



Material Compliance Policy

Substance Restriction Compliance Requirements in
Steinco Products

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1 Introduction

1.1 General

STEINCO Paul vom Stein GmbH (hereinafter referred to as STEINCO) is a manufacturer of castors and wheels, which are widely used in medical devices and are trusted by patients and users all over the world. Other areas in which our castors are used are the aviation industry, commercial kitchens, factory equipment, shopfitting and office and laboratory equipment.

At the time of writing, the STEINCO Material Compliance Policy describes the most important requirements of national and international laws, directives and regulations within the scope of which STEINCO products fall.

These requirements include prohibitions, restrictions or declaration obligations of certain substances, which are regulated, for example, in the REACH Regulation EC No. 1907/2006, the RoHS Directive 2011/65/EU & 2015/863/EU and the POP (Persistent Organic Pollutants) Regulation EU 2019/1021, which has been in force since 2019.

In order to ensure safe and environmentally friendly handling of STEINCO products for patients and users, it is necessary that all products distributed by STEINCO comply with all applicable regulations. This means that all parts, materials and components that are components or accessories of STEINCO products must also meet these requirements.

1.2 Scope

This Policy is the internal basis for the selection of materials for the development and manufacture of STEINCO products, as well as for the procurement of substances, mixtures and all products that are part / component / accessories of a STEINCO product.

This Policy therefore applies to STEINCO suppliers and their products delivered to STEINCO, as well as to the STEINCO specialist departments involved.

2 Duties

2.1 Obligations of STEINCO

STEINCO specialist departments are obliged to observe the following points:

- **Development:** In product development, current and future substance bans must be observed.
become.
- **Procurement:** Compliance with the STEINCO Material Compliance Policy is ensured by a
on the framework supply contracts, purchase orders or other supplier contracts.
- **Production:** consumables and consumables used in the production process and used in the
shall also be subject to the requirements of this Directive.

2.2 Supplier's Obligations

The Supplier undertakes to comply with all regulatory requirements for the products supplied to STEINCO as set out in section 3 below and, if required, to provide STEINCO with the relevant declarations.

The requirements of this Directive are treated in the same way as other product requirements.

This Policy complements the other agreements that are binding on STEINCO suppliers (main contract, quality assurance agreement, etc.) and is therefore the subject of every delivery.

If any changes in the law are not yet reflected in this Policy, this does not release the supplier from the obligation to take current changes into account in order to comply with the applicable legal requirements.

The supplier's obligation to comply with legal requirements is not affected by this policy.

The supplier is obliged to obtain the information on the respective legislation on its own authority.

The Policy is available on the STEINCO website in the "Info & Download for Suppliers" section. Changes to the policy will be communicated to suppliers.

Products and raw materials of unknown origin or / and composition may not be used.

Upon request (without cost calculation), details of the material specification (supplier declarations) relating to the delivered product must be submitted to STEINCO. These must meet the following criteria

- Traceability of the delivered product to which the supplier declaration refers
- Reference to the current version of the regulations to which it is explained
- If applicable, indication of the exemption that will be used*
- Date and signature with contact details of the contact person

*If the supplier makes use of exemptions from a law, a regulation, etc., this must be reported to STEINCO, in particular if changes in legal requirements and expiry of deadlines result in modifications to the delivered product.

STEINCO reserves the right to carry out tests and laboratory tests on materials.

The supplier shall comply with the obligation to provide information pursuant to Article 33 of the REACH Regulation without undue delay with each delivery (see point 3 / REACH Regulation / Supplier obligation).

