

SGS C&P – Connectivity & Products

Chemicals – A new EU standard for childcare articles




Juvenile Products Safety Forum | Pascale Lambert, Catherine Follin-Arbelet | October 25, 2022




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Speakers




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Agenda

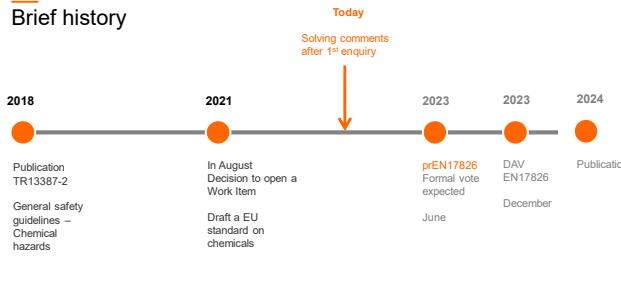
- Brief history of the document
- Scope
- Application to childcare articles
- Substances
- Q&A

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Brief history



Timeline events:


- 2018**: Publication TR13387-2, General safety guidelines – Chemical hazards
- 2021**: In August Decision to open a Work Item, Draft a EU standard on chemicals
- Today**: Solving comments after 1st enquiry
- 2023**: prEN17826 Formal vote expected, June
- 2023**: DAV EN17826, December
- 2024**: Publication



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Scope

- The European standard will apply to childcare articles in the scope of CEN/TC252
 - Any product designed or obviously intended to safely ensure and facilitate seating, bathing, changing and general body care, feeding, sleeping, transportation and protection for young children up to 4 years.
- Exclusions: soothers (EN1400), soother holders (EN12586), drinking equipment (EN14350) and cutlery and feeding utensils (EN14372) for which the relevant applicable standards already include comprehensive requirements
- The draft standard specifies chemical requirements and references relevant test methods
 - It does NOT duplicate the regulation



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Application to childcare articles

- Will be listed in the relevant products safety standards
- Products safety standards to determine parts of the products to which requirements will be applicable, taking into account accessibility, function, volume or mass, and reasonable exposure due to sucking, licking, swallowing, inhalation or prolonged contact with skin
- Requirements on Volatile Organic Compounds apply to all parts





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Substances – Certain elements



List of 19 elements


Considering parts which, due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing or prolonged contact with skin.



Hazard


- In excess, heavy metals pose a significant health risk. Cause of different pathologies :

Neurodegenerative diseases such as Alzheimer's, Parkinson's, multiple sclerosis. Disorders of the nervous system, respiratory tract, cancers, irritations and chronic fatigue




Method

EN71-3 : extraction in Gastric solution (HCl 0,07N)




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Substances – Flame retardants




Limit on 3 substances

Applied on plastics, foams, textiles and wood when used as flame-retardants



Hazard


Human toxicity (carcinogenic : liver and kidney damage, reprotoxic) + Eco-toxicity



Method


Total extraction in solvent (soxhlet or ultrasonic bath)

Compound	CAS number	Content limit
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	5 mg/kg
Tris(1,3-dichloropropyl-2) phosphate (TDCPP)	13674-87-8	5 mg/kg
Tris-mono-chloro-propyl phosphate (TCPP)	13674-84-5	5 mg/kg




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Substances – Aniline




- Max 30 mg/kg
- After reductive cleavage from parts made of textiles and leather
- Reasonably exposure due to sucking, licking, swallowing, or prolonged contact with skin due to accessibility, function, volume or mass



Hazard

Can cause skin allergy
Causes serious eye damage


Very toxic to aquatic organisms and dangerous for the environment



Method


- EN ISO 14362-1 : 2017
- EN ISO 17234-1 : 2020 adapted as appropriate

Textile : Extraction in boiling Xylene during 40 min.
Leather : extraction in n-Hexane at 40°C during 40 min




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Substances – Monomers




Requirement

Limits of migration of monomers from parts made of polymeric materials which can be placed in the mouth



Hazard


High toxicity, depending on substance



Method


EN71-10 & 11 : 2005
Extraction in water at 60°C during 1 hour

Compound	CAS number	Limit
Acrylamide	79-06-1	0,02 mg/l
Bisphenol A	80-05-7	0,04 mg/l
Formaldehyde	50-00-0	1,5 mg/l
Phenol	108-95-2	5 mg/l
Styrene	100-42-5	0,75 mg/l




