SLOVENSKI STANDARD
SIST-TP CEN/TR 18217:2026

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Varnost igrač - Migracija določenih elementov iz trdih polimerov

Safety of toys - Migration of certain Elements from "Hard" polymers

Sicherheit von Spielzeug - Migration bestimmter Elemente aus (Hart-) Polymeren

Sécurité des jouets - Migration de certains éléments à partir de polymères "durs"

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English Version

Safety of toys - Migration of certain elements from polymers

Sécurité des jouets - Migration de certains éléments à partir de polymères

Sicherheit von Spielzeug - Migration bestimmter Elemente aus Polymeren

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European foreword

This document (CEN/TR 18217:2025) has been prepared by Technical Committee CEN/TC 52 “Safety of toys”, the secretariat of which is held by DS.

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Introduction

The Toy Safety Directive 2009/48/EC sets out limits for the migration of certain elements (Annex II, chapter III, clause 13). This requirement is implemented by the European standard EN 71-3 which includes a specified test method.

This document addresses a lot of different material groups and materials, like polymers and other solid materials, liquids as well as scraped-off materials like coatings and specifies sample preparation and analytical test methods for these materials.

Toys or toy components containing accessible glass, ceramic or metallic materials are tested as a whole if they fit entirely within the small parts cylinder specified in EN 71-1. Glass, ceramic and metallic toy components which do not fit within the small parts cylinder do not need to be tested. They cannot be swallowed and due to their hardness are unlikely to release ingestible fragments. The exposure to certain elements from such components is, therefore, not considered significant.

Experience has shown that also the migration from polymers is neglectable because a migration from those materials appears scientifically not relevant due to insignificant diffusion of elements in solid matter (see annex B).

The review of a data set collected from several laboratories showed that testing of polymeric toy materials does, in practice, not result in any significant migration (see Annex B for representative test results of real toy samples collected from several test institutes).

Based on these observations the responsible working group CEN/TC 52/WG 5 "Safety of toys - Chemical properties" established task group CEN/TC 52/WG 5/TG 5 “Migration of certain elements regarding hard polymers” in order to investigate whether the migration from hard polymers can also be considered as negligible.

Sample Document

This document summarizes the results of the task group and provides a view on the behaviour of polymeric material during the migration in 0,07 mol/l hydrochloric acid in accordance with to EN 71-3.

Literature research regarding the theoretical background of the movement and diffusion of ionic molecules within solid matter was conducted. The empirical data were evaluated focussing on certain polymeric materials. Based on the results of the literature study a controlled interlaboratory comparison test was designed to prove the theoretical findings engaging nine accredited laboratories (notified bodies) in Europe and Asia.

The aim was to assess whether elements could exceed the migration limits specified in EN 71-3 in a migration test with certain spiked polymers. Hard polymers are defined in this context as those with a Shore A hardness >55 and are therefore unlikely to release ingestible fragments as a result of biting or chewing by children. In this study, the expert group found that the hardness of the polymers had no influence on the migration results. Because on the one hand migration of elements within polymers is negligible and is not related to the hardness of a polymer but on physical properties described below. Therefore, the expert group decided to address certain polymers used as toy materials, for example ABS, PP, PE, Polystyrene, Polycarbonate. Based on results of the literature research (see 4.2) it was realized that the diffusion behaviour of the mentioned polymers is comparable.

The comparison test was conducted with a polymer granulate (ABS) containing in total 13 410 mg/kg of certain elements.

In accordance with literature the release of metal ions from the polymers in discussion appear negligible due to the physico-chemical properties of the material and the low diffusion rates. Therefore, it can be assumed that no relevant amounts of metal ions migrate from polymers under the specified conditions.

In all analyses after migration (in accordance with EN 71-3:2013) metal ions were not detectable or found below the limit of quantification. Based on these results it can be concluded that measurable amounts of soluble metals do not migrate from polymers within the two hours specified in the test method and therefore testing for migration of metals from polymers appears not to be necessary.

The results can be applied to toy materials made from, among others, the polymers ABS, PP, PE, polystyrene, and polycarbonate containing no more than 20% additives. In conclusion these data can be used to support a risk assessment in accordance with to Directive 2009/48/EC.

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1 Scope

This document provides information on the migration behaviour of certain elements from polymers. The document can in particular assist manufacturers of toys in performing risk assessments.

Information on organic tin compounds can be found in Annex C.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp/

— IEC Electropedia: available at https://www.electropedia.org/

4 Theory

4.1 Toy Safety Directive

In accordance with Article 19 of the Toy Safety Directive (Directive 2009/48/EC, [1]) toy manufacturers can declare compliance for a toy by applying the relevant harmonised standards or applying a specific risk assessment.

EN 71-3 currently defines exemptions for glass, ceramics and metal parts, not fitting into the small parts cylinder, based on exposure and risk-based evaluations. These considerations can potentially be applied to other materials, like polymers.

4.2 Polymers

4.2.1 General

In accordance with Regulation (EC) 1907/2006 polymer means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules are distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.

A polymer comprises the following additional conditions:

a) a simple weight majority of molecules containing at least three monomers mainly carbon-based units which are covalently bound to at least one other monomer unit or another reactant.

b) less than a simple weight majority of molecules of the same molecular weight.

c) a maximum of 20% additives

4.2.2 Structure and interaction within a polymer

A polymer consists of long carbon chains [2]. The carbon atoms are covalently bound and exhibit a lipophilic and non-polar character [3]. Therefore, the polymers of common toy material like PVC, ABS, polystyrene, polyethylene, and polypropylene are not soluble in water or acids. Even PVC, which contains a high number of powerful electronegative substituents, is practically insoluble in water, but soluble in

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