

Prohibition and restriction of substances

new edition



Seeing beyond

Table of Contents

2	Terms and definitions	3
3	Compliance with legal substance prohibitions	3
3.1	General legal substance prohibitions	3
4	Compliance with legal material restrictions	4
4.1	General legal material restrictions	4
5 E	Exceptions to legal substance restrictions	4
5.1	Exceptions to legal substance restrictions	4
6	Duty of declaration for ingredients	4
7	Additional contractual prohibitions of certain substances	4
8	Regulations on the safety data sheet	5
9	Additional active information and declaration obligations, as well as rules on substances subject to declaration obligations	5
9.1	Regulation on declaration obligations for substances	5
9.2	Type, scope and time of declaration	5
10	Labeling of medical devices with plastic parts	6
	Other applicable documents	6
	Past Issues	6
	Changes	6
	specialized area	6
	contact person	6
	Original language	6
	Appendix A (normative) - REACH-SVHC template	7
	Appendix B (informative) - RoHS declaration template	9

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 applied for all suppliers of the ZEISS Group because this standard is also referred to in the general purchasing conditions or the separate framework supply agreements. This standard is thus applicable worldwide for all substances, mixtures, articles and packaging 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 exception to prohibitions on substances which aren't legally required.

2. Terms and definitions

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

3. Compliance with legal substance prohibitions

3.1 General legal substance prohibitions

The substances and mixtures to be supplied to ZEISS, as well as substances and mixtures in articles, must not contain any of the following ingredients:

1. All substances listed in Annex XVII (Restriction on the production, placing on the market and use of certain hazardous substances, mixtures and products) to REACH Regulation 1907/2006, as amended, and their prohibited uses (except the maximum permitted concentrations specified therein)
2. All substances listed in Annex XIV to REACH Regulation 1907/2006, as amended, that have exceeded the sunset date (unless an authorization has been granted, the authorized use and possible conditions for each delivery must be notified).
3. Mercury and its compounds and mixtures of mercury in accordance with the requirements of the Mercury Regulation 2017/852(EU).
4. Substances or materials which liberate gaseous formaldehyde with $>0.1 \text{ ml/m}^3$.

4. Compliance with legal substance restrictions

4.1 General legal material restrictions

The substances and mixtures to be supplied to ZEISS, as well as substances and mixtures in articles, may not contain any of the following ingredients except the legally specified limits or authorized uses.

1. Ozone-depleting substances contained in Council Regulation (EU) on substances that deplete the ozone layer (1005/2009) and substances of Class I and II of the United States Clean Air Act. Class I of this regulation includes fluorocarbons (CFCs), halons, bromomethane, tetrachloromethane and 1,1,1-trichloroethane; Class II includes hydrohalogenated fluorocarbons.
2. Restrictions according to RoHS Directive (EC) No 2011/65 with delegated Directive (EU) No 2015/863.
3. All mercury-added products listed in Annex II to Regulation (EU) 2017/852 (from the date specified therein) and new mercury-added products listed in Article 8.
4. All substances listed in Annex I to POP Regulation (EU) 2019/1021 as such or substances in mixtures and articles (except the maximum permitted concentrations specified therein).
5. All substances listed in Annex I No. 10.4.1 of Medical Device Regulation 2017/745/EC as such or substances in mixtures and products (except the maximum permitted concentrations specified therein).
6. Conflict minerals as defined in Section 1502 of the Dodd-Frank Act and the EU Conflict Minerals Regulation (EU) 2017/821: may only contain tin, tantalum, tungsten, their ores and gold (3TG) if they have been procured from certified conflict-free smelters.

5 Exceptions to legal substance restrictions

5.1 Exceptions to legal substance restrictions

Unless specified otherwise in the purchase order, the legal exceptions to the legal material restrictions may be applied. As soon as an exception is applied, ZEISS must be informed which ingredient is used in which product part and in what quantity (for RoHS also mention the exception number in accordance with Annex III Directive (EC) No. 2011/65).

6. Duty of declaration for 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 is possible for deliveries of substances and mixtures via the material safety data sheet in accordance with Article 31 of REACH Regulation (EC) No 1907/2006 or via a supplier certificate prepared in accordance with ZEISS guidelines. Proof of compliance with the substance prohibitions and substance restrictions must be provided on delivery of products via a suitable supplier declaration (all important contents according to ZEISS guidelines see appendices A and B) and, upon request, measurement reports from independent, accredited testing labs.

