GreenScreen Certified™

Clean Production Action

Standard for Medical Supplies & Devices

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Clean Production Action designs and delivers strategic solutions for green chemicals, sustainable materials and environmentally preferable products.

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Acknowledgments

The GreenScreen Certified™ Standard for Medical Supplies & Devices provides the means for manufacturers to communicate their use of safer chemicals per the GreenScreen® hazard assessment tools. GreenScreen Certified™ ensures value, usability, and relevance for industry professionals wanting to excel in offering products made with preferred chemistry for people and the planet.

Clean Production Action developed the GreenScreen Certified™ Standard for Medical Supplies & Devices in consultation with a diverse group of stakeholders, including manufacturers, purchasers, and external scientific experts from consulting firms, government, academic, and non-profit organizations.

This effort would not have been possible without the help of the technical peer reviewers and key contributors, who devoted their time and considerable expertise to the development of this standard. Providing advice and feedback during technical peer review shall in no way be construed as support for the final standard. The key contributors ultimately take responsibility for all content and any flaws or errors contained herein. In producing the final standard, we thank Ellen Goldberg, Kayla Williams, and Beverley Thorpe of Clean Production Action for their efforts in developing legal terms of use, and communication and website resources necessary to implement and launch the certification program.

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OVERVIEW

1. PURPOSE

1.1 This guidance document outlines the requirements and process for the GreenScreen Certified™ Standard for Medical Supplies & Devices administered by Clean Production Action.

1.2 Clean Production Action awards a GreenScreen Certified Certification Mark via license to manufacturers and suppliers, who have paid the required license fee and have demonstrated that their product(s) meet one of six levels of increasingly stringent certification requirements described herein.

2. SCOPE

2.1 The GreenScreen Certified Standard for Supplies & Medical Devices is for evaluation of a wide variety of products used in the healthcare industry, including but not limited to:

2.1.1 Medical devices classified by the U.S. Food and Drug Administration (FDA) as Class I or Class II devices. Class I devices are low-risk devices (e.g., bedpans, examination gloves, etc.). Class II devices are intermediate-risk devices (e.g., catheters, blood pressure cuffs, surgical gloves, etc.). Note that "medical device accessories" (2.1.2), "durable medical equipment" (2.1.3), or "consumable medical supplies" (2.1.4) may also be classified by the FDA as a medical device.

2.1.2 Medical device accessories (e.g., a stand used to support an infusion pump is an accessory to the functioning of the parent device).

2.1.3 Durable medical equipment (e.g., crutches, hospital beds, infusion pumps and supplies, wheelchairs, etc.).

2.1.4 Consumable medical supplies (e.g., consumable/disposable medical products such as bandages, gauze, home health care supplies, diabetic supplies, etc.).

2.1.5 Materials (e.g., coatings) or parts used in any of the above.

2.2 Product types that are out of scope of this standard include but are not limited to:

2.2.1 Medications (e.g., oral, injectable, etc.).

2.2.2 US FDA Class III Medical Devices are high risk devices (e.g., implantable pacemakers, breast implants, etc.).

2.3 The Applicant for certification should contact Clean Production Action (greenscreen@cleanproduction.org) if questions arise as to whether certain products are within the scope of this standard.

2.4 GreenScreen Certified Certification Marks do not guarantee adherence to any other external quality, performance, or regulatory requirements.

3. SERVICE OPTIONS FOR CERTIFICATION

The process for achieving certification involves both a review of the product against the criteria and issuance of the certification. The review of the product can be done by Clean Production Action or by a GreenScreen Certified Reviewer. The process steps vary for each of these options and are described in detail in Annex 1 and Annex 2, respectively. Issuance of the certification is by Clean Production Action.

Compiling necessary data for certification requires intensive supply chain engagement that is outside the scope of the certification process. These services are offered by GreenScreen Certified Reviewers and Clean Production Action. Contact a GreenScreen Certified Reviewer or Clean Production Action for more information.

4. TERMS AND DEFINITIONS

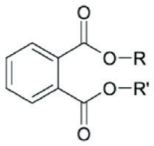
TERM	DEFINITION
Additive	A chemical compound, chemical substance, or mixture of chemical substances intentionally added to impart a desired characteristic to a product or serve a particular function in the product or homogeneous material (e.g., surfactant, solvent, stabilizer, colorant). Additives can be polymeric or non-polymeric in nature.
Alkylphenols (AP)	Chemical compounds that consist of one or more alkyl chains bound to a phenol. Phenol consists of an aromatic ring and a hydroxyl group. An alkyl chain is an acyclic saturated hydrocarbon (consisting of hydrogen and carbon atoms arranged in a tree structure in which all carbon-carbon bonds are single) with the general formula CnH_2n_{+1}.
Alkylphenol Ethoxylates (APEOs)	Derivatives of alkylphenols prepared by a chemical reaction between ethylene oxide and an alkylphenol, resulting in an ethoxylated chain with the general formula $–(OC_2H_4)_nOH$ replacing the hydroxyl group.
Antimicrobial Pesticide	"Substances or mixtures of substances used to destroy or suppress the growth of harmful microorganisms such as bacteria, viruses, or fungi on inanimate objects and surfaces." (US EPA; https://www.epa.gov/pesticide-registration/what-are-antimicrobial-pesticides, accessed 5/9/22)
Antimicrobial Pesticide Product, Non-Public Health	"Non-public health antimicrobial pesticide products are those products that bear a label claim to control microorganisms of economic or aesthetic significance, where the presence of the micro-organism would not normally lead to infection or disease in humans. Examples of non-public health claims would include, but are not limited to, algaecides, slimicides, preservatives and products for which a pesticidal claim with respect to odor sources is made." (US EPA; https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations#types, accessed 5/9/22)
Antimicrobial Pesticide Product, Public Health	"Public health antimicrobial pesticide products are those products that bear a claim to control pest microorganisms that pose a threat to human health, and whose presence cannot readily be observed by the user, including but not limited to, microorganisms infectious to man in any area of the inanimate environment." (US EPA; https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations#types, accessed 5/9/22)
Antimicrobials (Preservatives)	A type of antimicrobial pesticide used as "a preservative (e.g., fungicide or insecticide) built in or applied as a coating only to protect the product. . . . In these cases, the pesticide is registered for the intended use, and the sole purpose of treatment is to protect the product itself. These pesticides are widely used in the manufacture of textiles, plastics, paper, adhesives and coatings." (US EPA; https://www.epa.gov/safepestcontrol/consumer-products-treated-pesticides, accessed 5/9/22)
Antimicrobials (Surface Pathogens)	A type of antimicrobial pesticide intended to control microorganisms infectious to humans in any inanimate environment. The more commonly used public health antimicrobial products include the following: sterilants, sporicides, disinfectants, sanitizers, germicides. (Adapted from US EPA definition of Antimicrobial Pesticides; https://www.epa.gov/pesticide-registration/what-are-antimicrobial-pesticides, accessed 5/9/22) See Antimicrobial Pesticide Product, Public Health.
Applicant	An organization or entity that submits a product for certification according to a specific GreenScreen Certified™ standard.
Authorized GreenScreen Assessment	A GreenScreen assessment completed by an Authorized GreenScreen Practitioner™ for his or her registered organization only. An Authorized assessment can be upgraded to a Certified assessment through Clean Production Action, and would then qualify for use in the GreenScreen Certified™ standard.
Authorized GreenScreen Practitioner™	An individual who has completed advanced training in the GreenScreen method, has demonstrated scientific expertise and capacity to perform a high-quality GreenScreen assessment, and is licensed by Clean Production Action to conduct GreenScreen assessments for the registered organization.

TERM	DEFINITION
Bronze RSL Supplier Declaration	The form used by homogeneous material suppliers to attest to the absence of chemicals on the Bronze GreenScreen Certified Medical Supplies & Devices Restricted Substances List (RSL).
CASRN	Chemical Abstracts Service Registry Number (also known as "CAS#").
Catalyst	Chemical compound or substance that causes or accelerates a chemical reaction without itself being affected.
Certification Level	One of the levels of requirements for safer chemicals in products specified in the GreenScreen Certified Standards.
Certified GreenScreen Assessment	A GreenScreen assessment completed by a Licensed GreenScreen Profiler or Clean Production Action Consulting Toxicologist (including an assessment performed by an Authorized GreenScreen Practitioner and upgraded to a Certified assessment through Clean Production Action). Note: The term "Certified GreenScreen Assessment" is distinct from a GreenScreen Certified™ Product. The former refers to the assessment of an individual chemical using the GreenScreen method (see https://www.greenscreenchemicals.org/assess/assess-gs-details). The latter refers to a product that Clean Production Action has verified to meet the GreenScreen Certified™ Standard for the relevant product category and the manufacturer has signed a license agreement with Clean Production Action.
Chemical	See Chemical Compound.
Chemical Compound	A molecule (or molecular entity) composed of atoms of more than one element held together by chemical bonds and typically identified by CASRN. Synonyms used in this guidance include "chemical" or "compound."
Chemical Inventory	Used to characterize chemical compounds in each homogeneous material in the product according to the required thresholds. The Chemical Inventory is achieved by 1) attesting to the absence of specified chemicals of concern in the material using a Bronze or Silver-Gold Supplier Declaration, 2) providing a comprehensive list of chemicals present in the material, or 3) a combination of the two strategies for different materials in the product.
Chemical Substance (Substance)	"A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition." (REACH Article 3(1); http://www.reachonline.eu/REACH/EN/REACH_EN/article3.html, accessed 5/9/22) A chemical substance is comprised of constituents (i.e., chemical compounds and/or chemical elements), and a chemical substance can be a component within a mixture.
Compounds of Cadmium	A chemical compound containing the element cadmium (Cd).
Compounds of Lead	A chemical compound containing the element lead (Pb).
Compounds of Mercury	A chemical compound containing the element mercury (Hg).
Consumable Medical Supply	"Non-durable medical supplies that: are usually disposable in nature, cannot withstand repeated use by more than one individual, are primarily and customarily used to serve a medical purpose, generally are not useful to a person in the absence of illness or injury, and may be ordered and/or prescribed by a physician. (Cigna Healthcare; https://www.cigna.com/healthcare-professionals/resources-for-health-care-professionals/clinical-payment-and-reimbursement-policies/medical-supplies-definition, accessed 5/16/22)

