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European Drinking Water

Scheme for Assessment of Plastic and Silicone Products for Suitability for Contact with Drinking Water

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1. Definitions

For the purpose of this scheme of assessment, the following definitions shall apply:

a) 'Additive' means a substance which is intentionally added to plastics or silicone materials to achieve a physical or chemical effect during processing of the plastic or in the final material or product; it is intended to be present in the final material or product;

b) 'Production aid' shall mean any substance which initiates polymerization and/or controls the formation of the macromolecular structure and/or provide a suitable medium for polymer or plastic or silicone manufacturing; it may be present but is neither intended to be present in the final materials or products nor has a physical or chemical effect in the final material or product;

c) 'Ancillary substances, means all substances other than additives and/or monomers and starting substances;

d) 'Maximum reference concentration' shall mean the maximum allowable concentration of a substance in water intended for human consumption, which shall correspond to Drinking Water directive 98/83/EC or in reference bibliography;

e) 'Maximum tolerable concentration at the tap (MTC_{tap}) shall mean the maximum permitted amount of a substance that may migrate to tap water, in order to ensure that the material in contact with the water does not pose a risk to the health of consumers;

f) 'Component' shall mean a part manufactured out of a specific composition, placed on the market as a product, part of an assembled product or as a separate part. Components may be considered as products and be individually approved (e.g. o-ring, gaskets) or tested in the final product (e.g. valve);

g) 'Composition' or 'Chemical formulation' shall mean the description of the nature and proportions of the different chemical substances found in a material;

h) 'Constituents' shall mean: ingredients used to make a plastic or silicone material or product;

i) 'Conversion Factor' 'CF' shall mean the factor used to convert the result obtained in the migration test carried out on the product to be approved, for an average concentration representative of the real situation. The concentration is calculated and subsequently compared against the maximum tolerable concentration of the analyte in the water intended for human consumption;

j) 'Positive List' shall mean a list of chemical substances accepted for the manufacture of a material or product to be used in contact with water intended for human consumption, after being assessed and in compliance with the criteria laid down in the Annex to this Scheme of Assessment;

k) 'Material' shall mean the prepared form of a substance or combination of substances, in a specific formulation and suitable for use in a manufacturing process;

l) 'Composite Material' shall mean a material comprising different types of materials which are mixed and bonded together, but remain separately identifiable;

m) 'Product' shall mean the manufactured item or component thereof, which is clearly identified and in its finished form shall be submitted by the product supplier to the certification and/or approval process. The product may be a component or equipment which is in contact with water throughout the entire water supply system from the source, treatment and distribution network to the consumer's tap;

n) 'Substance' shall mean a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

o) ‘Product type’ may be the following: a product consisting of a single material or of different materials; a multicomponent product (a product assembled with two or more components, possibly of different materials, such as meters, taps, showers); a multilayer product (a product including two or more layers which are interlinked to form a single item).

p) ‘Product supplier’ is the person, company or organisation placing the product on the market in the European Union and responsible for its compliance certification.

q) ‘Material or component supplier’ is the person, company or organisation supplying a material or component which is used in the construction of the product by the product supplier.

r) ‘Certification body’ is the accredited third-party organisation responsible for conducting the relevant procedures for demonstrating compliance with this certification scheme

s) Programme of Requirements shall mean the programme prepared by the certification body, prior to its implementation, which contains the product conformity assessment requirements in accordance with this scheme of assessment.

t) Coated means the finished materials, prepared mainly from plastic and/or silicone materials, applied to form a layer/film on a substrate in such a way as to create a protective layer and/or to impart a technical performance

1.1 Abbreviations

CF	Conversion Factor
CMR	Carcinogenic, Mutagenic or toxic for Reproduction
CTap	Concentration of the substance in tap water
DoC	Declaration of Conformity
DWPLL	Drinking Water Positive List Limit
MTC	Maximum Tolerable Concentration
NIAS	Non-Intentionally Added Substance
S/V	Surface to volume ratio
TOC	Total Organic carbon

