German Environment Agency

As at: 16 March 2016

RECOMMENDATION

Guideline for hygienic assessment of organic coatings in contact with drinking water (Coating Guideline)[1,2]

Only the German version of this document is legally binding.

1 Scope of application

1.1 Validity of this Guideline

This Guideline defines hygienic requirements for organic coatings in contact with drinking water.

This Guideline replaces the Coating Guideline of 30 November 2010. It can be used for the hygienic assessment of organic coatings and similar products such as impregnating resins, groutings or adhesives. In addition, pursuant to this Guideline, aqueous polymer dispersion and plastic coatings as well as cementitious- coatings with a polymer content > 25 % intended to come into contact with drinking water may be assessed hygienically. Furthermore it contains requirements for the assessment of the testing in accordance with DIN EN 16421 to prove hygienic harmlessness with respect to microbial growth.

1.2 Legal status of the Guideline

This guideline is a revision of the coating guideline of 30 November 2010. It is also merely a recommendation and not yet an evaluation criteria within the meaning of the Drinking Water Ordinance (Trinkwasserverordnung-TrinkwV 2001) amended on 05.12.2012. Hence this Guideline is not legally binding. It represents the current state of scientific and technical knowledge relating to the hygienic requirements for organic coatings in contact with drinking water. Therefore, it can be anticipated that products meeting the requirements of this Guideline also

[1] Notified pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204 of 21.7.1998, p. 37), last amended by Article 26 (2) of the Regulation (EU) No. 1025/2012 of the European Parliament and of the Council of 25 October 2012 (OJ L316 of 14.11.2012, p. 12).

[2] Last amended on 16 March 2016, notified under 2013/472/D

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satisfy the hygienic requirements of the Drinking Water Ordinance (TrinkwV 2001).

Pursuant to Section 17 (3) of TrinkwV amended on 05.12.2012 it is intended to transfer this coating guideline into an evaluation criteria which are legally binding 2 years after being published.

Pursuant to Section 17 (5) of TrinkwV 2001 it can be assumed that products and procedures meet requirements of Section 17 if this was confirmed by means of a certificate by a certifier accredited in the field of drinking water. Until the date of completion and entry into force of the evaluation criteria for coatings pursuant to Section 17 (2) TrinkwV 2001 this Guideline relating to conformity assessment and confirmation of harmlessness of a coating to human health may be consulted.

If certificates from another Member State of the European Union, a signatory to the Agreement on the European Economic Area or from Turkey are consulted for conformity assessment and confirmation of harmlessness to human health the following conditions have then to be met:

- Material or product testing, if any, has to be done in accordance with EN standard test method and at least comply with the level of protection for existing regulations relating to materials and products in contact with foodstuffs.
- The assessment system taken as a basis has to be trackable.

1.3 Further requirements

Organic coatings in contact with drinking water must be appropriate for their intended use. Requirements in the technical regulations are valid regardless of this Guideline.

The compliance of a product in contact with drinking water with generally accepted rules of technology and the requirements of TrinkwV 2001 can be verified via certification by a certification body accredited in the field of drinking water.

2 Coatings and other products within the meaning of this Guideline

2.1 Materials within the meaning of this guideline

Coatings are produced from coating substances by means of application (DIN 55945:1990).

Coatings within the meaning of this Guideline are products made from substances or mixtures of predominantly organic substances and the final coating does not constitute a supporting layer but forms a solid layer with a technological effect when they are used on a substrate (metals, cementitious materials). Depending on the substrate coating structures made up of several layers (primer, intermediate, final coat) may be necessary.

Organic coatings contain resins and curing agents as binding agents. Such can be for example epoxy resins, polyurethanes, polyesters.

The coating substances are usually processed by means of procedures such as spreading, immersing, filling, spraying.

Coating systems used in contact with drinking water may present a multilayer structure (primer, intermediate and final coat). The assessment may be done as a complete system or

each layer may be assessed separately according to chapter 3. In the first place an extended testing of the migration test is not planned[3].

Resins within the meaning of this Guideline are solid to liquid organic polymers and oligomers presenting an amorphous structure when dry. They may be used as coating resins, as impregnating resins, injection resins or for chemically curing adhesives.

Impregnating resins are liquid or liquefiable resins by means of which porous materials such as casting materials are saturated and impregnated. By curing of the resin the pores are completely closed. Impregnating resins are based on epoxy resins, unsaturated polyester resins and polyurethane resins as well as acrylic resins.

Injection resins are liquid or liquefiable resins by means of which cracks in the basic material are filled under pressure and closed after curing. Injection resins are typically based on epoxy resins, polyurethane resins or polyester resins.

Aqueous polymer dispersions contain thermoplastics finely spread in water and are present as stable colloidal solutions. Acrylic resins are used among others as binding agent systems for such dispersions.. Aqueous polymer dispersions may be used e.g. as surface protection systems or dispersion adhesives.[4]

Adhesives are (in accordance with DIN EN 923: 2008-06) non-metallic substances which bond assembled parts by means of surface adhesion (adhesion) and inner strength (cohesion).

- Single-component reaction adhesives:

  Single-component reaction adhesives cure as a result of external effects. This may be systems reacting to moisture and using water in the substrates or ambient air or radiation curing adhesives. The polymerisation of radiation curing adhesives may be started by UV light. Adhesives based on acrylates are examples for radiation curing adhesives. The advantage of this kind of polymerisation is that the adhesive solidifies only when required as the reaction only begins if sufficient light of a certain wavelength is available. The required curing times for these adhesives are normally short, typically in the range of 0.5–60 seconds.

[3] An extended warm water test analogous to the KTW Guideline is not useful as the majority of coatings is not resistant at 60 °C. Products suitable for warm and hot water are applied in a single layer.

[4] Roland Benedix, Bauchemie-Einführung in die Bauchemie für Ingenieure (Introduction into construction chemistry for engineers), 3rd edition, Teubner, 2006, p. 457 ff.

- Multi-component reaction adhesives:

  Most multi-component reaction adhesives are mixed from two components (two-component adhesives). The basic material is brought together with a curing agent or an activator. Reaction adhesives may cure by different mechanisms. Reaction adhesives made of epoxy resins and anhydrides or polyamines (epoxy resin adhesives) react according to polyaddition mechanisms, cyanacrylates (cyanacrylate adhesives) or methacrylates (methacrylic ester) according to polymerisation mechanisms and systems based on aminoplast or phenoplast (cf. phenolic resins) according to polycondensation mechanisms.

Casting compounds are casting resins in which other components are cast. This serves among others to protect components against penetration of moisture, dust, foreign bodies, water etc.

Casting resins are liquid or by modest warming liquefiable synthetic resins which are poured into open moulds and may be cured in these without using pressure. Casting resins include reaction resins such as epoxy resins, formaldehyde resins, isocyanate resins, methacrylic resins and unsaturated polyester resins.

Apart from casting resins also casting compounds made of plastics, e.g. polyamides, may be used.

Cementitious coatings with a polymer content > 25%

Cementitious materials are hygienically assessed according to the DVGW worksheet W 347. Traditional cementitious materials contain organic additives only in small quantities, e.g. concrete admixtures. If polymers are added to cementitious materials in higher quantities (> 25% with regard to the proportion of cement) materials are comparable with the organic coatings. Up to now starting substances necessary for the manufacture of such materials are not included yet in the positive list (Annex 1).

2.2 Composition

Coating substances and other products within the meaning of this Guideline are typically composed of the following main components:

- Binding agents (resins and curing agents if any)
- Pigments and fillers
- Organic modifying agents
- Solvents/thinners
- Additives and adjuvants
- Polymer Production Aids and Aids to Polymerisation

The **binding agent** of a coating substance is considered to be the non-volatile component of the binding agent solution or dispersion which forms the coating (DIN EN 941-1: 1996).

Binding agents are polymer components of coatings and determine the type of coating (cf. chapter 2.3).

Pigments and fillers provide mechanical stabilisation and colouration. Fillers enhance the protective function. Through giving the coating substance a viscous consistency they enhance its applicability.

Organic modifying agents serve among other things to enhance the usability and/or drying properties.

Solvents are used to lower viscosity in order to enhance applicability. They should not remain present after the curing process. In aquaeous or water-dilutable coatings water is used as a solvent or thinner.

Additives and adjuvants are used to increase:

- the storage stability of the starting substances and preparations,
- the performance characteristics (e.g. rheological additives to enhance flow properties such as runoff behaviour and smoothness),
- film quantity (e.g. anti-foam additives to prevent formation of bubbles, pores and craters),
- moistening the surface to be coated,
- the surface structure of the coating.

Furthermore **aids to polymerisation and polymer production aids** may be contained:

"Aids to Polymerisation (AtP)" have an effect on polymerisation (such as catalysts) and are used in very low quantities. They may be present in the end product, but they are not intended for it. "Polymer Production Aids (PPA)" are used as adjuvants for manufacturing products within the meaning of this Guideline. They only have a function during the manufacturing process and are not intended to have an effect in the end product. They may, however, be present in the end product.

Binding agent systems:

In **epoxy resins** resins based on Bisphenol A diglycidyl ether, Bisphenol F diglycidyl ether and other glycidyl ethers with various molecular weights are used. Curing agents may be amines, amido-amines and amine adducts whose amine hydrogens react with the epoxy groups as well as isocyanates. Other compounds such as acids or other H-active compounds can also be used as curing agents.

In **polyurethane coatings** isocyanates and compounds containing hydroxyl groups (polyols) may be used as binding agents. The combination of isocyanates with amino-functional compounds produces polyurea coatings.

Polyester coatings contain polyester compounds as their binding agents which are produced through esterification of polyvalent alcohols and polycarbonic acids and may be cross-linked with e.g. isocyanates.

Acrylic resins are cross-linkable synthetic resins extracted by polymerisation of esters of acrylic acid methacrylic esters. They contain functional groups (hydroxy, *N*-hydroxymethyl, carboxyl, epoxy groups) which may be used for cross-linking. Acrylic resins may be self-cross-linked or (e.g. by adding polyisocyanates, epoxy resins or polycarboxylic acids) co-cross-linked.

Coating systems used in contact with drinking water may present a multilayer structure (primer, intermediate and final coat). The assessment may be done as a complete system or each layer may be assessed separately according to chapter 3.

2.3 Cross-linking conditions

Cold-cured binding agents have to cure at environment temperatures and are typically not heated after application (forced drying using heated air may be possible). Hot-cured binding agents are heated or annealed for hardening. The curing time of cold-cured systems depends on composition and environment temperature during the curing process. In some cases it may take more than two weeks until the product is ready for use. Hot-cured coatings are ready for use after the annealing time, typically less than an hour.

A further distinction is made between solvent-based and solvent-free binding agent systems. Solvent-free binding agents may be used to produce thicknesses of up to 2000 µm in a single application. Solvent-based binding agents may only be applied in thin layers since the solvent contained in them needs to evaporate through the surface before this is prevented by the physical drying process and/or the ongoing reaction of the reactive components.

3 Requirements for the products within the meaning of this guideline

3.1 Requirements for the composition

All substances used for the manufacture of products in contact with drinking water within the meaning of this Guideline must be included in the positive list according to their function (cf. Annex 1). Substrate structures are also permitted to contain only assessed substances. These requirements do not apply to marginal products (cf. 3.6).

For substances that are not included in the positive list the De Minimis Guideline can be applied if the requirements stipulated therein are met.

Solvents required as "Polymer Production Aids" for the manufacture of intermediate products such as Bisphenol A resins are typically not mentioned in the positive list (cf. Annex 1). They are contained in the end product in very low quantities. For assessing these solvents in the formulations the De Minimis Guideline can be applied.[5] If, however, solvents are used for cold-cured systems the latter have to be mentioned under "1.4 Solvents" in the positive list (Annex 1).

