Für Mensch & Umwelt

Umwelt Bundesamt

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EVALUATION CRITERIA DOCUMENT

Evaluation criteria for plastics and other organic materials in contact with drinking water[1,2] (KTW-BWGL)

General part

English translation – only the German document version is legally binding

[1] Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1)

[2] Notification numbers: 2018/480/D, 2019/646/D, 2020/726/D and 2021/596/D

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List of abbreviations	
ADI/TDI	Acceptable Daily Intake/Tolerable Daily Intake
c_0	initial substance concentration in finished product in mg/kg polymer
$c_{measured}$	analysed substance concentration in migration water in µg/l
c_{tap}	substance concentration expected at the tap in µg/l (calculated using conversion factor F_C and $c_{measured}$)
D	density of polymer in kg/cm³
ID	internal diameter in mm
EFSA	European Food Safety Authority
F_C	conversion factor in d/dm (see definition of terms)
FNU	Formazine Nephelometric Units –incident light scattering measurement (right angle 90°) according to DIN EN ISO 7027
G	basic requirement parameters
KM	body mass (human) in kg
L_p	product thickness in dm
LAWA	Federal/State working group on water
M	molecular mass in Dalton (Da)
MTC_{tap}	maximum tolerable concentration at the tap in µg/l
MTC_{tapTOC}	maximum tolerable concentration at the tap for parameter TOC in mg/l
N	requirement for unlisted starting substances
NPOC	Non-Purgeable Organic Carbon in mg/l
O/V	ratio of wetted surface to water volume in dm^{-1}
Pt	Platinum-Cobalt Scale (Pt/Co scale), also APHA Hazen colour scale
QM	residual content of polymer starting substance in mg/kg
QMA	residual content of polymer starting substance in relation to the wetted surface of the product in mg/dm²
R	formulation-specific requirements for individual substances
SCF	EU Commission Scientific Committee on Food
SML	Specific Migration Level in mg/kg (applies to food contact materials)
TOC	Total Organic Carbon
TON	Threshold Odour Number
TPE	Thermoplastic Elastomer
TrinkwV	Drinking Water Ordinance (Trinkwasserverordnung)
UBA	German Environment Agency (Umweltbundesamt)
WHO	World Health Organization
Z	additional requirement parameters
z.B.	e.g. (zum Beispiel)
% (m/m)	percentage by mass

Definition of terms [*German expression in brackets]*	
Additional requirement *[„Zusatzanforderung“]*	An additional requirement is a parameter that generally must be tested for a specific polymer (polymer-specific).
Additive *[„Additiv“]*	An additive is a substance intentionally added to organic material to achieve a physical or chemical effect during manufacture or in the end-product. An additive is intended to be present in the end-product (Commission Regulation (EU) No 10/2011).
Aid to Polymerisation (AtP) *[„Polymerisationshilfsmittel”]*	An aid to polymerisation is a substance which initiates polymerisation and/or controls the formation of the macro-molecular structure (Commission Regulation (EU) No 10/2011).
Base polymer *[„Base polymer”]*	A base polymer is defined by the used monomers that predominantly constitute the polymer chain.
Basic requirements *[„Grundanforderungen“]*	Basic requirements are parameters that apply to all products made of organic materials.
Component *[„Bauteil“]*	A component is the smallest, not dismountable unit that is used itself as a product or as part of a composite product in drinking water distribution.
Composite product *[„Zusammengesetztes Produkt“]*	A composite product is a product that consists of different components that can be dismantled.
Conversion factor (F_C) * *[„Konversionsfaktor“]*	The conversion factor is used to calculate c_{tap} and is based on worst case-assumptions on water contact times with relevant products and their surface-to-volume ratios in drinking water distribution.
Drinking water installation *[„Trinkwasserinstallation“]*	See term definitions in the Drinking Water Ordinance (TrinkwV).
End product *[„Endprodukt“]*	An end product is a product made of organic material or a multilayered product that will not be changed further except for possible mechanical processing. Note: In conformity assessment, this can also be a component of a composite product.
Extraction *[„Extraktion“]*	Extraction refers to the solubilisation of substances from a polymer by means of a solvent. Extraction aims at accomplishing total substance transfer where possible and thus yields markedly higher results than migration.
Formulation *[„Rezeptur“]*	Formulation is the list and relative amount of starting substances used to manufacture the material.
Formulation cut-off limit *[„Rezepturuntergrenze”]*	The formulation cut-off limit denotes a threshold value below which a formulation constituent needs not to be considered in formulation assessment. Its unit is a mass percentage.

Definition of terms [*German expression in brackets*]	
Formulation-specific requirement for individual substances *[„rezepturspezifische Einzelstoffanforderung"]*	A formulation-specific requirement for individual substances is a requirement that only needs to be tested if a starting substance is present in the formulation.
Functional barrier *[„Funktionelle Barriere"]*	A functional barrier is a material layer that delays but does not prevent the diffusion of migrating substances (does not correspond to the definition in Commission Regulation (EU) No 10/2011).
Intermediate product *[„Zwischenprodukt"]*	An intermediate product is a substance or admixture that is prepared for subsequent processing by which it will be exhausted or undergo conversion into another substance or polymer (according to REACH).
Migration *[„Migration"]*	Migration is the transfer of substances to be assessed from the product into drinking water.
Monomer *[„Monomer"]*	A monomer is 1. a substance that undergoes any type of polymerisation to manufacture polymers or 2. a natural or synthetic macromolecular substance used to manufacture modified macromolecules or 3. a substance used to modify existing natural or synthetic macromolecules (Commission Regulation (EU) No 10/2011).
Multilayered product *[„Mehrschichtig aufgebautes Produkt"]*	A multilayered product is a product made of multiple layers firmly attached to each other.
4MSI Positive Lists *[„4MSI Positivlisten"]*	Lists of starting substances and other additives for manufacture of organic materials in contact with drinking water established within the 4MSI collaboration framework (https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative#publication-of-common-approaches). Publication occurred in part B of the Common Approach document on organic materials. In this document, a subdivision is made into fully evaluated substances entirely accepted among 4MSI (Core List) and substances not fully accepted due to incomplete or inadequate evaluations regarding recent criteria (Combined List). Substances with outdated and/or incomplete evaluations not used any more are compiled in the Obsolete List for information purposes only and may not be used in Germany.

Definition of terms [*German expression in brackets]*	
Polymer *[„Polymer“]*	a polymer is a macromolecular substance obtained from 1. monomers via polymerisation such as polyaddition or polycondensation or a similar procedure, or 2. chemical modification of natural or synthetic macromolecules (partial definition from Commission Regulation (EU) No 10/2011).
Polymer Production Aids (PPA) *[„Hilfsstoff”]*	A polymer production aid is a substance used as a suitable medium for the manufacture of organic materials. It can be present in the end product but is not intended to be there nor does it have any physical or chemical effect on the end product (Commission Regulation (EU) No 10/2011).
Pre-product *[„Vorprodukt“]*	A pre-product is a polymer that may contain additives or other constituents like glass fibres and that does not undergo further reactions. It is used for the manufacture of a product intended to come into contact with drinking water (e.g. a granulate)
Product *[„Produkt“]*	A product is clearly identified in terms of its final form and surface area, placed on the market by a manufacturer and intended to come into contact with drinking water.
Product group *[„Produktgruppe“]*	A product group includes different products or components with the same conversion factor that are comparable in terms of their frequency of use in drinking water distribution and their surface-to-volume ratio.
Risk group *[„Risikogruppe“]*	The risk group of a product or component made of organic materials depends on its applicable conversion factor F_C and will thus define details of testing and evaluation efforts.
Starting substance *[„Ausgangsstoff“]*	A starting substance is a substance (monomer, additive, polymer production aid) used to manufacture organic materials (does not correspond to the definition in Commission Regulation (EU) No 10/2011).
Test sample *[„Prüfkörper“]*	A test sample is a product or a specifically manufactured specimen that is tested and assessed on a representative basis for one or more products.
Total barrier *[„Totale Barriere“]*	A total barrier is a barrier layer that prevents the diffusion of any substances towards the side in contact with drinking water.

* Derivation of F_C is made according to the scheme in Annex B of 4MSI Draft Common Approach on Organic Materials – Part C
https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative [Documents]

1 Introduction

Under § 17(2)(1) of the Drinking Water Ordinance (TrinkwV), materials and substances for the construction or maintenance of installations for the production, processing or distribution of drinking water, that come into contact with drinking water, may not

1. directly or indirectly reduce the protection of human health provided for in the TrinkwV,
2. negatively impact the odour or flavour of water, or
3. release substances into the drinking water in greater amounts than are considered unavoidable under the generally accepted rules of technology.

