



Record of Stakeholder Input and Response to Comments

Green Seal Criteria for Hand Sanitizers

September 10, 2020

Overview

From May to August 2020, Green Seal worked collaboratively with stakeholders to develop the Proposed Criteria for Hand Sanitizers. Participating stakeholders include product manufacturers, trade associations, supply chain specialists, public health and environmental researchers and advocates, and institutional and commercial procurement teams. Stakeholder input shaped and fueled Green Seal's initiative to define health and environmental leadership in this product category. Green Seal summarized stakeholder input that was gathered prior to the Public Comment Period in July 2020 within the Hand Sanitizers Background Report, which can be found in Green Seal's Library of Standards on our website. The input gathered during and after the Public Comment Period in August 2020 is captured in this document, along with Green Seal's responses to informal stakeholder input and formally-submitted comments. The informal stakeholder input was collected via information interviews and email correspondences. The formal stakeholder input was submitted via written comment. Green Seal received two written comments, and the full text of these comments is included in Section 3, herein.

Stakeholder Participants

The following stakeholders provided recommendations, shared technical expertise, and submitted statements of approval and substantive objections. Green Seal greatly appreciates the participation of more than 30 stakeholder groups that volunteered time and shared expertise to co-develop the Criteria for Hand Sanitizers.

American Cleaning Institute (ACI)
Breast Cancer Prevention Partners (BCPP)
Center for Environmental Health (CEH)
Diversey, Inc.
Ecolab
Essity Professional Hygiene North
America LLC
Household & Commercial Products
Association (HCPA)

Inopak Limited
Renewable Fuels Association (RFA)
Safer Chemicals, Healthy Families
Vi-Jon
Washington State Department of Health
Whisk Products, Inc.
Women's Voices for the Earth
Anonymous Stakeholders

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Section 1. Summary of and Green Seal Response to Stakeholder Input

From May to August 2020, Green Seal conducted stakeholder engagement by reaching out to product manufacturers, trade associations, supply chain specialists, public health researchers, public health advocates, environmental advocates, consumer protection organizations, and institutional and commercial procurement teams. This section provides a summary of the stakeholder input gathered via emails, discussions, and informational interviews. Below, stakeholder input is summarized by topic and includes a full response by Green Seal, as well as any actions taken noted in blue.

Stakeholder Input: General and Specific Support for Criteria

Stakeholders shared support for the following topics and concepts that were included within the Proposed Criteria for Hand Sanitizers.

- Rigorous health protections
- Exemption of asthmagen prohibitions for triethanolamine in gel hand sanitizers¹
- Prohibition of endocrine disruptors
- Prohibition of per and polyfluorinated alkyl substances (PFAS)

Green Seal Response: We appreciate that stakeholders stated their approval of these requirements and exemptions. Statements of approval allow Green Seal to record stakeholder preferences, priorities, and measure the value and effectiveness of the standard.

Stakeholder Recommendations and Objections by Topic

Stakeholders shared preferences, concerns, and detailed recommendations for how to adjust the proposed criteria in a way that would result in a meaningful,² feasible,³ and clear⁴ standard.

Requests for Scope Expansion:

Several stakeholders requested that Green Seal expand the criteria scope to include hand sanitizers designed for use in healthcare settings.

Green Seal Response: Green Seal identified that this was a feasible and meaningful opportunity to include this product category due to the fact that the US FDA safety and efficacy requirements for these products are not significantly different and the formulas for these products are similar if not identical to hand sanitizers marketed for use in non-healthcare settings. Therefore, Green Seal is updating the criteria scope to allow for the certification of healthcare-focused hand sanitizers.

Green Seal Action: The criteria scope was expanded to include this product category.

Performance Requirements

¹ Green Seal also received comments that stated objections to the proposed exemption for TEA.

² In this case, “Meaningful” is the following: accurately defining leadership, i.e., best practices that result in healthier, greener products and supply chains.

³ In this case, “Feasible” refers to the ability for both small and large manufacturers to achieve conformance to these requirements and undergo certification in a way that is not overly burdensome.

