Proposed Exemption for Titanium Dioxide in Enzyme-Based Cleaning Products

An Update to the April 2019 Exemption Proposal

August 16, 2019

Proposal Summary
Green Seal is proposing to allow (i.e., “exempt”) titanium dioxide as an ingredient in enzyme-based cleaning products. In some cleaning product formulations, titanium dioxide functions as a whitener for enzyme granules, which can otherwise appear beige. Titanium dioxide is currently prohibited in Green Seal’s cleaning product standards due to its classification as “a possible human carcinogen,” with the mode of action specific to the inhalation exposure route, as determined by the International Association for Research on Cancer (IARC).

Directly below is the proposed framework for the inclusion of titanium dioxide; these conditions are designed to prevent the inhalation of titanium dioxide particles during product application:

- Titanium dioxide is exempt from the prohibition on carcinogens (i.e., allowed in Green Seal certified products) when it is present only due to the use of enzymes.
- For products sold in solid form (e.g., powders, bars, tablets), titanium dioxide must be bound within the enzyme matrix or bound to other ingredients.

Green Seal’s cleaning product standards already set the following health protection requirement: Any enzyme-based cleaning product cannot be sold in spray packaging. Therefore, titanium dioxide particles in liquid enzyme-based products will also be prohibited from being spray-applied, preventing user inhalation.

Relevant Cleaning Product Standards:
- Household Cleaning Product Standards: GS-8 and GS-52
- Institutional Cleaning Product Standards: GS-37 and GS-53
- Laundry Care Product Standards: GS-48 and GS-51

Intention to Allow Titanium Dioxide as a Colorant for Enzyme-Based Cleaning Products
Enzyme-based cleaning products have fewer environmental impacts when compared to those of conventional cleaning products. For this reason, Green Seal seeks to encourage the wider adoption of enzyme-based cleaning products. These products are occasionally formulated with titanium dioxide for the purpose of ensuring a product with consistent single-toned coloring. Green Seal’s proposal includes conditions that protect the user by ensuring that titanium dioxide is bound within the product or enzyme matrix so that they
will not become airborne. It is Green Seal’s intention to maintain strict health protections for product users while allowing manufacturers to meet consumers’ preferences for fully white products.

This proposal is the result of analyses of the hazard and routes of exposure, a review of the latest published technical and public health research, and engagement with stakeholders in industry and public health.

**Initial Proposal in April 2019**
In April 2019, Green Seal proposed an exemption for titanium dioxide as an ingredient within a sub-category of cleaning products: enzyme-based products sold in solid form (powders, bars, tablets, etc.).

**Revised Proposal in August 2019**
The revised proposal, published August 16, 2019, contains similar technical justifications to the initial proposal, and has been expanded to include liquids, gel, and foam enzyme-based products in addition to solid enzyme-based products.

**Document Guide**

*Use the hyperlinks (blue text) below to jump to a specific section in this document.*

Section I. Instructions for Submitting Comments (This Page)

Section II. Technical Summary ([Page 3](#))

Section III. Redlined Standards Showing Proposed Exemption Text ([Page 7](#))

Section IV. Current Exemptions for Titanium Dioxide in Green Seal Standards ([Page 19](#))

**Section I. Instructions for Submitting Comments**

The deadline for comments is Friday, August 30, 2019, at 8 PM ET.

Submit all comments to standards@greenseal.org, subject line: “Titanium Dioxide Exemption."

For questions about this process or proposal, or requests for extensions, please contact:

- Brie Welzer, Standards Program Manager, bwelzer@greenseal.org

---

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

---

Section II. Technical Summary

Titanium Dioxide, Overview
Titanium dioxide is a colorant that is added to many types of products to whiten, brighten, and opacify. The compound is approved as a color additive by the US Food and Drug Administration (FDA) for use in food, drugs, cosmetics, and medical devices.2 It is a common ingredient in household products including sunscreen, toothpaste, and makeup, and is added in food-grade form to whiten and opacify foods such as mayonnaise, yogurt, and powdered sugar.

Titanium Dioxide in Enzyme-Based Household and Institutional Cleaning Products
Green Seal conducted a market review that included product formulation reviews and interviews with industry experts. Research confirmed that titanium dioxide is an ingredient within both dry and liquid enzyme blends – which are the raw materials that are added as the primary functional ingredients in household and institutional cleaning products. Titanium dioxide typically exists at less than 0.1% by weight in products.

