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**Material Compliance****1 Purpose**

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

This material compliance standard describes the requirements of MKN Maschinenfabrik Kurt Neubauer GmbH & Co. KG (hereinafter referred to as MKN) in terms of all known legally prohibited, regulated and declarable substances in the current form.

If any legal changes are not yet shown in this standard or laws are not included, this does not release the supplier from the obligation to take these legal changes / laws into account and to comply with the current, respectively applicable, legal requirements.

The supplier is obliged to obtain the respective current guideline, laws and standards himself.

Material compliance requirements apply equally with all other product requirements.

The material compliance standard requires all products and their packaging to meet the requirements of the necessary current guidelines, laws and standards to ensure their compliant marketing.

Articles, products, materials and raw materials of unknown origin and / or composition or raw materials for which insufficient material data are available may not be used.

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

The supplier of MKN is obliged to provide the material information required to verify compliance with the legal requirements and this standard free of charge.

The supplier is required to file the requested material data information, preferably in the DataCross platform, or make it available to MKN in other ways.

Suppliers can view MKN's current material compliance standard at the MKN website ([www.mkn.com](http://www.mkn.com)) and download it from there.

This material compliance standard was created in cooperation with tec4U - Solutions GmbH, Saar-Lor-Lux-Strasse 13, D-66115 Saarbrücken. The standard can be used and/or copied by MKN and parties involved in the supply chain. Its use outside the supply chain in whole or in parts requires permission by MKN and tec4U – Solutions GmbH.

**Material Compliance****2 Scope of application**

The factory standard applies to all areas of MKN Maschinenfabrik Kurt Neubauer GmbH & Co. KG as well as to its suppliers.

**3 Release - Creator**

Standard - tec4U - Solutions GmbH, Purchasing, Standard

**4 Definitions 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 section 3.1).

Examples for chemical compounds

Organic: ethanol, aldehyde

Metal: iron, copper, tin

Mineral: clay, loam

**Preparation:**

A batch, mixture or solution composed of two or more substances (mixture and preparation are synonyms).

Examples for preparations:

Batch: seeds

Mixture: alloy

Solution: octane in gasoline

**Homogenous material:**

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 (see RoHS section 3.20). Examples for homogenous materials are individual types of plastic, ceramic, glass, metal, alloy, synthetic resin and coating.

**Intentionally added:**

Generally known as the intentional use of a substance contained in an article to achieve a specific attribute, appearance or quality.

**Material Compliance****Battery or accumulator:**

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

**Packaging:**

All products made of any materials of any nature 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 (see EU Packaging Directive section 3.1).

**Packaging components:**

Parts of the packaging that are separable by hand or simple mechanical processes. Additional elements that are directly hanging on or fastened to a product and serve a packaging function are regarded as packaging unless they are an integral part of the product.

**Restricted substances:**

Prohibited substances may not be contained in products, components, materials, preparations as well as auxiliary and operating materials above the limit values specified in this document (the legal requirements are leading and primarily to be applied here; if a supplier has more recent knowledge, please contact us be reflected back). These substances may only be contained as naturally occurring impurities; they may not be added intentionally. Contamination with these substances must be reported qualitatively and quantitatively.

**Declarable substances:**

Substances classified as declarable are undesirable in a number of applications and must be declared above the stated limits. The listed substances must be declared for every product, component, material, substance preparation, process material and operating supply. Content limits for the individual substances are specified in this document. No declaration is required below these limits.

**Application:**

Means that the substance limit applies to the material or component wherein the substance is contained to achieve a desired functionality.

**Article:**

Object provided with a specific form, surface or design in the production process that determines its function to a greater extent than its chemical composition

**Material Compliance****Application deadline (Latest application date):**

Date by which an authorization application must be provided according to the REACH Regulation (at least 18 months before the sunset date) so that the substance can also be used in future (deadline).

Information on the authorization application and formal process of applying for authorizations is available at:

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

**Expiration date (Sunset date):**

Date after which the placing on the market and use of a substance listed in Annex XIV of the REACH Regulation is prohibited in the absence of an authorization.

**CAS Number:**

The CAS Number (also CAS Registry Number or CASRN, CAS = Chemical Abstracts Service) is an international identification standard for chemical substances. Every chemical substance (also biosequences, alloys, polymers) registered in the CAS database has a unique CAS Number.