The substances used must be of a technical quality and purity that is fit for the planned and proposed purpose of the product. The intermediate products (oligomers, reactive intermediate products) should be manufactured in accordance with "Good Manufacturing Practice" (GMP).

[5] An extension of the De Minimis Guideline is planned.

3.2 Basic requirements

The external characteristics (odour/flavour, clarity/colour/foaming) of the migration water pursuant to DIN EN 12873-1 or DIN EN 12873-2 must not be changed.

For the **cold water test** the odour and flavour thresholds (threshold odour number – TON, threshold flavour number – TFN) apply:

TON and TNF < 2	for the third migration period pursuant to DIN EN 1420-1, in case of extension of the migration test the 9th migration period pursuant to DIN EN 1420-1.

For the **warm water test** the following applies:

TON and TNF ≤ 4	for the seventh migration period pursuant to DIN EN 1420-1, in case of extension of the migration test the 22th migration period pursuant to DIN EN 1420-1.

In addition TON and TFN must indicate that there is no upward trend during testing according to DIN EN 1420-1[6].

For the release of organic substances measured as total organic carbon (TOC) the following applies to the

cold water test:

$DWPLL_{TOC} = 0.5$ mg/l

$c_{Tap} \leq DWPLL_{TOC}$	for the 3rd migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 9th migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2).

For the **warm water test** the following applies:

$DWPLL_{TOC} = 0.5$ mg/l

$c_{Tap} \leq DWPLL_{TOC}$	for the 7th migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 22nd migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2).

The TOC is defined as a non-volatile organic carbon (NPOC) in accordance with DIN EN 1484.

[6] For assessing the trend especially the last measured values and possible analytical fluctuations are taken into account.

In addition the measured concentrations in the migration waters according to DIN EN 12873-1 (or DIN EN 12873-2) must indicate that there is no upward trend [6].

3.3 Additional requirements

If the applicable additional requirement presents a migration restriction in the form of a DWPLL value (definition cf. 3.4) the migration shall be tested according to 4.3 and with respect to the indicated DWPLL value. These requirements do not apply to marginal products (see 3.6).

If types of binding agents are combined the additional requirements have to be tested for all types of binding agents contained.

For the **cold water test** the following applies:

$c_{Tap} \leq$ DWPLL for the 3rd migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 9th migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2).

For the **warm water test** the following applies:

$c_{Tap} \leq$ DWPLL for the 7th migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 22nd migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2).

In addition the measured concentrations in the migration waters must indicate that there is no upward trend according to DIN EN 12873-1 (or DIN EN 12873-2)[7].

Table 1 Overview of additional requirements for the different binding agent systems

Substances/substance groups	DWPLL in µg/l	Analytic method[8]
a) Coatings containing epoxy resins		
Bisphenol A	12[9]	DIN EN 13130-13:2005
Bisphenol F	2.5	DIN EN 13130-13:2005
BADGE including its hydrolysis products	450	Official method[10] L 00.00-51

[7] For assessing the trend especially the last measured values and possible analytical fluctuations are taken into account.

[8] The use of other equivalent analytic methods is possible.

[9] http://www.efsa.europa.eu/de/efsajournal/pub/3978

[10] Official method for the inspection of foodstuffs: Official compilation of inspection procedures pursuant to Section 64 LFGB (formerly Section 35 LMBG): www.methodensammlung-bvl.de

Substances/substance groups	DWPLL in µg/l	Analytic method[8]
BFDGE including its hydrolysis products	N. N.[11,12]	Official method[10] L 00.00-51
NOGE-isomers with M < 1000 D including its hydrolysis products	2.5	pr EN 15137:2004
Epichlorhydrin and 3-Mono-chloro-1,2-propandiol (hydrolysis product)	0.1 6	DIN EN 14207, 2003 Official method[13] B80.56-2
Formaldehyde	750	50th Notification (Federal Health Gazette 30 (1987)368)
Primary aromatic amines	N. N.[11] (0.1 µg/l)	Specific proof with GC-ECD/GC-MS with derivatisation[14]
b) Coatings containing polyurethanes		
Isocyanates	QM = 1mg/kg	DIN V ENV 13130-8: 1999
Alternatively the hydrolysing amines in the migration water may be determined.		
Primary aromatic amines	N. N.[11] (0.1 µg/l)	Specific proof with GC-ECD/GC-MS with derivatisation[14]
c) Coatings containing polyesters		
d) Coatings containing polyacrylates		
Acrylates	300 as acrylic acid	
e) Polyamides		
Primary aromatic amines	N. N.[11] (0.1 µg/l)	Specific proof with GC-ECD/GC-MS with derivatisation[14]

[11] Not detectable

[12] in case of using another analytic method the DWPLL should be set at 2,5 µg/l.

[13] Official method for the inspection of foodstuffs: Official compilation of inspection procedures pursuant to Section 64 LFGB (formerly Section 35 LMBG): www.methodensammlung-bvl.de

[14] Test method: Pietsch et al (1996) Fresenius j. Anal. Chem. 355:164-173 or Pietsch et. al. (1997) Vom Wasser 88: 119-135

Substances/substance groups	DWPLL in µg/l	Analytic method[8]
f) Conversion products of photoinitiators for adhesives		

3.4 Formulation-specific requirements for individual substances

The DWPLL is a human-toxicologically derived temporary drinking water maximum value for material-specific substances and is used to quantify a substance migration to be assessed as acceptable in the test system at the point in time determined in the Guideline.

The DWPLL is derived from the Tolerable Daily Intake (TDI value) or Acceptable Daily Intake (ADI value). This is done on the assumption of a daily consumption of 2 litres of drinking water, a body weight of 60 kg and a 10% share of total exposure for the respective substance through the drinking water (WHO concept).

The DWPLL may also have been calculated using the Specific Migration Level (SML) of Regulation (EU) No 10/2011 with the formula DWPLL = 1/20 SML of the German Environment Agency (UBA) or derived by UBA in cooperation with the Federal Institute for Risk Assessment (BfR) according to the principles of the EFSA.

The calculation of the DWPLL values from the SML values is done according table 2

Table 2 Derivation of the DWPLL value

Step	Place of validity	Limitation
0	Human being	TDI [mg/kg KM d][15]
1	drinking water	$DWPLL = \frac{TDI \cdot 60 kgKM}{2 l / d} \cdot 0{,}1$ $[mg / l] = \frac{[mg / kgKM \cdot d] \cdot kgKM}{[l / d]}$ DWPLL= 1/20 SML

If an SML value in the Regulation (EU) No. 10/2011 is specified as "not detectable", e.g. acrylonitrile, the detection limit is 0.1 µg/l.

[15] BM: Body mass

All substances with a migration limit that are used for manufacture have to be tested with regard to their migration according to 4.3. The concentration determined in the test is used to calculate the maximum concentration c_{Tap}(cf. 4.3.3) expected at the tap. These requirements do not apply to marginal products (cf. 3.6).

Instead of an experimental test the migration can also be estimated using the Modelling Guideline[16] (cf. 4.3.2).

Substances with a specific migration limit (SML) in the Regulation (EU) No. 10/2011 the SML value of which, multiplied by the molecular mass ratio of the carbon molecular mass of the substance (M_C) to the total molecular mass (M_{total}), is greater than or equal to 10 mg/l, need not be determined. The migration limit shall be covered by testing the TOC parameter of the basic requirement.

$$SML \times \frac{M_C}{\mathrm{M}_{\mathrm{gesamt}}} \geq 10\ mg/l$$

For substances with the QM or QMA limits a review of the residual content of the substance in the product is required. The QM and QMA limits apply independently of the product group of the organic material.

If a substance with a QMA limit may be determined in the test water testing of the requirement is also possible using a migration test. For that purpose, assuming that 1 kg of food is packaged in a cube with a surface area of 6 dm², an SML value can be derived from the QMA value from which the DWPLL is derived according to table 2.

$$DWPLL = {}^{1}/_{20} \times \mathrm{QMA} \times {}^{6\mathrm{dm}^2}/_{1\mathrm{kg}}$$

For some substances both a migration limit and a QM or QMA value must be indicated. In these cases only one restriction has to be tested. Preference should, however, be given to checking the DWPLL value.

For the **cold water test** the following applies:

$c_{Tap} \leq$ DWPLL for the third migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 9th migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2)

For the **warm water test** the following applies:

$c_{Tap} \leq$ DWPLL for the seventh migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2), in case of extension of the migration test the 22nd migration period pursuant to DIN EN 12873-1 (or DIN EN 12873-2)

[16] Guideline for the mathematical estimate of migration of individual substances from organic materials in the drinking water

In addition the measured concentrations must not show a rising trend[17].

3.5 Requirements for the testing of propagation of microorganisms

3.5.1 Different test methods

Testing with respect to promotion of microbial growth is done according to DIN EN 16421. The test can be performed on material sheets, end products or parts of end products (for details cf. DIN EN 16421).

In 4.4 requirements for the application of the different test procedures according to DIN EN 16421 are specified.

3.5.2 Requirements for tests in accordance with the potential of biomass production measured by ATP (procedure 1)

A product shall be deemed appropriate for the contact with drinking water with respect to promotion of microbial growth if the potential of biomass production is ≤ 1000 pg ATP /cm².

3.5.3 Requirements for tests in accordance with the volumetric procedure (procedure 2)

a) Products that demonstrate a firmly adherent surface colonisation (comparison of contact culture/abrasion of specimen to negative control) or surface growth ≤ (0.05 + 0.02) ml/800 cm², meet the requirements of this Guideline and are suitable for use in connection with drinking water.

b) For products to be used as large sealings[18] a threshold value of (0.12 + 0.03) ml /800 cm² applies. With the exception of the first one-month value (1a) all values must not exceed (0.12 + 0.03) ml /800 cm². Values plus measurement tolerance must show a constant or falling trend, i.e. value 1c must be ≤ 1b and value 3a must be ≤ 2a (cf. table 3).

c) For products to be used as small sealings[19] a threshold value of (0.20 + 0.03) ml /800 cm² applies. With the exception of the first one-month value (1a) all values must not exceed (0.20 + 0.03) ml /800 cm². Values plus measurement tolerance must show a constant or falling trend, i.e. value 1c must be ≤ 1b and value 3a must be ≤ 2a (cf. table 3).

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[17] For assessing the trend especially the last measured values and possible analytical fluctuations are taken into account.

[18] Large sealings and casting compounds for expansion joints, expansion units, compensating joints and silencers; sliders (wedge seals with tight coating); flaps if the slide is coated; air valves if the ball is coated; membranes of pressure reducers; hydrants if the stop valve is coated; plunger valves

[19] Other sealings and adhesives (no tile adhesives). All pipe connections not stated in D1 with elastic sealing elements such as flange gaskets, TYTON® socket joints, rolling rubber ring and rotating mechanical seals, surface-mounted fittings. All isolating valves not stated as large sealings such as slides with inserted or surrounding sealing, housing, spindle and wedge sealing (with inserted profile gasket). All flaps and check valves not stated as large sealings if the valves discs are not coated. All valves not stated as large sealings

d) For large sealings under b) and small sealings under c) the following additional possibility of assessment applies by including optional monthly values. Optional monthly values are only determined in those cases where materials or products are to be used as large or small sealings and where the first one-month value (1a) is within the corresponding threshold values, the second one-month value (1b) is over this value (cf. Annex 6).

e) Products not showing any surface growth nor surface colonisation (comparison of contact culture/abrasion of specimen to negative control) do not meet the requirements of this Guideline for use in connection with drinking water.

