M&C Material Compliance - Standard V1.0

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1 Introduction

The purpose of this Material Compliance Standard is to ensure material-compliant handling of substances and products in development, production, trade, and use.

This Material Compliance Standard describes the requirements of M&C TechGroup Germany GmbH (hereinafter referred to as M&C TechGroup) and its affiliated companies regarding all known legally prohibited, regulated, and declarable substances in an up-to-date version.

If any legislative amendments have not yet been incorporated in this Standard, this shall not exempt the supplier from the obligation to take these amendments to the law into account and to comply with the current, applicable legal requirements.

It is the supplier's responsibility to obtain the respective current regulations, laws and standards.

The Material Compliance requirements are considered equivalent to other product requirements.

The Material Compliance Standard requires that all products and their packaging meet the requirements of this Material Compliance Standard in order to ensure that the products are placed on the market in compliance with the regulations.

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

In individual cases, the technical data sheets of all raw materials and auxiliary materials used shall be submitted to M&C TechGroup for initial inspection upon request. M&C TechGroup reserves the right to carry out tests and laboratory examinations on materials in individual cases.

The supplier of M&C TechGroup is obligated to provide, free of charge, the material information required to verify the compliance with the legal requirements and this Standard.

M&C TechGroup makes the Material Compliance Standard available via its website.

The supplier is obligated to check at least every 6 months whether the Material Compliance Standard is available in an updated form. In the event of an amendment of the Material Compliance Standard, this supersedes the previous version and is valid with immediate effect.

The suppliers of M&C TechGroup are not notified of changes or updated versions of this Standard.

2 Definitions and Abbreviations

Substance:
Chemical element and its compounds in the natural state or obtained by a manufacturing process, including the additives necessary to preserve its stability and the impurities resulting from the process used, but excluding solvents which can be separated from the substance without affecting its stability and without altering its composition (see REACH Art. 3 Para. 1).

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

Preparation:
Batch, mixture or solution from two or more substances (mixture and preparation are synonymous).

Examples of preparations:
batch: seeds
mixture: alloy
solution: octane in gasoline

Homogenous Material:
A material of uniform composition throughout or a material consisting of different materials that cannot be broken down or separated into individual materials by mechanical processes such as unscrewing, cutting, crushing, grinding and sanding (cf. RoHS Art. 3 Para. 20). Examples of 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 particular property, quality, or appearance.

Battery or Accumulator:
A source of electrical energy consisting of one or more primary (non-rechargeable) cell(s) or of one or more secondary (rechargeable) cells obtained by direct conversion of chemical energy.

Packaging:
Products made of any material for storing, protecting, handling, transporting and presenting goods, which can range from raw materials to processed products and are passed on by the manufacturer to the user or consumer. All “disposable items” used for the same purpose are also to be regarded as packaging (cf. EU Packaging Directive Art. 3 Para. 1).

Packaging Components:
Parts of the packaging that can be separated manually or by simple mechanical procedures. Additional elements, directly affixed or attached to a product and fulfilling a packaging function, are considered to be packaging, unless they are an integral part of the product.

Restricted Substances:

Prohibited substances must not be contained in products, components, materials, preparations as well as auxiliary and operating materials above the limit values specified in this document. These substances may only be present as natural impurities, they must not be added intentionally. Impurities with these substances must be indicated qualitatively.

Declarable Substances:
Substances classified as declarable are not desired in some applications and must be declared above the specified limits. The substances listed must be indicated for each product, component, material, substance preparation, auxiliary or operating material. Content limits are specified in the document for the individual substances. Below these limits, there is no need for declaration.

Application:
Means that the threshold value of the substance refers to the material or the part in which the substance is included to achieve a desired functionality.

Product:
An object which, during manufacture, is given a specific shape, surface or design which determines its function to a greater extent than its chemical composition**.**

Latest Application Date:
An application for authorization must be submitted by this date in accordance with the REACH Regulation (the date is at least 18 months before the sunset date) so that the substance can continue to be used (deadline).

You can find information on the application for admission and the formal process of an application for admission at:

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

Sunset Date:
After this date, the marketing and use of a substance listed in Annex XIV to the REACH Regulation are prohibited unless an authorization has been granted.