**Sources/support:**

Platform for European laws, directives and resolutions in all existing versions and official European languages - with the year of publication and publication number needing to 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 operated by the German federal government:**

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

**REACH Helpdesk - German Federal Environment Agency:**

<http://www.reach-info.de>

**REACH@Baden-Württemberg:**

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

**Platform for German regulations:**

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

**Material Compliance****5 MKN - list of legally regulated substances****5.1 Substance regulations and prohibitions - required for all articles**

The statutory substance requirements detailed in this section 4.1 apply to all substances, mixtures and articles. The application context is detailed precisely in the respective law.

**5.1.1 Regulation (EC) No. 1907/2006 REACH - Annex XIV - List of substances subject to authorization**

Regulation (EC) No. 1907/2006 ("REACH" for short) came into force on June 1st, 2007.

The inclusion of a substance from the list of substances of very high concern in Annex XIV of the REACH Regulation makes its use subject to authorization at the end of the procedure. After a transition period, the substance must only be used with an authorization, or its use is prohibited altogether.

Please see section 2, definitions and abbreviations, for explanations of the terms "latest application date" and "sunset date".

The latest version of Annex XIV to the REACH Regulation is available here:

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

**5.1.2 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 applications/applications defined by the legislator.

The latest version of Annex XVII to the REACH Regulation is available here:

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



**Material Compliance**

**5.1.3 Directive 2011/65/EU - RoHS**

Directive 2011/65/EU of the European Parliament and of the Council of 08 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive) came into effect on 02 January 2013.

The RoHS substance regulations relate to the maximum concentration in the homogenous material of each article.

*Table 1: Substance regulations of the RoHS directive*

Substance groups	Maximum concentration in the homogenous material in percent
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)	

**5.1.4 Chemicals Prohibition Ordinance - ChemVerbotsV**

The Ordinance on Prohibitions and Restrictions of the Marketing of Dangerous Substances, Preparations and Products according to the Chemicals Act is a German law stipulating specific national requirements over and beyond the REACH Directive. As REACH is directly applicable in EU member states as a directive, an amendment of the ChemVerbotsV that combines the requirements of the REACH and CLP Directives with German chemicals law was passed in the year 2016. This serves the additional stipulation of national requirements for the following substances and substance groups:

*Table 1: ChemVerbotsV substances and substance groups*

Substances/Mixtures
Formaldehyde
Dioxins and furans
Pentachlorophenol
Bio-persistent fibers

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Please see the wording of the law for the requirements and listed exceptions, which came into force on 01/01/2019.

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

**5.1.5 Regulation (EC) No. 2019/1021 on persistent organic pollutants (POP)**

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 is available from the official website at the following link:

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

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

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

**5.1.6 Toxic Substance Control Act (TSCA)**

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

The sale of chemicals, mixtures and products containing the restricted substances is regulated in the USA. At this point in time, there is a host of different transition periods, and partly also exemptions, depending on the substance.

*Table 2: TSCA restricted PBT substances*

Substance	CAS Number
Decabromdiphenylether (decaBDE)	1163-19-5
Pentachlorothiophenol (PCTP)	133-49-3
Hexachlorbutadien (HCBD)	68937-41-7
2,4,6 tris (tert butyl)phenol (2,4,6 TTBP)	732-26-3
Hexachlorbutadien (HCBD)	87-68-3



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Besides these restrictions, there are also communication requirements if one of the five substances is present, comparable to the requirements of article 33 of the REACH regulation

The requirements which came into force between 01 and 08 March 2021, as well as the listed exceptions, can be found in the text of the law.

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

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

The Californian "Safe Drinking Water and Toxic Enforcement Act" of 1986 is often simply referred to as "California Proposition 65" or "CP65" for short. The key message of this act is the requirement that:

No person shall knowingly and intentionally expose an individual, in the course of their business, to a chemical known to the State [of California] to be carcinogenic or toxic to reproduction without first providing that individual with a clear and proportionate warning.

The State of California publishes a list of substances meeting these criteria on the following website:

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

Should a substance listed in Proposition 65 be contained in a product and an exposure of its users cannot be excluded, this fact needs to be communicated to MKN.

**5.2 Substance regulations and prohibitions - required for products from various scopes of application**

In contrast to the substance regulations in Section 5.1, the supplier must check whether his products fall within the scope of the respective requirement. Should the supplier not be able to clarify this matter independently, he must consult MKN.



