilic viruses (e.g., adenovirus, enterovirus, rhinovirus, and rotaviruses but not hepatitis A virus (HAV) or poliovirus).”²² According to peer-reviewed in vitro studies, alcohol-based hand sanitizers formulated with at least 60% ethyl alcohol showed “a 4 to 6 log reduction in 15-30 seconds against a range of bacterial and fungal species.”²³

To test the efficacy of their products, manufacturers typically use standardized ASTM or European tests. According to Green Seal’s market review and direct discussions with product formulators, two in-vitro tests are commonly used for efficacy testing to confirm antimicrobial activity.

ASTM E2783- 11 (2016)

Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure²⁴

This test evaluates the changes in a microbial population after exposure to a test product. Specifically, it “measures the changes of a population of aerobic and anaerobic microorganisms within a specific sampling time when tested against antimicrobial test materials in vitro.”²⁵ The test also provides specific requirements for microbial organism selection, growth, inoculation, and other testing parameters.

ASTM E2315-16

Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure²⁶

This test also evaluates the reduction of a microbial community after it is exposed to a test product within a specific sampling time. However, it provides more flexible options, such as “several options for organism selection and growth, inoculum preparation, sampling times, and temperature ...”

Additionally, as specified in the US FDA’s 1994 Monograph for Consumer Antiseptic Rubs, in vivo testing is an important demonstration of produce efficacy. Appropriate standardized test methods for in vivo testing are ASTM 2755 and E11774.

ASTM 2755

21 <https://www.cdc.gov/coronavirus/2019-ncov/hcp/hand-hygiene.html>; <https://www.mdpi.com/1660-4601/17/9/3326/htm>

22 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7246736/>

23 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7301780/>

24 <https://www.astm.org/Standards/E2783.htm>

25 <https://www.astm.org/Standards/E2783.htm>

26 <https://www.astm.org/Standards/E2315.htm>

Standard Test Method for Determining the Bacteria-Eliminating Effectiveness of Healthcare Personnel Hand Rub Formulations Using Hands of Adults

EN 1500, Hygienic Handrub Method

According to international test laboratories, this standard provides an evaluation framework for measuring “the number of viable bacteria remaining on the fingertips after contamination and handrub exposure.”²⁷

Overview of Product Life Cycle

To consider opportunities for impact reduction across the life cycle of hand sanitizers, Green Seal gathered information on each of the phases, listed and summarized below.

Ethyl alcohol is produced from corn biomass. Corn is a major US agricultural commodity; an estimated 40 percent of the US corn crop is refined into ethyl alcohol. Primary uses of ethyl alcohol, i.e., ethanol, include:

- A biofuel or fuel additive²⁸
- A solvent in cleaning products and personal care products
- Imbibed as alcoholic beverages
- And, in high concentrations, the antimicrobial active ingredient in most alcohol-based hand sanitizers

Data is not publicly available on the percentage of US corn crop converted into highly distilled, pharmaceutical-grade ethyl alcohol. Green Seal estimates that this segment of ethyl alcohol produced represents a small fraction compared to the ethanol developed as an additive to gasoline. Although the extent of distillation of the alcohol differs between fuel-grade and pharmaceutical-grade ethanol, the corn production, grain processing, and fermentation processes are generally the same.

1. Raw Materials and Manufacturing

Feedstock: corn. Corn production has the following lifecycle impacts: global warming (greenhouse gas emissions); water use; freshwater ecotoxicity and eutrophication; land use and transformation. Recent studies have shown improvements in the efficiency of corn production. Major impacts prioritized by industry and environmental groups include the unsustainable use of groundwater for irrigation; the eutrophication of waterways caused by fertilizer runoff from cornfields; land erosion when corn depletes soil nitrogen and phosphorus; and emissions of nitrous oxide, a “potent greenhouse gas with 300 times more warming potential than carbon dioxide,” caused by nitrogen fertilizer inputs to the soil.²⁹

Active ingredient: ethyl alcohol.³⁰ Ethyl alcohol is sourced and distributed to chemical mixing and formulating facilities, sometimes referred to as toll blenders. The ethanol is denatured—that is, a denaturant is added—either by the ethanol producer or at a separate manufacturing plant where all final

²⁷ <http://vivotesting.com/information/en-1500-hygienic-handrub-method>

²⁸ <https://www.agriculture.com/news/business/ethanol-market-is-disturbing-as-hell-to-american-farmers-and-now-there-s-covid-19>

²⁹ <https://www.ourenergypolicy.org/wp-content/uploads/2014/06/ceres-corn.pdf>

³⁰ **Note:** The Centers for Disease Control and Prevention (CDC) have historically, and more recently in response to the COVID-19 pandemic, specified that that alcohol-based hand sanitizers are a beneficial secondary tool for hand hygiene, when soap and water are unavailable. A non-alcohol active ingredient for consumer hand sanitizers is benzalkonium chloride, which are less widely available. According to the CDC, benzalkonium chloride has less reliable activity against certain bacteria and viruses than either of the alcohols.”³⁰

ingredients are added.³¹ The denaturant is required to make the ethanol and the final product unpalatable to prevent and deter its consumption, which could cause alcohol poisoning. [A previous section](#), herein, provides more detail on the FDA regulations on active ingredients in hand sanitizers that are regulated as consumer (non-healthcare) antiseptic products.

Manufacturing and compounding. The FDA requires that the production of hand sanitizer meet USP General Chapter 795. During manufacturing or toll blending (i.e., contract blending of formulated products), the denatured alcohol is mixed with such additives as skin conditioners, fragrances, preservatives, and other inactive ingredients.³² Manufacturing conditions are required to meet the FDA’s Good Manufacturing Practices (GMP).³³ [A previous section](#), herein, provides more detail on the FDA regulations on manufacturing hand sanitizers that are regulated as consumer (non-healthcare) antiseptic products.

Food-grade ethanol used temporarily in hand sanitizer during shortage. In early 2020, online and brick-and-mortar retailers in the United States saw a surge in demand for hand sanitizers: sales of hand sanitizer increased by an estimated 200 percent compared with 2019.³⁴ Supply issues ensued, and certain producers of ethanol fuel and thousands of medium-size and small distilleries began to shift production to supply hand sanitizer. Pharmaceutical-grade ethanol is more distilled than fuel-grade ethanol to ensure a reduced concentration of hazardous impurities, such as acetaldehyde, a carcinogen. Suppliers of ethanol fuel made significant investments to retrofit their processing facilities to make the pharmaceutical-grade product.³⁵ Distilleries were temporarily allowed to manufacture and sell hand sanitizers, despite not having been registered by FDA.³⁶

Final formulation testing. Final formulations are sent to product testing laboratories for purity, stability, and efficacy testing, as required by the FDA. These tests are conducted under the FDA’s Good Laboratory Practices.³⁷ [A previous section](#), herein, provides more detail on the FDA regulations established for hand sanitizer product testing.