This evaluation criteria document specifies, pursuant to § 17(3) TrinkwV, the above general hygienic requirements for organic materials listed within the scope of application.

Organic materials within the scope of this document are in accordance with the requirements of § 17(2)(1) TrinkwV if they comply with the requirements set out here.

Under § 17(3)(4) TrinkwV, the evaluation criteria document shall be mandatory 2 years after its publication, i.e. as from 21 March 2021. From this date, entrepreneur and other owner of a water supply pursuant to § 17(2)(2) TrinkwV must ensure that for the construction or maintenance of installations for the production, processing or distribution of drinking water, only such organic materials are used that meet the requirements of the present assessment guideline.

Proof of compliance of a product with the requirements of these evaluation criteria may be given e.g. in form of a certificate from a certifying body accredited for drinking water. The recommendation 'conformity assessment of the suitability of products for use in drinking water' clarifies certification as regards the requirements of this evaluation criteria document.

If, in the course of maintenance of existing installations, only a few components of a product need to be replaced and the required components are made from a material that does not meet the requirements of this evaluation criteria document but nonetheless demonstrably has no adverse effect on drinking water quality, then a replacement of the entire installation is not necessary. The replacement would represent undue hardship for the operator and other owners of the existing installation and would be disproportionate. Potential evidence that drinking water quality is not adversely affected can be provided using the German Environment Agency Recommendation on assessing environmental contaminants in drinking water.[3]

With the provisions of § 17(3) TrinkwV and the specific requirements laid down in this evaluation criteria document, the Federal Republic of Germany has implemented Article 10 of Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption, which requires Member States of the European Union to lay down requirements

[3] https://www.umweltbundesamt.de/dokument/beurteilung-materialbuertiger-kontaminationen-des (in German)

for materials in contact with drinking water. There is currently no harmonised European legislation for products in contact with drinking water. Four EU Member States, Germany, France, the Netherlands and the United Kingdom of Great Britain (4MS), shall cooperate in order to achieve an alignment of their national requirements. This evaluation criteria document implements the jointly prepared regulation proposal for organic materials in contact with drinking water.[4] The German Environment Agency is also working with the competent authorities of the Member States on preparing and updating the evaluation criteria.

2 Scope of application

The following organic materials currently come under the scope of application of this evaluation criteria document:

- plastics (see scope of application of Annex A)
- organic coatings (see scope of application of Annex B)
- lubricants (see scope of application of Annex C)
- elastomers (see scope of application of Annex D)
- thermoplastic elastomers (TPE) (see scope of application of Annex E)

Annex D and E will become mandatory from 1 March 2025.

The following organic materials shall also come under the scope of application once the relevant annexes are supplemented:

- silicones
- TPE based on silicones

A transitional regulation (transitional recommendation for silicones[5]) continues to apply to these organic materials that does not yet have the legal status of an evaluation criteria document under § 17(3) TrinkwV.

Cementitious materials with less than 25 % (m/m) organic content (with regard to cement content) do not come under the scope of application of this evaluation criteria document. A separate evaluation criteria document shall be developed for these materials, which will be done in accordance with the revised European Drinking Water Directive (Directive (EU) 2020/2184).

Coatings with cementitious fillers with over 25 % organic content (m/m) (with regard to cement content) come under the scope of application of Annex B of the Specific Part of this evaluation criteria document.

Ion-exchange resins do not currently fall under the scope of this evaluation criteria document.

[4] https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative

[5] https://cms.umweltbundesamt.de/en/document/transitional-recommendation-for-preliminary

Composite products, for example kitchen taps, can consist of different substances and materials. The components must be assessed in terms of each material. If there are components of organic material, these come under the scope of application of this evaluation criteria document.

3 Principle of assessment for products/components of organic materials

Products or components of organic materials must be assessed specifically per product or component because the production process (particularly extrusion, injection moulding and crosslinkage) can have significant impact on suitability of the end product for use in drinking water.

Products or components of organic materials are assessed on the basis of the starting substances used to manufacture them. The German Environment Agency (UBA) assesses the starting substances according to the principles of the European Food Safety Authority (EFSA) that apply to materials in contact with food. The assessment includes substance migration and the toxicological properties of the starting substance to be assessed, potential contaminants and reaction and degradation products. The assessed starting substances are listed in material-specific positive lists in the annexes to this evaluation criteria document.

Products or components of organic materials must be assessed in terms of substance migration into drinking water. Generally, migration testing is required, which involves starting substances with restrictions and additional requirements (potential reaction and degradation products). In addition, migration water samples must be assessed for adverse impact on odour and visual appearance.

Products or components must also be assessed with regard to the enhancement of microbial growth.

The extent of testing and assessment to determine hygienic suitability for use in drinking water are risk-based. The use of materials for individual products and components and the related risk of adverse impact on drinking water quality is a decisive factor in these costs.

4 Assessment of starting substances

4.1 Procedure

The German Environment Agency assesses starting substances used for manufacturing organic materials at the request of a manufacturer or association (applicant). The application procedure is regulated in the rules of procedure of the German Environment Agency on the management of positive lists of starting substances in contact with drinking water[6].

[6] https://www.umweltbundesamt.de/en/document/rules-of-procedure-of-the-german-environment-agency-0

The assessment is performed in line with the EFSA principles for the assessment of materials in contact with food. These are set out in the *Note for Guidance for the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials*[7]. For assessment of nanostructured substances, it is additionally referred to the EFSA manual *Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health*[8]. For the assessment of starting substances, not only the pure substances but also contaminants and potential reaction and degradation products are examined.

To assess starting substances, migration testing must be conducted in order to obtain statements on potential substance migration into drinking water. Where possible, this should be conducted according to the test conditions set out in this evaluation criteria document rather than the provisions on materials in contact with food. In addition, the 'TOC' (total organic carbon) parameter should be determined according to the test requirements of this evaluation criteria document.

Based on the migration determined, the applicant must submit the following toxicological examinations for assessing the migration substances originating from materials in contact with drinking water:

- Where migration leads to c_{tap} (see 6.3.3) of up to 2.5 µg/l, the substance must be shown to be non-genotoxic.
- Where migration leads to c_{tap} of over 2.5 µg/l and up to 250 µg/l, an oral 90-day feeding study is also necessary and it must be shown that the substance is not bioaccumulative. Assessment of studies by the German Environment Agency can result in the determination of MTC_{tap} values of over 2.5 µg/l.
- Where migration leads to c_{tap} of over 250 µg/l, the full toxicological data set is necessary. If the toxicological studies allow, the German Environment Agency shall derive a TDI value.

The necessary studies are set out in the Note for Guidance for the Preparation of an Application for the Safety Assessment of a Substance to be used in Plastic Food Contact Materials.

In addition, the applicant must mention additional toxicological examinations conducted alongside the required studies and reference the source.

If there already is an EFSA assessment for starting substances for the manufacture of materials in contact with food, the application procedure is simplified in line with the rules of procedure and migration testing is not generally required.

The German Environment Agency accepts substance assessments from other EU Member States, provided these are conducted in accordance with the provisions of the 4MS Initiative guidance document for organic materials[9]. These assessed substances shall also be included in the relevant positive lists.

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[7] https://www.efsa.europa.eu/en/efsajournal/pub/rn-21

[8] https://www.efsa.europa.eu/en/efsajournal/pub/5327

[9] https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative

4.2 Restrictions

Various restrictions may arise from the assessment of starting substances:

a) Migration-based restriction in the form of maximum tolerable concentration at the tap MTC_{tap}: the MTC_{tap} value is derived from the Tolerable Daily Intake (TDI value) or Acceptable Daily Intake (ADI value). This is done assuming daily intake of 2 l of drinking water, body weight of 60 kg and 10 % overall exposure for the relevant substance allocated to drinking water (4MS-concept[10]). For substances that can enter drinking water from other sources, for example water treatment reagents or geogenic components of raw water, an additional allocation factor of 10 % is applied.

For substances with a specific migration limit (SML) in Commission Regulation (EU) No 10/2011, $MTC_{tap} = \frac{1\ kg}{20\ l}$ SML applies.

Table 1: Derivation of MTC_{tap}

Stage	Area of validity	Limit
0	Humans	TDI [mg/(kg KM d)] (KM = body mass)
1	Drinking water	$MTC_{tap} = \frac{TDI \cdot 60 kgKM}{2l/d} \cdot 0{,}1$ $[mg/l] = \frac{[mg/kgKM \cdot d] \cdot kgKM}{[l/d]}$ $MTC_{tap} = \frac{1\ kg}{20\ l}$ SML

b) Residual content of polymer starting substance: a distinction is made between QM, the residual polymer content in relation to polymer mass (in mg of starting substance/kg polymer), and QMA, the residual polymer content in relation to the contact surface (in mg of starting substance in relation to 6 dm²).
c) Specifications for starting substance purities: the requirements apply to the starting substance used and cannot be checked on the end product.

