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1 Purpose

The purpose of this Material Compliance Guideline ("MCG") is to ensure a regulation-conform handling of substances and products during the development, production, trade, use, and disposal.

This MCG describes to the Supplier the requirements of LEICA CAMERA AG ("Leica") and its affiliated companies with regard to all known legally prohibited, regulated and declarable substances.

If any new laws or law changes have not yet been incorporated in this Guideline, this shall not release the Supplier from its obligation to consider them and to comply with the currently applicable statutory requirements.

The Supplier is obliged to procure itself the texts of the applicable regulations, directives, laws, standards and other requirements.

The material compliance requirements apply equivalent to other product requirements of Leica and do not replace those.

The Supplier undertakes to ensure that all products and their packaging ("Products") comply with both the statutory requirements and the requirements of the MCG to guarantee that they are placed on the market and disposed in conformity with all regulations.

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

In the individual case, Leica shall upon request for the initial sampling be provided with the technical data sheets of all raw materials and auxiliaries used. Leica reserves the right to carry out checks and laboratory tests on materials. If it turns out that a product or any raw material or auxiliary does not comply with the statutory requirements or those of the MCG, the Supplier shall bear the costs of the checks and laboratory tests.

The Supplier is obliged to provide the material information required for verifying the compliance with the statutory regulations and the MCG free of costs.

Leica prefers cooperating with Suppliers who deposit the requested material information on the DataCross platform.

Leica provides the MCG via its Internet site. The current version as amended from time to time replaces the previous version and is applicable with immediate effect.

The Supplier will not be informed about changes to the MCG. The Supplier is obliged to check at least every 6 months whether the MCG is available to it in its currently applicable version.

The present MCG was drawn up by tec4U - Solutions GmbH, Saar-Lor-Lux-Straße 13, 66115 Saarbrücken, Germany. Any use and/or duplication is permitted to Leica and the participants in



the supplier chain. For any use - whether as a whole or in parts - outside of the supplier chain, a written approval by tec4U - Solutions GmbH must be obtained.

2 Scope of application

This MCG applies to all Products of Leica Camera AG and its affiliated companies. Restrictions are described in the relevant chapters.

3 Definitions/abbreviations

Substance:

Chemical element and its compounds in the natural state or obtained by a manufacturing process, including any additives necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated from the substance without affecting its stability and without changing its composition (cf. REACH, Art. 3 (1)).

Examples of chemical compounds Organic: ethanol, aldehyde metallic: iron, copper, tin mineral: clay, loam

Preparation:

Batches, mixtures or solutions composed of two or more substances (mixture and preparation are synonymous).

Examples of preparations: Batches: seeds mixtures: alloy solution: octane in petrol

Homogeneous material:

A material of uniform composition throughout, or a material composed of different materials which cannot be disjointed or separated into individual materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes (cf. RoHS Art. 3 (20). Examples for homogeneous materials are individual types of plastics, ceramics, glasses, metals, alloys, synthetic resins and coatings.

Intentionally added:

Generally known as the intentional use of a substance contained in a product to create a specific property, appearance or quality.

Battery or accumulator:

A source of electrical energy consisting of one or several non-rechargeable primary cells or from rechargeable secondary cells, such energy generated by direct conversion of chemical energy.



Packaging:

Products manufactured from any substance for the containment, protection, handling, delivery and presentation of goods, which may range from raw materials to processed products and are passed on from the manufacturer to the user or consumer. Likewise, all "disposable items" used for the same purpose are to be considered as packaging (cf. EU Packaging Directive Art. 3 (1)).

Packaging components:

Parts of packaging that can be separated by hand or by simple mechanical processes. Additional elements which are directly attached or fixed to a product and perform a packaging function are considered to be packaging unless they are an integral part of the product.

Prohibited substances:

Prohibited substances must not be contained in products, components, materials, preparations and auxiliaries and operating materials to an extent exceeding the limits set out in this document. These substances may be contained only as natural impurities, they must not be intentionally added. Impurities with these substances are to be qualitatively indicated.

Declarable substances:

The substances classified as declarable are undesirable in some applications and must be declared above the specified limit values. The listed substances must be specified for each product, component, material, substance preparation, auxiliary or operating material. Content limits are specified for the individual substances in the document. Below these limits, the declaration obligation does not apply.



Application:

Means that the limit of the substance refers to the material or the part in which the substance is contained to achieve a desired functionality.

Product:

Object which during production is given a specific form, surface or shape which determines its function to a greater extent than the chemical composition.

Latest application date

By this date, an application for authorisation must have been submitted according to the REACH Regulation (date at least 18 months before the sunset date) to enable continued use of the substance (deadline).

Information on the application for authorisation and the formal expiry of an application for authorisation can be found at:

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

Sunset date:

After this date, it is prohibited to place a substance listed in Annex XIV of the REACH Regulation on the market and use it, unless authorisation was granted.

Allergen:

An allergen is a substance that can trigger hypersensitivity reactions (allergic reactions) via the immune system.