TERM	DEFINITION
Durable Medical Equipment	Equipment that "meet these criteria: durable (can withstand repeated use); used for a medical reason; not usually useful to someone who isn't sick or injured; used in your home; and generally has an expected lifetime of at least 3 years."(Medicare.gov, https://www.medicare.gov/coverage/durable-medical-equipment-dme-coverage, accessed 6/26/22)
Electronic Product	Products that are in EU RoHS Categories 1 through 11 in the European Union Restriction of Hazardous Substances Directives (RoHS 3 or later; https://rohsguide.com/rohs-categories.htm) Electronic components "include circuit boards, displays, and related wires and connectors." (Health Product Declaration Special Condition: Electronics; https://www.hpd-collaborative.org/wp-content/uploads/2018/07/SpecialCondition_Electronics.pdf, accessed 5/9/22)
Fastener	A hardware device that mechanically joins or affixes two or more objects together. For example: screws, nuts, bolts, staples, nails, anchors, washers, buckles, clamps, clasps, cable ties, clips, clutches, pins, hooks, latches, pegs, retaining rings, as well as ball and roller bearings; in addition, any uncoated/untreated thread or yarn used for sewing or stitching two or more fabric components together.
Flame Retardant	"Any chemical or chemical compound for which a functional use is to resist or inhibit the spread of fire. Flame retardant chemicals include, but are not limited to, halogenated, phosphorous-based, nitrogen-based, and nanoscale flame retardants, flame retardant chemicals listed as "designated chemicals" pursuant to Section 105440 of the Health and Safety Code, and any chemical or chemical compound for which "flame retardant" appears on the substance Safety Data Sheet (SDS) pursuant to Section 1910.1200(g) of Title 29 of the Code of Federal Regulations." (California Senate Bill 1019; https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140SB1019, accessed 5/9/22)
GreenScreen Assessment	The assessment of an individual chemical using the GreenScreen method (see https://www.greenscreenchemicals.org/assess/assess-gs-details). An Authorized GreenScreen assessment and a Certified GreenScreen assessment are two types of GreenScreen assessments and reflect the type of assessor producing the assessment.
GreenScreen Benchmark™ Score	A score that is assigned to a chemical evaluated using the GreenScreen® for Safer Chemicals method. GreenScreen Benchmark scores range from 1 to 4, with each increasing Benchmark score defining progressively less hazardous chemicals. (GreenScreen Guidance and Resources; https://www.greenscreenchemicals.org/learn/full-greenscreen-method)
GreenScreen Certified™ Certification Marks	The trademarked logos and phrase that may be licensed by Clean Production Action for use by a successful Applicant to describe the products that meet all of the requirements of a specified level of the GreenScreen Certified™ Standard for the relevant product category and as verified and approved by Clean Production Action.
GreenScreen Certified™ Reviewer	An organization approved by Clean Production Action to review products against the GreenScreen Certified standards. Reviewers also offer supply chain engagement services. Reviewers may be Licensed GreenScreen Profilers or Licensed GreenScreen Consultants.
GreenScreen List Translator™	A streamlined chemical hazard assessment method developed by Clean Production Action that produces a GreenScreen List Translator score. (GreenScreen Guidance and Resources Section IV; https://www.greenscreenchemicals.org/learn/greenscreen-list-translator)
GreenScreen List Translator™ Score	A score that is assigned to a chemical screened against all GreenScreen Specified Lists (Annex 11) using GreenScreen List Translator guidance. List Translator scores include LT-1, LT-P1, LT-UNK and NoGSLT. (GreenScreen Guidance and Resources Section IV; https://www.greenscreenchemicals.org/learn/full-greenscreen-method)
GSC-Reviewed Certificate	The document awarded to applicants that have gone through the certification process but did not meet all of the Bronze or Bronze+ certification requirements (See Annex 3).

TERM	DEFINITION
Hazardous Waste	Materials or substances that are regulated in the US as a federal or state hazardous waste when disposed after used for its intended purpose where: **1) Federal hazardous wastes** are substances or materials that are "listed" as hazardous wastes (per 40 CFR Subpart D) or that meet the "characteristic" of being a hazardous waste (per 40 CFR Subpart C); or contain hazardous materials or substances when disposed are regulated by other environmental laws (CERCLA, TSCA, Nuclear Waste Policy Act); and **2) State hazardous wastes** are substances "listed" as hazardous wastes by State regulations (e.g., 22 California Code of Regulations Appendix X) or meet the "characteristic" of hazardous waste under State toxicity criteria (e.g., 22 California Code of Regulations 66261.24, Characteristic of Toxicity).
Health Product Declaration (HPD)	The Health Product Declaration (HPD) Open Standard provides a framework for product manufacturers to provide information about product contents and associated health information. The HPD Open Standard is a consensus, stakeholder standard, governed by the HPD Collaborative, a not-for-profit member organization. (Health Product Declaration Collaborative; https://www.hpd-collaborative.org/hpd-open-standard-all-versions, accessed 5/16/22)
Health Product Declaration Collaborative (HPDC)	An organization composed of, and led by, stakeholders throughout the building industry. The HPD Collaborative is committed to the continuous improvement of building products through transparency, openness, and innovation throughout the product supply chain. It creates, maintains, and evolves the HPD Open Standard. (Health Product Declaration Collaborative; https://www.hpd-collaborative.org/hpd-open-standard-all-versions, accessed 5/16/22)
Homogeneous Material (Material)	"One material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes." (EU Directive 2008/98/EC; https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008L0098, accessed 5/9/22)
Impurity	"An unintended constituent present in a substance as manufactured. It may, for example, originate from the starting materials or be the result of secondary or incomplete reactions during the production process. While it is present in the final substance, it was not intentionally added. In most cases impurities constitute less than 10% of the substance." (ECHA; https://echa-term.echa.europa.eu, accessed 5/9/22)
Intentionally Added	Included to serve a desired function; not an impurity or a residual.
Licensed GreenScreen Profiler	An organization with expertise in toxicology and comparative chemical hazard assessment that is licensed by Clean Production Action to provide GreenScreen assessments for a fee to clients. (https://www.greenscreenchemicals.org/assess/profilers)
Material Function	A general description of what a material is used for in a product. Examples include but are not limited to adhesive, backing, binder, and filler.
Material Inventory	The portion of the Product Inventory Form used to characterize each homogeneous material in the product (including its parts or assemblies).
Material Type	A broad classification of a material based on chemical makeup and atomic structure. Examples include but are not limited to metal, ceramic, polymeric material, glass, electronic, composite, nanomaterial, biological material, geological material, or waste material.

TERM	DEFINITION
Medical Device	"An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." (US Food, Drug & Cosmetic Act. (FD&C Act); https://www.fda.gov/ForIndustry/ImportProgram/ImportBasics/RegulatedProducts/ucm510630.htm, accessed 5/16/22) "The Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure the various types of devices are safe and effective. **Class I** — These devices present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. Examples include enema kits and elastic bandages. 47% of medical devices fall under this category and 95% of these are exempt from the regulatory process. **Class II** — Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits. 43% of medical devices fall under this category. **Class III** — These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Examples of Class III devices include implantable pacemakers and breast implants. 10% of medical devices fall under this category. **Exempt** — If a device falls into a generic category of exempted Class I devices, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, the manufacturer is required to register their establishment and list their generic product with FDA. Examples of exempt devices are manual stethoscopes, mercury thermometers, and bedpans. Section 510(k) of the Food, Drug and Cosmetic Act requires those device manufacturers who must register to notify FDA their intent to market a medical device. This is known as Premarket Notification (PMN) or 510(k). Under 510(k), before a manufacturer can market a medical device in the United States, they must demonstrate to FDA's satisfaction that it is substantially equivalent (as safe and effective) to a device already on the market. If FDA rules the device is "substantially equivalent," the manufacturer can market the device. If the device you are researching has been in commercial distribution before 1976 or is substantially equivalent to a device already on the market, you should search FDA's 510(k) releasable database." (US FDA; https://www.fda.gov/medical-devices/consumers-medical-devices/learn-if-medical-device-has-been-cleared-fda-marketing, accessed 6/26/22)
Medical Device Accessory	"An accessory is a finished device that is intended to support, supplement, and/or augment the performance of one or more parent devices." (US FDA, https://www.fda.gov/medical-devices/classify-your-medical-device/medical-device-accessories#1, accessed 6/26/22)
Medication	A substance used for clinical treatment, especially a medicine or drug.
Minor Fastener	A minor fastener is a coated or uncoated fastener that is sourced from a third party and made to a generic specification (e.g., ASTM Fasteners that are made in-house, made to order, or made exclusively for a single customer are not considered commodity fasteners). (Health Product Declaration Special Condition: Minor Fasteners; https://www.hpd-collaborative.org/special-conditions, accessed 5/9/22)
Monomer	"A substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer forming reaction used for the particular process." (REACH Article 3(6); http://www.reachonline.eu/REACH/EN/REACH_EN/article3.html, accessed 5/9/22)

TERM	DEFINITION
Non-Disclosure Agreement (NDA)	A legally binding agreement between organizations for the purpose of protecting confidential information shared during the certification process.
Organohalogen	A chemical containing one or more halogen atoms (typically chlorine, bromine, fluorine, or iodine) bound to a carbon atom.
Organotin Compound	Organotin compounds (organotins) are substances composed of tin directly bound to different organic groups.
Ortho-Phthalates	 Dialkyl ortho-phthalates (or phthalate esters) have the general chemical structure shown to the left, where each R group only contains hydrogen and carbon either in a linear or branched chain or cyclic chain (Adapted from USEPA Phthalates Action Plan 2012; https://www.epa.gov/sites/production/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf, accessed 5/9/22)
Part	An optional functional grouping of contents to identify a portion of a product that is used modularly (e.g., cable, caster, chair arm). (Adapted from Health Product Declaration Open Standard 2.1; https://www.hpd-collaborative.org/hpd-open-standard-all-versions, accessed 5/9/22)
Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS)	"A class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." (SB 5135, Safer Products for WA ACT; http://lawfilesext.leg.wa.gov/biennium/2019-20/Pdf/Bills/Senate%20Passed%20Legislature/5135-S.PL.pdf?q=20210811124919, accessed 6/6/22)
Polymer Mixture	A mixture comprised of a polymer substance and unreacted monomer(s).
Polymer Species	"Molecules characterized by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. Polymer species comprise the following: (a) a simple weight majority (i.e., 50%) of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant; or (b) less than a simple weight majority of molecules of the same molecular weight." In the context of this definition a "monomer unit" means the reacted form of a monomer in a polymer." (REACH, Article 3(5); http://www.reachonline.eu/REACH/EN/REACH_EN/article3.html, accessed 5/9/22)
Polymer Substance	A substance comprised of constituents: polymer species, additives necessary to preserve stability, and impurities deriving from the manufacturing process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. (Based on REACH Article 3(1); http://www.reachonline.eu/REACH/EN/REACH_EN/article3.html, accessed 5/9/22)
Polymeric Material	A mixture of one or more polymer substance(s) or polymer mixture(s), all other additives (i.e., intentionally added substances), and unintentional impurities.
Post-Consumer Recycled Content	"Waste material generated by households or by commercial, industrial and institutional facilities in their role as end-users of the product, which can no longer be used for its intended purpose." (US Green Building Council; https://www.usgbc.org/credits/schools-nc/v2007/mrc4, accessed 5/9/22)
Primary Packaging	The layer of packaging in immediate contact with the product.
Product	A finished good composed of parts, homogeneous materials, and/or chemical substances. A product may function as part of another product. A product may be made of one or more homogeneous materials.
Product Inventory Form	A form for listing the product contents for each product being certified. See Section 6 for additional required information.
Product Review Report	The checklist and/or form used by Clean Production Action and/or GreenScreen Certified™ Reviewers to document evaluation of a product for compliance with all GreenScreen Certified™ standard requirements.

