



EU Published Amendment 2 to EN 1400 for Soothers

In September 2018, the European Committee for Standardization

(Comité Européen de Normalisation, CEN) published EN

1400:2013+A2:2018, the new safety standard for 'Soothers for Babies

and Young Children'. The new standard is applicable to products that

resemble or function as a soother. This European Standard specifies

safety requirements related to the materials, construction, performance,

packaging and product information for soothers. This standard is to be given the status of a national standard by March

2019 and conflicting national standards are to be withdrawn by this date at the latest.

EN 1400:2013+A2:2018 contains a number of important changes, including the following:

1. Amending the overview of the requirements and the related test methods for different materials as listed in Table 4.

The category 'Thermoplastics' is divided into two new categories: 'All Thermoplastics' and 'Polycarbonate and Polysulphone'.

2. Expanding the list of soluble elements from 17 to 19 in Table 5 and amending some of these migration limits. These changes include dividing the migration of (total) chromium into two types of chromium: chromium (III) and chromium (VI), a completely new entry for organotin, and new limits for arsenic, barium and nickel. It is important to note that the migration limit for nickel has been strengthened approximately 4-fold, but limits for arsenic and barium have become less stringent.



Table 5 Limits of element migration form soothers

Element	EN 1400:2013+A2:2014	EN 1400:2013+A2:2018
Arsenic (As)	2.5 mg/kg	5.0 mg/kg
Barium (Ba)	200 mg/kg	2000 mg/kg
Chromium (Cr)	50 mg/kg	--
Chromium (III) (Cr (VI))	--	50 mg/kg
Chromium (VI) (Cr (VI))	--	0.001 mg/kg



Nickel (Ni)	100 mg/kg	28 mg/kg
Organotin	--	1.3 mg/kg

3. Strengthening the migration limit for bisphenol A (BPA) in Table 10, from 0.125 mg/L to 0.01 mg/L. It is important to note that this limit is not applicable to certain member states in the EU due to national legislation (i.e. Austrian & French).

Table 10 Monomers (Migration)		
Compound	EN 1400:2013+A2:2014	EN 1400:2013+A2:2018
Bisphenol A (BPA)	0.125 mg/L	0.01 mg/L

Official Link:

https://standards.cen.eu/dyn/www/f?p=CENWEB:110:0:::FSP_ORG_ID,FSP_PROJECT:6233,66993&cs=11F972F57669F84033574493B24A3224B

HCT Solutions :

The Soothers standard ushered in the largest revision since 2014, with soluble heavy metals extending to 19 consistent with EN 71-3, while further reducing the migration of bisphenol A to 0.01 mg/L. This year, 18 Soothers manufacturers have been notified by the EU. It is expected that after the new standards are officially implemented in March next year, the EU will further strengthen supervision, and the relevant Soothers manufacturers will face even more impact.

With nearly 10 years of experience in testing and certification, HCT provides companies with professional testing services and personalized solutions for Soothers to help companies cope with various environmental impacts.

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