Example: Polydimethylsiloxane (Ref. No 76721) with specifications as per Commission Regulation (EU) No 10/2011.

[10] https://www.umweltbundesamt.de/sites/default/files/medien/5620/dokumente/common_approach_on_organic_materials_-_part_a_methodologies_for_testing_and_accepting_starting_substances_0.pdf

d) Restricted use in polymers: this is a usage restriction for the starting substance used to manufacture a specific polymer or for use with a specific function.

Examples: Iron phosphide (Ref. No 62245) or [3-(Methacryloxy)propyl]trimethoxysilane (Ref. No 76721) with usage restrictions as per Commission Regulation (EU) No 10/2011.

e) Biocidal additives are only allowed for in-can-application. To obtain an approval, it must be demonstrated that in the finished product the biocide does not lead to biocidal activity at the drinking water contact surface (see 5.6.2). As a prerequisite for the evaluation process, the biocidal substance must be approved according to Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.
f) Substances with nanosize properties may only be used if nanostructure is noted in column 5 “Other restrictions”.

4.3 Positive lists

Assessed starting substances are listed in the material-specific positive lists (see annexes). The positive lists are regularly updated in line with the provisions of § 17(4) TrinkwV.

The positive lists generally make a distinction between monomers, additives, polymerisation production aids (PPA) and aids to polymerisation (AtP) for the manufacture of organic materials. The positive list for organic coatings containing reactive components deviates from the above distinction in order to better reproduce the material-specific features. This is described in the polymer-specific part of Annex B. Positive lists also contain restrictions arising from assessment.

The positive lists are set out in table format.

Column 1 lists the ‘EEC Packaging Material Reference Number (Ref. No)’ from either Commission Regulation (EU) No 10/2011 or from the rejected SCF „Synoptic document“ working paper (“Provisional list of monomers and additives notified to European Commission as substances which may be used in the manufacture of plastics and coatings intended to come in contact with foodstuffs”).

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

Column 3 lists the substance name.

Column 4 shows the MTC_{tap} values for several substances that are to be applied as test criteria in the migration test (see 5.5).

Column 5 - other restrictions - ‘QM’ denotes the limit for residual substance content in the organic material, ‘QMA’ denotes the limit for residual substance content in the organic material related to a surface area of 6 dm^2 (area-based residual content).

5 Hygienic requirements for organic materials in contact with drinking water

5.1 General

This evaluation criteria document lays down requirements pertaining to the hygienic suitability of products or components made of organic materials in contact with drinking water. It contains no provisions on technical suitability. Products or components must be suitable for their intended use. The corresponding requirements are set out in the technical standards for example.

Requirements to ensure safe drinking water (Table 2) are formulated using the risk-based approach from the use of materials in individual products or components. The conversion factors (Table 7) of the products or components to be assessed are used as the basis for classification.

For assignment of the risk group, wetted surface proportions of components of the same base polymer (e.g. PE, EPDM) in a composite product must be added.

Elastomer sealing gaskets of gap or ring type are handled independently from other elastomer components made from the same base polymer (like expansion membranes and shaped parts). In this case adding up wetted surface proportions will only comprise gap and ring seals. While in exceptional cases these added surface proportions of gap and ring seals might exceed 10 %, nevertheless requirements of components with wetted surface proportions < 10 % apply to these gap and ring seals, and respective parts are assigned to risk group P2.

For products or components to which the requirements pertaining to formulation test samples apply, assessment of these test samples is sufficient. Products or components produced from the same formulation at various locations or by different manufacturers and belonging to the same risk group do not need to be also tested and assessed. The specifications of the production or processing conditions must be complied with.

Table 2: Risk-based requirements

Risk group	Conversion factor F_C in d/dm (See Table 7: Product groups with corresponding conversion factors)	Examples for products (See Table 8: Allocation of products to product groups)	Composition requirement	Basic requirements	Formulation-specific requirements for individual substances	Additional requirements	Microbiological requirements (For pipes $F_C \leq 10$ d/dm the microbiological requirements for formulation test samples apply)
P1	≥ 0.5	Pipes	Yes applies to formulation	Yes applies to product/ component	Yes applies to product/ component	Yes applies to product/ component	Yes applies to product/component
		Fittings/ ancillaries and containers	Yes applies to formulation	Yes applies to product/ component	Yes applies to product/ component	Yes applies to product/ component	Yes applies to formulation test samples
P2	$0.05 \leq F_C < 0.5$	Fitting/ ancillary components and components in containers	Yes applies to formulation	Yes applies to formulation test samples	Yes applies to formulation test samples	Yes applies to formulation test samples	Yes applies to formulation test samples
P3	$0.005 \leq F_C < 0.05$	Small fitting/ ancillary components and small components in containers	No	Yes applies to formulation test samples	No	No	Yes applies to formulation test samples
P4	< 0.005		No	No	No	No	No

5.2 Composition requirements

5.2.1 Assessed starting substances

The starting substances used to manufacture organic materials must be listed according to their technological function in the applicable material-specific positive list for the starting substance (see annexes).

For manufacture of products that fall within the scope of Annex A it is also possible to use substances from the positive list of Commission Regulation (EU) No 10/2011. In addition, the positive lists (Core List and Combined List)[11] prepared as part of the 4MSI cooperation can be used to assess starting substances for products that fall within the scope of Annexes A, B and C, including related restrictions defined therein. For products made of elastomers or chemically cross-linked TPE (products within the scope of Annexes D and E), in addition to the positive list of Annex D also starting substances from the Core List may be used for the manufacture of elastomers including related restrictions defined therein.

For some of the substances appearing in material-specific positive lists (annexes) or in the 4MSI Core List there have been defined more stringent migration requirements than would result from section 5.5.2 paragraph 2. This is due to contributions from various existing sources to drinking water.

Example: *Ethylenediamine-tetraacetic acid, migration restriction MTC_{tap}=60 µg/l.*

The starting substances used must also be of a technical quality and purity suitable for the planned and foreseeable purpose of the product.

5.2.2 Unlisted starting substances

In the following cases, notwithstanding the requirements in 5.2.1, starting substances can be used, even if they are not listed in the material-specific positive list for the starting substance:

a) Low use

Added substances making up less than 0.02 % (m/m) of the end product of a material or of the multilayered product do not need to be assessed and listed on the applicable positive list. This only applies if at the same time the total content of substances added in this manner is less than 0.1 % (m/m).

Note: *For composite products, additions to each component must be taken into account.*

Solvents that are not expected in the end-product due to their volatility and considering the manufacturing conditions are not taken into account when assessing and determining the contents of components.

[11] https://www.umweltbundesamt.de/en/topics/water/drinking-water/distributing-drinking-water/approval-harmonization-4ms-initiative [Documents]

b) The starting substance, its contaminants and potential reaction and degradation products do not migrate into drinking water

With the exception of monomers, starting substances of organic materials and products in contact with drinking water require no toxicological assessment and hence do not need to be listed in a positive list if they and their contaminants including reaction and degradation products are not transferred into drinking water from the product ('no detectable substance transfer') and are not classified under CLP Regulation No 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction or as substances in nanoform.

This condition is met if it can be demonstrated that the migration limit of MTC_{tap} = 0.1 µg/l is complied with for the relevant product group (see 6.3). If products manufactured from this starting substance are to be used in warm or hot water applications, it must also be demonstrated for these applications.

The following options are available to demonstrate compliance with the migration limit MTC_{tap} = 0.1 µg/l. In all cases, the concentrations calculated or determined must be converted into the maximum expected tap concentrations c_{tap} (see 6.3.3):

- Calculation of total migration (100 %) of the substance quantity of the material in question used in production from the product into the migration water (as per 'Note for guidance'):

$$c_{calculated} = c_0 \times S/V \times L_p \times D$$

$c_{calculated}$ = maximum possible migration of the substance into the migration water from the product in mg/l

c_0 = content of the substance in the finished product/product in mg/kg of polymer

S/V = ratio of wetted test sample surface to water volume in dm^{-1} as per specifications of DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07

L_p = thickness of the product in dm

D = Density of the product in g/cm^3

- Calculation of migration using the Modeling Guideline[12],
- Calculation of aqueous solubility of the substance by applying suitable software,
- Analytical determination of the substance in the test waters of the migration test as single substance migration with a suitable analysis method, the detection limit of which is at least 0.1 µg/l excluding the analysis tolerance.