Table 3 Overview of evaluation without optional monthly values

	1-Monthly samples			2-Monthly sample	3-Monthly sample
Type of material/ product	**Sample 1a**	**Sample 1b**	**Sample 1c**	**Sample 2a**	**Sample 3a**
All materials for general use in the field of drinking water (3.5.3 a)	All values ≤ (0,05 + 0,02) ml / 800 cm²				
Materials to be used as large seals (3.5.3 b, d)	If 1a ≥ 1b, 1a will not be subject to evaluation (in case 1a is much smaller than 1b cf. "optional monthly values")		All values ≤ (0.12 + 0.03) ml / 800 cm² where 1c ≤ 1b and 3a ≤ 2a		
Materials to be used as small seals (3.5.3 c, d)	If 1a ≥ 1b, 1a will not be subject to evaluation (in case 1a is much smaller than 1b cf. "optional monthly values")		All values ≤ (0.20 + 0.03) ml / 800 cm² where 1c ≤ 1b and 3a ≤ 2a		

3.6 Marginal products

Products for which a conversion factor smaller than or equal to 0.001 d/dm shall apply (cf. table 4), may be considered as marginal products. The starting substances of these products need not be assessed or mentioned in a positive list. Requirements for the migration of individual substances as well as additional requirements do not apply to these products and a corresponding test is therefore not necessary. Basic requirements (TOC, odour, flavour and

external characteristics) do, however, apply. Furthermore testing the propagation of microorganisms is necessary.

4 Testing

4.1 Formulation review

Formulation disclosure shall be done according to the template (Annex 2). All formulation components have to be entered on the template. Accordance of formulation components with the positive list in Annex 1 has to be determined. Not only entries of substances have to be checked but also stated restrictions on use e.g. with respect to technological function. When intermediate products are used according to part 2 of the positive list monomers and other starting substances as well as additives available in the starting substances have to be included in part 1 of the positive list.

For formulation review of the multi-layer structured coating formulation disclosure shall be done separately for each layer according to the template of Annex 2. For that purpose the layer structure has to be explained.

Based on the presented formulation all parameters to be tested are specified according to chapter 3.

4.2 Test specimens

The requirements for test specimens, for their manufacture and for recording of specimen manufacture (cf. Annex 4) described below are derived from the standards for the migration test DIN EN 12873-1, DIN EN 12873-2 and DIN EN 1420-1.

The test shall in principle be carried out on the completely cured products. If it is not possible to test the finished product the test specimens are in principle to be manufactured by the manufacturer/applicant or a representative in accordance with the application instructions of the manufacturer in consultation with the test laboratory.

The chosen substrate should correspond to the practical use of the coating. Substrate treatments required by the application instructions (e.g. primer, sublayers) should also be applied to test specimens.

Regardless of whether the coatings or impregnated castings have to be produced by the manufacturer or the applicant, specimens should always follow the usual practical mode of application (e.g. curing conditions).

Multilayer coating systems may be tested as a complete system or each layer separately. When combinations from different layers are used a possible addition of the same migrated substances e.g. BADGE has to be considered.

For testing pursuant to DIN EN 16421 either material sheets, end products or parts of end products can be used.

4.3 Testing of migration

4.3.1 Performance of migration test

According to the scope of application of the product the migration test shall be performed as a cold water test at (23 ± 2) °C and possibly as a warm water test (60 ± 2) °C or hot water test (85 ± 2) °C.

Manufacture of migration waters shall be carried out in accordance with the standards DIN EN 1420-1, DIN EN 12873-1 or DIN EN 12873-2. Annex 3 describes the migration test in abridged form and contains additional requirements. The migration waters provided for analysis have to be tested with respect to these parameters which arise as a result for the proposed product group according to the basic requirements, additional requirements and formulation-specific requirements for individual substances. The test method and test results must be carefully recorded (cf. 4.6).

If c_{Tap} for one or more substances, the TOC value, the TON or TFN in the third migration period of the cold water test exceeds the test value (cf. 3.2) or shows a rising trend[20], the test may be extended up to the 9th migration period according to Annex 3.

If c_{Tap} for one or more substances, the TOC value or the TON and TFN in the 7th migration period of the warm or hot water test exceeds the test value (cf. 3.2) or shows a rising trend[20], the test may be extended up to the 22nd migration period according to Annex 3.

No extended warm water test is provided for the test of multi-layer structured systems.

Standardised analytic procedures should normally be followed in testing the migration waters. Where no suitable analytic method currently exists for a particular substance an analytic method of suitable accuracy which enables an assessment of the recorded concentration to be made, may be applied. If there is no analytic method available for individual substances an estimate of the migration for this substance has to be performed, e.g. according to the Modelling Guideline.

4.3.2 Modelling

In place of the experimental test, migration for the formulation-dependent requirements for individual substances can also be assessed by means of the modelling guideline[21] if applicability of generally recognised diffusion models based on scientific evidence and parameters was defined.

In the report of Simoneau[22] specific parameters for the most important organic materials being in food contact are contained.

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[20] For assessing the trend especially the last measured values and possible analytical fluctuations are taken into account.

[21] Guideline for the mathematical estimate of migration of individual substances from organic materials in the drinking water

[22] Simoneau C. (ed) (2010), Publication Office of the European Union, Luxembourg, JRC Scientific and Technical Report, EUR 24514 EN. "Applicability of generally recognised diffusion models for the estimation of specific

In the case of other organic materials used in contact with drinking water these parameters must be determined specifically for each material or product before modelling can be applied. Testing necessary for that purpose is also described in the above mentioned test.

A prerequisite for the modelling is the determination of the amount of the relevant substance in the product tested ($c_{P,0}$).

The method of analysis for determining $c_{P,0}$ for the polymer must be presented by the raw material supplier if there is no validated method available from the "Community Reference Laboratory for Food Contact Materials" or a standard. Alternatively $c_{P,0}$ can be used from the required quantity if the substance does not change during the manufacture and processing of the product.

Modelling must consider the respective test conditions (test temperature and test cycle) under this Guideline (see Annex 3). The concentration profile for the previous test period is used to calculate the migration for the following test period. This is described in detail in the modelling guideline.

If a product does not meet the requirements of the Guideline concerning individual substances to be tested after modelling of migration, proof can still be provided by way of experimental testing. The results of experimental tests must be weighted higher than those of the modelling.

4.3.3 Calculation of the maximum expected tap concentration (c_{Tap})

The maximum expected tap concentrations (c_{Tap}) differ for the various product groups according to conversion factors F_C stated in table 4:

$$c_{Tap} = \frac{F_c \; x \; c_{gemessen}}{O/_V \; x \; t}$$

Where

F_C: Conversion factor according to table 4

$c_{measured}$: Concentration measured in the migration water according to DIN EN 12873-1

S/V: Surface-to-volume ratio according to DIN EN 12873-1 according to the test run

t: Duration of the migration period according to DIN EN 12873-1

Table 4 lists the product groups of pipes, tanks and fittings where the requirements are further differentiated according to their place of use within the water distribution system. The product groups of the fittings and the seals are assigned to the corresponding pipe dimensions.

Table 4 Product groups with the corresponding conversion factors

Product group	Conversion factor F_c in d/dm
Pipes with DN[23] < 80 mm (drinking water installation)	20
Pipes of diameter 80 mm ≤ DN < 300 mm (supply pipes)	10
Pipes with DN ≥ 300 mm (main pipes)	5
Fittings for pipes with DN < 80 mm	4
Fittings for pipes with 80 mm ≤ DN < 300 mm	2
Fittings for pipes with DN ≥ 300 mm	1
Seals for pipes with DN < 80 mm	0.4
Seals for pipes with 80 mm ≤ DN < 300 mm	0.2
Seals for pipes with DN ≥ 300 mm	0.1
Tanks in drinking water installations including repair systems	4
Tanks outside drinking water installations including repair systems	1
Repair systems for tanks in drinking water installations with $^1/_{100}$ of the tank surface	0.04
Repair systems for tanks outside drinking water installations with $^1/_{100}$ of the tank surface	0.01
Small components from materials for pipes presenting DN < 80 mm, installed only at one position in the supply system (e.g. slide bearings of a pump)	0.004
Small components from materials for pipes presenting 80 mm ≤ DN < 300 mm, installed only at one position in the supply system (e.g. slide bearings of a pump)	0.002
Small components from materials for pipes presenting DN ≥ 300 mm, installed only at one position in the supply system (e.g. slide bearings of a pump)	0.001

[23] Internal diameter

The product group of seals is of minor importance for the coating systems, e.g. for adhesives for bonding in the overlap area. Adhesives for relining procedures have to be assessed like the corresponding inliners.

In Annex 5 to the Coating Guideline typical products are assigned to the product groups stated in table 4.

4.3.4 Test report

A test report that shall contain the complete test results as Annex 1 according to the tables 4 and 5 of Annex 3, has to be produced. Compliance with the formulation-specific requirements for individual substances (DWPLL values) which are subject to confidentiality is shown with the number of substances and the note "Test value observed". The test report consists of the following annexes:

Annex I: Table with the complete test results (see Annex 3 relating to Guideline) with modelling documentation if applicable

Annex II: Formulation Declaration (Annex 2 of the Guideline, completed and signed by the manufacturer/applicant and the test laboratory),

Annex III: Record of the manufacture of the specimens

Annex IV: Record of the performance of the test (see 4.3)

Annex V: Selection and indicators for the test methods used or indicators for modelling.

Data which is subject to confidentiality is excluded.

A test report according to DIN EN 16421 has to be produced to test promotion of microbial growth.

4.4 Requirements for the application of the test DIN EN 16421 (microbial growth)

Testing of the products with respect to promotion of microbial growth is done according to DIN EN 16421. For using the three procedures described in the standard the following restrictions apply.

Procedure 3 (MDOD method) shows a too high detection limit compared to other procedures. The procedure is not suitable to assess products intended to be used with disinfectant-free drinking water. In Germany many drinking waters are distributed without the addition of chlorine or other disinfectants. For this reason testing according to another of the two procedures (BPP procedure or volumetric procedure) is necessary for the use in Germany.

The BPP procedure (procedure 1) is not suitable for the testing of multilayer composite products since also surfaces not being in contact with drinking water normally will get in touch with the test water.

Multilayer composite products are tested with procedure 2 in the test module for pipes and hoses.

The volumetric procedure (procedure 2) is not suitable to test lubricants and greases.

5 Attestation of conformity

5.1 General information

Conformity of a product with the requirements of these Guidelines may be confirmed by a test certificate. The attestation of conformity has to be provided according to the 1+-system pursuant to the Construction Products Regulation EU (Regulation (EU) No. 305/2011). For that purpose external monitoring of the manufacturer's works shall be necessary[24].

5.2 Applications

In order to receive an attestation of conformity according to this Guideline for products in contact with drinking water the applicant must provide the test laboratory with the formulation components (indication of all substances with the percentage by weight, the CAS No and technological function (e.g. resin, curing agent) (template for formulation declaration in Annex 2). For coating systems made of several layers formulations of all layers (e.g. primer) have to be specified.

The formulation information according to Annex 2 can be given separately by the product manufacturer and the manufacturer of the preparations if the exact designation of the respective products clearly indicates their unique assignment to the product.

This clarifies the extent of the DWPLL values and the residual contents (QM, QMA) to be tested for individual substances or substance groups of the product and the purity requirement for the listed substances or substance groups.

Furthermore the proposed product group (according to table 4) of the product must be stated.

5.3 Test laboratory

Testing in accordance with this Guideline shall be done by a test laboratory accredited pursuant to ISO/IEC 17025 or by a certification body recognised by an accredited certifier.

