



EIZO GmbH

Siemensallee 84, 76187 Karlsruhe/Germany
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Material Compliance Directive



Material Compliance Directive

History of the Material Compliance Directive

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www.tec4U-solutions.com

Signed: Peter Ziegler
Peter Ziegler
Managing Director (CEO)

Signed: Dirk Schwalm
Dirk Schwalm
Material Compliance Officer

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1 Introduction

This Material Compliance Directive is intended to ensure that substances and articles are handled in a material-compliant manner during development, production, trade, and use.

This Material Compliance Directive outlines EIZO GmbH's requirements with respect to known legally prohibited, regulated, and declarable substances in their current form.

In the event that legislative amendments are not yet reflected in this directive, suppliers are not released from the obligation to take these amendments into account and to comply with the legal regulations currently in force.

Suppliers are obliged to obtain the current directives, legislation, and guidelines for themselves.

The material compliance requirements are of equal validity with other product requirements.

The Material Compliance Directive requires that all products and their packaging conform to the requirements set out in this document, with the aim of guaranteeing that products are placed on the market in compliance with the regulations.

Products and raw materials of unknown origin or composition, or raw materials for which there are no sufficient material data, must not be used.

In individual cases, EIZO GmbH must be provided on request with technical data sheets for all used raw materials and auxiliary materials for initial sampling. EIZO GmbH reserves the right, in individual cases, to carry out tests and laboratory investigations on materials.

Suppliers of EIZO GmbH are obliged to submit, free of charge, the material information required in order to test materials for compliance with the legal regulations and with this directive.

EIZO GmbH's Material Compliance Directive is available on its website.

Suppliers are obliged to check, at least every 6 months, that the latest version of the Material Compliance Directive is available. If the Material Compliance Directive is amended, the amended version replaces the previous version and comes into force immediately. EIZO GmbH will not notify suppliers of amendments to the Material Compliance Directive.

This Material Compliance Directive was created by tec4U-Solutions GmbH, Saar-Lor-Lux-Strasse 13, D-66115 Saarbrücken, Germany. The directive may be used and/or reproduced by the company EIZO GmbH and all participants in its supply chain. Approval must be obtained from tec4U-Solutions GmbH for any use of the directive, either in whole or in part, by parties outside the supply chain.

2 Terms and abbreviations

Substance

A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (see REACH, Article 3, paragraph 1).

Examples of chemical compounds

- Organic: ethanol, aldehyde
- Metallic: iron, copper, tin
- Mineral: clay, loam

Preparation

A mixture or solution comprising two or more substances (mixture and preparation are synonyms).

Examples of preparations

- Mixture: seeds
- Mixture: alloy
- Solution: octane in benzene

Homogeneous material

A material of uniform composition throughout or a material consisting of a combination of materials that cannot be disjoined or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding, and abrasive processes (see RoHS Article 3, paragraph 20). Examples of homogeneous materials include individual types of plastics, ceramics, glass, metals, alloys, resins, and coatings.

Intentionally added

Generally refers to the intentional use of a substance contained in an article in order to generate a certain characteristic, function, appearance, or intended quality.

Battery or accumulator

A source of electrical energy, consisting of one or more (non-rechargeable) primary cells or one or more (rechargeable) secondary cells, obtained by the direct conversion of chemical energy.

Packaging

Products manufactured from any substance for the containment, protection, handling, delivery, and presentation of goods, ranging from raw materials to processed articles that are transmitted from the manufacturer to the user or consumer. All “disposable items” used for the same purpose shall also be considered as packaging (see EU Packaging Directive, Article 3, paragraph 1).

Packaging components

Parts of the packaging that can be detached by hand or by simple mechanical processes. Additional elements that are suspended from or attached directly to a product and that fulfill a packaging function are also considered as packaging, unless they are integral parts of the product.

Prohibited substances

Prohibited substances must not be contained in articles, components, materials, preparations, or auxiliary and operating materials in quantities exceeding the limit values specified in this document. These substances may be contained only in the form of naturally existing impurities; they must not be intentionally added. Qualitative information must be provided for impurities containing these substances.

Declarable substances

Declarable substances are substances that are undesirable in particular applications, and that must be declared if they exist in quantities that exceed the specified limit values. The listed substances must be specified for every article, component, material, substance, preparation, and auxiliary or operating material. Limit values are specified for the individual substances in this document. These substances do not need to be declared if they exist in quantities below the limit values.

Article

An object that, during production, is given a special shape, surface, or design that determines its function to a greater degree than does its chemical composition.

