# CALL FOR COMMENTS

## Second Public Comment Period

## Proposed Revisions to Criteria for Microbial-Based Cleaning Products

July 22, 2021. Green Seal® is inviting feedback on proposed revisions to the standard criteria for microbial-based cleaning products (MBCPs) to allow spray packaging and reduce labeling requirements. This proposal is an update to a previous document published for comment in March 2021.[1]

We are seeking comments from all stakeholders including industry experts, public health researchers, product designers, raw material suppliers, product testing laboratories, purchasers, end users, and the public. Instructions for submitting comments are on Page 5 of this document.

**An Updated Approach for Spray-Applied Microbial-Based Products**

This updated proposal includes a new approach developed in response to stakeholder input. This new approach was developed via collaboration with many user, producer, and public interest stakeholders including academic microbiologists, US and European microbe suppliers, manufacturers of cleaning products, and US trade associations. Green Seal appreciates the effort and expertise volunteered by these groups and individuals.

In the March 2021 proposal,[1] Green Seal recommended to remove the prohibition on spray packaging and to reduce the amount of user instructions and precautionary statements required on the product label. The supporting evidence and objectives of the original proposal are included, herein. Via a 30-day public comment period and extensive outreach over the last four months, Green Seal received input from a wide range of stakeholders that generally supported Green Seal's proposal to allow certification of microbial products sold in spray packaging. Green Seal also received strong support for reducing the required product label statements.

Additionally, two stakeholders submitted written comments advocating for Green Seal to include inhalation exposure testing for these products. In discussions with stakeholders, Green Seal identified a resolution to address stakeholder concerns while maintaining a range of feasible options for manufacturers of these products (see Section V).

[1] https://greenseal.org/green-seal-standards/standard-revisions

### Feasible Requirements for Leaders on Today's Market

Green Seal develops standards according to international best practices to define health and environmental leadership and set certification requirements for products. To accomplish this goal, Green Seal conducts rigorous research to define practices that are carried out by, or determined as feasible for, the top 20 percent of sustainability leaders on the North American market.

Green Seal has conducted assessments of standard criteria and identified those that are not feasible for today's leaders, e.g., they are aspirational requirements rather than achievable requirements. Aspirational requirements result in no or very few Green Seal certified products and therefore, aspiration requirements prevent this organization from achieving a priority goal: provide buyers a simple way to find proven safer, healthier options.

In the development or revision of Green Seal standards, stakeholders have occasionally advocated for aspirational requirements with the stated or implied intent to address gaps and uncertainties in health and environmental risk science. Green Seal's goal is to identify opportunities where market leaders can feasibly shift from conventional to green practices. We recognize that health and environmental impact assessments of products include uncertainties (as noted in the March 2021 proposal, and included herein on Page 22), in particular, in regard to the risk of user exposure to the product during the use phase.

For example, there is evidence that frequent and long-term exposure to spray-applied cleaning products (of varying formulas) result in damage to the human respiratory system. However, spray-applied cleaning products are the norm in North America and globally. As product application types become more innovative and those innovations are adapted on the market by a significant minority, Green Seal will move to update our requirements to reflect the evolution of best practices. To reiterate, Green Seal works to set criteria that can be met by leaders today in order to incentivize greater adoption of leadership practices and provide consumers and procurement professionals a simple choice for today's purchases.

### Stakeholders' Recommendations

In April 2021, two stakeholders advocated for a requirement that Green Seal has defined as aspirational. The stakeholders have recommended that spray-applied products undergo an inhalation exposure test and achieve a certain maximum threshold for a product user's exposure to airborne microorganisms.

### Feasibility Review

According to Green Seal's research, conducted from March 2021 to July 2021, the test recommended by stakeholders does not have an accepted or publicly available test protocol; there are no known testing laboratories that provide this service; and there is not yet evidence that spray-applied microbial-based cleaning products can meet the proposed maximum threshold. It is possible that there are products available on the market that have undergone this test and have met this threshold, but Green Seal has not yet seen evidence of such.

Green Seal greatly values expert stakeholder input and strongly agrees with the stakeholders' driving intent: to verify respiratory health protections for product users and bystanders, and therefore, Green Seal is committed to finding common ground.

For this purpose, Green Seal, in collaboration with stakeholders, has developed a resolution that includes the test and threshold recommended by stakeholders as one prescriptive option for these products. This resolution is detailed, herein.

**Summary of Proposed Revisions:**

**Allow Products Sold in Spray Packaging:** Products that are intentionally formulated with non-pathogenic microorganisms can be certified if designed for use and/or sold in spray packaging.

**July 2021 Update:** Products sold in or designed for use in spray packaging must meet at least one of three requirements:

(1) Include precautionary statements on the product label
(2) Formulate only with microbes listed on the European Food Safety Authority's Qualified Presumption of Safety list
(3) Undergo inhalation exposure testing and meet a maximum threshold of airborne microbes.

**Reduce Labeling Requirements:** Green Seal's proposed revisions to labeling criteria is unchanged from the March 2021 proposal.

Products that are intentionally formulated with non-pathogenic microorganisms will no longer be required to list eight precautionary statements on product labels.

Green Seal proposes to maintain certain requirements:

(1) the disclosure of microorganisms on product labels and, for professional products, Safety Data Sheets,
(2) to inform product users that the presence of sanitizers and disinfectants will lower the effectiveness of microbial-based cleaning products.

**Green Seal Standards with Criteria Proposed for Revision**

- GS-8 Standard, General Purpose Cleaning Products for Household Use
- GS-37 Standard, General Purpose Cleaning Products for Industrial and Institutional Use
- GS-48 Standard, Laundry Care Products for Household Use
- GS-51 Standard, Laundry Care Products for Industrial and Institutional Use
- GS-52 Standard, Specialty Cleaning Products for Household Use
- GS-53 Standard, Specialty Cleaning Products for Industrial and Institutional Use

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

# Document Guide

## Section I. Instructions for Submitting Comments

Green Seal develops standards though an open, transparent process that prioritizes stakeholder input. Public comment periods are a mechanism for soliciting input and promoting Green Seal's intended outcomes for product certification against the new or revised criteria.

**Guidelines for Submitting Comment**

- Comments should be specific in nature.
- Comments should include a technical or market-focused justification.
- Comments should include references from reputable sources.
- Comments should include actionable solutions.