[12] Modelling Guideline: Guideline for the mathematical estimate of the migration of individual substances from organic material in drinking water, Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2009:52(11): 1105-1112, https://www.umweltbundesamt.de/en/document/modelling-guideline

c) Salts of listed acids, phenols or alcohols

Salts of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium and zinc of acids, phenols or alcohols listed in the material-specific positive lists may also be used as starting substances. For the cations mentioned, 10 % of the limit values in TrinkwV and the following additional restrictions apply as MTC_{tap} values:

aluminium 20 µg/l

ammonium 50 µg/l

barium 70 µg/l (10 % of the WHO guideline value)

cobalt 1.0 µg/l (10 % of the LAWA guideline value)

copper 200 µg/l

iron 20 µg/l

lithium 30 µg/l (1/20 of SML 5 mg/kg from Regulation (EU) No 2016/1416)

manganese 5 µg/l

zinc 250 µg/l (1/20 of SML 5 mg/kg from Regulation (EU) No 2016/1416)

d) Mixtures of substances

Mixtures obtained without chemical reactions by mixing listed starting substances can be used.

e) Additives with molecular mass > 1000 Da

Substances with molecular mass over 1 000 Da normally are not absorbed in the human body. For this reason, their health risk is classified as low. Additional assessment of these substances is not required if the starting substances necessary for manufacturing are assessed and the low-molecular oligomer matter with molecular mass below 1 000 Da have been estimated. If unlisted substances are present in these additives, assessment can be made according to a) through d) above.

f) Pre-polymers from listed starting substances

Pre-polymers and natural or synthetic macromolecular substances, as well as their mixtures, do not need to be separately listed if the starting substances used for manufacturing are listed. However, if during polymerisation intermediate structures arise that are not fully polymerised and that could migrate into drinking water, these require assessment in line with the procedure outlined in Chapter 4.1.

Example: *For organic coatings, pre-polymers are listed in Table B-2 of the positive list for 'intermediate product' coatings with possible monomer starting substances.*

g) Colourants

Colourants (including pigments) are not listed in the positive list because it is assumed that these are not transferred to drinking water. However, additional requirements apply when colourants are used (see 5.4.3).

Other constituents of colourant preparations must be assessed if no other exclusion criterion is fulfilled.

h) Ceramic fillers

Ceramic fillers do not need to be listed in the material-specific positive list if they meet the specifications of the evaluation criteria document for enamels and ceramic materials. The relevant evidence must be indicated on the end-product (see 5.4.2).

i) Cementitious fillers

Cementitious fillers for coatings are listed in Annex B under B.3.1.3 (see annexes). The requirements of DVGW standard W 347 (May 2006): 'Hygiene requirements applying to cement-bound materials in the drinking water sector — testing and evaluation' apply to these fillers.

j) Gaseous Polymer Production Aids (PPA) and Aids to Polymerisation (AtP)

PPA and AtpP which are employed in gaseous form for polymer manufacturing (e.g. for "endcapping") and which, after polymerisation has been completed, cannot be detected analytically, do not require listing in material-specific positive lists. This exemption does not apply to gaseous starting substances with technological function as monomer according to "definition of terms".

Note: *"Endcapping" reagents are monofunctional and interact with reactive sites of the propagating polymer matrix. This way non-reactive end groups are formed which do not participate in further polymerisation processing and thus cease polymerisation. Such substances therefore cannot be considered as monomers.*

k) Solvents

Solvents are needed as production aids for the manufacture of organic materials. Due to their high volatility, they generally disappear from the product at process temperatures above boiling point and are present in the end product in only very small quantities. There is no need to determine migration in this case, provided it can be assumed that the requirement described in b) can be met. If the residual content of the solvent in the final product does not exceed 0.02 %, assessment of the solvent can be omitted. For solvents that are classified under CLP Regulation No 1272/2008 as Category 1A or 1B carcinogenic, mutagenic or toxic to reproduction, the migration restriction of 0.1 µg/l has to be tested for.

l) Glass fibre sizing agents

Glass fibre sizing agents are comprised of coupling agents, film forming agents and other processing aids. Coupling agents must be listed in the positive list of organic coatings of Annex B, in 4MSI Core List or Combined List. In case other constituents intended to manufacture the sizing agent are not listed, it has to be ensured that requirements for the starting substances, including their monomers, oligomers, reaction- and degradation products, are fulfilled according to a) through f).

5.3 Basic requirements

5.3.1 General

Migration waters must be examined for the parameters odour, turbidity, colouring and foaming. The migration water must be produced in line with the specifications of DIN EN 1420: 2016-05 and in particular the surface to volume ratios must be considered during testing (see Table 4).

Another basic requirement is that the migration water is examined for the TOC parameter. The migration water must be produced in line with the specifications of DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07. In particular the surface to volume ratios must be considered during testing (see Table 4).

The migration water samples to be examined are specified in Table 5 and Table 6.

5.3.2 Requirements pertaining to odour threshold value

Products in water supply systems outside buildings (exclusively cold water application, product group pipes and components thereof with generally ID ≥ 80 mm)

For the **cold-water test**, the following odour threshold value applies:

TON ≤ 2 for the 3rd migration period; for the 9th migration period if the test is extended. Testing can only be extended if TON of 4 in the 3rd migration period is not exceeded.

Pipes in the drinking water system with generally ID < 80 mm (intended to come into contact with cold and warm water or hot water in special applications)

For **cold-, warm- and hot-water testing**, the following odour threshold value applies:

TON ≤ 8 for the 3rd migration period of the cold-water test; for the 9th migration period if the test is extended. Testing can only be extended if TON of 16 in the 3rd migration period is not exceeded.

TON ≤ 8 for the 7th migration period of the warm- or hot-water test; for the 22nd migration period if the test is extended. Testing can only be extended if TON of 16 in the 7th migration period is not exceeded.

Components or products in the drinking water system with generally ID < 80 mm (intended to come into contact with cold and warm water or hot water in special applications)

For the **cold-water test**, the following odour threshold value applies:

TON ≤ 2 for the 3rd migration period of the cold-water test; for the 9th migration period if the test is extended. Testing can only be extended if TON of 4 in the 3rd migration period is not exceeded.

For **warm- and hot-water testing**, the following odour threshold value applies:

TON ≤ 4 for the 7th migration period of the warm- or hot-water test; for the 22nd migration period if the test is extended. Testing can only be extended if TON of 8 in the 7th migration period is not exceeded.

Additionally, the odour threshold value must not show a rising trend during testing according to DIN EN 1420:2016-05.[13]

5.3.3 Requirements pertaining to turbidity and colouring

The turbidity parameter is determined in accordance with DIN EN ISO 7027: 2016-11 using nephelometry (scatter radiation) and the colouring parameter is determined in accordance with DIN EN ISO 7887: 2012-04 using procedure C.

For the **cold-water test**, the following turbidity and colouring values apply:

Turbidity ≤ 0.5 FNU
Colour ≤ 10 mg/l Pt
for the 3rd migration period; for the 9th migration period if the test is extended.

For **warm and hot-water testing**, the following applies:

Turbidity ≤ 0.5 FNU
Colour ≤ 10 mg/l Pt
for the 7th migration period; for the 22nd migration period if the test is extended.

5.3.4 Foaming

Foaming shall be assessed by visual inspection of the migration water in accordance with DIN EN 1420: 2016-05.

Note: Examination of the foaming parameter can provide information on undesirable substance transfers into drinking water.

5.3.5 TOC requirements

The migration water shall be produced in line with the specifications of DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07. The TOC is defined as non-volatile organic carbon (NPOC) in accordance with DIN EN 1484: 2019-04.

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

Cold-water test:

$MTC_{tapTOC} = 0.5$ mg/l

$c_{tap} \leq MTC_{tapTOC}$ for the 3rd migration period; for the 9th migration period if the test is extended. Testing can only be extended if c_{tap} of 2 mg/l in the 3rd migration period is not exceeded.

[13] When assessing the trend, the most recent measured values and possible analytical fluctuation margins are taken into account.

Warm and hot-water testing:

$MTC_{tapTOC} = 0.5$ mg/l

$c_{tap} \leq MTC_{tapTOC}$ for the 7th migration period; for the 22nd migration period if the test is extended. Testing can only be extended if c_{tap} of 2 mg/l in the 7th migration period is not exceeded.

Additionally, the measured concentrations in the migration water according to DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07 must not show any rising trend. To assess rising trend, the measured concentrations of migration water from consecutive migration periods are used.

