

Total Lead and Soluble Lead Requirements in Toys and Consumer Products Compliance with EU and US Regulations and Standards

In 2007, lead in toys has received widespread international attention. These recalls and settlements have been related to excessive levels of either total lead (lead content) or soluble lead (lead migration) or a combination of these two forms of lead standards.

Lead is a highly toxic metal found in small quantities in the earth's crust. Lead and its compounds have been used in a variety of products including ceramics, paints on their own or on consumer products, solders and cosmetics. In children, exposure to low levels of lead can affect mental development and behaviour including hyperactivity; deficits in fine motor function, hand-eye coordination and reaction time.

Lead requirements in toys in the European Union (EU) and the United States (US) are governed by a series of regulations and/or standards. The requirements are total lead (lead content) and soluble lead (lead migration/leachable lead). Total lead is determined by dissolving the material using a mixture of hot concentrated acids. Soluble lead is determined using a weak acid under defined conditions (often at a temperature similar to that of the human body) and is evaluated on the quantity of lead migrated from the material.

In the EU, the legal requirement for lead in toys is defined in the Toy Directive 88/378/EEC. Under EN 71-3 'Safety of Toys Part 3: Migration of Certain Elements', the summed daily intake for the various toy materials (8 mg/kg) and the bioavailability of lead (0.7 mg) have translated the requirements for soluble lead to a maximum concentration of 90 mg/kg. The soluble lead requirement is also applicable to packaging materials which are 'part of the toy' or 'have intended play value'. Soluble lead requirement for finger paints is defined under EN71-7 'Safety of Toys Part 7: Finger Paints—Requirements and Test Methods' and the limit is no more than 25 mg/kg.

Total lead in non-electrical consumer products is not harmonised in the EU but is regulated by certain Member States (eg Danish Statutory Order Number 1012 'Prohibition of Import and Marketing of Products Containing Lead where the limit is no more than 100 mg/kg). Total lead in electrical toys and consumer products, however, is governed by Directive 2002/95/EC and its amendments 'Restriction of the use of Certain Hazardous Substances in Electrical and Electronic Equipment', commonly known as 'Rohs', where the requirement is no more than 0.1 % (1000 mg/kg).

In the US, total lead in paints/surface coatings in toys, amongst other



consumer products, is regulated by 16 CFR 1303 'Ban of Lead-Containing

Paint and Certain Consumer Products Bearing Lead-Containing Paint' and is no more than 0.06 % (600 ppm). At the State level, total lead is regulated under California's Proposition 65 (lead-containing consumer products have been consistently targeted in recent years¹) and a number of States such as Illinois² (children's products) and Minnesota³ (children's jewellery). The Governor of the State of Michigan signed into law a set of four tie-barred Bills in relation to lead content in consumer products in December 2007. Bills SB 174 'Toxic Substances on Children's Products' (Khan et al., 2007), HB 4132 'Lead-Bearing Substances' (Gaffney et al., 2007) and HB 4399 'Lunch Boxes' (Wojno et al., 2007) specified the total lead requirements and the scope of products. The fourth Bill, HB 4936 'Childhood Lead Poisoning Prevention and Control Commission' (Coulouris et al., 2007), will reinstate the childhood lead poisoning prevention and control commission.

¹ Safeguards 099/07 'California Proposition 65'

² Safeguards 040/07 'Lead in Consumer Products including Jewellery Illinois Lead Poisoning Act'

³ Safeguards 060/07 'The State of Minnesota Restricts Lead Content in Jewellery'

There are a number of US standards available for lead in consumer products. Lead in toys can meet the requirements in ASTM F 963-07 for demonstrating compliance. Under ASTM F 963-07, surface coatings are required to meet total lead (600 ppm) and soluble lead (90 ppm) requirements. Toy jewellery with metal components can comply with the total and soluble lead requirements in accordance with the Standard Operating Procedure from the Consumer Product Safety Commission (CPSC)³.