**Public Comment Closing Date**

The comment period closes on Friday, August 13, 2021.

**Submit Comments via Email**

Submit all comments to standards@greenseal.org using the subject line: "MBCP Criteria Revision."

**Requests for Comment Period Extension**

Any request for comment period extensions should be submitted via email to standards@greenseal.org. If granted, extensions will be publicly announced on Green Seal's website.

**Comment Review Process**

Upon receiving comments, Green Seal will confirm receipt and may reach out to schedule a brief conference call to request clarifications.

Within 90 days of the close of the comment period, Green Seal publishes a Response to Comments document which includes the text of all written comments submitted during the Public Comment Period and summarizes actions taken and justifications for inaction regarding the changes to the standard.

## Section II. Proposal Overview

Green Seal published a proposal in March 2021 to (1) allow microbial-based cleaning products that were spray-applied to be eligible for certification and (2) delete certain required product label statements for microbial products of all application types.

From March through June 2021, Green Seal received input from a wide range of stakeholders that generally supported the intentions of this proposal. Two stakeholders submitted written comments: American Cleaning Institute (ACI) and Household & Commercial Products Association (HCPA), the text of which is included, herein (Section III). These stakeholders also generally supported the intent of Green Seal's proposal while advocating for the inclusion of an inhalation exposure test and corresponding threshold for the purpose of addressing uncertainties around health risks of inhaling non-pathogenic microbes. Note: Green Seal's considerations around health risks were originally presented in Green Seal's March 2021 proposal, and are included, herein (Section VI).

Although not specified within the written comments submitted by stakeholders, subsequent discussions with those stakeholders confirmed their intention that Green Seal should require an inhalation test that generally aligns with the A.I.S.E. spray protocol (2020).[2] Stakeholders clarified a recommendation for a specific threshold maximum of 1 x $10^4$ CFU/$m^3$, which is noted by a study as a safe exposure level.[2]

Research conducted from March 2021 to June 2021 resulted in the following findings: Green Seal confirmed that there are no publicly available inhalation exposure test protocols designed for microbial-based cleaning products; Green Seal could identify no testing laboratory that offers inhalation exposure testing for cleaning products as a service; and there is no evidence that spray-applied microbial-based cleaning products can meet the proposed airborne concentration threshold.

Therefore, Green Seal has determined that including the inhalation exposure test as the sole requirement for spray-applied microbial-based cleaning products is not feasible and would not result in a change from the status quo: these products would not be able to achieve Green Seal certification because manufacturers would not be able to conduct the testing.

However, Green Seal is aligned with the goals of these two stakeholders – to establish a product attribute verification framework that addresses and reduces certain possible health risks to users. In this case, stakeholders are seeking to address the uncertainty of health risks of inhaling the product mist and the microbes within the product formulation. Additionally, these products, as unique applications of biotechnology, are not strongly regulated by the US, Canadian, or European governments, which is the reason for Green Seal's other seven requirements that these products must meet in addition to all other health and environmentally protective criteria in each standard.

Additionally, Green Seal agrees that products undergoing an inhalation exposure test and meeting a maximum airborne concentration threshold would be a useful indicator of a health-protective product and lower possibility of health risk to the product user and bystanders.

Therefore, Green Seal has designed a flexible approach, determined as feasible for sustainability leaders, to increase the level of protections compared to the proposal published in March 2021. This approach, if enacted, will allow Green Seal to demonstrate support for and continuously monitor the industry acceptance of and investment in product inhalation exposure testing.

Green Seal's new approach allows three options, of which products would need to meet at least one: spray-applied microbial products must include precautionary statements on the product label; or the microbial ingredients in the product must be those classified as safer for use in food and food production;

[2] https://www.sciencedirect.com/science/article/abs/pii/S0278691517306968

or the product must undergo inhalation exposure testing and meet an airborne microbial concentration of no more than 1 x 10^4 CFU / m^3.

Below, the boxed text provides the proposed criteria for which Green Seal is seeking additional stakeholder input.

**Additional Requirements for Products in Spray Packaging.** For products formulated with *microorganisms* and designed for use in, or sold in, *spray packaging*, at least one of the following requirements must be met:

- The microbial *ingredients* in the product shall be restricted to those included in the European Food Safety Authority's (EFSA) Qualitied Presumption of Safety (QPS) List.
- The product label shall state the following precautionary statements*

  Product should not be sprayed into the air.
  Avoid inhalation of the product.
  Repeated and prolonged exposure may cause sensitization of the respiratory system.

- The product shall demonstrate, via inhalation exposure testing, an airborne concentration of microbes at or below 1 x $10^4$ CFU/$m^3$. Testing parameters shall be in alignment the A.I.S.E. spray protocol (2020).[2]

* Or other substantially similar terms and phrases, as approved by Green Seal

Stakeholders noted via outreach discussions, and Green Seal confirms, that these three requirements are anticipated to be unequal in the extent to which they protect the product user and by-stander, with product label statements as the weakest approach; the level of protections is dependent on user behavior (there is no guarantee that the product user will read the label and follow instructions, and therefore avoid inhalation of this product, etc.). However, this approach is intended to be flexible and feasible, providing a more protective option than what was previously proposed in March 2021, and setting a higher bar for these products via additional requirements for user information.

The proposed option of formulating only with QPS List microbes is a strong approach that can be viewed as an extension an existing health protective requirement: Green Seal already requires that microbial-based cleaning products are only formulated with WHO Risk Category 1 microbes to verify that the microbe is classified as non-pathogenic. However, this classification is more applicable and relevant to the use of microbes in laboratory settings. The QPS List provides a stronger indicator for verifying that these microorganisms are deemed safer for a use setting (food use and production) that is more akin to household and professional cleaning.

The inhalation exposure test is also a strong option for addressing uncertainties by verifying low airborne levels of microbes: an indicator of low likelihood of user inhalation with the intention of preventing possible adverse health effects from daily or periodic inhalation of the product mist and the non-pathogenic microbes within the product.

Green Seal has confirmed general and wide support regarding this multi-option approach from many stakeholders in this industry and subject matter experts in microbiology. One way that Green Seal has determined feasibility for this approach is that several products on the market make claims that they formulate only with microbes from the QPS List and other products already carry similar precautionary statements.

