



für Mensch und Umwelt

Federal Environmental  
Agency

[*Umweltbundesamt*]

"For people and their  
environment"

Recommendation

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## **Guideline for Hygienic Assessment of Organic Materials in Contact with Drinking Water (KTW Guideline)<sup>1</sup>**

**Last update: 7 October 2008**

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<sup>1</sup> Account has been taken of the obligations pursuant to Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204 of 21 July 1998, p. 37), most recently amended by Directive 2006/96/EC of 20 November 2006 (OJ L 363 of 20 December 2006, p. 81).

## 1. Preliminary remark

This Guideline may be used to conduct a hygienic assessment of organic materials in contact with drinking water.

This Guideline replaces the Second Communication of the KTW Recommendations [1] and the KTW Recommendations for the plastics polyvinyl chloride, polyethylene, polypropylene and acetal resins. It includes the adjusted conversion factors for the different uses of these products as set forth in the EAS proposal [2]. These may be used by the test laboratory to calculate the relevant test values. Testing at higher temperatures (warm-water test, hot-water test) should be performed with a contact time of 24 hours in accordance with the European standard for migration testing (DIN EN 12873-1: 2004 and DIN EN 12873-2: 2005).

This Guideline should be used for testing plastics such as polyethylene, polypropylene, polybutene, polyvinyl chloride, chlorinated polyvinyl chloride and cross-linked polyethylene.

For coatings based on epoxy resins, polyurethanes, polyesters and polyacrylates, and mixtures thereof, the separate Guideline for hygienic assessment of organic coatings in contact with drinking water [3] should be applied.

For lubricants, the separate Guideline for hygienic assessment of lubricants in contact with drinking water (hygienic lubricants) should be applied [4].

For rubber materials, a guideline document is currently in preparation. Until its publication, the KTW recommendation 1.3.13. [5] shall be applicable.

Cementitious materials should be tested in accordance with DVGW Data Sheet W 347 on "Hygienic requirements for cementitious materials in drinking water – testing and assessment".

Bituminous coatings should be tested in accordance with DVGW Data Sheet W 348 on "Requirements for bituminous coatings of fittings made of ductile cast iron and in connections of pipes made of ductile cast iron, non-alloy and low-alloy steel".

### 1.1 Legal status

This Guideline is not a legal instrument and is therefore non-binding. It represents the current state of scientific and technical knowledge with regard to the hygienic requirements, which should be met by organic materials in contact with water intended for human consumption (drinking water) within the sense of the Drinking Water Ordinance [*Trinkwasserverordnung, TrinkwV*] of 2001. Article 17(1) of the *TrinkwV 2001* states that for construction or maintenance of installations which process or distribute water for human consumption, "only such materials [*may*] be used which, when in contact with water, do not release substances in concentrations exceeding the limits considered unavoidable according to generally accepted technical standards, directly or indirectly affect the level of protection of human health provided for by this Regulation, or alter the odour or flavour of the water..."

It can therefore be assumed that organic materials in contact with drinking water, which comply with the requirements of this Guideline will also satisfy the hygienic requirements of the *TrinkwV 2001*.

## **1.2. Certification symbols and the tests on which they are based**

Organic materials used in water supply installations shall be deemed to fulfil the requirements of Article 17(1) of the *TrinkwV 2001* if they are used in compliance with -- at least -- generally accepted technical standards.

For hygienic safety in terms of microbiological criteria, organic materials should, in addition to and independently of this Guideline, pass a test in accordance with DVGW standard W 270.

Generally accepted technical standards include, for instance, the Technical Rules of the German Technical Association for Gas and Water (DVGW).

The fact that a product in contact with drinking water made from organic materials complies with generally accepted technical standards and with the requirements of the Drinking Water Ordinance, shall be indicated by labelling it with a certification symbol issued by a certifying authority such as the DVGW.

## **2. Changed test methods**

Testing should be done in the following manner, in accordance with DIN EN 1420-1: 1999 and DIN EN 12873-1: 2004, DIN EN 12873-2: 2005, and taking into account the choices still left open in the relevant European standards:

### **2.1 Migration testing in accordance with DIN EN 12873-1: 2004 and DIN EN 12873-2: 2005**

#### **2.1.1 Details of the cold-water test at $(23 \pm 2) ^\circ\text{C}$**

- a) The test pieces are not subjected to a disinfection pre-treatment (superchlorination).
- b) The test pieces are pre-treated according to the following sequence:
  - 1 h of flushing with tap water,
  - 24 h of stagnation with test water at  $(23 \pm 2) ^\circ\text{C}$ ,
  - 1 h of flushing with tap water,
  - rinsing with test water.
- c) Water as defined in 5.1.2 DIN EN 12873-1 should be used as test water.
- d) At least two identical contact tests and two blank tests should be performed simultaneously.
- e) Pipes with an internal diameter of  $\text{DN} < 80 \text{ mm}$  should be tested by filling them. Pipes with an internal diameter of  $80 \leq \text{DN} < 300 \text{ mm}$  should be tested by inserting a glass cylinder with an area-to-volume ratio of approx.  $5 \text{ dm}^{-1}$ . Pipes with an internal diameter of  $\geq 300 \text{ mm}$  may be tested by inserting a glass cylinder or by filling pipe segments at an area-to-volume ratio of  $5 \text{ dm}^{-1}$ . Coatings of tanks should be tested using coated plates at an area-to-volume ratio of approx.  $5 \text{ dm}^{-1}$ . Sealings and fittings should be tested by immersing the products at an area-to-volume ratio of approx.  $5 \text{ dm}^{-1}$  (see Table in Appendix 1).
- f) If pipes, sealings or fittings do not differ in their material composition and manufacturing process, testing of the smallest diameter of the product range will be sufficient.

- g) The migration water samples from the first three test periods of three days contact time each shall be used for further analyses.
- h) The TOC shall be determined in terms of the non-purgeable organic carbon (NPOC) in all 3 migration water samples, in accordance with DIN EN 1484.
- i) The specific migration of individual substances shall be determined using these migration water samples.

### **2.1.2 Details of the warm-water test at $(60 \pm 2) ^\circ\text{C}$ and hot-water test at $(85 \pm 2) ^\circ\text{C}$**

- a) The test pieces are not subjected to a disinfection pre-treatment (superchlorination).
- b) The test pieces are pre-treated according to the following sequence:
  - 1 h of flushing with tap water,
  - 24 h of stagnation with test water at the test temperature  $((60 \pm 2) ^\circ\text{C}$  or  $(85 \pm 2) ^\circ\text{C})$ ,
  - 1 h of flushing with tap water,
  - rinsing with test water
- c) Water as defined in 5.1.2 DIN EN 12873<sup>-1</sup> shall be used as test water.
- d) At least two identical contact tests and two blank tests should be performed simultaneously.
- e) Pipes with an internal diameter of  $\text{DN} < 80 \text{ mm}$  should be tested by filling them. Pipes with an internal diameter of  $80 \leq \text{DN} < 300 \text{ mm}$  should be tested by inserting a glass cylinder with an area-to-volume ratio of approx.  $5 \text{ dm}^{-1}$ . Pipes with an internal diameter of  $\geq 300 \text{ mm}$  may be tested by inserting a glass cylinder or by filling pipe segments at an area-to-volume ratio of  $5 \text{ dm}^{-1}$ . Coatings of tanks should be tested using coated plates at an area-to-volume ratio of approx.  $5 \text{ dm}^{-1}$ . Sealings and fittings should be tested by immersing the products at an area-to-volume ratio of approx.  $5 \text{ dm}^{-1}$  (see Table in Appendix 1).
- f) If pipes, sealings or fittings do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
- g) The test pieces are filled with or immersed in test water at the test temperature. Each test run should be kept at the required temperature by means of a heating circulator or thermostat.
- h) After pre-treatment, the test involves 7 migration periods at the test temperature (cf. Appendix 2: Diagram of the test procedure for migration testing at higher temperatures). The migration water samples from the first three and last two test periods, each with a contact time of 24 hours, shall be used for the subsequent analyses.
- i) The TOC is determined in accordance with DIN EN 1484 in the 5 migration water samples.
- j) The specific migration of individual substances is determined in the migration water samples from the 1st, 6th and 7th periods.

## **2.2 Odour and flavour test in accordance with DIN EN 1420-1: 1999 and DIN EN 1622: 2006**

### **2.2.1 Details of the cold-water test at $(23 \pm 2) ^\circ\text{C}$**

- a) The test pieces are not subjected to a disinfection pre-treatment (superchlorination).