Market Review Summary
- Titanium dioxide is an ingredient in certain enzyme-based cleaning products in all forms: liquids, solids, gels, and foams.
- Titanium dioxide is an ingredient in both conventional products and those products that make claims of environmental preferability.
- Products formulated with titanium dioxide exist on both industrial and institutional (“I&I”) and household markets.

Hazard Classification of Titanium Dioxide
Titanium dioxide is currently prohibited as an ingredient in Green Seal standards due to its classification as a Possible Human Carcinogen (Group 2B) via inhalation, as defined and listed by the International Agency for Research on Cancer (IARC). 3

Green Seal standards for paints, personal care products, and sanitary paper4 include exemptions for titanium dioxide because it is a functional ingredient and there are currently no readily-available substitutes that provide the same function; the compound is listed in these standards as fully exempted (no conditions) or is exempted with conditions. Additionally, in these cases, Green Seal analyzed and confirmed that inhalation is unlikely due to the ways in which these products are used and the typical concentrations of titanium dioxide in the final products. Note: See excerpts of these standards and the titanium dioxide exemptions on Page 5 of this document.

Existing Protections that Limit User Exposure to Hazard
The classified human health hazard of titanium dioxide is specific to the inhalation exposure pathway. Green Seal’s standards currently set requirements intended to preclude user inhalation of enzymes because certain

---

2 Summary of Color Additives for Use in the United States in Foods, Drugs, Cosmetics, and Medical Devices, https://www.fda.gov/forindustry/coloradditives/coloradditiveinventories/ucm115641.htm
4 GS-11, Standard for Paints, Coatings, Stains, and Sealers, GS-50 for Personal Care Products, GS-1 for Sanitary Paper Products
enzymes are classified as respiratory sensitizers. Requirements that prevent user exposure to enzymes are the following:

- solid enzymes must be in an encapsulated form (Enzyme Annexes, Criterion A of the standards)
- solid enzymes must be no smaller than 0.15 mm (Enzyme Annexes, Criterion A of the standards)
- products that contain enzymes cannot be sold in or with spray packaging (Scope of standards)

By ensuring an encapsulated form, the generation of inhalable (airborne) dust is prevented/practically eliminated. By ensuring a larger size enzyme, the potential for respiration (the particles entering the lungs) is avoided. The known presence of titanium dioxide in solid enzyme-based cleaning products is specific to its presence within the enzyme granule.

According to industry experts, titanium dioxide is usually included inside the enzyme granule, bonded to the enzyme itself, and unlikely to become airborne. To provide for flexibility in product design, Green Seal has also included a condition that allows for these particles to be bonded to other ingredients when in solid cleaning products.

Titanium dioxide is exempt from the prohibition on carcinogens (criterion 3.2) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

Extension of Proposal Exemption – Health Considerations for Liquid, Gel, and Foam Products
The original proposal for the exemption of titanium dioxide, published in April 2019, was specific to products sold as solids. At that time, Green Seal did not have evidence that titanium dioxide was included as an ingredient in other forms of cleaning products (liquids, gels, and foams). Public comments submitted during April and May 2019, subsequent discussions with stakeholders, and additional market research have since confirmed the use of this whitening compound in liquids, gels, and foams.

For gel and foam products, the heaviness (non-aerodynamic quality) and thicker consistency prevent the product from becoming airborne, therefore avoiding/preventing user inhalation of any product particles. For liquid products, the primary concern is the product being sprayed within breathing distance of the user, entering the respiratory tract, and entering the lungs. This scenario is more likely to occur when titanium dioxide particles are loose, solid powers, airborne particles, or aerosolized. Products are also more likely to be inhaled when spray products create a dispersion of particles in the air, rather than liquids that are poured or squirted in a liquid stream. The following protective requirements already exist in these standards to address these scenarios: enzyme-based cleaning products are prohibited from being sold in spray packaging and all Green Seal products are prohibited from being packaged for use as aerosols.

Environmental Impacts
The presence of titanium dioxide is an insignificant lifecycle impact in comparison to other impacts of cleaning products. Titanium dioxide is mined from ore and chemically processed for purity, with environmental impacts expected to be equivalent to other mining and chemical purification industry

---

5 Definition of Respiratory Sensitizer in Green Seal Standards: A substance designated as leading to hypersensitivity of the airways following inhalation of the substance and meeting the classification criteria of Category 1 respiratory sensitization (H334), in accordance with the GHS.