Latest application date

The date by which the authorization application must be received (at least 18 months before the sunset date) in order that the substance can continue to be used (deadline).

Information on the authorization application and the formal process can be found at:

<https://echa.europa.eu/de/applying-for-authorisation>

Sunset date

The date after which the placing on the market or use of any substance listed in Annex XIV of the REACH Regulation is prohibited, unless an authorization has been granted.

Allergens

An allergen is a substance that can trigger hypersensitivity reactions (allergic reactions) due to activation of the immune system.

CAS number

The CAS number (also known as the CAS registration number or CAS registry number; CAS = Chemical Abstracts Service) is an international naming standard for chemical substances. There is a unique CAS number for all chemical substances (including biosequences, alloys, and polymers) registered in the CAS database.

Biocidal products

A biocidal product is any substance or mixture in the form in which it is provided to the user, that comprises one or more active substances or that contains or produces such substances, and that is intended to destroy, deter, render harmless, or exert a controlling effect on any harmful organism by any means other than mere physical or mechanical action.

A biocidal product is also any substance or mixture that is produced by substances or mixtures that are not themselves covered by the first point, and that is intended to destroy, deter, render harmless, or exert a controlling effect on any harmful organism by any means other than mere physical or mechanical action.

Goods treated with biocidal products

All substances, mixtures, or articles that have been treated with one or more biocidal products, or that intentionally contain one or more biocidal products, are referred to as treated goods.

Resources/assistance

- Platform for European regulations, directives, and decisions, in all existing versions and official European languages – the year of publication and the publication number must be entered in the search field:
<http://eur-lex.europa.eu/>
- Support area of the European Chemicals Agency (ECHA):
<https://echa.europa.eu/support/guidance>
- REACH CLP Biocide Helpdesk – National Federal Information Center:
<http://www.reach-clp-biozid-helpdesk.de/de/Startseite.html>
- REACH Helpdesk – German Federal Environment Agency:
<http://www.reach-info.de>
- Platform for German legislation:
<https://www.gesetze-im-internet.de/>

3 EIZO GmbH list of legally regulated substances

3.1 Substance regulations and prohibitions – Relevant for all products

The substance-related requirements set out under Section 3.1 apply to all substances, preparations, and articles. The application framework is described in detail in the respective law.

3.1.1 Regulation (EC) No. 1907/2006 REACH – Annex XIV – Authorization List

If a substance from the List of Substances of Very High Concern is included in Annex XIV of the REACH Regulation, it means that the substance will require authorization at the end of the procedure. Following a transitional period, the substance will be permitted for use exclusively with an authorization, or its use will be prohibited.

Explanations of the terms “latest application date” and “sunset date” are provided in Section 2 – Terms and abbreviations.

The current version of Annex XIV of the REACH Regulation can be found on the following link:

<https://echa.europa.eu/de/authorisation-list>

3.1.2 Regulation (EC) No. 1907/2006 REACH – Annex XVII – Restricted Substance List

In Annex XVII of the REACH Regulation, precisely defined substances are regulated or prohibited in individual applications.

The current version of Annex XVII of the REACH Regulation can be found on the following link:

<https://echa.europa.eu/de/substances-restricted-under-reach>

3.1.3 Directive 2011/65/EU – RoHS

Directive 2011/65/EU of the European Parliament and of the Council of June 8, 2011, on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) entered into force on January 2, 2013.

The RoHS substance regulations relate to maximum concentrations in the homogeneous material of each article.

Table 1: Substance regulations from the RoHS Directive

| Substance groups | Maximum concentration in homogeneous material, in percent |
|---|---|
| Cadmium and cadmium compounds | 0.01% |
| Hexavalent chromium (Cr6+) and Cr6+ compounds | 0.10% |
| Lead and lead compounds | 0.10% |
| Mercury and mercury compounds | 0.10% |
| Polybrominated diphenyl ether (PBDE) | 0.10% |
| Polybrominated biphenyl (PBB) | 0.10% |
| Extension as of 07/22/2019 | |
| Bis(2-ethylhexyl) phthalate (DEHP) | 0.10% |
| Benzyl butyl phthalate (BBP) | 0.10% |
| Dibutyl phthalate (DBP) | 0.10% |
| Diisobutyl phthalate (DIBP) | 0.10% |

The restriction on DEHP, BBP, DBP, and DIBP applies to all medical devices, including in vitro diagnostics, as well as to monitoring and control equipment, including monitoring and control equipment in industry, as of July 22, 2021.