**Determining Market Transformation and Raising the Bar**

As possible, Green Seal will monitor the market and evaluate the opportunity to raise the bar when indicators demonstrate that this category of products has met Green Seal's top 20 percent target. The first opportunity to raise the bar would be for Green Seal to remove the weakest option, which is to no longer allow precautionary labeling in lieu of the two more protective product attributes. The strongest opportunity for health protections would be to require only QPS List microbes and additionally require the inhalation exposure testing.

**Accelerating Market Transformation**

In addition to setting these requirements, if enacted, Green Seal sees opportunity in making these requirements more valuable, increasing demand for these product attributes among purchasers, and simplifying the process for manufacturers in order to make it easier for them to achieve health protective leadership. With this aim, Green Seal intends to take the following actions:

- Develop general guidance for companies to encourage use of QPS List microbes in their products.
- Continue outreach to identify testing laboratories that offer inhalation exposure testing of cleaning products. The list of confirmed laboratories will be published on our website.
- Encourage trade associations and test laboratories to develop an accepted publicly available testing protocol for microbial-based cleaning products.

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**Original Proposal Overview – Published for Comment in March 2021**

In 2011, Green Seal issued criteria for products formulated with microbes, along with requirements for products that are formulated with enzymes. Green Seal is now proposing to adjust the criteria related to microbial-based cleaning products (MBCPs) to remove unnecessary barriers to certification and burdensome requirements that are not critical for the verification of health protections. These adjustments will allow Green Seal to reward health and environmental leadership, e.g., products in the top 20% of the market in regard to health and environmental protections. Certifying MBCP that can meet Green Seal standards will provide greater assurance and easier access to important information regarding ingredient transparency and effective product use. See the Intended Outcome section below for more details.

In 2020, Green Seal completed an assessment of the criteria set for MBCPs that involved a market review and outreach with stakeholders. The results of the assessment highlighted two criteria necessary for revision:

1.) A prohibition on spray packaging

2.) Excessive labeling requirements

**Proposed Deletion of Prohibition on Spray Packaging:** MBCPs exist on the market as stain removers, odor eliminators, laundry pre-treaters, and general-purpose cleaners. These products, and the majority of general-purpose cleaners on the North American market, are packaged and applied via spray bottles (squeeze pump handle, adjustable nozzle) for the convenience of the user. The spray mechanism allows for a limited amount of product to disperse onto a surface. Green Seal has determined that these products are no more hazardous to respiratory health than

cleaning products formulated without microorganisms. Therefore, allowing this packaging type is acceptable for these products due to their safety profiles.

**Proposed Simplification of Labeling Requirements**: Current labeling criteria lists eight statements that must be printed on the labels of MBCPs. Green Seal has determined that these labeling requirements are excessive and too rigidly defined, making them impractical for product labels. Additionally, Green Seal proposes that these statements are unnecessary due to the safety profiles of these products. Green Seal proposes to delete many of the label statements and maintain but adjust two requirements. Green Seal proposes to maintain ingredient disclosure of microorganisms on product labels and Safety Data Sheets and to require manufacturers to post instructions for users to avoid applying these products in presence of antimicrobial agents, which would lower their efficacy as cleaners.

## Intended Outcomes

### Recognizing Leadership on Today's Market

Market research conducted by Green Seal demonstrated the major product types in this product category - odor eliminators, drain de-cloggers, laundry pre-treaters, and pet odor and cleaning products - are spray-applied. It was evident from a limited review of the North American market that approximately 95% of these products are intended for use and/or sold in spray packaging, except for drain cleaners which are more commonly poured. Therefore, the current requirements for these products set an aspirational bar, i.e., this requirement does not reflect leadership practices on the North American market. By removing this barrier for microbial-based cleaning products, Green Seal will more accurately reflect today's leadership on this market in regard to health and environmental protections.

### Maintaining Strong Health Protections

Green Seal has set a highly health protective requirement for these products that goes significantly beyond US and Canadian regulation. In this case, Green Seal determined that the proposed revisions did not compromise the health protective framework of the standard. Studies show low health risks associated with MBCPs compared to solvent-based alternatives. This distinction and specific green chemical accomplishments of MBCPs were noted by Green Seal in 2011 when the criteria for MBCPs was first issued. Green Seal's rigorous disclosure requirements and parameters for microbes set a strong health-protective framework for verifying low risk to human health. Specifically, Green Seal requires that manufacturers disclose to Green Seal the microbe species, verification that microbial strains are categorized within the World Health Organization's Risk Group 1: "a microorganism that is unlikely to cause human and animal disease,"[3] and these products are required to adhere to Green Seal's overall health-protective requirements (for example, prohibitions on carcinogens, mutagens, reproductive toxins, verification that products will not cause skin or eye damage, and will not harm aquatic life).

### Providing Significant Environmental Benefits

Allowing spray packaging for this product category provides greater recognition of green chemistry applications. These products are often less harmful to ecosystems in their production and disposal compared to conventional cleaning products. There is evidence that, compared to products formulated with petroleum-based surfactants and solvents, MBCPs are less toxic to aquatic life[4] and biodegrade more readily than conventional options. It is also expected that these products have low, or no volatile organic compounds (VOCs) and are generally more neutral (safer for skin and eyes) than conventional and greener products with synthetic ingredients.

### Following Standard Development Best Practices

Green Seal systematically reviews standards in accordance with international best practices to ensure standards remain relevant, feasible for all types of enterprises, and reflect good sustainability practices. Standard revisions carried out within a transparent, stakeholder-engaged process.

[3] WHO Laboratory biosafety manual. https://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf
[4] Surfactants in aquatic and terrestrial environment: occurrence, behavior, and treatment processes. https://link.springer.com/article/10.1007/s11356-015-5803-x

## Section III. Written Comments Submitted by Stakeholders

Green Seal opened a 30-day public comment period in March 2021. During that time, two written comments were formally submitted to Green Seal for inclusion in the standard revision record from the following stakeholder groups:

- American Cleaning Institute (ACI)
- Household and Commercial Products Association (HCPA)

Green Seal appreciates the participation and input of these two stakeholders. The substantive text from the two comments is included below.

