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by: Bölcsházy, Emese von, Duda, Wolff-Christian, Brohl, Angelika, Gath, Carina	from: Metzele, Dr. Michael, Schäfer, Florian, Bergmann, Frank , 01_BIC Kernteam (Editoren), Martins, Daniela	from: Dück, Dr. Benjamin

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1 Purpose

The purpose of this Material Compliance Guideline ("MCG") is to ensure the legally compliant composition and use of substances, mixtures and articles in development, production, trade, use and disposal.

This MCG describes to the supplier the requirements of LEICA CAMERA AG ("Leica") and its affiliated companies regarding all legally restricted and declarable substances, mixtures and products.

If new laws or amendments to laws have not yet been taken into account in this guideline, this does not release the supplier from the obligation to take these into account and to comply with the currently applicable legal requirements.

The supplier is obliged to procure the texts of the applicable regulations, directives, laws, standards and other provisions himself.

The material compliance requirements are equivalent to other Leica product requirements and do not replace them.

The Supplier warrants that all products and packaging supplied to Leica ("Leica Product") comply with the applicable statutory regulations, directives, laws, standards and other regulations as well as this MCG in order to ensure compliant placing on the market and disposal.

Substances, mixtures, products and articles for which sufficient material information is not available may neither be supplied to Leica nor used in "Leica products".

The Supplier undertakes to provide the material information required to check compliance with the statutory requirements and the MCG free of charge.

As soon as the supplier has information that substances, mixtures or products do not comply with the legal requirements or those of the MCG, Leica must be informed immediately in writing and any costs incurred for tests and laboratory examinations must be borne. Leica prefers to work with suppliers who store the requested material information in the DataCross platform.

Leica makes the MCG available on its website. The current version replaces the previous version and is valid with immediate effect.

The Supplier shall not be notified of changes to the MCG. He is obliged to check at least once a year whether he has the MCG in the currently valid version.

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2 Scope of application

This MCG applies to all substances, mixtures or products supplied to Leica or its affiliates, unless otherwise specified below.

3 Additional definitions

This section defines terms that are not used directly in this guideline but are important for understanding the wider subject area. These definitions serve to ensure clarity and a common understanding.

Added on purpose:

Generally known as the intentional use of a substance contained in an article to produce a particular property, appearance, function or quality.

Application:

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

Application deadline (Latest application date):

According to Regulation (EC) No. 1907/2006, an application for authorization must be submitted by this date (date is at least 18 months before the expiry date) so that the substance can continue to be used (deadline). Information on the application for authorization and the formal procedure for an application for authorization can be found at:

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

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 (cf. Regulation (EC) No. 1907/2006 Art. 3 para. 3).

Battery:

means any device delivering electrical energy generated by direct conversion of chemical energy, having internal or external storage, and consisting of one or more non-rechargeable or rechargeable battery cells, modules or of packs of them, and includes a battery that has been subject to preparation for re-use, preparation for repurposing, repurposing or remanufacturing (cf. EU Regulation 2023/1542 Art. 3 para. 1)

Biocidal product:

any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring,
rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.

(cf. Regulation (EU) 528/2012 Art. 3 para. 1 no. 1 (a)).

CAS number:

The CAS number (also CAS registration number, CAS registry number, CAS = Chemical Abstracts Service) is an international designation standard for chemical substances. There is a unique CAS number for every chemical substance registered in the CAS database (including biosequences, alloys and polymers).

Contamination:

Substances whose presence in a article is not intended are called impurities. They can come from various sources, e.g. from the substances used in the supply chain (e.g. unreacted monomers in polymers), from the (undesired) presence of process aids (e.g. lubricants from machines, solvent residues) or from substances intentionally used during transportation (e.g. biocide treatment of textiles to prevent mould growth).

Declarable substances:

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

Endocrine disruptors:

Endocrine disruptors (EDs) are chemicals or mixtures of chemicals that disrupt the natural biochemical action of hormones and thus cause harmful effects (e.g. disruption of growth and development, negative influence on reproduction or increased susceptibility to specific diseases).

Full declaration:

The full declaration states that all chemical compounds and elements present above a declaration threshold must be declared. The sum of all declared compounds and elements must equal 100%.

Homogeneous material:

means one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes (cf. EU Directive 2011/65/EU Art. 3 Para. 20).