Impacts Reduction Opportunities, Raw Materials and Manufacturing

Green Seal did not identify feasible impact reduction opportunities within the raw materials and manufacturing lifecycle phases. Green Seal noted that compliance with the regulatory codes, which set requirements for quality manufacturing, the use of low-contamination USP grade ethyl alcohol, and product efficacy and stability testing, is critical to the production of healthier hand sanitizers. Therefore, Green Seal has proposed information disclosure requirements that would allow Green Seal to verify that the product and manufacturing process meet certain FDA regulatory requirement. [See proposed requirements](#), herein.

2. Packaging and Labeling

Manufacturers have several considerations when selecting plastic packaging, including chemical compatibility, temperature, shelf life, and UV light. A common packaging material for hand sanitizers is polyethylene terephthalate (PET) plastic. This type of plastic can be recycled or rinsed out and reused. PET is a relatively green plastic in part because it is not fluorinated, and it is widely recyclable.

31 <https://www.usp.org/covid-19/hand-sanitizer-information>

32 <https://www.linkedin.com/pulse/what-toll-blending-roland-schellen/>

33 <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>

34 <https://www.cnn.com/2020/03/13/business/hand-sanitizer-sales/index.html>

35 <https://www.cnbc.com/2020/05/07/worlds-largest-ethanol-producer-forced-to-find-a-new-market-hand-sanitizer.html>

36 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-temporary-compounding-certain-alcohol-based-hand-sanitizer-products-during-public-health>

37 <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/nonclinical-laboratories-inspected-under-good-laboratory-practices>

Hand sanitizer dispensers for the professional market are commonly designed for use with refill bags, which are made of flexible, soft plastic. Bag-in-box and cartridge systems are intended to prevent the contamination that can occur when dispensers are manually refilled. The “top-off” method—a worker opens the bag and pours in new liquid—is prohibited in food-handling settings in Canada, to prevent risk of bacterial contamination.³⁸ Product labels are required to meet the requirements set in the FDA’s OTC Monograph.³⁹

Impacts Reduction Opportunities, Packaging and Labeling

Green Seal identified several opportunities to verify that the product packaging was produced with a lower health and environmental impact. Specifically, Green Seal proposes to include requirements for minimized packaging or the incorporation of post-consumer content material and hazardous chemical restrictions. Additionally, Green Seal proposes to prohibit hand sanitizers sold in aerosol packaging due to their unnecessary use of propellants, as well as the unnecessary health risk to the product user via aerosol inhalation. The proposed requirements for packaging are consistent with those included in existing Green Seal standards for soaps, cleaners, and shower products (GS-44 Standard) and personal care products (GS-50 Standard). Green Seal requires certified products to include a Basis of Certification Statement on product labels that include the Green Seal Mark, as demonstration of conformance to the Federal Trade Commission Green Guides, which require substantiation of ecolabels on product packaging.

3. Distribution

Hand sanitizers are sold in both retail and professional markets. The products are transported to distribution warehouses and, if intended for retail, to retail locations. Because of its flammability, alcohol-based hand sanitizer is classified as a hazardous material and must therefore meet US Department of Transportation (DOT) hazardous materials regulations for transportation.⁴⁰

One documented life-cycle impact from distribution comes from the transportation of the main active ingredient, ethanol. According to the ethanol industry’s trade association, “More than 90 percent of the ethanol produced in the United States is shipped by train or truck.”⁴¹ The US Department of Agriculture notes that “CO2 emissions from combusting gasoline and diesel fuels occur in transporting corn from farm to refinery, ethanol from refinery to retail station, and co-products from refinery to end users. While this category accounts for 5-6 percent of ethanol’s GHG profile, transportation vehicles and systems have become more fuel and GHG efficient since 2010.”⁴²

Impacts Reduction Opportunities, Distribution

Because the crucial active ingredient is transported primarily by two modes of transportation that emit lower levels of greenhouse gas emissions than, for example, air transport, Green Seal did not identify feasible opportunities to reduce the health or environmental impact of the distribution lifecycle phase. As more companies shift to fleets of electric vehicles, Green Seal may further evaluate impact reduction opportunities for product distribution.

4. Use

38 <https://www.cleanlink.com/cp/article/Bulk-Soap-Dispensers-Examining-The-Potential-For-Bacterial-Contamination---14669>

39 <https://www.federalregister.gov/documents/2019/04/12/2019-06791/safety-and-effectiveness-of-consumer-antiseptic-rubs-topical-antimicrobial-drug-products-for>

40 <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-04/PHMSA%20Hand%20Sanitizer%20Relief%20Notice.pdf>

41 <https://ethanolrfa.org/producers/regulations/>

42 https://www.researchgate.net/publication/312621455_A_Life-Cycle_Analysis_of_the_Greenhouse_Gas_Emissions_of_Corn-Based_Ethanol/link/5894ba9e4585158bf6e95397/download

Individuals apply approximately 1.5 to 3 ml to their hands, rub the liquid or gel over the surface of their skin, including palms and between fingers, and sometimes the tops of hands and knuckles.

Hand sanitizers are designed to be applied directly to hands and are not intended for use elsewhere on the body.⁴³ Hand sanitizers are not intended to be used with water or washed down the drain during or after use. Directions on hand sanitizers product labels should state the following:

Put enough product in your palm to cover hands and rub together briskly until dry. Children under 6 years of age should be supervised when using this product.⁴⁴

Hand sanitizers are intended to function quickly—within 15 to 30 seconds—with the expectation that the antimicrobial activity occurs, the alcohol evaporates, and the remaining ingredients moisturize the skin and treat or prevent any dryness or irritation that may occur from contact with alcohol. A percentage of the alcohol and inactive ingredients may enter the body via dermal absorption and via inhalation.⁴⁵ Evaluations of the potential for adverse health effects from skin absorption of alcohol found that for healthcare workers who apply the product 30 times a day, the effect was on par with consuming one 10th of a glass of wine.⁴⁶

Skin and Eyes. Studies show that both methods of hand hygiene, hand washing with soap and the application of hand sanitizers, can cause skin dryness, irritation, damage due to dryness, and sensitization (allergy).⁴⁷ The dryness and associated irritation and damage are attributed to the high concentration of alcohol. Ethyl alcohol is a neutral molecule, at 7.33 pH, but it can cause “significant eye irritation” and inflammation of the cornea.⁴⁸

Skin Irritation and Allergic Reactions (Sensitization). A 2020 review published in the *International Journal of Environmental Research and Public Health* summarizes the adverse reactions associated with hand sanitizers:

The most commonly reported skin reactions with the use of [alcohol-based hand sanitizers] are irritant contact dermatitis (ICD) and allergic contact dermatitis (ACD). The symptoms of ICD can range from mild to debilitating with manifestations like dryness, pruritus, erythema and bleeding, if severe. As for ACD, the symptoms can either be mild and localized or severe and generalized, with most severe forms of ACD being manifested as respiratory distress or other anaphylactic symptoms.⁴⁹

Skin Damage. Some hand sanitizers can irritate human skin. According to public health peer-reviewed studies,