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Substances – Plasticizers



Requirement


Limits of migration of substances typically used as plasticizers (but may be used for other purposes) from parts made of soft polymeric materials which can be placed in the mouth



Hazard

acute toxicity by skin or oral contact / Suspected endocrine disruptor


Neurotoxic (may cause paralysis)



Method


EN71-10 & 11 : 2005
Extraction in water at 60°C during 1 hour

Compound	CAS number	Limit
Triphenyl phosphate	115-96-6	0,03 mg/l
Tri-o-cresyl phosphate	78-30-8	0,03 mg/l
Tri-m-cresyl phosphate	563-04-2	0,03 mg/l
Tri-p-cresyl phosphate	78-32-0	0,03 mg/l



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Substances – Sensitizers - Fragrances




Requirements

Any intentionally scented part or material shall not contain any of the 58 allergenic fragrances listed


The names of the 72 allergenic fragrances in a second, Table shall be listed on the article, on an affixed label, on the packaging or in an accompanying leaflet, if intentionally added to any scented part or material at concentrations exceeding 100 mg/kg

Intentionally scented fragranced products shall be labelled with the words "contains fragrance"




Hazard

Allergenic substances:
Headaches/ eye, nose, and throat irritation /nausea / forgetfulness / loss of coordination / and other respiratory and/or neurotoxic symptoms




Method

Documental Check or testing (solvent extraction – chromatography analysis)



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Substances – Formaldehyde (other than monomer or preservative)



Requirement


Free and hydrolysed formaldehyde contained in parts made of textile and leather materials, which due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to sucking, licking, swallowing, inhalation or prolonged contact with skin shall not exceed 30 mg/kg.

The release of formaldehyde from resin-bonded wood panels used in the manufacture of parts of child use and care articles which due to their accessibility, function, volume or mass, can reasonably lead to an exposure due to inhalation shall not exceed 0,124 mg/m³ (0,1 ppm) corresponding to E1 classification.




Hazard

Highly volatile
High toxicity for human ; carcinogenic + very irritating to skin, nose, throat, eyes (= allergen)




Method

- Textile : EN ISO 14184-1:2011 (water extraction at 40°C during 1h – colorimetric analysis with UV/visible spectrophotometer)
- Leather : EN ISO 17226-1:2021 (extraction in detergent solution , 1hour at 40°C – LC analysis)
- Resin bounded wood panels : EN 717-1:2004 (emission + colorimetric analysis with UV/visible spectrophotometer)




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Substances – Polycyclic Aromatic Hydrocarbons (PAHs)




Requirement

- Natural and synthetic rubber part excluding silicone rubber
- Due to accessibility, function, volume or mass, can reasonably lead to exposure due to sucking, licking, swallowing or prolonged contact with skin



Hazard


Human : toxic, carcinogenic, causes cell dysfunction
Environment: soil pollution



Method


AFPS GS 2019-01-PAK (German GS-Mark)
Extraction in toluene - ultrasonic bath – 1h/60°C – GC/MS analysis

Name of PAHs	CAS number	Limit	Name of PAHs	CAS number	Limit
Benzo[ghi]perylene	191-24-2	≤ 0,2 mg/kg	Anthracene	120-12-7	Σ < 1 mg/kg
Indeno[1,2,3-cd]pyrene	193-39-15	≤ 0,2 mg/kg	Fluoranthene	206-44-0	
Naphthalene	91-20-3	≤ 1 mg/kg	Phenanthrene	85-01-8	
SUM OF PAHs		< 1 mg/kg	Pyrene	129-00-0	




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Substances – Formamide




Requirement

- EVA (ethylene-vinyl acetate) based foam materials, with a surface greater than 0,45 m² in childcare articles intended for indoor use.
- Containing more than 200 mg/kg formamide (cut-off limit based on content)
- Maximum release of formamide 20 µg/m³ after a maximum of 28 days from commencement of the emission testing of foam materials.




Hazard

Reprotoxic
Causes skin reaction



Method

- ISO 16000- 6 and ISO 16000-9
- Chamber size: minimum 200 liters
- Temperature: 23 °C
- Humidity: 50%
- Air exchange rate: 0,5 h-1
- Air speed: 0,1 – 0,3 m/s
- Loading: 0,04 m²m³
- Duration: maximum 28 days.



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Thank you for listening

- Enter your questions in the Q&A box
- Let us hear your thoughts by answering the polls by the end of Q&A

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