TERM	DEFINITION
Proprietary Ingredient	An ingredient in a product that is confidential to the manufacturer or producer.
Recyclable	"A product or package is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program for reuse or use in manufacturing or assembling another item, with recycling facilities for the item available to at least 60 percent of communities where the item is sold." (FTC Regulation; https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-green-guides/greenguides.pdf, accessed 5/9/22)
Recycled Content	"Refers to the portion of materials used in a product that have been diverted from the solid waste stream. If those materials are diverted during the manufacturing process, they are referred to as pre-consumer recycled content (sometimes referred to as post-industrial). If they are diverted after consumer use, they are post-consumer." (Building Green; https://www.buildinggreen.com/primer/defining-recycled-content, accessed 5/9/22)
Residual	Chemical or substance added upstream in the supply chain to serve a desired function: 1) In the additive or homogeneous material but not in the final product as placed on the market; or 2) In the production of the additive or homogeneous material. For example, this may refer to substances included in a manufacturing process to aid processing, as well as inputs to a reaction process such as reagents, catalysts, monomers, or preservatives for raw materials.
Residual Monomer	An unintended impurity in a polymer substance. (GreenScreen Guidance and Resources; https://www.greenscreenchemicals.org/learn/full-greenscreen-method)
Restricted Substances List (RSL)	The list of chemicals and chemical classes that certified products shall not contain as defined in the standard.
Restricted Substances List (RSL) Reference List	The list of chemical group members for restricted chemical groups in the standard.
RSL Threshold	A "not to exceed" limit used in an RSL.
Secondary Packaging	Protects the product and the primary packaging. An example of secondary packaging is a cardboard box or plastic crate containing multiple products in primary packaging.
Siloxanes	"Siloxanes, often also described as silicones, are molecules with an oxygen–silicon backbone (Si–O–Si), where each silicon atom carries two organic groups, mostly methyl, ethyl, or phenyl groups. Depending on their molecular weight, siloxanes can be characterized as linear or cyclic volatile methylsiloxanes, polydimethylsiloxanes (PDMS), or polyethermethylsiloxanes (PEMS)." (Fromme, Hermann. Cyclic Volatile Methylsiloxanes: Occurrence and Exposure. Reference Module in Earth Systems and Environmental Sciences. 2018; (https://www.sciencedirect.com/topics/medicine-and-dentistry/siloxane, accessed 5/9/22)
Silver-Gold RSL Supplier Declaration	The form used by homogeneous material suppliers to attest to the absence of chemicals on the Bronze and Silver-Gold GreenScreen Certified Medical Supplies & Devices Restricted Substances List.
Substance Impurity	An impurity of a chemical substance or polymer substance, such as a residual catalyst. See also "Impurity."
Substance Role	The specific purpose that a chemical serves in a material, product, or process. (Adapted from Tickner, Joel A. et al, "Advancing Safer Alternatives Through Functional Substitution", DOI: 10.1021/es503328m, Environ. Sci. Technol. 2015, 49, 742–749; https://pubs.acs.org/doi/abs/10.1021/es503328m, accessed 5/9/22)

TERM	DEFINITION
Supplier Declaration	The attestation form(s) used in the GreenScreen Certified Standard for Medical Supplies & Devices to verify specific certification claims. See Section 9 Documentation Requirements for a list of the specific Supplier Declaration forms.
Unreacted Monomer	An intended component in a polymer mixture. (GreenScreen Guidance and Resources; https://www.greenscreenchemicals.org/learn/full-greenscreen-method)
Valid GreenScreen Assessment	A GreenScreen Assessment report that is not expired or has not been superseded. See GreenScreen Terms of Use for details.

CERTIFICATION REQUIREMENTS

All certification requirements are outlined in sections 5 through 8 below. The Product Inventory section specifies how to characterize the chemicals in the homogeneous materials that make up the product. Then, using the product inventory constructed, section 6 outlines the hazard assessment requirements, which vary for each certification level and type of product inventory.

5. PRODUCT INVENTORY

The Product Inventory includes a Material Inventory and a Chemical Inventory. The Chemical Inventory requirements shall be met through attesting to the absence of specified chemicals of concern in the material, providing a comprehensive list of chemicals present in the material, or a combination of the two strategies for different materials in the product. Chemical Inventory requirements vary by certification level.

Refer to Table 1 below for a summary of requirements for the Product Inventory for each certification level. Follow the section hyperlink for detailed requirements. See also Section 7 Certification Amendments for information on any criteria modifications for specific material types, as applicable to the product undergoing certification.

TABLE 1: **Product Inventory Summary of Requirements**

Section	Requirement	Certification Levels					
		Bronze	Bronze+	Silver	Silver+	Gold	Gold+
Material Inventory	Each material in the product (present > 0 ppm) is listed in the Material Inventory.	√	√	√	√	√	√
Chemical Inventory	Signed **Bronze Supplier Declaration** for at least 95% by mass of materials in the product.	√					
	Signed **Bronze Supplier Declaration** for 100% of the materials in the product.		√				
	Comprehensive list of chemicals in each material for at least 95% by mass of materials in the product. Signed **Silver-Gold Supplier Declaration** for each of the remaining materials in the product.			√		√	
	Comprehensive list of chemicals in each material for 100% by mass of materials in the product.				√		√

5.1 Material Inventory Requirements

A Material Inventory is required for application to the GreenScreen Certified Standard for Medical Supplies & Devices program and is a requirement for all six levels of Certification. Each Material Inventory must:

5.1.1 Identify 100% by mass of the homogeneous materials in the product; and

5.1.2 List the following information for each homogeneous material in the product:

1. Material trade name(s) and/or metal alloy grade/unified numbering system (UNS) #; include part number(s) for assemblies,[1]
2. Material supplier name,
3. Material type,[2]
4. Material function,
5. Material color or coating,[3] and
6. Material percent by mass (%) in product.

5.2 Chemical Inventory Requirements

The Chemical Inventory requirements shall be met through attesting to the absence of specified chemicals of concern in the material using a Bronze or Silver-Gold Supplier Declaration, providing a comprehensive list of chemicals present in the material, or a combination of the two strategies for different materials in the product. Chemical Inventory requirements vary by certification level, and are described for each level below.[4]

5.2.1 Bronze Chemical Inventory Requirements

1. The Applicant or its supplier(s) must submit a signed Bronze Supplier Declaration for each material in the product for a total of at least 95% by mass of materials in the product.

5.2.2 Bronze+ Chemical Inventory Requirements

1. The Applicant or its supplier(s) must submit a signed Bronze Supplier Declaration for each material in the product for a total of 100% by mass of materials in the product.

5.2.3 Silver and Gold Chemical Inventory Requirements

1. The Applicant or its supplier(s) must submit a Comprehensive List of Chemicals (See Section 5.3.2) for each material totaling at least 95% by mass of materials in the product, and

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1 For products with multiple parts or assemblies, each homogeneous material in each part and/or each assembly must be included in the Material Inventory.

2 Biological and geological materials often contain treatments and/or additives such as binders, coatings, and finishes that must be inventoried separate from the biological or geological material. For biological materials list the Genus name and species name. For geological materials, list the Series or Group name and all other information known about the material.

3 Colorants and coatings, finishes and/or metal plating on any material type must be listed as separate homogeneous materials in the Material Inventory.

4 Which tier of supplier signs the declaration depends on the level of knowledge of the material itself. In general, the supplier with the most transparent visibility into the chemical composition of the material is required to sign the declaration.

2. The Applicant or its supplier(s) must submit a signed Silver-Gold Supplier Declaration for each remaining material in the product for a maximum total of 5% by mass of materials in the product.

5.2.4 Silver+ and Gold+ Chemical Inventory Requirements

1. The Applicant or its supplier(s) must submit a nested Comprehensive List of Chemicals (See Section 5.3.2) for each material in the product totaling 100% by mass of materials in the product.

5.3 Product Inventory Documentation Requirements

5.3.1 Attestation by Supplier Declaration: The Applicant or its supplier(s) must submit a signed RSL Supplier Declaration for each material in the product for the required percent (%) by mass of materials in the product (i.e., 95% for Bronze, 100% for Bronze+, or for each remaining material in the product for a maximum total of 5% for Silver and Gold). The Supplier Declaration attests to the absence of GreenScreen Certified RSL chemicals above specified thresholds.

5.3.2 Comprehensive List of Chemicals: Comprehensive List of Chemicals: The Applicant or its supplier(s) must submit a list of each chemical compound (intentionally added, impurity or residual) present ≥ 0.01% by mass (100 ppm) in the material for each material totaling the required % by mass of materials in the product (i.e., 95% for Silver and Gold, or 100% for Silver+ and Gold+. Inventories shall include the following information: [6,7]

1. Additive trade name,
2. Additive supplier name,
3. Additive function,
4. Additive percent by mass (%) in homogeneous material,
5. Chemical name and CASRN,
6. Chemical percent by mass (%) in additive,
7. Substance role if intentionally added or residual, and
8. Description if impurity.

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5 Applicants can redact chemical name and CASRN only if accompanied by a valid GreenScreen Assessment. Where hazard scores are used for redacted chemical name(s), the name of the assessor and date of assessment must be provided along with a traceable alphanumeric ID number. Service options and provider directory available at: https://www.greenscreenchemicals.org/certified/service-providers.

