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ZEISS standard



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Prohibition and restriction of substances

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Table of Contents

1	Scope and purpose	2
2	Definition Material	2
3	Material changes	3
4	Reasons for a material declaration.....	3
5	Compliance with legal substance prohibitions.....	3
6	Compliance with legal substance restrictions	3
7	Exemptions to legal substance restrictions.....	4
8	Information and declaration obligations regarding ingredients	4
8.1	Type and Scope of a Material Declaration	5
9	Deliveries of components for medical devices (applies only to deliveries of components used in medical devices)	6
10	Deliveries of batteries (applies only to deliveries of batteries used in ZEISS products)	6
11	Deliveries of packaging (applies only to deliveries of packaging that are passed on to ZEISS)...	6
12	Additional legal requirements for deliveries of articles/products	7
13	Deliveries of products and articles that contain PFAS.....	7
14	Additional contractual prohibitions of certain substances	7
	Other applicable documents	9
	Past Issues	9
	Changes	9
	specialized area	10
	contact person.....	10
	Original language.....	10

1 Scope and purpose

This standard defines the handling of prohibitions, restrictions and declaration obligations of substances for ZEISS suppliers in order to comply with applicable legal provisions, customer-specific stipulations and ZEISS specifications. This standard must be mandatorily applied by all suppliers of Carl Zeiss AG and all companies associated with it (hereinafter referred to as 'ZEISS'). This standard is also referenced in the General Terms and Conditions of Purchase of ZEISS or the respective framework supply agreements. This standard is thus applicable worldwide for materials delivered to ZEISS.

The legal material and material regulations applicable to the respective article, other legal requirements and contractual regulations with ZEISS concerning the quality of the article are not affected by this ZEISS standard and are equally valid.

In case of specific material requirements or of reference to specific legislation by ZEISS, this does not relieve the supplier of the responsibility to check the validity of further statutory provisions or those which exceed the contractual requirements and to ensure that they are complied with. In the following sections, reference is made to legislation, as an example and for clarification.

The supplier is obligated to immediately contact the responsible ZEISS Purchasing Department in writing if the legal material and material regulations applicable to the respective article, other legal requirements and contractual regulations with ZEISS regarding the quality of the article aren't fulfilled or aren't applied and implemented for other reasons. ZEISS Purchasing can only grant an exemption to prohibitions on substances which aren't legally required.

2 Definition Material

In the context of this standard, the term 'material' is defined as follows:

substance	means 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
mixture	means a mixture or solution composed of two or more substances
article	means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition

The term 'Material' includes all components that remain in a ZEISS product, including the manufacturing auxiliaries used by ZEISS, as well as all packaging delivered to ZEISS by partners and suppliers, and the packaging that ZEISS provides to external customers.

Examples of material are:

- Pure substances and mixtures
- Materials and semi-finished products
- Complete products, including commercial goods
- Soldering materials and adhesives
- Packaging materials

3 Material changes

Suppliers are obliged to coordinate changes to the delivered materials with the responsible purchasing department of ZEISS immediately upon becoming aware of them or, if possible, at least 6 months before a change takes effect. This is particularly important if legal changes require an adjustment of the materials. In such cases, the supplier must promptly inform the responsible purchasing department of ZEISS about the changed legal regulation, including specifying the specific legal source (e.g., changes to the RoHS Directive 2011/65/EU). Furthermore, the measures taken or planned for implementation, as well as the timeframe for implementation, must be clearly outlined.

4 Reasons for a material declaration

Suppliers are obliged to provide valid material declarations in accordance with currently applicable regulations to keep the technical documentation at ZEISS up to date. A new material declaration must be provided in the following cases, among others:

- First Delivery: A material is being sampled, launched, or delivered for the first time.
- Missing Declaration: A declaration has not been provided so far and must be made available to ZEISS.
- Incorrect Declaration: The previous declaration was incorrect or incomplete. In this case, the supplier must provide ZEISS with a corrected version immediately upon becoming aware of the deficiency.
- Change of Material: The material or at least one ingredient has been changed.
- New Legal Requirements: There are new substance bans and/or obligations for substance declaration that affect the delivered material.