3.1.4 Chemicals Prohibition Ordinance – ChemVerbotsV (Chemikalien-Verbotsverordnung)

The Ordinance on Prohibitions and Restrictions on the Marketing and Placing on the Market of Certain Hazardous Substances, Mixtures, and Articles under the German Chemicals Act is a German federal law that sets out special national requirements in addition to the REACH Regulation. Due to the fact that the REACH Regulation applies directly to EU member states, an amendment to the Chemicals Prohibition Ordinance was adopted in 2016 that combines the requirements of the REACH and CLP regulations with existing German chemicals legislation. National requirements for the following substances and groups of substances are also defined:

Table 2: ChemVerbotsV substances and substance groups

| Substance/mixture |
|--------------------------|
| Formaldehyde |
| Dioxins and furans |
| Pentachlorophenol |
| Biopersistent fibers |

Specific requirements and exceptions can be found in the text of the law.

The requirements of the new Chemicals Prohibition Ordinance entered into force on 01/01/2019.

<http://www.gesetze-im-internet.de/chemverbotsv/>

3.1.5 Regulation (EC) No. 850/2004 on persistent organic pollutants (POPs)

This EU regulation implements the Stockholm Convention on persistent organic pollutants, among other substances. The Stockholm Convention, also known as the POPs Convention, is an agreement on measures that are binding under international law to prohibit and restrict certain long-lasting organic pollutants. The convention prohibits or restricts the production, use, and trade of 22 hazardous chemicals.

More information on the Stockholm Convention and the listed substances can be found on the official website on the following link:

<http://chm.pops.int/>

The text of the European implementation of the convention can be found on the European Union platform:

<http://eur-lex.europa.eu/>

3.1.6 Directive 94/62/EC – The Packaging Directive

DIRECTIVE 94/62/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, of December 20, 1994, on packaging and packaging waste restricts the concentration of heavy metals in packaging.

Table 3: Restrictions on substances in packaging

| Pure substances and substance groups | Maximum concentration in packaging or packaging components in ppm by weight |
|---|---|
| Lead, cadmium, mercury, and hexavalent chromium | 100* |

3.1.7 Product Safety Act (ProdSG – Produktsicherheitsgesetz)

The German Product Safety Act (ProdSG) is the successor act to the original Equipment and Product Safety Act and has been in force since December 1, 2011. It is the central legal regulation for the safety of equipment, products, and systems.

A total of 11 European internal market directives, as well as the General Product Safety Directive 2001/95/EC, have been transposed into German law by the ProdSG and the Product Safety Regulations (ProdSV – Produktsicherheitsverordnungen), which were published on the basis of Article 8 of the ProdSG.

This law is applicable whenever products are placed on the market, displayed, or used for the first time as part of business operations. In accordance with Article 3, placing on the market is permitted only “if there is no danger to the health and safety of persons when used for its intended purpose or under conditions that can reasonably be foreseen.”

In addition to these European aspects, the ProdSG also contains sections of purely German origin, for example regulations on the GS mark in Article 5 of the law.

http://www.gesetze-im-internet.de/prodsg_2011/index.html

3.2 Substance regulations and prohibitions – Relevant to products with different scopes of applicability

Unlike the substance regulations referred to in Section 3.1, in this case suppliers must ascertain whether their products fall within the scope of applicability of the particular requirement. If a supplier is not able to clarify this independently, they must consult with EIZO GmbH. Another decisive factor for suppliers is the specific division of EIZO GmbH with which they have a business relationship.

3.2.1 Directive 2006/66/EC – The Battery Directive

Directive 2006/66/EC of the European Parliament and of the Council of September 6, 2006, on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC, restricts the use of mercury and cadmium in batteries and accumulators.

Table 4: Substance regulations in the Battery Directive

| Pure substances | Maximum concentration in the produce in percent | Application restrictions |
|-------------------------------|---|-----------------------------------|
| Mercury and mercury compounds | 0.0005% | Batteries and accumulators |
| Cadmium and cadmium compounds | 0.002% | Device batteries and accumulators |

3.3 Declarable substances

3.3.1 SVHC Candidate List

The current version of the official SVHC Candidate List in accordance with the REACH Regulation (1907/2006/EC) can be accessed at the following address:

http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

at any time.

In accordance with Article 33 of the REACH Regulation, all suppliers are subject to the following obligations:

(1) Any supplier of an article containing a substance meeting the criteria in Article 57 and identified pursuant to Article 59(1) in a concentration above 0.1% (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article, including, as a minimum, the name of that substance.