CAS Number:
The CAS number (also CAS Registration Number and CAS Registry Number, CAS = Chemical Abstracts Service) is an international designation standard for chemical substances. For each chemical substance registered in the CAS database (also biosequences, alloys, polymers), there is a unique CAS number.

Sources of Supply/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 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 Center of the German Federal Government:
http://www.reach-clp-biozid-helpdesk.de/de/Startseite.html

REACH Helpdesk – German Federal Environmental Agency:
http://www.reach-info.de

REACH@Baden-Wuerttemberg:
https://www.reach.baden-wuerttemberg.de/

Platform for German laws:
https://www.gesetze-im-internet.de/

3 M&C TechGroup – Overview of Legally Regulated Substances

3.1 Substance Regulations and Bans – Necessary for all Products

The legal substance requirements as described under item 3.1 apply to all substances, mixtures and products. The context of application is described in detail in the corresponding law.

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

Regulation (EC) No. 1907/2006 (in short “REACH”) became effective on June 1, 2007.

The inclusion of a substance from the list of substances of very high concern in Annex XIV to the REACH Regulation leads to an authorization requirement for this substance at the end of the process. After a transitional period, the substance may only be used with an authorization; otherwise its use is prohibited.

Explanations regarding the terms “Latest Application Date” and “Sunset Date” can be found under item 2 “Definitions and Abbreviations”.

Click on the following link to access the current Annex XIV to the REACH Regulation:

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

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

Annex XVII to the REACH Regulation regulates or prohibits specified substances in individual/legally defined applications.

Under the following link, you can find the current Annex XVII to the REACH Regulation:

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

3.1.3 Directive 2011/65/EU – RoHS

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

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

Table 1: Substance Regulations of the RoHS Directive

Substance Groups	Maximum concentration in the homogeneous material as a percentage
Cadmium and cadmium compounds	0.01 %
Hexavalent chromium (Cr6+) and Cr6+ compounds	0.10 %
Lead and lead compounds	
Mercury and mercury compounds	
Polybrominated diphenyl ethers (PBDE)	
Polybrominated biphenyls (PBB)	
Di(2-ethylhexyl) phthalate (DEHP)	
Butyl benzyl phthalate (BBP)	
Dibutyl phthalate (DBP)	
Diisobutyl phthalate (DIBP)	

3.1.4 Chemicals Prohibition Ordinance – ChemVerbotsV

The Regulation on Prohibitions and Restrictions regarding the Marketing of Hazardous Substances, Preparations and Products under the Chemicals Act is a German federal law that stipulates specific national requirements in addition to the REACH Regulation. As REACH is a regulation that applies directly in the EU member states, an amendment to the ChemVerbotsV was adopted in 2016 that combines the requirements from the REACH and CLP regulations with the German chemicals law. In addition, the national requirements for the following substances and substance groups are specified:

Table 2: ChemVerbotsV – Substances and Substance Groups

Substances/Mixtures
Formaldehyde
Dioxins and furans
Pentachlorophenol
Biopersistent fibres

The requirements that came into force on January 1, 2019, as well as the listed exceptions, can be found in the legal text.

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

3.1.5 Regulation (EC) No. 2019/1021 on Persistent Organic Pollutants (POPs)

This EU regulation implements, among other things, the Stockholm Convention on Persistent Organic Pollutants. The Stockholm Convention is an agreement on prohibition and restriction measures for certain persistent organic pollutants that are binding under international law. Thus, the Convention bans or restricts the production, use, and trade of hazardous chemicals.

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

http://chm.pops.int/

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

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

3.1.6 Product Safety Act (ProdSG)

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

The ProdSG and the Product Safety Regulations (ProdSV) issued on the basis of § 8 ProdSG transpose a total of 11 European internal market directives and the General Product Safety Directive 2001/95/EC into German law.

This law applies when products are placed on the market, exhibited or used for the first time in the course of a business activity. According to § 3, a market introduction is only permitted “if it does not endanger the safety and health of persons when used as intended or in a foreseeable manner”.

In addition to these European aspects, however, the ProdSG also contains parts that are of purely German origin, such as the regulations on the **GS label** in Section 5 of the Act.

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

3.2 Substance Regulations and Prohibitions – Necessary for Products from Different Areas of Application

In contrast to the substance regulations in section 3.1, the supplier must check here whether his products fall within the scope of the respective requirement. If it is not possible for the supplier to clarify this matter independently, he must consult M&C TechGroup.

