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# Material Compliance Guideline

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## 1 Purpose

This Material Compliance Policy (“MCP”) aims to ensure the legally compliant composition and use of substances, mixtures, and articles during development, manufacturing, trading, use, and disposal. This MCP defines Leica Camera AG’s (“Leica”) requirements, and those of its affiliated companies, toward suppliers with respect to all legally restricted and declaration-relevant substances, mixtures, and articles. If new legislation or legislative amendments are not yet reflected in this policy, this does not release the supplier from the obligation to consider them and comply with the currently applicable legal requirements. The supplier is responsible for obtaining the texts of all applicable regulations, directives, laws, standards, and other provisions.

The material compliance requirements apply equally to all other product requirements of Leica and do not replace them.

The supplier guarantees that all products and packaging supplied to Leica (“Leica Product”) comply with the applicable regulations, directives, laws, standards, and other provisions as well as with this MCP, in order to ensure compliant placing on the market and disposal.

Substances, mixtures, articles, and components for which no sufficient material information is available may neither be supplied to Leica nor used in Leica Products.

The supplier commits to providing, free of charge, the material information required to verify compliance with legal requirements and with the MCP. As soon as the supplier becomes aware that any substances, mixtures, or articles do not comply with legal requirements or with the MCP, Leica must be notified immediately in writing. Any costs arising from inspections or laboratory analyses shall be borne by the supplier. Leica prefers to work with suppliers who upload the requested material information to the DataCross platform.

Leica provides the MCP on its website. The most recent version replaces the previous one and becomes effective immediately.

The supplier will not be notified of updates to the MCP. It is the supplier’s responsibility to verify at least once a year that they hold the current valid version.

This MCP was prepared by tec4U - Solutions GmbH, Saar-Lor-Lux-Straße 13, D-66115 Saarbrücken. Use and reproduction are permitted for Leica and the participants of the supply chain. Any use, in whole or in part, outside the supply chain requires prior written consent from tec4U - Solutions GmbH.

## 2 Scope

This MCP applies to all substances, mixtures, or articles delivered to Leica or to companies affiliated with Leica, unless otherwise specified below.



### 3 Additional Definitions

This section defines terms that are not used directly in this policy but are relevant for understanding the broader subject matter. These definitions are intended to provide clarity and a common understanding.

#### **Sunset Date:**

The date after which the placing on the market and use of a substance listed in Annex XIV of Regulation (EC) No. 1907/2006 is prohibited unless an authorisation has been granted.

#### **Intentionally Added:**

Commonly known as the deliberate use of a substance incorporated into an article to achieve a specific property, appearance, function, or quality.

#### **Latest Application Date:**

The date by which an authorisation application under Regulation (EC) No. 1907/2006 must be submitted (at least 18 months prior to the sunset date) in order to allow continued use of the substance.

Information on authorisation applications and the formal procedure can be found at:  
<https://echa.europa.eu/applying-for-authorisation>

#### **Application:**

Indicates that the concentration limit of the substance refers to the material or component in which the substance is present to achieve a desired functionality.

#### **Battery:**

A device that supplies electrical energy generated by direct conversion of chemical energy, has an internal or external storage function, consists of one or more non-rechargeable or rechargeable cells, modules, or packs, and includes batteries prepared for reuse, repurposing, or remanufacturing (see Regulation (EU) 2023/1542, Art. 3(1)(1)).

#### **Biocidal Product:**

Any substance or mixture, in the form supplied to the user, consisting of, containing, or generating one or more active substances, and intended to destroy, deter, render harmless, prevent the action of, or otherwise control harmful organisms other than by mere physical or mechanical action; and any substance or mixture generated from substances or mixtures not falling under the first indent but intended for any of the same purposes (see Regulation (EU) 528/2012, Art. 3(1)(1)(a)).

#### **Treated Article with a Primary Biocidal Function:**

A treated article whose primary function is biocidal is considered a biocidal product (see Regulation (EU) 528/2012, Art. 3(1)(1)(e)).

#### **Restricted Substances:**

Substances that must not be present in mixtures or articles above applicable limit values.

#### **CAS Number:**

The CAS number (Chemical Abstracts Service Registry Number) is an international identifier for



chemical substances. Each substance registered in the CAS database (including biosequences, alloys, and polymers) has a unique CAS number.

