Sustainable Glove criteria

Sustainable procurement attributes for examination and surgical gloves in health care.

December 2023

This document provides guidance for manufacturers wishing to meet Health Care Without Harm's examination and surgical glove criteria. The criteria apply to examination and surgical gloves used within healthcare. The criteria do not apply to gloves used for other purposes.

Guidance for manufacturers

This chart summarizes the required criteria. Criteria details and a rationale for their inclusion are included below the chart.

Required Chemical Criteria		
	Chemical of Concern	Criteria
1	Accelerants (thiurams, dithiocarbamates or thiazoles)	A list of accelerants and other allergens contained in the product (such as thiurams, dithiocarbamates, or thiazoles) has been compiled and is available. *For surgical gloves only: The product does not include the accelerant diphenyl guanidine (DPG) (CAS 102-06-7)
2	Antimicrobial/Biocidal	Product is not treated with or does not intentionally contain biocidal chemicals.
3	Bisphenol A (BPA) and Analogs	Product does not contain added bisphenol A (CAS No. 80-05-7) or any BPA structural analogs in amounts over 0.01% by weight (100 mg/kg).
4	Chlorinated Paraffins	Product does not contain chlorinated paraffins in concentrations above 0.1% by weight.
5	Dyes and Pigments	Product does not contain dyes in concentrations above 0.1% by weight.
6	Fluorinated substances	Product does not contain per- or polyfluorinated substances in concentrations above 0.1% by weight.
7	Phthalates (esters of orthophthalic acid)	Product does not contain phthalates, esters of orthophthalic acid, at concentrations above 50 ppm (50 mg/kg) per substance, including di (2-ethylhexyl) phthalate) (DEHP).
8	Polyvinyl Chloride	Product does not contain polyvinyl chloride.
9	Powder Residues	Product is free of powder residue.
10	Skin Moisturizers/Skincare Additives	Product is not treated with or does not contain substances intended to moisturize or soften the hands (skincare additives).
11	Sterilization Method	If the product is sterilized, radiation methods are used.
12	Substances of High Concern	Product is free of Substances of High Concern in concentration above 0.1% by weight (1,000 mg/kg per substance).
	Product Performance	Criteria
13	Disposability	Disposable medical gloves are tested according to: a) EN ISO 10993-5 (biological evaluation of medical devices, part 5: in vitro cytotoxicity testing), b) EN ISO 10993-10

		(Biological evaluation of medical devices, Part 10: Test for irritation and skin sensitization) or equivalent standard.
14	Weight of Product	Average weight per unit (g/unit) for medium-sized products, and the permitted error range, is known.
	Product Packaging	Criteria
15	Materials	Packaging does not contain plastics.
16	Materials	Packaging does not contain materials for which recycling schemes are unlikely to be established.
17	Minimization	Packaging is reduced to the greatest extent possible.
18	Recyclability	Packaging is selected based on ease of recycling.
19	Additives	Packaging does not contain additives that impede recycling.
20	Materials	Secondary and tertiary packaging is made of recycled material and Forest Stewardship Council (FSC) or equivalent for paper products.
21	Utilization	Product waste reduction is achieved through optimal packaging design (i.e. preventing multiple gloves being dispensed at once.)
	Supplier Requirements	Criteria
22	Anti- corruption	An anti-corruption policy including for contractors and subcontractors must be in place and be provided.
23	Forced Labor Audits	The Code of Conduct/modern slavery audits for any factories producing products must be provided.
24	Forced Labor Policy	Management teams must be regularly informed of forced or compulsory labor/modern slavery risks and involved in related decision-making.
25	Forced Labor Policy	A forced labor/modern slavery policy or code of conduct is in place and must be provided. It is required that these standards be implemented within the supply chain, inline with the company's policy/code of conduct.
26	Labor Force Statistics	Percentage of migrant workers at all sites must be reported. Factories with more than 10% migrant workers must have policies in place to ensure that migrant workers are protected, that there are zero recruitment fees, and that workers are not deprived of passports or other ID.
27	Labor Laws	The contract is performed in accordance with the International Labour Organization (ILO) Eight Core Conventions. (Nos. 29, 87, 98, 100, 105, 111, 138 and 182). Supplier will ensure that the conditions are met by subcontractors.
28	Supply Chain Transparency	Supply chain is mapped, including raw materials, to understand potential risks of forced labor/modern slavery.
29	Supplier Site Location	Addresses of all manufacturing sites involved in the manufacturing of the product must be provided.
End of Required Criteria		

Chemical and material criteria details

Accelerants

Supplier will provide a list of accelerants and other allergens contained in the product (e.g. thiurams, dithiocarbamates, thiazoles). *For surgical gloves only: The product does not include the accelerant diphenyl guanidine (DPG) (CAS 102-06-7).