⁴ In this case, “Clear” refers to the ability to quickly understand the details of a requirement and plan to demonstrate conformance to the requirement.

Recommendation to remove the requirement for in vivo testing from the performance requirements.

Green Seal Response: Green Seal appreciates this input. Via informational interviews, Green Seal confirmed that in vivo testing for hand sanitizers is not explicitly required by the US FDA but is identified as a valuable opportunity for product manufacturers to submit efficacy data on the active ingredient of these products (primarily ethyl alcohol). Green Seal has confirmed that in vivo testing is financially burdensome for small and medium-sized hand sanitizer manufacturers. Additionally, Green Seal agrees that in vitro testing documentation is sufficient for demonstrating antimicrobial efficacy for this product category. If the US FDA establishes new requirements for these products, Green Seal will update this standard to accurately reflect the legal requirements for this product category.

Green Seal Action: The in vivo requirement for product performance was deleted and not included in the final criteria.

Ingredient Exemptions and Prohibitions

Recommendation to expand prohibition of bisphenol A (BPA) to include other bisphenols.

Green Seal Response: Green Seal appreciates the suggestion to prohibit bisphenols beyond Bisphenol-A, for example, Bisphenol-S. Both chemicals show endocrine disruption in animal studies. According to studies conducted by the National Academies, “BPA and BPS exert remarkably similar effects on placental gene expression, metabolome, and placental organization as well as on the content of the neurotransmitters, dopamine and 5-HT, raising the likelihood that the substitute chemical is potentially as harmful as its predecessor.” Green Seal has not identified BPA or BPS as ingredients or contaminants in hand sanitizers. Green Seal will conduct additional research to evaluate the benefits of expanding this prohibition to include BPS and other bisphenols.

Green Seal Action: No change was made to the criteria. Green Seal will conduct research to assess a future revision to this criterion.

Recommendation to adjust the prohibition of endocrine disruptors to reference a different authoritative body for a more relevant list of chemicals.

Green Seal Response: We agree that there is an opportunity to improve this requirement for these criteria and across other Green Seal standards by referencing a new authoritative list. Currently, Green Seal references a chemical list populated the US Environmental Protection Agency, but recognizes a different list populated by the European Union may provide greater health protections.⁵ Additional research is required to assess the value and feasibility of this update to Green Seal standards. Green Seal will conduct research to assess this opportunity.

Green Seal Action: No change was made to the criteria. Green Seal will conduct research to assess a future revision to this criterion.

⁵ <https://edlists.org/the-ed-lists/list-i-substances-identified-as-endocrine-disruptors-by-the-eu>

Objections regarding the exemption for the chemical triethanolamine (TEA), which is classified as an asthmagen.

Green Seal Response: See Green Seal response in Section 3, herein.

Green Seal Action: No change was made to the criteria. Green Seal will monitor the hand sanitizer market to assess the feasibility of removing this exemption in the future.

Ethanol Purity Requirements

Recommendation for clarification of USP grade requirements to show that ethyl alcohol purity can be verified either by USP grade certification or by laboratory analysis.

Green Seal Response: We agree that there are acceptable alternative pathways for demonstrating that the sourced ethyl alcohol meets USP purity levels. This pathway may be critical for ensuring a feasible certification process due to the current supply chain disruptions which have resulted in shortages of readily available ethyl alcohol.

Green Seal Action: The USP grade requirements for ethanol were clarified to allow for a flexible conformance pathway.

Labeling Requirements

Objections called for requiring label disclosure of EU Fragrance.

Green Seal Response: See Green Seal response in Section 3, herein.

Green Seal Action: No change was made to the criteria.

Stakeholder Recommendations for Green Seal Consumer Awareness Campaigns

Encourage the Phase-Out of Triethanolamine (TEA) from Gel Hand Sanitizers.