### **Declarable Substances:**

Substances classified as declarable are undesirable in certain applications and must be declared when present above specified thresholds. The listed substances must be reported for each article, component, material, mixture, auxiliary, or operating material. Below the threshold, declaration is not required.

### **Endocrine Disruptors:**

Chemicals or mixtures that interfere with the natural biochemical activity of hormones and may cause harmful effects (e.g., growth or developmental disorders, reproductive impairment, or increased susceptibility to certain diseases).

### **Article:**

An object which during production is given a special shape, surface, or design that determines its function to a greater degree than its chemical composition (see Regulation (EC) No. 1907/2006, Art. 3(3)).

### **Mixture:**

A mixture or solution composed of two or more substances (see Regulation (EC) No. 1907/2006, Art. 3(2)).

Examples include:

- Mixture: paint
- Solution: octane in gasoline
- Blend: seeds

### **Portable Battery:**

A sealed battery with a weight of 5 kg or less, not specifically designed for industrial use, and not an electric vehicle battery, LV battery, or starter battery (see Regulation (EU) 2023/1542, Art. 3(1)(9)).

### **Homogeneous Material:**

A material of uniform composition throughout, or a material consisting of multiple substances that cannot be mechanically disjointed into separate materials (e.g., by unscrewing, cutting, crushing, grinding, or abrasion) (see Directive 2011/65/EU, Art. 3(20)).

Examples: plastic, ceramic, glass, alloy, coating.

### **Industrial Battery:**

A battery specifically designed for industrial use, prepared for reuse or repurposing for industrial use, or any other battery weighing more than 5 kg that is neither an LV battery, electric vehicle battery, nor starter battery (see Regulation (EU) 2023/1542, Art. 3(1)(13)).

### **Micro, Small, and Medium-Sized Enterprises (SMEs):**

As defined in Article 3 of Directive 2013/34/EU.

### **Persistence (Chemistry/Biology):**

Resistance of organic chemical compounds to chemical, physical, or biological degradation.

**Product:**

Any item, supplied or made available—whether for payment or free of charge, including in the context of a service—that is intended for consumers or is reasonably foreseeable to be used by consumers even if not intended for them (see Regulation (EU) 2023/988, Art. 3(1)(1)).

**Safe Product:**

Any product that, under normal or reasonably foreseeable conditions of use (including duration of use), presents no risks or only minimal, acceptable risks compatible with a high level of health and safety protection for consumers (see Regulation (EU) 2023/988, Art. 3(1)(2)).

**Substance:**

A chemical element and its compounds in the natural state or obtained by any manufacturing process, including additives necessary to preserve stability and impurities deriving from the process, but excluding solvents which may be separated without affecting stability or composition (see Regulation (EC) No. 1907/2006, Art. 3(1)).

Examples include:

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

**Partial Declaration:**

Refers to a declaration that only addresses the presence of declarable or restricted substances above relevant thresholds. It does not provide information on the full composition of the item.

**Packaging:**

Any item—regardless of material—intended to contain, protect, handle, deliver, or present a product.

This includes sales packaging, outer packaging, and transport packaging.

The PPWR adopts the definition from Directive 94/62/EC without substantive changes.

**Full Declaration:**

A declaration requiring all chemical compounds and elements present above a declaration threshold to be listed. The total of all reported substances must equal 100%.

**Support Resources:**

EUR-Lex platform for European regulations, directives, and decisions: <http://eur-lex.europa.eu/>

European Chemicals Agency (ECHA) guidance portal: <https://echa.europa.eu/support/guidance>

German REACH-CLP-Biocides Helpdesk: <http://www.reach-clp-biozid-helpdesk.de/de/Startseite.html>

German legislation platform: <https://www.gesetze-im-internet.de/>

REACH network Baden-Württemberg: <https://www.reach.baden-wuerttemberg.de/>

## 4 List of Legally Regulated Substances

### 4.1 Substance Regulations and Prohibitions – Applicable to All Products

The substance-related regulatory requirements described in Section 4.1 apply to all substances, mixtures, and articles.