“Hand hygiene products such as sanitizer and soaps can be damaging to the skin through several mechanisms: denaturation of the stratum corneum proteins, alteration of intercellular lipids, decrease in corneocyte cohesion and reduction of stratum corneum water-binding capacity. The biggest concern is the depletion of the lipid barrier, especially with repeated exposure to lipid-emulsifying detergents and lipid-dissolving alcohols as it may penetrate deeper into the skin layers and change the skin flora, resulting in more frequent colonization by bacteria. In order of decreasing frequency of ICD [irritant contact dermatitis] including handwashing soaps are

43 <https://www.cdc.gov/handwashing/show-me-the-science-hand-sanitizer.html>

44 <https://www.frontierlabel.com/blog/how-to-create-fda-approved-hand-sanitizer-labels>

45 Respiratory exposure to ethanol vapor during use of hand sanitizers, *Journal of Analytical Toxicology*, 2011

46 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3367283/>

47 <https://www.ncbi.nlm.nih.gov/books/NBK144008/>

48 <https://iovs.arvojournals.org/article.aspx?articleid=2188992>

49 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7246736/>

iodophors, chlorhexidine, chloroxylenol, triclosan and alcohol-based products. Among the alcohol-based formulations, ethanol has the least skin-irritant property compared to n-propanol and isopropanol.”⁵⁰

Green Seal conducted a product and ingredient survey covering 80 hand sanitizers sold on the US market, made of more than 100 ingredients. Eight ingredients were found to be irritating to either skin or eyes if they were present in the product above a certain concentration. Examples include the following:

- Aminomethyl propanol, a pH buffer found in gel products, has been found to be irritating to skin and eyes if its concentration exceeds 0.59 percent.
- Benzophenone-4, a UV blocker, has been identified as corrosive to skin and eyes.⁵¹
- Fragrance components—Gamma-octalatone and gamma-non-lactone (both coconut fragrances)—were found to be irritating to skin.
- Certain quaternary ammonium compounds have also been used in hand sanitizers as emulsifiers and, at certain concentrations, can cause skin irritation and be corrosive to eyes.

An excerpt of Green Seal’s [ingredient review](#) is included, herein.

Skin Conditioners to Heal or Prevent Skin Damage. Hand sanitizer formulas include emollients or humectants, also known as skin conditioners. In Green Seal’s ingredient review of 80 hand sanitizers available on the US market, the following conditioners were identified: aloe, tocopherol acetate (synthetic form of vitamin E), glycerol, and isopropyl myristate.

Misconceptions about Application of Hand Sanitizers. Studies of healthcare workers have shown that users frequently do not apply a large enough volume of hand sanitizer. Approximately 2.25 ml of hand sanitizer may be required to fully treat both sides of both hands.⁵²

Unsafe Storage and Child Poisonings. According to the National Poison Control Center, “a lick of hand sanitizer won’t hurt a child Drinking it can cause alcohol poisoning ... coma and seizures.”⁵³ Other symptoms of alcohol poisoning include excessive sleepiness, vomiting, and lung irritation. The National Capital Poison Center recommends that “hand sanitizers ... should be stored, like other potential poisons, out of sight and out of reach of children.” All alcohol-based hand sanitizers sold in the United States are required to be formulated with a denaturant, a chemical that makes the ethyl alcohol bitter and unpalatable. Isopropyl alcohol, for example, is added to ethyl alcohol as a denaturant.⁵⁴

The National Poison Data Center observed a 79 percent increase in calls related to hand sanitizer in March 2020 compared with March 2019, most involving young children, and the FDA warned that some alcohol-based products lacked the bitterants that would deter children from drinking them.⁵⁵

Shelf Life

Products are required to be stable for up to three years after production, after which bacterial contamination or product degradation may occur, potentially reducing their antimicrobial performance.

50 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7246736/>

51 <https://echa.europa.eu/substance-information/-/substanceinfo/100.021.612>

52 <https://www.reuters.com/article/us-health-workers-hand-sanitizer/health-workers-may-not-use-hand-sanitizer-properly-idUSKBN1ZT2U9>

53 <https://www.poison.org/articles/2007-jun/hand-sanitizer-whats-the-real-story>

54 <https://www.law.cornell.edu/cfr/text/27/21.151>

55 <https://abcnews.go.com/Health/children-ingesting-hand-sanitizers-due-manufacturing-lapses-fda/story?id=70366578>

Impacts Reduction Opportunities, Use

Green Seal has identified the product use phase, and the health impacts on the user, as the most significant and measurable impact reduction opportunities for alcohol-based hand sanitizers. Green Seal proposes requirements that protect the users from exposure to ingredients that may cause acute and chronic adverse health outcomes, including skin and eye irritation, skin sensitization (allergy), cancer, reproductive harm, and asthma.

Green Seal also proposes to set prohibitions on certain chemical classes with extensive evidence of health hazard, including parabens, phthalates, alkylphenol ethoxylates, musks, and per- and polyfluoroalkyl substances (PFAS). See proposed requirements, herein, which are based on reducing adverse impacts to the product user:

- Verification of a non-toxicity product
- Prohibitions on ingredients classified as carcinogens, mutagens, and reproductive toxins
- Prohibitions on ingredients classified as endocrine disruptors
- Prohibitions on ingredients classified as asthmagens
- Restrictions on ingredients known to cause skin irritation, eye damage, and skin sensitization
- Prohibitions on ingredients and chemical classes known to be hazardous to human health

5. Disposal

Hand sanitizers are marketed as “leave-on” personal care products, unlike hand soaps, which are intended to be applied with water and then rinsed off, with the diluted product effluents captured by sanitary sewer systems. Hand sanitizers based on alcohol simply evaporate. As a result, the product itself does not have a disposal route other than evaporation into the air.

The packaging of hand sanitizers also affects the life-cycle impacts. “The most common packaging material for hand sanitizers and soaps is PET plastic.”⁵⁶ PET is derived from crude oil or natural gas. However, PET bottles are recyclable,⁵⁷ and thus the packaging of most hand sanitizers can be commercially recycled.

Impacts Reduction Opportunities, Disposal

Green Seal identified environmental impact reduction opportunities in the product disposal phase. As “leave-on” products, hand sanitizers pose a lower risk to aquatic life than general purpose cleaners, hand soaps, and shower products. However, there is the potential for the final product to end up in freshwater or saltwater bodies during disposal either via solid waste streams or disposal down the drain. Green Seal proposes requirements that protect aquatic life and water quality by setting prohibitions of ingredients that are shown to be non-biodegradable, toxic to aquatic life, or known to bioaccumulate. Green Seal sets this requirement according to a 1:200 dilution level (5 mL product per liter water), under the assumption that the product is rinsed off skin or out of the product package using water from a faucet. This dilution level is consistent with Green Seal’s aquatic protection requirements set in existing Green Seal standards for hand cleaners (GS-41 Standard), soaps, cleaners, and shower products (GS-44 Standard), and personal care products (GS-50 Standard). Details of the [proposed requirements](#) are included, herein.