For conflict minerals, the current RMI Conflict Minerals Reporting Template is used to query for affected suppliers. When using 3TG, the supply chain must be checked for smelters and reported.

7. Additional contractual prohibitions of certain substances

The substances and mixtures to be delivered to ZEISS, as well as substances and mixtures in articles, may not contain any of the following ingredients, unless these substances were explicitly approved by ZEISS in the order. If an exception has been granted in the order, the legal material and material regulations applicable to the respective product, as well as other legal requirements, must still be observed.

1. Carcinogenic ingredients in accordance with EU classifications of chemicals legislation, Cat. 1A, 1B and 2. (referred to in Part 3 of Annex VI to Regulation (EC) No 1272/2008)
2. Substances that are toxic for reproduction according to EU classifications of chemicals legislation, Cat. 1A, 1B and 2. (referred to in Part 3 of Annex VI to Regulation (EC) No 1272/2008)
3. Genetically modifying ingredients in accordance with EU classifications of chemicals legislation, cat. 1A, 1B and 2. (as defined in Part 3 of Annex VI to Regulation (EC) No 1272/2008.)
4. Ingredients with endocrine disrupting properties which, based on scientific evidence, are likely to have serious effects on human health and which are determined in accordance with the procedure laid down in Article 59 of REACH Regulation (EC)

No 1907/2006 or, once the Commission has adopted a delegated act in accordance with Article 5(3)(1) of Regulation (EU) No 528/2012, in accordance with the criteria relating to human health laid down therein.

5. Very toxic and toxic ingredients according to EU classifications of chemicals legislation, Cat. 1, 2 and 3.
6. Materials or products containing harmful organisms, such as insects, worms and fungi.
7. Radioactive substances, mixtures and products capable of emitting, for example, alpha, beta or gamma rays.
8. asbestos (e.g. actinolite, amosite, anthophyllite, chrysotile, crocidolite, tremolite).

8. Regulations on the material safety data sheet

In the case of supplies of substances or mixtures containing dangerous ingredients in accordance with the criteria for classification under Titles I and II of Regulation (EC) No 1272/2008, the supplier shall provide a material safety data sheet in accordance with Article 31 and Annex II (REACH Regulation (EC) No 1907/2006).

9. Additional active information and declaration obligations, as well as rules on substances subject to declaration obligations

9.1 Regulation on declaration obligations for substances

Declaration obligations according to Article 33 of REACH Regulation (EC) No 1907/2006 are to be reported to ZEISS at the time of initial delivery and upon request; a transfer of the SCIP number of the product is desirable.

Ozone-damaging ingredients must be reported if the substances, mixtures or products to be supplied to ZEISS contain these substances (or have been used in their production).

The ingredients of metal alloys are deemed to be declared if they are listed and defined with limit values in a national or international standard (e.g. DIN, EN, ISO, ...) or in a specification agreed between ZEISS and the manufacturer.

9.2 Type, scope and time of declaration

The ingredients subject to declaration specified in this standard and other statutory declaration obligations must be specified during initial delivery and upon request by ZEISS. Templates for the preparation of a supplier declaration for selected rules are available in Appendix A and B (e.g. REACH-SVHC and RoHS).


Important content that a supplier declaration should contain are:

- Complete description of the legal text currently to be confirmed
- For certain lists, the list output date to be confirmed (e.g. REACH-SVHC candidate list)
- Name and address of the manufacturer and contact details
- ZEISS bill of materials/material number (and the manufacturer if applicable)
- Product description/name
- Date and location
- Name and signature of the authorized representative
- Where the products contain substances or substances subject to a declaration which use an exemption, the following additional information shall be required:
 - » The name of the substance
 - » CAS number
 - » The concentration in %
 - » An indication of the component in question in the component
 - » Number of the exception applied (e.g. in case of application of RoHS exceptions)
 - » Weight of the component concerned

10. Labeling of medical devices with plastic parts

For medical devices containing natural rubber or natural rubber latex, this symbol must be used on the medical device itself, on its packaging or in the relevant documents.

Excerpt from ISO 15223-1:

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.