3 Excerpt of the relevant regulatory requirements

Regulations	Legal basis	Scope	Explanation	Supplier's Obligations
REACH Regulation EC No 1907/2006	European Regulation, directly valid in all EU member states	Relevant for all products that become part of a STEINCO product, are a STEINCO product or are accessories of a STEINCO product	European chemicals legislation (registration, evaluation and authorisation of chemicals). This regulation applies to all participants in the supply chain who either manufacture, place on the market or process a substance or mixture into an article, at least through an obligation to provide information within the supply chain (Art. 33) if a substance of very high concern listed on the Candidate List (so-called SVHC - see definition) is present in the product in a concentration of more than 0.1 % by weight (in relation to the individual article and not the composite product). The substances on the Candidate List are the substances of very high concern that are eligible for authorisation. This list shall be updated twice a year, and the inclusion of a substance on the list shall give rise to the immediate obligation to provide information in accordance with Article 33. After a transitional period, substances subject to authorisation (Annex XIV) may only be used with an authorisation or their use will be completely banned. Where a substance is included in Annex XVII, the manufacture, placing on the market and use of those substances in individual applications shall be restricted or prohibited. Link: • REGULATION (EC) No 1907/2006 • REACH Candidate List	As part of its duty to provide information pursuant to Article 33, the supplier shall immediately provide STEINCO with information if a product supplied by it contains a substance on the candidate list in a mass concentration higher than 0.1%. The same applies if the supplier uses a substance subject to authorisation in accordance with Annex XIV in its articles or a substance listed in Annex XVII. Again, the information must be provided. Suppliers of substances and mixtures provide STEINCO with up-to-date safety data sheets for hazardous substances and mixtures in accordance with Article 31 and Annex II of the REACH Regulation. The supplier shall provide STEINCO with a REACH supplier declaration upon request.

RoHS Directive 2011/65/EU & 2015/863/EU	European Directive, transposition into national law of the EU member states (in Germany ElektrostoffV)	Relevant for all STEINCO products that become part of an electrical appliance Example: Component (partial product, substance or mixture) of a hospital bed roll (Unless otherwise noted, it must be assumed that this set of rules applies to the respective products supplied.)	This Directive restricts the use of certain hazardous substances in electrical and electronic equipment (including cables and spare parts). Annex II lists the restricted substances with an indication of the maximum permissible concentration. Directive EU 2015/863 amended Annex II and added 4 more substances. The transition period for medical technology products ended in 07/2021. The substance bans always refer to the homogeneous material (see definition) of a product. Overview of regulated substances: <table><tr><th>Substance</th><th>Limit [Mass%]</th></tr><tr><td>Lead (Pb)</td><td>0,1</td></tr><tr><td>Cadmium (Cd)</td><td>0,01</td></tr><tr><td>Polybrominated biphenyls (PBB)</td><td>0,1</td></tr><tr><td>Polybrominated Diphenyl Ethers (PBDE)</td><td>0,1</td></tr><tr><td>Hexavalent chromium</td><td>0,1</td></tr><tr><td>Mercury (Hg)</td><td>0,1</td></tr><tr><td>Butylbenzyl phthalate (BBP)</td><td>0,1</td></tr><tr><td>Di(2-ethylhexyl)phthalate (DEHP)</td><td>0,1</td></tr><tr><td>Dibutyl phthalate (DBP)</td><td>0,1</td></tr><tr><td>Diisobutyl