⁵⁶ <https://www.packagingnews.co.uk/news/packing-firms-struggle-meet-rising-demand-hand-sanitisers-26-03-2020>

⁵⁷ http://www.petresin.org/news_introtoPET.asp

Ingredient Survey Results

Green Seal conducted a market survey of 80 hand sanitizers classified as “consumer antiseptic rubs” (i.e., products not regulated as healthcare antiseptic rubs), approximately half of which are sold on the professional market.

Using publicly available sources, Green Seal identified just over 100 chemical ingredients. Green Seal evaluated each ingredient according to the following foundational criteria categories:

Carcinogens and mutagens	Skin irritation and sensitization
Reproductive toxins	Aquatic toxicity, fish, daphnia, algae
Endocrine disruptors	Biodegradability and bioaccumulation
Asthmagens	Phosphates / Eutrophication potential

Results of the Market Survey Ingredient Review

Of 80 chemicals reviewed, approximately 30 were found to have hazard classifications based on Green Seal’s GS-44 Standard criteria. The following table lists the results for the more common ingredients.

Ingredient	Function	Hazard summary	Green Seal Proposed Action
Triethanolamine CAS No. 102-71-6	pH buffer	This chemical is designated asthmagen by AOEC.	Exempt in Gel Products Exempt because it is used in more than 40% of products surveyed. Exempt from prohibitions on asthmagens only, allowed only in gel products.
Aminomethyl propanol CAS 124-68-5	pH buffer	This chemical is irritating to skin at 0.59%.	RESTRICTED This ingredient can exist in Green Seal–certified products at less than 0.59%.
Benzophenone-4 CAS 4065-45-6	UV blocker	This chemical is corrosive to skin and eyes (no threshold identified) and sensitizing to skin at concentrations >5%.	RESTRICTED Green Seal is examining this ingredient to identify acceptable concentration.
D-Limonene CAS 5989-27-5	Fragrance ingredient	This chemical is irritating to skin (no threshold identified) and sensitizing to skin at concentrations >8%.	RESTRICTED Green Seal is examining this ingredient to identify acceptable concentration.
Cocamidopropyl PG-Dimonium Chloride Phosphate CAS 83682-78-4	Foaming agent or stabilizer	This chemical is irritating to skin (≥4%) and contains phosphorus (2% by weight).	RESTRICTED This ingredient can exist in Green Seal–certified hand sanitizer at 4%.
Tea Tree Leaf Oil CAS No. 68647-73-4	Fragrance ingredient	This chemical is irritating to skin (no threshold identified).	RESTRICTED Green Seal is examining this ingredient to identify acceptable concentration.
Ethylenediamine tetraethanol CAS No. 140-07-8	Preservative	This chemical is corrosive to skin and eyes (no threshold identified)	RESTRICTED Green Seal is examining this ingredient to identify acceptable concentration.
Famesol CAS No. 4602-84-0	Fragrance ingredient	This chemical is irritating to skin (no threshold identified) and sensitizing to skin (≥5%).	RESTRICTED Green Seal is examining this ingredient to identify acceptable concentration.
Diazolidinyl urea CAS No. 78491-02-8	Preservative	This chemical is formaldehyde (carcinogen) releaser.	PROHIBITED Under proposed criteria, this chemical would be prohibited in Green Seal–certified hand sanitizer.
DMDM Hydantoin CAS No. 6440-58-0	Preservative	This chemical is formaldehyde (carcinogen) releaser.	PROHIBITED Under proposed criteria, this chemical would be prohibited in Green Seal–certified hand sanitizer.
Ethylhexylglycerin CAS No. 70445-33-9	Preservative	This chemical is not readily biodegradable and is acutely toxic to aquatic organisms.	PROHIBITED Under proposed criteria, this chemical would be prohibited in Green Seal–certified hand sanitizer.
Tetrahydroxyethyl ethylenediamine (HEDTA) CAS No. 111-41-1	Preservative	This chemical is corrosive to skin and eyes, sensitizing to skin (≥3%), a designated asthmagen by AOEC,	PROHIBITED Under proposed criteria, this chemical would be prohibited in Green Seal–certified hand sanitizer.

PART II. SUMMARY OF PROPOSED CRITERIA

Guidance for Reviewing the Proposed Criteria

Boxed Text

The Proposed Criteria, including normative definitions, are presented in the boxed text that follows the criterion description summaries.

Simplified Proposed Criteria

Proposed Criteria have been simplified in minor ways that do not substantively change the intent or implementation, to provide clarity for the reader. The simplification is necessary because the criteria will be inserted into two parent standards that differ slightly in their wording and requirements:

- GS-41, Standard for Hand Cleaners for Industrial and Institutional Use
- GS-44, Standard for Soaps, Cleansers, and Shower Products

Italicized Text

In the boxed text, italics identify words or phrases that are defined in “Annex A: Definitions” of Green Seal standards. The definitions themselves are normative—that is, they convey substantive text that is critical to the interpretation, implementation, and intent of the criteria.

Efficacy Testing

Green Seal proposes to require product testing to verify efficacy that at least meets the marketed claim on the product label or marketing materials. Verification that efficacy testing has been conducted and that it shows effective antimicrobial performance is critical as new producers enter the hand sanitizer market in response to strong demand for these products during the COVID-19 public health emergency.

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).

Foundational Health and Aquatic Life Requirements

Green Seal has a portfolio of standards for formulated products including cleaning products, hand soaps, and personal care products. Given the similarities of these products—their functions and exposure routes—Green Seal has applied a consistent approach for developing criteria. Green Seal has gained support for this approach with confirmation from stakeholders that a protective framework focused on

eliminating hazardous ingredients from the supply chain results in products that are healthier for users, products that pose lower risks to workers throughout the supply chain, and reduces water pollution which harms water quality and aquatic life. Foundational criteria are designed to be worded and applied consistently across Green Seal’s formulated product standards, though certain exceptions are required because of the slight differences of product types, ingredient mixtures, and user expectations.

The foundational health and environmental criteria include the following:

- Verification that a product is non-toxic via ingestion and inhalation
- Restrictions on ingredients known to cause skin and eye damage
- Prohibitions on ingredients classified as carcinogens, mutagens, and reproductive toxins
- Prohibitions on ingredients classified as asthmagens
- Prohibitions on ingredients that are ozone-depleting compounds
- Verification that a product is non-toxic to aquatic life
- Verification that a product is biodegradable
- Prohibitions on ingredients known to bioaccumulate

Skin Protective Requirements: Unique Criteria Proposed for Hand Sanitizers

In addition to the criteria listed directly above, Green Seal has proposed to include additional criteria that were previously developed for shower and personal care products, which, like hand sanitizers, are intended for application to the skin.

- Verification that the product is non-toxic via dermal exposure
- Restrictions on ingredients classified as skin sensitizers

Additional Proposed General Health Requirement

Green Seal’s newer standards for formulated products also prohibit endocrine disruptors, as defined by the EPA’s Tier 1 list. Green Seal is proposing inclusion of this requirement because of the direct application of these products to skin and the potential frequent exposures, as well to incentivize the elimination of these chemicals from the supply chain.