The type and scope of the required material declaration are described in detail in Chapter 8.1. There you will find detailed information on the specific requirements and the documents to be provided.

5 Compliance with legal substance prohibitions

General legal substance bans: To ensure compliance with legal regulations, the materials supplied to ZEISS must not contain any of the following prohibited ingredients:

1. All substances listed in Annex XIV of the REACH Regulation (EC) No. 1907/2006 in its current version, whose sunset date has passed, unless an authorization has been granted. In this case, it is necessary to communicate the authorized use and any conditions for each delivery.
2. All substances listed in Annex I of the POP Regulation (EU) 2019/1021, whether as such or in mixtures and articles, are prohibited, except for the permissible maximum concentrations specified therein.
3. Mercury and its compounds as well as mercury mixtures in accordance with the provisions of the Mercury Regulation (EU) 2017/852.

The provisions of this chapter are binding and must be complied with without exemption. Any deviation from the legal substance bans is not permitted.

6 Compliance with legal substance restrictions

General legal substance restrictions: The materials to be supplied to ZEISS must not contain any of the following ingredients except within the legally specified limits or authorized uses.

1. Substances that are subject to the restrictions of the RoHS Directive 2011/65/EU with delegated directives (EU) 2015/863, (EU) 2017/2102, and (EU) 2021/1925.
2. All substances listed in Annex XVII (Restrictions on the manufacture, placing on the market, and use of certain dangerous substances, mixtures, and articles) of the REACH Regulation (EC) No. 1907/2006 in its current version and their prohibited uses, except for the permissible maximum concentrations specified therein.
3. All substances listed in Annex II-V of the POP Regulation (EU) 2019/1021 as such or substances in mixtures and articles (except for the permissible maximum concentrations specified therein).
4. All substances listed in Annex I No. 10.4.1 of the Medical Devices Regulation (EU) 2017/745 as such or substances in mixtures and articles (except for the permissible maximum concentrations specified therein) for medical devices.
5. Ozone-depleting substances listed in the Council Regulation on substances that lead to the depletion of the ozone layer (EU) No. 2024/590 and substances in Classes I and II of the U.S. Clean Air Act. Class I includes chlorofluorocarbons (CFCs), halons, bromomethane, tetrachloromethane, and 1,1,1-trichloroethane; Class II includes partially halogenated chlorofluorocarbons.
6. All products containing mercury listed in Annex II of the Mercury Regulation (EU) 2017/852 (from the date specified therein) and new mercury-containing products under Article 8.
7. Conflict minerals as defined in Section 1502 of the Dodd-Frank Act and the EU Conflict Minerals Regulation (EU) 2017/82, including tin, tantalum, tungsten, their ores, and gold (3TG), may only be included if they are sourced Conflict-Free from certified smelters.
8. Fluorinated greenhouse gases according to Regulation (EU) 2024/573 (particularly substances in Annexes I–III) as such or in mixtures and articles, provided that their placing on the market, use, or emissions are prohibited or restricted therein (except for the exemptions, quotas, or licensing arrangements specified therein).

The provisions of this chapter are binding and must be complied with without exemption. Any deviation from the legal substance restrictions is not permitted.

7 Exemptions to legal substance restrictions

Unless otherwise specified in the order, the legal exemptions to the substance restrictions may be applied. Once an exemption is applied, ZEISS must be informed about which ingredient is used, in what quantity, and in which material. For the confirmation of EU RoHS, the exemption number according to Annexes III and IV of Directive 2011/65/EU and its delegated acts must also be provided.

8 Information and declaration obligations regarding ingredients

Substances and mixtures containing hazardous ingredients must report them to ZEISS via the material safety data sheet. Proof of compliance with substance prohibitions and restrictions can be provided through the safety data sheet in accordance with Article 31 of the REACH Regulation (EC) No. 1907/2006 or a material declaration according to Chapter 8.1. For deliveries of products, a suitable material declaration is required, containing all essential information as per Chapter 8.1 (see additionally provided templates for material declarations). Upon request, measurement protocols from independent, accredited testing laboratories must be submitted.