Note: *There is a rising trend in the measured TOC values if for example the following criteria are fulfilled simultaneously:*

- *the measured TOC concentration of the relevant migration period is over 0.1 mg/l, and*
- the *measured TOC concentration in the migration water of the relevant migration period has doubled significantly (i.e. more than can be accounted for by measurement uncertainty) compared to the lowest measured concentration, and*
- *the measured concentration of the relevant migration period is the highest measurement value of the migration series.*

5.4 Additional requirements

5.4.1 Additional requirements for migration

Additional requirements are laid down specifically for each material (see annexes).

Note: *During the manufacture of organic materials substances such as reaction and degradation products or contaminants may unintentionally be contained in the end product. Known reaction and degradation products and contaminants are regulated in the form of additional material-specific requirements.*

If the additional requirement parameter to be checked is a migration limit in the form of an MTC_{tap} value (see 6.3.3), migration must be examined as per 6.3.1and reviewed as per the MTC_{tap} value indicated. The migration water shall be produced in line with the specifications of DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07.

If for a parameter no sufficiently sensitive analytical method exists, it is possible to apply a higher surface/volume-ratio in migration testing. provided the respective substance displays sufficiently high aqueous solubility (as e.g. for primary aromatic amines).

Note: *Aqueous solubility may be too low to allow diffusion-controlled substance migration to take place. In these cases, measured concentrations from migration testing obtained with elevated surface/volume-ratios are not appropriate to decide on fulfilling the parameter requirement because substance concentrations in migration waters will only rise up to the solubility limit (saturation).*

For the **cold-water test** the following shall apply:

$c_{tap} \leq MTC_{tap}$ for the 3rd migration period; for the 9th migration period if the test is extended.

For **warm and hot-water testing**, the following applies:

$c_{tap} \leq MTC_{tap}$ for the 7th migration period; for the 22nd migration period if the test is extended.

In addition, the measured concentrations in the migration water must not show a rising trend. To assess rising trend, the measured concentrations of migration water from consecutive migration periods are used.

Note: *There is a rising trend in the measured concentrations for the additional requirements parameter if for example the following criteria are fulfilled simultaneously:*

- *the measured concentration of the relevant migration period is over $^1/_{10}$ of the migration limit, and*
- *the measured concentration of the relevant migration period has doubled significantly (i.e. more than can be accounted for by measurement uncertainty) compared to the lowest measured concentration, and*
- *the measured concentration of the relevant migration period is the highest measurement value of the migration series.*

5.4.2 Filler requirements

The following purity requirements must be met for fillers listed in the positive lists:

Filler matter soluble fraction in 0.07 N hydrochloric acid determined as per DIN 53 770[14] Parts 1, 2, 3, 5, 6 and 13 must not exceed the following for

lead	0.01 %
arsenic	0.01 %
mercury	0.0005 %
cadmium	0.01 %
antimony	0.005 %

[14] DIN 53770: Pigments and extenders - Determination of matter soluble in hydrochloric acid
Part 1: 2014-12 Preparation of acid extracts
Part 2: 2007-09 Antimony content
Part 3: 2007-09 Arsenic content
Part 4: 2007-09 Barium content
Part 5: 2007-09 Lead content
Part 6: 2007-09 Cadmium content
Part 7: 2007-09 Chromium content
Part 13: 2007-09 Mercury content
Part 14: 2007-09 Selenium content
Part 16: 2007-09 Determination of 12 elements by inductively coupled plasma atomic emission spectroscopy

Purity requirements for barium sulfate: Barium matter soluble in 0.07 N hydrochloric acid determined as per DIN 53 770-1: 2014-12 and DIN 53 770-4: 2007-09[14] must not exceed 0.01 %. The water-soluble constituents of barium sulfate, determined as per DIN ISO 787-3[15], must not exceed 0.4 %.

Apart from listed fillers it is also possible to employ fillers of natural origin with other salt-like impurities if the corresponding anions are regulated parameters of the German TrinkwV. For these anions, migration restrictions amounting to 10 % of the respective parameter value apply (see also 5.2.2 c).

Example: *Fluorides (10 % of the TrinkwV parameter value as fluoride) 150 µg/l*

Ceramic fillers not listed in the applicable material-specific positive list must be assessed in line with the evaluation criteria document for enamels and ceramic materials[16]. The migration requirements shall be checked on the end product.

Cementitious fillers for coatings are listed in Annex B under B.3.1.3 (see annexes). The requirements of DVGW standard W 347 (May 2006): Hygiene requirements for cement-bound materials intended for use in drinking water supply systems - Testing and evaluation, apply to these fillers.

5.4.3 Colourant requirements

Colourants are not listed in the material-specific positive lists. Other additives and polymerisation production aids must be listed in the relevant material-specific positive list.

Note: *It is assumed that potential colourant transfer can be detected with the basic requirement parameters (colouring and turbidity).*

The following purity requirements must be complied with for the colourants used:

Colourant matter soluble fraction in 0.07 N hydrochloric acid related to colourant must not exceed the following for

lead	0.01 %
arsenic	0.01 %
mercury	0.005 %
selenium	0.01 %
barium	0.01 %
chromium	0.1 %
cadmium	0.01 %
antimony	0.05 %

Soluble matter is determined in line with the specifications of DIN 53 770: Pigments and extenders - Determination of matter soluble in hydrochloric acid, Parts 1 through 7, 13, 14 or 16.

If colourants bear the risk that primary aromatic amines are released, an MTC_{tap} = 0.1 µg/l applies which must be tested with the specific product.

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[15] General methods of test for pigments and extenders - Part 3: Determination of matter soluble in water; Hot extraction method

[16] https://www.umweltbundesamt.de/en/document/evaluation-criteria-document-for-enamels-ceramic-0

Azo dyes that can decompose to such primary aromatic amines that are classified as Category 1A and 1B mutagenic, carcinogenic or reprotoxic substances under the CLP Regulation (EC) No 1272/2008 must not be used.

5.5 Formulation-specific requirements for individual substances

5.5.1 Various requirements

The formulation-specific requirements for individual substances are derived from the evaluation of composition requirements as per 5.2. According to the starting substances, the formulation requirements for individual substances are determined in the form of

a) migration-based requirements
b) maximum residual contents
c) specifications, purities of starting substances used
d) restrictions on the use of the starting substance or the product manufactured from it

For some substances, both a migration limit as well as a requirement in terms of residual content (QM or QMA value) are indicated. In these cases, only one restriction has to be tested. Preference should be given to checking MTC_{tap}.

5.5.2 Migration-based requirements

If migration-based requirements in the form of MTC_{tap} values are determined for specific starting substances, these must be tested.

The positive lists in Commission Regulation (EU) No 10/2011 apply to plastics as per Annex A. Substances for with a specific migration limit (SML) has been defined in this regulation, $MTC_{tap} = \frac{1\ kg}{20\ l}$ SML applies. For substances with a specific migration level (SML) in Commission Regulation (EU) No 10/2011 whose SML value multiplied with the molecular mass ratio of the carbon molar mass (M_c) to the overall molecular mass (M_{total}) is larger than or equal to 10 mg/kg:

$$SML \times \frac{M_C}{\mathrm{M}_{\mathrm{total}}} \geq 10\ mg/kg$$

the migration-based requirements need not to be determined. In this case, the migration level is covered by the TOC parameter testing in the basic requirements.

Where an SML value is listed as 'not detectable' in Commission Regulation (EU) No 10/2011, e.g. acrylonitrile, the migration limit MTC_{tap} 0.1 µg/l applies to materials in contact with drinking water.

The migration limit can be tested using

a) analytical migration testing as per 6.3 or
b) migration modelling using Modelling Guideline[17] (see 6.3.2)

The concentration determined is converted as per 6.3.3 into the expected tap concentration c_{tap}.

The requirements are as follows:

[17] Guideline for the Mathematical Estimate of the Migration of Individual Substances from Organic Material in Drinking Water (Modelling Guideline): https://www.umweltbundesamt.de/en/document/modelling-guideline

For the **cold-water test** the following shall apply:

$c_{tap} \leq MTC_{tap}$ for the 3rd migration period; for the 9th migration period if the test is extended.

The following applies for **warm and hot-water testing**:

$c_{tap} \leq MTC_{tap}$ for the 7th migration period; for the 22nd migration period if the test is extended.

In addition, the measured concentrations must not show a rising trend. To assess rising trend, the measured concentrations of migration water from consecutive migration periods are used.

