

TECHNICAL REQUIREMENTS, TEST METHODS FOR TOYS

**WITH RESPECT TO CHEMICAL RISKS AND THE
CONTENT OF HAZARDOUS SUBSTANCES**



ITC activities abroad are co-financed by the European Regional
Development Fund and the Ministry of Industry and Trade

EE Directives and Czech Legislation Related to Hazardous Substances in Toys

Order No.	Hazardous chemical substance monitored at toys	EU legislation (EU Directive)	Czech legislation (acts, decrees)
1.	- cadmium content in plastics	Commission Directive 76/769/EEC related to restrictions on the marketing and use of certain dangerous substances and preparations, as amended by the Commission Directive 91/338/EEC (content of cadmium)	Act No. 356/2003 Coll. on chemical substances and chemical agents; Decree No. 221/2004 Coll.
2.	- azocolourants in textile and leather	Directive 2002/61/EC of the European parliament and of the council amending Council Directive 76/769/CE relating to restriction on the marketing and use of certain dangerous substances and preparations (azocolourants)	Act No. 356/2003 Coll. on chemical substances and chemical agents, Decree No. 221/2004 Coll.
3.	- phtalates in plastics	Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005 amending for the 22nd time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (phtalates in toys and child care articles)	Decree of the Ministry of Health No. 84/2001 Coll. as amended –fully compliant with the Decree No. 284/2006 (amendment to the Decree No. 221/2004 Coll. defining lists of hazardous chemical substances and hazardous chemical agents, whose marketing is prohibited or whose marketing or distribution are restricted)
4.	- plastics – chemical properties – contact with consumables	Commission Directive 2004/19/EC of 1 March 2004 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs. Directive EP and C 1935/2004	Act No. 258/200 Coll. as amended, Decree No. 38/2001 Coll. on hygienic requirements for products intended for contact with foodstuffs
5.	- ceramics – chemical properties – contact with consumables	Council Directive 84/500/EEC of 15 October 1984 relating to ceramic articles intended to come into contact with foodstuffs.	Act No. 258/2000 Coll. as amended, decree No. 38/2001 Coll. on hygienic requirements for products intended for contact with foodstuffs
6.	- content of lead, mercury, cadmium, hexavalent chromium, PBB, PBDE	Directive 2002/95/EC of the European parliament and of the council on the restriction of the use of certain hazardous substances in electrical and electronic equipment	Act No. 185/2001 Coll. as amended, amendment No. 7/2005 Coll., Decree No. 352/2005 Coll.

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1. Content of cadmium in plastics (91/338/EHS)

- This directive relates to toys and any parts thereof made of plastics of any colour type as it is used both for colouring as well as stabilising polymer materials. Red and yellow plastics prove less frequent content of cadmium based pigments and products in such shades shall be treated with higher attention.

2. Content of azocolourants in textile and leather (2002/61/ES)

- This directive applies to toys and any parts thereof made of textile and/or leather of any age category or colour shade.

3. Content of phthalates in plastics (2005/84/ES)

- This directive applies to toys and any parts thereof made of softened plastics of any colour type. Whereas the restriction of DINP, DIDP and DNOP phthalates relates to toys inserted into mouths, without any limitation of child age.

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4. Plastics intended for contact with foodstuffs (2002/72/ES as amended by 2004/19/ES)

- This directive applies to toys and any parts thereof made of plastics to imitate kitchen cookware and functioning kitchen appliances.

5. Ceramics intended for contact with foodstuffs (84/500/EHS)

- This directive applies to ceramic toys and any parts thereof to imitate kitchen cookware.

6. The RoHS directive (2002/95/ES)

- This directive applies to electric and electronic toys, where the basic play function is subject to presence of electric components.

Analysis of Selected Regulations for Hazardous Substances

- **2005/84/ES Directive on Phtalates in Toys**
- **91/338/EHS Directive of Cadmium Limitations**
- **2002/95/ES RoHS Directive**
- **Decree No. 84/2001 Coll.**

2005/84/ES Directive on Phthalates in Toys

- This directive was issued on 14th February 2005 and provided for the end of the long period, during which the Commission was concerned with analysis of the hazards imposed by six selected phthalates, with repeated extension of three-months period of validity pertaining to the Commission Resolution No. 1999/815/ES on restriction of six phthalates in toys intended for insertion in mouths by children of up to 3 years of age.
- The 2005/84/ES Directive, which became valid on 16th January 2006 obliges member states for its implementation till 16th July 2007 and utilisation as of 16th January 2007.