- b) The test pieces are pre-treated according to the following sequence:
  - 1 h of flushing with tap water,
  - 24 h of stagnation with reference water at  $(23 \pm 2)^{\circ}\text{C}$ ,
  - 1 h of flushing with tap water,
  - rinsing with reference water.
- c) The reference water should be in accordance with 6.3.1 DIN EN 1420.
- d) At least two identical contact tests and two blank tests should be performed simultaneously.
- e) Pipes with an internal diameter DN of  $< 300$  mm should be tested by filling them. Pipes with an internal diameter DN of  $\geq 300$  mm may be tested by inserting a glass cylinder or by filling pipe segments at an area-to-volume ratio of  $2.5 \text{ dm}^{-1}$ . Coatings of tanks should be tested using coated plates at an area-to-volume ratio of approx.  $2.5 \text{ dm}^{-1}$ . Sealings and fittings should be tested by immersing the products at an area-to-volume ratio of approx.  $1.5 \text{ dm}^{-1}$  (accessories) or  $0.2 \text{ dm}^{-1}$  (sealings) (see table in Appendix 1).
- f) If pipes, sealings or fittings do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
- g) The migration water samples from the first three test periods of three days' contact time each shall be used for determining the threshold odour number (TON) / threshold flavour number (TFN). If the threshold odour number fails to meet requirements, the threshold flavour number need not be determined.

### **2.2.2 Details of the warm-water test at $(60 \pm 2)^{\circ}\text{C}$ and hot-water test at $(85 \pm 2)^{\circ}\text{C}$**

- a) The test pieces are not subjected to a disinfection pre-treatment (superchlorination).
- b) The test pieces are pre-treated according to the following sequence:
  - 1 h of flushing with tap water,
  - 24 h of stagnation with reference water at the test temperature
  - 1 h of flushing with tap water,
  - rinsing with reference water.
- c) The reference water should be in accordance with 6.3.1 DIN EN 1420.
- d) At least two identical contact tests and two blank tests should be performed simultaneously.
- e) Pipes with an internal diameter DN of  $< 300$  mm should be tested by filling them. Pipes with an internal diameter DN of  $\geq 300$  mm may be tested by inserting a glass cylinder or by filling pipe segments at an area-to-volume ratio of  $2.5 \text{ dm}^{-1}$ . Coatings of tanks should be tested using coated plates at an area-to-volume ratio of approx.  $2.5 \text{ dm}^{-1}$ . Sealings and fittings should be tested by immersing the products at an area-to-volume ratio of approx.  $1.5 \text{ dm}^{-1}$  (accessories) or  $0.2 \text{ dm}^{-1}$  (sealings) (see table in Appendix 1).
- f) If pipes, sealings or fittings do not differ in their material composition and process of manufacture, testing of the smallest diameter of the product range is sufficient.
- g) After pre-treatment, the test involves 7 migration periods at the test temperature (cf. the Diagram of the test procedure for migration testing at higher temperatures). The migration water samples from the 1st, 6th and 7th periods, each with a contact time of 24 hours, shall be used to determine the TON and TFN.

- h) If the threshold odour number fails to meet requirements, the threshold flavour number need not be determined.

### **2.2.3 Details of the determination of the threshold odour number (TON) and the threshold flavour number (TFN)**

The finalisation involves the following points of DIN EN 1622: 2006:

- Dilution steps are graded by a factor of 2.
- The "unforced pair test" shall be used.
- At least three test persons are required.
- The results of the test persons should display at least 70% agreement.
- If the migration water of the final test period does not produce the required agreement, the test should be repeated. The results produced by one test person should lie within a single dilution step of each other.

### 3. New test values and areas of use

#### 3.1 Test results

In the migration tests, concentrations are measured in the migration water in accordance with Chapter 10 of DIN EN 12873-1: 2004 and DIN EN 12873-2: 2005. The concentration of the substance being measured is calculated by subtracting the concentration measured in the migration water from the concentration measured in the blank sample.

On the basis of these concentrations, the migration rates  $M_{\text{measured}}$  for the individual test periods should then be calculated using the linear migration equation

$$c = M * S/V * t$$

and recorded as test results in accordance with 11.5 (table) of DIN EN 12873-2. For each parameter, a table of test results should be produced in accordance with Appendix 4. The migration rates may be determined either experimentally or by means of modelling.

In the migration equation,  $c$  is the concentration of a substance in mg/l or µg/l,  $M$  is the migration rate in mg/(dm<sup>2</sup> d) or µg/(dm<sup>2</sup> d),  $S$  is the surface area of the test piece in dm<sup>2</sup>,  $V$  the volume brought into contact with the test piece in dm<sup>3</sup>, and  $t$  is the contact time in days.

Compliance with the specific migration test requirements may also be assessed by determining the quantity of a substance in the product under review ( $c_{P,0}$ ), provided the ratio between this quantity and the specific migration rate of the relevant substance was determined by means of generally accepted, scientifically proven diffusion models and characteristic values.

For materials in contact with foodstuffs, the migration for individual substances may now be modelled pursuant to EU Directive 2002/72.