**Comment Submitted by the American Cleaning Institute (ACI)**

> I write on behalf of the American Cleaning Institute[1] (ACI) to Green Seal, to provide comment on Green Seal's Proposed Revisions to Criteria for Microbial-Based Cleaning Products.
>
> [1] The American Cleaning Institute® (ACI – www.cleaninginstitute.org) is the Home of the U.S. Cleaning Products Industry® and its members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors.
>
> ACI is an industry leader in serving the cleaning products industry, advancing the health and quality of life of people and protecting our planet. We focus on the advancement, promotion, and utilization of science to drive informed dialogue and decision making. We are pleased to have the opportunity to provide comment to the proposed revisions to Green Seal Standards GS-8, GS-37, GS-48, GS-51, GS-52, and GS-53, as relevant.
>
> **ACI offers the following response on Green Seal's proposed revision on the *Deletion of Prohibition on Spray Packaging*:**
>
> In review of the proposed standard revision of deleting the prohibition of "microorganisms" that are sold in spray packaging, ACI seeks to provide additional input for consideration. Biosafety level 1 (BSL-1) organisms can be diverse, and some may present health hazards through inhalation, including risks to immunocompromised and sensitive populations, as noted in multiple references to the proposal for revision to the Standard presented by Green Seal.
>
> …

***Comment Continued on Page 12***

***Comment Continued from Page 11***

ACI recommends a risk and safety assessment be conducted on spray products before commercialization. Referencing the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment report provided by Green Seal[2], there are important considerations when determining hazardous properties or risk factors of viable microorganisms and their inclusion in cleaning products. Recommendations may include but are not limited to:
o Identification of species and strains
o Characterization of species and strains
o Pathogenic potential- cytotoxin production profiles, virulence genes
o Resistance profiles (AMR—anti-microbial resistance)
o Application/intended use- exposure assessment of product during use (considering frequency, duration, and dose)

[2] Current knowledge of the health and environmental risks of microbial-based cleaning products: https://www.vkm.no/english/riskassessments/allpublications/healthandenvironmentalassessmentofmicrobialbasedcleaningproducts.4.1aaadf0516963f003a25dde5.html

**ACI offers the following response on Green Seal's proposed revision on the *Deletion of Unnecessary and Burdensome Labeling Requirements*:**
ACI proposes that if a product risk assessment is conducted that supports product safety, then reduced labeling requirements may be appropriate for those products. While this reduction in burden on formulators will be appreciated, ACI emphasizes that the consideration of human health effects, in particular sensitive populations (e.g. immunocompromised individuals), are essential as it concerns product application and use. As the organisms employed in microbial based cleaning products will differ between manufacturers, it is important to recognize that certain organisms though normally considered non-pathogenic, may opportunistically infect individuals with compromised immune systems. These items are important to consider for consumer awareness and safety.

ACI thanks you for consideration of our input during this public comment period.

**Comment Submitted by the Household and Commercial Products Association**

The Household & Commercial Products Association (HCPA) appreciates the opportunity to provide comment on Green Seal's proposed revisions to the standards for microbial-based cleaning products[1]. HCPA is the premier trade association representing the interests of companies engaged in the manufacture, formulation, distribution, and sale of more than $180 billion annually in the U.S. of familiar and trusted consumer products that help household and institutional customers create cleaner and healthier environments. Our membership manufactures, supplies, and incorporates microorganisms into end-use products.

HCPA supports Green Seal for allowing products containing bacterial spores of class 1 organisms to be approved under the following standards: GS-8 / GS-37 – Green Seal Standards for General Purpose Cleaners; GS-48 / GS-51 – Green Seal Standards for Laundry Care Products; and GS-52 / GS-53 – Green Seal Standards for Specialty Cleaners. However, HCPA would urge that microbes that are sprayed would have a completed risk assessment evaluating this application method to ensure that they will not cause negative effects in a respirable form. HCPA members are particularly encouraged by the changes to labeling requirements which will reduce consumer confusion and allow products to be better received in the market. These changes to the Standard will continue to bolster support for these products. Thank you for the opportunity to provide comment on this topic.

**Green Seal Response to Stakeholder Comments:**

Thank you for your input on this proposal. To better understand these comments, Green Seal reached out to both organizations to ask questions and discuss shared objectives.

In response to HCPA's interest in encouraging manufacturers to invest in a risk and safety assessment before commercialization: Green Seal certifies products that exist in the market and are commercially available.

In response to ACI's recommendation for a safety and risk assessment that includes five steps, quoted below, Green Seal's existing requirements framework currently aligns with the first four steps on this list.

> o Identification of species and strains
> o Characterization of species and strains
> o Pathogenic potential- cytotoxin production profiles, virulence genes
> o Resistance profiles (AMR—anti-microbial resistance)
> o Application/intended use- exposure assessment of product during use (considering frequency, duration, and dose)

Green Seal currently requires the following for any microbial-based cleaning product:[5]

- (Strain and characterization) Strain Identification via taxonomic review
- (Pathogenic potential) Microorganisms must be Biosafety Level 1 / Risk Group 1
- (Resistance profile) Effective Prevention Measures and Treatment

These data points are meaningful attributes of safe use of microorganisms and the disclosure of this information is currently a pre-requisite for achieving Green Seal certification. The remaining and fifth step "Application/intended use exposure assessment" is the step that Green Seal has now proposed, herein (Section V) as one of three optional requirements for spray-applied products. Green Seal's reasoning for including inhalation exposure testing as one of three options for spray-applied products is detailed on Pages 7 and 8, herein.

**Lack of Evidence of Associated Health Risks for Immunosuppressed Individuals**
In response to ACI's recommendation that Green Seal consider the effect of these products on sensitive populations, e.g., immunocompromised individuals, specifically, the possibility that these non-pathogenic microorganisms may lead to infection (assumedly of the upper or lower respiratory tract and due to respiration of airborne microorganisms):

Green Seal reviewed the report cited by ACI.[6] Although this report mentions immunocompromised individuals as a consideration, within the report there are no quotes from research studies, no stated evidence, nor cited references that point or allude to infections associated with or reportedly due to the use of spray-applied or otherwise applied microbial-based cleaning products. In fact, sources sited within that report provide examples of how use of these products are associated with reduced "HAI" – hospital acquired infections.

[5] The full text of Green Seal's requirements for microorganisms is included, herein (Appendix 1).

[6] https://www.vkm.no/english/riskassessments/allpublications/healthandenvironmentalassessmentofmicrobialbasedcleaningproducts.4.1aaadf0516963f003a25dde5.html

The report also summarized two instances where applications of these products were studied for inhalation exposure as an indicator of risk of adverse health outcomes – "the authors concluded that the Bacillus-based carpet cleaning products pose minimal risk for consumers."