Substances of Very High Concern (SVHC Candidate List) in

- Components
- Spare parts
- Accessories
- Packaging

If the supplied articles contain SVHC substances included in the Candidate List pursuant to Article 59, paragraph 1, of Regulation 1907/2006/EC in a concentration above 0.1% (w/w), the contractor is obliged to provide at the time of delivery, and without being requested, all information pursuant to Article 33, Section 1, of Regulation 1907/2006/EC. This also applies if the substance is included in the Candidate List only during the supply relationship.

The information must be provided to private consumers free of charge within 45 days of receipt of the request.

In accordance with the decision of the European Court of Justice, the concept “once an article, always an article” applies. As soon as an article exceeds the concentration limit of 0.1%, the existence of this SVHC candidate substance must be reported.

3.3.2 Proposition 65

The Californian Safe Drinking Water and Toxic Enforcement Act of 1986 is commonly abbreviated to the “California Proposition 65,” or simply “CP65.” Central to this law is the following requirement:

“No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state [of California] to cause cancer or reproductive toxicity without first giving clear and reasonable warning.”

The State of California publishes a list of substances that meet these criteria on the following website: <https://oehha.ca.gov/proposition-65/proposition-65-list>

Firstly, it must be ascertained whether a product is a consumer product or a product for trade and industry. Proposition 65 applies exclusively to consumer products.

If a product contains a substance listed in Proposition 65, and if user exposure cannot be ruled out, this must be communicated to MEDI-GLOBE TECHNOLOGIES GMBH.

Further information can be found at: <https://oehha.ca.gov/proposition-65>

Table 5: Likely Proposition 65 substances in electrical and electronic components

| Pure substance, substance group | Concentration |
|---|--|
| Lead and lead compounds | 0.009% (90 ppm) of any material |
| Bisphenol A (BPA) | 0.0003% (3 ppm) of any material |
| Plasticizers | |
| Diisononyl phthalate (DiNP) | No intentionally added content |
| Diisodecyl phthalate (DIDP) | No intentionally added content |
| Di-n-hexyl phthalate (DnHP) | No intentionally added content |
| Flame retardants and plasticizers | |
| Tris(1.3-dichloro-2-propyl)phosphate (TDCPP) | 0.0025% (w/w) (25 ppm) of any material |
| Tris(2-chloroethyl) phosphate | 0.0025% (w/w) (25 ppm) of any material |
| Tris(2.3-dibromopropyl)phosphate | 0.0025% (w/w) (25 ppm) of any material |
| Flame retardants | |
| Antimony oxide (antimony trioxide) | 0.1% (w/w) (1000 ppm) of any material |
| Tetrabromobisphenol A | 0.1% (w/w) (1000 ppm) of any material |
| 2.2-bis(bromomethyl)-1.3-propanediol | 0.1% (w/w) (1000 ppm) of any material |
| Mirex* | 0.1% (w/w) (1000 ppm) of any material |
| UV protection agents | |
| Benzophenone | 0.1% (w/w) (1000 ppm) of any material |
| Dyes | |
| Benzidine-based dyes | 0.1% (w/w) (1000 ppm) of any material |
| 3.3'-Dimethoxybenzidine-based dyes metabolized to 3.3'-Dimethoxybenzidine | 0.1% (w/w) (1000 ppm) of any material |
| 3.3'-Dimethylbenzidine-based dyes metabolized to 3.3'-Dimethylbenzidine | 0.1% (w/w) (1000 ppm) of any material |
| D&C Orange No. 17 | 0.1% (w/w) (1000 ppm) of any material |
| 1-Amino-2.4-dibromoanthraquinone | 0.1% (w/w) (1000 ppm) of any material |
| 1-Amino-2-methylantraquinone | 0.1% (w/w) (1000 ppm) of any material |
| Direct Blue 6 (Technical Grade) | 0.1% (w/w) (1000 ppm) of any material |
| Direct Brown 95 (Technical Grade) | 0.1% (w/w) (1000 ppm) of any material |
| Disperse Blue 1 | 0.1% (w/w) (1000 ppm) of any material |
| Naphthalene | 0.0001% (w/w) (1 ppm) of any material |

* Source of regulation: POPs Regulation

3.3.3 Conflict minerals

USA

The Dodd–Frank Act is a US law, passed in July 2010, which obliges companies listed on the US stock market to refrain from using raw materials from regions of conflict. Since the law was passed, companies that use conflict minerals must provide a separate report on the origin of the minerals. Within the terms of the law, conflict minerals are considered to be cassiterite, coltan, wolframite, and gold, which are used to produce the following four metals, referred to collectively as 3TG:

- Gold
- Tin
- Tantalum
- Tungsten

If EIZO GmbH receives any inquiries from its customers regarding the origin of conflict minerals, it will forward these inquiries to its suppliers.