Definition: Chemical accelerants are used in glove manufacturing to hasten the linkage of molecules in natural rubber latex or in synthetic rubber latex like nitrile and vinyl. The accelerants transform the liquid materials into thin, strong, and elastic glove films.

Rationale: Many gloves are made with accelerants that can be contact allergens and can cause skin irritation and/or sensitization. Recent research suggests a small percentage of users (3.6%) with suspected allergic contact dermatitis (ACD) were found to react to an accelerant. Transparency of product ingredients is critical for assessing potential occupational and environmental risks of products, throughout their life cycle, including potential exposures during use.

Verification: A specification sheet or other disclosure sheet with this information is sufficient to meet this criterion.

Antimicrobials/Biocidals

Product is not treated with or does not intentionally contain biocidal chemicals.

Definition: Antimicrobials are substances or mixtures of substances designed to destroy or suppress the growth of harmful microorganisms whether bacteria, viruses, or fungi on inanimate objects or surfaces. These products are typically used for two purposes: 1) Disinfect, sanitize, reduce, or mitigate growth of microbiological organisms; 2) Protect inanimate objects (gloves, floors, walls, and/or furniture), industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

Rationale: Human toxicity and ecotoxicity profiles differ among antimicrobial agents, but none are entirely benign. The addition of antimicrobials can also contribute to more widespread antibiotic resistance.

Bisphenol A (BPA)

Product does not contain added Bisphenol A (CAS No. 80-05-7) or any BPA structural analogs. Impurities/residues shall not be present in amounts over 0.01% by weight (100 mg / kg) in any individual part of the product.

Definition/Scope:

Structural analogs to be avoided include:

- bisphenol AP
- bisphenol AF
- bisphenol B
- bisphenol C
- bisphenol Cl2
- bisphenol E
- bisphenol F
- bisphenol G
- bisphenol M
- bisphenol S
- bisphenol P
- bisphenol PH
- bisphenol TMC
- bisphenol Z
- 4-cumylphenol (HPP).

A more extensive list of structural analogs to be avoided includes any compound with the following characteristics:

1. All compounds with a Tanimoto Coefficient of 0.9-1.0 (compared to bisphenol-A CAS NO 80-05-7) are restricted. For these purposes, Tanimoto Coefficients are obtained at 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 would not be included.
3. Chemicals with a Tanimoto Coefficient of <0.8 would be restricted if either of the following are true:
    a. the compound has demonstrated endocrine-disrupting potential (estrogen or androgen receptor agonism or antagonism) and is used as a functional substitute for BPA, or
    b. the compound is detected in environmental media or human biomonitoring studies and is used as a functional substitute for BPA and publicly available hazard data to evaluate endocrine-disrupting potential (estrogen or androgen receptor agonism or antagonism) are lacking.

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

Rationale: Bisphenol A (BPA) is a reproductive and developmental toxicant and endocrine disruptor. Emerging evidence finds an association between prenatal or postnatal exposure to BPA and a variety of adverse health outcomes. Listed BPA structural analogs are also prohibited because virtually all currently studied have some evidence of toxicity.

Chlorinated Paraffins

Product does not contain chlorinated paraffins in concentrations above 0.1% by weight.

Definition: Chlorinated paraffins (CPs) are complex mixtures of polychlorinated n-alkanes (paraffin wax). The chlorination degree of CPs can vary between 30 and 70 wt%. CPs are subdivided according to their carbon chain length into short-chain CPs (SCCPs, C10–13), medium-chain CPs (MCCPs, C14–17) and long-chain CPs (LCCPs, C>17).

Rationale: Chlorinated paraffins are persistent, bioaccumulative, and toxic to aquatic organisms at low concentrations - and vary in toxicity depending on chain length and amount of chlorination. They are often used as plasticizers.

Dyes/Pigments

Product does not contain dyes in concentrations above 0.1% by weight.

Definition: Pigments are particles of color that are insoluble in water, oils, and resins. They need a binder or to be suspended in a dispersing agent to impart or spread their color. Dyes are usually water-soluble and depend on physical and/or chemical reactions to impart their color

Rationale: Many common dyes have a variety of hazard properties associated with them. For example, some azo dyes can break down into more hazardous aromatic amines that are mutagenic and carcinogenic.

