

**REGULATORY DATASHEET – REG1****Toy specific restrictions**

Market : European Union, Norway and Switzerland

Topic : Toy specific chemicals restrictions, not including the restrictions required by Directive 2009/48/EC relative to the safety of toys.

Version No. / Date

V13.00 – 3 May 2018

Summary :**Summary of restrictions in toys****Chapter 1 : Restrictions relative to phthalates in toys****Chapter 2 : Restrictions relative to benzene in toys****Chapter 3 : Restrictions relative to toys intended to be placed in the mouth and toys intended for children of less than 36 months**

3.1 Germany/Austria Restrictions relative to toys intended to be placed in the mouth and toys intended for children of less than 36 months (Colourfastness)

3.2 Germany : Restrictions relative to toys made of natural or synthetic rubber intended for children under 36 months which are intended/likely be brought into the mouth (nitrosamines and N-nitrosatable substances)

Chapter 5 : Germany : Restrictions relative to balloons**Chapter 6 : France/Austria : Restrictions relative to Bisphenol A in toys****Chapter 7 : Germany : Migration of heavy metals in toys****Chapter 8 : Restrictions relative to polycyclic aromatic hydrocarbons (PAHs) in toys**



History of modifications

V1.00	Initial version published on 20 December 2013
V2.00 – 29/09/2014	Switzerland: ref of texts updated Norway: ref of texts updated France: puzzle mats – Regulation to be renewed Germany: heavy metals – General Court Decision of 14 May 2014
V3.00 – 13/01/2015	Norway: ref of text updated France: puzzle mats – New Arrêté of 15 September 2014
V4.00 – 14/04/2015	Norway: ref of text updated
V5.00 – 31/07/2015	Chapters 1 and 2 : Switzerland and Norway: texts updated Chapter 7 : Court Decision of 9 July 2015 Chapter 8 : text Norway added
V6.00 – 18/12/2015	Norway: ref of text updated Chapter 3.3 : cancelled (no more applicable to toys – cf. Act No 258/2000 (Act on Public Health Protection) amended) Chapter 4 : Arrêté of 26 October 2015 published Chapter 7 : Regulation of 21 October 2015 (Regulation on Safety of Toys amended) Chapter 8 : Switzerland restriction added
V7.00 – 05/04/2016	Chapter 1, 2 and 8: Switzerland and Norway: texts updated Chapter 3.2 and 5 : « Bedarfsgegenständeverordnung » (Decree relative to consumer products) of 23 December 1997 updated Chapter 6 : Law No 2016-41 of 26 January published
V8.00 – 19/09/2016	Chapter 7: Legislation of 13 Juli 2016 amended (Regulation on the Safety of Toys) Chapter 1, 2, 8: Norway: ref of texts updated
V9.00 – 28/02/2017	Chapter 4: French Arrêté of 9 December 2016 Chapter 1, 2, and 8: Norway - Regulation FOR 2008-05-30 nr 516 reference updated Chapter 6 : new presentation but no modification in content
V10.00 – 01/08/2017	Various updates of references of regulations (Germany/Norway/Switzerland) Chapter 4 : removal of French arrêté on formamide Chapter 8: Switzerland : PAHs scope in line with entry 50 of Annex XVII / REACH
V11.00 – 02/11/2017	Norway: ref of text updated
V12.00 – 01/02/2018	Norway: ref of text updated Suppression of dates of application (PAHs) Chapter 8
V13.00 – 03/05/2018	Norway, Switzerland: ref of text updated



Summary of restrictions in toys

Note 1 : EU requirements are applicable in all EU countries.

Note 2 : Specific national requirements or additional requirements to EU requirements.

Note 3 : Specific national requirements or requirements identical to EU requirements.

Country Substance	EU See Note 1	EU countries See Note 2				Non EU countries (EFTA) See Note 3	
		Germany	Austria	Denmark	France	Switzerland	Norway
Phthalates	X			X		X EU id.	X EU id.
Benzene	X					X EU id.	X EU id.
DIN 53160		X					
N-nitrosamines and N-nitrosatable substances		X					
Bisphenol A			X		X		
Heavy metals (Lead)		X					
PAHs	X					X EU id.	X EU id.