6 For additives that are polymeric materials, each polymer species, monomer, and catalyst in a polymer substance or polymer mixture must be listed as a separate ingredient. Polymeric materials include one or more polymer substances and/or polymer mixtures and potentially one or more additives (see Section II—Assessing Polymers in the GreenScreen® for Safer Chemicals Hazard Assessment Guidance Version 1.4).

6. GREENSCREEN HAZARD EVALUATION

The Product Inventory completed in Section 5 will be used to evaluate the product using Restricted Substances List screening, List Translator screening, and/or assessment using GreenScreen for Safer Chemicals, depending on the certification level. Refer to Table 2 below for a summary of GreenScreen hazard evaluation requirements across certification levels. Follow the section hyperlink for detailed guidance on each requirement.

TABLE 2: **GreenScreen Hazard Evaluation Summary of Requirements**

Section	Requirement	Certification Levels					
		Bronze	Bronze+	Silver	Silver+	Gold	Gold+
RSL Screening	No Bronze RSL chemicals	95%	100%	100%	100%	100%	100%
	No Silver-Gold RSL chemicals			100%	100%	100%	100%
List Translator Screening	No LT-1 chemicals			100%	100%	100%	100%
GreenScreen Assessment	No Benchmark-1 chemicals					95%	100%
Analytical Testing	Total Fluorine for each fabric and each molded fiber	Required for all levels					

Note: The percentage shown in Table 2 represents the mass percent of the materials in the product that require RSL screening, List Translator screening, or a GreenScreen assessment.

6.1 Screening against Restricted Substances List (RSL)

All levels of certification require screening each homogeneous material in the product and the product itself against one or more restricted substances lists (RSLs). The screening method used for a homogeneous material is dependent on the type of chemical inventory required (see Section 5.2). Screening against the Bronze or Silver-Gold RSL is achieved either by reviewing a comprehensive list of chemicals in the homogeneous material or reviewing RSL Supplier Declarations for the homogeneous material(s).

Scope:

Electrical Products: the only restricted chemical groups applicable for electronic products are the European Union Restriction of Hazardous Substances (EU RoHS) Directive, PVC, and Halogenated Flame Retardants in Table 3.

Non-Electrical Products: all restricted chemical groups in Table 3 and 4 are applicable for non-electrical products except the European Union Restriction of Hazardous Substances (EU RoHS) Directive.

Non-electrical and electrical products must meet one of the following requirements:

6.1.1 Bronze and Bronze+ levels: Supplier declarations are used to verify compliance against the Bronze RSL in Table 3. The product must meet all detailed RSL requirements for each chemical group listed in Table 3.

6.1.2 Silver and Gold levels: A combination of Supplier Declaration(s) and a comprehensive list of chemicals is used to verify compliance with the Bronze RSL in Table 3 and the Silver-Gold RSL in Table 4. The product must meet all detailed RSL requirements for each chemical group in Tables 3 and 4.

6.1.3 Silver+ and Gold+ levels: A comprehensive list of chemicals is used to verify compliance with the Bronze RSL in Table 3 and the Silver-Gold RSL in Table 4. The product must meet all detailed RSL requirements for each chemical group in Tables 3 and 4.

TABLE 3: **BRONZE Restricted Substances List (RSL) Summary**

Chemical Group	Product Threshold	Material Threshold	Detailed RSL Requirements
European Union Restriction of Hazardous Substances (EU RoHS) Directive (Electronics)	N/A	Per regulation, excluding exemptions	Annex 4, Section A4.1
Bisphenols (Bronze List)	N/A	≥ 0.1% by mass (1000 ppm)	Annex 4, Section A4.2
Polyvinyl Chloride (PVC)	1000 ppm	N/A	Annex 4, Section A4.3
Halogenated Flame Retardants	N/A	≥ 0.1% by mass (1000 ppm)	Annex 4, Section A4.4
Ortho-phthalates (Bronze List)	N/A	≥ 0.1% by mass (1000 ppm)	Annex 4, Section A4.5
California Proposition 65 Chemicals	Below labeling requirement	N/A	Annex 4, Section A4.6
Antimicrobials (Surface Pathogens)	N/A	> 0 ppm (see exemption in Annex 4)	Annex 4, Section A4.7
Antimicrobials (Preservatives)	N/A	> 0 ppm	Annex 4, Section A4.8
Persistent, Bioaccumulative, and Toxic chemicals (PBTs)	N/A	≥ 0.1% by mass (1000 ppm)	Annex 4, Section A4.9
Non-Halogenated Flame Retardants	N/A	≥ 0.1% by mass (1000 ppm)	Annex 4, Section A4.10
Metals and their compounds: Cadmium, Lead, Mercury, and Organotin	N/A	Lead ≥ 0.0004% by mass (40 ppm); Mercury ≥ 0.01% by mass (100 ppm); Cadmium ≥ 0.01% by mass (100 ppm); Organotin ≥ 0.01% by mass (100 ppm)	Annex 4, Section A4.11
Per- and Polyfluoroalkyl Substances (PFAS)	N/A	≥ 0.01% by mass (100 ppm)	Annex 4, Section A4.12

Note: Each restricted chemical group on the RSL has either a material threshold or a product threshold specified, but not both. Product level thresholds apply to the sum of the mass of the chemical in each homogeneous material divided by the total mass of the product.

TABLE 4: **SILVER-GOLD Restricted Substances List (RSL) Summary**

Chemical Group	Material Threshold	Detailed RSL Requirements
Bisphenols (Silver-Gold)	≥ 0.01% by mass (100 ppm)	Annex 4, Section A4.13
Ortho-phthalates (Silver-Gold)	≥ 0.01% by mass (100 ppm)	Annex 4, Section A4.14
Alkylphenols and Alkylphenol Ethoxylates	≥ 0.01% by mass (100 ppm)	Annex 4, Section A4.15
Cyclic Volatile Methyl Siloxanes (cVMS)	≥ 0.01% by mass (100 ppm)	Annex 4, Section A4.16
ZDHC Manufacturing Restricted Substances List (MRSL) Version 2.0	≥ 0.01% by mass (100 ppm)	Annex 4, Section A4.17
Organohalogens	≥ 0.01% by mass (100 ppm)	Annex 4, Section A4.18
GreenScreen List Translator LT-1	≥ 0.01% by mass (100 ppm)	Annex 4, Section A4.19

6.2 Screening with GreenScreen List Translator™

6.2.1 For the Silver, Silver+, Gold, and Gold+ levels of certification:

6.2.1.1 GreenScreen List Translator scores are required for each chemical (intentionally added, impurity or residual) in the Product Inventory.

6.2.1.2 Only List Translator scores of LT-P1, LT-UNK, and/or NoGSLT are permitted.

6.2.1.3 No LT-1 scores are permitted.[7]

6.2.2 For each material with a Comprehensive List of Chemicals, each chemical (intentionally added, impurity or residual) present ≥ 0.01% by mass (100 ppm) in the material is screened by CASRN using the automated GreenScreen List Translator databases.[8]

6.2.3 For each material with a Silver-Gold Supplier Declaration, the supplier must attest that the material does not contain any LT-1 chemicals present ≥ 0.01% by mass (100 ppm) in the material.

6.3 Assessment with GreenScreen® for Safer Chemicals (GreenScreen)

6.3.1 GreenScreen assessments[9] are required for each chemical (intentionally added, impurity or residual) in the Product Inventory for the Gold, and Gold+ levels of certification with the following exception and modification:

6.3.1.1 Exception: GreenScreen assessments are not required for substances listed on the US Environmental Protection Agency Safer Chemical Ingredients List (USEPA SCIL). Presence on the USEPA SCIL list is considered equivalent to "not GreenScreen Benchmark-1."

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7 No GreenScreen Benchmark-1 scores are permitted in assessed materials of certified products, where there is a freely and publicly available GreenScreen assessment.

8 Clean Production Action screens each entry in the Product Inventory using GreenScreen List Translator. An Applicant may wish to perform an optional pre-screen of chemicals in the Product Inventory to determine if any have a GreenScreen List Translator score of LT-1 before applying to the program. Online tools that provide automation for GreenScreen List Translator scoring include Pharos (no cost) and toxnot (no cost). See the GreenScreen website for a list of Licensed GreenScreen List Translator™ Automators.

9 An Applicant may use valid Certified GreenScreen assessment(s) obtained either through public databases or through commissioning an assessment. New Certified GreenScreen assessments are generated (typically by a Licensed GreenScreen Profiler) for all remaining substances. Authorized assessments generated by Authorized GreenScreen Practitioners and upgraded to Certified assessments through Clean Production Action qualify for use in the GreenScreen Certified™ program.

6.3.1.2 Modification: GreenScreen assessments of polymer substances for the Gold and Gold+ level of certification do not require a potential chemical of high concern analysis to be conducted (See Section 15.4 in the GreenScreen® for Safer Chemicals Hazard Assessment Guidance Version 1.4). Instead, each residual monomer and each catalyst present ≥ 0.01% by mass (100 ppm) in the homogeneous material must meet the requirement of 6.2.

6.3.2 For Gold, each chemical substance (intentionally added, impurity or residual) in 95% by mass of the materials in the product and present in the material ≥ 0.01% by mass (100 ppm) is assessed with GreenScreen.

6.3.3 For Gold+, each chemical substance (intentionally added, impurity or residual) in 100% of the materials in the product and present in the material ≥ 0.01% by mass (100 ppm) is assessed with GreenScreen.

6.3.4 Chemical substances assigned a score of Benchmark-1, Benchmark-1_{TP}, or Benchmark-1_{CoHC} are not permitted in Gold certified products.[10]

6.4 Analytical Testing Requirement for Total Fluorine in Fabric and Molded Fiber

Given the widespread use of per- and poly-fluorinated alkyl substances (PFAS) in fabrics and molded fiber, all levels of certification require fabric and molded fiber to be tested for total fluorine. All products must meet the total fluorine requirements specified below. These requirements apply whether the product being reviewed for certification is made exclusively of fabric or molded fiber, or whether the product being reviewed for certification is a more complex product that contains fabric and/or molded fiber.

6.4.1 If none of the assets (equipment) used to produce the product under review for certification have any contact with PFAS at any time (i.e., production uses completely dedicated assets only), Applicant must meet Level 1 Total Fluorine Testing Requirements.

6.4.2 If one or more of the assets used to produce the product under review for certification have any contact with PFAS at any time, Applicant must meet the Level 1 and Level 2 Total Fluorine Testing Requirements.

6.4.3 Product-level total fluorine testing of all required samples shall verify total fluorine content is < 0.01% by mass (100 ppm).