The requirements for total lead and soluble lead in toys and children’s products in the EU and the US are summarised below (Table 1)

Table 1. Total lead and soluble lead requirements in toys and consumer products in the EU and the US

Substance	Location	Regulation / Standard	Restriction	Product
Soluble Lead	EU	Directive 88/378/EEC EN 71 Part 3	90 mg/kg	Toys (accessible material)
		Directive 88/378/EEC EN 71 part 7	25 mg/kg	Finger Paints
	US Standard	ASTM F963-07 ⁵	90 ppm	Toy (Paint / surface coating)
		CPSC SOP (second-step procedure) ⁴	175 mg	Children jewellery with metal
Total Lead	Denmark	Statutory Order No.1012 ⁶	100 mg/kg (General)	Toys and other Consumer Products
	US	16 CFR 1303 ⁷	600 ppm	Paint / Surface Coating
	US Standard	ASTM E 1645 ⁸	NA	Paint / Surface Coating
		CPSC SOP (1st step) ⁴	600 ppm	Children’s jewellery with metal components
	Illinois	Lead Prevention Poisoning Act ⁹	600 ppm	Toys and children’s products
	Minnesota	Items Containing Lead Prohibited ¹⁰	Various (Material Dependent)	Jewellery (adult and children)
	Baltimore	Regulatory Action on Lead in Children’s Jewellery	600 ppm	Children’s jewellery with metal components
	California	Lead Containing Jewellery ¹¹	Various (Material Dependent)	Jewellery (adult and children)
		Proposition 65	Unless otherwise specified (eg court case), warning label is required	Consumer Products
	Michigan ⁹	SB 174 Toxic Substances in Children’s Products	600 ppm	Children’ Toys and Childcare Articles Exemption Glass or crystal decorative components
		HB 4399 Lunchbox (Public Act 160)	600 ppm	Lunchboxes
		HB 4132 Lead-bearing substances (Public Act 161)	600 ppm	Toys, jewellery, accessories, clothing and other consumer products Exemption Glass or crystal decorative components

⁴ CPSC Standard Operating Procedure for determining Lead (Pb) and its Availability in Children’s Metal Jewellery (3 Feb 2005)

⁵ Standard Consumer Safety Specification for Toy Safety

⁶ Prohibition of Import and Marketing of Products Containing Lead, Nov 2000

⁷ Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint

⁸ Preparation of Dried Paint Samples by Hotplate or Microwave Digestion for Subsequent Lead Analysis

⁹ House Bill (HB) 4853, 2006

¹⁰ Chapter 325E. Section 1 [325.385]

¹¹ Chapter 415, Article 10.1.1 [Assembly Bill (AB) 1681, Pavley, 2006]

In the US, lead in toys and children's products has been a major concern in the US. Since 2007, a number of Bills on the restriction of lead in children's products have been introduced in the US Congress. Bill 'HR 4040' 'Consumer Product Safety Modernisation Act (Rush 2007)' was passed in the House in December 2007. If eventually approved, it would set new lead standards for toys and children's products at the Federal level. Major highlights on lead and other requirements in this proposal (Engrossed as agreed to or Passed by the House) are summarised below:

Table 2. HR 4040. Proposed lead requirements for children's products

Bill	Scope	Restriction
HR4040 Consumer Product Safety Modernisation Act	Children's Products (for up to 12 years old)	600 ppm 180 Days after enactment
		300 ppm 2 years after enactment
	100 ppm 4 Years after enactment unless Commission determines that such standard is not feasible	
	Paint	0.009 % (90 ppm) [from the present 0.06 % (600 ppm) under 16 CFR 1303.1] Not later than 180 days after enactment
	Paint and surface coating on children's products and furniture	0.009 mg/cm ² [to modify 16 CFR 1303.1] Not later than 180 days after enactment



Key

mg/kg = Milligram per kilogram

ppm = Parts per million

µg = Microgram

NA = Not Applicable

Throughout our global network of laboratories, SGS is able to provide a range of services, including analytical testing and consultancy for total and soluble lead in toys and other consumer products for worldwide markets. SGS is also committed to keeping you informed as developments occur. Please do not hesitate to contact us for further information.

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