The Practical Guide (Annex 1) contains the required specific characteristic values for important organic materials (*Practical Guide was no longer available by EU-Commission.: The Annex 1, Mathematical Models, can be download from*

[http://crl-fcm.jrc.it/files/PRACTICAL%20GUIDE%20 2003.04.15 \\_annex%201%20modelling.pdf](http://crl-fcm.jrc.it/files/PRACTICAL%20GUIDE%20 2003.04.15 _annex%201%20modelling.pdf)

In future: C. Simoneau, ed., "Estimation of specific migration by generally recognised diffusion models in support of EU Directive 2002/72/EC", JRC Scientific and Technical Reports, 2008).

For other organic materials used in contact with drinking water, modelling can be undertaken after the relevant material- or product-specific characteristic values have been determined. The necessary tests are also described in the Practical Guide (Annex 1).

The method of analysis for the determination of  $c_{P,0}$  for the polymer shall be submitted by the raw material manufacturer, unless a method validated by the Community Reference Laboratory for Food Contact Materials ([http://crl-fcm.jrc.it/index.php?option=com\\_methods&Itemid=80](http://crl-fcm.jrc.it/index.php?option=com_methods&Itemid=80)) or a DIN standard is already available. Alternatively, the  $c_{P,0}$  of the application quantity may be used, provided the  $c_{P,0}$  does not change in manufacture and/or processing of the product.

Modelling shall be based on the migration found in single test periods and under the corresponding test conditions (test temperature and test cycle) of this Guideline (see 2). For the calculation of the migration in the following test period, the concentration profile of the preceding test period shall be used. The Modelling Guideline contains a description of the modelling process with a flow diagram, and is intended to integrate proper modelling into the hygienic assessment of products as referred to in this Guideline.

Validated software shall be used for modelling. The requirements for the software solutions to be used have been included in the modelling guideline.

If, after modelling, a product does not fulfil the requirements of the Guideline with respect to individual substances, proof may still be produced through experimental testing, since the results of experiments should always be given more weight than those of modelling.

### 3.2 New test requirements

The test requirements are the maximum permitted migration rates  $M_{\max}$ , which the test laboratory should calculate for individual substances from the DWPLL (Drinking Water Positive List Limit) values given in the positive lists (Table 1) and the conversion factors  $F_c$  (Table 2) applying to the intended product group.

The DWPLL values correspond to a maximum permitted concentration at the point of use (the "tap") of the consumer and have been derived from the scheme shown in Table 3 (cf. WHO Guideline [6]). Since the positive lists define specific migration limits (SML) as restrictions for foodstuffs and commodities, the DWPLL value is derived as 1/20 of the SML value.

For the sum parameter TOC (basic requirements), the following DWPLL value shall be used:

Parameter	DWPLL value
TOC	0.5 mg/l



**Table 1: Positive lists for checking the formulation and for determining the requirements to be met by formulation-dependent individual substances**

Organic materials		Source of positive list
<b>Plastics</b>	Monomers and additives	Directive 2002/72/EC <sup>2</sup> , Consumer Goods Ordinance [Bedarfsgegenständeverordnung] ,
	(additionally for additives only)	National assessments by the Federal Institute for Risk Assessment [BfR] <sup>3</sup> [7], and European assessments by EFSA (formerly SCF) [8],
	Colorants and fillers	BfR Recommendations IX and LII
	Polymerization aids, aids to polymerization incl. cross-linking agents	National assessments of the BfR [7]
<b>Coatings</b>		Organic Coatings Guideline [3] with listings of DWPLL for the individual substances and relevant sum parameters
<b>Silicones</b>		BfR Recommendation XV. [7]
<b>Lubricants</b>		Guideline for lubricants [4]

**Table 2: Product groups with conversion factors**

Product group	Conversion factor $F_c$ in d/dm
Pipes of diameter DN <80 mm (domestic installation)	20
Pipes of diameter 80 mm ≤ DN < 300 mm (supply pipes)	10
Pipes of diameter DN ≥ 300 mm (main pipes)	5
Fittings for pipes of diameter DN < 80 mm (domestic installation)	4
Fittings for pipes of diameter 80 mm ≤ DN < 300 mm (supply pipes)	2
Fittings for pipes of diameter DN ≥ 300 mm (main pipes)	1

<sup>2</sup> Commission Directive 2002/72/EC and its amending acts, relating to plastic materials and articles intended to come into contact with foodstuffs, includes in Annex II the list of monomers and other starting substances, and in Annex III the incomplete list of additives which may be used in the manufacture of plastic materials and articles. The Annexes formulate limitations on the use of these substances in articles intended to come into contact with foodstuffs that depend on their toxicological evaluation.