6.4.4 Total fluorine shall be determined by Combustion Ion Chromatography or Combustion followed by Ion Selective Electrode. Test method detection limit must be 0.005% by mass (50 ppm) or lower.

6.4.5 Testing laboratories are approved by Clean Production Action. Clean Production Action provides the Applicant with information necessary to submit samples for testing. Threshold exceedances due to naturally occurring fluorine may be accepted if the Applicant provides sufficient analytical testing data demonstrating the source is not from a fluorinated chemical.

6.4.6 Level 1 Total Fluorine Testing Requirements: During the certification process, product-level total fluorine testing of each fabric and/or molded fiber is required on three samples, one sample each from three different production lots, runs, or batches. For Applicants subject to both Level 1 and Level 2 Total Fluorine Testing Requirements, each of the three samples required for Level 1 shall be from the very start of a different run that was directly preceded by assets being used to produce PFAS-containing products.

10 For GreenScreen Benchmark-U, filling data gaps with the "worst-case" hazard level must result in a GreenScreen Benchmark score that fulfills the certification level requirements.

6.4.7 Level 2 Total Fluorine Testing Requirements for each fabric and/or molded fiber:

6.4.7.1 Applicant collects an attestation from each fabric and/or molded fiber manufacturer that all manufacturing facilities that make the fabric or molded fiber have robust procedures in place to minimize contamination from production of PFAS-containing products to ensure every fabric or molded fiber meets the requirement of < 100 ppm total fluorine. These procedures at a minimum must include cleaning protocols for changeovers from production of PFAS-containing products to PFAS-free products, validation, sampling and testing protocols, and corrective actions. Contamination may result from shared equipment, shared recycling of process chemicals, or use of recycled raw materials.

6.4.7.2 During the duration of a valid certification, total fluorine testing of each fabric and/or each molded fiber is required on three samples per quarter (three-month period) from each manufacturing facility. Each of the samples shall be from the very start of a different run that was directly preceded by assets being used to produce PFAS-containing products. Analytical test results verifying the product contains < 100 ppm total fluorine shall be submitted to Clean Production Action once per year during annual renewal.

6.4.7.3 Throughout the duration of a valid certification, Clean Production Action shall be immediately informed if any fabric or molded fiber sample contains ≥ 100 ppm total fluorine.

7. CERTIFICATION AMENDMENTS

Sections 7.1 to 7.6 below describe exceptions (i.e., amendments) to the certification requirements in Sections 5 and 6 for a variety of material types. Products may be certified if the product meets each applicable amendment.

7.1 Minor Fasteners [Bronze, Bronze+, Silver, and Silver+ Levels of Certification]

7.1.1 Scope

This certification amendment applies to but is not limited to coated or uncoated commodity fasteners including screws, nuts, bolts, staples, nails, anchors, washers, buckles, clamps, clasps, cable ties, clips, clutches, pins, hooks, latches, pegs, retaining rings ball and roller bearings and sewing thread.[11]

The following types of materials are outside the scope of this amendment and must meet the Product Inventory and hazard screening requirements outlined in Section 5 and Section 6, respectively:

1. Gaskets, grommets, adhesives, adhesive tapes.
2. Any coating, finish or metal plating that is a) custom (e.g., made to order or exclusively produced for a single customer), or b) applied to the fastener during Applicant product manufacturing.
3. Any fastener that is a) custom (e.g., made to order or exclusively produced for a single customer), or b) manufactured during Applicant product manufacturing.

7.1.2 Amendment

The Chemical Inventory requirements in Section 5.2 are waived for all commodity fasteners up to a total of 5% by mass of the product. Applicants shall instead provide attestation of compliance with GreenScreen Certified certification requirements by using the "Commodity Fastener Supplier Declaration," which includes attestation for:

1. **Material Inventory.** See Section 5.1 for requirements;
2. **Restricted Substances.** The commodity fastener shall comply with the following material restrictions:[12]
   - Lead (Pb): < 1000 ppm
   - Mercury (Hg): < 1000 ppm
   - Cadmium (Cd): < 100 ppm
   - Hexavalent Chromium: (Cr VI) < 1000 ppm
   - Polybrominated Biphenyls (PBB): < 1000 ppm
   - Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm
   - Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
   - Benzyl butyl phthalate (BBP): < 1000 ppm

11 Brass keys shall be exempt from all certification requirements.

12 This list of chemicals is aligned with Annex II of EU Directive 2015/863, which amends Article 4 of the RoHS Directive (2011/65/EU).

- Dibutyl phthalate (DBP): < 1000 ppm
- Diisobutyl phthalate (DIBP): < 1000 ppm

3. **EU REACH SVHC Content**. EU REACH Substances of Very High Concern (SVHC) Content. The commodity fastener shall not contain any SVHCs at levels ≥ 0.1% by mass (1000 ppm), and shall be compliant with all relevant restrictions of Annex XVII. The date on which the list of SVHCs is referenced should be noted, and should be the most currently available list at the date the Commodity Fastener Supplier Declaration Form is signed.

7.1.3 Rationale

Commodity fasteners are often purchased from distributors, who may source the item from multiple vendors, therefore sourcing may shift frequently, and chemical composition information can be difficult to obtain. Complete Chemical Inventory information meeting the requirements of Section 5.2 is often very difficult to obtain for commodity fasteners. These amended certification requirements are intended to address the relevance to toxic chemicals that may be present in commodity fasteners, as well as the broad availability of this information in the supply chain. RoHS restricts several toxic metals and flame retardants that could be present in commodity fasteners. Due to demand from the electronics industry, a large volume of RoHS compliant fasteners is available on the market. Under REACH regulations, there is an obligation to alert the supply chain if an article contains over 0.1% by mass of a SVHC.

7.2 Undefined Post-Consumer Recycled Content [applies to all certification levels]

7.2.1 Scope

This certification amendment applies to undefined post-consumer recycled (PCR) content in homogeneous materials and does not apply to recycled metal or recycled glass. Due to variability in sourcing of this material type, it is difficult or impossible to obtain a comprehensive inventory of each chemical in the material including impurities above the specified thresholds (100 ppm or RSL threshold). Adherence to the GreenScreen Hazard Evaluation requirements cannot be determined without a Chemical Inventory for the recycled material in the product.

7.2.2 Bronze and Bronze+ Level Amendments

The Chemical Inventory requirements are waived for undefined post-consumer recycled content up to a total of 25% by mass of the product for the Bronze and Bronze+ levels. Applicants shall instead provide attestation of compliance with GreenScreen Certified certification requirements by using the "Undefined Recycled Content Supplier Declaration," which includes attestation for:

1. **Material Inventory.** See Section 5.1 for requirements, and
2. **Restricted Substances.** The material containing undefined post-consumer recycled content shall comply with the following material restrictions:[13]
   - Lead (Pb): < 1000 ppm
   - Mercury (Hg): < 1000 ppm
   - Cadmium (Cd): < 100 ppm

13 This list of chemicals is aligned with Annex II of EU Directive 2015/863, which amends Article 4 of the RoHS Directive (2011/65/EU).

- Hexavalent Chromium: (Cr VI) < 1000 ppm
- Polybrominated Biphenyls (PBB): < 1000 ppm
- Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm
- Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
- Benzyl butyl phthalate (BBP): < 1000 ppm
- Dibutyl phthalate (DBP): < 1000 ppm
- Diisobutyl phthalate (DIBP): < 1000 ppm

7.2.3 Silver, Silver+, Gold, or Gold+ Level Amendments

1. Applicants shall meet the Bronze or Bronze+ level amendment in Section 7.2.2 above; and
2. **Analytical Testing.** Each material that contains undefined post- consumer recycled content shall meet the analytical testing requirements outlined in Table 5 below. The frequency of testing must be sufficient to capture potential variability in different batches of materials. The Applicant shall submit a test report.

TABLE 5: **Silver, Silver+, Gold or Gold+ Level Analytical Requirements for Undefined Recycled Content**

Tested Substances	Material Threshold (PPM)	Test Method(s)
Lead (Pb)	≥ 0.1% by mass (1000 ppm)	• X-Ray Fluorescence Spectroscopy (XRF), as per ASTM F2617, • Fourier Transform Infra-red Spectroscopy (FTIR), or • Scanning Electron Microscope (SEM) testing.[14]
Mercury (Hg)	≥ 0.1% by mass (1000 ppm)	
Cadmium (Cd)	≥ 0.01% by mass (100 ppm)	
Hexavalent Chromium (Cr VI)	≥ 0.1% by mass (1000 ppm)	
Polybrominated Biphenyls (PBB)	≥ 0.1% by mass (1000 ppm)	
Polybrominated Diphenyl Ethers (PBDE)	≥ 0.1% by mass (1000 ppm)	
Hexabromocylcododecane (HBCD)	≥ 0.1% by mass (1000 ppm)	Gas chromatography (GC) or high-performance liquid chromatography (HPLC) with mass spectroscopy.[15]
Bis(2-Ethylhexyl) phthalate (DEHP)	≥ 0.1% by mass (1000 ppm)	Gas chromatography coupled with mass spectrometry (GC/MS) or coupled with flame ionization detection (GC/FID).[16]
Benzyl butyl phthalate (BBP)	≥ 0.1% by mass (1000 ppm)	
Dibutyl phthalate (DBP)	≥ 0.1% by mass (1000 ppm)	
Diisobutyl phthalate (DIBP)	≥ 0.1% by mass (1000 ppm)	

14 Source for test methods as per RoHS Directive are summarized here: https://www.rohsguide.com/rohs-testing.htm. Other analytical methods can be considered on a case by case basis if the method employs good laboratory practices by an accredited lab with adequate detection limits.

15 Source for test method as per Law et. al., "Hexabromocyclododecane Challenges Scientists and Regulators," Environmental Science and Technology, 2005.

16 Source for test methods as per RoHS Directive are summarized here: https://www.rohsguide.com/rohs-testing.htm. Other analytical methods can be considered on a case by case basis if the method employs good laboratory practices by an accredited lab with adequate detection limits.

7.3 Electronic Components [applies to all certification levels]

7.3.1 Scope

This Product Inventory amendment applies to electronic components.

7.3.2 Amendments

The Chemical Inventory requirements in Section 5.2 are waived for all electronic components in the product. Applicants shall instead provide attestation of compliance with the GreenScreen Certified certification requirements by using the "Electronic Component Supplier Declaration," which includes attestation for:

1. **Material Inventory.** To the extent practical for electronic components, follow the Material Inventory requirements outlined in Section 5.1 for external cases, housings, and other identifiable elements; and
2. **RSL Conformance.** The electronic component shall comply with the following sections of the GreenScreen Certified Restricted Substances List applicable to electronics:
    1) A4.1 EU RoHS Directive (Electronics),
    2) A4.3 Polyvinyl Chloride (PVC), and
    3) A4.4 Halogenated Flame Retardants.