For due diligence, Green Seal reviewed all previously collected studies, conducted outreach, and conducted further research to identify studies or occupational health reports that recorded instances of infection that were associated with spray-applied microbial-based cleaning products or otherwise applied microbial-based cleaning products. No sources were identified.

Due no identified evidence of use of these products associated with respiratory infections in immunocompromised individuals, Green Seal has determined an adjustment to the initial proposal, to address this comment, is not warranted.

## Section V. Red-Lined Tracked Changes

Green Seal proposes revisions to the following standards:

- GS-8 Standard, General Purpose Cleaning Products for Household Use
- GS-37 Standard, General Purpose Cleaning Products for Industrial and Institutional Use
- GS-48 Standard, Laundry Care Products for Household Use
- GS-51 Standard, Laundry Care Products for Industrial and Institutional Use
- GS-52 Standard, Specialty Cleaning Products for Household Use
- GS-53 Standard, Specialty Cleaning Products for Industrial and Institutional Use

Text in the boxes below show the details of the proposed revisions.
The red text shows proposed additions. The text ~~with strikethrough lines~~ are proposed deletions.

**Proposed Changes to Remove Prohibition of Spray Packaging**

**Proposed Revision to Scope of all standards listed above:**

| |
|---|
| This standard does not include products that contain *enzymes* ~~or *microorganisms*~~ that are sold in *spray packaging*. |

**July 2021 Update:**
**Proposed Revision to Microorganism Annexes in all standards listed above:**

**H. Additional Requirements for Products in Spray Packaging.** For products formulated with *microorganisms* and designed for use in, or sold in, *spray packaging*, at least one of the following requirements must be met:

- The microbial *ingredients* in the product shall be restricted to those included in the European Food Safety Authority's (EFSA) Qualified Presumption of Safety (QPS) List.
- The product label shall state the following precautionary statements*

  Product should not be sprayed into the air.
  Avoid inhalation of the product.
  Repeated and prolonged exposure may cause sensitization of the respiratory system.

- The product shall demonstrate, via inhalation exposure testing, an airborne concentration of microbes at or below 1 x $10^4$ CFU/$m^3$. Testing parameters shall be in alignment with the A.I.S.E. spray protocol (2020).[2]

* Or other substantially similar terms and phrases, as approved by Green Seal

[2] "Spray Protocol," https://www.aise.eu/our-activities/standards-and-industry-guidelines/safe-handling-of-enzymes.aspx

**Proposed Changes to Labeling Requirements for All Microbial-Based Cleaning Products**

**Note Regarding Stakeholder Input:** The proposed revisions to the label requirements are not substantively changed from the March 2021 proposal. Stakeholders shared input that resulted in minor clarifications to the red-line proposal below.

**Household Cleaning Product Standards (GS-8, GS-48, GS-52)**

**Proposed Revisions to Labeling Requirements in Microorganisms Annexes**

~~**G. Labeling Requirements.** Products containing microorganisms shall include the following on the product label.~~

**G. Product Label and User Information.** The ingredient line on the product label shall list the bioactive *ingredient*, e.g., "microorganisms," "live bacillus cultures," "bacterial spores," or an equivalent term or phrase approved by Green Seal. Manufacturers shall also provide the following information on the product label: the product may not be effective when used in conjunction with disinfectants, such as chlorine bleach.

- ~~A declaration that the product contains *microorganisms*~~
- ~~A statement that immune-compromised individuals should avoid exposure to products containing *microorganisms* from both direct use and incidental contact during or shortly after application to these products, especially when the treated areas are still wet~~
- ~~Contact with open cuts or sores should be avoided~~
- ~~Users should wash their hands after using the product~~
- ~~Instructions that *microorganisms* may not be effective in the presence of *antimicrobial agents* such as chlorine bleach~~
- ~~Instructions that the product shall not be used on food-contact surfaces~~
- ~~Instructions that products containing *microorganisms* should not be sprayed directly into the air.~~

~~**The following statement can appear on the product label**~~

- ~~A statement that immune-compromised individuals should avoid exposure to products containing *microorganisms* from both direct use and incidental contact during or shortly after application to these products, especially when the treated areas are still wet~~

**Institutional and Industrial Products Standards (GS-37, GS-51, GS-53)**

**Proposed Revisions to Labeling Requirements in Microorganism Annex**

~~**G. Labeling Requirements.** Products containing microorganisms shall include the following on the product label.~~

**G. Product Label and User Information.** The ingredient line on the product label and the product Safety Data Sheet shall list the bioactive *ingredient*, e.g., "microorganisms," "live bacillus cultures," "bacterial spores," or an equivalent term or phrase approved by Green Seal. Manufacturers shall also provide the following information on the product label: the product may not be effective when used in conjunction with disinfectants, such as chlorine bleach.

- ~~A declaration that the product contains *microorganisms*~~
- ~~A statement that the product should not be used in patient areas of hospitals and that immune-compromised individuals should avoid exposure to products containing microorganisms from both direct use and incidental contact during or shortly after application to these products, especially when the treated areas are still wet~~
- ~~Contact with open cuts or sores should be avoided~~
- ~~Users should wash their hands after using the product~~
- ~~Instructions that *microorganisms* may not be effective in the presence of *antimicrobial agents* such as chlorine bleach~~
- ~~Instructions that the product shall not be used on food-contact surfaces~~
- ~~Instructions that products containing *microorganisms* should not be sprayed directly into the air.~~

**~~The following statement can appear on the product label~~**

- ~~A statement that immune-compromised individuals should avoid exposure to products containing *microorganisms* from both direct use and incidental contact during or shortly after application to these products, especially when the treated areas are still wet~~

# Section VI. Research Record

**Note Regarding Second Public Comment Period:**
The content in this section remains unchanged and no new content was added this section.

The following section summarizes research studies on the functions, compositions, packaging, and unique attributes of microbial-based cleaning products (MBCPs). This section includes references to the presence and demand for these products on the North American markets.

## Overview of Microbial-Based Cleaning Products

The terms "microbes" and "bacteria" are commonly used to refer to pathogens – microorganisms that cause human sickness and disease. However, it is estimated that less than 1% of microorganisms on Earth cause human disease.[7] Non-pathogenic microbes, primarily bacterial species, are included as functional ingredients in household and institutional cleaning products. Upon application for cleaning, the microbes produce enzymes which degrade stains and soils. The use of microbes in cleaning products can provide a safer and environmentally preferable alternative to petroleum-based surfactants and solvents in cleaning products.