2. Scope

Plastic and silicone materials used in products made of, or containing organic and/or inorganic substances which may be in contact with water intended for human consumption and as specified in this certification scheme shall be subject to an assessment of the potential adverse effects on the quality of water intended for human consumption. For the purposes of this scheme of assessment, a plastic product is one for which all or part of the product, which comes into contact with water intended for human consumption, are composed of plastic materials. It includes plastic coated products (including plastic coated metal, ceramic, etc) when coated with a plastic material such as epoxy, polyurethane, etc., but it does not include elastomers prepared from natural or synthetic rubber materials. The silicone materials are directly coming into contact with drinking water but may also act as sealants to glue plastic parts together. Silicone materials also include coatings prepared from silicone resins and copolymers with plastic materials.

The requirements specified in this certification scheme shall apply to plastic and silicone products, including plastic and silicone coatings, (not metallic and not cementitious), in contact with water intended for human consumption along the entire water supply system, from capture to the consumer's tap (Table 1).

The type of materials frequently used in the water sector are plastics composed of macromolecular organic compounds , categorised into thermoplastics, thermosets, or silicone elastomers or resins in which one or more ancillary substances or additives may be added.

Table 1 – Type of product and application

Application	Components or Products
Capture Treatment system Storage Distribution network Building network (hot and cold water)	Pipe systems Tanks Conduits Pipes (coated or uncoated) Pipe fittings Coatings Films Valves Taps Flow meters Pumps Water treatment equipment Water heaters, etc

3. Conformity of the material formulation

On the basis of the data of the toxicological conformity assessment of the chemical formulation of the product, the Programme of Requirements shall at least define the following elements: Collection conditions and preparation of the samples to be tested; Assessment tests of the effects on water quality; Identification of the relevant substances/parameters to be controlled in the migration water; Assessment criteria of the laboratory results; Product acceptance criteria; Conditions of application or use.

All the materials - whether organic or inorganic - used in the manufacture of the finished product in contact with water, shall be subject to the confirmation of conformity of the chemical formulation applied to chemical substances which comprise raw materials or ancillary materials, in accordance with the following requirements:

a) For the conformity assessment, the material or component supplier shall confirm to the product supplier or the certification body that all monomers, and additives used in the material are included on the positive list of substances (Annex). However substances with specific migration limit must be disclosed.

In the following cases only, disclosure of the identity of a substance in the DoC is not mandatory if the certification body is informed on the presence of non-disclosed substances, and the certification body confirms that:

i) the substance is not migrating in detectable concentrations, with indication of the detection limit[1], if the material is used under the conditions of use explicitly specified in the DoC. or
ii) one tenth of the restriction cannot be exceeded up to a given material layer thickness or concentration of material in a blend, provided the conditions of use for which compliance is calculated or tested are clearly specified, or
iii) the residual concentration is so low that one tenth of the restriction is not exceeded on the basis of worst case calculation or modelling or migration data.

Sub- paragraphs (i) (ii) and (iii) can be refined based on the appropriate level of communication, allowing the certification body to prove on the basis of the information

[1] The detection limits can be an experimental value or a threshold used from modelling or worst case calculation. The detection limit of the analytical method has to be below the applicable restriction of the given substance

received on the other materials supplied from the same or other suppliers that the SML cannot be exceeded

b) Substances used in the manufacture of materials or products may contain impurities originating from their manufacturing or extraction process. These impurities are non-intentionally added together with the substance in the manufacture of the plastic or silicone material (non-intentionally added substance – NIAS) [1]. As far as they are relevant for the risk assessment the main impurities of a substance should be considered and if necessary be included in the specifications of a substance. However it is not possible to list and consider all impurities in the authorisation. Therefore they may be present in the material or product but not included in the positive list of substances (see Annex).

   Also, during the manufacture and use of materials and products, reaction and degradation products can be formed. These reaction and degradation products are non-intentionally present in the material (NIAS). As far as they are relevant for the risk assessment the main reaction and degradation products of the intended application of a substance should be considered and included in the restrictions of the substance. However it is not possible to list and consider all reaction and degradation products in the authorisation. Therefore they should not be listed as single entries in the positive list of substances (see Annex).