6 Titanium, https://mineralseducationcoalition.org/elements/titanium/
processes. Specific to the use and disposal phases, titanium dioxide is not known to be toxic to aquatic life or to bioaccumulate. After review of the major environmental impacts of titanium dioxide, Green Seal does not consider the absence of titanium dioxide to be a definitive requirement for environmentally-preferable cleaning products.

Examples of significant environmental issues for cleaning products include the eutrophication of waterways due to the release of phosphates; the use and transportation of water in highly diluted cleaning products; surfactants of high concern such as alkylphenol ethoxylates (APEOs) and nonylphenol ethoxylates (NPES), which are toxic to aquatic life, bio-accumulative, and reproductively toxic; ingredients that are non-biodegradable; and volatile organic compounds that contribute to indoor air pollution and are pre-cursors to smog.

**Environmental and Health Leadership Aspects of Enzyme-Based Cleaning Products**

Enzyme-based cleaning products have reduced environmental and human health impacts compared to conventional detergents. Enzymes in cleaning products allow for lower content of surfactants and builders, which are more environmentally hazardous components, in particular, phosphates. In general, enzymatic cleaners are more pH neutral and therefore less caustic to skin and less damaging to fabrics. They work effectively in lower temperatures, reducing energy expenditure of the laundry process. According to the American Cleaning Institute, “about 90% of the energy the washing machine uses goes towards heating the water.” Enzymes are effective in very low concentrations which lower the potential of user inhalation, and the potential for respiratory sensitization.

**Technical Review Summary**:

<table>
<thead>
<tr>
<th>Areas of Analysis</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ingredient with Hazard Classification</strong></td>
<td>Titanium dioxide</td>
</tr>
<tr>
<td><strong>Function of Ingredient</strong></td>
<td>Colorant, Opacifier, Whitener. In this case, specifically for enzyme granulates.</td>
</tr>
<tr>
<td><strong>Hazard Classification</strong></td>
<td>Group 2B (IARC) - Possible Carcinogen via Inhalation</td>
</tr>
<tr>
<td><strong>Product Groups</strong></td>
<td>Solid Cleaning Products – Powders, Bars, Tablets Liquid Cleaning Products – Non-Spray Applications Gel Cleaning Products – Squeeze Bottle Applications Foam Cleaning Products – Trigger Bottle Application</td>
</tr>
<tr>
<td><strong>Analysis of Exposure Event I</strong></td>
<td>Inhalation of Airborne TiO2 from Solid Products</td>
</tr>
<tr>
<td><strong>Exposure Events II</strong></td>
<td>Dermal and Ingestion Exposures – Titanium dioxide is not classified as a hazard for these exposure routes.</td>
</tr>
</tbody>
</table>

---

9 Cold-water laundry detergent is a hot idea - *Technology Solutions*, ACS Publications,
Titanium dioxide is a common ingredient in sunscreens (dermal application) and is allowed in food at up to 1% of the product (ingestion).

<table>
<thead>
<tr>
<th>Concentration in Enzyme-based Products, from Market Review</th>
<th>Low: Less than 0.1% of the product.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical Health Protection Requirement</td>
<td>For solid products, Green Seal proposes to require that titanium dioxide is bound within the matrix of the enzyme or bound to other ingredients in the product.</td>
</tr>
</tbody>
</table>
Section III. Details of the Proposed Revisions

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 Revisions to GS-8, Standard for Cleaning Products for Household Use

3.2 Prohibition of Carcinogens, Mutagens, and Reproductive Toxins. The undiluted product shall not contain any ingredients that are carcinogens, mutagens or reproductive toxins. For the purposes of this standard, naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered ingredients if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 CFR Part 141.

Note: Refer to Annex C for the exemption of titanium dioxide in products that contain enzymes.

ANNEX C – Enzymes (Normative)

Products Containing Enzymes. Products that contain enzymes shall meet all of the following:

A. Enzyme Form. Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. Enzyme Source. The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. Enzyme Source Microorganisms. For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

D. Exemptions Sensitization and Asthma. Enzymes are exempt from being categorized as asthmagens or respiratory sensitizers. Titanium dioxide is exempt from the prohibition of carcinogens (criterion 3.2) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. Labeling Requirements. Products containing enzymes shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment

F. Industrial Hygiene. Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzymes and worker illness/sensitization due to the enzymes. An example of best practices that may be applicable for this plan is available at AISE.