7.3.3 Rationale

Electronic components are complex parts containing many materials and chemicals that are challenging to track down from often complicated supply chains. Therefore, a Chemical Inventory is difficult to obtain. Where a full Chemical Inventory and a GreenScreen List Translator or GreenScreen assessment may be difficult or impossible to achieve for electronic components, these amended certification requirements are intended to address the relevance to toxic chemicals that may be present as well as the broad availability of this information in the supply chain. RoHS restricts many toxic metals and flame retardants that could be present in electronic components, so due to demand from the electronics industry, a large volume of RoHS compliant electronics is available on the market.

7.4 Metal Parts [applies to all certification levels]

7.4.1 Scope

This RSL amendment applies to specific alloy elements in product parts made of metal alloys. Minor fasteners made of metal are covered in Section 7.1 and not covered by this RSL amendment.

The metals listed below are present on the Silver-Gold Restricted Substances List or have been assessed and have been assigned a score of Benchmark-1 in the elemental form:

- Aluminum (Al)
- Antimony (Sb)
- Beryllium (Be)
- Cobalt (Co)
- Nickel (Ni)
- Silver (Ag)
- Vanadium (V)

7.4.2 Amendment

Al, Sb, Be, Co, Ni, Ag, and V metals are allowed in certified products for the Silver level of certification when the metals are a part of the alloy crystallites in a true alloy such as steel. In a true alloy, substances present in the alloy are integral parts of the alloy (i.e., part of the alloy crystallites as opposed to being present between the crystallites).

7.5 Specified Chemicals with Form-Specific Hazards [applies to all certification levels]

7.5.1 Scope

The form-specific hazard amendment applies to the substances listed in Table 6, where the hazard is specific to unbound particles of respirable size (<10 micrometers). The toxicity of chemicals with form-specific hazards is defined as adverse effects limited to the respiratory tract, characterized as the nasal and oral cavities, pharynx, larynx, trachea, bronchi, and lungs, following inhalation exposure.[17]

TABLE 6: **Substances with Known Form-Specific Hazards**

Chemical Name	CASRN
Carbon Black	1333-86-4
Titanium dioxide	13463-67-7
Quartz	14808-60-7
Cristobalite	14464-46-1
Tridymite	15468-32-3
Tripoli	1317-95-9

7.5.2 Amendment

Chemicals in Table 6 are restricted in certified products that are ≥ 0.01% by mass (100 ppm) of the material and are airborne, unbound particles of respirable size (i.e., < 10 micrometers in diameter).

This RSL amendment allows the use of the chemicals in Table 6 in certified products provided the following requirements are met:

7.5.2.1 For materials sold in powder form, a certificate of analysis from a qualified laboratory must be submitted and show the material's particle size distribution is >10 micrometers.[18]

7.5.2.2 For materials sold as liquids or non-powder solids (e.g., paints, joint compounds, abrasives, and fillers) the chemicals in Table 6 are acceptable for use in certified products provided that the substance does not volatilize, leach, emit, or abrade from the liquid or bulk material in the particle size and physical form of concern in normal use for the lifetime of the product.

7.5.2.3 All certified products that meet the amendment requirements shall bear the following warning statement:

"This product contains a form-specific hazard. The hazard is related to particulate inhalation, which is expected to occur only during manufacture or activities that result in destruction such as cutting, tearing, smashing, and disposal."

17 Adapted from Health Product Declaration Collaborative Best Practices for Special Conditions for form-specific hazards, accessed 3/19/20.

18 This requirement can be demonstrated in a sieving assessment report or certification of analysis or technical data sheet presenting the sieving distribution for the product. The particle size distribution (D0.01, D10, D50, D90) must be reported. This measure refers to the diameter sizes for which 0.01%, 10%, 50%, and 90% of particles, respectively, have diameters less than 10 micrometers. The D0.01 must be less than 10 micrometers for products or materials sold in powdered form to qualify for certification (i.e., 0.01% of the particulates have diameters less than 10 micrometers).

8. ADDITIONAL REQUIRED CRITERIA

The following criteria must be met for certified products for all levels of certification.

8.1 Waste and Recyclability Criteria

To achieve certification at any level, each finished product or its packaging must meet two (2) of the following eight (8) Waste and Recyclability Criteria. The Waste and Recyclability Form is used to document detailed information to enable verification of all claims.

8.1.1 DOES NOT CREATE A HAZARDOUS WASTE—When used for its intended purpose, the product is not regulated as a state or federal hazardous waste (i.e., does not become or generate a hazardous waste product according to state or federal hazardous waste rules):

1. The California Department of Toxic Substances Control's (DTSC) hazardous waste regulations (California Code of Regulations (CCR) Title 22, Division 4.5), or
2. Resource Conservation and Recovery Act (RCRA) regulations (Code of Federal Regulations (CFR) Title 40, parts 239 through 282).

8.1.2 10% OR MORE POST-CONSUMER RECYCLED CONTENT—Product contains more than 10% post-consumer recycled content, excluding steel.

8.1.3 RECYCLABILITY—Product is recyclable (See definition in Terms & Definitions).

8.1.4 10% OR MORE POST-CONSUMER RECYCLED CONTENT—Primary Packaging contains more than 10% post-consumer recycled content.

8.1.5 30% OR MORE POST-CONSUMER RECYCLED CONTENT—Secondary Packaging contains more than 30% post-consumer recycled content.

8.1.6 FOREST STEWARDSHIP COUNCIL—Packaging is currently certified under one of the following Forest Stewardship Council (FSC) Certifications:

1. 100%—From well-managed forests,
2. Mix—From responsible sources, or
3. Recycled—Made from recycled material.

8.1.7 CONSUMER-FRIENDLY RECYCLING LABELS—Packaging label meets US Federal Trade Commission Green Guides specifications in PART 260—GUIDES FOR THE USE OF ENVIRONMENTAL MARKETING CLAIMS, § 260.12 Recyclable Claims. An example of a consumer-friendly label is the How2Recycle Label®.

8.1.8 RECYCLABILITY—Packaging is recyclable (both primary and secondary packaging).

9. DOCUMENTATION REQUIREMENTS

Clean Production Action performs a certification review of the following required documents against the certification requirements. All documentation is submitted by the Applicant.

1. Product Inventory
2. Safety Data Sheets (SDSs)
3. Signed attestation forms, as applicable:[19]
    a) Product-level RSL Applicant Disclosure
    b) Bronze RSL Supplier Declaration
    c) Silver-Gold RSL Supplier Declaration
    d) Product-Level PFAS in Manufacturing Declaration
    e) Commodity Fastener Supplier Declaration
    f) Metal Parts Supplier Declaration
    g) Undefined Post-Consumer Recycled Content Supplier Declaration
    h) Electronic Components Supplier Declaration
4. GreenScreen List Translator scores[20]
5. GreenScreen assessments and Benchmark scores (Gold and Gold+ only)
6. Results from analytical testing, if applicable, including a signed attestation for each product (3d above).
7. Form-specific warning labels, if applicable
8. Waste and Recyclability Form

10. CERTIFICATION AND LICENSING

The Applicant must submit all required documentation as applicable to the certification level to Clean Production Action and sign a license agreement with Clean Production Action in order to be awarded certification. A license agreement is required to use the GreenScreen Certified Certification Mark on products and marketing materials.

A certificate for a certified product (or products) is issued by Clean Production Action after the certification review is complete and a License Agreement is executed.

Note: Applicants that have undergone an evaluation but do not meet the certification requirements for Bronze or Bronze+, may still receive a certificate indicating “GSC-Reviewed.” No license agreement is executed with this type of certificate.

19 The forms must be signed by the CEO or a senior manager with decision-making authority at the organization.

20 GreenScreen List Translator scores are generated by a GreenScreen Reviewer or Clean Production Action.

11. CERTIFICATION, LABELING, AND DURATION

11.1 Disclaimer of Liability

Clean Production Action, as the developer of this standard, shall not incur any obligations or liability for any loss or damages, including, without limitation, indirect, consequential, special, or incidental damages, arising out of or in connection with the interpretation or adoption of, reliance upon, or any other use of this standard by any party. Clean Production Action makes no express or implied warranty of merchantability or fitness for a particular purpose, nor any other express or implied warranty with respect to this standard.

11.2 Certification Mark

The appropriate GreenScreen Certified Mark may appear on the product, packaging, secondary documents, and promotional materials, only in conjunction with the certified product, and only the core design Mark or the design Mark with the corresponding level which the product has achieved may be used in conjunction with that certified product. All of the Applicant's use of the GreenScreen Certified Mark(s) shall be in accordance with the terms of the executed license agreement. No sub-licensing of the Mark(s) is allowed.

The GreenScreen Certified Mark shall not be used in conjunction with any modifying terms, phrases, or graphic images that might mislead customers as to the extent or nature of the certification. Clean Production Action must review all uses of the GreenScreen Certified Mark prior to printing or publishing.

11.3 Use with Other Claims

The GreenScreen Certified Mark shall not appear in conjunction with any human health or environmental claims, unless verified and approved in writing by Clean Production Action.

11.4 Duration of Certification

Certificates for Version 1 of this standard are valid through August 31, 2027 and require annual renewal. Any changes to the product's chemical or material composition must be reported to Clean Production Action and may invalidate the certificate.

After the first year of the certificate, and each subsequent year during the valid duration, the licensee must renew the certificate by: 1) paying an annual renewal fee; 2) reporting any product changes; and 3) signing a statement by the CEO or a senior manager that no changes have been made to the product's chemical composition.

Clean Production Action reserves the right to perform product testing on a certified product at any time. Results of the product testing could invalidate the certificate.