phthalate (DIBP)</td><td>0,1</td></tr></table> Annex III lists the applications that are exempt from the restriction (these are temporary) Left: • EUROPEAN DIRECTIVE 2011/65/EU • EUROPEAN DELEGATED DIRECTIVE 2015/863/EU • ElektrostoffV	Substance	Limit [Mass%]	Lead (Pb)	0,1	Cadmium (Cd)	0,01	Polybrominated biphenyls (PBB)	0,1	Polybrominated Diphenyl Ethers (PBDE)	0,1	Hexavalent chromium	0,1	Mercury (Hg)	0,1	Butylbenzyl phthalate (BBP)	0,1	Di(2-ethylhexyl)phthalate (DEHP)	0,1	Dibutyl phthalate (DBP)	0,1	Diisobutyl phthalate (DIBP)	0,1	The substance restrictions must be complied with. If the supplier invokes a derogation in accordance with Annex III, STEINCO must be informed of the derogation in question and when this derogation expires. This information is particularly important in the event that the expiration of the derogation entails modifications that affect the characteristics of the product supplied to STEINCO. The supplier will provide STEINCO with a RoHS supplier declaration upon request.
Substance	Limit [Mass%]																									
Lead (Pb)	0,1																									
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POP Regulation EU 2019/1021	European Regulation, directly valid in all EU member states	Relevant for all products that become part of a STEINCO product, are a STEINCO product or are accessories of a STEINCO product.	This regulation regulates the management of persistent organic pollutants and lays down detailed requirements regarding the production, placing on the market, use and release of persistent organic pollutants. The aim is to protect human health and the environment from POPs (persistent organic pollutants) in accordance with the precautionary principle. In addition, the regulation restricts the release of these substances and lays down rules for the disposal of waste. The POPs Regulation and the REACH Regulation are independent pieces of legislation that must be observed in parallel. The stricter regulation applies in each case. The POPs Regulation implements the Stockholm Convention, which aims to end or restrict the production, use and release of POPs. Link: • REGULATION (EU) 2019/1021	The substance bans must be observed. If a substance is used on the basis of an exemption, STEINCO must be informed. The Supplier shall provide STEINCO with a POP Supplier Declaration upon request.
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Biocidal Products Regulation EU 528/2012	European Regulation, directly valid in all EU member states	Relevant for all products that become part of a STEINCO product, are a STEINCO product or are accessories of a STEINCO product.	This regulation regulates the authorisation of biocides in the European Union and harmonises the provision and use of biocidal products on the European market. Link: • REGULATION (EU) 528/2012	The requirements and obligations for biocidal products and products treated with them that are supplied to STEINCO must be met. Furthermore, the information obligations must be complied with as soon as a delivered product has been treated with a biocide for which appropriate labelling is required according to the regulation.
Packaging and Packaging Waste Regulation (PPWR) Verordnung (EU) 2025/40	European law	Packaged, delivered goods or delivered packaging in which STEINCO products are packed.	Regulation (EU) 2025/40, known as the Packaging and Packaging Waste Regulation (PPWR), is the new central law for packaging in the European Union. It replaces the previous Directive 94/62/EC and introduces uniform, binding standards throughout the EU. The regulation aims to reduce the amount of packaging waste and strengthen the circular economy. Link: • Regulation (EU) 2025/40	The substance restrictions must be observed.