Declaration obligations according to Article 33 of the REACH Regulation (EC) No. 1907/2006 must be reported to ZEISS in accordance with the provisions in Chapter 4 and upon request. The provision of the SCIP number of the product is encouraged.

Ozone-depleting substances must be reported if they are contained in the materials to be supplied or were used in their production.

Ingredients of metal alloys are considered declared if they are listed in a national or international standard (e.g., DIN, EN, ISO) or a specification agreed upon between ZEISS and the manufacturer, along with established limit values.

For conflict minerals, affected suppliers must use the current RMI Conflict Minerals Reporting Template. When using 3TG (tin, tantalum, tungsten, gold), the supply chain must be verified and reported. ZEISS conducts an annual inquiry regarding the use or provision of 3TG, which must be answered by affected suppliers.

Requests for Extended Minerals Reporting (EMRT) may be directed by ZEISS to suppliers and must be answered to fulfil ZEISS's due diligence obligations.

8.1 Type and Scope of a Material Declaration

The ingredients subject to declaration obligations and other duties must be specified in accordance with the provisions in Chapter 4 and upon request by ZEISS. Furthermore, templates for creating a material declaration for selected regulations can be provided (e.g., REACH Regulation (EC) No. 1907/2006 and Directive 2011/65/EU and their delegated acts).

Mandatory information for a material declaration:

- Complete designation of the currently confirmed legal text
- Currently confirmed revision date (e.g., REACH-SVHC candidate list)
- Name and address of the manufacturer with the contact person's details
- ZEISS bill of materials/material number (and possibly the manufacturers)
- Product description/name
- Date and location
- Traceability of the information must be clearly recognizable, e.g., through the name, role, and signature of the contact person
- For substances subject to declaration or substances using an exemption:
 - Name of the substance
 - CAS number
 - Concentration in mass percent
 - Information on the affected component in the part
 - Number of the applied exemption (e.g., RoHS exemptions)
 - (Weight of the affected component)

8.2 Regulations on the Material Safety Data Sheet

For the first delivery of substances or mixtures that meet the criteria for classification as hazardous according to Titles I and II of Regulation (EC) No. 1272/2008, the supplier must provide a current safety data sheet free of charge, either on paper or electronically, in accordance with Article 31 and Annex II of Regulation (EC) No. 1907/2006 (REACH). Furthermore, this also applies to all other cases where a safety data sheet is required under Article 31 of the REACH Regulation, as well as after

revision of the safety data sheet (or in case of changes to the legal requirements for safety data sheets).

9 Deliveries of components for medical devices (applies only to deliveries of components used in medical devices)

9.1 Reference to Medical Devices Regulation

Suppliers delivering products that are incorporated into medical devices must ensure that their products, in addition to the aforementioned regulations, meet the requirements of the Medical Devices Regulation (EU) 2017/745. This includes compliance with strict quality and safety standards as well as the provision of comprehensive technical documentation. Suppliers must ensure that their products are properly labelled and contain all relevant information for safe use.

9.2 Reference to the In Vitro Diagnostic Regulation

Suppliers delivering products that are incorporated into In Vitro Diagnostics (EU) 2017/746 must ensure that their products comply with the aforementioned regulations and are correctly labelled according to regulatory requirements. Additional evidence in the form of technical documentation, test reports, and/or certificates must be provided upon request.

9.3 Labelling of Medical Devices

For medical devices that contain natural rubber or natural rubber latex, it is required to affix the corresponding symbol either directly on the medical device itself, on its packaging, and/or in the accompanying documents.

Excerpt from ISO 15223-1, 21 CFR:

Reference number of symbol	Title of symbol	Description of symbol ^a	Requirements	Informative notes	Restrictions of use	Additional requirements
5.4.5 	Contains or presence of natural rubber latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.		NOTE This symbol is intended to warn those people who may have allergic reactions to certain proteins in latex.	This symbol should not be used for medical devices containing "synthetic rubber".	In Europe ^b , this symbol shall be explained in the information supplied by the manufacturer.