Requirements for a Non-Toxic Product

Acute toxicity. The product shall not be toxic to humans. A product is considered toxic if any of the following criteria apply⁵⁸:

Oral lethal dose (LD ₅₀)	≤ 5,000 mg/kg
Inhalation lethal concentration (LC ₅₀)	≤ 20 mg/L at 1 hr
Dermal lethal dose (LD ₅₀)	≤ 2,000 mg/kg

The Consumer Product Safety Commission (CPSC) has established criteria for hazardous substances with definitions for “toxic” and “highly toxic” products. Following this guidance, the Proposed Criteria requires that the product shall not have toxic characteristics such that it falls under the labeling

⁵⁸ 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.

requirements as a toxic or highly toxic product, as defined by CPSC regulations found at 16 Code of Federal Regulations (CFR) Chapter II, Part 1500.3.⁵⁹

For example, this would exclude products that have an oral LD₅₀ ≤ 5 g/kg (rat); an inhalation LC₅₀ ≤ 20,000 ppm (1 hour, rat, vapor) or ≤ 200 mg/L (1 hour, rat, mist or dust)⁶⁰; or a dermal LD₅₀ ≤ 2 g/kg (rabbit); or that contain a known or probable chronic toxicant (e.g., carcinogens, neurotoxins, developmental or reproductive toxins).

Prohibitions on Carcinogens, Reproductive Toxins, and Mutagens

In Green Seal standards, “Prohibition” applies as follows: Compounds classified as carcinogens, reproductive toxins, and mutagens cannot exist in Green Seal certified hand sanitizers at or above 100 ppm, whether intentionally added or as a contaminant.

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*.

Exemption: Ethyl alcohol, as an active ingredient, is exempt from this requirement for hand sanitizers.

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.

The use of ingredients and intentional additives that are likely, potential, possible, probable, reasonably anticipated, or known human carcinogens will be prohibited. Green Seal references carcinogen lists with the priority for international and national lists, including IARC, National Toxicology Program (NTP), US EPA, US OSHA.

Definition of *carcinogen*

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)).

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

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

⁵⁹ CFR.2009. Definitions. 16 CFR 1500.3. Accessed 6-24-10. http://www.access.gpo.gov/nara/cfr/waisidx_09/16cfr1500_09.html

⁶⁰ Note that the GHS has a lower threshold for this value, 20 mg/L at 1 hour.

Prohibition on Formaldehyde Releasers (See Carcinogen Prohibition Above)

Formaldehyde is carcinogenic to humans (IARC group 1) and would be a prohibited ingredient, according to the proposed carcinogen criterion. However, some commonly used preservative ingredients are known to release formaldehyde over time (Bronopol; DMDM-hydantoin; Tris Nitro, 2-bromo-2-nitropropane-1,3-diol; 5-bromo-5-nitro-1,3-dioxane; diazolidinyl urea; imidazolidinyl urea; sodium hydroxy methyl glycinate). To further limit the content of known carcinogens, these “formaldehyde donors” or “formaldehyde releasers” are specified as well.

Exemption for Ethyl Alcohol (Ethanol)

The most common active ingredient in alcohol-based hand sanitizers, ethyl alcohol,⁶¹ is classified as a Group 1 IARC carcinogen via ingestion. Topical application of ethanol is not associated with an increased risk of skin cancer. Ethyl alcohol is exempt from the prohibition on carcinogens.

Prohibition on Mutagens

Mutagens are proposed as prohibited and defined according to the GHS criteria for germ cell mutagenicity. These include any substance that meets the criteria for Hazard Category 1 (H340), chemicals known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans. Category 1 criteria are consistent with the EU classification and labeling criteria for Category 1 and 2 mutagenic substances.⁶²

Definition of *mutagen*

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.

Prohibition on Reproductive Toxins

Further, chemicals known to cause reproductive toxicity are proposed to be prohibited and include both male and female reproductive toxins and developmental toxins. California Prop 65 is the most readily available and accepted source for these compounds and shall be cited⁶³.

Definition of *reproductive toxin*

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).

Prohibition on Endocrine Disruptors

In 2010, the EPA published the final guidelines for endocrine disruptor screening testing.⁶⁴ The final guidelines are part of a series of test guidelines developed by the Office of Chemical Safety and Pollution

1 CAS # 64-17-5

62 Langezaal, I. 2002. The Classification and Labelling of Carcinogenic, Mutagenic, Reprotoxic, and Sensitising Substances. Ispra, October.

63 State of California Environmental Protection Agency. 2010. Chemicals Known to the State to Cause Cancer or Reproductive Toxicity. June 11, 2010. http://oehha.ca.gov/prop65/prop65_list/files/P65single061110.pdf

64 EPA. 2010. OCSPP Harmonized Test Guidelines. Accessed 6-16-10. http://www.epa.gov/ocsp/pubs/frs/publications/Test_Guidelines/series890.htm

Prevention. As a result, the Proposed Criteria recommends the use of the test guidelines for chemicals identified as priority chemicals by the EPA and EU⁶⁵.

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.

By far the largest group of chemicals with endocrine disruptor effects is the phthalates; examples include dibutylphthalate, diethylhexylphthalate, butyl benzyl phthalate, and bis-(2-etoxyethyl) phthalate.

Because some phthalates may be endocrine disruptors and because phthalates are not important functional ingredients in hand sanitizers, phthalates are proposed as a prohibited ingredient class. Prohibition of the broad group of phthalates is currently included in other Green Seal standards: GS-40, GS-37, GS-44, and GS-8. Other classes of chemicals found in hand sanitizers that may exhibit endocrine-disrupting effects are phenolics, such as o-Phenylphenol, which is on the EPA's final list of chemicals for Initial Tier 1 Endocrine Disruptor Screening.⁶⁶

Other common endocrine disruptors in personal care products: toluene, resorcinol, petroleum distillates, butylated hydroxyanisole (BHA), boric acid and sodium borate, phthalates, parabens, and phenoxyethanol.

Restrictions on Ingredients That Harm Skin and Eyes

Damaging, irritating, and sensitizing ingredients can be found in hand sanitizers. Some of these ingredients may not be disclosed on the product label if they exist in a proprietary blend, such as a fragrance.

An exemption for such ingredients at 0.01 percent in the product is protective but still allows the formulator to include these chemicals at de minimus levels. This approach, of restricting rather than prohibiting ingredients known to cause skin or eye damage, is applied consistently across Green Seal standards for hand soaps, cleaning products, and personal care products.

The GHS includes definitions and classification criteria for skin corrosion and "serious eye damage."⁶⁷ These definitions are consistent with the definitions used by the United States and the European Union for acute dermal irritation and corrosion and for acute eye irritation/corrosion. However, the GHS more precisely defines these terms and uses the term "serious eye damage" instead of "eye corrosion." OECD defines skin (dermal) irritation in OECD Guidelines for Testing Chemicals, Section 404.⁶⁸

Green Seal uses existing data to evaluate for these effects, so testing is typically not required unless data are not available or indicate a need for testing.