ANNEX 1 – CERTIFICATION PROCESS STEPS WITH CPA

1. Applicant registers on the GreenScreen Certified website.
2. Applicant contacts Clean Production Action to begin the certification process.
3. Clean Production Action determines whether product(s) are within scope.
4. Clean Production Action sends the following Application materials:
    a) Non-disclosure agreement (NDA); and
    b) Application Form.
5. Applicant signs NDA and completes Application Form. Applicant sends signed NDA and signed Application Form to Clean Production Action.
6. Clean Production Action countersigns NDA and sends executed NDA to Applicant.
7. Clean Production Action sends Applicant an invoice.
8. Applicant pays the invoice.
9. Clean Production Action sends Applicant the following materials:
    a) Product Inventory Form;[21] and
    b) Instructions for analytical testing.
10. Applicant submits the completed Product Inventory Form, Safety Data Sheets, and GreenScreen assessment reports (for Gold and Gold+ only) for all inputs including mixtures and polymers purchased from suppliers, and analytical testing results.
11. Clean Production Action performs product and certification reviews. Clean Production Action requests additional information from Applicant as needed.
12. Clean Production Action informs Applicant of the results of the product and certification reviews.
13. Applicant informs Clean Production Action whether they will proceed with either:
    a) A License Agreement for products that meet the certification requirements; or
    b) A GSC-Reviewed certificate for products that meet the GSC-Reviewed requirements but do not meet the certification requirements. See Annex 3 for GSC-Reviewed requirements.
14. Clean Production Action sends Applicant a License Agreement.
15. Applicant signs and returns the License Agreement.
16. Clean Production Action countersigns the License Agreement and sends an executed copy to the Applicant.
17. Clean Production Action lists certified product(s) on the Clean Production Action website and sends Applicant certificate(s) for certified product(s).

21 A Health Product Declaration (HPD) could also be used for meeting the Product Inventory requirements described in Section 5. The HPD Builder can be used as a tool for creating the HPD to be consistent with the HPD Open Standard.

ANNEX 2 – CERTIFICATION PROCESS STEPS WITH GREENSCREEN CERTIFIED REVIEWER

A2.1 Product Review Process using a GreenScreen Certified Reviewer

1. Applicant registers on the GreenScreen Certified website.
2. Applicant contacts Clean Production Action-approved GreenScreen Certified Reviewer to begin the product review process (Access Reviewer list).
3. GreenScreen Certified Reviewer confirms with Clean Production Action that Applicant is registered for GreenScreen Certified and determines whether product(s) are within scope.
4. Applicant hires GreenScreen Certified Reviewer to complete the product review.
5. GreenScreen Certified Reviewer informs Applicant of the results of the product review and provides Applicant a completed Product Review Report.

A2.2 Certification Process with CPA

1. Applicant submits completed Product Review Report to Clean Production Action to initiate certification review and licensing services.
2. Clean Production Action sends Applicant an invoice.
3. Applicant pays the invoice.
4. Clean Production Action performs certification review. Clean Production Action requests additional information from Applicant or GreenScreen Certified Reviewer, as needed.
5. Clean Production Action informs Applicant of the results.
6. Applicant informs Clean Production Action whether they will proceed with either:
   a. A License Agreement for products that meet the certification requirements; or
   b. A GSC-Reviewed certificate for products that meet the GSC-Reviewed requirements but do not meet the certification requirments. (See Annex 3 for GSC-Reviewed requirements).
7. Clean Production Action sends Applicant a License Agreement.
8. Applicant signs and returns the License Agreement.
9. Clean Production Action countersigns the License Agreement and sends an executed copy to the Applicant.
10. Clean Production Action lists certified product(s) on the Clean Production Action website and sends Applicant certificate(s) for certified product(s).

ANNEX 3 – REQUIREMENTS FOR A GSC-REVIEWED CERTIFICATE

A3.1 Products that have been reviewed through the GreenScreen Certified process for the Bronze or Bronze+ level of certification but do not meet all of the certification criteria may be eligible to receive a GSC-Reviewed certificate.

A3.2 The Applicant must submit the following required information to Clean Production Action:

A3.2.1 A complete Material Inventory for the product.

A3.2.2 A list with the chemical name and CASRN for each chemical in the product that does not meet RSL requirements.

A.3.2.3 A completed supplier attestation for each material in the product indicating the chemical present for any requirement that is not met.

A3.3 Clean Production Action will provide Applicant with a certificate stating that the product has been reviewed and reporting on the requirements that were not met.

ANNEX 4 – GREENSCREEN CERTIFIED MEDICAL SUPPLIES & DEVICES RESTRICTED SUBSTANCES LIST (RSL)

Sections A4.1 through A4.12 of this Annex apply to all Certification Levels: Bronze, Bronze+, Silver, Silver+, Gold, and Gold+. Sections A4.13 through A4.19 apply to Silver, Silver+, Gold, and Gold+.

A4.1 EU RoHS Directive (Electronics)

[Go Back to RSL Summary Table]

A4.1.1 Each electrical and/or electronic part in the product must be compliant with EU Directive 2011/65/EU and EU Directive 2015/863.[22] This means each homogeneous material in each electrical and/or electronic part shall be compliant with all maximum concentration values excluding all exemptions.

A4.1.2 The restricted substances and their maximum concentration values are included in Table A1 below for reference only.[23] Attestation is made in reference to the most recent version of the Directive and excludes all exemptions.

TABLE A1: **RSL Reference List for EU RoHS Directive Chemicals (Electronics)**

Restricted Substance	RoHS Maximum Concentration Value (Weight % of Homogeneous Material)
Cadmium (Cd)	100 ppm (0.01%)
Lead (Pb)	1000 ppm (0.1%)
Mercury (Hg)	1000 ppm (0.1%)
Hexavalent Chromium (Cr VI)	1000 ppm (0.1%)
Bis(2-Ethylhexyl) phthalate (DEHP)	1000 ppm (0.1%)
Benzyl butyl phthalate (BBP)	1000 ppm (0.1%)
Dibutyl phthalate (DBP)	1000 ppm (0.1%)
Diisobutyl phthalate (DIBP)	1000 ppm (0.1%)
Polybrominated Biphenyls (PBB)	1000 ppm (0.1%)
Polybrominated Diphenyl Ethers (PBDE)	1000 ppm (0.1%)

22 EU Directive 2015/863 is an amendment to RoHS Directive (2011/65/EU); however, the requirements of both shall apply.

23 Access the regulatory list in Annex II of EU Directive 2015/863, which amends Article 4 of the RoHS Directive (2011/65/EU).

A4.2 Bisphenols (Bronze list)

[Go Back to RSL Summary Table]

A4.2.1 Homogeneous materials in the certified products shall not contain any chemical (intentionally added, impurity or residual) ≥ 0.1% by mass (1000 ppm) of the material that is listed in Table A2.

TABLE A2: **RSL Reference List for Bisphenols (Bronze list)**

Chemical Name	CASRN
Bisphenol G	127-54-8
Bisphenol TMC	129188-99-4
Bisphenol M	13595-25-0
Bisphenol AF	1478-61-1
Bisphenol C2	14868-03-2
Bisphenol AP	1571-75-1
Bisphenol E (BPE)	2081-08-5
Bisphenol P	2167-51-3
Bisphenol PH	24038-68-4
4-cumylphenol (HPP)	599-64-4
Bisphenol F (BPF)	620-92-8
Bisphenol B (BPB)	77-40-7
Bisphenol A (BPA)	80-05-7
Bisphenol C	79-97-0
Bisphenol S (BPS)	80-09-1
Bisphenol Z	843-55-0

A4.3 Polyvinyl Chloride (PVC)

[Go Back to RSL Summary Table]

A4.3.1 Certified products (electronic and non-electronic) shall not contain PVC (CASRN 9002-86-2) ≥ 0.1% by mass (1000 ppm) of the product.

A4.4 Halogenated Flame Retardants

[Go Back to RSL Summary Table]

A4.4.1 Homogeneous materials in certified products (electronic and non-electronic) shall not contain any halogenated flame retardant chemical (intentionally added, impurity or residual) as defined below, which is ≥ 0.1% by mass (1000 ppm) of the material.

For Electronic products, this criterion applies only to product housing as defined by TCO (i.e., the external enclosure or casing that protects the internal parts of a product. This includes a product stand and external power supplies.)

- **Organohalogen:** A chemical containing one or more halogen atoms (typically chlorine, bromine, fluorine, or iodine) bound to a carbon atom.
- **Flame retardant:** "Any chemical or chemical compound for which a functional use is to resist or inhibit the spread of fire." (Excerpt from California Senate Bill 1019; https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201320140SB1019, accessed 5/16/22)

A4.5 Ortho-Phthalates (Bronze List)

[Go Back to RSL Summary Table]

A4.5.1 Homogeneous materials in the certified products shall not contain any chemical (intentionally added, impurity or residual) ≥ 0.1% by mass (1000 ppm) of the material that is listed in Table A3.

TABLE A3: **RSL Reference List for Ortho-Phthalates (Bronze List)**

Chemical Name	CASRN
Di(2-ethylhexyl)phthalate (DEHP) (primary CASRN)	117-81-7
Di-n-pentyl phthalate (DNPP)	131-18-0
Di-isodecyl phthalate (DIDP)	26761-40-0
Diisononyl phthalate (DINP-2 or DINP-3, mixture of isomers as manufactured)	28553-12-0
Diisononyl phthalate (DINP) (synonym)	68515-48-0 (synonym 28553-12-0)
Di-isodecyl phthalate (DIDP) (synonym)	68515-49-1 (synonym 26761-40-0)
Di-cyclohexyl phthalate (DCHP)	84-61-7
Di-isobutyl phthalate (DIBP)	84-69-5
Dibutylphthalate (DBP)	84-74-2
Di-n-hexyl phthalate (DnHP)	84-75-3
Benzylbutylphthalate (BBP)	85-68-7

A4.6 California Proposition 65 Chemicals

[Go Back to RSL Summary Table]

A4.6.1 The Applicant shall attest that the product does not contain chemicals listed by the State of California to cause cancer, birth defects, or reproductive harm that require a warning or are prohibited from release to the environment under the California Safe Drinking Water and Toxic Enforcement Act of 1986.

Additional Prop 65 Guidance:

See https://www.p65warnings.ca.gov for official regulatory guidance in order to meet the requirements above. The following is adapted from the "For Businesses" section of the website, accessed 5/29/22:

> To guide businesses in determining whether a warning is necessary or whether discharges of a chemical into drinking water sources are prohibited, the Office of Environmental Health Hazard Assessment (OEHHA) has developed safe harbour levels for many chemicals on the CA Prop 65 List.[24] A safe harbour level identifies a level of exposure to a listed chemical. If the chemical is below the safe harbour limit in the material, it does not require a Proposition 65 warning.
>
> If OEHHA has not established a safe harbor level for a chemical, businesses that expose individuals to that chemical would be required to provide a Proposition 65 warning, unless the business can show that the anticipated exposure level will not pose a significant risk of cancer or reproductive harm.[25] OEHHA has adopted regulations that provide guidance for businesses in calculating their own level in the absence of an OEHHA safe harbor level. Regulations are available at Article 7 (No Significant Risk levels for cancer) and Article 8 (No Observable Effect Levels for Repro/Developmental) of Title 27, California Code of Regulations.

