



SLOVENSKI STANDARD
SIST EN 1400:2013+A1:2014/oprA2:2017
01-februar-2017

Izdelki za otroke - Dude za dojenčke in mlajše otroke - Varnostne zahteve in preskusne metode - Dopolnilo A2

Child use and care articles - Soothers for babies and young children - Safety requirements and test methods

Artikel für Säuglinge und Kleinkinder - Schnuller für Säuglinge und Kleinkinder - Sicherheitstechnische Anforderungen und Prüfverfahren

Articles de puériculture - Sucettes pour nourrissons et jeunes enfants - Exigences de sécurité et méthodes d'essai

Ta slovenski standard je istoveten z: EN 1400:2013+A1:2014/prA2:2016

ICS:

97.190 Otroška oprema Equipment for children

SIST EN 1400:2013+A1:2014/oprA2:2017 en,fr,de

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
EN 1400:2013+A1:2014
prA2

December 2016

ICS 97.190

English Version

Child use and care articles - Soothers for babies and young children - Safety requirements and test methods

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Artikel für Säuglinge und Kleinkinder - Schnuller für Säuglinge und Kleinkinder - Sicherheitstechnische Anforderungen und Prüfverfahren

This draft amendment is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 252.

This draft amendment A2, if approved, will modify the European Standard EN 1400:2013+A1:2014. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN 1400:2013+A1:2014/prA2:2016) has been prepared by Technical Committee CEN/TC 252 “Child use and care articles”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

EN 1400:2013+A1:2014/prA2:2016 (E)

1 Modification to the Introduction

Add the following text

"Since the publication of EN 1400:2013+A1:2014 it has come to the attention of the Technical Committee that some of the TDI's used to calculate the limits of a certain number of element migration from soothers are out of date. During the drafting of this amendment the Technical committee reviewed all the previous sources of TDI's to ascertain the current state of knowledge.

The migration limits for Arsenic, Barium, and Nickel have been changed to reflect the latest information. In addition migration limits for Chromium VI and Organic Tin have been added.

The Technical Committee has also included a requirement for Bisphenol A (BPA) in soothers based on the most recent TDI from the 2015 EFSA Opinion and an A-Deviation from France."

2 Modification to 10.2 Materials

Replace Table 4 by the following:

Table 4 — Requirements and Tests on materials

	Migration of certain elements	N-Nitrosamines and N-Nitrosatable release	2-Mercaptobenzothiazole release	Antioxidants release	Formaldehyde release	Bisphenol A release	Colour Fastness	Volatile compound content
Requirement Clause	10.3.1	10.4.1	10.5.1	10.5.1	10.5.1	10.6.1^a	10.7.1	10.8.1
Test Clause	10.3.2	10.4.2	10.5.2	10.5.2	10.5.2	10.6.2	10.7.2	10.8.2
Vulcanised rubber	x	x	x	x	x		x	
Silicone rubber	x	x			x		x	x
All Thermoplastics	x						x	
Polycarbonate and Polysulphone	x					x	x	
TPEs	x	x					x	
All Decorations	x						x	

^a Bisphenol A Migration is only carried out on thermoplastics that use Bisphenol A in their manufacture, such as polycarbonates. Bisphenol A is not used in the production of other common thermoplastics, such as polypropylene and polyethylene.

3 Modification to 10.3 Migration of certain elements (see B.21)

Replace Table 5 by the following:

Table 5 — Limits of element migration from soothers

Element	Limit mg/kg
Aluminium, Al	1 430
Antimony, Sb	60
Arsenic, As	5,0
Barium, Ba	2 000
Boron, B	1 600
Cadmium, Cd	1,8
Chromium III, Cr	50
Chromium VI, Cr	0,001
Cobalt, Co	14
Copper, Cu	830
Lead, Pb	2,5
Manganese, Mn	300
Mercury, Hg	10
Nickel, Ni	28
Selenium, Se	50
Strontium, Sr	6 000
Tin, Sn	20 000
Organic tin	1,3
Zinc, Zn	5 000

4 Modification to 10.6 Bisphenol A release (see B.20.5, B.26 and Annex H)

Replace the first sentence in 10.6.1 by the following:

"When tested in accordance with 10.6.2, the migration of Bisphenol A from polycarbonate or polysulphone shall not exceed the limit given in Table 10."