5.4 Issuance of a attestation of conformity

The test report or certificate must contain the closing paragraph:

"The product... (precise designation) has been tested in accordance with the Guideline on the hygienic assessment of organic coatings in contact with drinking water by the German Environment Agency and has passed the test for the proposed product group(s) ... in the temperature range up to ... °C."

Test certificates issued in accordance with this Guideline are valid for a period of 5 years.

Test certificates for products of the same manufacturer that are produced in accordance with this Guideline may, if they complied with all requirements under chapter 3 in the initial test, be extended for 5 years without further experimental testing, providing that there has been no change in the formulation, in the relevant substance assessments (restrictions in the positive

[24] Implementing rules required for the external monitoring shall be specified in the technical regulations.

lists) and in the manufacturing process. Prior to extending the test certificate the test laboratory must check that the formulation, the manufacturing process and the underlying positive list have not changed.

As at: 16 March 2016

Annex 1 to the Coating Guideline

Structure of positive list

The positive list contains starting substances for the manufacture of organic coatings and similar products within the meaning of this Guideline in contact with drinking water.

The positive list is broken down into two parts: Part 1 contains all toxicologically assessed substances (cf. 3.4), Part 2 names examples of possible intermediate products.

In this positive list the "Monomers for resins and curing agents" must satisfy the **"Monomers and other starting substances"** of regulation (EU) No 10/2011.

They are divided into phenolic compounds, aldehydes, oxirane and glycidyl compounds, amines, isocyanates, diols/polyols, monoalcohols, oils and acids.

Novolaks and blocked isocyanates must only be used in powder coatings.

In accordance with the SCF Guidelines ("Note for guidance") higher molecular substances made of listed monomers (e.g. Mannich bases) are considered as reactive intermediate products. They do not require a separate listing. Smaller molecules which can migrate into drinking water (e.g. reactive diluents such as n-Butylglycidylether) and possess a toxicological significance, are assigned to the starting substances and must be assessed.

Polymer additives (molecular weight > 1000), made of monomers mentioned in part 1 of the positive list are not listed either (e.g. polyacrylate). Migrating components such as contained additives must be assessed and mentioned in the positive list of the coating guideline.

In addition the positive list contains the further formulation components of pigments/fillers, organic modifiers, solvents, additives and adjuvants and aids to polymerisation.

The positive list is set out in table format.

Column 1 shows the "EEC Packaging Material Reference Number (Ref. No) from Regulation (EU) No 10/2011.

Column 2 contains the CAS (Chemical Abstracts Service) number.

The substance name is included in **Column 3**.

Column 4 shows the DWPLL values for several substances that are used as test criteria in the migration test (see 4.3).

Column 5 shows the "QM" limit for the residual content in the plastic, "QMA" comprises a determination of the residual content which is based on a surface area of 6 dm^2 (area-based residual content).

For some substances a restriction is indicated both as DWPLL and as a QM or QMA value (derived according to chapter 3.4). In these cases only one restriction has to be tested. Preference should be given to checking the DWPLL value.

The positive list also contains substances (acids, alcohols and phenols) that can occur in the form of salts. Since the salts in the stomach are normally converted into acids, alcohols or phenols it is possible to use salts of listed acids, alcohols or phenols. This means that the salts (including double salts and acid salts) of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium and zinc of the listed

acids, phenols or alcohols are included. For the aforementioned cations the migration restriction is based on 10% of the limit values of Annexes 2 and 3 of TrinkwV 2011.

for barium	70[25] µg/l
for cobalt	1.0[26] µg/l
for zinc	300[27] µg/l

For all of the fillers used the purity requirements of the BfR Recommendation LII must be met[28].

For all of the colourants used the purity requirements of the BfR Recommendation IX must be met[28].

Inclusion of new substances in the positive lists

The addition of a substance to the positive list is only permitted on application by a manufacturer (applicant) to the German Environment Agency pursuant to the rules of procedure[29]of the German Environment Agency for keeping the positive list of substances to manufacture organic materials in contact with drinking water (cf. UBA website: http://www.umweltbundesamt.de/wasser/themen/trinkwasser/verteilung.htm).

The positive list is updated approximately once per year.

To apply for an assessment of a substance to be added to the positive list a substance dossier has to be submitted containing information on transitions of the proposed substances, its contaminations and possible resulting reaction products (e.g. decomposition products of a stabiliser) into drinking water under the most unfavourable conditions. Data to be submitted are based on the questionnaire of the European Commission for plastics in contact with foodstuff ("Note for Guidance") which is divided into sections 1 to 8.

When applying for substances not only pure substances but also contaminations shall be considered. Test conditions of this Guideline have to be used for this migration test. In place of global migration the parameter "TOC " (total organic carbon) will be determined in accordance with the requirements of the Guideline.

Section 8 of the questionnaire describes the requirements for the toxicological data to be submitted, the scope of which depends on the migration level of the requested substance in deionised water. For migrations up to 2.5 µg/l it is to be shown that the substance is not mutagenic (mutagenicity test by OECD No. 471,473 and 476). For migrations exceeding 2.5 µg/l to 250 µg/l a 90-day oral feeding study and data on bioaccumulation are necessary in

[25] 10% of the WHO guideline

[26] 10% of the LAWA guideline

[27] 10% of the WHO guideline

[28] https://bfr.ble.de/kse/faces/DBEmpfehlung.jsp

[29] http://www.umweltbundesamt.de/themen/wasser/trinkwasser/trinkwasser-verteilen/bewertungsgrundlagen-leitlinien

addition. If the migration exceeds 250 µg/l, the complete toxicological data set is required. Furthermore all existing toxicological data must be presented.

When applying for substances to be added to the positive list for manufacture of organic materials in contact with drinking water the following 3 cases shall be distinguished. The procedure depends on which toxicological assessment is available for the substance.

1 There is no publicly available assessment of the substance by an authority or organisation.

2 There is an assessment of the substance by EFSA/SCF[30] for the use in plastics in case of food contact.

3 There is a publicly available assessment of the substance by another authority or organisation, e.g. WHO, ECHA.

In case 1 the whole questionnaire has to be filled in. In case 2 points 1 to 4 have to be filled in sufficiently and in case 3 the points 1 to 7 have to be filled in. Further details for application of substances are included in the rules of procedure of the German Environment Agency for the management of the positive list of starting substances for organic materials in contact with drinking water.[31]

Within the framework of the mutual recognition in the 4MS process substance assessments from other European member states may also be accepted provided that they were carried out in accordance with the requirements of the 4MS process[32]. These substances may also be added to the positive list (Annex 1 Parts 1 and 2).

[30] European Food Safety Authority (http://www.efsa.europa.eu/de/)/ Scientific committee on food

[31] http://www.umweltbundesamt.de/sites/default/files/medien/419/dokumente/geringsfuegigkeits-leitlinie2011.pdf

[32] http://www.umweltbundesamt.de/wasser/themen/trinkwasser/4ms-initiative.htm

Part 1: Positive list of starting substances required for the manufacture of products within the meaning of this Guideline

Table 1 starting substances for coatings assessed by the UBA or recognised within the framework of the 4MS collaboration

1 List of assessed substances

1.1 Starting substances for resins and curing agents

1.1.1 Phenolic compounds

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
13480 13607	80-05-7	2,2-Bis(4-hydroxphenyl)propane (Bisphenol A)	12[33]	
14020	98-54-4	p-tert-Butylphenol	2.5	
14710	108-39-4	m-Cresol		
14740	95-48-7	o-Cresol		
14770	106-44-5	p-Cresol		
15880 24051	120-80-9	1,2-Dihydroxybenzene	300	
15910 24072	108-46-3	1,3-Dihydroxybenzene	120	
15940 18867	123-31-9	1,4-Dihydroxybenzene	30	
16000	92-88-6	4,4'-Dihydroxybiphenyl	300	
16360	576-26-1	2,6-Dimethylphenol	2.5	
22960	108-95-2	Phenol		
25927	27955-94-8	1,1,1-Tris(4-hydroxyphenyl)-ethane	0.25	
-	8007-24-7	Cashew Nut Shell liquid (›90 % 3-(n-Penta-8'-decenyl)phenol)*	2.5	

[33] http://www.efsa.europa.eu/de/efsajournal/pub/3978

1.1.2 Aldehydes

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
10060	75-07-0	Acetaldehyde	300	
14110	123-72-8	Butyraldehyde		
17260	50-00-0	Formaldehyde	750	
23860	123-38-6	Propionaldehyde		

1.1.3 Oxirane and Glycidyl compounds

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
13160 22552	28064-14-4	Novolac Glycidyl ether (NOGE)**; only for powder paints	2.5	
13460 12976	54208-63-8 39817-09-9 2095-03-6 9003-36-5	Bisphenol-F-diglycidylether**	2.5	
13510 13610	1675-54-3	Bisphenol-A-diglycidylether**	450	
13780	2425-79-8	1,4-Butandioldiglycidylether	0.1	QM = 1 mg/kg
16750 14570	106-89-8	Epichlorohydrine	0.1	
17020	75-21-8	Ethylene oxide	0.1	QM = 1 mg/kg
21823	598-09-4	2-Methylepichlorohydrine**	0.1	
24010	75-56-9	Propylene oxide	0.1	QM = 1 mg/kg
25360	26761-45-5	2,3-Epoxypropyl-trialkyl(C_5-C_{15})acetate	0.1	QM = 1 mg/kg
88640	08/07/8013	Soyabean oil, epoxidized	TOC	

1.1.4 Amines

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
12670	2855-13-2	1-Amino-3-aminomethyl-3,5,5-trimethylcyclohexane	300	
12761	693-57-2	12-Aminododecanoic acid	2.5	
12763 35170	141-43-5	2-Aminoethanol	2.5	
12788	2432-99-7	11-Aminoundecanoic acid	250	
12789 35320	7664-41-7	Ammonia	50 as NH_4^{+}[34]	
13000	1477-55-0	1,3-Benzenedimethanamine	2.5	
13075 15310	91-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	250	
13210	1761-71-3	Bis(4-aminocyclohexyl)methane	2.5	
13250	101-77-9	Bis(4-aminocyclohexyl)methane**	0.1	
15250	110-60-1	1,4-Diaminobutane		
47440	461-58-5	Dicyanodiamide		
15790	111-40-0	Diethylenetriamine	250	
16145	124-40-3	Dimethylamine**	3	
16150	108-01-0	Dimethylaminoethanol	900	
16960 15272	107-15-3	Ethylenediamine	600	
17005	151-56-4	Ethyleneimine	0.1	
18460 15274	124-09-4	Hexamethylenediamine	120	
18670	100-97-0	Hexamethylenetetramine	750 as formaldehyde	

[34] 10% of threshold value of TrinkwV 2001

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
21754	15520-10-2	2-Methyl-1,5-diaminopentane*	5	
21765	106246-33-7	4,4'-Methylenbis(3-chloro-2,6-diethylaniline)	2.5	
22331	25513-64-8	Mixture of (40 %) 1,6-Diamino-2,2,4-trimethylhexane and (60%) 1,6-Diamino-2,4,4-trimethylhexane	2.5	
23050	108-45-2	1,3-Phenylenediamine	0.1	
23505	110-85-0	Piperazine[35]**		
25180	102-60-3	N,N,N‘,N‘-Tetrakis(2-hydroxy-propyl)ethylenediamine		
25420 19975	108-78-1	2,4,6-Triamino-1,3,5-triazine	1500	
25960	57-13-6	Urea		
45760	108-91-8	Cyclohexylamine		
94560	122-20-3	Triisopropanolamine	250	
-	936-49-2	2-Phenylimidazoline*	2.5	