^a At the moment, only countries applying the principles laid down in the EU Directives have this requirement or restriction.

10 Deliveries of batteries (applies only to deliveries of batteries used in ZEISS products)

Suppliers of batteries are obligated to ensure that their products comply with the requirements of the Battery Regulation (EU) 2023/1542. This includes the proper labelling of batteries with information about their chemical composition and recyclability. Furthermore, battery manufacturers are required under the Battery Regulation to fulfil all legal requirements. This particularly includes the registration of their products and ongoing reporting to the competent authorities as part of extended producer responsibility to ensure compliance with the regulations.

11 Deliveries of packaging (applies only to deliveries of packaging that are passed on to ZEISS)

Suppliers of products in packaging and suppliers of packaging must ensure that their packaging complies with the requirements of the Packaging Regulation (EU) 2025/40 as well as country-specific packaging requirements. This includes the selection of materials that are environmentally friendly

and easily recyclable. The packaging must be clearly labelled to support recyclability, and the use of composite materials should be minimized. Furthermore, suppliers of packaging materials are obligated under the Packaging Regulation to fulfil all resulting obligations within the framework of extended producer responsibility. This particularly includes the registration of their products, participation in packaging take-back systems, and compliance with reporting and declaration obligations.

12 Additional legal requirements for deliveries of articles/products

- Products delivered to ZEISS must not contain ingredients that are considered hazardous and prohibited under TSCA Section 6a and 6h, unless a specific exemption is granted.
- Suppliers must inform and assist ZEISS if their products contain chemicals listed under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Proposition 65; CP65).
- The active support of suppliers is of great importance. They should provide comprehensive information and facilitate coordination if necessary to ensure that all legal requirements are met, and the safety of the products is guaranteed.

13 Deliveries of products and articles that contain PFAS

Suppliers are obligated to already begin collecting information on whether and which per- and polyfluoroalkyl substances (PFAS) are contained in the delivered materials. They must inform ZEISS immediately upon becoming aware of changes in legislation and if their products contain PFAS. This information must include the name of PFAS substance (if possible, including the CAS number) as well as their concentration in the delivered products. Once regulatory requirements become mandatory worldwide, suppliers are required to provide the necessary information immediately upon becoming aware of it.

14 Additional contractual prohibitions of certain substances

The substances and mixtures to be delivered to ZEISS, as well as substances and mixtures in articles, must not contain any of the following ingredients unless these substances have been explicitly approved by ZEISS in the order. If an exemption is granted in the order, the applicable legal substance and material regulations, as well as other legal requirements, must still be adhered to.

1. Substances that meet the criteria for classification in the hazard class Carcinogenicity category 1A, 1B, or 2 according to Annex I section 3.6 of Regulation (EC) No. 1272/2008.
2. Substances that meet the criteria for classification in the hazard class Germ cell mutagenicity category 1A, 1B, or 2 according to Annex I section 3.5 of Regulation (EC) No. 1272/2008.
3. Substances that meet the criteria for classification in the hazard class Reproductive toxicity category 1A, 1B, 2, or the category for effects on lactation according to Annex I section 3.7 of Regulation (EC) No. 1272/2008.
4. Substances that meet the criteria for classification in the hazard class Acute toxicity category 1, 2, or 3 according to Annex I section 3.1 of Regulation (EC) No. 1272/2008.
5. Substances that meet the criteria for classification in the hazard class Endocrine disruption affecting human health category 1 or 2 according to Annex I section 3.11 of Regulation (EC) No. 1272/2008.
6. Substances with endocrine-disrupting properties or those with persistent, bioaccumulative, and toxic properties (PBT) or very persistent and very bioaccumulative properties (vPvB), which are likely to have serious effects on human health or the environment according to

scientific knowledge, as per Article 57 letters d to f and Article 59 paragraph 1 of Regulation (EC) No. 1907/2006.

7. Materials or articles that contain harmful organisms, such as insects, worms, and fungi.
8. Radioactive substances, mixtures, and articles that undergo alpha, beta, or gamma decay, for example.
9. Asbestos (e.g., actinolite, amosite, anthophyllite, chrysotile, crocidolite, tremolite).