<sup>3</sup> Only until the publication of the EU Commission's provisional additives list in Directive 2002/72/EC

Sealings for pipes of diameter DN < 80 mm (domestic installation)	0.4
Sealings for pipes of diameter 80 mm ≤ DN < 300 mm (supply pipes)	0.2
Sealings for pipes of diameter DN ≥ 300 mm (main pipes)	0.1
Tanks in domestic installations and repair systems for such tanks	4
Tanks not in domestic installations and repair systems for such tanks	1

**Table 3: Derivation of the test requirement**

Level	Area of validity	Limit
0	Human	<b>TDI</b> [mg/kg KM d]*
1	Drinking water	$DWPLL = \frac{TDI \cdot 60 \text{ kg KM}}{2 \text{ l} / d} \cdot 0.1$ $[\text{mg} / \text{l}] = \frac{[\text{mg} / \text{kg KM} \cdot d] \cdot \text{kg KM}}{[\text{l} / d]}$ <b>DWPLL = 1/20 SML</b>
2	Test water	<b>M<sub>max</sub> = DWPLL / F<sub>c</sub></b> $[\text{mg} / \text{dm}^2 \text{ d}] = [\text{mg} / \text{dm}^3] / [d / \text{dm}]$

\*KM = body mass

## 4. Requirements for products

Only substances included in the positive lists in Table 1 are allowed to be used for the production of organic materials in contact with drinking water.

The values measured in the migration water samples from the individual test periods should not show any increasing tendency. The value measured in the final test period should satisfy the requirement.

### 4.1 Basic requirements

1. **The external characteristics** of clarity, colour, turbidity and foaming should be assessed by visual observation and should not have changed. For the cold-water test, the required threshold odour number and the threshold flavour number are TON, TFN < 2 in the third test period. For the warm-water test, the threshold odour number and the threshold flavour number are TON, TFN ≤ 4 in the seventh test period.

2. For the **sum parameter TOC** (total organic carbon), the following is required:

$$M_{\text{TOC, measured}} \leq M_{\text{TOC, max}}$$

#### **4.2 Formulation-dependent requirements for individual substances**

1. Formulation-dependent requirements for individual substances may be determined either experimentally or in accordance with Section 3.1. The following holds:

$$M_{\text{substance, measured}} \leq M_{\text{substance, max}}$$

2. The QM or QMA values should be met independently of the product groups. QM and QMA values are the maximum permitted residues of substances in the finished components or products, relative to 1 kg of polymer or to 6 dm<sup>2</sup> of contact surface.

#### **4.3 Exceptions for formulation-dependent requirements for individual substances**

4.3.1 In the case of formulation-dependent individual substances, if a maximum permitted migration rate is exceeded, this shall not lead to denial of the KTW test certificate -- unlike the parameters of the basic requirements.

Only in the case that the migration rate of the third migration period (cold-water test) or the seventh migration period (warm-water test) clearly exceeds the SML value as per Directive 2002/72/EC<sup>1</sup> for the substance, shall the test certificate be denied.

4.3.2 However, where a test for an individual substance with a restriction in a positive list has not been carried out (for instance if no suitable test procedure is available), this shall not lead to denial of a test certificate.

4.3.3 The manufacturer of the material or product should be notified by the test laboratory of exceptions in accordance with 4.3.1 or 4.3.2. The test certificate will be issued for a period of 5 years and cannot be extended.

### **5. Applicability and issue of KTW test certificates in accordance with this Guideline**

#### **5.1 Test laboratory**

Testing in accordance with this Guideline shall be done by an accredited test laboratory. In addition, the test laboratory should be recognised by a certification body (e.g. the DVGW certification body) which is itself accredited for the certification of products in contact with drinking water.

#### **5.2 Test report and test certificate**

If the test is passed, a test report should be prepared by the test laboratory which should include information specified in DIN EN 12873-1 and DIN EN 12873-2,

including all test results (appendix 4). In case of modelling, corresponding documentation should be submitted.

From 1 January 2006, the new test procedures should be applied in conjunction with the new test values for all organic materials in order for a KTW test certificate to be issued.

To distinguish them from "old" KTW test certificates, test certificates in accordance with this Guideline bear the title "Test Certificate in Accordance with the Guideline on the Hygienic Assessment of Organic Materials in Contact with Drinking Water" [*Prüfzeugnis nach der Leitlinie zur hygienischen Beurteilung von organischen Materialien im Kontakt mit Trinkwasser*] (abbreviated as: "Test certificate in accordance with the KTW Guideline of the Federal Environmental Agency" [*Prüfzeugnis gemäß der KTW-Leitlinie des Umweltbundesamtes*])

### 5.3 Validity of test certificates

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

Test certificates for products from the same manufacturer which are produced in accordance with this Guideline may, if they comply with 4.1 and 4.2 in the initial test, be extended for 5 years without further experimental testing, providing that there has been no change in their formulation, in the relevant substance assessments (restrictions in the positive lists) or in the manufacturing process.