These products are widely available globally on consumer and institutional markets, including in the US and Canada. These products are marketed as odor elimination, stain removal, drain de-clogging, and pet odor and clean-up. They have also been studied for use as sanitizers and disinfectants. For example, MBCPs have and are currently being studied as safer alternatives to chlorine disinfectants in healthcare settings, particularly as a protective measure against healthcare-associated infections.[8] Specialty cleaning products with microorganisms have also been applied for decades for restoration and protection of historic artifacts. [9]

**Functional Overview.**
MBCPs are known to have formulas as simple as bacterial cultures and water. However, more commonly, products contain additional ingredients such as surfactants, buffers, emulsifiers, and fragrances. Microbial cultures, such as bacterial strains, are selected for their ability to breakdown target soils via enzymatic action. Enzymes, such as protease, break down the contaminants into smaller, digestible compounds which are then consumed by the microorganisms in the product and microorganisms that were residing on surfaces. Common "targets" or contaminants include:

- Biofilm
- Petroleum compounds – crude oil, gasoline, diesel fuel
- Organic matter, e.g. food, urine, dust mites,
- Chlorinated solvents
- Hydrogen sulfide
- Grease lines (commercial kitchens)
- City sewage / wastewater treatment plants

[7] Microbiology by the Numbers, *Nature*, https://www.nature.com/articles/nrmicro2644
[8] Impact of a Probiotic-Basedk Cleaning Intervention on the Microbiota Ecosystem of the Hospital Surfaces: Focus on the Resistome Remodulation. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4757022/
[9] The Potential Use of Microorganisms as Restorative Agents: An Update. https://www.mdpi.com/2071-1050/11/14/3853

**Odor Elimination.** These products can be employed as a means of odor control[10] specifically through the microorganisms' ability to out-compete the microbes associated with odor problems, and the naturally occurring metabolic action in which "substances creating odour [sic] problems such as $NH_3$ can be metabolised, [sic] or the formation of $H_2S$ may be avoided by transforming $SO_4^{2-}$ into $S_2$,"[11]. Ammonia ($NH_3$) and hydrogen sulfide ($H_2S$) are gases that give off unpleasant smells, and the metabolism of these compounds by microorganisms gives way to less-offensive by-products.

**Types of Microbes in Cleaning Products.** More than 30 species have been identified in these products, mostly bacteria, though yeast and fungal species have also been noted. Common microbes are species within the genus *Bacillus*, as well as *Bifidobacterium*, *Lactobacillus*, *Rhodopseudomonas*, and *Saccharomyces*.[12] The most common microorganism in this category of cleaning products is *Bacillus subtilis*, which is non-pathogenic, ubiquitous in nature (dirt, water bodies, raw food),[13] and has been historically used as a probiotic supplement for digestive health and for the production of fermented food.[14]

## Safety Profile of MBCPs.

Ingredients in conventional cleaning products such as solvents and surfactants can pose health risks including acting as skin irritants and allergens[15], and reproductive toxins[16]. Long-term exposure to solvents can also lead to effects on multiple organs such as damage to the respiratory, cardiovascular, and nervous systems.[17] Microorganisms are considered a healthier, green chemistry alternative to these ingredients.

Microorganisms have been used for decades in several industries such as processing food and animal feed and in many cases can be considered harmless to human health.[18] The World Health Organization classifies the risk of microorganisms into four groups – with Risk Group 1 classified as a "microorganism, or material containing microorganisms, that are already present in the environment, and are unlikely to cause human, plant, in sector animal disease, disrupt a region or an industry." Labs that use microorganisms in this Risk Group require no safety equipment or ventilation requirements.[19] Green Seal currently requires that any microorganisms in cleaning products are classified as WHO Risk Group 1 or

[10] Environmental, Health and Legal Aspects of Cleaners Containing Living Microbes as Active Ingredients. http://www.tb-klade.at/wp-content/uploads/2015/06/IFZ-EWP-3-2010.pdf
[11] Status of Microbial Based Cleaning Products in Statutory Regulations and Ecolabelling in Europe, the USA, and Canada. https://doi.org/10.1016/j.fct.2017.12.057
[12] Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings. https://doi.org/10.1787/23114622
[13] Final Risk Assessment of Bacillus Subtilis, US EPA, https://www.epa.gov/sites/production/files/2015-09/documents/fra009.pdf
[14] The safety of Bacillus subtilis and Bacillus indicus as food probiotics. https://sfamjournals.onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2672.2008.03773.x
[15] Contact allergens and irritants in household washing and cleaning products. https://doi.org/10.1111/j.1600-0536.2009.01647.x
[16] ECHA Classification and Labeling Inventory Database. https://echa.europa.eu/information-on-chemicals/cl-inventory-database
[17] Impact of Solvents Leading to Environmental Pollution https://www.jchps.com/specialissues/Special%20issue3/06%20jchps%20si3%20nanni%2049-52.pdf
[18] Status of Microbial Based Cleaning Products in Statutory Regulations and Ecolabelling in Europe, the USA, and Canada. https://doi.org/10.1016/j.fct.2017.12.057
[19] WHO Laboratory biosafety manual. https://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

an equivalent biosafety designation – a requirement that would also apply to any products sold as spray packaging.

While any health assessment of MBCPs would be specific to the strain of microorganism used, for microorganisms in WHO Risk Group 1, reviews have concluded no "clear immediate hazard could be identified" from exposure. Also, several of the microorganisms found in cleaning products have been considered GRAS – generally recognized as safe – by the U.S. Food and Drug Administration or given a rating of QPS – qualified presumption of safety for use in other categories. For example *Bacillus subtilis* is commonly used as a dietary probiotic due to its ability to utilize growth nutrients, produce high levels of enzymes and grow quickly in aerobic and anaerobic conditions.[20] Strains that are used in other functions are expected to have a "sufficient track record of safe use and handling," if they are classified as a WHO Risk Group 1.[21]

## Inhalation Exposure

The main pathways of exposure to microorganisms from cleaning products is inhalation after a product is sprayed onto a surface. With spray applications, a percentage of the aerosolized particles emitted out of a trigger nozzle do not reach the intended surface and therefore remain in the inhalation range (sometimes referred to as the "breathing zone") of the product user. Additionally, following a spray application, it is known that a small percentage of cleaning product particles that hit the surface and become resuspended.

