Für Mensch & Umwelt

Umwelt Bundesamt

As at: 11 March 2019
Rev02

RECOMMENDATION

Transitional recommendation on the provisional hygienic assessment of products made from thermoplastic elastomers in contact with drinking water (TPE transitional recommendation)

English translation – only the German document version is legally binding

1 Preliminary remark

The Recommendation at hand can be used for the hygienic assessment of products made from thermoplastic elastomers (TPEs) in contact with drinking water.

This recommendation does not constitute an Evaluation Criteria Document according to § 17 Section 3 of the German TrinkwV, and therefore is not mandatory. It reflects the current status of scientific and technical knowledge with regard to hygienic requirements applicable to thermoplastic elastomers in contact with drinking water.

Prospectively, it is intended to transfer the hygienic requirements set out in this recommenation to the existing Evaluation Criteria Document for plastics and other organic materials (KTW-BWGL).

2 Scope of application

This Transitional Recommendation applies to all types of TPEs according to DIN EN ISO 18064: 2015-03 in contact with drinking water.

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3 Information on thermoplastic elastomers

TPEs occupy a special position between plastics and elastomers. They exhibit elastic properties similar to those of vulcanised rubber and can be processed like thermoplastics.

TPEs can be composed of different polymers, with soft and hard segments occurring in separate phases. TPEs typically have physical (thermally labile, reversibly cleavable) or chemical cross-linking sites. DIN EN ISO 18064: May 2005 distinguishes between different TPE types and classifies them in a nomenclature system.

4 Inclusion of new TPE types

The list in Table 1 can be extended. To have a new type included, an application must be filed with the German Environment Agency and the following information submitted on the TPE type in a product by way of example:

- Composition and manufacture of the TPE type
- Migration results of the basic, additional and formulation-specific requirements for individual substances defined in the KTW-BWGL or Elastomer Guideline
- Concentration of volatile[1] and extractable[2] substances in migration waters of the cold-water and warm-water tests according to DIN EN 12873-1

The data will be used to evaluate which substances are likely to migrate from the relevant TPE type. UBA then decides whether the evaluation of the TPE should be carried out according to the KTW-BWGL or the Elastomer Guideline.

5 Requirements for TPE

TPE in contact with drinking water must be suited for this purpose. Requirements covered by technical regulations apply, irrespective of this recommendation.

[1] KOCH, Andreas: *Gaschromatographische Verfahren zum Nachweis der Freisetzung von Inhaltsstoffen aus Polymermaterialien im Trinkwasserkontakt ("Gas-chromatographic methods for detection of substance liberation from polymeric materials in drinking water contact")*. 1. Aufl. Osnabrück: Der Andere Verlag, 2004 - ISBN 3-89959-225-5

[2] DIN EN 15768 "Influence of materials on water intended for human consumption - GC-MS identification of water leachable organic substances"

5.1 Positive list for the manufacturing of TPE

Assessment and testing of drinking water hygienic suitability of the different types of TPEs takes place as a function of the type of cross-linkage:

Physically cross-linked TPEs in contact with food are deemed to be covered by Regulation (EU) No 10/2011, in accordance with the European Commission's position (Union Guidance on Regulation (EU) No 10/2011)[3]. In keeping with this position, the suitability of physically cross-linked TPE with a plastics-like formulation for drinking water hygiene can be proven according to the Evaluation Criteria Document for plastics and other organic materials in contact with drinking water (KTW-BWGL)[4] if the TPE type concerned is listed in Table 1.

Chemically cross-linked TPEs more resemble elastomers in terms of composition. Therefore, the suitability of these types of TPEs for drinking water hygiene can be evaluated according to the Elastomer Guideline[5] if the TPE type concerned is listed in Table 1.

Information available to the German Environment Agency indicates that the TPE types listed in Table 1 can be used for the manufacture of products hygienically suitable for contact with drinking water.

[3] https://ec.europa.eu/food/sites/food/files/safety/docs/cs_fcm_plastic-guidance_201110_en.pdf

[4] https://www.umweltbundesamt.de/en/document/evaluation-criteria-document-for-plastics-other

[5] https://www.umweltbundesamt.de/en/document/guideline-for-hygienic-assessment-of-elastomers-in

Table 1: List of TPE types for the manufacture of products hygienically suitable for contact with drinking water[6]

TPE type	Composition requirements
a) Physically cross-linked TPEs	
Compounds on the basis of styrene block polymerisates (TPS)	Polymer composition according to requirements set out in the KTW-BWGL document
Thermoplastic copolyester elastomers (TPC)	
Thermoplastic polyolefines (TPO)	
Thermoplastic silicones (TPSi)	Composition of polyolefines and silicones according to requirements set out in KTW-BWGL and in transitional recommendation silicones
Thermoplastic polyurethanes (TPU)[7]	Polymer composition according to requirements set out in the KTW-BWGL document
b) Chemically cross-linkedTPE	
No entry so far	

5.2 Basic requirements

Reference values set out in the Elastomer Guideline apply (cf. Chapter 5.1 of the Elastomer Guideline).

5.3 Additional requirements

For physically cross-linked TPEs additional requirements according to Annex A of the KTW-BWGL document apply; for chemically cross-linked TPEs those additional requirements set out in the Elastomer Guideline.

These requirements are not applicable to marginal products.

5.4 Formulation-specific requirements for individual substances

All individual substances contained in the product for which an MTC_{tap} value (maximum tolerable concentration) is specified in one of the positive lists, have to be tested with regard to their migration according to Chapter 6.4 of the Elastomer Guideline.

The concentration determined by way of this analysis is used to calculate the maximum expected substance concentration at the tap, c_{tap} (cf. Chapter 5.4 of the Elastomer Guideline).

For marginal products these requirements do not apply (cf. Chapter 5.7 of the Elastomer Guideline).

[6] Proof of the suitability of products made from TPE for drinking water hygiene requires testing to be performed in accordance with either the KTW-BWGL or the Elastomer Guideline.

[7] for cold-water application only

5.5 Requirements for the testing of enhancement of microbial growth

The requirements set out in Chapter 5.6 of the Elastomer Guideline apply.

6 Testing

The requirements set out in Chapter 6 of the Elastomer Guideline apply.

7 Requirements for the issuance of a test certificate

The issue of test certificates shall follow the requirements of Chapter 6 of the Elastomer Guideline.