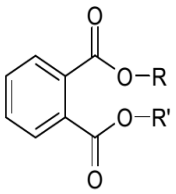
Table B - Dyes	
Substance	CAS number
Dinatrium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl] -4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene -2,7-disulfonate	1937-37-7

Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonapthalene-1-sulfonate)	573-58-0
4-o-tolylazo-o-toluidine	97-56-3
(6-(4-hydroxy-3-(2-metoxyphenylazo) -2-sulfonate-7-naphtylamin) -1,3,5-triazin-2,4-diyl)bis[(amino-1-metyletyl) ammonium] formate	108225-03-2
Disodium[5-[[4'-[[2,6-dihydroxy-3-[(2-hydroxy-5-sulphophenyl)azo]phenyl]azo][1,1'-biphenyl]-4-yl]azo]salicylato(4-)]cuprate(2-) (CI Direct Brown 95)	16071-86-6
Trisodium[4'-(8-acetylamino-3,6-disulfonato-2-naphthylazo)-4''-(6-benzoylamino-3-sulfonato-2-naphthylazo)-biphenyl-1,3',3'',1'''-tetraolato-O,O',O'',O''']copper(II)	164058-22-4
Tetrasodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis[5-amino-4-hydroxynaphtalene-2,7-disulfonate]	2602-46-2
4-aminoazobenzene	60-09-3

Ortho-Phthalates (esters of orthophthalic acid)

Product does not contain phthalates, esters of orthophthalic acid, at concentrations above 50 ppm (50 mg/kg) per substance, including di (2-ethylhexyl phthalate) (DEHP).

Definition: Ortho-phthalates have the general chemical structure shown below:



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

Rationale: Ortho-phthalates have been linked to hormone disruption, reproductive and developmental impacts, and kidney toxicity, and increased risk of asthma. Exposure to some phthalates during critical periods of development can interfere with testosterone production and disrupt normal male reproductive tract development. Some recent studies suggest that prenatal exposure to phthalates is

associated with adverse impacts on neurodevelopment, including lower IQ, and problems with attention and hyperactivity, and poorer social communication.

Fluorinated Substances

Product does not contain any intentionally added per- or polyfluorinated substances (PFAS)

Definition: PFASs are fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinatedmethylene group (–CF2–) is a PFAS.

Rationale: Perfluorinated compounds are generally highly persistent chemicals or break down into highly persistent chemicals. They have been called “forever chemicals” because of their extreme persistence. The health effects of the most well studied include high cholesterol, thyroid disorders, pregnancy-induced hypertension and preeclampsia, cancer (testicular and kidney), and altered metabolism, among others. Many of these compounds have not been adequately evaluated.

Polyvinyl Chloride (PVC)

Product does not contain polyvinyl chloride (PVC).

Definition: PVC, or vinyl, is a synthetic thermoplastic material made by polymerizing vinyl chloride. The properties of the material depend on the additives, including plasticizers.

Rationale: Polyvinyl chloride (PVC) is derived from vinyl chloride, a known human carcinogen. Manufacturing and burning PVC can result in the formation of other highly toxic chemicals. Recycling PVC is challenging and can hinder the recycling of other kinds of plastic.

Powder Residues

Product is free of powder residue.

Definition: Powder is used in the manufacturing process as a mold releasing agent and a donning lubricant. It is one possible cause of sensitization because the glove powder can absorb some soluble protein.

Rationale: Latex proteins can become fastened to the lubricant powder used in some latex gloves. Powder can spread through the air and cause inflammation, knots in the connective tissue of the skin and allergic reactions in the airways. Allergic reactions to powdered latex are well described in the

literature. Test results (according to EN ISO 21171 or ASTM D6124) can serve as evidence of meeting this criterion.

**The U.S. Food and Drug Administration has determined that powdered surgeon's gloves, powdered patient examination gloves and absorbable powder for lubricating surgeon's gloves, present an unreasonable and substantial risk of illness or injury and that the risk cannot be corrected or eliminated by labeling or a change in labeling. This final regulation will ban these products.*

Skin Moisturizers/Skincare Additives

Product is not treated with or does not contain substances intended to moisturize or soften the hands (skincare additives).

Definition: Substances added to gloves and intended to moisturize or soften the hands

Rationale: Avoiding unnecessary additives that do not contribute to the barrier properties of the glove can help reduce potential hypersensitivity. Substances added to gloves have the potential to be allergens.

Substances of High Concern

Product is free of substances of high concern.

Definition: The product offered shall not contain substances listed on the current candidate list Article 59 of Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) in concentrations above 0.1% by weight (1000 mg/kg) per substance.

Rationale: The REACH candidate list includes substances that are hazardous to humans and/or the environment that may be added to the REACH restriction list, so early phasing out is preferable. The candidate list is regularly updated by the European Chemicals Agency (ECHA) and updates are available on the ECHA website.