Revisions to GS-37, Standard for Cleaning Products for Industrial and Institution Use

3.3 **Carcinogens, Mutagens, and Reproductive Toxins.** The undiluted product shall not contain any ingredients or components that are carcinogens, mutagens, or reproductive toxins. The undiluted product shall not contain any ingredients that, according to published uses,\(^{12}\) are typically added for the purpose of releasing substances into a raw material or the final product, if those substances are carcinogens.

**Note:** Refer to Annex D for the limited exemption of titanium dioxide in solid products that contain enzymes.

---

**ANNEX D – Enzymes (Normative)**

**Products Containing Enzymes.** Products that contain enzymes shall meet all of the following:

A. **Enzyme Form.** Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. **Enzyme Source.** The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. **Enzyme Source Microorganisms.** For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

D. **Exemptions Sensitization and Asthma.**

Enzymes are exempt from being categorized as asthmagens or respiratory sensitizers.

Titanium dioxide\(^{8}\) is exempt from the prohibition on carcinogens (criterion 3.3) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. **Labeling Requirements.** Products containing enzymes shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment

F. **Industrial Hygiene.** Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzyme/s and worker illness/sensitization due to the enzyme/s. An example of best practices that may be applicable for this plan is available at AISE.

---

\(^{8}\) Titanium Dioxide: EC Number 236-675-5, CAS Number 13463-67-7

---

\(^{12}\) Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
Proposed Exemption for Titanium Dioxide in Cleaning Products, 2019

Revisions to GS-48, Laundry Care Products for Household Use

3.5 *Carcinogens and Reproductive Toxins. The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The undiluted product shall not contain any components at 0.01% or more that, according to published uses, are typically added for the purpose of releasing substances into a raw material or the final product, if those substances are carcinogens.

Note: Refer to Annex C for the limited exemption of titanium dioxide in solid products that contain enzymes.

ANNEX C – Enzymes (Normative)

Products Containing Enzymes. Products that contain enzymes shall meet all of the following:

A. Enzyme Form. Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. Enzyme Source. The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. Enzyme Source Microorganisms. For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

D. Exemptions Sensitization and Asthma.

Enzymes are exempt from being categorized as asthmagens or respiratory sensitizers. Titanium dioxide is exempt from the prohibition on carcinogens (criterion 3.5) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. Labeling Requirements. Products containing enzymes shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment

F. Industrial Hygiene. Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzyme/s and worker illness/sensitization due to the enzyme/s. An example of best practices that may be applicable for this plan is available at AISE.


13 Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
Proposed Revisions to GS-51, Laundry Care Products for Industrial and Institutional Use

3.5 *Carcinogens and Reproductive Toxins. The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The undiluted product shall not contain any components at 0.01% or more that, according to published uses, are typically added for the purpose of releasing substances into a raw material or the final product, if those substances are carcinogens.

Note: Refer to Annex E for the limited exemption of titanium dioxide in solid products that contain enzymes.

ANNEX E – Enzymes (Normative)

Products Containing Enzymes. Products that contain enzymes shall meet all of the following:

A. Enzyme Form. Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. Enzyme Source. The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. Enzyme Source Microorganisms. For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

D. Exemptions Sensitization and Asthma.

Enzymes are exempt from being categorized as asthmagens or respiratory sensitizers.

Titanium dioxide is exempt from the prohibition on carcinogens (criterion 3.5) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. Labeling Requirements. Products containing enzymes shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment

F. Industrial Hygiene. Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzyme/s and worker illness/sensitization due to the enzyme/s. An example of best practices that may be applicable for this plan is available at AISE.


14 Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
Revisions to GS-52, Standard for Specialty Cleaning Products for Household Use

**3.5 *Carcinogens and Reproductive Toxins.* The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The undiluted product shall not contain any components at 0.01% or more that, according to published uses, are typically added for the purpose of releasing substances into a raw material or final product, if those substances are carcinogens.

*Note:* Refer to Annex C for the limited exemption of titanium dioxide in solid products that contain enzymes.