Note: *There is a rising trend in the measured concentrations for the formulation-specific requirements parameter, if for example the following criteria are fulfilled simultaneously:*

- *the measured concentration of the relevant migration period is over $^1/_{10}$ of the migration limit, and*
- *the measured concentration of the relevant migration period has doubled significantly (i.e. more than can be accounted for by measurement uncertainty) compared to the lowest measured concentration, and*
- *the measured concentration of the relevant migration period is the highest measurement value of the migration series.*

If for a parameter no sufficiently sensitive analytical method exists, it is possible to apply a higher surface/volume-ratio in migration testing. provided the respective substance displays sufficiently high aqueous solubility (see also 5.4.1).

5.5.3 Maximum residual content

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

Where a substance with a QMA limit can be determined in the migration water, the requirement may also be tested via migration testing. In this case an SML value derived from the QMA value, assuming 1 kg of food is packed in a cube with a surface area of 6 dm², from which in turn the MTC_{tap} value is determined according to Table 1:

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

For some starting substances, both an MTC_{tap} (derived according to Chapter 5.5) as well as a QM or QMA value are indicated as restriction. In these cases, only one restriction has to be tested. Preference should be given to checking the MTC_{tap} value.

5.5.4 Other requirements

In addition to the requirements pertaining to migration or residual content, requirements may also be laid down in respect of specifications or purities of starting substances or application restrictions for the starting substance in a product (see 4.2).

5.6 Requirements pertaining to the enhancement of microbial growth

5.6.1 Different testing methods

Testing of products with respect to the enhancement of microbial growth is performed in accordance with DIN EN 16421: 2015-05. The following restrictions apply here to the use of the three procedures described in the standard.

Procedure 3 (the MDOD procedure) has an excessive detection limit compared to the other procedures. The procedure is unsuitable for the assessment of products which are to be used with drinking water free of disinfectants. In Germany, drinking water is often supplied without adding chlorine or other disinfectants. For this reason, a test using one of the other two procedures (BPP procedure or volumetric procedure) is necessary for use in Germany.

The BPP procedure (procedure 1) is unsuitable for the testing of multi-layer composite products (e.g. pipes or hoses), since surfaces which normally have no contact with drinking water will thereby also come into contact with the migration water during the test.

Multi-layer composite products (e.g. pipes or hoses) are to be tested with procedure 2 in the testing module for pipes and tubes.

There is no standardised test procedure currently available for lubricants.

5.6.2 Requirements during testing of biomass production potential (BPP) measured as ATP[18] (procedure 1)

The following requirements shall apply:

a) A product is considered suitable for contact with drinking water with respect to the enhancement of microbial growth if the biomass production potential (BPP) is ≤ 1000 pg ATP/cm².
b) The surface of the products must not have any biocidal effects on drinking water.

5.6.3 Requirements during testing using the volumetric procedure (procedure 2)

The following requirements shall apply:

a) The surface of the products must not have any biocidal effects on drinking water. Therefore, products without surface colonisation (comparison of contact culture/test sample smear with that of the negative control) do not satisfy this requirement.

b) Products that fall within the scope of Annexes A and B must, in all test periods, only exhibit firmly adherent surface colonisation (comparison of contact culture/test

[18] ATP: Adenosine triphosphate

sample smear with that of the negative control) or surface growth
≤ (0.05 + 0.02) ml/800 cm².

c) Products that fall within the scope of Annex D, the following stepwise requirements of Table 3a apply:
   - M1: ≤ (0,05+0,02) ml/800 cm²
   - M2: ≤ (0,12+0,03) ml/800 cm²
   - M3: ≤ (0,20+0,03) ml/800 cm²

For assessment of test results, criteria as defined in Table 3b shall apply.

Assignment of requirements M1, M2, and M3 is carried out with respect to the conversion factor F_C of products or components and takes into account their wetted surface proportions according to Table 7. For derivation of the applicable product group with respective criterion M1, M2 or M3, requirements as defined in Chapter 5.1 apply.

Table 3a: Requirements on testing according to procedure 2 of DIN EN 16421 for different products or components

	Product group	F_C in d/dm	Requirements on testing according to procedure 2 of DIN EN 16421	
			Products/components according to Annex A and B	Products/components according to Annex D
Pipes	with ID < 80 mm (ID=inner diameter)	20	M1	M1
	with 80 mm ≤ ID < 300 mm	10	M1	M1
	with ID ≥ 300 mm	5	M1	M1
Fittings / ancillaries	for pipes with ID < 80 mm	2	M1	M1
	for pipes with 80 mm ≤ ID < 300 mm	1	M1	M2
	for pipes with ID ≥ 300 mm	0.5	M1	M2
Components of fittings/ancillaries with wetted surface proportion < 10 % in the fitting/ancillary	for pipes with ID < 80 mm	0.2	M1	M2
	for pipes with 80 mm ≤ ID < 300 mm	0.1	M1	M3
	for pipes with ID ≥ 300 mm	0.05	M1	M3
Small components of fittings/ancillaries with wetted surface proportion < 1 % in the fitting/ancillary	for pipes with ID < 80 mm	0.02	M1	M3
	for pipes with 80 mm ≤ ID < 300 mm	0.01	M1	M3
	for pipes with ID ≥ 300 mm	0.005	M1	M3

	Product group	F_C in d/dm	Requirements on testing according to procedure 2 of DIN EN 16421	
			Products/components according to Annex A and B	Products/components according to Annex D
Containers and components of containers with wetted surface proportion ≥ 10 % in the container	in drinking water installations water volume < 10 l including repair systems	4	M1	M1
	in drinking water installations water volume ≥ 10 l including repair systems	2	M1	M1
	outside drinking water installations including repair systems	1	M1	M1
Components of containers with wetted surface proportion < 10 % in the container	in drinking water installations water volume < 10 l	0.4	M1	M2
	in drinking water installations water volume ≥ 10 l	0.2	M1	M2
	outside drinking water installations	0.1	M1	M2
	in drinking water installations water volume < 10 l	0.04	M1	M3

	Product group	F_C in d/dm	Requirements on testing according to procedure 2 of DIN EN 16421	
			Products/components according to Annex A and B	Products/components according to Annex D
Small components of containers with wetted surface proportion < 1 % in the container	in drinking water installations water volume ≥ 10 l	0.02	M1	M3
	outside drinking water installations including repair systems	0.01	M1	M3

Table 3b: Assessment of test results according to procedure 2 of DIN EN 16421: 2015-05

Requirement	Details of test results of procedure 2 according to DIN EN 16421						
	1a	1b	1c	1d optional	2a	2b optional	3a
M1	all values ≤ (0.05 + 0.02) ml/800 cm²						
M2	if 1a ≥ 1b, 1a will **not** be considered for assessment		all values ≤ (0.12 + 0.03) ml/800 cm², at the same time 1c ≤ 1b and 3a ≤ 2a				
optional	if 1a < 1b and 1a ≤ (0.12 + 0.03) ml/ 800 cm²	if 1b ≥ 1c, 1b will **not** be considered for assessment	all values ≤ (0.12 + 0.03) ml/800 cm², at the same time 1d ≤ 1c and 2b ≤ 2a and 3a ≤ 2a				
M3	if 1a ≥ 1b, 1a will **not** be considered for assessment		all values ≤ (0.20 + 0.03) ml/800 cm², at the same time 1c ≤ 1b and 3a ≤ 2a				
optional	if 1a < 1b and 1a ≤ (0.20 + 0.03) ml/ 800 cm²	if 1b ≥ 1c, 1b will **not** be considered for assessment	all values ≤ (0.20 + 0.03) ml/800 cm², at the same time 1d ≤ 1c and 2b ≤ 2a and 3a ≤ 2a				

Legend to table 3b:

1a	result for the monthly harvested biofilm after 4 weeks
1b	result for the monthly harvested biofilm after 8 weeks
1c	result for the monthly harvested biofilm after 12 weeks
1d (optional)	result for the monthly harvested biofilm after 16 weeks
2a	result for the 2-monthly harvested biofilm after 8 weeks
2b (optional)	result for the 2-monthly harvested biofilm after 16 weeks
3a	result for the 3-monthly harvested biofilm after 12 weeks

5.7 Requirements pertaining to multilayered products

Multilayered products are made of different, firmly attached layers/strata.

Composite products are separated into their components and each material assessed for suitability in contact with drinking water. This is not possible with multilayered products.

The individual layers of a multilayered product must be assessed in terms of each material in line with the annexes to this evaluation criteria document. The migration limits of all layers must be assessed. Multilayered products with a total barrier are exempt. In this case, only

the layers facing the drinking water need to be assessed. The total barrier itself need not be assessed as a material.