Dodd-Frank Act	USA Legislation	Relevant for all products that become part of a STEINCO product, are a STEINCO product or are accessories of a STEINCO product.	The minerals gold, tin, tungsten and tantalum are among the so-called conflict minerals, as they are mined in some African countries on the basis of massive human rights violations and the proceeds are used to finance armed conflicts. Publicly traded companies in the U.S. have an obligation to prove that the minerals they purchase are mined without conflict.	The supplier shall inform STEINCO if its delivered products contain the raw materials tantalum, tin, gold and tungsten (hereinafter referred to as "conflict minerals"). All minerals should be DRC-free, i.e. they should not contain minerals that directly or indirectly finance or benefit armed groups in the Democratic Republic of the Congo (DRC) or any adjoining country. In the event that the products supplied contain conflict minerals, the supplier STEINCO will name these products and disclose at least the country of origin and the name of the industrial processor (smelter) for each mineral contained.
Regulation on Conflict Minerals EU 2017/821 (applies only to importers)	European Regulation, directly valid in all EU Member States		This regulation only applies to EU importers of these substances. The regulation has been in force since June 2017, and due diligence will apply from 1 January 2021. The law ensures more transparency within the supply chain	

California Proposition 65	U.S. – California Law	Relevant for all products that become part of a STEINCO product, are a STEINCO product or are accessories of a STEINCO product, which is distributed in California. (Unless otherwise noted, it must be assumed that this set of rules applies to the respective products supplied.)	California's Safe Drinking Water and Toxic Enforcement Act is often referred to simply as California Proposition 65, or CP65 for short. The essence of this regulation is: "No one shall knowingly and intentionally expose an individual in the course of his business activities to a chemical known to the State of California to be carcinogenic or toxic to reproduction without first giving such individual a clear and proportionate warning." Specifically, around 900 substances listed by the OEHHA are affected and which are carcinogenic, cause birth defects or are otherwise toxic to reproduction. A warning must be given if any of the substances are present in the product and there may be an exposure of the consumer. So there is no need to warn about gallium arsenide in the semiconductors of a smartphone, but there is about DEHP in the USB cable. Since STEINCO products usually do not come into direct contact with the consumer, the likelihood of possible exposure is very low. The CP65 list contains so-called "safe harbor levels" for around 250 substances, below which no harm is to be expected. If the exposure limit value is not reached, there is no need to warn the consumer. Link: • Cal. Proposition 65 Fabric List	The supplier shall inform STEINCO if listed substances are present in the products it delivers.
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TSCA - Regulation of Certain Chemical Substances and mixtures under section 6 of The Toxic Substances Control Act	USA Legislation	Relevant for all products that become part of a STEINCO product, are a STEINCO product or are accessories of a STEINCO product	The Toxic Substance Control Act (TSCA) is the most important chemical control law in the United States. In December 2020, the EPA introduced new restrictions on persistent, bioaccumulative, and toxic (PBT) chemicals within the TSCA Act (pursuant to Section 6). The new PBT rule aims to reduce exposure to certain (currently five) chemicals that are persistent, bioaccumulative and toxic. These chemicals accumulate in the environment over time and can therefore pose potential risks. <table><tr><td>PBT Chemicals</td></tr><tr><td>2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CAS 732-26-3)</td></tr><tr><td>Decabromodiphenyl Ether (Deca-BDE) (CAS 1163-19-5)</td></tr><tr><td>Hexachlorobutadiene (HCBd) (CAS 87-68-3)</td></tr><tr><td>Pentachlorothiophenol (PCTP) (CAS 133-49-3)</td></tr><tr><td>Phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CAS 68937-41-7)</td></tr></table> The new PBT rule prohibits the manufacture (including import), processing and distribution in trade of five PBT chemicals/substances or products or articles containing the defined PBT chemicals/substances. Link: TSCA Chemical Substance Inventory	PBT Chemicals	2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CAS 732-26-3)	Decabromodiphenyl Ether (Deca-BDE) (CAS 1163-19-5)	Hexachlorobutadiene (HCBd) (CAS 87-68-3)	Pentachlorothiophenol (PCTP) (CAS 133-49-3)	Phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CAS 68937-41-7)	The substance restrictions must be complied with. Supplier shall provide STEINCO with a TSCA Supplier Declaration upon request.
PBT Chemicals										
2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CAS 732-26-3)										
Decabromodiphenyl Ether (Deca-BDE) (CAS 1163-19-5)										
Hexachlorobutadiene (HCBd) (CAS 87-68-3)										
Pentachlorothiophenol (PCTP) (CAS 133-49-3)										
Phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CAS 68937-41-7)										

4 STEINCO specific substances to be declared

Fabric	Explanation	Supplier's Obligations
Latex	Latex can cause allergies and should therefore not be included in a STEINCO product	The supplier shall inform STEINCO if the delivered products contain latex.
Silicones	As synthetic products, they are difficult to degrade in nature and should therefore not be included in a STEINCO product	The supplier shall inform STEINCO if the products supplied contain silicones.
Materials of animal origin	The Medical Device Regulation includes a declaration obligation for materials of animal origin, so materials of animal origin should not become part of a STEINCO product.	The supplier shall inform STEINCO if the products supplied contain materials of animal origin.
Nanomaterials	With the use of nanomaterials, the level of environmental exposure is also increasing. However, little is known about the possible behaviour of the particles in the event of leakage into the air, water or soil. Like other pollutants, they could travel from one organism to another, potentially moving up the food chain. In order to avoid possible environmental risks that are not yet foreseeable today, nanomaterials should not be included in a STEINCO product.	The supplier shall inform STEINCO if the products supplied contain nanomaterials.
PFAS	Per- and polyfluorinated alkyl substances (PFAS) (based on the OECD structural definition of 2021) are used in tens of thousands of products. Once released, however, they remain in the environment for decades due to their extraordinary chemical stability and can have harmful effects on humans and the environment. The European Chemicals Agency (ECHA) has published the proposal for a ban on the manufacture, use and placing on the market (including import) of at least 10,000 PFAS. The proposed ban was developed by authorities from Germany, the Netherlands, Denmark, Norway and Sweden within the framework of the EU chemicals regulation REACH. If implemented, this would be one of the most extensive bans on chemical substances since the REACH Regulation came into force in 2007. STEINCO wants to take a proactive approach to this issue and avoid the use of PFAS as far as possible.	The supplier shall inform STEINCO if the products supplied contain PFAS (as defined in the OECD Structural Definition of 2021).