1.1.5 Isocyanates

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
14877	2556-36-7	1,4-Cyclohexanediisocyanate**		QM(T) = 1 mg/kg as NCO
14950	3173-53-3	Cyclohexyl isocyanate		QM(T) = 1 mg/kg as NCO
15700	5124-30-1	Dicyclohexylmethane-4,4‘-diisocyanate		QM(T) = 1 mg/kg as NCO

[35] Proposed for deletion

As at: 16 March 2016

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
16240	91-97-4	3,3‘-Dimethyl-4,4‘-diisocyanatobiphenyl		QM(T) = 1 mg/kg as NCO
16570	4128-73-8	Diphenylether-4,4‘-diisocyanate		QM(T) = 1 mg/kg as NCO
16600	5873-54-1	Diphenylmethane-2,4‘-diisocyanate		QM(T) = 1 mg/kg as NCO
16630	101-68-8	Diphenylmethane-4,4‘-diisocyanate		QM(T) = 1 mg/kg as NCO
16920	87057-87-2	2-Ethylbutane-1,4-diisocyanate**		QM(T) = 1 mg/kg as NCO
18640	822-06-0	Hexamethylene diisocyanate		QM(T) = 1 mg/kg as NCO
19110 19147	4098-71-9	1-Isocyanato-3-isocyanatomethyl- 3,5,5-trimethylcyclohexane		QM(T) = 1 mg/kg as NCO
22065	34813-62-2	2-Methylpentane-1,5-diisocyanate**		QM(T) = 1 mg/kg as NCO
22420	3173-72-6	1,5-Napthalene diisocyanate		QM(T) = 1 mg/kg as NCO
22570	112-96-9	Octadecyl isocyanate		QM(T) = 1 mg/kg as NCO
23060	104-49-4	1,4-Phenylene diisocyanate**		QM(T) = 1 mg/kg as NCO
23125	103-71-9	Phenylisocyanate**		QM(T) = 1 mg/kg as NCO
25208	26471-62-5	Toluene diisocyanate		QM(T) = 1 mg/kg as NCO
25210	584-84-9	2,4-Toluene diisocyanate		QM(T) = 1 mg/kg as NCO
25240	91-08-7	2,6-Toluene diisocyanate		QM(T) = 1 mg/kg as NCO
25270	26747-90-0	2,4-Toluene diisocyanate dimer		QM(T) = 1 mg/kg as NCO
25445	28807-72-9	Tricyclodecane diisocyanate**		QM(T) = 1 mg/kg as NCO

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
25573	16938-22-0	2,2,4-Trimethylhexane-1,6-diisocyanate**		QM(T) = 1 mg/kg as NCO
25574	15646-96-5	2,4,4-Trimethylhexane-1,6-diisocyanate**		QM(T) = 1 mg/kg as NCO

1.1.6 Diols/Polyols

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
13390 14880	105-08-8	1,4-Bis(hydroxymethyl)-cyclohexane		
13690	107-88-0	1,3-Butanediol		
13720 40580	110-63-4	1,4-Butanediol	250	
14500 43280	9004-34-6	Cellulose		
15760 13326 47680	111-46-6	Diethyleneglycol	TOC	
16390 22437	126-30-7	2,2-Dimethyl-1,3-propanediol, Neopentylglycol	2.5	
16480	126-58-9	Dipentaerythritol		
16660 13550	110-98-5 25265-71-8	Dipropyleneglycol		
53280	9004-57-3	Ethylcellulose		
16990 53650	107-21-1	Ethyleneglycol, 1,2-Ethanediol	TOC	
17530	50-99-7	Glucose		
18100	56-81-5	Glycerol		
18700	629-11-8	1,6-Hexanediol	2.5	
65520	87-78-5	Mannitol		
22190	2163-42-0	2-Methyl-1,3-propandiol**	250	
22840	115-77-5	Pentaerythritol		

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
23590	25322-68-3	Polyethylene glycol		
23651	25322-69-4	Polypropylene glycol		
23740	57-55-6	1,2-Propanediol		
23770	504-63-2	1,3-Propanediol	2.5	
24490	50-70-4	Sorbitol		
24880	57-50-1	Sucrose		
25090	112-60-7	Tetraethylene glycol		
25510	112-27-6	Triethylene glycol		
25600 13380	77-99-6	1,1,1-Trimethylolpropane	300	
25910	24800-44-0	Tripropylene glycol		

1.1.7 Monoalcohols

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
12375 33120	-	Alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{22})		
13150	100-51-6	Benzyl alcohol		
13840	71-36-3	1-Butanol		
13845	75-65-0	tert-Butanol**	500	
15100	112-30-1	1-Decanol		
16701	112-53-8	1-Dodecanol**		
16780	64-17-5	Ethanol		
17050	104-76-7	2-Ethyl-1-hexanol	TOC	
17160	97-53-0	Eugenol	0.1	
18150	111-70-6	1-Heptanol**		
18310	36653-82-4	1-Hexadecanol		
18780	111-27-3	1-Hexanol**		

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
21550	67-56-1	Methanol		
22480	143-08-8	1-Nonanol		
22555	112-92-5	1-Octadecanol**		
22600	111-87-5	1-Octanol		
69760	143-28-2	Oleyl alcohol		
22870	71-41-0	1-Pentanol		
23800	71-23-8	1-Propanol		
23830	67-63-0	2-Propanol		
25070	112-72-1	1-Tetradecanol**		

1.1.8 Oils and acids

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
10030	514-10-3	Abietic acid		
10090	64-19-7	Acetic acids		
10150	108-24-7	Acetic anhydride		
10599/90A 10599/91	61788-89-4	Dimers of unsaturated fatty acids (C18), not hydrogenated, distilled and non distilled	2.5	
10599/92A 10599/93	68783-41-5	Dimers of unsaturated fatty acids (C18), hydrogenated, distilled and non distilled		
10690	79-10-7	Acrylic acid	300	
12130	124-04-9	Adipic acid		
12280	2035-75-8	Adipic anhydride		
12810	506-30-9	Arachidic acid**		
12813	7771-44-0	Arachidonic acid**		
12820	123-99-9	Azelaic acid		
12970	4196-95-6	Azelaic anhydride		

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
12980	8015-74-5	Beechnut oil**		
12990	112-85-6	Behenic acid**		
13090	65-85-0	Benzoic acids		
13620	10043-35-3	Boracic acid	100[36]	
14140	107-92-6	Butyric acid		
14320	124-07-2	Caprylic acid		
14411	8001-79-4	Castor oil		
42960	64147-40-6	Castor oil, dehydrated		
14445	-	Castor oil fatty acids**		
14450/1	-	Castor oil fatty acids, dehydrated**		
14453	61790-39-4	Castor oil fatty acids, hydrogenated**		
14470	8001-78-3	Castor oil, hydrogenated**		
14680	77-92-9	Citric acid		
14685	8001-31-8	Coconut oil**		
14693	8001-30-7	Corn oil**		
14695/1	-	Corn oil fatty acids**		
14698	8001-29-4	Cottonseed oil**		
14700/1	-	Cottonseed oil fatty acids**		
15095	334-48-5	n-decanoic acid		
16697	693-23-2	Dodecanedioic acid		
52730	112-86-7	Erucic acid		
17170	61788-47-4	Fatty acids, coco		
17175	68938-15-8	Fatty acids, coco, hydrogenated**		
17200	68308-53-2	Soya fatty acids		

[36] 10% of threshold value of TrinkwV 2001

As at: 16 March 2016

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
17215	-	Fatty acids, sunflower oil**		
17230	61790-12-3	Fatty acids, tall oil		
17236	61790-37-2	Fatty acids, tallow**		
17245	8016-13-5	Fish oil**		
17247/1	-	Fish oil fatty acids**		
55040	64-18-6	Formic acid		
17290	110-17-8	Fumaric acid		
55190	29204-02-2	Gadoleic acid		
18010	110-94-1	Glutaric acid		
18070	108-55-4	Glutaric anhydride		
18124	8016-24-8	Hempseed oil**		
18126/1	-	Hempseed oil fatty acids		
18250 14527	115-28-6	Hexachloroendomethylene-tetrahydrophthalic acid	0.1	
18280	115-27-5	Hexachloroendomethylene-tetrahydrophthalic anhydride		
59360	142-62-1	n-Hexanoic acid		
18880	99-96-7	4-Hydroxybenzoic acid		
61840	106-14-9	12-hydroxystearic acid		
19150	121-91-5	Isophthalic acid	250	
19270	97-65-4	Itaconic acid		
19460	50-21-5	Lactic acid		
19470	143-07-7	Lauric acid		
19515	557-19-5	Lignoceric acid**		
64015	60-33-3	Linoleic acid		
64150	28290-79-1	Linolenic acid		
19532 64160	8001-26-1	Linseed oil**		
19534/1	68424-45-3	Linseed oil fatty acids**		

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PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
19540 64800	110-16-7	Maleic acid	TOC	
19960 64900	108-31-6	Maleic acid anhydride	TOC	
19965 65020	6915-15-7	Malic acid		
65040	141-82-2	Malonic acid		
22350 67891	544-63-8	Myristic acid		
22763 69040	112-80-1	Oleic acid		
22769/1	-	Olive oil fatty acids**		
22775 69920	144-62-7	Oxalic acid	300	
22780 70400	57-10-3	Palmitic acid		
22785 71020	373-49-9	Palmitoleic acid**		
22790/1	-	Palm kernel oil fatty acids**		
22795/1	-	Palm oil fatty acids**		
22867	109-52-4	Pentanoic acid**		
22945	68132-21-8	Perilla oil**		
22950/1	-	Perilla oil fatty acids**		
23170 72640	7664-38-2	Phosphoric acid		
23173	1314-56-3	Phosphoric anhydride**		
23200 74480	88-99-3	o-Phthalic acid		
23380 76320	85-44-9	Phthalic anhydride		
23730	07/11/8002	Poppyseed oil**		
23733/1	-	Poppyseed oil fatty acids**		
23890	79-09-4	Propionic acid		

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PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
23950	123-62-6	Propionic anhydride		
24045	8016-49-7	Pumpkinseed oil**		
24047/1	-	Pumpkinseed oil fatty acids**		
24055 13040	89-05-4	Pyromellitic acid**	2.5	
24057	89-32-7	Pyromellitic anhydride		
24065/1	-	Rapeseed fatty acids**		
24070 83610	73138-82-6	Resin acids		
83700	141-22-0	Ricinoleic acid	TOC	
24078	-	Ricinoleic acid, dehydrated**		
24100 24130 24190	07/09/8050	Rosin		
24160	06/10/8052	Rosin tall oil		
24260	8001-23-8	Safflower oil**		
24262/1	-	Safflower oil fatty acids**		
24270	69-72-7	Salicyclic acid		
24280	111-20-6	Sebacin acid		
24430	2561-88-8	Sebacic anhydride		
24435	8008-74-0	Sesame oil**		
24437/1	-	Sesame oil fatty acids**		
24520	8001-22-7	Soybean oil		
24550	57-11-4	Stearic acid		
24820	110-15-6	Succinic acid		
24850	108-30-5	Succinic anhydride		
24895	8001-21-6	Sunflower oil**		
24900/1	-	Fatty acids, sunflower oil**		
24905	8002-26-4	Tall oil**		

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
24910	100-21-0	Terephthalic acid	325	
24940	100-20-9	Terephthalic acid dichloride		
25540 13050	528-44-9	Trimellitic acid	250	
25550	552-30-7	Trimellitic anhydride		
26340	07/09/8024	Walnut oil**		
26345/1	-	Walnut oil fatty acids**	TOC	
36000	50-81-7	Ascorbic acid		
52000	27176-87-0	Dodecylbenzenesulphonic acid	TOC	
80720	8017-16-1	Polyphosphoric acid		
83440	03/09/2466	Pyrophosphoric acid		
92160	87-69-4	Tartaric acid		