Existing ("old") KTW test certificates retain the validity specified on the certificate itself, but will not be extended.

If the test certificate was issued pursuant to one of the exceptions listed under 4.3, and may therefore not be extended, this should be clearly indicated on the certificate.

### References

- [1] Bundesgesundheitsamt, Gesundheitliche Beurteilung von Kunststoffen und anderen nichtmetallischen Werkstoffen im Rahmen des LMBG für den Trinkwasserbereich, 2. Mitteilung, Bundesgesundheitsblatt 1977, 20, p. 124-129.
- [2] Proposal of the Regulators Group on Construction Products in contact with Drinking Water (RG-CPDW 186 Final, February 2005)
- [3] Umweltbundesamt, Leitlinie zur hygienischen Beurteilung von organischen Beschichtungen im Kontakt mit Trinkwasser: can be downloaded from <http://www.umweltbundesamt.de/wasser/themen/trinkwasser/beschichtungsleitlinie.htm>
- [4] Umweltbundesamt, Leitlinie zur hygienischen Beurteilung von Schmierstoffen im Kontakt mit Trinkwasser (Sanitärschmierstoffe). Can be downloaded from <http://www.umweltbundesamt.de/wasser/themen/trinkwasser/schmierstoffleitlinie.htm>
- [5] BGA (1985, 1987): Gesundheitliche Beurteilung von Kunststoffen und anderen nicht metallischen Werkstoffen im Rahmen des Lebensmittel- und Bedarfsgegenständegesetzes für den Trinkwasserbereich (KTW-Empfehlung: 5. und 6. Mitteilung) *Bundesgesundheitsblatt* 28: 371-374, 30: 178

[6] WHO (2004): Guidelines for Drinking Water Quality, Third Edition, Volume 1, Recommendations.

[7] BfR Recommendations. Can be downloaded from <http://bfr.zadi.de/kse/>

[8] „Scientific Opinion of the Panel on food contact materials, enzymes, flavourings, producing aids (CEF)“, downloadable from [http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa\\_locale-1178620753812\\_CEF.htm](http://www.efsa.europa.eu/EFSA/ScientificPanels/efsa_locale-1178620753812_CEF.htm) and

Previous outcome of discussion of Scientific Committee on Food (SCF), downloadable from [http://ec.europa.eu/food/fs/sc/oldcomm7/previous\\_en.html](http://ec.europa.eu/food/fs/sc/oldcomm7/previous_en.html) .

[9] Umweltbundesamt, Empfehlung des Umweltbundesamtes zur weiteren Anwendung der KTW-Empfehlungen in der Übergangszeit bis zum In-Kraft-Treten des EAS, Bundesgesundheitsbl-Gesundheitsforsch-Gesundheitsschutz 2004, 47, p. 809.