ANNEX C – Enzymes (Normative)

**Products Containing Enzymes.** Products that contain enzymes shall meet all of the following:

A. **Enzyme Form.** Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. **Enzyme Source.** The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. **Enzyme Source Microorganisms.** For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

D. **Exemptions Sensitization and Asthma.** Enzymes are exempted from the requirements for Asthmagens (3.8) and Respiratory sensitzers (3.9) herein. Titanium dioxide is exempt from the prohibition on carcinogens (criterion 3.5) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. **Labeling Requirements.** Products containing enzymes shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment

F. **Industrial Hygiene.** Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzyme/s and worker illness/sensitization due to the enzyme/s. An example of best practices that may be applicable for this plan is available at AISE.


---

15 Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
Revisions to GS-53, Standard for Specialty Cleaning Products for Industrial and Institutional Use

3.5 *Carcinogens and Reproductive Toxins. The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The undiluted product shall not contain any components at 0.01% or more that, according to published uses, 16 are typically added for the purpose of releasing substances into a raw material or final product, if those substances are carcinogens.

Note: Refer to Annex D for the limited exemption of titanium dioxide in products that contain enzymes.

ANNEX D – Enzymes (Normative)

Products Containing Enzymes. Products that contain enzymes shall meet all of the following:

A. Enzyme Form. Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. Enzyme Source. The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. Enzyme Source Microorganisms. For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

D. Exemptions. Sensitization and Asthma. Enzymes are exempted from the requirements for Asthmagens (3.8) and Respiratory Sensitization (3.9) herein. Titanium dioxide is exempt from the prohibition on carcinogens (criterion 3.5) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. Labeling Requirements. Products containing enzymes shall include the following on the product label:

A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line
A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment

F. Industrial Hygiene. Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzyme/s and worker illness/sensitization due to the enzyme/s. An example of best practices that may be applicable for this plan is available at AISE.


16 Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
Revisions to GS-8, Standard for Cleaning Products for Household Use

3.2 **Prohibition of Carcinogens, Mutagens, and Reproductive Toxins.** The undiluted product shall not contain any *ingredients* that are *carcinogens, mutagens or reproductive toxins*. For the purposes of this standard, naturally occurring elements and chlorinated organics, which may be present as a result of chlorination of the water supply, are not considered *ingredients* if the concentrations are below the applicable maximum contaminant levels in the National Primary Drinking Water Standards found in 40 CFR Part 141.

*Note:* Refer to Annex C for the limited exemption of titanium dioxide in products that contain *enzymes*.

ANNEX C – Enzymes (Normative)

**Products Containing Enzymes.** Products that contain *enzymes* shall meet all of the following:

A. **Enzyme Form.** *Enzymes* in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne *enzyme* concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. **Enzyme Source.** The source from which *enzymes* were derived shall be identified to a species level and disclosed to the certification program.

C. **Enzyme Source Microorganisms.** For *enzymes* derived from *microorganisms*, documentation shall be provided that the source *microorganism* is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all *microorganisms* shall meet the requirements in Annex D herein.

D. **Exemptions Sensitization and Asthma.**

*Enzymes* are exempt from being categorized as *asthmagens* or *respiratory sensitizers*.

Titanium dioxide is exempt from the prohibition on *carcinogens* (criterion 3.5) when it is present only due to the use of *enzymes*. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. **Labeling Requirements.** Products containing *enzymes* shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing *enzymes* from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment

F. **Industrial Hygiene.** Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne *enzymes* (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the *enzyme/s* and worker illness/sensitization due to the *enzyme/s*. An example of best practices that may be applicable for this plan is available at AISE.

Titanium Dioxide: EC Number 236-675-5, CAS Number 13463-67-7
Revisions to GS-37, Standard for Cleaning Products for Industrial and Institution Use

3.3 Carcinogens, Mutagens, and Reproductive Toxins. The undiluted product shall not contain any ingredients or components that are carcinogens, mutagens, or reproductive toxins. The undiluted product shall not contain any ingredients that, according to published uses,\textsuperscript{17} are typically added for the purpose of releasing substances into a raw material or the final product, if those substances are carcinogens.

\textbf{Note:} Refer to Annex D for the limited exemption of titanium dioxide in solid products that contain enzymes.

ANNEX D – Enzymes (Normative)

Products Containing Enzymes. Products that contain enzymes shall meet all of the following:

A. **Enzyme Form.** Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. **Enzyme Source.** The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. **Enzyme Source Microorganisms.** For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

D. **Exemptions Sensitization and Asthma.** Enzymes are exempt from being categorized as asthmagens or respiratory sensitizers. Titanium dioxide\textsuperscript{8} is exempt from the prohibition on carcinogens (criterion 3.3) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. **Labeling Requirements.** Products containing enzymes shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment.