1.1.9 Other monomers

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
10120	108-05-4	Vinyl acetate	600	
10690	79-10-7	Acrylic acid	300 as acrylic acid	
10780	141-32-2	n-Butyl acrylate		
11470	140-88-5	Ethyl acrylate		
11510 11830	818-61-1	Ethylenglycolmonoacrylat		
11710	96-33-3	Methyl acrylate		
11530	999-61-1	2-Hydroxypropyl acrylate	2.5	
13870	106-98-9	Butene		
10630	79-06-1	Acrylamide	0.1	
10660	15214-89-8	2-Acrylamido-2-methylpropan sulphonic acid	2.5	
11500	103-11-7	2-Ethylhexylacrylate	2.5	

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
12100	107-13-1	Acrylonitrile	0.1	
13630	106-99-0	Butadiene	0.1	QM = 1mg/kg
14380/23155	75-44-5	Carbonyl chloride	0.1	QM=1 mg/kg
16950	74-85-1	Ethylene		
19490	947-04-6	Laurolactam	250	
20020	79-41-4	Methacrylic acid	300 as methacrylic acid	
20110	97-88-1	Butylmethacrylate		
21130	80-62-6	Methylmethacrylate		
21190	868-77-9	Ethyleneglycol monomethacrylate		
20440	97-90-5	Ethyleneglycol dimethacrylate	2.5	
20530	2867-47-2	2-(Dimethylamino)-ethyl methacrylate	0.1	
20590	106-91-2	2,3-Epoxypropyl methacrylate	1	QMA = 0,02 mg/6 dm^2
25120	116-14-3	Tetrafluorethylene	2.5	only as monomer for polymer additive
25150	109-99-9	Tetrahydrofuran	30	
26050	75-01-4	Vinyl chloride	0.1	QM = 1mg/kg
26110	75-35-4	Vinylidene chloride	0.1	
22660	111-66-0	1-Octene	TOC	
23980	115-07-1	Propylene		
24610	100-42-5	Styrene		

1.1.10 Blocking agents (only for hot-cured coatings)

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PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
-	96-29-7	2-Butanoneoxime**		
14200 41840	105-60-2	Caprolactam	750	

1.2 Fillers/pigments[34]

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
86160	409-21-2	Silicium carbide		
96180	-	Zinc dust**	300[37]	

Additionally all colourants complying with BfR Recommendation IX and all fillers complying with BfR Recommendation LII[38].

(BfR Recommendations may be downloaded under www.bfr.bund.de under "Datenbank-Kunststoffempfehlung")

The relevant requirements follow from this (method: DIN 53770).

1.3 Modifying agents, organic

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
13150	100-51-6	Benzyl alcohol		
47520	-	Dicyclopentadiene-Indene-Styrene-alpha-Methyl-Styrene-Vinyl-Toluene-Isobutylene-Copolymer, hydrogenated**	250	
74560	85-68-7	Phthalic acid, benzyl butyl ester	1500	
74640	117-81-7	Phthalic acid, bis(2-ethylhexyl) ester	75	
74880	84-74-2	Phthalic acid, dibutyl ester	15	
75105	68515-49-1 26761-40-0	Phthalic acid diesters with primary saturated branched alcohols (C_9-C_{11}), › 90 % C_{10}	450	
92200	6422-86-2	Terephthalic acid, bis(2-ethylhexyl) ester	TOC	

[37] 10% of the WHO guideline

[38] Purity requirements according to BfR recommendation LII and requirements according to BfR Recommendation IX

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1.4 Solvents

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
13840	71-36-3	1-Butanol		
25150	109-99-9	Tetrahydrofuran	30	
30045	123-86-4	Acetic acid, butyl ester		
30140	141-78-6	Acetic acid, ethyl ester		
30295	67-64-1	Acetone		
48030	112-34-5	Diethyleneglycol monobutyl ether**	150	
48050	111-90-0	Diethyleneglycol monoethyl ether**		
53765	111-76-2	Ethyleneglycol monobutyl ether,** Butylglycol		
53820	110-80-5	Ethyleneglycol monoethyl ether**		
16999	112-25-4	Ethyleneglycol monohexyl ether**		
53860	109-86-4	Ethyleneglycol monomethyl ether**		
49540	67-68-5	Dimethylsulfoxide		
52800	64-17-5	Ethanol		
53255	100-41-4	Ethylbenzene**	30	
66655	78-93-3	Methyl ethyl ketone**	250	
66725	108-10-1	Methyl isobutyl ketone**	250	
81882	67-63-0	2-Propanol, Isopropanol		
93540	108-88-3	Toluene**	60	
95855	7732-18-5	Water	according to TrinkwV 2001	
95945	1330-20-7	Xylene**	60	

1.4.1 Blowing agents

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
-	115-10-6	Dimethyl ether*	‹ 1	

1.5 Additives and adjuvants

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
-	-	Polymeric additives from monomers under 1.1.9		
12786	919-30-2	3-Aminopropyltriethoxysilane	2.5	
26320	07/02/2768	Vinyltrimethoxysilane	2.5	
43120	8001-78-3	Castor oil, hydrogenated		
57520	31566-31-1	Glycerol monostearate**		
19960	108-31-6	Maleic acid hydride	TOC	
69760	143-28-2	Oleyl alcohol		
76960	25322-68-3	Polyethylene glycol		
81840	57-55-6	1,2-Propanediol		
30280	108-24-7	Acetic anhydride		
34230	-	Alkyl(C_8-C_{22}) sulphonic acids	300	
33801	-	n-Alkyl(C_{10}-C_{13}) benzene sulphonic acid	1500	
34240	91082-17-6	Alkyl(C_{10}-C_{21})sulphonic acid, esters with phenol	2.5	
35600	1336-21-6	Ammonium hydroxide	50 as NH_4^{+34}	
37280	1302-78-9	Bentonite		
37520	2634-33-5	1,2-Benzothiazolin-3-one**	25	only can preservation
39090	-	N,N-Bis(2-hydroxyethyl) alkyl(C_8-C_{18}) amine	60 as tert. amin	
42500	-	Carbonate		
42720	8015-86-9	Carnauba wax		

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PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
43730	55965-84-9	Mixture of 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one 3:1**	7.5	only can preservation, QMA=25µg/dm²
45640	5232-99-5	2-Cyano-3,3-diphenylacrylic acid, ethyl ester	2.5	
45705	166412-78-8	1,2-Cyclohexyldicarbonic acid-diisononyl ester	TOC	
46640	128-37-0	2,6-Di-tert-butyl-p-cresol	150	
50640	3648-18-8	Di-n-octyltin dilaurate	0.3 as tin	
53520	110-30-5	N,N'-Ethylene bisstearamide		
58960	57-09-0	Hexadecyl trimethyl ammonium bromide	300	
59120	23128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionamide)	TOC	
60560	9004-62-0	Hydroxyethylcellulose		
61600	06/05/1843	2-Hydroxy-4-n-octyloxy benzophenone	300	
62140	6303-21-5	Hypophosphorous acid		
63760	8002-43-5	Lecithin		
64270	7447-41-8	Lithium chloride**		
66715	693-98-1	2-Methylimidazole*	2.5	
66755	2682-20-4	2-Methyl-4-isothiazolin-3-one	25	
67850	8002-53-7	Montan wax		
68320	2082-79-3	Octadecyl-3(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	300	
71680	6683-19-8	Pentaerythritoltetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate		
74240	31570-04-4	Tris(2,4-di-tert-butylphenyl) phosphite		
77360	06/07/9005	Polyethyleneglycol dioleate**	TOC	
77520	61791-12-6	Polyethyleneglycol ester of castor oil	TOC	

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PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
77600	61788-85-0	Polyethyleneglycol ester of hydrogenated castor oil		
77702	-	Polyethyleneglycol ester of aliphatic monocarbon acids (C_6-C_{22}) and their ammonium and sodium sulphates		
77895	68439-49-6	Polyethylene glycol (EO=2-6) monoalkyl (C_{16}-C_{18}) ether	2.5	
78160	9004-96-0	Polyethyleneglycol monooleate**	TOC	
80000	9002-88-4	Polyethylene wax		
80077	68441-17-8	Polyethylene wax, oxidised	TOC	
80480	82451-48-7	Poly(6-morpholino-1, 3, 5-triazine-2,4-diyl)-[(2, 2, 6, 6-tetramethyl-4-piperidyl)imino]-hexamethylene-[(2, 2, 6, 6-tetramethyl-4-piperidyl)-imino]	250	
80640	-	Siliconpolyether, Polyoxyalkyl(C_2-C_4)dimethyl-polysiloxane		
81870	35674-65-8	N,N“-1,3-Propanediylbis(N‘-octadecylurea)	2.5	
85360	109-43-3	Sebacic acid, dibutyl ester	TOC	
86000	67762-90-7	Silicic acid, silanated		
86240/85580	7631-86-9	Silicon dioxide		requirements in table 1 of Regulation 10/2011
87680	1338-43-8	Sorbitan monooleate		
80720	8017-16-1	Polyphosphoric acid		
87760	26266-57-9	Sorbitan monopalmitate		
91530	-	Sulfosuccinic acid, Alkyl (C_4-C_{20}) oder Cyclohexyl diester, Salts	250	
95020	6846-50-0	2,2,4-Trimethyl-1,3-pentanediol-diisobutyrate	250	

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
95859	-	Waxes, refined, extracted from crude oil-based or synthetic hydrocarbons, high viscosity		requirements in table 1 of Regulation 10/2011
95883	-	white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks		requirements in table 1 of Regulation 10/2011
95935	11138-66-2	Xanthan gum		

1.5.1 Photo initiators for adhesives

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
38240	119-61-9	Benzophenone	30	
48640	131-56-6	2,4-Dihydroxy-benzophenone	300	
48720	611-99-4	4,4-Dihydroxy-benzophenone		
92470	106990-43-6	N,N',N'',N''-Tetrakis(4,6-bis(N-butyl(N-methyl-2,2,6,6-tetramethyl-piperidin-4-yl)amino)triazin-2-yl-4,7-diazadecane-1,10-diamine	2.5	
94000	102-71-6	Triethanolamine	2.5	
94560	122-20-3	Triisopropanolamine	250	

Additionally all substances listed under Solvents, Organic modifying agents, Binding agents or Fillers/pigments as well as Silicons which comply with BfR Recommendation XV. Silicons

(BfR Recommendations may be downloaded under www.bfr.bund.de under "Datenbank-Kunststoffempfehlung")

1.6 Aids to polymerisation

PM REF No.	CAS No.	Name	DWPLL in µg/l	other restrictions
-	7727-54-0	Ammonium persulphate*	50 as NH_4^{+34}	
-	7727-21-1	Potassium persulphate*		
94000	102-71-6	Triethanolamine	2.5	

Footnote:

*: Substances that have been assessed nationally within the framework of this Guideline.