Other applicable documentsn

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

- REACH Regulation 1907/2006/EC
- CLP Regulation 1272/2008/EU
- POP Regulation 2019/1021/EU
- Stockholm Convention on Persistent Organic Pollutants (BGBl. 2002 II p. 803, 804 and BGBl. 2009 II P. 1060, 1061)
- Minamata Convention on Mercury (BGBl. 2017 II p. 610, 611)
- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE-recast)
- Directive 2011/65/EC on the restriction of the use of certain hazardous substances in electrical and electronic components (RoHS recast with adaptation of Annex III and IV on 15.11.2017) + delegated directive (EU) 2015/863
- Medical Device Regulation 2017/745/EC
- Chemicals Act (ChemG)
- Ordinance on Hazardous Substances (GefStoffV)
- Chemicals Prohibition Ordinance (ChemVerbotsV)
- chemical ozone layer regulation
- German Packaging Act (VerpackG)
- Electrical and Electronic Equipment Act (ElektroG)
- Electrical Substances Ordinance (ElektroStoffV)
- Packaging Directive 94/92/EC
- Directive on batteries and accumulators 2006/66/EC
- Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act in short), Section 1502 Conflict Minerals
- EU Conflict Minerals Regulation (EU) 2017/821

Past Issues

new edition

Changes

specialized area

Sustainability / Environmental protection / Occupational health and safety

contact person

Birgit Rose, Alexandra Eisen

Original language

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

REACH SVHC - Statement

Liesupplier's name

Name of contact person

road

Zip/postal code and city

country

Hereby, _____ declares compliance with Article 33 of the REACH regulation (Regulation (EC) No. 1907/2006) of the European Parliament and of the Council according to "revision date of the last approved candidate list".

All substances identified as SVHC can be found at the following linked candidate list of the European Chemicals Agency (ECHA): <https://echa.europa.eu/de/candidate-list-table>.

In general, additional substances are added to the list twice a year.

_____ hereby declares that:

articles do not contain substances of very high concern (above 0,1% w/w)

articles containing substances of very high concern above 0,1 % (w/w)

The following table shows all ZEISS material numbers for which the declaration applies.

If the article contains substances of very high concern, the name of the substance of very high concern, the corresponding CAS number and its concentration in % are listed. If more detailed information about the affected components are available, these are also mentioned.

ZEISS material number(s) 000000-XXXX-XXX	Product description	SVHC > 0.1% (w/w) Yes or no	Substance name	CAS number	concentration (in %)	Affected component (with weight of the component concerned in g)

In case of a SVHC substance above the limit, are there activities planned to replace the substance with an alternative material to minimize the risk for humans and the environment? (Includes a modification of the material formula)

Yes

No

If not, should the product be discontinued in the foreseeable future (< 2 years)?

Yes

No

Place, date

Name of authorized representative

Authorized representative signature

position in the company

RoHS - material declaration

(Corresponds to the template set out in Directive 2011/65/EU and (EU) 2015/863, Annex VI)

Liesupplier's name

Name of contact person

road

Zip/postal code and city

country

We hereby confirm that the concerned product complies with Directive 2011/65/EU and Delegated Directive (EU) 2015/863 of the European Parliament and of the Council on the restriction of the use of hazardous substances in electrical and electronic equipment.

Articles do not contain any declarable substances / contain substances below the limit values in accordance with the RoHS directive (without the use of RoHS exceptions!)

(maximum permissible concentration in homogeneous materials referred to in Article 4, Paragraph 1 Annex II to Directive 2011/65/EU, limit values see the following)

substance	Limit value (percentage by weight)	substance	Limit value (percentage by weight)
Lead (Pb)	0,1	Polybrominated biphenyl ethers (PBDE)	0,1
Mercury (Hg)	0,1	Bis(2-ethylhexyl)phthalate (DEHP)	0,1
Hexavalent chromium (Cr(VI))	0,1	Butyl benzyl phthalate (BBP)	0,1
Cadmium (Cd)	0,01	Dibutyl phthalate (DBP)	0,1
Polybrominated biphenyls (PBB)	0,1	Diisobutyl phthalate (DIBP)	0,1

Articles contain declarable substances above the limit values, with the exception listed in the table below (Derogations exist for certain equipment groups, applications, components, and materials as defined in Article 4, Paragraph 1, Annex III and IV of Directive 2011/65/EU)

Articles contain declarable substances above the limit values (As a result, the products are considered "non-compliant")

The following table shows all ZEISS material numbers for which the declaration applies.

If articles contain declarable substances with concentrations higher than the specified limit values, the name of the declarable substance and its concentration in % is also given (if applicable for each affected component). If more detailed information about the affected component is available, these are also mentioned.

If any exemptions apply, they shall be indicated with the relevant number.

ZEISS material number(s) 000000-XXXX-XXX	Product description	Name of the declarable substance	Concentration (in %)	Affected component	Exception with no.

Place, date

Name of authorized representative

Authorized representative signature

position in the company