Green Seal Response:

No Related Health Risk to Product Users

TEA is classified as an asthmagen by the Association of Occupational and Environmental Clinics (AOEC). Green Seal prohibits chemicals that are classified as astmagens, however in hand sanitizers, the criteria notes an exception for one chemical: TEA. TEA is a common ingredient in gel hand sanitizers, and functions as a pH buffer, ensuring a neutral and non-corrosive/non-irritating final product. As established within Green Seal's Background Report, gel hand sanitizers are thick and highly viscous liquid products and therefore pose no inhalation exposure risk to product users because they are pumped onto hands and not dispersed as a spray. Green Seal appreciates the commenters' recommendation for Green Seal to encourage the phase out TEA with the intention of protecting product formulators and workers in manufacturing facilities who may be exposed to this chemical hazard during the manufacturing (hand sanitizer compounding) process. Green Seal agrees that the ultimate goal is to fully eliminate health and

environmental hazards from this supply chain to protect both the health of workers and product users.

Monitoring the Market to Raise the Bar

Green Seal maintains standards within a continuous improvement approach; our standards team periodically assesses each standard, its market, and evaluates opportunities to raise the bar. In this case, Green Seal will monitor the US hand sanitizer markets, and when 20% of gel products on this market have phased out TEA and incorporated a pH buffer that is not classified as hazardous, Green Seal will propose to remove this exception.

Green Seal Action: Green Seal will consider other opportunities outside of the standard criteria to encourage the phase-out of TEA in hand sanitizers and monitor the market to raise the bar when feasible.

Promote Fragrance-Free Hand Sanitizers to Provide Options for Individuals with Respiratory Health Issues and Chemical Sensitivities.

Green Seal Response: Green Seal concurs that access to fragrance-free certified products will be a valuable service to individuals with fragrance sensitivities.

Green Seal Action: Green Seal will provide a searchable product directory of certified hand sanitizers that includes a filter for fragrance-free products.

Section 2. Comments Submitted During Public Comment Period

Green Seal solicited input and written comments on the Proposed Criteria for Hand Sanitizers via a Public Comment Period, which took place between July 30 and August 13 2020. During this time, Green Seal received two written comments. The full text of these comments is housed within the two boxes in this section. These comments include statements of support and substantive objections.

Green Seal appreciates these submissions and the expertise and perspectives shared. Green Seal sees opportunities to apply the recommendations and perspectives to consider opportunities to fill gaps in Green Seal’s work via future standard revisions, or the development of supplementary programs with the intention of accelerating the market transformation of this product category toward healthier, greener hand sanitizers.

Written comments submitted by:

- Breast Cancer Prevention Partners (BCPP)
- Women’s Voices for the Earth (VWE)

Comment Submitted by Breast Cancer Prevention Partners (BCPP)

To whom it may concern:

I am submitting these comments on behalf of Breast Cancer Prevention Partners and our Campaign for Safe Cosmetics on the Proposed Criteria for Hand Sanitizers

Breast Cancer Prevention Partners (BCPP) is a national organization focused on preventing breast cancer by reducing exposure to chemicals and radiation linked to the disease. We work with advocates and decision-makers to encourage research and policy initiatives to better understand, and respond to, exposures to toxic chemicals that contribute to increased rates of breast cancer and other diseases.

BCPP has been focused for over a decade on securing full disclosure of the ingredients in personal care and beauty products that consumers and salon workers use every day, particularly the hidden fragrance and flavor ingredients through our Campaign for Safe Cosmetics. A federal labeling loophole coupled with an unregulated \$100 billion domestic cosmetic industry and a \$70 billion global fragrance industry allows dozens – sometimes even hundreds – of chemicals to hide under the word “fragrance” on the product labels of beauty and personal care products. As a result, the public is exposed to a shocking number of unlabeled, unregulated toxic fragrance and flavor chemicals from common beauty and personal care products without their knowledge or consent. The lack of transparency of fragrance ingredients – and fragrance allergens – in personal care and beauty products creates a serious – and potentially life-threatening – buyer beware situation for consumers and workers, particularly for those people who suffer from fragrance allergies.

We believe Fragrance allergen disclosure should NOT be exempted from your proposed criteria for Green Seal certification of hand sanitizers.

We were disappointed to see the proposal that hand sanitizers be exempted from fragrance allergen disclosure – and further that there are plans to eliminate fragrance allergen disclosure in GS-44 in 2021. We believe this is the wrong direction for Green Seal (and the manufacturers that have Green Seal certified products) to take.