**: Substances which have been assessed by SCF/EFSA

Part 2: Intermediate coat products

Note: The smallest components susceptible to migration have been included in the positive list according to their toxicological assessment

Some examples are given below:

Table 2 Intermediate products

German designation	English designation	Components
Intermediate products with epoxy groups		
BPA-Harze	Bisphenol A resins	Epichlorhydrine, Bisphenol A
BPF-Harze	Bisphenol F resins	Epichlorhydrine, Bisphenol F
Phenol-Novolac-Harze (nur für Pulverlacke)	Phenol novolac resins	Bisphenol F diglycidyl ether
Epoxyesterharze	Epoxyester resins	Epoxy resins, Fatty acids
Intermediate products with amines		
Kondensationsprodukt von Aldehyd und Polyamin	Condensation product of aldehyd and polyamine	Aldehydes, Amines
Mannich Basen und Salze hiervon	Mannich base and salts out of these	Phenols, Formaldehyde, Amines
Michael Additions Produkte	Michael addition products	Unsaturated compound such as unsaturated acid, amines
Polyaminoamide	Polyaminoamides	Monomeric fatty acids, dimeric fatty acids, Amines
Intermediate products with isocyanates		
Urethanpolyamine	Urethane polyamines	Isocyanates, Amines
Poly-/Oligomere von Isocyanaten (Uretdion, Isocyanurat, Biuret)	Polymers or Oligomers of Isocyanates (Uretdione, Isocyanurate, Biurete)	Isocyanates
Blockierte Isocyanate (nur für heißhärtende Beschichtungen)	blocked Isocyanates (only hot cured coatings)	Isocyanates, Caprolactame, Butanonoxime
Prepolymere	Prepolymers	Isocyanates, Alcohols, Amines

German designation	English designation	Components
Various types of polymers		
Polyacrylate	Polyacrylates	
z. B. Copolymer aus Ethylacrylat und Ethylhexylacrylat	Ethyl acrylate - ethyl hexyl acrylate, copolymer	Ethyl acrylate, ethyl hexyl acrylate
z. B. Polybutylacrylate	Polybutylacrylate	Butyl acrylate
Polymethacrylate	Polymethacrylate	
Poly(meth)acrylatpolyole	Poly(meth)acrylate polyole	Acrylic acid, mathacrylic acid, alcohols
z. B. Polyethylenglycol-1000-diacrylat		Polyethyleneglycol, Acrylic acid
Polyacrylnitrilpolyole	Polyacrylonitrile Polyols	Acrylic acid, methacrylic acid, Acryl nitril, Alcohols
Polyetherpolyole	Polyether Polyols	Oxirane compounds, Alcohols, Tetrahydrofurane, Amines
Polyesterpolyole	Polyester Polyols	Carbonic acids, Alcohols
Polyamid	Polyamide	Lactame
Phenol-Formaldehydharze	Phenol formaldehyde resin	Phenol, Formaldehyde
Harnstoff-Formaldehydharze	Urea formaldehyde resin	Formaldehyde, Urea
Copolymer aus Vinylidenchlorid	Vinylidene chloride copolymer	Vinylidene chloride, other monomers

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Annex 2 to the Coating Guideline

Template for formulation disclosure

Address of the manufacturer: .....

Annex to test application dated ... by the company ...

Product or brand name: ....

Declaration on the formulation in accordance with the Guideline on the hygienic assessment of organic coatings in contact with drinking water of the German Environment Agency

This declaration must be used to determine the scope of testing and the requirements for individual substances.

Please list all starting substances/components (resin, curing agent, processing aids, etc.) required to manufacture the product. If there is more than one supplier for certain starting substances these must be recorded individually.

The table must be completed in full.

Starting substance/ Trade name	Chemical description	CAS Number	Descrip-tion of the starting substance	Percentage by weight (in %)	Supplier (Address, phone, fax, email, contact)

All information is treated as confidential.

Signature of manufacturer:

Formulation disclosure is done according to the form in Annex 2. In this table all formulation components including further formulation components of preparation such as solvents and contaminations shall be specified by the manufacturer. A current safety data sheet for the substance or preparation may typically provide information on the purity of the substance and which other substances are contained in the formulation. In each individual case information shall be presented by the supplier.

If a product consists of several layers the composition of each layer has to be disclosed for assessment of the formulation of the product.

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Annex 3 to the Coating Guideline

Performance of migration testing and odour/flavour testing of coating materials in contact with drinking water

Testing is to be done in accordance with DIN EN 1420-1 and DIN EN 12873-1, DIN EN 12873-2 by taking into account the options available in the European standards as follows:

I. Migration test at (23 ± 2) °C (cold water test) in accordance with DIN EN 12873-1 and -2

1. The specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The specimens are pre-treated according to the following sequence:
   - · 1 h flushing with tap water,
   - · 24 h stagnation with test water at (23 ± 2)°C,
   - · 1 h flushing with tap water,
   - · rinsing with test water.
3. Deionised water as defined in 5.1.2 DIN EN 12873-1 is used as test water.
4. At least two of the same specimens are used in the test and two blind tests are carried out.
5. Pipes and hoses with an internal diameter < 80 mm are tested by filling them. Pipes and hoses with an internal diameter 80 mm ≤ DN < 300 mm are tested by setting a glass cylinder with a S/V ratio of at least 5 dm^{-1}. Pipes and hoses with an internal diameter≥ 300 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of at least 5 dm^{-1}. Test plates are tested using a S/V ratio of at least 5 dm^{-1}. Fittings and other equipment are tested by immersing the products or immersing the test plates with a S/V ratio of at least 5 dm^{-1} (see table 3 of this Annex).
6. If pipes and hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. The migration waters of the first three migration periods of three days contact time each shall be used for further analyses as described below.
8. The parameters of the basic requirements (TOC, colour, turbidity and tendency to foaming) are tested on the migration waters of migration periods 1, 2 and 3.
9. Clarity, colour and tendency to foaming are tested visually on the undiluted migration water.
10. Mixed samples are created from the tests using the migration water from migration periods 1 and 3 respectively to determine the parameters with migration restriction stated in table 1 as additional requirements. These mixed samples are then tested. The control water from the migration periods must be tested at least once.
11. Mixed samples are created from the tests using the migration water from migration periods 1 and 3 respectively to determine the individual substances specific to the formulation. These mixed samples are then tested. The control water from the migration periods must be tested at least once.

12. When the cold water test is extended migration waters (mixed samples) of the fifth, seventh and ninth migration period shall be examined to determine the basic, additional and formulation-dependent requirements for individual substances (see table 1 of this Annex).

II. Migration test at elevated temperatures (60 ± 2) °C (warm water test) and (85 ± 2) °C (hot water test)) in accordance with DIN EN 12873-1 and -2

1. The specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The test objects are pre-treated according to the following sequence:

   · 1 h flushing with tap water,

   · 24 h stagnation with test water at test temperature,

   · 1 h flushing with tap water,

   · rinsing with test water.
3. Deionised water as defined in 5.1.2 DIN EN 12873-1 is used as test water.
4. At least two of the same specimens are used in the test and two blind tests are carried out simultaneously.
5. Pipes and hoses with an internal diameter < 80 mm are tested by filling them. Pipes and hoses with an internal diameter 80 mm ≤ DN < 300 mm are tested by setting a glass cylinder with a S/V ratio of at least 5 dm^{-1}. Pipes and hoses with an internal diameter≥ 300 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of at least 5 dm^{1}. Test plates are tested using a S/V ratio of at least 5 dm^{-1}. Fittings and other equipment are tested by immersing the products or immersing the test plates with a S/V ratio of at least 5 dm^{-1} (see table 3 of this Annex).
6. If pipes or hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. 7 migration periods shall follow the pre-treatment at test temperature (10 days of total contact time).
8. Migration waters of the first second, third, sixth and seventh migration periods shall be used for examining the parameters of the basic requirement (TOC, colour, turbidity and tendency to foaming). Clarity, colour and tendency to foaming are tested visually on the undiluted migration water.
9. Mixed samples are created from the tests using the migration water from migration periods 1 and 7 respectively to determine the parameters with migration restriction stated in table 1 as additional requirement. The mixed samples from the migration water from the 1st, 6th and 7th migration periods are then tested. The control water from the migration periods must be tested at least once.
10. The test for formulation-specific substances is conducted in the migrates of the 1^{st}, 6^{th} and 7^{th} test periods (mixed samples from the tests). The control water from the migration periods must be tested at least once.
11. When the migration test at elevated temperatures is extended migration waters of the 11th, 12th, 16th, 17th, 21st and 22nd migration period (mixed samples from the test

runs) shall be tested to determine the basic, additional and formulation-dependent requirements of individual substances (cf. table 2).

III. Odour/flavour test at (23 ± 2) °C (cold water test) in accordance with DIN EN 1420-1 and DIN EN 1622

1. The specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The specimens are pre-treated according to the following sequence:

   · 1 h flushing with tap water,

   · 24 h stagnation with reference water at (23 ± 2) °C,

   · 1 h flushing with tap water,

   · rinsing with reference water
3. The reference water must be in accordance with DIN EN 1420.
4. At least two of the same specimens are used in the test and two blind tests are carried out simultaneously.
5. Pipes and hoses with an internal diameter DN < 80 mm are tested by filling them. Pipes and hoses with an internal diameter DN≥ 80 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of 2.5 dm^{-1}. Test plates are tested using a S/V ratio of at least 2.5 dm^{-1}. Fittings and other equipment are tested by immersing the products or by immersing the test plates with a S/V ratio of at least 1.5 dm^{-1} small repair systems for containers with a S/V ratio of at least 0.2 dm^{-1} (see table 3 of this Annex).
6. If pipes and hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. The migration waters of the first three migration periods of three days contact time each are used to determine the odour/flavour threshold values. If the odour threshold value fails to meet the requirements the flavour threshold value need not be determined.
8. In several test series the migration waters from migration periods 1, 2 and 3 are combined into mixed samples.
9. The mixed samples from the migration water of the 1st and 2nd migration periods are tested tentatively[39] in the laboratory to determine the odour/flavour limits. The results are presented in the test report and marked accordingly.
10. The mixed sample of the migration water from the 3rd migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.
11. When the migration test is extended migration waters of the 5th, 7th and 9th migration period shall be tested. Odour and flavour threshold values of the migration waters of the 5th and 7th migration periods are determined tentatively. The results are presented in

[39] The tentative determination is a short test in which the migration water is diluted until no odour/flavour can be perceived.

the test report and marked accordingly. The mixed sample of the migration water from the 9th migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.

12. To determine the odour/flavour thresholds, the unforced pair test is applied in accordance with DIN EN 1622 2006.

IV. Odour/flavour test at elevated temperatures (60 ± 2) °C (warm water test) and (85 ± 2) °C (hot water test)) in accordance with DIN EN 1420-1 and DIN EN 1622

1. The specimens are not subject to a disinfection pre-treatment (superchlorination).
2. The test objects are pre-treated according to the following sequence:

   · 1 h flushing with tap water,

   · 24 h stagnation with reference water at test temperature,

   · 1 h flushing with tap water,

   · rinsing with reference water
3. The reference water must be in accordance with DIN EN 1420.
4. At least two of the same specimens are used in the test run and two blind tests are carried out simultaneously.
5. Pipes and hoses with an internal diameter DN < 80 mm are tested by filling them. Pipes and hoses with an internal diameter DN≥ 80 mm can be tested by setting a glass cylinder or by filling pipe segments or by submerging test plates with a S/V ratio of 2.5 dm^{-1}. Test plates are tested using a S/V ratio of at least 2.5 dm^{-1}. Fittings and other equipment are tested by immersing the products or by immersing the test plates with a S/V ratio of at least 1.5 dm-1, small-scale repair systems for tanks with a S/V ratio of at least 0.2 dm^{-1} (see table 3 of this Annex).
6. If pipes and hoses do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
7. 7 migration periods shall follow the pre-treatment at test temperature. The migration waters of the 1st, 6th and 7th test periods are used to determine the odour-/flavour threshold values. If the odour threshold value fails to meet the requirements the flavour threshold value need not be determined.
8. In several test series the migration waters from migration periods 1, 6 and 7 are combined into mixed samples.
9. The mixed samples from the migration water of the 1st and 6th migration periods are tested tentatively in the laboratory to determine the odour/flavour threshold values. The results are presented in the test report and marked accordingly.
10. The mixed sample of the migration water from the 7th migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.
11. When the migration test is extended migration waters of the 11th, 12th, 16th, 17th, 21st and 22nd migration period shall be tested. Odour and flavour threshold values of the migration waters of the 11th, 12th, 16th, 17th and 21st migration periods are determined tentatively. The results are presented in the test report and marked

accordingly. The mixed sample of the migration water from the 22nd migration period is tested in accordance with point 12. The control water from the migration periods must be tested at least once.