3.2.1 Directive 2006/66/EC – Battery Directive

The European Parliament and Council Directive 2006/66/EC dated September 6, 2006 on batteries and accumulators and waste batteries and accumulators as well as revoking 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 Product as a Percentage	Restrictions on Use
Mercury and mercury compounds	0.0005 %	Batteries and accumulators
Cadmium and cadmium compounds	0.002 %	Device batteries and accumulators

3.2.2 Directive 94/62/EC – Packaging Directive

The European Parliament and Council Directive 94/62/EC dated December 20, 1994 on packaging and packaging waste restricts the concentration of heavy metals in packaging.
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Table 4: 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*

***cumulative**

3.2.3 Toxic Substance Control Act (TSCA)

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

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

The substances are as follows:

Pure Substances	CAS Number
Decabromdiphenyl ether (decaBDE)	1163-19-5
Pentachlorothiophenol (PCTP)	133-49-3
Phenol, isopropylated phosphate (3:1) (PIP (3:1))	68937-41-7
2,4,6 tris (tert butyl) phenol (2,4,6 TTBP)	732-26-3
Hexachlorobutadiene (HCBD)	87-68-3

In addition to the restrictions, communication obligations come into force in the case of one of the five substances being present, which are to be seen as comparable to the obligations under Article 33 of the REACH Regulation.

The requirements, which 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

3.3 Substances Subject to Declaration

3.3.1 SVHC Candidate List

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

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

According to Article 33 of the REACH Regulation, each supplier is required to do the following:

(1) Any supplier of a product containing a substance meeting the criteria of Article 57 and identified in accordance with Article 59(1) in a concentration greater than 0.1 per cent by mass (w/w) shall provide the purchaser of the product with the information available to him that is sufficient for the safe use of the product but shall provide at least the name of the substance concerned.

This applies to substances of very high concern (SVHC candidate list) in

- Components
- Spare Parts
- Accessories
- Packaging

Insofar as 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 1907/2006/EC, the contractor is obligated to provide all information in accordance with Art. 33 Para. 1 of Regulation 1907/2006/EC at the time of delivery without being requested to do so. This also applies if such a substance is only included in the candidate list during the ongoing supply relationship.

Private consumers must be provided with this information free of charge within 45 days upon request.

According to the decision of the European Court of Justice, the principle “once a product, always a product” applies. As soon as a product exceeds the concentration limit of 0.1 %, the presence of this SVHC candidate substance must be communicated.

3.3.2 Conflict Minerals (CM) – Dodd-Frank Act

The Dodd-Frank Act is a U.S. regulation signed in July 2010 that requires companies listed on the U.S. stock exchange to refrain from using raw materials from conflict regions. Since then, companies that use a conflict mineral must submit a separate report on its origin. Conflict minerals as defined by the law are tungsten, coltan, wolframite and gold, from which the following four metals – known as 3TG – are produced:

- Gold
- Tin
- Tantalum
- Tungsten

Should M&C TechGroup receive inquiries from its customers regarding the origin of conflict minerals, it will forward these inquiries to its suppliers.

See further information:
https://www.sec.gov/News/Article/Detail/Article/1365171562058

As the reporting template for declaration, the Excel file of the

http://www.responsiblemineralsinitiative.org/

is preferred.

3.4 Production Auxiliaries and Operating Materials

3.4.1 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
- Arising hazards
- Safe handling
- Prevention measures
- Measures in case of danger

The requirements for the contents and format of the safety data sheet are regulated 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 technically correct and completed in full.

The safety data sheet is provided to M&C TechGroup free of charge on paper, in electronic form or as a download option no later than on the day of the 1st delivery.

Suppliers shall update the SDS without delay (Art. 31 (9)) if:

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

The corrected version must be made available to the customer if he has been supplied within the last 12 months.

Change Log:

Version	Change	Date	Officer
00	Document creation	17.10.2022	tec4u GmbH
00	Verification	01.02.2023	Dr. Jackelyn Aragón Gómez, Material Compliance Management (MCM)
01	Authorization	01.06.2023	Hans-Jörg Rumm, Chief Technology Officer/Head of Sales