Examples of homogeneous materials:

Plastic, ceramic, glass, alloy, coating

Industrial battery:

means a battery that is specifically designed for industrial uses, intended for industrial uses after having been subject to preparation for repurposing or repurposing, or any other battery that weighs more than 5 kg and that is neither an electric vehicle battery, an LMT battery, nor an SLI battery (cf. EU Regulation 2023/1542 Art. 3 para. 1 no. 13).

Micro, small and medium-sized enterprises or "SMEs":

Micro, small and medium-sized enterprises within the meaning of Article 3 of Directive 2013/34/EU of the European Parliament and of the Council. (cf. EU Directive 2013/34/EU Art. 3 Para. 1 No. 3).

Mixture:

means a mixture or solution composed of two or more substances (cf. Regulation (EC) No. 1907/2006 Art. 3 para. 2).

Examples of mixtures:

- Mixtures: Seeds

- Mixture: Color
- Solution: Octane in gasoline

Packaging:

shall mean all products made of any materials of any nature to be used for the containment, protection, handling, delivery and presentation of goods, from raw materials to processed goods, from the producer to the user or the consumer. 'Non-returnable' items used for the same purposes shall also be considered to constitute packaging (cf. EU Directive 94/62/EC Art. 3 Para. 1 No. 1).

Packaging components:

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

Partial declaration (part declaration):

The partial declaration specifically asks about the presence of declarable, restricted chemical compounds and elements above the relevant limit value. The partial declaration does not provide any information about the actual composition of the article.

Persistence (chemistry/biology):

In biology and environmental chemistry, persistence refers to the resistance of - usually - organic chemical compounds to chemical, physical and biological degradation.

Portable battery:

means a battery that is sealed, weighs 5 kg or less, is not designed specifically for industrial use and is neither an electric vehicle battery, an LMT battery, nor an SLI battery (cf. EU Regulation 2023/1542 Art. 3 Para. 1 No. 9).

Product:

means any item, whether or not it is interconnected to other items, supplied or made available, whether for consideration or not, including in the context of providing a service, which is intended for consumers or is likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them (cf. EU Regulation 2023/988 Art. 3 (1) No. 1).

Restricted substances:

Restricted substances may not be contained as substances in mixtures and articles above the applicable limit values.

Safe product:

means any product which, under normal or reasonably foreseeable conditions of use, including the actual duration of use, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of the health and safety of consumers (cf. EU Regulation 2023/988 Art. 3 para. 1 no. 2).

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 (cf. Regulation (EC) No 1907/2006 Article 3(1)(1)).

Examples of substances:

- organic: ethanol, aldehyde
- metallic: iron, copper, tin
- mineral: clay, loam

Sunset date:

After this date, the placing on the market and use of a substance listed in Annex XIV of Regulation (EC) No 1907/2006 is prohibited unless an authorization has been granted.

Assistance:

Platform for European regulations, directives and decisions, available in all existing versions and languages of the member states - the year of publication and the publication number must be entered in the search mask:

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

Support area of the European Chemicals Agency (ECHA):

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

REACH-CLP-Biocide Helpdesk - National information center of the federal government:

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

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 bans - necessary for all products

The substance-related legal requirements described under point 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 authorization

The inclusion of a substance from the list of substances of very high concern in Annex XIV of Regulation (EC) No. 1907/2006 leads to an authorization requirement for this substance at the end of the procedure. After a transitional period, the substance may only be used with an authorization, otherwise its use is restricted.

The important dates "Application deadline" and "Expiry date" must be observed in this context (see section 3 Definitions).

Under the following link you can access the current Annex XIV of the REACH Regulation:

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 Regulation (EC) No. 1907/2006 lists substances that are restricted by the legislator in defined applications.

The following link will take you to the current Annex XVII of Regulation (EC) No. 1907/2006:

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 products supplied by a supplier must also comply with these substance restrictions.

The substance restrictions of Directive 2011/65/EU refer to the maximum concentrations in the homogeneous material.