Product performance criteria details

Disposability

Disposable medical gloves are tested according to: a) EN ISO 10993-5 (biological evaluation of medical devices, part 5: in vitro cytotoxicity testing), b) EN ISO 10993-10 (Biological evaluation of medical devices, Part 10: Test for irritation and skin sensitization) or equivalent standard.

Rationale: These International Standardization Organization (ISO) standards address the evaluation of health products for biological impacts (cytotoxicity, skin sensitization evaluation, etc)

Weight of Product

Average weight per unit (g/unit) for medium-sized products, and the permitted error range, is known.

Rationale: The information will inform the assessment of resource consumption and waste generation.

Product packaging criteria details

Additives

The supplier must avoid packaging additives that impede recycling including those listed below:

- Halogenated organic compounds
- Phthalates
- Organotin compounds
- Compounds based on Lead (Pb), Cadmium (Cd), ChromiumVI(Cr6+) and Mercury (Hg)
- Dimethylfumarate (DMFu, CAS 624-49-7)
- Bisphenols
- PFAS chemicals
- Carbon-based master-batches, e.g. carbon black pigments (CAS no. 1333-86-4).

*Impurities up to 100 ppm are, however, permitted.

Definition: Additives are chemicals or chemical compounds added to a material to confer desired properties. Some of the most commonly used additives in paper for example include fillers, retention aids, sizing agents, wet strength agents, dry strength agents, defoamers, and dyes and pigments.

Rationale: Thousands of additives can be used to give packaging different colors and technical properties. Materials of the same type often contain different combinations of additives, resulting in recycled material with unpredictable and often suboptimal additive combinations. Some of these chemicals pose hazards to health and the environment. Some can impede the process of recycling, and others degrade the quality of the resulting product.

Materials

Packaging does not contain plastics.

Packaging does not contain materials for which recycling schemes are unlikely to be established.

Secondary and tertiary packaging is made of recycled material and Forest Stewardship Council (FSC) or equivalent for paper products.

Definition: Materials are a substance or mixture of substances that makes up an object.

Rationale: The supplier must avoid materials listed for which recycling schemes are unlikely to be established:

- polyvinyl chloride
- polyvinylidene chloride
- polystyrene
- expanded polystyrene
- regenerated cellulose
- non-recyclable plastics/paper combinations

FSC certification ensures that products come from responsibly managed forests that provide environmental, social and economic benefits.

Minimization

Packaging is reduced to the greatest extent possible.

Rationale: Suppliers minimize packaging while ensuring that it prevents damage and preserves product integrity. Packaging is appropriate for the size, shape, and weight of products. If excess packaging can be eliminated, significant resource and cost savings can be achieved.

Recyclability

Packaging is selected based on ease of recycling.

Rationale: Suppliers use packaging that easily allows the reclamation of mixed materials with minimum effort and avoids bonding systems that prevent separation of individual materials. Labels are recyclable or easy to remove to support recycling; alternatively use embossing or in-mold direct printing.

Utilization

Product waste reduction is achieved through optimal packaging design (i.e. preventing multiple gloves being dispensed at once.)

Rationale: Suppliers reduce product waste through improvements in packaging design. A study from Region Skåne showed that 6% of gloves were discarded due to falling on the floor and becoming unusable.

Supplier Requirements

Anti-Corruption

An anti-corruption policy including for contractors and subcontractors must be in place and be provided.

There are many resources available to assist in drafting and reviewing a policy.

Forced Labor

Management teams must be regularly informed of forced or compulsory labor/modern slavery risks and involved in related decision-making. A forced labor/modern slavery policy or code of conduct is in place and must be provided. It is required that these standards be implemented within the supply chain, inline with the company's policy/code of conduct.

Rationale: Business enterprises must respect human rights. This means that they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved. In 2016, over 21 million people were the victims of forced labor. Respecting human rights can reduce business risks.

Recent reports have documented worker exploitation around glove manufacturing including forced labor, poor working conditions and debt bondage. The U.S. Customs and Border Protection (CBP) agency barred some products from being distributed in the country after finding “reasonable evidence” that the companies were using forced labor. Allegations of abuse in glove production also include passport confiscations, illegal withholding of pay, and restricted freedom of movement. Gloves have also been identified by the US Department of Labor as a high risk category for child labor and forced labor.

Labor Force

The percentage of migrant workers at all sites must be reported. Factories with more than 10% migrant workers must have policies in place to ensure that migrant workers are protected, that there are zero recruitment fees, and that workers are not deprived of passports or other ID.