   Any potential health risk in the final material or product arising from use of production aids which are not listed in the Annex, or from reaction and degradation products should be assessed by the certification body in accordance with internationally recognised scientific principles on risk assessment.

   The product supplier shall confirm that the material or component suppliers are contracted to maintain consistent formulation and production methods for any wetted-part materials or components which are supplied for use in the product; and to provide any advance notification of any change to the composition or processing of such materials or components to the product supplier or the relevant test institute.

c) Monomers and other precursors, production aids and additives shall be of good technical quality and not used in amounts exceeding those strictly required for the production of the product. Substances used in the manufacture of plastic layers in plastic materials and products shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or products. The composition shall be known to the manufacturer of the substance and made available to the product supplier or certification body on request.

d) The Positive List (see Annex) is not exhaustive and does not exclude the use of other substances. A substance not included in the Positive List may be accepted in the approval of the product, if demonstrated, on a case-by-case basis, by migration tests or validated mathematical modelling (e.g. Piringer) and using a suitable conversion factor, that the expected concentration of the substance in the water is lower than 0.1 µg/l at the tap. Based on this evidence the substances can be used without the need to add these substances to the positive list. The concentration level 0.1 µg/l for C_{tap} may be raised to 2.5 µg/l if the genotoxicity tests show no genotoxic effect [2].

e) In the assessment to be carried out, it shall be recognised that not all chemical substances used in the manufacture of the product will migrate to the water. Some substances form the stable part of a polymer and others will disappear during production, while others will completely decompose.

f) The conformity assessment of the chemical formulation of the product shall constitute a precondition for defining the migration tests of the effects on water quality.

4. Assessment of the effects on water quality

The product shall be submitted to migration tests, conducted in accordance with the testing standards laid down in e.g. EN 12873 part 1 to 4 or migration modelling, intended to assess the migration of chemical substances to water and the organoleptic assessment (odour, flavour, colour and turbidity) of the water, e.g. EN 1420, EN 13052-1, EN 14395-1, EN ISO 7887, EN ISO 7027

Migration tests shall be carried out on (or using) a sample, collected randomly in a batch of a product, if applicable, representative of the family of products intended to be placed on the market, provided that their chemical constitution and manufacturing and packaging conditions are identical or certified to be equivalent.

4.1 Organoleptic assessment of the water

The materials in contact with water intended for human consumption shall not result in any odour, flavour, colour or turbidity of the water which renders it unsuitable for consumer acceptability.

In order to assess the organoleptic influence of the organic materials of the product, applied in transport and storage systems for water, the migration tests indicated in Table 3 shall be conducted, applying the testing standards and acceptance criteria for odour, flavour, colour and turbidity shown in Table 4.

Table 3 – Migration tests to assess organoleptic aspects in Plastic and Silicone materials

Product	Applicable standard
Plastic and Silicone materials used in factory-made piping systems, fittings ancillary components, repair products .	Odour and Flavour: EN 1420 Colour and Turbidity: EN 13052-1
Plastic and Silicone materials used in factory-made tanks or site-applied.	Odour, Flavour, Colour and Turbidity: EN 14395-1
The migration test shall be carried out with demineralised water. Depending on the application of the product, the product supplier shall indicate if, in addition to cold water (23 ºC), migration tests with hot water (60 ºC or 85 ºC) are intended.	

Table 4 – Applicable requirements in the analysis of organoleptic parameters

Parameter	Applicable standard	Acceptance criteria
Odour	EN 1420	Recommended value ≤ 8 (dilution factor)
Flavour	EN 1420	Recommended value ≤ 8 (dilution factor)
Colour	EN ISO 7887 or other method accredited for that purpose	No visible change in colour or foaming
Turbidity	EN ISO 7027 or other method accredited for that purpose	No visible change in turbidity

4.2 Assessment of the migration of substances to water

In order to assess the migration of chemical substances from the material to water, the product applied in systems for the treatment, transport and storage of water shall be subject to migration tests, carried out in accordance EN 12873 part 1 to 4 whatever is applicable. References are given in table 5 and table 6.