2005/84/ES Directive on Phthalates in Toys

- This Directive allowed for the first division of six phthalates into two groups with different hazard levels and implemented two different methods of restrictions with respect to toys made of softened plastics.
- The first group includes di-(2-ethylhexyl)-phthalate (DEHP, No. CAS 117-81-7, EINECS 204-211-0), further the dibutylphthalate (DBP, No. CAS 84-74-2, EINECS 201-557-4) and benzylbutylphthalate (BBP, No. CAS 85-68-7, EINECS 201-622-7).
- These phthalates may not be present in concentrations higher than 0,1 % of the mass, in toys and childcare items made of softened plastic without any limitation of use or the child age group.

2005/84/ES Directive on Phtalates in Toys

- The second group includes diisononylphtalate (DINP, No. CAS 28553-12-0 and 68515-48-0, No. EINECS 249-079-5 and 271-090-9) further the diisodecylphtalate (DIDP, No. CAS 26761-40-0 and 68515-49-1, No. EINECS 247-977-1 and 271-091-4) and the di-(n-octyle)-phtalate (DNOP, No. CAS 117-84-0, No. EINECS 204-214-7). Phtalates from this group may not be present in concentrations higher than 0,1 % of the mass, in toys and childcare products, which can be inserted into child's mouth.

2005/84/ES Directive on Phthalates in Toys

- With respect to the fact, that presence of phthalates in toys is not amended by any harmonized standard, the manufacturer of all the toys made of softened plastic, which are amended by the “phthalate” directive 2005/84/ES or the resolution 1999/815/ES, shall ask the Notified Body to perform an EC type re-test (in accordance with §3, section 2, NV19, respectively the article 8, section 2, letter a) TSD) and the issuance of Certificate of EC Type Re-test. The procedure stipulated in §3, art. 1, NV 19 may not

91/338/EHS Directive of Cadmium Limitations

- 91/338/EHS Directive (the tenth amendment to the 76/769/EHS Directive) imposes a limit on the use of cadmium in plastic products to the value of 100 mg/kg. Since recent times, the cadmium issue was solved by means of compliance with the harmonized standard EN 71-3 limiting the biological availability of cadmium to the daily dose of 0,6 ug. Despite cadmium in toys is assessed by means of migration in accordance with EN 71-3, this regulation must be also fulfilled, concerning the overall content of Cd in toy mass.

91/338/EHS Directive of Cadmium Limitations

- The 91/338/EHS Directive shall be applied in case of plastic toys and toys comprising parts made of plastic. Whereas it is not important, whether the affected plastic parts are situated on accessible surfaces of particular toys or not.
- Owing to the fact that the said safety aspect is not amended by a harmonized standard, yet it is controlled by other regulations, the above mentioned document and conclusions obtained from the chapter 2.4 herein impose the obligation of the manufacturer to ask the Notified Body for EC Type Re-test and the issuance of Certificate on EC Type Re-test. The procedure stipulated under §3, art. 1, NV 19 may not be applied as the existing harmonized standard does not address the overall content of cadmium in toys.

2002/95/ES RoHS Directive

- The scope of applicability of RoHS is defined by reference to the Appendix IA of the Directive No. 2002/96/ES (WEEE The Waste from Electric and Electronic Appliances Directive), which stipulates relevant categories of electric and electronic appliances by means of an exhaustive list, where toys are included under item 7 (Toys, leisure and free time equipment).
- The amended RoHS Directive was approximated into the Czech legislation by means of an implementing order to the Waste Management Act (Order No. 352/2005 Coll.).
- The use of hazardous listed in the RoHS Directive in electric and electronic appliances is not actually acceptable, however, owing to technical feasibility of production as well as options for material analysis there were general permissible limits stipulated (Table)

2002/95/ES RoHS Directive

General permissible limits to the content of substances restricted by the 2002/95/ES RoHS Directive.

i	Substance restricted by RoHS	General limit [mg/kg]
1	Cd (Cadmium)	100
2	Pb (Lead)	1000
3	Cr ⁶⁺ (Hexavalent chromium)	1000
4	Hg (Mercury)	1000
5	PBB (Polybrominated Biphenyls)	1000
6	PBDE (Polybrominated Diphenyleters)	1000

2002/95/ES RoHS Directive

- The 2002/95/ES Directive shall be applied in case of electric and electronic toys made of any materials, where this electric feature is essential for toy functioning (e.g. the RoHS does not amend removable clothing of dolls or exchangeable toy car wheels). All the EU member states set the validation date for RoHS to 1st July 2006.
- With respect to the fact that neither the determination of limits nor the testing procedures were not issued with any harmonized standard, the document 1) imposes the manufacturer's obligation to ask the Notified Body for performance of EC Type Re-test and issuance of the Certificate on EC Type Re-test. The procedure defined under §3, art. 1

Decree No. 84/2001 Coll.