## 4.1.1 Regulation (EC) No. 1907/2006 (REACH) – Annex XIV – List of Substances Subject to Authorisation

The inclusion of a substance from the Candidate List of Substances of Very High Concern (SVHC) in Annex XIV of Regulation (EC) No. 1907/2006 ultimately results in an authorisation requirement for that substance. After a transitional period, the substance may only be used if an authorisation has been granted; otherwise, its use is restricted.

The relevant dates – the Latest Application Date and the Sunset Date – must be observed (see Section 3, Definitions).

The current version of REACH Annex XIV can be accessed at the following link:

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

## 4.1.2 Regulation (EC) No. 1907/2006 (REACH) – Annex XVII – List of Restricted Substances

Annex XVII of Regulation (EC) No. 1907/2006 lists substances that are restricted by the legislator for defined applications. The current version of Annex XVII of Regulation (EC) No. 1907/2006 can be accessed at the following link:

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

## 4.1.3 Directive 2011/65/EU – RoHS

Directive 2011/65/EU of the European Parliament and of the Council regulates the restriction of the use of certain hazardous substances in electrical and electronic equipment. All substances, mixtures, or articles supplied by a supplier must also comply with these substance restrictions.

The substance restrictions under Directive 2011/65/EU refer to the maximum concentration values in homogeneous materials.

Any exemptions listed in Annex III that are used by a supplier must be communicated to Leica without prior request. The current catalogue of exemptions can be accessed at:

[https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive\\_en](https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en)

**Table 1: Substance Restrictions under Directive 2011/65/EU**

Substances / Substance Groups	CAS-Nr.	Maximum Concentration in Homogeneous Material (percent by weight)
Cadmium and cadmium compounds	Stoffgruppen	0,01 %
Hexavalent chromium (Cr6+) and Cr6+ compounds		0,1%
Lead and lead compounds		
Mercury and mercury compounds		
Polybrominated diphenyl ethers (PBDE)		



Substances / Substance Groups	CAS-Nr.	Maximum Concentration in Homogeneous Material (percent by weight)
Polybrominated biphenyls (PBB)		
Di(2-ethylhexyl) phthalate (DEHP)	117-81-7	
Butylbenzylphthalate (BBP)	85-68-7	
Dibutylphthalate (DBP)	84-74-2	
Diisobutylphthalate (DIBP)	84-69-5	

#### 4.1.4 Ordinance on Prohibitions and Restrictions on the Placing on the Market of Hazardous Substances, Mixtures, and Articles (ChemVerbotsV)

The Ordinance on Prohibitions and Restrictions on the Placing on the Market of Hazardous Substances, Mixtures, and Articles under the German Chemicals Act is a national regulation that defines specific German requirements in addition to Regulation (EC) No. 1907/2006.

It additionally establishes national requirements for the following substances and substance groups:

**Table 2: Prohibitions on Placing Substances/Mixtures on the Market under the ChemVerbotsV**

Substances / Mixtures
Formaldehyde
Dioxins and furans
Pentachlorophenol
Biopersistent fibres

Suppliers must refer to the legal text for the requirements effective as of 1 January 2019, including all applicable exemptions.

[http://www.gesetze-im-internet.de/chemverbotsv\\_2017/index.html](http://www.gesetze-im-internet.de/chemverbotsv_2017/index.html)

#### 4.1.5 Regulation (EU) 2019/1021 on Persistent Organic Pollutants (POPs)

This EU regulation implements the Stockholm Convention on Persistent Organic Pollutants. The Stockholm Convention is an international agreement establishing legally binding prohibitions and restrictions on certain long-lasting organic pollutants. Accordingly, the Convention prohibits or restricts the manufacture, use, and trade of hazardous substances, mixtures, and articles.

Further information on the Stockholm Convention is available on the official website at the following link:

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

#### 4.1.6 Regulation (EU) 2025/40 on Packaging and Packaging Waste (PPWR)

To implement the EU Packaging Regulation (PPWR), which becomes applicable from 12 August 2026, new requirements for packaging must be observed. Packaging may not contain certain hazardous substances – such as lead, cadmium, mercury, and hexavalent chromium – in concentrations



exceeding 100 mg/kg each; PFAS are prohibited in certain cases. Material data, recycling evidence, and information on material origins must be provided.

From August 2026 onward, only compliant packaging may be used.