⁶⁵ EU. 2008. Endocrine Disruptors: What is Being Done. Accessed 6-16-10.

http://ec.europa.eu/environment/endocrine/strategy/substances_en.htm

⁶⁶ EPA, Endocrine Disruptor Screening Program (EDSP), Final List of Chemicals for Initial Tier 1 Screening (2010),

<http://www.epa.gov/endo/pubs/prioritysetting/finallist.html>

⁶⁷ United Nations, Globally Harmonized System of Classification and Labeling of Chemicals (GHS), Revision 1, ST/SG/AC.10/30/Rev.1 (New York and Geneva, 2005), www.unece.org/trans/danger/publi/ghs/ghs_rev01/01amend_e.html

⁶⁸ <https://www.oecd.org/env/test-no-404-acute-dermal-irritation-corrosion-9789264242678-en.htm>

Restrictions on Ingredients That Cause Skin Sensitization

A skin sensitizer is a substance that causes an immunologically mediated cutaneous reaction, also known as allergic contact dermatitis.

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.

Prohibition on Ingredients Known to Cause Asthma

The Association of Occupational and Environmental Clinics (AOEC) provides a list of asthmagens. It is periodically updated through a peer-reviewed process; new chemicals are added, and inaccurate or outdated listings are deleted or modified. It is based on clear criteria, including the references relied on for listing, and accessible online. Oversight is provided by medical professionals with no financial incentive. Thus, the AOEC list is sufficiently authoritative to address this very important health concern. As a result, this standard and criteria shall use the AOEC list to prohibit ingredients that are known to cause asthma. Testing is not needed to meet this requirement.

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

See Proposed Exemption for Triethanolamine below.

Definition of *asthmagen*

Asthmagen. A substance designated as an *asthma* causing agent by the Association of Occupational and Environmental Clinics (AOEC), which after review by AOEC has met the AOEC sensitization criteria.

Proposed Exemption for Triethanolamine (TEA) in Gel Hand Sanitizers

Green Seal proposes to exempt triethanolamine (TEA) from the prohibition of asthmagens. This compound is classified by the Association of Occupational and Environmental Centers (AOEC) as an asthmagen. Asthmagens are chemicals that are known to cause the onset of asthma,⁶⁹ with asthma defined as “a condition of variable airflow obstruction, commonly presenting with symptoms of cough, wheeze, dyspnea, or chest tightness.”⁷⁰

TEA is a common ingredient in gel hand sanitizers, estimated at being an ingredient in more than thirty percent of gel hand sanitizers, based on Green Seal’s market review. TEA is described as a pH buffer; its function is to increase the pH of the product, ensuring that it is neutral (around a pH of 7), and therefore

⁶⁹ https://www.researchgate.net/publication/266317838_Asthmagens_in_Building_Materials_The_Problem_and_Solutions

⁷⁰ http://www.aoec.org/content/Asthmagen_Protocol_10-25_08.pdf

less irritating to skin. TEA is required to adjust the pH because of the effects carbomers, which are thickeners and gelling agents, high molecular weight acrylates, which can make the product acidic and therefore irritating to skin and potentially damaging to eyes. According to Green Seal's review, TEA exists in formulations at or below 0.1 percent in gel hand sanitizer products.

Hazard Classification: Asthmagens according to the AOEC. TEA is not classified as hazardous according to the other proposed requirements for hand sanitizers, i.e., TEA is not a carcinogen, mutagen, reproductive toxin, endocrine disruptor; it is not irritating to skin, damaging to eyes, and is not a skin sensitizer; it is readily biodegradable, and not known to bioaccumulate.

Exposure Assessment: Hazard occurs via the inhalation exposure pathway. Gel products are viscous and do not become aerosolized. TEA is not a volatile chemical. Even in the case of a less viscous gelled hand sanitizer dispensed via a trigger spray, Green Seal notes that the product is unlikely to become airborne and inhalable or respirable, due to the estimated particle sizes of the sprayed product.

Exemption for Restrictions on Volatile Organic Compounds (VOCs)

Green Seal proposes to exempt hand sanitizers from VOC restrictions.

VOCs are chemicals that have a high vapor pressure and a corresponding low boiling point, which means they easily evaporate from liquids or sublime from solids. VOCs in consumer and professional products are considered to be a major source of tropospheric ozone and smog. These air pollutants are human health hazards, pose risks to animals and plant-life, and are detrimental to agricultural production.⁷¹

Green Seal sets limits on VOCs in several product category standards including standards for cleaning products, paints, and hand soaps, based on those established by the State of California's Air Resources Board (CARB). As of July 2020, CARB has not set VOC limits for hand sanitizers. In 2019, CARB held committee meetings on the development of VOC restrictions on hand sanitizers and other products, however a final rule has not yet been proposed.⁷²

Prohibited Ingredients List

Green Seal proposes to prohibit the following individual compounds. Certain chemical compounds below may be prohibited due to their classification as hazards to human health or aquatic life. Green Seal calls out these already-prohibited chemicals for clarity. In other cases, chemicals listed below have not yet been classified as hazardous, however Green Seal has identified strong evidence to prohibit these chemicals using a precautionary approach.

2-butoxyethanol (CAS No. 111-76-2). Also known as ethylene glycol, this chemical is a solvent in cleaning products and a fragrance carrier in personal care products. Green Seal has not identified this compound in hand sanitizers. 2-butoxyethanol is consistently prohibited across most Green Seal standards including standards for hand cleaners, laundry care products, and personal care products. There are conflicting views of the weight of evidence for carcinogenicity, however, certain US states require this product to be handled as though it were classified as a carcinogen.⁷³

⁷¹ <https://www.epa.gov/ground-level-ozone-pollution/ground-level-ozone-basics>

https://www.ceh.ac.uk/sites/default/files/files/GNC_OzoneFactSheets_AgriCropEffects.pdf

⁷² https://ww2.arb.ca.gov/sites/default/files/2020-04/Remediated_work_group_presentation_101719.pdf

⁷³ <https://nj.gov/health/eoh/rtkweb/documents/fs/0275.pdf>

Alkylphenol ethoxylates (APEs). These compounds degrade into nonylphenol and other products that are known to persist and bioaccumulate in waterways and aquatic life and act as endocrine disrupters.

Diethanolamine (DEA) (CAS No. 111-42-2). These compounds are prohibited. Most nitrosamines, including those formed from DEA or TEA, are carcinogenic. Further, a 1998 National Toxicology Program study found an association between the topical application of diethanolamine (and some related ingredients) and cancer in laboratory animals (FDA 2006). For the DEA-related ingredients, the study suggested that the carcinogenic response was linked to possible residual levels of DEA.

Ethoxylated alcohols. These compounds are prohibited because they can be contaminated with 1,4-dioxane.