We encourage Green Seal to expand and strengthen rather than limit the disclosure of fragrance allergens in Green Seal approved products. In a study of 800 female cleaning workers, more than 80% were found to suffer from

occupational hand dermatitis. Fragrance mix was the fourth most common relevant allergen tested in these women. (Liskowsky, J, Geier, J. and Bauer, A. (2011) Contact allergy in the cleaning industry: analysis of contact allergy surveillance data of the Information Network of Departments of Dermatology. Contact Dermatitis. Vol. 65. pp: 159-166.) The disclosure of fragrance allergens is vital to all users of cleaning products to allow for avoidance of allergic symptoms. The existing Green Seal criteria for sensitizers (while strong) still allow for fragrance allergens to be present. And for people who are already sensitized, very small amounts of these allergens can cause reactions. The only way to avoid reactions is to prevent exposures to the allergens that are relevant to the individual – which varies from person to person. And this means disclosure is needed. Recent research has shown that since the pandemic began, adverse skin reactions on hands have increased significantly in healthcare workers. The majority of the workers surveyed attributed their reactions to increased usage of alcohol-based hand sanitizers. (Source: <https://pubmed.ncbi.nlm.nih.gov/32757376/>) While the drying properties of the alcohol itself is likely responsible for some of these reactions, no doubt the increased exposure to fragrance allergens are playing a role as well. (And reactions may be exacerbated by the combination of alcohol and fragrance.) Increased hand sanitizer use will continue among healthcare workers and others for some time – and Green Seal should be supporting (not hindering) ways for healthcare workers and others to find the products that work the best for them and cause the least reactions. Allowing manufacturers to hide the presence and identity of allergens simply works against this goal.

We find preposterous the argument that allergen declaration puts certified products at a disadvantage compared to non-certified products. This argument is counter to why consumers shop for certified products to begin with. Transparency is what consumers want and what builds brand loyalty. To hide the presence of an allergen in a hand sanitizer to make that product more “competitive” is unethical and medically dangerous, given it could compromise the health of the consumer who suffers from that fragrance allergy. The trend in product labelling is moving towards greater allergen disclosure across numerous product sectors. Many multinational cosmetic companies already voluntarily disclose fragrance allergens on the product labels of the personal care products they make and sell.

Furthermore, as a result of enactment of the Cleaning Product Ingredient Disclosure Right to Know Act of 2017 (SB258), as of January 2020, all cleaning products sold in California must disclose fragrance allergens online, and will be required to include those allergens on the label by next year. Similar CA legislation for cosmetic products is expected to be signed into law in October 2020 and will also require disclosure of fragrance allergens via the California Safe Cosmetics Program who will then make that information publicly available via their online database. Allergen disclosure is becoming the new normal, and justifiably so, given the importance of consumers being able to avoid the allergens of importance to them in personal care and cleaning products. Green Seal should be leading the way and encouraging manufacturers to reach for the highest possible bar of ingredient disclosure and ingredient safety – rather than endangering public health by catering to the cosmetic industry’s lowest common denominator.

(2) Support for the Prohibited Ingredients List

We support the current prohibited ingredients list, and especially appreciate the new inclusion of PFAS chemicals to this list. We also appreciate that Green Seal is further determining appropriate restrictions for fragrance ingredients identified in hand sanitizers (such as D-Limonene and farnesol). We encourage Green Seal to continue to review the safety of fragrance ingredients identified as hand sanitizer products are going through certification. We suggest looking carefully at butylphenyl methylpropional as one example, which is a fragrance ingredient soon to be banned in the EU when it is officially declared a reproductive toxicant (CMR1).

We question however the exemption for TEA from gel hand sanitizers. While we understand that a significant proportion of these products contain TEA, it would be preferable if Green Seal could include language in the standard that discourages its use and encourages the development of safer alternatives. While TEA as an asthmagen may not be as relevant a concern in a gel-form product, we remain concerned for the workers manufacturing these gel products who maybe exposed to TEA in an inhalable and more concentrated form during manufacture.

Thank you again for the opportunity to comment on the proposed criteria.