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**5.2.1 Directive 94/62/EC - Packaging Directive**

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

*Table 3: Substance restrictions in packaging*

Pure substances and substance groups	Maximum concentration in packaging or packaging components in ppm by weight
Lead, cadmium, mercury and chromium VI	100 cumulative

**5.2.2 Drinking Water Ordinance (TrinkwV 2001)**

To be considered is the Ordinance on the Quality of Water Intended for Human Consumption (Drinking water regulation - TrinkwV 2001). The following standards and regulations need to be consulted for products coming into contact with drinking water:

- DIN 2001-2:2018-01: Drinking water supply from small units and nonstationary plants - Part 2: Nonstationary units - Guidelines for requirements for drinking water and the planning, construction, operation and maintenance of facilities,
- DIN EN 16421:2015-05: Influence of materials on water for human consumption - Enhancement of microbial growth (EMG)
- Technical rule DVGW work sheet W 270 (Deutscher Vereinigung des Gas- und Wasserfaches e.V. - German Technical and Scientific Association for Gas and Water).
- Evaluation criteria for plastics and other organic materials in contact with drinking water (KTW-BWGL)
- Evaluation criteria of the Federal Environmental Agency for materials in contact with drinking water, e.g., evaluation criteria for metal materials

All materials, materials and components that are intended to come into contact with drinking water must meet the requirements of the Drinking Water Ordinance and must be delivered dry and in a hygienically harmless condition.

**Material Compliance****5.2.3 Consumer Goods Ordinance**

The Consumer Goods Ordinance is a federal German regulation defining materials that are permitted in articles intended to come into contact with food. See definitions and abbreviations for an exact definition.

All materials and components coming into contact with food need to meet the BGV's requirements.

More information on this ordinance is available from the official website at the following link:

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

**5.2.4 Ordinance (EC) No. 1935/2004 - Food contact materials and articles**

"Regulation (EC) No. 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food" is a "framework" regulation applicable to all food-contact materials.

Its scope embraces:

Materials and articles which, in their finished state,

- a) are intended to be brought into contact with food
- b) are already in contact with food and were intended for that purpose
- c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

Examples: packaging materials, conveyor belts, tanks, chopping boards, crockery, cutlery, etc.

The regulation's general requirements are:

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could

- a) endanger human health
- b) bring about an unacceptable change in the composition of the food
- c) bring about a deterioration in the organoleptic characteristics thereof.

**Material Compliance****5.3 Declarable substances****5.3.1 SVHC candidate list**

The latest version of the official SVHC Candidate List as per REACH (Regulation 1907/2006/EC) is always retrievable at the following address:

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

Article 33 of the REACH Regulation requires every supplier to ensure 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.

Substances of very high concern (SVHC Candidate List) contained in

- components
- replacement parts
- accessories
- packaging

If supplied articles contain SVHCs published in the so-called Candidate List as per section 59.1 of Regulation 1907/2006/EC in proportions exceeding 0.1 % by weight, the supplier is required to include all the information as per section 33.1 of Regulation 1907/2006/EC with the delivery unprompted. This also applies if such a substance has only been included in the Candidate List during the ongoing supply relationship.

According to a ruling by the European Court of Justice, the concept of "Once an Article, Always an Article" applies. As soon as an article exceeds the concentration limit of 0.1 %, the presence of this SVHC candidate substance must be communicated.

If you supply articles with SVHC candidate substances greater than 0.1% by weight, we expect you to submit your SCIP dossier number in addition to your article 33 notification.

**Material Compliance****5.4 Auxiliary production materials and supplies****5.4.1 Safety data sheets (SDS)**

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

- identity of the product
- associated risks
- safe handling
- prevention measures
- emergency measures

The requirements for safety data sheet contents and formats 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 completing the safety data sheet in full and technically correct.

The safety data sheet needs to be provided to the MKN free of charge on paper, in electronic form or as a download option no later than on the day of the first delivery.

Suppliers need to immediately update (section 31 (9)) the SDS as soon as

- new information becomes available that is able to affect risk management measures
- an authorization has been granted or rejected
- a restriction has been passed

The corrected version must be provided to clients who have been supplied with deliveries during the last twelve months.

**Material Compliance****6 Notes****7 Other applicable documents****8 Changes****9 Distributor**

Purchasing, Production, Construction and Development, Product Management, Quality Assurance, Safety Officer, Technical Management, Distribution, Certification

**10 Traceability**

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