Studies on probiotic cleaning products in professional settings have noted a low respiratory exposure to the microorganisms within the product and did not identify adverse health effects. For example, a study conducted on biological de-greasing stations concluded that "no respiratory protection was recommended as the study showed that workers…had very low respiratory exposure to bioaerosols." [22] Several studies have been conducted using probiotic cleaners in hospital settings, noting these products as effective in reducing pathogens and antimicrobial resistance,[23,24,25] and with results identifying no known adverse health effects to hospital patients.

While studies in household settings are less robust than in institutional and professional settings, there is evidence that in-home use of MBCPs are relatively safe for product users. A study in 2018 noted that while the trigger spray of a MBCP does generate aerosolized spores, the spores consisted of mainly non-respirable particles and the overall counts were below recommended safe exposure levels, except in the use of a carpet spot cleaner. The study concluded that carpet-based cleaning products presented a low potential for inhalation exposure and thus, minimal risk of adverse health effects for the user.[26]

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[20] Novel insight on probiotic *Bacillus subtilis*: Mechanism of action and clinical applications. https://www.researchgate.net/publication/312364707_Novel_insight_on_probiotic_Bacillus_subtilis_Mechanism_of_action_and_clinical_applications

[21] Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings. https://doi.org/10.1787/23114622

[22] Current knowledge of the health and environmental risks of microbial-based cleaning products. Scientific opinion of the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment. https://vkm.no/download/18.5d0520eb16b30ebbc06dbc82/1560760721358

[23] Reducing healthcare-associated infections incidence by a probiotic-based sanitation system: A multicentre, prospective, intervention study. https://doi.org/10.1371/journal.pone.0199616

[24] Impact of a probiotic-based cleaning intervention on the microbiota ecosystem of the hospital surfaces: focus on the resistome remodulation. https://doi.org/10.1371/journal.pone.0148857

[25] Hard surface biocontrol in hospitals using microbial-based cleaning products. https://doi.org/10.1371/journal.pone.0108598

[26] Safety assessment of the use of Bacillus-based cleaning products. https://pubmed.ncbi.nlm.nih.gov/29175187/

## Environmental Benefits

Because of the variety of the formula compositions for products in these categories, it is expected that the environmental impacts are dependent on the full composition of each product. For example, in certain cases, a cleaner formulated with microbes may be more harmful to the environmental through a choice of a certain additive (an area that would be addressed by Green Seal's other protective criteria). However, through the substitution of synthetic and petroleum-based ingredients with naturally occurring microorganisms, these products can have several life-cycle benefits.

A review of several microbial cleaners noted "most microbial cleaner products contain much lower levels of acids and surfactants… are less alkaline and indicate a potential for reducing the amount of organic solvents used." [27] Surfactants and solvents can be toxic to aquatic and terrestrial life when discharged at high levels[28,29], and solvents are considered volatile organic compounds (VOCs). VOCs have high impacts on both indoor and outdoor air quality through the creation of ground-level ozone and smog, which has numerous environmental effects: impacts on photosynthesis in vegetation[30], contributions to climate change, and contamination of groundwater[31].

The use of microorganisms is also supported in large-scale industrial applications. For example, the U.S. EPA supports using bioremediation – the use of natural biological agents such as bacteria, enzymes, or fungi, to break down organic compounds – for carbon-based contaminants (grease, oil) as an alternative to solvent cleaners.[32] The endpoints of these reactions are carbon dioxide and water – less harmful than chemicals used in conventional cleaners.

There is even evidence that use of these products may generate long-term performance as microorganisms applied via the product outcompete other pathogenic microbes over time.[33] Thus, less product may be needed with fewer applications resulting in resource savings in manufacturing, distribution, and corresponding savings in waste reduction.

The use of MBCPs is not expected to pose any environmental risks. The main pathway through which microorganisms used in cleaning products would reach the environment is by disposal through sewage systems where most would encounter a wastewater treatment plant. The conditions in such a plant would make it unlikely that microorganisms would survive, and studies have shown that decay rate of bacterial communities in these environments is high.[34] Even if microorganisms were to be introduced into an

[27] Environmental, Health and Legal Aspects of Cleaners Containing Living Microbes as Active Ingredients. http://www.tb-klade.at/wp-content/uploads/2015/06/IFZ-EWP-3-2010.pdf
[28] Surfactants in aquatic and terrestrial environment: occurrence, behavior, and treatment processes. https://link.springer.com/article/10.1007/s11356-015-5803-x
[29] Impact of Solvents Leading to Environmental Pollution. https://www.jchps.com/specialissues/Special%20issue3/06%20jchps%20si3%20nanni%2049-52.pdf
[30] Impacts of ozone on trees and crops. https://globalchange.mit.edu/sites/default/files/MITJPSPGC_Reprint07-21.pdf
[31] What are volatile organic compounds (VOCs)? https://www.epa.gov/indoor-air-quality-iaq/what-are-volatile-organic-compounds-vocs
[32] Application of Microbial Cleaning Technology for Removal of Surface Contamination. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7149890/
[33] Biosafety and the Environmental Uses of Micro-Organisms: Conference Proceedings. https://doi.org/10.1787/23114622
[34] Decay of sewage-associated bacterial communities in fresh and marine environmental waters and sediment. https://doi.org/10.1007/s00253-018-9112-4

ecosystem, the risk of the microorganisms survival, persistence, and outcompeting native bacterial communities is very low.[35]

## Uncertainties Regarding Health and Environmental Risks

Green Seal recognizes that these products there is limited information on these products regarding long-term health and environmental effects. These products are not regulated on the North American market. MBCPs are not identified or classified as more hazardous than other types of cleaning products. Since 2011, when Green Seal opted for a precautionary approach by de facto prohibiting certification for these products when sold for designed for use in spray packaging. Since 2011, there has continued to be the production, use, and disposal of these products with no publicly recorded or reported adverse health or environmental effects in institutional, professional, or household settings. This body of evidence, at the time of publication, indicates that WHO Risk Group 1 (non-pathogenic) microorganisms pose no known health or environmental risks that would support their exclusion from spray-packaging products or warrant excessive labeling requirements. Therefore, with the intention of offering recognition to all types of cleaning products that can meet Green Seal's rigorous standards, Green Seal is proposing to remove this barrier and allow certification for these products in spray packaging.