Reference for additional information:

<https://www.sec.gov/News/Article/Detail/Article/1365171562058>

The Excel sheet available at

<http://www.responsiblemineralsinitiative.org/>

is the preferred form for making a declaration.

European Union

The European Parliament has opted for an approach of due diligence regarding imports of conflict minerals. The EU regulation on supply chain due diligence obligations for European Union importers of tin, tantalum, and tungsten and their ores and gold originating from conflict-affected and high-risk areas from May 17, 2017, entered into force on June 8, 2017.

Larger manufacturers must also provide information on how they are achieving compliance with the requirements of the new regulation, right from the source of the raw materials.

Large companies with over 500 employees that purchase tin, tantalum, tungsten, and gold for use in their products will have to disclose their procurement practices in future. They will then be recorded in an EU register.

3.4 Requirements of the BOMcheck material database

In order for EIZO AG to meet the extended requirements of its customers with regard to material declarations, it requires additional information from its suppliers in relation to the substances and substance groups listed under Sections 3.4.1 and 3.4.2.

3.4.1 Substances restricted by industry

In addition to the laws and regulations already mentioned, there are additional substance restrictions imposed by industry. If a listed substance is present in quantities above the specified limit values, this must be declared.

Table 6: Substances restricted by industry

| Pure substance, substance group | Concentration | Note – source of the regulation |
|---|--|---------------------------------------|
| Brominated flame retardants (except for PBBs, PBDEs or HBCDD) | 0.1% (w/w) total bromine content from brominated flame retardants | Original equipment manufacturer (OEM) |
| Brominated flame retardants (except for PBBs, PBDEs or HBCDD) | 0.09% (w/w) total bromine content from brominated flame retardants in PCB laminate | |
| Chlorinated flame retardants | 0.1% (w/w) total chlorine content from chlorinated flame retardants | |
| Chlorinated flame retardants | 0.09% (w/w) total chlorine content from chlorinated flame retardants in PCB laminate | |
| Polyvinyl chloride (PVC) and PVC copolymers | 0.1% (w/w) total chlorine content from PVC | |
| Antimony trioxide in plastic articles | 0.1% (w/w) in plastic parts | |
| Phthalates | 0.1% (w/w) | |

3.4.2 Additional restricted or declarable substances

Table 7: Additional restricted or declarable substances

| Pure substance, substance group | Concentration | Note – source of the regulation |
|---|--|---------------------------------|
| Formaldehyde | No intentionally added content in wood composite products or components (plywood, chipboard, and MDF) and textiles | REACH Regulation |
| Pentachlorophenol (PCP) | No intentionally added content | POPs Regulation |
| Polychlorinated and polybrominated dioxins and furans | No intentionally added content | POPs Regulation |
| Radioactive substances | No intentionally added content | |
| Biocides | No intentionally added content | Biocide Regulation |
| PFOS | 0.1% (w/w) | POPs Regulation |
| HBCDD (hexabromocyclododecane) | 0.01% (w/w) | POPs and REACH Regulations |
| Chlorinated paraffins (SCCP C10–C13) | No intentionally added content | POPs Regulation |
| Polychlorinated biphenyls (PCB) | No intentionally added content | POPs Regulation |
| Polychlorinated naphthalenes | No intentionally added content | POPs Regulation |
| Bisphenol A (BPA) | | REACH Regulation |

3.5 Auxiliary production substances and operating substances

3.5.1 Safety data sheets (SDS)

The safety data sheet is the central element of communication in the supply chain for harmful substances and mixtures. It provides information on the following aspects:

- Identity of the product
- Hazards
- Safe handling
- Prevention measures
- Measures in the event of a hazard.

The requirements in terms of the content and format of the safety data sheet are set out in Article 31 and Annex II of the REACH Regulation (EC) No. 1907/2006.

The supplier of a substance/mixture is responsible for ensuring that the safety data sheet is filled out correctly and completely.

The safety data sheet must be submitted to EIZO GmbH on paper, in electronic form, or as a free download on the day of the first delivery at the latest.

Suppliers must immediately update the SDS (Article 31[9]) if

- new information becomes available that could affect the risk management measures,
- an approval has been granted or rejected,
- a restriction has been issued.

The corrected version must be submitted to the customer if the customer has received a delivery within the last 12 months.

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