The layers of a product can consist of different materials. The composition of individual layers must correspond to the relevant material-specific positive list.

Example 1: *A hose, such as that typically used to supply drinking water to public festivals with the following structure: plastic inliner, adhesive, fabric-reinforced elastomer.*
The layer in contact with drinking water is a plastic inliner and must be assessed according to Annex A. The outer layer must be assessed according to the elastomer guideline. The adhesive that joins both layers is assessed according to its chemical structure (for example as per Annex B).

Example 2: *Plastic pipes with an organic oxygen passage barrier layer can be designed as follows: plastic inliner made of PE-X or PE-RT, adhesive based on PE-LLD, oxygen barrier layer made of EVOH and possibly other polyolefinic exterior layers. In this case all layers have to be assessed according to Annex A - Plastics.*

Example 3: *Rubberised metallic products require a priming adhesion layer. The primer must be assessed according to Annex A or B. The rubber coating must fulfill the requirements according to Annex D.*

The following options are available for testing migration limits on the layer not directly in contact with drinking water:

- evaluation of total mass transfer (100 % migration) or
- mathematical estimate of migration in drinking water with extended warm-water testing after a 30-day storage period at room temperature or
- implementation of warm water testing with 22 migration periods regardless of area of use after a storage period of at least 30 days at room temperature or
- separate assessment and, where appropriate, testing of individual layers.
  The migration results for individual layers must add up to the multilayered product. The same migrants of all layers to be assessed must be added to assess MTC_{tap}.

Comments: *Storage of at least 30 days at room temperature for a multilayered product is necessary to maintain the distribution of migrants to be assessed in the product. Extended warm water testing can also be applied to products used only with cold water to demonstrate that the migration limits of the starting substances from the rear layers are met.*

For hot-water applications, extended hot-water testing must be conducted instead of warm water testing.

During migration testing, it is important to ensure that there are no extractions of substances from the materials during the warm-water / hot-water test.

For pipes or fittings with colour coding, for example stripes, that are exclusively used in cold water, the cold-water test with the corresponding parameters is sufficient if the outer layer is suitable for use in contact with drinking water. This can be demonstrated on a representative test sample (e.g. test plate) taken from the pre-product (granulate).

For layers that are not in direct contact with drinking water, unlisted starting substances may be used if requirements according to 5.2.2 are fulfilled. In addition, unlisted monomers may be used if it can be demonstrated that these monomers including related oligomers with molecular weight below 1000 Da, impurities and reaction-/degradation products cannot migrate into drinking water.

6 Testing

6.1 Formulation assessment

The following information is required for formulation assessment:

- description of the exact structure of the product/component,
- designation of material type(-s) and
- list of all starting substances used to manufacture the product (monomers, additives, polymerisation production aids and other starting substances) along with chemical names, brand names, CAS No, technological functions, quantities used, suppliers and safety data sheet (instead of safety data sheet, specifications of starting substances with respective purity information may be used).

Formulation assessment must determine whether the requirements pertaining to composition (5.2) are met. It must also check compliance with the usage restrictions, e.g. with regard to the technological function and specifications of the listed substances.

In cases where no information on purity or possible impurities of starting substances are available, e.g. from safety data sheet or specifications like data sheet, dedicated determination of purity including relevant impurities (cf. 5.2.2 a)) is necessary for these starting substances.

Formulation assessment for multilayered products shall involve testing each layer individually.

For multilayered products comprising a barrier layer the provisions in Chapter 5.7 apply.

Formulation assessment shall also specify which parameters are to be determined in migration testing (see 6.3) or further testing. These are:

- substances with a migration limit in the form of an MTC_{tap} or a QMA etc. (additional and formulation-specific requirements for individual substances; see 5.4, 5.5),
- non-assessed substances (see 5.2.2).

Substances (assessed starting substances according to 5.2.1 and unlisted starting substances according to 5.2.2 a)) which fall below the formulation cut-off limit 0.02 % (m/m) and at the same time in total do not exceed an amount of 0.1 % (m/m) for all such substances, need not to be considered for the definition of parameters in migration testing.

6.2 Requirements for test samples

The actual product made of a material or the multilayered product must be tested.

For low-risk products and components, specific test samples can be tested (see Table 2). In these cases, it must be ensured that the test samples correspond to the finished products in terms of composition and manufacture. This must be documented in the test report. The thickness of the material affects migration and must be taken into account when choosing test sample geometry. For this reason, films are not suitable test samples. Correspondence of materials both in test samples and actual finished samples should be verified by applying identity testing methods.

When choosing test samples, the provisions of standards DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07 and DIN EN 1420: 2016-05 and DIN EN 16421: 2015-05 must be observed. The test sample must have high substance emissions compared to the actual products (e.g. with pipes of different diameters, this is pipe with the smallest diameter).

In the case of coatings, the carrier must correspond to that applied to coatings in practice and the substrate treatment set out in the application instruction (e.g. primer, undercoats) must also be applied to test samples. The requirements for multilayered products apply (see 5.7). Coated pipes must be used as test samples for coatings used for the internal repair of pipes.

Note: *For the certificate of conformity, the certification body must pay particular attention to the selection of test samples. The properties of these must correspond to those of products on the market (see also recommendation on attestation of conformity).*

6.3 Migration testing

6.3.1 Implementation of migration testing

The migration test is carried out pursuant to DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07. The migration test to determine odour threshold value, colouring, turbidity and tendency to foaming is carried out pursuant to DIN EN 1420: 2016-05. According to the area of application of the product, the migration test is conducted as a cold-water test at 23 °C ± 2 °C (all products) and possibly as a warm-water test (60 °C ± 2 °C) (products in the drinking water system) or hot-water test 85 °C ± 2 °C (special hot-water applications).

Testing of filter membranes is performed according to DIN EN 12873-1: 2014-09. Testing only covers the external surface area of the membrane as being in contact with drinking water.

Regardless of the product's area of application, a cold-water test must always be conducted. The test conditions in Table 4 are allocated to product groups.

The following clarification for standardised testing applies:

For testing according to DIN EN 12873-1: 2014-09, DIN EN 12873-2: 2020-07 and DIN EN 1420: 2016-05, unchlorinated test water must be used.

The surface to volume ratios to be set for testing pursuant to the standards are summarised in Table 4.

Table 4: Surface-to-volume (S/V-) ratio for migration testing

Test run / Area of use	Migration according to DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07 at 23°C / 60°C / 85°C	Odour, colour, turbidity, tendency to foaming acc. to DIN EN 1420: 2016-05 at 23°C / 60°C / 85°C
Pipes ID < 80 mm	S/V > 5 dm^{-1} (fill)	S/V > 5 dm^{-1} (fill)
Pipes 80 mm ≤ ID < 300 mm	S/V ≥ 5 dm^{-1} (fill, fill with cylinder inserted or fill pipe segments)	S/V ≥ 2.5 dm^{-1} (fill, fill with cylinder inserted or fill pipe segments)
Pipes ID ≥ 300 mm	S/V ≥ 5 dm^{-1} (fill with cylinder inserted, fill pipe segment or immerse special test samples)	S/V = 2.5 dm^{-1} (fill with cylinder inserted, fill pipe segment or immerse special test samples)
Fittings/ancillaries, components of containers	S/V ≥ 5 dm^{-1} (immerse products or special test samples)	S/V = 1.5 dm^{-1} (immerse products or special test samples)
Seals and lubricants	S/V ≥ 5 dm^{-1} (immerse products or special test samples)	S/V = 0.2 dm^{-1} (immerse products or special test samples)
Tanks and repair systems	S/V ≥ 5 dm^{-1} (immerse special test samples)	S/V ≥ 2.5 dm^{-1} (immerse special test samples)

At least two of the same samples are used in the test and one blind test is carried out. Migration waters of parallel test batches are combined for analysis.

The migration water to be analysed shall be examined according to parameters arising from the basic requirements, additional requirements and formulation-specific requirements for individual substances and from unlisted starting substances for the proposed product group. The migration water to be examined is specified in Table 5 and Table 6.

Testing lasts 10 days (cold-water test: 3 migration periods, warm or hot-water test: 7 migration periods).

Note: *In contrast to DIN EN 12873-1: 2014-09, DIN EN 12873-2: 2020-07 and DIN EN 1420: 2016-05, the warm and hot-water test is in principle extended to seven migration periods. The reason for this is that examination of the first three migration periods in the warm and hot-water test is not generally sufficient to reach equilibrium between the material surface and the test water. The migration period relevant to assessment is therefore set at 10 days contact time. This means that the duration of the warm and hot-water test is the same as that of the cold-water test.*

Testing can be conducted for an extended test duration in line with Table 5 and Table 6 if the requirements (see 5.3, 5.4, 5.5) are not met.