Table 5 – Migration tests of substances in plastic and silicone materials

The migration test shall be carried out with water as specified in EN12873.
Depending on the application of the product, the product supplier shall specify whether migration testing with cold water (23 ºC), hot water (60 ºC or 85 ºC) or both are required, whereat the test at 85°C also covers 60°C.
For plastics, dissemination models are recognised which are based on experimental data for the estimated calculation of the level of migration of a substance under certain conditions, avoiding more complex, time consuming and costly tests. In these cases, instead of the migration test, mathematical models may be used, such as the Piringer model for certain types of plastic defined in the study, to calculate the estimated level of migration of substances from materials in contact with water intended for human consumption, under the conditions described in the Document CEN/TR 16364 (*Prediction of migration from organic materials using mathematical modelling*).

Table 6 – Testing for the assessment of the concentration of substances present in migration water (MTC)

Depending on the intended use, different scenarios of successive migration tests need to be considered.

e.g. According to EN 12873-1 (or EN 12873-2), the DWPLL in cold water should be fulfilled for the third migration period. The migration test could be extended to the tenth migration period according to EN 12873-1 (or EN 12873-2) to finally meet the requirement of the DWPLL if not fulfilled by the third migration period. For warm or hot water the 7th migration or respective the 22nd migration period is valid [2].

Testing of relevant substances in migration water
Total organic carbon (TOC) Specific substances of the Positive List Relevant parameters specified in, the Drinking Water Directive[3]
The relevant parameters (chemical substances) to be analysed in the migration water shall be those set out in the Programme of Requirements, defined on the basis of the data of the assessment of the chemical formulation of the product.

4.3 Assessment of the enhancement of microbial growth

In the approval of the product, the influence of the plastic and silicone material on the microbiological quality of the water intended for human consumption is assessed, according to the test indicated in Table 7.

Table 7 – Assessment test of the enhancement of microbial growth

Test	**Applicable standard**
Enhancement of microbial growth (EMG)	EN 16421 Method 1 - Measured by ATP - for all plastic and silicone materials except for multilayer or granular materials or Method 2 - Measured by biofilm volume - explicit for multilayer or granular materials If either of the methods is applicable, Method 2 is the preferred one

5. Assessment criteria

Product approval shall only be given provided that there is compliance with all the assessment criteria specified in this Scheme for Assessment.

5.1 Conversion Factors

Conversion factors (CF) shall be used to convert the migration test result into an average concentration representative of the real situation. The calculated concentration shall be subsequently compared with the MTC (in mg/l or µg/l) of the substance in the tap water set out in the Positive List.

In accordance with the requirements set out at European level, 4MS Approach [4], a CF is composed of a geometric factor (F_g, which depends on the surface area/volume ratio stated in dm^{-1}) of the product and an operational factor (F_o, residence or contact time of the water, stated in days).

CF for pipes are estimated, considering the worst case situation, in accordance with the following criteria (Table 8):

Table 8 – Criteria applied to the conversion factors

Product group: Piping	F_g = S/V (in dm^{-1})	F_O = t (in days)	CF = $F_g \times F_o$ (in days. dm^{-1})
Building network: (hot & cold)	Max 40*	0.5	Max 20
Distribution network: (cold, ID < 300 mm)	5*	2	Max 10
Supply network: (cold, ID ≥ 300 mm)	1.33*	4	Max 5

*use real Surface to Volume Ratio (S/V) of the smallest dimension, max. 40, max, 5 max. 1.33

In Table 9 CFs for product groups are shown, depending on their application.