Heavy metals. Lead, hexavalent chromium, and selenium are prohibited because of their neurotoxicity.

Halogenated organic solvents. These are known neurotoxins or carcinogens.

Methyldibromo glutaronitrile (CAS No. 35691-65-7). This compound is prohibited. The Scientific Committee on Cosmetic Products, a European group, evaluated data on this compound and concluded that its use should be limited due to its demonstrated contact allergy effects.

Musks. Nitro-musks and polycyclic musks are prohibited because of their bioaccumulation and aquatic effects.

Nitrilotriacetic acid (NTA) (CAS No. 139-13-9) and ethylene diaminetetra-acetic acid (EDTA) (CAS Nos. 60-00-4 (free acid) 6381-92-6 (dihydrate disodium salt)). These compounds are poorly degradable and are suspected of remobilizing heavy metals in riverbeds. NTA is also a suspected carcinogen.

Per- and Polyfluoroalkyl Substances (PFAS). Green Seal proposes to prohibit these chemicals as a class. A database for identifying these substances is EPA's CompTox PFAS Masterlist.⁷⁴ Sub-categories of this class of chemical include perfluoroalkyl acids, fluoropolymers, and fluorosurfactants. These chemicals are known for being "very persistent," according to the European Commission,⁷⁵ and for evidence that it bioaccumulates.⁷⁶ According to the EPA, the most studied compounds in this chemical class, PFOA and PFOS, "can cause reproductive and developmental, liver and kidney, and immunological effects in laboratory animals," as well as tumors, with human exposure levels correlated with "low infant birth weights, effects on the immune system, cancer, and thyroid hormone disruption).⁷⁷ Green Seal did identify these chemicals in hand sanitizer formulations sold in the US, however, based on Green Seal's market review, these chemicals are not common ingredients.

Parabens and preservatives. Parabens are compounds with endocrine disruptor activity. Examples include methylparaben, ethylparaben, propylparaben, butylparaben, isobutylparaben, isopropylparaben, and benzylparaben. These compounds are commonly used as preservatives in personal care products. Parabens have been prohibited in certain products by the European Union since 2012. According to the National Institutes of Health (NIH, 2004), parabens bind to estrogen receptors and regulate estrogen-responsive reporter gene expression in experimental cell systems. The estrogenic activities of the parabens increase as the length and branching of the alkyl ester increase. The ER relative binding activity of parabens is in the following approximate order: 2-ethylhexyl > heptyl > benzyl > butyl > propyl = ethyl

⁷⁴ https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster

⁷⁵ <https://ec.europa.eu/environment/chemicals/non-toxic/pdf/Sub-study%20d%20very%20persistent%20subst.%20NTE%20final.pdf>

⁷⁶ <https://pubs.acs.org/doi/full/10.1021/acs.est.7b06128>

⁷⁷ <https://www.epa.gov/pfas/basic-information-pfas#tab-3>

> methyl. Parabens can also cause skin irritation and contact dermatitis in the small percentage of individuals with paraben allergies (Nagel et al. 1977).⁷⁸

Phthalates. Phthalates have been associated with endocrine disruption. Common ingredients in personal care products, they are used as solvents in fragrance ingredients. Alternative solvents for fragrances are widely available. Examples of phthalates include the following: Bis(2-ethylhexyl) phthalate DEHP (CAS 117-81-7), Dibutyl phthalate DBP (84-74-2), Benzyl butyl phthalate BBP (85-68-7), Diisobutyl phthalate DIBP (84-69-5).

Protection for Aquatic Life and Water Quality

Hand sanitizers and their ingredients can end up in the environment and waterways throughout the lifecycle, most significantly at manufacturing or during disposal when the product is rinsed off of skin or rinsed out of the plastic bottle. Hand sanitizers sold on the North American market are sometimes formulated with skin conditioners, preservatives, and fragrances that are known to be poorly biodegradable and potentially harmful to aquatic life. To protect aquatic life and water quality, Green Seal proposes to include requirements that limit aquatic toxicity, verify biodegradability, and prevent bioaccumulation and eutrophication.

The environmental fate of hand sanitizers that are rinsed off from skin or from the product bottle includes the following pathway: chemicals are diluted with the rinse water, washed down the drain and then flushed into municipal wastewater treatment plants (WWTPs), where they undergo degradation.

To evaluate the impacts of these chemicals on aquatic life and water quality, Green Seal takes into account the dilution rates of the product during its disposal down the drain. According to environmental impact studies and product use modeling, a 5 ml to 1 liter dilution rate is an appropriate estimate. Green Seal has used the 1 mL to 1 L dilution rate for approximately 15 years to evaluate hand soaps, shower products, and personal care products.

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).

Requirement of Nontoxicity to Aquatic Life

To protect water quality and aquatic life, Green Seal proposes setting requirements that verify that a product and its ingredients are not toxic to aquatic life, are biodegradable, and will not contribute to eutrophication.

Based on the OECD and GHS criteria, a product with an acute aquatic toxicity above 100 mg/L would not be classified in an acute toxicity hazard category. Acute aquatic toxicity is maintained as a distinct criterion, rather than being combined with biodegradability and possibly other environmental fate considerations, because compounds can cause adverse environmental impacts before they biodegrade.

Meeting this requirement is based on available information about the weighted average of ingredients, rather than on whole-product testing, to keep testing requirements and costs down and to reduce the demand for animal testing. Green Seal looks at each ingredient (compounds at and above 100 ppm in the product, whether intentionally added or contaminants at that level), identifies the concentration of the

⁷⁸ <https://jamanetwork.com/journals/jama/article-abstract/352443>

ingredient in the final product, and calculates the weighted average of the acute toxicity for both fish and daphnia testing results. Green Seal then identifies the specific chemical's LC₅₀ value for the calculation, using ECHA and other sources as needed.

Toxicity to Aquatic Life. The *product as rinsed off* shall not be toxic to aquatic life. A product is considered not toxic to aquatic life if the lowest available and most representative acute LC₅₀ 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* (LC₅₀)
n = number of *ingredients*

Note: Tocopheryl acetate (CAS 7695-91-2) is exempt from this requirement for hand sanitizers.

Requirement for Aquatic Biodegradability

The test methods cited in the criterion include currently available ISO test methods 9408 and 14593 and OECD test methods 301 A-F and OECD 310^{1,2,3}. The criterion applies to specific individual organic ingredients. If a product raw material is a blend of two or more organic ingredients, each of those organic ingredients must meet the biodegradability criterion.

Biodegradability is maintained as a distinct criterion, rather than being combined with toxicity to aquatic life and possibly other environmental fate considerations, because compounds can cause toxic effects before they biodegrade. However, an exception to the requirement for ready biodegradability is proposed here for ingredients that do not have acute aquatic toxicity <100 mg/L, that are not bioaccumulating, and that exhibit inherent, ultimate biodegradability, defined by OECD [2003] as biodegradation rates above 70 percent, measured as BOD, DOC, or COD⁴.