F. **Industrial Hygiene.** Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzyme/s and worker illness/sensitization due to the enzyme/s. An example of best practices that may be applicable for this plan is available at AISE.

Titanium Dioxide: EC Number 236-675-5, CAS Number 13463-67-7

\textsuperscript{17} Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
Proposed Revisions to GS-48, Laundry Care Products for Household Use

3.5 *Carcinogens and Reproductive Toxins.* The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The undiluted product shall not contain any components at 0.01% or more that, according to published uses,\(^{18}\) are typically added for the purpose of releasing substances into a raw material or the final product, if those substances are carcinogens.

**Note:** Refer to Annex C for the limited exemption of titanium dioxide in solid products that contain enzymes.

ANNEX C – Enzymes (Normative)

**Products Containing Enzymes.** Products that contain enzymes shall meet all of the following:

A. **Enzyme Form.** Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. **Enzyme Source.** The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. **Enzyme Source Microorganisms.** For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

D. **Exemptions Sensitization and Asthma.**

Enzymes are exempt from being categorized as asthmagens or respiratory sensitizers. Titanium dioxide\(^8\) is exempt from the prohibition on carcinogens (criterion 3.5) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. **Labeling Requirements.** Products containing enzymes shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line. A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment.

F. **Industrial Hygiene.** Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzymes and worker illness/sensitization due to the enzymes. An example of best practices that may be applicable for this plan is available at AISE.

Titanium Dioxide: EC Number 236-675-5, CAS Number 13463-67-7

\(^{18}\) Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
Proposed Revisions to GS-51, Laundry Care Products for Industrial and Institutional Use

3.5 *Carcinogens and Reproductive Toxins. The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The undiluted product shall not contain any components at 0.01% or more that, according to published uses,\textsuperscript{19} are typically added for the purpose of releasing substances into a raw material or the final product, if those substances are carcinogens.

\textbf{Note:} Refer to Annex E for the limited exemption of titanium dioxide in solid products that contain enzymes.

\textbf{ANNEX E – Enzymes (Normative)}

\textbf{Products Containing Enzymes.} Products that contain enzymes shall meet all of the following:

\textbf{A. Enzyme Form.} Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

\textbf{B. Enzyme Source.} The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

\textbf{C. Enzyme Source Microorganisms.} For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

\textbf{D. Exemptions Sensitization and Asthma.}

Enzymes are exempt from being categorized as asthmagens or respiratory sensitizers. Titanium dioxide\textsuperscript{8} is exempt from the prohibition on carcinogens (criterion 3.2) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

\textbf{E. Labeling Requirements.} Products containing enzymes shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment.

\textbf{F. Industrial Hygiene.} Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzyme/s and worker illness/sensitization due to the enzyme/s. An example of best practices that may be applicable for this plan is available at AISE.

\textsuperscript{8} Titanium Dioxide: EC Number 236-675-5, CAS Number 13463-67-7

\textsuperscript{19} Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
3.5 **Carcinogens and Reproductive Toxins.** The *undiluted product* shall not contain any *components* that are *carcinogens* or *reproductive toxins*. The *undiluted product* shall not contain any *components* at 0.01% or more that, according to published uses, are typically added for the purpose of releasing substances into a raw material or final product, if those substances are *carcinogens*.

**Note:** Refer to Annex C for the limited exemption of titanium dioxide in solid products that contain *enzymes*.

---

**ANNEX C – Enzymes (Normative)**

**Products Containing Enzymes.** Products that contain *enzymes* shall meet all of the following:

A. **Enzyme Form.** *Enzymes* in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne *enzyme* concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. **Enzyme Source.** The source from which *enzymes* were derived shall be identified to a species level and disclosed to the certification program.

C. **Enzyme Source Microorganisms.** For *enzymes* derived from *microorganisms*, documentation shall be provided that the source *microorganism* is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all *microorganisms* shall meet the requirements in Annex D herein.

D. **Exemptions Sensitization and Asthma.**

*Enzymes* are exempted from the requirements for *Asthmagens (3.8)* and *Respiratory sensitizers (3.9)* herein. Titanium dioxide is exempt from the prohibition on *carcinogens* (criterion 3.5) when it is present only due to the use of *enzymes*. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. **Labeling Requirements.** Products containing *enzymes* shall include the following on the product label: A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing *enzymes* from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment.