**Table 3: Substance Restrictions under the PPWR**

Substances	CAS-Nr.	Maximum Concentration in Packaging or Packaging Components (ppm by weight)
Cadmium and its compounds	7440-43-9	100 mg/kg per individual substance ( $\approx$ 100 ppm)
Lead and its compounds	7439-92-1	
Chromium VI and its compounds	1333-82-0	
Mercury and its compounds	7439-97-6	

## 4.1.7 Product Safety Act (ProdSG)

The Regulation (EU) 2023/988 (General Product Safety Regulation, GPSR) entered into force on 12 June 2023 and becomes applicable on 13 December 2024. This regulation replaces Directive 2001/95/EC, which had been implemented in Germany through the Product Safety Act (ProdSG).

Products may be placed on the Union market only if, under normal or reasonably foreseeable conditions of use, they pose no risks or only minimal risks that are considered acceptable and compatible with a high level of protection of consumers' health and safety.

"Placing on the market" refers to any supply of a product for distribution, consumption, or use on the Union market in the course of a commercial activity, whether for consideration or free of charge. Regulation (EU) 2023/988 (GPSR) replaces the previous General Product Safety Directive. The German Product Safety Act (ProdSG) will be amended accordingly.

For product groups that fall under specific EU harmonisation legislation – such as radio equipment (RED), machinery, low voltage, or EMC – those sector-specific regulations take precedence.

The GPSR applies only in a supplementary manner to the extent that sector-specific legislation does not cover certain safety aspects.

## 4.2 Substance Restrictions – Applicable to Products within Their Respective Scopes

In contrast to the substance restrictions in Section 3.1, the supplier must verify whether its products fall within the scope of the respective requirement described in this chapter. If the supplier is unable to clarify this matter independently, Leica must be informed immediately.



## 4.2.1 Regulation (EU) 2023/1542 – Battery Regulation 2023

The Regulation on batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) 2019/1020, entered into force on 17 August 2023. Annex I of the Regulation restricts the use of mercury, cadmium, and lead.

**Table 5: Maximum Concentration Limits for Batteries**

Substances	Maximum Concentration in the Article	Application Restrictions
Mercury and mercury compounds	0,0005%	Batteries (in devices and vehicles)
Cadmium and cadmium compound	0,002%	Portable batteries (in devices and vehicles)
Lead and lead compounds	0,01%	Portable batteries (as of 18 August 2024)

## 4.2.2 Directive 2009/48/EC – Toy Safety Directive

Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys applies to products that are – exclusively or not exclusively – intended or designed to be used by children under 14 years of age for play. The wording “not exclusively” also applies to products that are not considered toys in the conventional sense but may nevertheless be perceived and used as such by children.

The directive sets out comprehensive requirements regarding:

- physical and mechanical properties
- flammability
- chemical properties
- electrical properties
- hygiene
- radioactivity

The corresponding requirements must be taken directly from the legal text.

## 4.2.3 Proposition 65 - Safe Drinking Water and Toxic Enforcement Act, 1986

The Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly known as California Proposition 65) is a California state law that came into force in 1986 to promote the protection of drinking water. Its purpose is to prevent carcinogenic substances and substances that may cause birth defects from entering consumer products.



*“No person in the course of doing business shall knowingly or unknowingly expose any individual to a chemical known to the State of California to cause cancer or reproductive toxicity without first providing a clear and reasonable warning.”*

– California Proposition 65, The Safe Drinking Water and Toxic Enforcement Act, 1986

The supplier is obligated to inform Leica immediately if any article supplied by them contains substances listed under California Proposition 65..

<https://oehha.ca.gov/proposition-65/proposition-65-list>

#### 4.2.4 Regulation (EU) No. 528/2012

Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products governs the authorisation of biocides within the European Union.

Every supplier of Leica is required to fully comply with the requirements and obligations for

- biocidal products, and
- treated articles,

if their product falls within the scope of the Regulation.

The supplier must ensure that all materials, substances, and components that have been treated with biocidal active substances comply with the requirements of Regulation (EU) No. 528/2012. In the event that such a treatment has been applied, the supplier must notify Leica without being asked, using the following email address: [material.compliance@leica-camera.com](mailto:material.compliance@leica-camera.com).