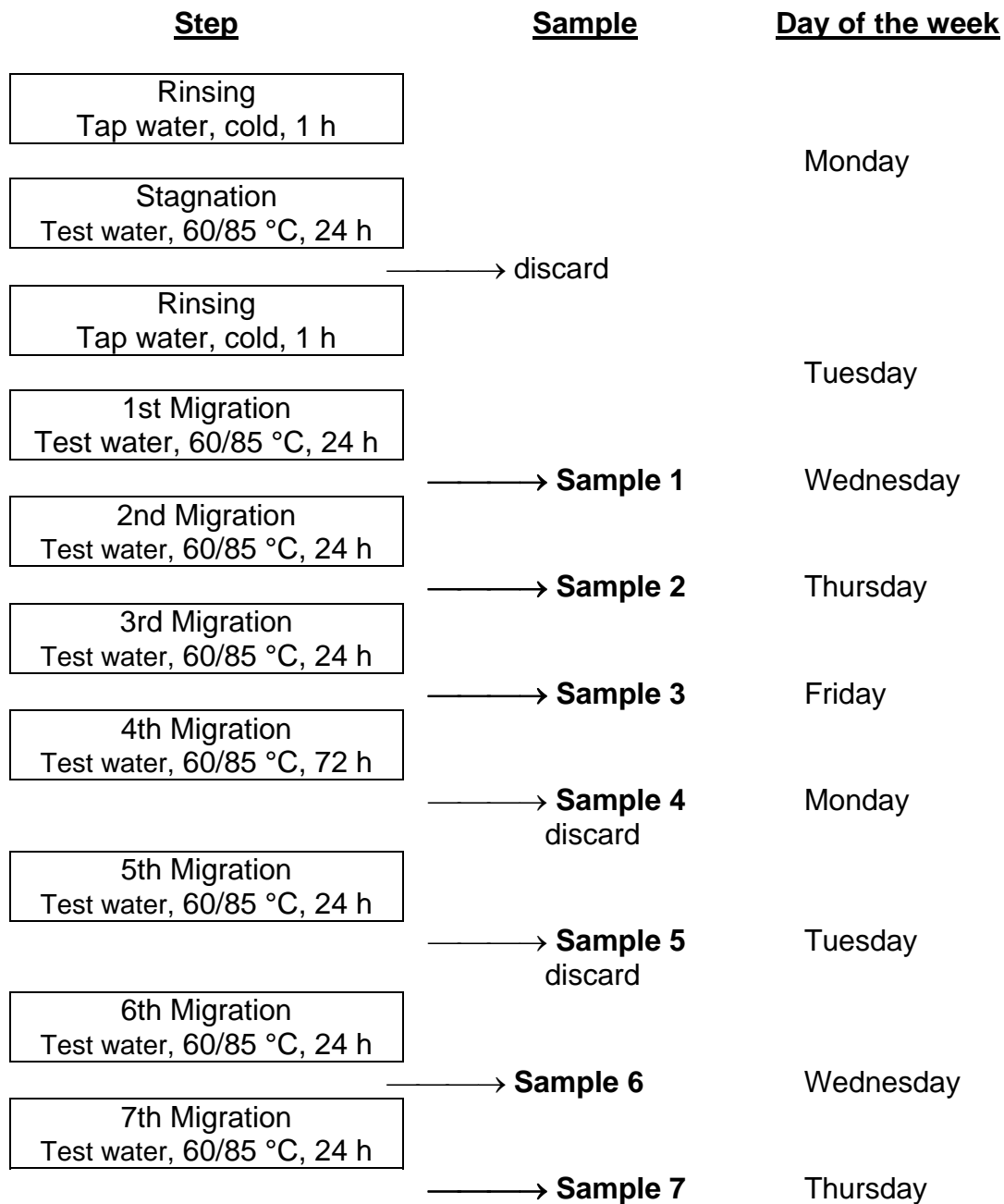
## Annex 1 to the KTW Guideline

Table of the surface-to-volume (S/V) ratios in testing of non-metallic materials in contact with water

Area of use	Migration at 23 °C	Migration at higher temperature	Odour/flavour at 23 °C	Odour/flavour at higher temperature
Pipes DN < 80	$S/V \geq 5 \text{ dm}^{-1}$ (fill)	$S/V \geq 5 \text{ dm}^{-1}$ (fill)	$S/V \geq 5 \text{ dm}^{-1}$ (fill)	$S/V \geq 5 \text{ dm}^{-1}$ (fill)
Pipes $80 \leq \text{DN} < 300$	$S/V \geq 5 \text{ dm}^{-1}$ (fill with cylinder inserted)	$S/V \geq 5 \text{ dm}^{-1}$ (fill with cylinder inserted)	$S/V \geq 2.5 \text{ dm}^{-1}$ (fill)	$S/V \geq 2.5 \text{ dm}^{-1}$ (fill)
Pipes DN $\geq 300$	$S/V \geq 5 \text{ dm}^{-1}$ (fill with cylinder inserted or fill pipe)	$S/V \geq 5 \text{ dm}^{-1}$ (fill with cylinder inserted or fill pipe)	$S/V \geq 2.5 \text{ dm}^{-1}$ (fill with cylinder inserted or fill pipe)	$S/V \geq 2.5 \text{ dm}^{-1}$ (fill with cylinder inserted or fill pipe)
Fittings	$S/V \geq 5 \text{ dm}^{-1}$ (immersing product)	$S/V \geq 5 \text{ dm}^{-1}$ (immersing product)	$S/V \geq 1.5 \text{ dm}^{-1}$ (immersing product)	$S/V \geq 1.5 \text{ dm}^{-1}$ (immersing product)
Sealings and adhesives	$S/V \geq 5 \text{ dm}^{-1}$ (immersing product)	$S/V \geq 5 \text{ dm}^{-1}$ (immersing product)	$S/V \geq 0.2 \text{ dm}^{-1}$ (immersing product)	$S/V \geq 0.2 \text{ dm}^{-1}$ (immersing product)
Tanks	$S/V \geq 5 \text{ dm}^{-1}$ (immersing coated plates)	$S/V \geq 5 \text{ dm}^{-1}$ (immersing coated plates)	$S/V \geq 2.5 \text{ dm}^{-1}$ (immersing coated plates)	$S/V \geq 2.5 \text{ dm}^{-1}$ (immersing coated plates)