CAS number:

The CAS number (also CAS Registry Number; CAS = Chemical Abstracts Service) is an international designation standard for chemical substances. Each chemical substance registered in the CAS Database (also biosequences, alloys, polymers) has a unique CAS number.

Sources/support:

Platform for European Regulations, Directives and Decisions, retrievable in all existing versions and languages of the Member States - the publication year and the publication number must be inserted in the search mask:

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

Support section of the European Chemicals Agency (ECHA):

https://echa.europa.eu/support/guidance

REACH-CLP-Biocide Helpdesk – national information centre of the federal government:

http://www.reach-clp-biozid-helpdesk.de/de/Startseite.html



REACH Helpdesk – German Federal Environmental Agency:

http://www.reach-info.de

Platform for German laws

https://www.gesetze-im-internet.de/

Network REACH@Baden-Württemberg

https://www.reach.baden-wuerttemberg.de/

4 List of legally regulated substances

4.1 Substance regulations and prohibitions – <u>necessary for all products</u>

The substance law requirements described in point 4.1 apply to all substances, preparations and products. The application context is precisely described in the corresponding law.

4.1.1 Regulation (EC) No. 1907/2006 REACH - Annex XIV - List of substances subject to authorisation

Regulation (EC) No. 1907/2006 (in short "REACH") entered into effect on 01 June 2007.

The inclusion of a substance from the list of substances of very high concern in Annex XIV of REACH does at the end of the procedure result in an authorisation requirement for that substance. After a transitional period, the substance may be used only with an authorisation, otherwise its use is prohibited.

The terms "latest application date" and "sunset date" can be found under point 3 "Definitions/Abbreviations".

The current Annex XIV of the REACH Regulation can be accessed via the following link:

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

4.1.2 Regulation (EC) No. 1907/2006 REACH - Annex XVII - List of restricted substances

Annex XVII of REACH regulates or prohibits specified substances in individual applications defined by the legislator.

The current Annex XVII of the REACH Regulation can be accessed via the following link:

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

4.1.3 Directive 2011/65/EC - RoHS

Directive 2011/65/EC of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) entered into force on 02 January 2013.

The RoHS substance regulations refer to the maximum concentrations in the homogeneous material of each product.



Substance groups	Maximum concentration in the homogeneous material in per cent
Cadmium and cadmium compounds	0.01%
Hexavalent chromium (Cr6+) and Cr6+ compounds	
Lead and lead compounds	
Mercury and mercury compounds	
Polybrominated diphenyl ethers (PBDE)	
Polybrominated biphenyls	0.10%
Bis(2-ethylhexyl)phthalate (DEHP)	
Butylbenzylphthalate (BBP)	
Dibutylphthalate (DBP)	
Diisobutylphthalate (DIBP)	

Table 1: Substance regulations of the RoHS Directive

4.1.4 Chemicals Prohibition Ordinance (ChemVerbotsV)

The Regulation on prohibitions and restrictions on the marketing of dangerous substances, preparations and products under the Chemicals Act is a Federal German law that stipulates special national requirements in addition to the REACH Regulation. Given that REACH is a regulation directly applicable in the EU Member States, an amendment to the ChemVerbotsV was adopted in 2016, which combines the requirements of the REACH and Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP) with the German chemicals law. The national requirements are additionally determined for the following substances and substance groups:

Table 2: ChemVerbotsV substance and substance groups

Substances/mixtures	
Formaldehyde	
Dioxins and furans	
Pentachlorophenol	
Bio-persistent fibres	

The requirements which entered into force on 01 January 2019 as well as the listed exceptions are specified in the text of the law.

http://www.gesetze-im-internet.de/chemverbotsv_2017/



4.1.5 Regulation (EU) No 2019/1021 on persistent organic pollutants (POPs)

This EU Regulation inter alia implements the Stockholm Convention on Persistent Organic Pollutants. The Stockholm Convention is an agreement on binding international measures to prohibit and restrict specific persistent organic pollutants. Thus, the Convention prohibits or restricts the manufacturing, use and trade of hazardous chemicals.

Further information on the Stockholm Convention can be found on the official website at the following link:

http://chm.pops.int/

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

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

4.1.6 Directive 94/62/EC - Packaging Directive

Directive 94/62/EC of the European Parliament and Council of 20 December 1994 on packaging and packaging waste restricts the concentration of heavy metals in packaging.

Table 3: Substance restriction packaging

Pure substances and substance groups	Maximum concentration in packaging or packaging components in weight-ppm
Lead, cadmium, mercury and chromium VI	100*
* our mulatively	

*cumulatively

4.1.7 Product Safety Act (ProdSG)

The Product Safety Act (ProdSG) replaced the Equipment and Product Safety Act (GPSG) and has been in force since 01 December 2011. It is the central legal regulation for the safety of devices, products and installations.

With the Product Safety Act and the product safety regulations issued on the basis of Section 8 Product Safety Act, a total of 11 European internal market directives and the directive on general product safety 2001/95/EC are implemented into German law.

This law applies when within the scope of a business transaction products are provided, displayed or for the first time used in the market. According to Section 3, a market launch is permitted only "if it does not endanger the safety and health of persons when used as intended or in a foreseeable manner".