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 *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%

- CO2 evolution, as % of theoretical CO2 > 60%

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

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.

Alternative Evaluation Options: Substances That Do Not Exhibit Ready Biodegradability.

For organic *ingredients* in the product 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.

Prohibitions on Ingredients That Bioaccumulate

Product ingredients can be released into the environment during the manufacturing, distribution, use, and disposal phases and pose a threat to water quality and aquatic life. Environmental health researchers define bioaccumulation as “the accumulation of a chemical in an organism relative to its level in the ambient medium” and categorize this occurrence as a “major environmental concern.”⁷⁹ To provide stringent protections for water quality and aquatic life, Green Seal is proposing to apply the foundational prohibition on bioaccumulating compounds to hand sanitizers.

Bioaccumulating Compounds. The product *as rinsed off* 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.

Restrictions on Ingredients That Cause Eutrophication

Phosphorus that enters and dissolves in water bodies acts as a nutrient, stimulating the growth of aquatic plant life, which then depletes dissolved oxygen, which is critical for the survival of fish and aquatic life.

⁷⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5044975/>

The effects of excess nutrients also post a risk to human health from exposure to harmful algal blooms during the consumption of fish, exposure from swimming or ingesting the water,⁸⁰ and respiratory distress.⁸¹

Hand sanitizers are not expected to be a major source of phosphorus, unlike dishwasher detergents; however, these compounds have also not been identified as critical to the function of hand sanitizers. Therefore, taking the precautionary approach used consistently across Green Seal's standards for formulated products, Green Seal is proposing to include a requirement that restricts phosphorus in hand sanitizers.

To implement this requirement, Green Seal reviews all products in the hands sanitizer formula and calculates the total weight of phosphorous in the final ingredient.

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

Requirements for Fragrances and Label Declarations

Green Seal requires that all chemicals included in the product at or more than 100 parts per million (.01 percent), including fragrance ingredients, undergo review against all criteria. Green Seal proposes additional requirement for fragrances in order to align with existing requirements set within Green Seal's Standard for Hand Cleaners (GS-41) and Green Seal's Standard for Soaps, Cleansers, and Shower products (GS-50).

Proposed Additional Requirements for Fragrances

Fragrances are common ingredients in hand sanitizers for both consumer and professional markets. The International Fragrance Association (IFRA) Guidelines in the Code of Practice aim to limit the use of fragrance ingredients with undesirable effects.

Fragrances. Any *fragrances* used shall have been produced or handled following the code of practice of the International Fragrance Association.

Proposed Requirements for Fragrance Declarations

Fragrance Labeling. The product label shall declare if the product contains *fragrance ingredients*. The *fragrance* declaration can be included in the ingredient line. For *hand sanitizers* marketed for professional use, safety data sheets shall declare that the product is formulated with a *fragrance*.

Definition of fragrance

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.

80 <https://www.niehs.nih.gov/health/topics/agents/algal-blooms/index.cfm>

81 <https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/eutrophication>

Proposed Exemption for Allergen Declaration

The GS-44 Standard for Soaps, Cleansers, and Shower Products sets a declaration requirement for cosmetic allergens, as classified by the European Commission in the Cosmetic Directive, and food allergens, as classified by the US Food and Drug Administration.

Green Seal proposes to exempt this requirement for hand sanitizers. Green Seal has proposed highly protective limits on ingredients known to cause skin irritation or skin sensitization (allergic reactions) and has proposed prohibitions on ingredients classified as asthmagens. The proposed criteria set a strong safety net to catch and remove critical human health hazards.

Green Seal has identified allergen labeling as a detrimental complexity for the GS-44 Standard that has been a hindrance both for product manufacturers and for consumers seeking healthier products.

As a labeling requirement, the declaration puts certified products at a disadvantage when compared to non-certified products, which are not required to declare cosmetic allergens even when they are present at significant levels. Those conventional products are sometimes also formulated with carcinogens, mutagens, non-biodegradability ingredients, and in many other ways may be hazardous to human health and the environment.

To correct this issue systematically, Green Seal is intending to propose the deletion of the allergen declaration requirement in a revision to the GS-44 Standard in 2021. With this intention, Green Seal seeks to align hand sanitizers with Green Seal's other standards, including the GS-41 Standard for Hand Soaps, which does not require allergen declaration.

Proposed Requirements for Packaging

For hand sanitizers, Green Seal was unable to identify specific opportunities for recognizing environmentally preferable packaging. For consistency, Green Seal is proposing to apply two packaging requirements that exist in other standards for formulated products.

Verifying that the product packaging is generally environmentally preferable via a materials review, allowing several conformance pathways:

- a. Source-reduced packaging
- b. Recyclable packaging
- c. Packaging that contains at least 25 percent postconsumer material
- d. Or demonstrate that efforts were made to use source-reduced packaging and/or maximum available *postconsumer material* in the package.

Ensuring packaging that is free of certain hazardous ingredients:

- e. Heavy metals lead, mercury, cadmium, and hexavalent chromium are prohibited from being intentionally introduced to the packaging, and the sum concentration levels of those metals present cannot exceed 100 parts per million (0.01 percent). These heavy metals may exist up to 100 ppm in the packaging if they exist because of the incorporation of recovered (i.e., recycled) material.

- f. Phthalates, bisphenol A, and chlorinated packaging cannot be intentionally introduced (added to the final packaging) but are acceptable if they exist in packaging due to the incorporation of recovered or recycled material.

Green Seal is not proposing requirements for secondary packaging for hand sanitizers at this time.

Primary Package

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 *component* is not desired or deliberate, if the final packaging or packaging *component* 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.

Aerosol Packaging

Aerosol cans are proposed as prohibited for this product category. Aerosol containers are generally used for the application of foam hand sanitizers, but these products appear to be uncommon in both retail and professional markets. Aerosol cans do not provide any particular benefit for application, and increase the potential for user inhalation of the product, and they also require additional chemicals as propellants within the aluminum can. Trigger sprays and pump bottles for foam and gel products are environmentally preferable and more protective of human health.

Aerosol Packaging. Aerosol packages are prohibited.

Requirements for Labeling

Statement of Basis for Certification

To ensure compliance with the U.S. Federal Trade Commission's (FTC) guidance on environmental marketing claims, Green Seal requires that a statement of the basis for certification be included with the Green Seal certification mark. The statement is customized for each standard to ensure that it accurately represents the claim that is made through the use of the mark. This customized statement for hand sanitizers is included in the Proposed Criteria.

Hand Sanitizers Sold for Professional Use

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

Hand Sanitizers Sold in Retail Market

“This product is certified to the Green Seal® Standard GS-44 based on meeting limits on human & environmental toxicity, skin/eye irritation, and its minimized/recycled packaging. GreenSeal.org.”

Variations on the statements above may be considered and approved on a case-by-case basis with the requirement that they meet the intent of the US FTC’s Green Guide requirements for Certifications and Seals of Approval (FTC Green Guides, Section 260.6).⁸²

⁸² <https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-green-guides/greenguides.pdf>