5 Definitions

Regulatory definitions can be found in the context of the respective law or regulation

Concept	Definition
Product	Product means everything that is made available to STEINCO as a delivery item, as well as everything that is manufactured by STEINCO itself and remains on/in a product that is placed on the market by STEINCO. Examples: • Complete product (including merchandise) plus packaging • Component, Component • Consumables and consumables
Product	Material / object where the shape, surface or shape is more important than the chemical composition
Fabric / Blend	Material/object where the chemical composition is more important than the shape, surface or shape.
Prohibited Substances	Prohibited substances are substances for which a general ban is imposed according to the applicable regulations or for which a ban results due to other requirements (restriction of use, authorisation requirement, etc.). Prohibited substances may not be contained in articles, components, materials as well as auxiliary and operating fluids above the limits specified in applicable regulations. The substances must only be present as naturally occurring impurities and must not be added intentionally. The impurities must be declared qualitatively.
Declarable substances	Declarable substances are all substances for which there is a declaration obligation according to the applicable regulations. The substances classified as declarable must be declared above the specified limit values.
Restricted Substances	Restricted substances are subject to conditions for the manufacture, use or placing on the market or a ban on these activities. Substances whose manufacture, marketing or use pose an unacceptable risk to human health or the environment may be subject to restriction or even prohibition (REACH Regulation).
SVHC (Substance of Very High Concern)	A substance of very high concern is a chemical substance that has been identified under the REACH Regulation as having particularly hazardous properties and may have serious effects on human health or the environment. These include substances with the following properties: CMR = carcinogenic, mutagenic or toxic to reproduction PBT = persistent, bioaccumulative and toxic Endocrine disruptors (substances that disrupt the endocrine system) Neurotoxic substances (substances that have a damaging effect on the nervous system)
Homogeneous material	Relevant for RoHS: A homogeneous material refers to a material of consistently uniform composition or a material consisting of different materials that cannot be broken down or separated into individual materials by mechanical processes such as unscrewing, cutting, crushing, grinding and grinding. Example: a non-homogeneous component such as a painted metal part contains 3 homogeneous materials - the metal, the primer and the paint.
Slate	Relevant for REACH: The status as a substance of very high concern is officially confirmed by ECHA by publishing the substance in the candidate list on its homepage (updated every six months). The candidate list is the shortlist for substances subject to authorisation. The Agency makes recommendations for the inclusion of a substance in Annex XIV of the REACH Regulation at least every 2 years, after which the substance may only be used with authorisation after the end of the transition periods, unless the use has been exempted (research, regulation by other directives/regulations).

Admission required	Relevant for REACH: The authorisation requirement is a prohibition subject to authorisation, i.e. the use of a substance listed in Annex XIV of the REACH Regulation is generally prohibited unless an authorisation has been granted (see e.g. chromium trioxide).
ECHA	European Chemicals Agency, based in Helsinki
Biocide	Biocides are used to kill or repel harmful organisms. They work, for example, by paralyzing the nervous system or impairing the ability of harmful organisms to reproduce. At the same time, this also makes them potentially dangerous for humans and the environment.
Marketing	Supply to third parties for payment or free of charge or provision for third parties. Importation is considered to be placing on the market.

6 Contact

Do you have any questions about STEINCO's Material Compliance Policy?

Please contact:

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Head of Quality Management / Management Officer

Head of quality management / quality management representative



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7 Change history

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0	M. Fuchs	M. Fuchs	25.01.2024	i.v. M. Fuchs
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