Exemptions from Annex III, if used by a supplier, must be communicated to Leica without request. The current catalog of exceptions can be viewed at:

https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive/implementation-rohs-directive_en

Table 1: Substance restrictions of Directive 2011/65/EU

<table>
<tr><th>Substances/substance groups</th><th>CAS No.</th><th>Maximum concentration in the homogeneous material</th></tr>
<tr><td>Cadmium and cadmium compounds</td><td rowspan="6">Substance groups</td><td>0,01%</td></tr>
<tr><td>Hexavalent chromium (Cr6+) and Cr6+ compounds</td><td rowspan="10">0,1%</td></tr>
<tr><td>Lead and lead compounds</td></tr>
<tr><td>Mercury and mercury compounds</td></tr>
<tr><td>Polybrominated diphenyl ethers (PBDE)</td></tr>
<tr><td>Polybrominated biphenyls (PBB)</td></tr>
<tr><td>Di(2-ethylhexyl) phthalate (DEHP)</td><td>117-81-7</td></tr>
<tr><td>Butyl benzyl phthalate (BBP)</td><td>85-68-7</td></tr>
<tr><td>Dibutyl phthalate (DBP)</td><td>84-74-2</td></tr>
<tr><td>Diisobutyl phthalate (DIBP)</td><td>84-69-5</td></tr>
</table>

4.1.4 Chemikalien-Verbotsverordnung - ChemVerbotsV

The Chemikalien-Verbotsverordnung on the Marketing of Hazardous Substances, Mixtures and Articles under the Chemicals Act is a German federal law that prescribes special national requirements in addition to Regulation (EC) No. 1907/2006. The national requirements for the following substances and substance groups are also specified:

Table 2: Prohibitions on placing substances/mixtures on the market ChemVerbotsV

Substances/mixtures
Formaldehyde
Dioxins and furans
Pentachlorophenol
Biopersistent fibers

The requirements that came into force on 01.01.2019 and the listed exceptions can be found in the legal text.

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

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

This EU regulation implements the Stockholm Convention on Persistent Organic Pollutants. The Stockholm Convention is an agreement on internationally binding prohibition and restriction measures for certain persistent organic pollutants. The Convention thus prohibits or restricts the production, use and trade of hazardous substances, mixtures and articles.

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

http://chm.pops.int/

4.1.6 Directive 94/62/EC - 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 Substance restrictions Directive 94/62/EC

Fabrics	CAS number	Maximum concentration in packaging or packaging components in ppm by weight
Cadmium	7440-43-9	100 (cumulative)
Lead	7439-92-1	
Chromium VI	1333-82-0	
Mercury	7439-97-6	

4.1.7 Directive 2001/95/EC

Directive 2001/95/EC of the European Parliament and of the Council ensures that all products placed on the European internal market have a certain level of safety.

According to Directive 2001/95/EC, a product is considered safe if it complies with all legal regulations relating to health and safety in the area of application of the product.

4.1.8 Produktsicherheitsgesetz (ProdSG)

Regulation 2023/988/EU (Product Safety Regulation) came into force on 12.06.2023 and will come into force on 13.12.2024. This regulation replaces Directive 2001/95/EC, which is implemented by the Produktsicherheitsgesetz (ProdSG) in Germany.

Products may only be placed on the Union market if they present no or only low agreed risks to the health and safety of consumers under normal or reasonably foreseeable conditions of use.

Making available on the market means any supply of a product for distribution, consumption or use on the Union market in the course of its business, whether in return for payment or free of charge.

4.2 Substance restrictions - valid for products from the respective areas of application

In contrast to the substance restrictions in section 3.1, for the regulations described in this chapter the supplier must check whether his products fall within the scope of the respective requirement. If it is not possible for the supplier to clarify this independently, he must inform Leica immediately.

4.2.1 Directive 2006/66/EC - 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 3 Substance regulations of the Battery Directive

Pure substances	Maximum concentration in the article	Application restrictions
Mercury and mercury compounds	0,0005%	Batteries and accumulators
Cadmium and cadmium compounds	0,002%	Portable batteries and accumulators

4.2.2 EU Regulation (2023/1542) - Battery Regulation 2023

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

Table 5: Maximum concentration for batteries

Pure substances	Maximum concentration in the article	Application restrictions
Mercury and mercury compounds	0,0005%	Battery (in devices and means of transportation)
Cadmium and cadmium compounds	0,002%	Appliance batteries (in devices and means of transportation)
Lead and lead compounds	0,01%	Appliance batteries (from 18.08.2024)

4.2.3 Directive 2009/48/EC - Toys Directive

Directive 2009/48/EC of the European Parliament and of the Council of June 18, 2009 on the safety of toys applies to products intended or designed to be used exclusively or not exclusively for play by children under 14 years of age. The wording "non-exclusively" in this directive also applies to products that are not to be understood as toys but may be regarded as such by children.