12. To determine the odour/flavour thresholds, the unforced pair test is applied in accordance with DIN EN 1622.

Table 1 of Annex 3 Migration cycles of extended cold water test

Week	Migration cycle	Total contact time in days	End of migration period	Contact period in days per migration	Analysis
1	0 (pre-treatment)	1	Tuesday	1	No
1	1	4	Friday	3	Yes
2	2	7	Monday	3	Yes
2	3	10	Thursday	3	Yes
3	4	14	Monday	4	No
3	5	17	Thursday	3	Yes
4	6	21	Monday	4	No
4	7	24	Thursday	3	Yes
5	8	28	Monday	4	No
5	9	31	Thursday	3	Yes

Table 2 of Annex 3 Migration cycles of extended warm or hot water test

Week	Migration cycle	Total contact time in days	End of migration period	Contact period in days per migration	Analysis
1	0 (pre-treatment)	1	Tuesday		No
1	1	2	Wednesday	1	Yes
1	2	3	Thursday	1	Yes
1	3	4	Friday	1	Yes
2	4	7	Monday	3	No
2	5	8	Tuesday	1	No
2	6	9	Wednesday	1	Yes
2	7	10	Thursday	1	Yes
2	8	11	Friday	1	No
3	9	14	Monday	3	No
3	10	15	Tuesday	1	No
3	11	16	Wednesday	1	Yes
3	12	17	Thursday	1	Yes
3	13	18	Friday	1	No
4	14	21	Monday	3	No
4	15	22	Tuesday	1	No
4	16	23	Wednesday	1	Yes
4	17	24	Thursday	1	Yes
4	18	25	Friday	1	No
5	19	28	Monday	3	No
5	20	29	Tuesday	1	No
5	21	30	Wednesday	1	Yes
5	22	31	Thursday	1	Yes

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Table 3 of Annex 3 S/V ratio to be met at least in test runs

Test run / Area of use	Migration at 23 °C	Migration at elevated temperature	Odour/flavour at 23 °C	Odour/flavour at elevated temperature
Pipes DN < 80 mm	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)
Pipes 80 mm ≤ DN < 300 mm	S/V ≥ 5 dm^{-1} (fill, fill with cylinder inserted or fill pipe segment)	S/V ≥ 5 dm^{-1} (fill, fill with cylinder inserted or fill pipe segment)	S/V > 2.5 dm^{-1} (fill)	S/V > 2.5 dm^{-1} (fill)
Pipes DN ≥ 300 mm	S/V ≥ 5 dm^{-1} (fill with cylinder inserted or fill pipe segment or immerse coated plates)	S/V ≥ 5 dm^{-1} (fill with cylinder inserted or fill pipe segment or immerse coated plates)	S/V ≥ 2.5 dm^{-1} (fill with cylinder inserted or fill pipe segment or immerse coated plates)	S/V ≥ 2.5 dm^{-1} (fill with cylinder inserted or fill pipe segment or immerse coated plates)
Fittings	S/V ≥ 5 dm^{-1} (immerse products or coated plates)	S/V ≥ 5 dm^{-1} (immerse products or coated plates)	S/V ≥ 1.5 dm^{-1} (immerse products or coated plates)	S/V ≥ 1.5 dm^{-1} (immerse products or coated plates)
Seals	S/V ≥ 5 dm^{-1} (immerse products or coated plates)	S/V ≥ 5 dm^{-1} (immerse products or coated plates)	S/V ≥ 0.2 dm^{-1} (immerse products or coated plates)	S/V ≥ 0.2 dm^{-1} (immerse products or coated plates)
Tanks, repair systems	S/V ≥ 5 dm^{-1} (immerse coated plates)	S/V ≥ 5 dm^{-1} (immerse coated plates)	S/V ≥ 2.5 dm^{-1} (immerse coated plates)	S/V ≥ 2.5 dm^{-1} (immerse coated plates)

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Test run / Area of use	Migration at 23 °C	Migration at elevated temperature	Odour/flavour at 23 °C	Odour/flavour at elevated temperature
Small components for pipes DN < 300 mm	S/V ≥ 5 dm^{-1} (immerse coated plates)	S/V ≥ 5 dm^{-1} (immerse coated plates)	S/V ≥ 0.2 dm^{-1} (immerse coated plates)	S/V ≥ 0.2 dm^{-1} (immerse coated plates)
Small components for pipes DN ≥ 300 mm	S/V ≥ 5 dm^{-1} (immerse coated plates)	-	S/V ≥ 0.2 dm^{-1} (immerse coated plates)	-

Table 4 of Annex 3 Specified table of the test results for the TOC in accordance with DIN EN 12873-1 and -2

Product:

Date of the test:

Test temperature:

Surface/volume ratio:

Conversion factor for the tested product:

Number of migration periods:

Test method:

	Sequential number of the migration period n				
	1	2	3[40]	6	7
a_n^T					
$\bar{a}_n^T$					
b_n^T					
$\bar{b}_n^T$					
$\bar{c}_n^T = \bar{a}_n^T - \bar{b}_n^T$					
$\overline{\overline{c_{Tap}}}_n^T$					

Where

a_n^T is the concentration of a substance measured in the migration water in mg/l,

b_n^T is the concentration of a substance measured in the migration water in mg/l,

$\bar{c}_n^T$ is the concentration of the substance detected

$\overline{\overline{c_{Tap}}}_n^T$ is the maximum expected tap concentration of a migrating substance,

n is the sequential number of the migration period,

T is the test temperature

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[40] The cold water test ends with the third or ninth test period.

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Table 5 of Annex 3 — Specified table of the test results for the additional requirements and the formulation-specific requirements for individual substances in accordance with DIN EN 12873-1 and -2

Product:

Date of the test:

Test temperature:

Surface/volume ratio:

Conversion factor for the tested product:

Number of migration periods:

Tested substance:

Test method:

	Sequential number of the migration period n			
	1	3[41]	6	7
α_n^T				
β_n^T				
$\chi_n^T = \alpha_n^T - \beta_n^T$				
$\overline{c_{Tap}}_n^T$				

Where

α_n^T is the concentration of a substance measured in the migration water of the mixed sample in mg/l,

β_n^T is the concentration of a substance measured in the control water of the mixed sample in mg/l,

χ_n^T is the concentration of the substance detected

$\overline{c_{Tap}}_n^T$ is the maximum expected tap concentration of a migrating substance,

n is the sequential number of the migration period,

T is the test temperature

For the modelled concentrations a record should be produced of all the data entered (printout of the relevant software report) which shall constitute part of the test report. The recorded values shall include the characteristic values used and the details of the test run (temperature, surface of the specimen, volume of the migration water, contact time).

[41] The migration test at elevated temperatures ends with the 7th or 22nd test period.

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The formulation-specific requirements are subject to confidentiality and cannot therefore be stated in the report. Proof that a test has been carried out on these parameters and that the requirements have been met is reported in the test report as follows: "Formulation component subject to confidentiality; reference value observed."

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Annex 4 to the Coating Guideline

Template for the recording of the manufacture of specimens

The following data should be included:

1. Address of applicant,
2. accurate description of the coating substance (for unequivocal classification in terms of application, recipe statement, test record and test certificate),
3. Place of specimen manufacture (e.g. climatic chamber, production facility, laboratory, construction site),
4. Address of manufacturer, name of responsible employees,
5. Date of specimen manufacture,
6. Substrate (test plate, specimen including dimensions)
7. Surface pre-treatment of substrate,
8. Coating build-up (primer, intermediate, final coating),
9. Mixing ratios and mixing techniques,
10. Application method, application technique, application temperature, environment temperature, humidity etc.,
11. Curing temperatures and times (also of intermediate layers),
12. Special curing conditions, e.g. humidity, temperature, time curve etc.,
13. Film thickness of each layer and total strength of finished coating,
14. Differences between specimen manufacture and application instruction of manufacturer.

The products and the test plates must be packaged in suitable diffusion-resistant packaging materials (e.g. aluminium film, glass) ad must be stored accordingly to avoid contamination with other substances.

As at: 16 March 2016

Annex 5 to the Coating Guideline

Exemplary overview of different products and their assignment to product groups (section 4.5, table 7)

Table 1 of Annex 5 Overview of different products and their assignment to product groups

Product group	Products
Pipes: Areas are dimension-dependent: DN < 80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	Coatings of pipes Adhesives for multilayer hoses Adhesives for inliners
Fittings for pipes: DN < 80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	Coatings for fittings e.g. valves, taps, meters etc. Impregnating resins for fittings
Seals for pipes: DN < 80 mm 80 mm ≤ DN < 300 mm DN ≥ 300 mm	Adhesives for pipes and hoses for compounding Adhesives for fittings
Tanks: large repair systems for tanks	Coatings for tanks
Repair systems for tanks with $^{1}/_{100}$ of the tank surface	Crack grouting materials
Small components for pipes: DN ≥ 300 mm, installed only at one position in the distribution system	

Annex 6 to the Coating Guideline

Assessment of test in accordance to DIN EN 16421 – Procedure 2 (volumetric procedure) by using optional monthly values

1. General information

Optional monthly values are only determined in those cases where products are to be used as large or small seals and where the first one-month value (1a) is within the corresponding threshold values, the second one-month value (1b) is over this value (cf. table 1). Then the optional monthly values, forth one-month-value (1d) as well as second two-month-value (2b) shall be determined (cf. table 1) and used for assessment. The first one-month-value (1a) shall not be taken into account for the assessment. Assessment of the overall results shall be done without considering the value 1a (cf. table 1).

2. Large seals

With the exception of the second one-month value (1b) all values must not exceed (0.12 + 0.03) ml /800 cm². Values plus measurement tolerance must show a constant or falling trend, i.e. value 1d must be ≤ 1c, the value 2b ≤ 2a and value 3a must be ≤ 2a (cf. table of Annex 6).

3. Small seals

With the exception of the second one-month value (1b) all values must not exceed (0.20 + 0.03) ml /800 cm². Values plus measurement tolerance must show a constant or falling trend, i.e. value 1d must be ≤ 1c, the value 2b ≤ 2a and value 3a must be ≤ 2a (cf. table of Annex 6).

Table 1 of Annex 6 Overview of assessment by using optional monthly values

	1-Monthly samples				2-Monthly samples		3-Monthly sample
Type of material/ product	**Sample 1 a**	**Sample 1 b**	**Sample 1 c**	**Sample 1 d**	**Sample 2a**	**Sample 2 b**	**Sample 3 a**
Products to be used as large seals (3.5.3 d)	1a much smaller than 1b and 1a below threshold value	Where 1b ≥ 1c, 1b shall not be used for assessment	All values ≤ (0.12 + 0.03) ml / 800 cm² where 1d ≤ 1c and 2b ≤ 2a and 3a ≤ 2a				
Products to be used as small seals (3.5.3 d)	1a much smaller than 1b and 1a below threshold value	Where 1b ≥ 1c, 1b shall not be used for assessment	All values ≤ (0.20 + 0.03) ml / 800 cm² where 1d ≤ 1c and 2b ≤ 2a and 3a ≤ 2a				