Apart from these European aspects, the Product Safety Act also includes parts which are of purely German origin, including but not limited to the regulations on the **Quality Seal** *(GS-Zeichen)* in Section 5 of the Act.

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



4.2 Substance regulations and prohibitions - necessary for products from different scopes of application

In contrast to the substance regulations in section 4.1, the Supplier must here check whether its products fall under the scope of application of the respective requirement. If the Supplier is unable to independently clarify the facts, it has to inform Leica accordingly without undue delay.

4.2.1 Directive 2006/66/EC - Batteries Directive

Directive 2006/66/EC of the European Parliament and of the Council of 6 September 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.

Pure substances	Maximum concentrations in the article in per cent	Restrictions of use
Mercury and mercury compounds	0.0005%	Batteries and accumulators
Cadmium and cadmium compounds	0.002%	Device batteries and accumulators

Table 4 Substance regulations of the batteries directive

4.2.2 Directive 2009/48/EC - Toys 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 which are - exclusively or non-exclusively - intended or designed to be used as toys by children under the age of 14 years. The formulation "non-exclusively" in this Directive also applies to products which are not to be understood as toys but might nonetheless be seen as such by children.

For all accessible parts of toys the Directive prohibits the use of so-called CMR-substances (CMR = carcinogenic - mutagenic - reprotoxic). Likewise, allergenic fragrances with a high allergenic potential are entirely prohibited or must at a lower potential be specified on the toy.

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

The Safe Drinking Water and Toxic Enforcement Act, 1986 (also known as California Proposition 65) is a Californian law enacted in 1986, which promotes the cleanliness of drinking water. It shall furthermore prevent carcinogenic substances as well as substances which might lead to malformations from entering consumer products.

"No person shall in the course of his business, whether knowingly or unknowingly, expose any other person to a chemical which according to current knowledge may cause cancer or



neonatal malformations without providing clear, precise and adequate information to consumers about such risk." – California Proposition 65, The Safe Drinking Water and Toxic Enforcement Act, 1986.

The Supplier is obliged to inform Leica without undue delay if any of the articles delivered by it contains any substances that fall under the California Proposition 65.

4.2.4 Regulation (EU) No. 528/2012 - Biocidal Products Regulation

The regulation on biocidal products (BPR, EU Regulation No. 528/2012) concerning the making available on the market and use of biocidal products) in the European market entered into force on 1 September 2013. With this Regulation, the authorisation of biocides in the European Union is uniformly regulated and takes place in a staged procedure.

Each Supplier of Leica is obliged to fully comply with the requirements and obligations applicable to

- biocidal products
- treated goods

if its product falls within the scope of the Regulation.

All materials and components treated with substances with a biocidal effect must comply with the requirements of the EU Biocide Regulation.

4.3 Declarable substances

4.3.1 SVHC list of candidates

The current version of the official SVHC list of candidates according to REACH (Regulation 1907/2006/EC) can be accessed at any time at:

http://echa.europa.eu/chem_data/authorisation_process/candidate_li st_table_en.asp

According to Article 33 of the REACH Regulation, each Supplier is obliged to the following:

"(1) Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59 (1) in a concentration above 0,1 % weight by weight (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." In the relationship with Leica, this in particular applies to substances of very high concern (SVHC list of candidates) in:

- components
- spare parts
- accessories
- packaging



Insofar as the delivered articles contain substances of more than 0.1% by weight of substances of very high concern, which are published in the so-called candidate list according to Art. 59 (1) of Regulation 1907/2006/EC, the contractor is without request obliged to provide all information according to Art. 33 (1) of Regulation 1907/2006/EC with the delivery. This also applies if such substance is included in the list of candidates only during the ongoing supply relationship.

In respect of the reference value for the concentration limit, the following applies: Each part of a product which is composed of several parts (so-called complex product) is a product in the sense of the regulation. The product character is not lost by the combination or amalgamation with other objects. This means that on the basis of the principle "once a product - always a product" the individual product and not the composite product is used as a reference value.

Private consumers must be provided with this information regarding substances of very high concern upon enquiry within 45 days, free of charge.

4.4 Production auxiliaries and operating materials

4.4.1 Safety data sheets (SDS)

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

- product identity
- emerging hazards
- safe handling
- prevention measures
- measures in case of danger

The requirements for the contents and format of the safety data sheet are stipulated in Article 31 and Annex II of REACH Regulation (EC) No. 1907/2006.

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

The safety data sheet shall be provided to Leica on paper, in electronic form or as a download option, free of charge, at the latest on the day of first delivery.

Dispatch via e-mail is made to <u>material.compliance@leica-camera.com</u> Suppliers shall update the SDS without undue delay (Art. 31 (9)) when:

• new information becomes available which may affect the risk management measures



- an authorisation has been granted or refused
- a restriction has been imposed.

The corrected version must be provided to Leica without undue delay if Leica has received a delivery within the last 12 months.

5 Further applicable documents

(see Leica-internal documentation)

6 Documentation

(see Leica-internal documentation)

7 Other

(intentionally left blank)

8 Cause of last amendment

Rev. 11/20: Initial drafting