- In 2001, the Decree No. 84/2001 Coll, as subsequently amended, stipulated hygienic and chemical requirements for items for children of up to 3 years of age, including toys.
- As the time this regulation was created, the Czech Republic was not a member of the EU and no regulation of such nature would be subject to notification to EU member states.
- The Decree was temporarily accepted during screening negotiations related to harmonization of technical legislation. In 2005, this Decree was further amended by means of the Decree No. 521/2005 Coll., which was subject to the notification procedure already.
- Nevertheless, it is still a fact that this Decree does not establish the obligation to submit affected products to compulsory performance by a third party. All the duties and obligations are imposed on the manufacturer.
- If the Notified Body follows the EC type re-test method to assess toys for children of up to 3 years of age amended by any of the articles within the Decree 84, this safety aspect of particular toy shall be also assessed.

Safety aspects of toys not covered by harmonized standards

No.	Safety aspects	Document	Document contents
1	Chemical properties of toys made of textile with non-metallic surface treatment	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No. 521/2005 Coll., App. 7, App.10, App. 12; + §13 art.1; Decree No.38/2001 Coll. App.11	Formaldehyde content
2	Chemical properties of toys with possible mouth contact	Decree by the Ministry of Health No. 84/2001 Sb. Coll. as amended by No 521/2005 Coll., §2, art. 6	Resistance to saliva
3	Chemical properties of toys made of plastics, elastomers and with surface treatment	Decree by the Ministry of Health No. 84/2001 Sb. Coll. as amended by No 521/2005 Coll., §2, art. 6	Resistance to sweat
4	Chemical properties of toy materials	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., §13, art. 6	Optical brighteners content
5	Chemical properties of toys with non-metallic treatment	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., §13, art.1; Decree No. 38/2001 Coll. App.11	Phenolic mixtures content
6	Chemical properties of toys with non-metallic treatment	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., §13 art.1; Decree No.38/2001 Coll. App.11	Content of mixtures with NH ₂ group

Safety aspects of toys not covered by harmonized standards

No.	Safety aspects	Document	Document contents
7	Chemical properties of toys with non-metallic treatment	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., §13 art.1; Decree No. 38/2001 Coll. App.11	Aromatic mixtures content
8	Chemical properties of toys made of plastics and elastomers	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., App. 8, App. 9, art. 2	Overall migration at 37°C
9	Chemical properties of toys made of softened plastics	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., §6, art. 3	Organic tin stabiliser content
10	Chemical properties of toys made of polymers and vinyl chloride co-polymers	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., App. 8, art. 2	Vinyl chloride monomer content
11	Chemical properties of toys made of elastomers	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., App. 9, art. 1	Reduction agents content
12	Chemical properties of toys made of elastomers	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., App. 9, art. 1	Content of primary aromatic amines
13	Chemical properties of toys made of elastomers	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., App. 9, art. 1	Ammonium content

Safety aspects of toys not covered by harmonized standards

No.	Safety aspects	Document	Document contents
14	Chemical properties of toys made of elastomers intended for insertion in mouths	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., §7, art. 2; Decree No. 38/2001 Coll. App. 7/item 9	Leach opalescence
15	Chemical properties of toys made of elastomers intended for insertion in mouths	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., §7, art. 2; Decree No.38/2001 Coll. App. 7 /item 9	Content of sulphides and sodium sulphides
16	Chemical properties of toys made of elastomers intended for insertion in mouths	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., §7, art. 2; Decree No. 38/2001 Coll. App. 7/item 9	Thiosulphate content
17	Chemical properties of toys made of elastomers intended for insertion in mouths	Decree by the Ministry of Health No. 84/2001 Coll. as amended by No 521/2005 Coll., §7, art. 2; Decree No. 38/2001 Coll. App. 7/item 9	Content of secondary aliphatic amines

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