Sincerely,

Janet Nudelman

Director of Program and Policy, Breast Cancer Prevention Partners
Director, Campaign for Safe Cosmetics

www.bcpp.org

www.safecosmetics.org

Comment Submitted by Women's Voices for the Earth

To whom it may concern:

I am submitting these comments on behalf of Women's Voices for the Earth on the Proposed Criteria for Hand Sanitizers. Women's Voices for the Earth (WVE) is a national women's environmental health advocacy organization based in Missoula, MT. Our mission is to amplify women's voices to eliminate the toxic chemicals that harm our health and communities. We appreciate the opportunity to comment on the proposed criteria to be added to the GS-41 and GS-44 standards.

1) Fragrance allergen disclosure should NOT be exempted:

We were disappointed to see the proposal that hand sanitizers be exempted from fragrance allergen disclosure – and further that there are plans to eliminate fragrance allergen disclosure in GS-44 in 2021. We believe this is the wrong direction for Green Seal (and the manufacturers that have Green Seal certified products) to take.

We encourage Green Seal to improve rather than limit the disclosure of fragrance allergens in Green Seal approved products. In a study of 800 female cleaning workers, more than 80% were found to suffer from occupational hand dermatitis. Fragrance mix was the fourth most common relevant allergen tested in these women. (Liskowsky, J, Geier, J. and Bauer, A. (2011) Contact allergy in the cleaning industry: analysis of contact allergy surveillance data of the Information Network of Departments of Dermatology. Contact Dermatitis. Vol. 65. pp: 159-166.) The disclosure of fragrance allergens is vital to all users of cleaning products to allow for avoidance of allergic symptoms. The existing Green Seal criteria for sensitizers (while strong) still allow for fragrance allergens to be present. And for people who are already sensitized, very small amounts of these allergens can cause reactions. The only way to avoid reactions is to prevent exposures to the allergens that are relevant to the individual – which varies from person to person. And this means disclosure is needed. Recent research has shown that since the pandemic began, adverse skin reactions on hands have increased significantly in healthcare workers. The majority of the workers surveyed attributed their reactions to increased usage of alcohol-based hand sanitizers. (Source: <https://pubmed.ncbi.nlm.nih.gov/32757376/>) While the drying properties of the alcohol itself is likely responsible for some of these reactions, no doubt the increased exposure to fragrance allergens are playing a role as well. (And reactions may be exacerbated by the combination of alcohol and fragrance.) Increased hand sanitizer use will continue among healthcare workers and others for some time – and Green Seal should be supporting (not hindering) ways for healthcare workers and others to find the products that work the best for them, and cause the least reactions. Allowing manufacturers to hide the presence and identity of allergens simply works against this goal.

We disagree with the argument that allergen declaration puts certified products at a disadvantage compared to conventional products. The trend in product labelling is moving towards greater allergen disclosure across numerous product sectors. As a result of legislation passed in 2017 (SB258), all cleaning products sold in California must

currently disclose fragrance allergens online, and will be required to include those allergens on the label by next year. Similar CA legislation for cosmetic products is currently in play which will require disclosure of fragrance allergens for all cosmetic products to the publicly available California Safe Cosmetics Database. Any perceived disadvantage by manufacturers is at most short-lived as allergen disclosure gradually becomes the norm – and consumers will be able to avoid the allergens of importance to them for all products. Green Seal should be leading the way and encouraging manufacturers in this direction – rather than further supporting fragrance industry secrecy – which hampers public health.

2) Support for the Prohibited Ingredients List

We support the current prohibited ingredients list, and especially appreciate the new inclusion of PFAS chemicals to this list. We also appreciate that Green Seal is further determining appropriate restrictions for fragrance ingredients identified in hand sanitizers (such as D-Limonene and farnesol). We encourage Green Seal to continue to review the safety of fragrance ingredients identified as hand sanitizer products are going through certification. We suggest looking carefully at butylphenyl methylpropional as one example, which is a fragrance ingredient soon to be banned in the EU when it is officially declared a reproductive toxicant (CMR1).