Chapter 1 : Restrictions relative to phthalates in toys

Phthalates restrictions

European regulation :

- REACH Regulation 1907/2006 – Annex XVII – Entries 51 and 52

National regulations :

- Denmark : BEK nr 855 of 05 Sept 2009 Phthalates restrictions in toys and child care articles

Non EU countries (EFTA) :

- Switzerland : Ordinance relative to safety of toys 817.023.11 (OsJO) of 15 August 2012 (Last updated **1 May 2018**)
- Norway : FOR 2008-05-30 nr 516: Forskrift om registrering, vurdering, godkjenning og begrensning av kjemikalier (REACH) (last updated **FOR 2018-03-23-505**)

Scope :

- Toys

Europe/Switzerland/Norway requirements :

- Entry 51 : Plasticized materials of toys
“DEHP, DBP and BBP shall not be used as substances or constituents of preparations, at concentrations of greater than 0.1% by mass of the plasticized material, in toys and childcare articles : such toys and childcare articles containing these phthalates in a concentration greater than the above mentioned limit shall not be placed on the market”
- Entry 52 : Plasticized materials of toys which can be placed in the mouth
“DINP, DIDP and DNOP shall not be used as substances or as constituents of preparations, at concentrations of greater than 0.1% by mass of the plasticized material, in toys and childcare articles which can be placed in the mouth by them : such toys and childcare articles containing these phthalates in a concentration greater than the above mentioned limit shall not be placed on the market”

Additional national requirements : Denmark

- Toys designed or manifestly intended to be used by children of 0-36 months :

Prohibition of use of phthalates in the manufacture of toys or parts of toys in concentrations over 0.05%. This prohibition is not applicable to phthalates subjected to restrictions of Annex XVII of REACH, as described above.
(Limit is 0.05% per phthalate) (no list defined)



Chapter 2 : Restrictions relative to benzene in toys

Benzene restrictions (Annex XVII – REACH Regulation)

European regulation :

- REACH Regulation 1907/2006 – Annex XVII – Entry 5

National regulations :

Non EU countries (EFTA) :

- Switzerland : Ordinance relative to safety of toys 817.023.11 (OsJO) of 15 August 2012 (Last updated **1 May 2018**)
- Norway : FOR 2008-05-30 nr 516: Forskrift om registrering, vurdering, godkjenning og begrensning av kjemikalier (REACH) (last updated **FOR 2018-03-23-505**)

Scope :

- Toys

Requirements :

- Benzene must not be used in toys or parts of toys where the concentration of benzene in the free state is greater than 5 mg/kg of the weight of the toy or part of toy.



Chapter 3 : Restrictions relative to toys intended to be placed in the mouth and toys intended for children of less than 36 months

3.1 Germany/Austria : Restrictions relative to toys intended to be placed in the mouth and toys intended for children of less than 36 months

Chemical properties - Recommendations
<u>National regulations :</u> <ul style="list-style-type: none">• Germany : Recommendation XLVII. Spielzeug aus Kunststoffen und anderen Polymeren sowie aus Papier, Karton und Pappe (January 2003)
<u>Scope :</u> <ul style="list-style-type: none">• Toys intended to be placed in the mouth and toys intended for children of less than 36 months in plastic, paper or cardboard
<u>Recommendations :</u> <ul style="list-style-type: none">• DIN 53160 Determination of the colourfastness of articles for common use Part 1 : 2010 Test with artificial saliva Part 2 : 2010 Test with artificial sweat Specification : value 5 on grey scale rating
<u>Note :</u> <ul style="list-style-type: none">• Also recommended for Austria



3.2 Germany : Restrictions relative to toys made of natural or synthetic rubber intended for children under 36 months which are intended/likely be brought into the mouth

Restrictions N-nitrosamines and N-nitrosatable substances
<p><u>National regulations :</u></p> <ul style="list-style-type: none">• Germany : « Bedarfsgegenständeverordnung » (Decree relative to consumer products) of 23 December 1997 (last modified on 15 February 2016)
<p><u>Scope of application :</u></p> <ul style="list-style-type: none">• Toys made of natural or synthetic rubber intended for children under 36 months which are intended/likely be brought into the mouth
<p><u>Requirements :</u></p> <p><u>Limits :</u></p> <ul style="list-style-type: none">• N-nitrosamines < 0,01 mg/kg of parts of toys,• N-nitrosatable substances < 0,1 mg/kg of parts of toys <p>According to test methodology of Directive 93/11/EC Restrictions relative to N-nitrosamines and N-nitrosatable substances in elastomer teats and soothers (migration / saliva solution)</p>