The directive sets out comprehensive requirements regarding:

- Physical and mechanical properties
- Flammability
- Chemical properties

- Electrical properties
- Hygiene
- Radioactivity

The relevant requirements can be found directly in the legal text.

4.2.4 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 that came into force in 1986 and promotes the cleanliness of drinking water. It is intended to prevent carcinogenic substances and substances that can lead to deformities from entering consumer products.

"No person shall, in the course of business, knowingly or unknowingly, expose any person to any chemical which, according to current knowledge, may cause cancer or birth defects without providing clear, conspicuous and adequate information to consumers about the risk." - California Proposition 65, The Safe Drinking Water and Toxic Enforcement Act, 1986.

The supplier is obliged to inform Leica immediately if an article delivered by him contains substances that fall under California Proposition 65.

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

4.2.5 Regulation (EU) No. 528/2012

Regulation (EU) No. 528/2012 concerning the making available on the European market and use of biocidal products regulates the authorization of biocides in the European Union.

Every Leica supplier is obliged to fulfill the requirements and obligations for

- Biocidal products
- Treated goods

in full if its product falls within the scope of the regulation.

The supplier must ensure that all materials and components that have been treated with substances with a biocidal effect comply with the requirements of Regulation (EU) No. 528/201. In the event of treatment, Leica must be informed of this unsolicited at material.compliance@leica-camera.com.

4.2.6 Toxic Substance Control Act (TSCA)

The United States Environmental Protection Agency (EPA) has placed restrictions on five substances in the Toxic Substances Control Act (TSCA) Section 6 (h).

The sale of chemicals, mixtures and articles containing the restricted substances is regulated in the USA. Depending on the substance, there are currently many different transition periods and, in some cases, exemptions.

Table 6: TSCA restricted PBT substances

Pure substances	CAS number
Decabromodiphenyl ether (decaBDE)	1163-19-5
Pentachlorothiophenol (PCTP)	133-49-3
Hexachlorobutadiene (HCBD)	68937-41-7
2,4,6 tris (tert butyl)phenol (2,4,6 TTBP)	732-26-3

Hexachlorobutadiene (HCBD)	87-68-3

If one of the substances is contained in the mixtures or products delivered to Leica, this must be reported, including any exceptions used.

The requirements that came into force between March 1 and 8, 2021, as well as the listed exceptions can be found in 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 according to Regulation (EC) No. 1907/2006 can be downloaded at any time from the address:

https://echa.europa.eu/de/candidate-list-table

can be called up.

According to Article 33 of Regulation (EC) No 1907/2006, each supplier is obliged to do the following: If the delivered products contain substances of very high concern in a proportion of more than 0.1% by weight, which are published in the so-called candidate list in accordance with Art. 59 Para. 1 of Regulation (EC) No. 1907/2006, the supplier is obliged to provide all information in accordance with Art. 33 Para. 1 of Regulation (EC) No. 1907/2006 with the delivery without being requested to do so. This also applies if such a substance is only included in the candidate list during the current supply relationship.

With regard to the reference value for the concentration limit, the following applies: Every partial product of a product that is composed of several partial products (so-called complex product) is a product within the meaning of the regulation. The product property is not lost by combining or joining with other items. 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 the reference value.

Assistance and simplified specification of data in DataCross.

4.4 Production consumables and supplies

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:

- Identity of the product
- Hazards that occur
- Safe handling
- Prevention measures
- Measures in the event of danger

The requirements for the content and format of the safety data sheet are regulated 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 technically correct and complete.

The safety data sheet will be provided to Leica in electronic form free of charge on the day of the first delivery at the latest.

The mailing will be sent to the following e-mail address:

material.compliance@leica-camera.com

Suppliers shall update the SDS immediately (see REACH Regulation (EC) No. 1907/2006 Art. 31 (9)) if:

- new information is available that may have an impact on risk management measures
- an authorization has been granted or refused
- a restriction has been imposed

The corrected version must be made available to Leica immediately if it has been supplied within the last 12 months.

5 Applicable documents

(see Leica internal documentation)

6 Documentation

(see Leica internal documentation)

7 Other

(not used)