F. **Industrial Hygiene.** Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne *enzymes* (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the *enzyme/s* and worker illness/sensitization due to the *enzyme/s*. An example of best practices that may be applicable for this plan is available at AISE.


---

[20] Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
3.5 *Carcinogens and Reproductive Toxins.* The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The undiluted product shall not contain any components at 0.01% or more that, according to published uses, are typically added for the purpose of releasing substances into a raw material or final product, if those substances are carcinogens.

**Note:** Refer to Annex D for the limited exemption of titanium dioxide in products that contain enzymes.

---

**ANNEX D – Enzymes (Normative)**

**Products Containing Enzymes.** Products that contain enzymes shall meet all of the following:

A. **Enzyme Form.** Enzymes in the product shall be in liquid form or an encapsulated solid (or other dust-free solid) with a minimum diameter of 0.15 mm. Smaller diameters may be permitted for solid products if they are demonstrated to result in airborne enzyme concentrations equivalent to or less than encapsulated solids with a 0.15mm diameter.

B. **Enzyme Source.** The source from which enzymes were derived shall be identified to a species level and disclosed to the certification program.

C. **Enzyme Source Microorganisms.** For enzymes derived from microorganisms, documentation shall be provided that the source microorganism is absent from the finished product. Test methodology and results shall be documented in sufficient detail and provided to the certification program. If the product does not conform to this provision, then all microorganisms shall meet the requirements in Annex D herein.

D. **Exemptions. Sensitization and Asthma.**

Enzymes are exempted from the requirements for Asthmagens (3.8) and Respiratory Sensitization (3.9) herein. Titanium dioxide is exempt from the prohibition on carcinogens (criterion 3.5) when it is present only due to the use of enzymes. For products sold in solid form, e.g., powders, bars, tablets, titanium dioxide must be bound within the product matrix or bound to other ingredients.

E. **Labeling Requirements.** Products containing enzymes shall include the following on the product label:

A declaration that the “product contains enzymes”, in addition to the listing in the ingredient line

A statement that immune-compromised individuals or those with asthma should avoid exposure to products containing enzymes from both direct use and incidental contact during or shortly after application of these products and instruction, when necessary or appropriate, for follow-up treatment

F. **Industrial Hygiene.** Documentation shall be provided to the certification organization that demonstrates that the manufacturer has implemented an industrial hygiene plan intended to minimize concentrations of and exposure to airborne enzymes (e.g., engineering controls, work practices, and personal protective equipment) and monitor the air concentrations of the enzyme/s and worker illness/sensitization due to the enzyme/s. An example of best practices that may be applicable for this plan is available at AISE.


---

21 Published uses include sources such as peer-reviewed research, industry practice, or manufacturer documentation.
Section IV. Current Exemptions for Titanium Dioxide in Green Seal Standards

Several Green Seal product standards include stated exceptions to titanium dioxide:

Sanitary Paper Products, GS-1 Standard, Last Issued in 2018

3.5.3 Carcinogens, Mutagens, and Reproductive Toxins. The product shall not contain any functional papermaking additives or contaminants that are carcinogens, mutagens, or reproductive toxins or that are known to produce or release carcinogens. **An exception shall be made for titanium dioxide** and carbon black used in colorants.

Personal Care and Cosmetic Products, GS-50 Standard, Last Issued in 2013

3.5 Carcinogens and Reproductive Toxins. The undiluted product shall not contain any components that are carcinogens or reproductive toxins. The product shall not contain any components known to produce or release carcinogens or reproductive toxins. **An exception shall be made for titanium dioxide.** An exception shall also be made for essential vitamins and minerals, which shall not exceed the lowest tolerable upper limit in the product.

Paints, Coatings, Stains, and Sealers, GS-11 Standard, Last Issued in 2015

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

**Exemption: An exception shall be made for titanium dioxide** and, for products that are pre-tinted by the manufacturer, carbon black. As allowed under this exception, carbon black shall be less than or equal to 1% by weight of the product.22

---

22 Titanium Dioxide: EC Number 236-675-5, CAS Number 13463-67-7
Contact:

For Technical Inquiries:
Brie Welzer, Program Manager, Green Seal
Email: BWelzer@greenseal.org

For General Inquiries about Green Seal’s Programs:
Email: GreenSeal@GreenSeal.org