We question however the exemption for TEA from gel hand sanitizers. While we understand that a significant proportion of these products contain TEA, it would be preferable if Green Seal could include language in the standard that discourages its use and encourages the development of safer alternatives. While TEA as an asthmagen may not be as relevant a concern in a gel-form product, we remain concerned for the workers manufacturing these gel products who may be exposed to TEA in an inhalable and more concentrated form during manufacture.

Thank you again for the opportunity to comment on the proposed criteria.

Sincerely,

Alexandra Scranton
(Pronouns: She/Her)
Director of Science and Research
Women's Voices for the Earth
www.womensvoices.org

Section 3. Green Seal Response to Formal Comments

Green Seal acknowledges the two comments, which are fully quoted in Section 3, herein. This information is a valuable contribution to the public record of this standard development initiative. These comments address an important issue: adverse health effects potentially caused by exposure to formulated products. This public health challenge is important and relevant to Green Seal's mission.

Summary of Green Seal Response

- Green Seal appreciates the participation of these commenters, their expertise on these issues, and the information they have brought to light with the intent of strengthening Green Seal's Criteria for Hand Sanitizers.
- Green Seal agrees that skin protection is a critical issue for this product category.
- Green Seal maintains that the rigorous framework of health protections proposed for hand sanitizers is an accurate reflection of leadership in this product category on the US market. By requiring full disclosure of all ingredients and contaminants in the final product to this certification body for screening against rigorous requirements, Green Seal provides strong health protections and reduces the risk that these products will cause skin irritation and allergic reactions.
- Green Seal does not agree that fragrance ingredient disclosure on product labels is a critical requirement for these products at this time. We will further study ingredient disclosure on product labels assess the benefits to consumers and procurement professionals.
- Green Seal will assess the opportunity to build new tools designed to provide consumers with more information on these products and offer services that encourage product manufacturers to phase out the chemicals classified as fragrance allergens by the EU.
- Green Seal is glad to participate in a collaborative dialogue with these commenters and their partners to support consumer protection initiatives and to accelerate the transformation of this market toward healthier products and safer supply chains.

Existing Framework for the First Edition Criteria

Green Seal agrees that skin allergies, i.e., sensitization are a concern for this product category, as these products are applied directly to the skin, and may be used from 20 (consumer) – 200 times (healthcare workers) each day. As the commenters have noted, Green Seal's existing and strong framework is designed to address and prevent skin sensitizing events caused by these products via ingredient prohibitions and restrictions. Green Seal gathers information via the European Chemical Agency (ECHA) and other authoritative groups to identify the acceptable level of these ingredients in products.

Consumer Preferences for Fragranced Products

A large segment of consumers consider fragrance a highly valuable attribute. Fragrances can cover up the disagreeable smell of alcohol and provide a pleasing experience during the application of hand sanitizers. Green Seal seeks to provide a wide selection of certified products for consumers and institutional/commercial procurement professionals.

Preference for Full Prohibition of Fragrance Allergens for Simplicity and Effectiveness

Green Seal does not currently prohibit the 26 chemicals listed by the European Union as Fragrance Allergens, however, we will commit to studying this opportunity further. Green Seal will also revisit the benefits of hazardous chemical disclosure on product labels. It is critical to consider in what ways and to what degree this type of hazardous chemical disclosure is meaningful and useful to consumers and procurement professionals.

Presently, Green Seal will provide supplementary tools and services that may further support consumer education around healthier products, provide a simple choice for consumers experience chemical sensitivities to fragrance ingredients, and encourage the design of allergen-free fragrances.

Easy Access to Fragrance-Free Green Seal Certified Products

As hand sanitizers achieve Green Seal certification, Green Seal will explore ways to identify fragrance-free hand sanitizers in our certified product database to allow website visitors to quickly find these options.

Product Claim Validation

For products that have achieved Green Seal certification and are formulated with a fragrance, Green Seal will consider offering an additional verification process to distinguish fragranced hand sanitizers that are free of EU fragrance allergens.

Verification for Fragrances

Green Seal will consider offering raw material verification to distinguish fragrance formulations that are free of EU fragrance allergens – thus providing healthier fragrance choices to hand sanitizer product designers.