## Annex 2 to the KTW Guideline

Diagram of the test procedure at higher temperatures as specified in 2.1.2 and 2.2.2



## Annex 3 to the KTW Guideline

Examples of different products and their classification in product groups  
(Section 3, Table 2)

<i>Product group</i>	<i>Products</i>
<b><i>Pipes:</i></b> <b><i>grouped according to size:</i></b> <i>DN &lt; 80 mm</i> <i>80 mm ≤ DN &lt; 300 mm</i> <i>DN ≥ 300 mm</i>	<ul style="list-style-type: none"> <li>- <i>plastic pipes and hoses</i></li> <li>- <i>plastic pipe linings (inliners)</i></li> <li>- <i>pipes lined by manufacturer</i></li> <li>- <i>pipes lined on-site</i></li> <li>- <i>pipes made of composite materials</i></li> <li>- <i>control cables submerged in drinking water pipes</i></li> <li>- <i>hoses in domestic installations (excluding connection hoses for washing machines and dishwashers)</i></li> <li>- <i>hoses for time-limited transport of drinking water</i></li> </ul>
<b><i>Fittings</i></b>	<ul style="list-style-type: none"> <li>- <i>valves</i></li> <li>- <i>taps</i></li> <li>- <i>meters</i></li> <li>- <i>fittings</i></li> <li>- <i>filter housings for filters in domestic installations</i></li> <li>- <i>casting compounds for fixed joints</i></li> <li>- <i>casting compounds for movable joints</i></li> <li>- <i>tile adhesives</i></li> <li>- <i>connecting pipes in waterworks</i></li> <li>- <i>feeder cables (e.g. for underwater pumps)</i></li> <li>- <i>coated slide valves</i></li> <li>- <i>linings of slide valve housings</i></li> <li>- <i>membranes for expansion tanks</i></li> <li>- <i>connecting hoses for washing machines and dishwashers</i></li> </ul>
<b><i>Sealings</i></b>	<ul style="list-style-type: none"> <li>- <i>sealings for pipes and hoses</i></li> <li>- <i>expansion joints, compensating parts, mufflers</i></li> <li>- <i>wedge sealings for slide valves</i></li> <li>- <i>clapper sealings with complete surface coating</i></li> <li>- <i>pressure regulator membranes</i></li> <li>- <i>plunger valves</i></li> <li>- <i>coated hydrant stop cocks</i></li> <li>- <i>O-rings</i></li> <li>- <i>rolling rubber ring and sliding ring sealings</i></li> <li>- <i>flange sealings</i></li> <li>- <i>sleeve sealings</i></li> <li>- <i>tapping sleeves</i></li> <li>- <i>inlaid or surrounding sealings for slide</i></li> </ul>



	<b>valves</b> <ul style="list-style-type: none"> <li>- <b>spindle sealings and wedge sealings with inlaid profile sealing</b></li> <li>- <b>clapper seal with inlaid or surrounding coating</b></li> <li>- <b>valve sealings</b></li> <li>- <b>adhesives for pipes</b></li> <li>- <b>lubricants for fittings</b></li> <li>- <b>screw thread sealants</b></li> </ul>
<b>Tanks</b>	<ul style="list-style-type: none"> <li>- <b>drinking water supply reservoirs and tank linings made of plastic</b></li> <li>- <b>storage tanks in waterworks</b></li> <li>- <b>drinking water tanks in domestic installation</b></li> <li>- <b>feed tanks for pressure boosting systems in domestic drinking water installations</b></li> <li>- <b>pressure vessels without membrane</b></li> <li>- <b>bubble membrane for pressure vessels</b></li> <li>- <b>water heaters (other than continuous-flow water heaters)</b></li> <li>- <b>electric water heater (e.g. below sink)</b></li> <li>- <b>repair systems for containers and tanks</b></li> </ul>

## Annex 4 to the KTW Guideline

**Table of test results specified in accordance with DIN EN 12873-1 and DIN EN 12873-2**

	Sequential number of the migration period n				
	1	2	3	6	7
$a_n^T$					
$\bar{a}_n^T$					
$b_n^T$					
$\bar{b}_n^T$					
$\bar{c}_n^T = \bar{a}_n^T - \bar{b}_n^T$					
$\bar{M}_n^T$					

Where

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

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

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

$\bar{M}_n^T$  is the migration rate of the migrating substance,

n is the sequential number of the migration period,

T is the test temperature

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