Other applicable documents

When referring to legal texts, the currently valid versions must be used.

- DIN IEC 63000
- REACH Regulation (EC) No. 1907/2006
- POP Regulation (EU) 2019/1021
- Stockholm Convention on Persistent Organic Pollutants (POPs)
- Mercury Regulation (EU) 2017/852
- Minamata Convention on Mercury
- RoHS Directive 2011/65/EU with delegated directives (EU) 2015/863, (EU) 2017/2102, and (EU) 2021/1925
- Medical Devices Regulation (EU) 2017/745
- EU Regulation for In-vitro Diagnostics (EU) 2017/746
- ISO 15223-1, 21 CFR
- Regulation (EU) 2024/590 on substances that lead to the depletion of the ozone layer, and repealing Regulation (EC) No. 1005/2009
- Clean Air Act
- Dodd–Frank Wall Street Reform and Consumer Protection Act (Dodd–Frank Act), Section 1502 Conflict Minerals
- EU Conflict Minerals Regulation (EU) 2017/821
- Fluorinated Greenhouse Gases Regulation (EU) 2024/573
- CLP Regulation (EC) No. 1272/2008
- Battery Regulation (EU) 2023/1542
- Packaging Regulation (EU) 2025/40
- TSCA Section 6a and 6h
- Safe Drinking Water and Toxic Enforcement Act of 1986 (California Proposition 65; CP65)

Past Issues

June 2023

Changes

- a) Chapter 1: The wording of the ZEISS Group was expanded to include "and all affiliated companies."
- b) Chapter 2 Definition 'Material': The definitions and terminology related to "Material" were expanded.
- c) Chapter 3 "Material Changes": A chapter to clarify the procedure for material changes was added.
- d) Chapter 4 "Material Declaration": A chapter to clarify the scenarios that trigger a new material declaration was added.
- e) Chapter 5 "Legal Substance Bans": Annex XVII of the REACH Regulation was moved to Chapter 6 "Consideration of Legal Substance Restrictions."
- f) Chapter 6 "Legal Substance Restrictions": The numbering of the legal requirement listings was changed; adjustment of wording and legal numbers; expansion to include fluorinated greenhouse gases according to Regulation (EU) 2024/573.
- g) Chapter 7 "Exemptions to Substance Restrictions": Additional mention of Annex IV of the RoHS Directive (EC) No. 2011/65; mandatory indication of the RoHS exemption number.

- h) Chapter 8 "Information and Declaration Obligations": The previous chapters 6 (Declaration obligation for ingredients), 8 (Regulations on the safety data sheet), and 9 (Further active information and declaration obligations, as well as regulation on declarable substances) were combined into one chapter.
- i) Chapter 9 "Medical Devices": A chapter to clarify the legal requirements according to MDR and IVDR was added; integration of the previous Chapter 10 "Labelling of Medical Devices with Plastic Parts" as Subchapter 9.3.
- j) Chapter 10 "Batteries": A chapter to clarify the legal requirements regarding batteries was added.
- k) Chapter 11 "Packaging": A chapter to clarify the legal requirements regarding packaging was added.
- l) Chapter 12 "Additional Legal Requirements": A chapter to clarify the requirements regarding TSCA Section 6a and 6h and the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Proposition 65; CP65) was added.
- m) Chapter 13 "PFAS-containing Products": A chapter to clarify the requirements regarding impending PFAS restrictions and bans was added.
- n) Chapter 14 "Contractual Substance Bans": The previous Chapter 7 was reformulated and moved to Chapter 14.
- o) Chapter "Applicable Documents": Adjustment of wording and legal numbers; expansion of the list to include additional legal requirements; removal of national legal requirements and outdated requirements.
- p) Annexes: Annexes for RoHS and REACH declarations were removed from the document and transferred to a separate Excel document.
- q) The department "Sustainability / Environmental Protection / Occupational Safety" was renamed to "Sustainability / Material Compliance."

specialized area

Sustainability / Material Compliance

contact person

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Original language

German; In case of discrepancies with the translation, the German original text is decisive.