Table 9 – Conversion factors per product group

Product group		CF (day.dm^{-1})
A.	**Pipes and their internal coating**	
A1	hot & cold (building networks, buildings)	20
A2	cold, ID < 300 mm (distribution network)	10
A3	cold, ID ≥ 300 mm (supply network)	5
B.	**Fittings**	
B1	hot & cold (building networks, buildings)	4
B2	cold, ID < 300 mm (distribution network)	2
B3	cold, ID ≥ 300 mm (supply network)	1
C.	**Ancillary components**	
C1	hot & cold (building networks, buildings)	0.4
C2	cold ID < 300 mm (distribution network)	0.2
C3	cold ID ≥ 300 mm (supply network)	0.1
D.	**Storage system (tanks) and treatment equipment**	
D1	In building networks and buildings	4
D2	In water supply systems	1
E.	**Repair products for storage systems**	
E1	In building networks, buildings:	
E1.1	Products which cover the total surface area or a substantial part thereof (e.g. coverings)	4
E1.2	Products which cover less than 1 % of the total surface area	0.04
E2	In the water supply system:	
E2.1	Products which cover the total surface area or a substantial part thereof (e.g. coverings)	1
E2.2	Products which cover less than 1 % of the total surface area	0.01

Notes:

(1) If a series of different products is made from the same raw material and the same ancillary materials under the same manufacturing process (the so-called product family), and the product with the highest Surface to Volume Ratio (S/V) is assessed and approved, then the whole range of products shall be permitted to be used for all areas of application within the product group without requiring additional testing. A clause will be requested in certificates and product approvals to indicate the conversion factor used and its implications on the conditions of use.

For example, if for a series of pipes of different diameters made with the same raw materials and ancillary materials by the same manufacturing process the pipe with the smallest diameter is tested and approved, all the pipes of the same series with a larger diameter may be used in the areas of application without the need for additional testing.

For process verification and audit tests other than the smallest pipe diameter may be tested. If, in this case the field concentration C_{tap} exceeds MTC_{tap} and half the value of the last measured concentration does not exceed MTC_{tap} the test shall be repeated on a pipe sample made of the same material but smaller diameter, e.g. worst case ID = 10 mm.

(2) Fittings are considered to be a complete functional unit made up of one or more components or materials, which may be in contact with water, e.g. taps, valves, meters pipe links, flexible fittings.

(3) Fitting components are considered to be O-rings and parts of components of products. If a product is tested as a unit (not disassembled), then the CF of Group B shall apply.

The CF fixed for the Group B fittings are calculated using a reduction factor (Rf) in relation to the CF of the pipes (and their interior coatings) of Group A, due to water only coming into contact with the product *less than* the length of the pipe.

For Group B products (fittings), this reduction factor (Rf) is fixed at 0.2:

$$\text{CF of Group B} = 0.2 \times \text{CF of Group A}$$

Similarly, a Rf of 0.1 is fixed for fitting components (Group C), stated in relation to the CF of the products of Group B:

$$\text{CF of Group C} = 0.1 \times \text{CF of Group B}$$

For products for which individual CF are not fixed, if a check in relation to the MTC is needed, a CF calculated in accordance with the latest scientific and technological knowledge should be used.

5.2 Calculation of the expected concentration of the substance in water

The migration of substances from materials to water depends on the type of material and migration conditions (temperature, contact time, S/V ratio and hydraulic condition of the water). The (S/V) ratio of the tested sample and contact time in the migration test, carried out in accordance with EN 12873 are different from the real use of the product in situations of normal operation.

The migration speed (M_n) of the test substances for water should be calculated as specified in the migration testing standards:

$$M_n = C_n/(S/V \times t) \text{ , stated in } (mg.dm^{-2}.d^{-1})$$

To assess product conformity, the results of the maximum concentration of substances (in mg/l or µg/l) obtained at laboratory-scale should be converted to real-scale by applying a CF.