A4.7 Antimicrobials (Surface Pathogens)

[Go Back to RSL Summary Table]

A4.7.1 All antimicrobials used for surface pathogens are prohibited in certified products. The following amendment defines the very limited and specific conditions an antimicrobial used for surface pathogens must meet to be used in a certified product.

A4.7.2 Use of antimicrobials for surface pathogens is only allowed in a certified product if the manufacturer can provide a current US EPA registration as a public health antimicrobial pesticide product for the use pattern proposed with the full data required by 40 CFR Part 158 submitted to EPA. [Note: conditional registration without a full data set is not acceptable]. If claims against any specific public health microorganism are made, the registration must also include efficacy testing to reduce hospital acquired infections for each such microorganism.

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24 The CA Prop 65 list of chemicals is available at: https://www.p65warnings.ca.gov/chemicals, accessed 5/2922.

25 The CA Prop 65 Frequently Asked Questions for Businesses is available at: https://www.p65warnings.ca.gov/frequently-asked-questions-businesses, accessed 5/29/22.

A4.8 Antimicrobials (Preservatives)

[Go Back to RSL Summary Table]

A4.8.1 Certified products shall not contain any of the following chemicals in Table A4 > 0% (0 ppm) in the product for the purpose(s) of preserving the product.

A4.8.2 If one or more of the chemicals listed in Table A4 are present for the purpose of reducing surface pathogens, either the criteria in the Bronze RSL Summary Table (Table 3) or the criteria in Section A4.7 applies.

TABLE A4: **RSL Reference List for Antimicrobials (Preservatives)**

Chemical Name	CASRN
Didecyl Dimethyl Ammonium Chloride (DDAC)	7173-51-5
Diiodomethyl p-tolyl sulfone	20018-09-1
Free of Hexamethylenetetramine	100-97-0
Kathon 886 (CIT/MIT mixture)	55965-84-9
Methylchloroisothiazolinone (CIT, CMIT)	26172-55-4
Methylisothiazolinone (MIT)	2682-20-4
N-octadecyldimethyl ammonium chloride	1613-17-8
Silver (nano)	7440-22-4
Silver sodium hydrogen zirconium phosphate	265647-11-8
Silver zinc zeolites	130328-20-0
Triclocarban	101-20-2
Triclosan	3380-34-5
Zinc Pyrithione	13463-41-7
Benzisothiazolin 3-one (BIT)	2634-33-5

A4.9 Persistent, Bioaccumulative, and Toxic chemicals (PBTs)

[Go Back to RSL Summary Table]

A4.9.1 Homogenous materials in certified products shall not contain Persistent, Bioaccumulative, and Toxic chemicals (PBTs) (intentionally added, impurity or residual) ≥ 0.1% by mass (1000 ppm) of the material, including chemicals on any of the following lists:

1. US EPA—Priority PBTs and US EPA—Priority PBTs (NWMP)
2. OSPAR—Priority PBTs & EDs & equivalent concern
3. UNEP Stockholm Convention—Persistent Organic Pollutants
4. US EPA—Toxics Release Inventory PBTs

A4.10 Non-Halogenated Flame Retardants

[Go Back to RSL Summary Table]

A4.10.1 Homogeneous materials in non-electronic components in the certified product shall not contain any non-halogenated flame retardant chemical (intentionally added, impurity or residual) ≥ 0.1% by mass (1000 ppm) of the material as defined below:

Any chemical or chemical compound for which a functional use is to resist or inhibit the spread of fire, including but not limited to phosphorous-based and nitrogen-based chemicals.

A4.11 Metals and their Compounds (Non-Electronic): Cadmium, Lead, Mercury, Organotin

[Go Back to RSL Summary Table]

A4.11.1 Homogeneous materials in certified products shall not contain mercury, lead, cadmium, or organotin compounds (intentionally added, impurity or residual) in the following amounts:

1. Lead and lead-containing compounds ≥ 0.004% by mass (40 ppm),
2. Mercury and mercury-containing compounds ≥ 0.01% by mass (100 ppm),
3. Cadmium and cadmium-containing compounds ≥ 0.01% by mass (100 ppm), and
4. Organotin compounds [e.g., tributyltin (TBT), dibutyltin (DBT)] ≥ 0.01% by mass (100 ppm).

A4.12 Per- and Polyfluoroalkyl Substances (PFAS)

[Go Back to RSL Summary Table]

A certified product shall not contain any PFAS chemical that meets the definition in A4.12.1 and/or is included on the reference list specified in A4.12.2 below that is:

1. Intentionally added ≥ 0.01% by mass (100 ppm) in each homogeneous material, or
2. An impurity ≥ 0.01% by mass (100 ppm) in each homogeneous material.

A4.12.1 PFAS Definition: see Terms and Definitions for "PFAS."

A4.12.2 PFAS Reference List: The Comprehensive Global Database of PFAS by the Organisation for Economic Cooperation and Development (OECD) available here: http://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals, accessed 5/16/22.

A4.13 Bisphenols (Silver-Gold)

[Go Back to RSL Summary Table]

A4.13.1 Homogeneous materials in the certified products shall not contain BPA or one or more Bisphenols (intentionally added, impurity or residual) ≥ 0.01% by mass (100 ppm) of the material as defined below:

Structural analogs to be avoided include any compound with the following characteristics:

1. All compounds with a Tanimoto Coefficient of 0.9-1.0 (compared to Bisphenol-A CASRN 80-05-7) are restricted. [Note: Tanimoto Coefficient as calculated using EPA's CompTox Dashboard].
2. Any compound with a Tanimoto Coefficient of 0.8-0.9 is restricted until there are publicly available, valid in vitro or in vivo hazard data that enable evaluation of estrogen and androgen receptor agonism and antagonism. If a compound does not have significant endocrine disrupting potential, it is not included.
3. Chemicals with a Tanimoto Coefficient <0.8 shall be considered restricted if the compound:
   a) Has demonstrated endocrine disrupting potential (estrogen and/or androgen receptor agonism and/or antagonism) and is used as a functional substitute for BPA, or
   b) Is detected in environmental media or human biomonitoring studies and it is used as a functional substitute for BPA and publicly available hazard data to evaluate endocrine disrupting potential (estrogen and/or androgen receptor agonism and/or antagonism) are lacking.

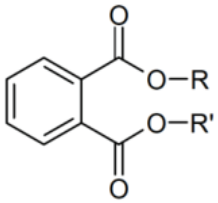
Note: If the compound is detected in environmental media or human biomonitoring studies and it is used as a functional substitute for BPA, but has sufficient publicly available hazard data to demonstrate that it does not have endocrine disrupting potential (estrogen and/or androgen receptor agonism and/or antagonism), it is not restricted.

A4.14 Ortho-phthalates (Silver-Gold)

[Go Back to RSL Summary Table]

A4.14.1 Homogeneous materials in the certified products shall not contain any ortho-phthalates (intentionally added, impurity or residual) ≥ 0.01% by mass (100 ppm) of the material as defined below:

Dialkyl ortho-phthalates (or phthalate esters) are defined by the chemical structure below, and contain alkyl side groups, meaning the side groups contain only carbon and hydrogen.



(R, R' groups can be linear, branched, or linear/branched or cyclic ring)

A4.15 Alkylphenols and Alkylphenol Ethoxylates

[Go Back to RSL Summary Table]

A4.15.1 Homogeneous materials in the certified products shall not contain any chemical (intentionally added, impurity or residual) meeting the definition of alkylphenol or alkylphenol ethoxylate below or contain one or more alkyl chains with a carbon chain length of six carbons or more present ≥ 0.01% by mass (100 ppm) of the material.

- Alkylphenols (AP): Chemical compounds that consist of one or more alkyl chains bound to a phenol. Phenol consists of an aromatic ring and a hydroxyl group. An alkyl chain is an acyclic saturated hydrocarbon (consisting of hydrogen and carbon atoms arranged in a tree structure in which all carbon-carbon bonds are single) with the general formula CnH2n+1.
- Alkylphenol Ethoxylates (APEs): Derivatives of alkylphenols prepared by a chemical reaction between ethylene oxide and an alkylphenol, resulting in an ethoxylated chain with the general formula -(OC2H4)nOH replacing the hydroxyl group.

A4.16 Cyclic Volatile Methyl Siloxanes (cVMS)

[Go Back to RSL Summary Table]

A4.16.1 Homogeneous materials in the certified products shall not contain any chemical (intentionally added, impurity or residual) that is listed in Table A5 ≥ 0.01% by mass (100 ppm) of the material.

TABLE A5: **RSL Reference List for Cyclic Volatile Methyl Siloxanes (VMSs)**

Chemical Name	CASRN
Dodecamethylcyclohexasiloxane (D6)	540-97-6
Decamethylcyclopentasiloxane (D5)	541-02-6
Octamethylcyclotetrasiloxane (D4)	556-67-2
Mixtures containing one or more of D4, D5, D6	Mixture

A4.17 ZDHC Manufacturing Restricted Substances List (MRSL)

[Go Back to RSL Summary Table]

A4.17.1 Homogeneous materials in the certified products shall not contain any chemical that is listed on the ZDHC Manufacturing Restricted Substances List version 2.0 (MRSL) at or above the thresholds specified in the MRSL.

A4.18 Organohalogens

[Go Back to RSL Summary Table]

A4.18.1 Homogeneous materials in the certified products shall not contain any organohalogens (intentionally added, impurity or residual) ≥ 0.01% by mass (100 ppm) of the material as defined below.

Organohalogen: A chemical containing one or more halogen atoms (typically chlorine, bromine, fluorine, or iodine) bound to a carbon atom.

A4.19 Green List Translator LT-1

[Go Back to RSL Summary Table]

A4.19.1 Homogeneous materials in the certified products shall not contain any chemicals (intentionally added, impurity or residual) that have a GreenScreen List Translator score of LT-1 ≥ 0.01% by mass (100 ppm) of the material.

Standard for Medical Supplies & Devices

The GreenScreen Certified™ Standard for Medical Supplies & Devices is for evaluation of medical supplies and devices. This standard provides the means for manufacturers to communicate their use of safer chemicals per the GreenScreen® hazard assessment tools. GreenScreen Certified ensures value, usability, and relevance for industry professionals wanting to excel in offering products made with preferred chemicals for people and the planet.

Clean Production Action

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