Chapter 5 : Germany : Restrictions relative to balloons

Balloons
<p><u>National regulations :</u></p> <ul style="list-style-type: none">Germany : « Bedarfsgegenständeverordnung » (Decree relative to consumer products) of 23 December 1997 (last modified on 15 February 2016)
<p><u>Scope :</u></p> <ul style="list-style-type: none">Balloons
<p><u>Requirements :</u></p> <ul style="list-style-type: none">Requirements relative to <u>balloons made of natural or synthetic rubber</u> : Restrictions nitrosamines and N-nitrosatable substances : N-nitrosamines ≤ 0.05 mg/kg balloon N-nitrosatable substances ≤ 1 mg/kg balloon <p>According to test methodology of Directive 93/11/EC Restrictions relative to N-nitrosamines and N-nitrosatable substances in elastomer teats and soothers (migration / saliva solution)</p>
<p><u>Markings :</u></p> <ul style="list-style-type: none">Requirements for <u>all types of balloons</u> : <p>on packaging :</p> <ul style="list-style-type: none">« Zum Aufblasen eine Pumpe verwenden » <i>(translation : Use a pump to inflate)</i>



Chapter 6 : France/Austria : Restrictions relative to BPA in toys

Restrictions relative to bisphenol A (BPA) in toys

National regulations :

- France : Law No 2012-1442 of 24 December 2012 for the suspension of the manufacture, import, export and marketing of all-purpose food packaging containing bisphenol A
- France: Law No 2016-41 for modernizing the Health System of 26 January 2016. Its article 59 provides an amendment of the French Public Health Code for prohibition of toys containing Bisphenol A.
- Austria : « Verordnung des Bundesministers für Gesundheit über das Verbot der Verwendung von Bisphenol A in Beruhigungssaugern und Beißringen” of 6 October 2011 (Regulation prohibiting the use of bisphenol A in soothers and teething rings)

Scope :

- Teething rings, toys and amusing products

Requirements :

Teething rings

- Manufacturing and placing on the market of teething rings containing bisphenol A are prohibited.
- In France, the prohibition is not limited to “placing on the market”, it includes all marketing stages.

Toys and amusing products

- France (Law 2016-41) : Prohibition of manufacturing, sale, put for sale, exposure and import of toys and amusing products containing Bisphenol A which do not respect the content limit or the migration limit for this substance as defined by an Arrêté of the ministries of health, consumption, industry and environment.



Chapter 7 : Germany : Migration of heavy metals in toys

Migration of heavy metals
<p><u>National regulations :</u></p> <ul style="list-style-type: none">• Germany : « Zweite Verordnung zum Geräte- und Produktsicherheitsgesetz (Verordnung über die Sicherheit von Spielzeug) » of 7 July 2011,<ul style="list-style-type: none">- modified by “Erste Verordnung zur Änderung der Verordnung über die Sicherheit von Spielzeug” of 13 Juli 2016) (amendment to the Regulation on the safety of toys) published on 22 Juli 2016- modified by “Gesetz zur Neuordnung des Rechts zum Schutz vor der schädlichen Wirkung ionisierender Strahlung” of 27 June 2017
<p><u>Scope :</u></p> <ul style="list-style-type: none">• Toys
<p><u>Requirements :</u></p> <ul style="list-style-type: none">• Germany is authorised to keep in its national toy safety regulation the “migration” limits of Directive 88/378/EEC and standard EN 71-3: 1994 for lead. Objective is to apply limits stricter than those adopted under Directive 2009/48/EC and standard EN 71-3: 2013.• “Erste Verordnung zur Änderung der Verordnung über die Sicherheit von Spielzeug” of 13 Juli 2016: Bioavailability resulting from the use of toys must not exceed the following levels per day: 0.7 µg for lead



Chapter 8 : Restrictions relative to polycyclic aromatic hydrocarbons (PAHs) in toys

Restrictions relative to polycyclic aromatic hydrocarbons

European regulation :

- REACH regulation 1907/2006 – Annex XVII – Entry 50

National regulations :

Non EU countries (EFTA) :

- Norway : FOR 2008-05-30 nr 516: Forskrift om registrering, vurdering, godkjenning og begrensning av kjemikalier (REACH) (last updated **FOR 2018-03-23-505**)
- Switzerland : Ordinance relative to safety of toys 817.023.11 (OsJO) of 15 August 2012 (Last updated **1 May 2018**)

Scope :

- Toys with rubber or plastic components that come into direct as well as prolonged or short-term repetitive contact with the human skin or the oral cavity, under normal or reasonably foreseeable conditions of use.

Requirements :

- Concentration: $\leq 0,5$ mg/kg (0,00005 % by weight of the component) of any of the targeted PAHs
Targeted PAHs (8 PAHs): BaP, BeP, BaA, CHR, BbFA, BjFA, BkFA, DBA_hA



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