Green Seal implements systematic maintenance of standards and supporting evidence. At least bi-annually, Green Seal monitors updates to chemical and biological hazard classifications. In the case that new evidence emerges regarding the safety of these products, Green Seal will consider revisions to existing criteria.

## Labeling Requirements

As noted above, Risk Category 1 microorganisms, as functional ingredients in cleaning products, are not classified as hazardous and are not known currently to cause adverse health or environmental effects.

Product labels on the household and professional markets do not require precautionary statements on either labels or on Safety Data Sheets related to the inclusion of microorganisms in the cleaning product. For example, Safer Choice[36,37], ECOLOGO[38], and Cradle to Cradle,[39] for which these products are eligible for recognition, do not require precautionary statements on the product label.

However, transparency in this product space is lacking at a federal levels in the United States even as more legislation is passed that requires ingredient transparency on labels.[40] Green Seal recognizes this lack of transparency as problematic and has therefore proposed to maintain the requirement for ingredient

[35] Current knowledge of the health and environmental risks of microbial-based cleaning products. Scientific opinion of the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment. https://vkm.no/download/18.5d0520eb16b30ebbc06dbc82/1560760721358
[36] EPA's Safer Choice Standard. https://www.epa.gov/sites/production/files/2013-12/documents/standard-for-safer-products.pdf
[37] EPA's Safe Choice Supplemental Considerations for Partnership on Microorganism-based Products. https://www.epa.gov/sites/production/files/2013-12/documents/considerations_for_microorganisms.pdf
[38] ECOLOGO Certification Program. https://www.ul.com/resources/ecologo-certification-program
[39] Cradle to Cradle Certified™ Product Standard Version 3.1 https://s3.amazonaws.com/c2c-website/resources/certification/standard/C2CCertified_ProductStandard_V3.1_160107_final.pdf
[40] SB-258 Cleaning Product Right to Know Act of 2017. https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201720180SB258

disclosure of microorganisms. Green Seal is also maintaining a flexible labeling requirement in which manufacturers must provide language on labels, a product website page, or marketing materials that informs the user the product will not be effective when used with antimicrobial cleaning agents, such as bleach, which is in alignment with the approach by Ecologo (UL Standard 2798). Because antimicrobial agents will neutralize the effects of these products, this requirement decreases potential product waste.

Additionally, the Green Seal standards relevant to this proposal currently include specific labeling requirements including instructions for proper use, training (for institutional products), and responsible disposal of the product, to which MBCPs would need to conform. As a result, it is Green Seal's position that, even with the deletion of most labeling requirements defined in the Microorganisms Annexes of these standards, certified MBCPs would still be held to a leadership level for ingredient transparency, user instructions, and disposal instructions.

# Appendix 1 – Current Requirements for Microorganisms

The following is an excerpt from the GS-8 Standard for General Purpose Cleaning Products for Household Use, the Annex D – Requirements for Microorganisms. The text below does not incorporate or note proposed updates to these requirements but is intended as a reference to show Green Seal's full protective and disclosure requisites for these raw materials in Green Seal certified products as of July 20, 2021.

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**GS-8 Standard, ANNEX D**

**Products Containing Microorganisms.** Products that contain *microorganisms* shall meet all of the following with any specified testing conducted with an objective, scientifically-validated method under controlled and reproducible laboratory conditions (and appropriate testing details provided to the certification program):

**A. Genetically Modified Microorganisms in Microbial Products**. The presence of *GMM* as a deliberate addition or as a contaminant above 0.01% in the finished product is prohibited.

**B. Microorganism Biosafety.** All *microorganisms* shall be classified as *WHO Risk Group 1* or equivalent biosafety designation. For strains that do not appear on any international biosafety designation lists, alternative means may be acceptable; consultation with the certifying organization may be required.

**C. Microorganism Strain Identification.** *Microorganism* strains shall be identified through a taxonomic review (e.g., genetic or phenotypic analysis) that is provided by a full-service culture collection listed with the World Federation of Culture Collections, whether or not the strain is part of the collection.

**D. Absence of Contaminants.** *Pathogenic microorganisms* shall not be present in the microbial strain, finished product, or at the end of the product's intended shelf life. Testing for the presence of *pathogenic microorganisms* shall be conducted according to the Joint Food and Agriculture Organization of the United Nations/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications standard microbiological analytical methods or comparable method and a Certificate of Analysis shall be provided to the certification program.

**E. Effective Prevention Measures and Treatment.** All *microorganisms* shall be demonstrated to be susceptible to the following prevention and treatment measures:

- An *Antimicrobial agent*, as demonstrated by testing the microbial strain against an acceptable substance (i.e., an EPA general disinfectant, Center for Disease Control low-level disinfectant, or a registered *antimicrobial agent* by Health Canada) in accordance

with the EPA/Office of Pesticide Programs Standard Operating Procedure (SOP) or the AOAC International Use Dilution Method for Testing Disinfectants, SOP Number: MB-05-04.

- One of the five major antibiotic classes (aminoglycoside, macrolide, beta-lactam, tetracycline and fluoroquinolones), as demonstrated by testing the microbial strain in accordance with the Kirby-Bauer disk method.

**F. Microbial Count.** A *microorganism* used to serve the *primary cleaning function* in the undiluted product shall have a plate count that is greater than or equal to $1x10^7$ *CFU* per milliliter for liquid products and $1x10^9$ *CFU* per gram for solid products. A total plate count shall be conducted in accordance with the methods for microbiological analyses listed in the JECFA Combined Compendium of Food Additive Specifications or comparable method. An exception shall be made for *microorganisms* used to serve a *secondary function* in the undiluted product.

**G. Labeling Requirements.** Products containing *microorganisms* shall include the following on the label:

- A declaration that the product contains *microorganisms*
- A statement that immune-compromised individuals should avoid exposure to products containing *microorganisms* from both direct use and incidental contact during or shortly after application to these products, especially when the treated areas are still wet
- Contact with open cuts or sores should be avoided
- Users should wash their hands after using the product
- Instructions that *microorganisms* may not be effective in the presence of *antimicrobial agents* such as chlorine bleach
- Instructions that the product shall not be used on food-contact surfaces
- Instructions that products containing *microorganisms* should not be sprayed directly into the air.