The results obtained in the last migration period (at 23 ºC and high temperatures) are used to estimate the concentration of the substance in tap water (C_{tap}):

$$C_{tap} = M_n \times CF, \text{ stated in (in mg/l or µg/l)},$$

where:

M_n is the migration speed of migration period n
n is the sequence number of the migration period (1, 2, 3, …22) (Period 22 corresponds to day 30 at 60°C and 85°C)
C_n is the concentration of the substance measured in mg/l for migration period n
S/V is the ratio of the surface area by volume in dm^{-1}
t is the duration of the migration period in days (1 or 3 days)
CF is the conversion factor applicable to the product tested

In the case of a low risk product, conformity may be demonstrated, without the need for migration tests, by calculating the estimated concentration of the substance to the migration water, from the assessment of its chemical formulation presented with the level of specification of 0.1 % (m/m). For this purpose, the product supplier or certification body shall demonstrate the conformity assessment of the product and provide all the relevant information on the application thereof, as follows:

- Average amount used in the application of the product;
- Potential disappearance of solvents due to evaporation;
- Possible interaction between substances;
- Configuration of the piping systems, such as number of connections;
- Contact surface;
- Volumes of water in the system.

The estimated concentration of the migration of substances to the water may be calculated by one of the following methods:

- Analytical determination of the substance in the migration water, using an appropriate method of analysis, with a limit of detection of at least 0.1 µg/l;
- Mathematical modelling recognised by the 4MS Group

- Calculation of the average migration of the amount of the substance, used in the manufacture of the product, to the migration water over 100 days, based on the “wetted thickness” [5] of the plastic material in contact with water, which is specified as 100 µm for polyolefin and 50 µm for all other plastic products:

$$C\ (\mu g/l) = Q\ (\%) \times (S/V) \times E_w \times D \times 10^6 / (100 \times 100)$$

where:

C - Average concentration over 100 days of the migrant into the water in µg/l
Q - Content of the migrant in the organic material in %
S/V - surface/volume ratio of the product in dm^{-1}
E_w - Wetted thickness (m). It is 100 µm for polyolefin and 50 µm for other materials
D - Density of the product in kg/m^3
10^6 - Factor due to the conversion of concentration in g/l into µg/l
100 - Factor due to the expression of the concentration in %
100 - Migration on 100 days

Using the following mathematical relation, the maximum concentration of a migrant in the plastic or silicone material can be calculated for having an average worst-case migration over 100 days equal to 0.1 µg/l.

$$Q(\%) = 0.1\ (\mu g/l) \times 10^{-2} / [E_p \times (S/V) \times (D_{pol}/D_{water})]$$

where:

Q – content of the migration substance in the plastic or silicone material
E_p - the total thickness of the plastic or silicone material
S/V - the surface/volume ratio
D_{pol} – density of product
D_w – density of water

However, this assessment does not apply to substances classified, proven or suspected, as carcinogenic, mutagenic or toxic to reproduction (CMR), if not authorized by the Commission.

5.3 Assessment of product conformity

When assessing product conformity, the following requirements shall be applied:

- The toxicological conformity of the materials of the product with the criteria set out in the positive lists of the Annex.
- Products must fulfil the requirements for the organoleptic aspects set out in in accordance with clause 4.1 after three, respective nine migration periods for cold water and after seven, respective twenty-two migration periods for warm and hot water, as far as relevant to the product concerned.
- The concentration of the substance in the water should not increase during the migration test. If more than three migration periods are necessary to demonstrate the downward trend of the concentration of the substance in the water, the total migration test time may be extended to 9 migration periods for cold water and twenty-two for warm or hot water.
- The expected concentration of the substance at the tap (C_{tap}), determined by migration tests in accordance with the standards specified in this Scheme for Assessment [4] and after the conversion factor has been applied, should be compared to the maximum tolerable concentration at the tap (MTC_{tap}): $M_n \leq (MTC_{tap} / CF)$; $C_{tap} \leq MTC_{tap}$.
- If the C_{tap} value is not in accordance with the MTC_{tap} value on day 9 of the migration time,(3^{rd} migration at 23°C, or 7^{th} migration at 60/85 °C) [4] and if it is expected that the migration speed of the substance shall decrease over time, the migration test may be extended to a total migration time of up to 9 migration periods in cold water and twenty-two for 60/85°, in compliance with that specified in the migration testing standard.