EN 1400:2013+A1:2014/prA2:2016 (E)

Replace Table 10 by the following:

Table 10 — Monomers (migration) - see B.26

Compound	CAS number	Limit ^a mg/l
Bisphenol A (2,2-bis(4-hydroxyphenyl)propane) ^a	80-05-7	0,01
^a Limits are expressed as amount of substance per litre of simulant (see EN 71-11).		

5 Modification to Annex B

Replace Table B.1 by the following:

Table B.1 — TDI Values for certain elements and calculated migration limits

Element	Symbol	TDI µg/kg body weight/day	Allocation of TDI	Sources of TDI	Migration limits mg/kg
Aluminium	Al	143	0,10	[13]	1 430
Antimony	Sb	6	0,10	[36]	60
Arsenic	As	1	0,05	[36]	5,0
Barium	Ba	200	0,10	[37]	2 000
Boron	B	160	0,10	[36]	1 600
Cadmium	Cd	0,36	0,05	[38]	1,8
Chromium III	Cr	5	0,10	[36]	50
Chromium VI	Cr	0,0002	0,05	[39]	0,001
Cobalt	Co	1,4	0,10	[36]	14
Copper	Cu	83	0,10	[36]	830
Lead	Pb	0,5	0,05	[11], [19]	2,5
Manganese	Mn	30	0,10	[36]	300
Mercury	Hg	2	0,05	[36]	10
Nickel	Ni	2,8	0,10	[40]	28
Selenium	Se	5	0,10	[36]	50
Strontium	Sr	600	0,10	[36]	6 000
Tin	Sn	2 000	0,10	[36]	20 000
Organic tin		0,25	0,05	[36]	1,3
Zinc	Zn	500	0,10	[36]	5 000

*In B.21, **add** the following three paragraphs below Table B.1:*

During the drafting of this amendment the Technical committee reviewed all the previous sources of TDI's to ascertain the current state of knowledge.

The migration limits for Arsenic, Barium, and Nickel have been changed to reflect the latest information. In addition migration limits for Chromium VI and Organic Tin have been added.

The migration limit for Chromium VI was derived from the SCHER opinion [39] of a virtual safe dose of 0,0002 µg/kg bw/day and the Organic tin limit was derived using the data given in the 2008 RIVM Report [36] of 0,25 µg/kg bw/day which is the same as that expressed by EFSA in 2004 as a group-TDI for organotins.

*In B.26, **add** the following paragraph after the second paragraph:*

The latest EFSA Opinion was issued in March 2015 [35] The CEF Panel applied a total uncertainty factor of 150 (for inter- and intra-species differences and uncertainty in mammary gland, reproductive, neurobehavioural, immune and metabolic system effects) to establish a temporary Tolerable Daily Intake (t-TDI) of 4 µg/kg bw per day. By comparing this t-TDI with the exposure estimates, the CEF Panel concluded that there is no health concern for any age group from dietary exposure and low health concern from aggregated exposure. The CEF Panel noted considerable uncertainty in the exposure estimates for non-dietary sources, whilst the uncertainty around dietary estimates was relatively low.

*In B.26, **replace** the 4th and 5th paragraphs by the following:*

However, the EU has temporarily banned the use of BPA in infant bottles (for children less than one year old) as from 1 May 2011 [31], [32] but this does not apply to soothers. However the Technical Committee has included a requirement for BPA in soothers based on the most recent TDI from the 2015 EFSA Opinion.

Using a defined method such as EN 71-10 [33] (see B.20.5) which simulates the effect of mouthing, a maximum migration limit can be calculated on the amount of the migration solution volume. Using the allocated percentage of the t-TDI (10%) (see B.20.4), the migration solution volume (100 ml) (see B.20.5 Common migration rules), and the weight of a child (2.5 kg) (see B.20.2), the migration limit can be calculated with the same formula used in B.24, which results in a migration limit of 0,01 mg/l.

*In B.26, **add** the following sentence at the end of the subclause:*

If the EFSA amends the TDI for BPA in the future, this migration limit will be reconsidered.