Rationale: Factories with more than 10% migrant workers must have policies in place to ensure migrant workers are protected, that there are zero recruitment fees, and that workers are not deprived of passports or other ID. It is required that the supplier submit a copy of the audit of compliance with this requirement. Recent reports have documented exploitation of migrant workers at manufacturing sites.

Labor Laws

The contract is performed in accordance with the International Labour Organization (ILO) Eight Core Conventions. (Nos. 29, 87, 98, 100, 105, 111, 138 and 182). Suppliers will ensure that the conditions are met by subcontractors.

Rationale: Requiring potential suppliers to abide by UN ILO Conventions ensures materials supplied have been produced responsibly and can reduce company risks. Please see the requirements for this criterion on the Swedish National Procurement Agency website.

Supply Chain Transparency

Supply chain is mapped, including raw materials, to understand potential risks of forced labor/modern slavery.

Definition: The entire supply chain includes:

- Tier 1 – Suppliers work directly with vendors
- Tier 2 - Suppliers provide Tier 1 with materials
- Tier 3 - Suppliers supply Tier 2 or work in raw materials

Rationale: The entire supply chain is identified in order to affirm compliance with other labor-related criteria. UN Guiding Principles on Business and Human Rights clarifies that it is not enough that businesses only work with their direct suppliers, but that they include the largest risks for negative impacts and human rights which can often be found amongst Tier 2 and Tier 3. Businesses that are serious about mitigating negative impacts in the value chain, prioritize their efforts there.

Supplier Site Location

The addresses of all manufacturing sites involved in the manufacturing of the product must be provided.

Rationale: Providing this information allows procurers the possibility of verifying supplier information.

Climate Requirements

The Health Care Without Harm Climate Excellence Standard (CES)

The Climate Excellence Standard defines superior performance in decarbonization on the part of individual suppliers – including manufacturers and distributors – to ensure the health care supply chain is aligned with achieving net-zero emissions by 2050, while improving resilience. Reducing the health care sector's reliance on fossil fuels is critical for reducing deaths and diseases related to greenhouse gas emissions, and the time is now for deep engagement across the supply chain.

The U.S. Health Care Climate Council established this standard to use its considerable purchasing power to signal to the market the need for significant progress in addressing the severe human health consequences of climate change. By acting collectively, healthcare can achieve greater visibility for targeted actions to address supply chain opportunities, while committing to collaborate with suppliers to accelerate decarbonization. By decarbonizing, suppliers enhance their operational resilience and competitive advantage. The Greenhealth Approved Seal educates suppliers and collects climate data in support of Health Care Without Harm's climate initiatives. Answers to the CES are required but a "No" answer will not invalidate the supplier from receiving the Greenhealth Approved Seal.

The Climate Excellence Standard (CES)

Phase 1 (2023-2025):

1. Emissions target and plan has been submitted to the Science Based Target Initiative (SBTi) for approval, or the company has an SBTi-approved plan with near-term or short-term targets, OR

    a) Publicly commit to a near-term or long-term science-based emissions reduction target as defined by SBTi, *and*
    b) Measure Scopes 1, 2, and 3 emissions using the Greenhouse Gas Protocol, *and*
    c) Disclose emissions through CDP, EcoVadis, or similar publicly accessible and recognized platforms (disclosures only on suppliers' corporate websites do not meet this criteria), *and*
    d) Assure Scopes 1 and 2 emissions data through a third-party verifier.

AND

2. Minimize use of carbon offsets to only those emissions that currently do not have a realistic, practical solution. Applicable through 2025 only.

3. Prepare and execute a publicly available plan to reduce operational emissions (Scopes 1 and 2) and the most relevant Scope 3 categories (e.g., emissions from staff commuting, waste, and business travel).
4. Incentivize major vendors or subcontractors that reflect at least 20% of spend to commit to a science-based target along with the other requirements described in this section.

Verification

Greenhealth Approved reviews products against the criteria outlined in this document. We encourage suppliers to apply for the Greenhealth Approved seal.

For more information on how to apply for the Greenhealth Approved seal, please visit Greenhealth Approved Sustainable Gloves.

Vetting disclosures and documentation reviewed during vetting for the seal include:

- Completion of the Sustainable Glove product information form, which includes full chemical inventory disclosure and confirmation that products meet the Sustainable Glove criteria.
    - A non-disclosure agreement (NDA) can be entered into to meet the full chemical inventory requirement.
- Submission of required documentation to support validation of the criteria including: policies and procedures,reports, images, certification certificates, specification sheets, and test results.
- A signed affidavit stating that the information provided during the vetting process is true and accurate.