- To assess the level of impact of the product on water quality, an assessment must be carried out of the results of the maximum concentration of the substances analysed in the water (C_{tap}), after the application of the CF as set out in this Annex, applying the criteria given in Table 10.

Table 10 – Requirements applied to the assessment of plastic or silicone products including plastic and silicone coatings

Test	Applicable standard	Acceptance criteria (C_{tap})
Total organic carbon (TOC)	EN 1484 or other provided it is accredited for that purpose	C_{tap} ≤ 2 mg/l C Note 1
Parameters Drinking Water Directive	Accredited method to determine the substance to be analysed	C_{tap}≤ 20 % of the parametric value set out in Drinking Water Directive [3] Note 2
Specific substances of the Positive List	Validated method to determine the substance to be analysed, with a limit of quantification less than or equal to the DWPLL value specified in the Positive List.	C_{tap} ≤ limit specified in the Positive List Note 3
Enhancement of microbial growth	EN 16421	BPP-Method less than 1000pg ATP / cm² and volumetric method a) products with <=(0,05+0,02)ml/ 800cm² b) large area sealing < (0,12+0.03) ml / 800 cm² c) small area sealing < (0,20+0.03) ml / 800 cm²
For the substances for which a maximum reference concentration is given, but whose use in the product is essential, the precautionary principle shall apply, and the migration of the substance into the water expressed in C_{tap}, on the basis of an appropriate dose, shall be lower than 20% of the maximum reference concentration in the water.		

Notes:

1) The value obtained in the TOC test may be used to demonstrate that the levels of organic carbon are so low that the concentration limits of a particular substance in the tap water cannot be exceeded.

2) The constituent substances of products which have implications for human health shall not have a contribution higher than 20 % in relation to the parametric values mentioned in the Drinking Water Directive [3], in the final concentration of the water, except for the parameters with a parametric value equal to 0.1 µg/l and this value shall be maintained as the limit in water. WHO Guidelines [6] state “In the absence of adequate exposure data, the normal allocation of the total daily intake to drinking-water is 20%, which reflects a reasonable level of exposure based on broad experience, while still being protective. This value reflects a change from the previous allocation of 10%, which was found to be excessively conservative”, resulting in a reduction factor of 10.

3) For substances which are not included in the Annex to this Scheme, and to which a maximum reference concentration is given, the value for the maximum tolerable concentration in water shall be determined in accordance with the methodology mentioned in Annex to this certification scheme.

ANNEX
POSITIVE LIST FOR PLASTIC AND SILICONE MATERIALS

The list of substances used for plastic and silicone products shall comply with the current published version of the 4MS
http://www.umweltbundesamt.de/en/topics/water/drinking-water/distributingdrinking-water/approval-harmonization-4ms-initiative:
4MS Common Approach, Positive Lists for Organic Materials, Part A – Compilation and management of a suite of Positive Lists (PLs) for organic materials [2]

4MS Common Approach, Positive List for Organic Materials Part B – Assessment of products for compliance with Positive List requirements [4]
4MS GROUP COMBINED POSITIVE LIST Of Organic Substances in Contact with Drinking Water

Bibliography

[1] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Annex 1

[2] 4MS Common Approach, Positive Lists for Organic Materials, Part A – Compilation and management of a suite of Positive Lists (PLs) for organic materials, clause 2.5

http://www.umweltbundesamt.de/sites/default/files/medien/419/dokumente/4ms_positive_list_0.pdf

[3] COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption

[4] 4MS Common Approach, Positive List for Organic Materials Part B – Assessment of products for compliance with Positive List requirements (Conversion Factors - CFs)
http://www.umweltbundesamt.de/sites/default/files/medien/419/dokumente/4ms_positive_list_0.pdf

[5] Circular DGS-VS4_1999-217 dated 1999 04 12

[6] WHO Guidelines for Drinking-water quality, fourth edition 2011, page 163.