#### 4.2.5 Toxic Substance Control Act (TSCA)

The United States Environmental Protection Agency (EPA) has restricted five substances under Section 6(h) of the Toxic Substances Control Act (TSCA).

The sale of chemicals, mixtures, and articles containing these restricted substances is regulated in the United States. Currently, depending on the substance, there are numerous different transitional periods and, in some cases, specific exemptions.

**Table 6: TSCA-Restricted PBT Substances**

Substances	CAS-Nr	Restriction
<b>PIP (3:1) — phenol, isopropylated phosphate (3:1)</b>	68937-41-7	Prohibited at > 0.1% w/w
<b>Decabromodiphenyl ether (DecaBDE)</b>	1163-19-5	Prohibited at > 0.1% w/w
<b>2,4,6-Tris(tert-butyl)phenol (TTBP)</b>	732-26-3	Prohibited at > 0.1% w/w
<b>Pentachlorothiophenol (PCTP)</b>	133-49-3	Prohibited at > 1% w/w

If any of these substances are present in mixtures or articles supplied to Leica, this must be reported, including any applicable exemptions that may have been used.



The requirements that entered into force between 1 and 8 March 2021, as well as the listed exemptions, must be taken from the legal text.

<https://www.epa.gov/chemicals-under-tsca>

## 4.3 Declarable Substances

### 4.3.1 SVHC Candidate List

The current version of the official SVHC Candidate List under Regulation (EC) No. 1907/2006 can be accessed at any time at:

<https://echa.europa.eu/candidate-list-table>

According to Article 33 of Regulation (EC) No. 1907/2006, every supplier is obliged to provide the following:

If the supplied articles contain substances of very high concern (SVHC) listed on the Candidate List pursuant to Article 59(1) of Regulation (EC) No. 1907/2006 at concentrations greater than 0.1% weight by weight, the supplier must, without being requested, provide all information required under Article 33(1) together with the delivery.

This obligation also applies if a substance is added to the Candidate List during an ongoing supply relationship.

Regarding the reference point for the concentration threshold, the following applies:

Each component article of a product composed of multiple component articles (a so-called complex object) is considered an article within the meaning of the regulation. The status of an object as an article is not lost when it is assembled or combined with other objects.

This means that, based on the principle “Once an article – always an article”, the individual article – not the assembled product – must be used as the reference point.

The supplier shall provide SCIP-relevant data, preferably via the DataCross platform.

### 4.3.2 Conflict Minerals – Due Diligence Requirements for Mineral Raw Materials

Suppliers of Leica must comply with the requirements of EU Regulation 2017/821 on conflict minerals (tin, tantalum, tungsten, gold) if they process these raw materials or supply components that contain them.

The following information must be provided:

- Origin and smelters, with certified RMAP-conformant smelters preferred
- Confirmation of a risk-based due diligence system in accordance with the OECD Due Diligence Guidance
- Annual updates in case of changes within the supply chain

These requirements apply even if the supplier is not directly subject to the EU Regulation.



## 4.4 Auxiliary Materials and Operating Materials

### 4.4.1 Safety Data Sheets (SDS)

The Safety Data Sheet (SDS) is the central communication element within the supply chain for hazardous substances and mixtures. It provides essential information regarding:

- identification of the product
- associated hazards
- safe handling
- preventive measures
- measures in case of an emergency

The requirements regarding the content and format of the Safety Data Sheet are defined in Article 31 and Annex II of the REACH Regulation (EC) No. 1907/2006.

The supplier of a substance or mixture is responsible for ensuring that the Safety Data Sheet is professionally accurate and complete.

The Safety Data Sheet must be provided to Leica in electronic form, free of charge, no later than on the day of the first delivery.

It shall be sent to the following email address: [material.compliance@leica-camera.com](mailto:material.compliance@leica-camera.com)

Suppliers must update the SDS without delay (see Article 31(9) of Regulation (EC) No. 1907/2006) when:

- new information becomes available that may affect risk management measures
- an authorisation has been granted or refused
- a restriction has been issued

The revised version must be provided to Leica without delay, provided Leica has received deliveries from the supplier within the previous 12 months.

## 5 Associated Documents

(see Leica internal documentation)

## 6 Documentation

(see Leica internal documentation)

## 7 Miscellaneous

(not assigned)