Table 5: Migration cycles for the cold-water test

Week	Migration cycle	Total contact time in days	End of migration period	Contact period in days per migration	Analysis
1	Preliminary treatment	1	Tuesday	1	No
1	1	4	Friday	3	G, Z, R, N
2	2	7	Monday	3	G, Z, R, N
2	3	10	Thursday	3	G, Z, R, N
3	4	14	Monday	4	No
3	5	17	Thursday	3	(G), (Z), (R), (N)
4	6	21	Monday	4	No
4	7	24	Thursday	3	(G), (Z), (R), (N)
5	8	28	Monday	4	No
5	9	31	Thursday	3	(G), (Z), (R), (N)

Table 6: Migration cycles for the warm-water or hot-water test

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

Validated analytic procedures should normally be followed in testing migration water. 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. Where there is no analysis method for individual substances, the migration of these substances must be estimated, e.g. calculation of total migration or modelling (see 6.3.2).

If when testing pipes of larger dimensions (larger than that with the smallest diameter) the standardised concentration c_{tap} exceeds the MTC_{tap} value and simultaneously the measured concentration $c_{measured}$ does not exceed double the MTC_{tap} value, evidence of compliance with the requirements for a pipe with a larger S/V ratio can be repeated.

6.3.2 Modelling

Instead of an experimental test, the migration for formulation-specific requirements for individual substances can also be estimated using the Modelling Guideline[19].

The prerequisite for this is that the material or product-specific parameters for modelling are listed in the Modelling Guideline.

The concentration of substance in the product to be assessed (c_0) must also be determined. Alternatively, c_0 can be calculated from the required quantity, if the substance does not change during the manufacture and/or processing of the product.

Modelling must satisfy the respective test conditions (test temperature and test cycle) (see 6.3.1). The concentration profile for the previous test period is used to calculate the migration for the following test period. This is set out in detail in the Modelling Guideline.

If the modelling result for a product does not meet the requirements, evidence still can be provided through experimental testing. The results of experimental tests must be weighted higher than those of the modelling.

6.3.3 Calculation of expected tap concentration (c_{tap})

The expected tap concentration (c_{tap}) differs for the various product groups according to the conversion factors F_c stated in Table 7:

$$c_{tap} = \frac{F_c \times c_{measured}}{{}^{O}/_{V} \times t}$$

Where:

F_C :	Conversion factor as per Table 7
$c_{measured}$:	Concentration in the migration water, measured according to DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07 or estimated according to 6.3.2.
S/V:	Ratio of wetted surface to water volume as per DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07, according to the respective test run
t:	Duration of the migration period as per DIN EN 12873-1: 2014-09 or DIN EN 12873-2: 2020-07

[19] Guideline for the Mathematical Estimate of the Migration of Individual Substances from Organic Material in Drinking Water (Modelling Guideline): https://www.umweltbundesamt.de/en/document/modelling-guideline

Table 7 lists the product groups of pipes, tanks and ancillaries (fittings/ancillaries), where the requirements are further differentiated according to their place of use within the water distribution system. The product group of ancillaries and seals is assigned to the corresponding pipe dimensions.

To define the applicable product group of components, wetted surface proportions of components of the same base polymer must be summarized (see 5.1)

Table 7: Product groups with corresponding conversion factors

	Product group	Conversion factor F_C in d/dm
Pipes	where ID < 80 mm (ID=Internal Diameter)	20
	where 80 mm ≤ ID < 300 mm	10
	where ID ≥ 300 mm	5
Ancillaries	for pipes with ID < 80 mm	2
	for pipes with 80 mm ≤ ID < 300 mm	1
	for pipes with ID ≥ 300 mm	0.5
Ancillary components where the proportion of surface area in contact with water < 10 % in ancillary	for pipes with ID < 80 mm	0.2
	for pipes with 80 mm ≤ ID < 300 mm	0.1
	for pipes with ID ≥ 300 mm	0.05
Small ancillary components where the proportion of surface area in contact with water < 1 % in ancillary	for pipes with ID < 80 mm	0.02
	for pipes with 80 mm ≤ ID < 300 mm	0.01
	for pipes with ID ≥ 300 mm	0.005
Containers and components of containers where the proportion of surface area in contact with water ≥ 10 % in the container	in drinking water installations water volume < 10 l including repair systems	4
	in drinking water installations water volume ≥ 10 l including repair systems	2
	outside drinking water installations including repair systems	1

	Product group	Conversion factor F_C in d/dm
Components of containers where the proportion of surface area in contact with water ‹ 10 % in ancillary	in drinking water installations water volume ‹ 10 l	0.4
	in drinking water installations water volume ≥ 10 l	0.2
	outside drinking water installations	0.1
Small components of containers where the proportion of surface area in contact with water ‹ 1 % in ancillary	in drinking water installations water volume ‹ 10 l	0.04
	in drinking water installations water volume ≥ 10 l	0.02
	outside drinking water installations including repair systems	0.01
Products with negligible influence on drinking water quality	Special products for containers and drinking water distribution purposes outside of domestic installations (see table 8) Installation aids and paste-like sealants for hemp	‹ 0.005

By categorizing products or components into a product group, the applicable conversion factor according to Table 7 results. The conversion factor in turn determines the respective risk group as per Table 2.

In Table 8, typical products are assigned to the product groups stated in Table 7.

6.3.4 Test report

The test reports shall be drawn up in line with the specifications of DIN EN 12873-1: 2014-09, DIN EN 12873-2: 2020-07 and DIN EN 1420: 2016-05. It must be clear from the information in the test report which products are covered by the test report.

6.4 Testing the enhancement of microbial growth

The enhancement of microbial growth is often tested independently of the migration testing on the product. The test report must contain information on which products are covered and assessed with this test.

A test report must be drawn up in line with DIN EN 16421: 2015-05.

There is currently no standardised test procedure for lubricants available to test the enhancement of microbial growth.

7 Entry into force

This amendment of the evaluation criteria document comes into force the date after publication in the German Federal Gazette as of 16 March 2022.

Annex 1 Exemplary overview of products in the product groups

Table 8 displays typical products or components of respective product groups (see Table 7). To assign components of composite products to product groups, effective wetted surface proportions of individual components must be regarded. This requires to add up surface proportions of components made of the same base polymer (see 5.1).

Table 8: Allocation of products to product groups

Product group	Products
Pipes (P1[20]):	Pipes and hoses Pipe liners, pipe coatings Pipes made of composite materials Adhesives for multilayered hoses Adhesives for inliners Inliners for reinforced hoses Hoses in domestic installation systems (apart from washing machine and dishwasher connecting hoses) Hoses for the occasional transportation of drinking water
Ancillaries (P1):	Valves Taps Meters Fittings Filter housings for filters in domestic installation systems Supply cables (e.g. for submersible pumps) Linings of valve spool housings Membranes for expansion vessels (ID ‹ 80 mm) Coatings and impregnating resins for ancillaries Connecting hoses for washing machines and dishwashers Filter membranes for drinking water treatment in waterworks and domestic installations Expansion joints of pass-through or junction configuration Gummed ancillaries (housings, wedge gate valves, shutters etc.)

[20] See Table 2: Risk based requirements

Product group	Products
Ancillary components where the proportion of surface area in contact with water ‹ 10 % in ancillary (P2):	Seals for pipes and hoses Seals for ancillaries Adhesives for joining pipes and hoses, adhesives for fittings/ancillaries Other components Sliding lacquers for gaskets Reinforcement rings Membranes for pressure reducing devices Wristbands Profiled gaskets (inserted or framed gaskets for slides and wedges) Lubricants for sanitary ancillaries
Small ancillary components where the proportion of surface area in contact with water ‹ 1 % in ancillary (P3):	Seals, sealing tapes from PTFE Other components
Containers and tanks (P1):	Containers and tanks and linings/coatings thereof in drinking water supply systems made of plastic Containers and tanks in drinking water installations and their coatings Containers and tanks in waterworks and their coatings Repair systems for containers and tanks in waterworks Elastomer sheetings
Small components of containers and tanks where the proportion of surface area in contact with water ‹ 1 % (P3):	Crack sealant/injection agents
Products with a negligible impact on drinking water quality (P4):	Components where the proportion of surface area in contact with water ‹ 0.1 % in the ancillary outside drinking water installations or in the container/tank outside drinking water installations Dowel systems incl. chemical anchor mounting systems (cartridge or injection material) for fastening purposes in drinking water storage tanks; installation aids; paste-like thread sealing agents