

SAFEGUARDS

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SOFTLINES

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FULL COMPLIANCE TO PHTHALATES BAN IN TEXTILES

Phthalates are mainly used as plasticizers in PVC intended to make the material soft. Addition of these plasticisers imparts a variety of properties to materials, leading to the use of these substances in a wide range of products. In the EU and the US, six phthalates are regulated in childcare articles and toys.

TEXTILE INDUSTRY APPLICATIONS

Phthalates are a class of compounds used most commonly as a softener for plastic and have diverse uses in modern commerce. One of their primary uses is as a plasticiser in flexible polyvinyl chloride (PVC) products. Phthalates are very often found in plastisol prints on garments, PVC based materials used for coating, out-soles in shoes and many PVC-based apparel and shoe accessories. Phthalates are also used as fixatives, detergents, lubricating oils and solvents. As a result of these diverse uses, phthalates may be found in many consumer products, including textiles and footwear, creating the potential for human exposure.

HAZARDS

Classed as endocrine disruptors and exhibiting bioaccumulative properties, phthalates are purported to alter the estrogen level in human hormonal systems, resulting in serious health problems such as cancers and reproductive and developmental impairments. Currently, in the EU, 6 phthalates (DEHP, DBP, BBP, DINP, DIDP and DNOP) are regulated. In the US, while the scope of the substances subject to regulation at the federal level mirrors that of the EU, a "seventh phthalate" (DnHP) is regulated regionally in the State of California under Proposition 65. Under EU Directive 67/548/EEC, DEHP, DBP and BBP have been identified as toxic to reproduction category 2. With the change in the hazard classification and labelling

system under the CLP (Regulation on the classification, labelling and packaging of substances and mixtures), this hazard classification will transition to reproductive toxin category 1B in line with the terminology of the Globally Harmonised System for classification and labelling.

While scientific information regarding DINP, DIDP and DNOP is either lacking or conflicting, these substances are regulated in a precautionary approach to avoid any risk if used in children's toys and childcare articles.



OVERVIEW OF THE REGULATIONS

- EU market

First regulated under an amendment to the Market and Use Directive (76/768/EEC) and transitioned to the Annex XVII restrictions under REACH (Regulation (EC) 1907/2006), six phthalates are restricted in toys and childcare articles in the European Union in any plasticized material. Phthalates are regulated under the REACH regulation as shown in table below:



Reference for Restriction	Scope	Recommended Max. Limit
Entries 51 and 52 in Annex XVII to REACH (Regulation (EC) 1907/2006) as amended by Regulation (EC) 552/2009 (previously restricted under the Market and Use Directive)	Toys and childcare articles	In plasticised material of toys and childcare articles DEHP+DBP+BBP = 0.1% (sum) In plasticised material of toys and childcare articles that can be placed in a child's mouth DINP+DIDP+DNOP = 0.1% (sum)

Remarks: "Childcare article" means any product intended to facilitate sleep, relaxation, hygiene, the feeding of children including such articles that can be placed in a child's mouth.

DEHP, DBP and BBP are also substances listed on the REACH candidate list. Any product, including textiles, toys and electrical and electronic equipment containing substances on the candidate list require:

1. Communication down the supply chain of the name of the substance and safe use instructions if the substance is present >0.1% (w/w) per article (Article 33)
2. From 1 June 2011, notification to the European Chemicals Authority if the substance is present >0.1% (w/w) per article and over 1 tonne is imported in any one year unless the substance has already been registered by another entity in the EU for the same use (Article 7)

- US market

1. Consumer Product Safety Improvement Act of 2008 (CPSIA)

According to the Consumer Product Safety Improvement Act (CPSIA) of 2008, mandatory permanent and interim bans on phthalates apply to toys for children and childcare articles. The phthalate requirements for CPSIA are shown in the table on following page.



Reference for Restriction	Scope	Recommended Max. Limit
Public Law 110-314 (Consumer Product Safety Improvement Act of 2008)	Toys and Childcare Articles	<p>Permanent Ban Toys for children 12 and under and childcare articles for children 3 and under DEHP, DBP or BBP $\leq 0.1\%$ (each component part)</p> <p>Interim ban Toys for children 12 and under that can be placed in a child’s mouth and childcare articles for children 3 and under DINP, DIDP or DNOP $\leq 0.1\%$ (each component part)</p>

Remarks: “Placed in the mouth” is defined if a toy or a part of a toy in one dimension is smaller than 5 cm. If the children’s product can only be licked, it is not regarded as able to be placed in the mouth.

2. California Assembly Bill 1108 (AB 1108) and Proposition 65

The State of California has informed the CPSC that the California Assembly Bill (AB 1108) regulation on phthalates in toys and childcare products is NOT pre-empted by the CPSIA. The reason for this is two-fold. One, AB 1108 defines “toys” and “childcare articles” with a wider scope than the CPSIA, thus enveloping more products under the restriction. Two, AB 1108 places enforcement of the phthalate ban under provisions requiring fair business practices, providing a very different framework for the enforcement of the regulation than the federal ban. The phthalate requirements under California AB 1108 are shown in the table below:



Reference for Restriction	Scope	Recommended Max. Limit
California AB 1108	Toys and Childcare Articles	<p>Any toy or childcare article DEHP+DBP+BBP $\leq 0.1\%$ (sum) (in individual parts or material)</p> <p>Any toy or childcare article intended for use by a child under 3 years of age if that product can be placed in the child's mouth. DINP+DIDP+DNOP $\leq 0.1\%$ (sum) (in individual parts or material)</p>

Although the above phthalate regulations only apply to children’s products, childcare articles, or toys, there is a market trend for buyers to test for phthalates in plastic materials and printing on adult products since phthalates are considered to be a high risk substance for human health and often targeted for litigation based Proposition 65.

The second form of regulatory control on phthalates in the State of California is maintained under Proposition 65 which requires the disclosure of listed substances in products or in environments that may expose the general public to listed substances. Currently, the Proposition 65 list includes the six phthalates regulated under AB 1108 (DEHP, DBP, BBP, DINP, DIDP and DNOP) in addition to a seventh phthalate, DnHP.



DEFINITION OF “TOYS” AND “CHILDCARE ARTICLES”

There are different definitions of toys and childcare articles in the EU and the US as given below:

	EU	US
Definition of toys	A toy is any product or material designed or clearly intended for use in play by children of less than <u>14 years</u> of age.	The CPSC defines a toy as a consumer product designed or intended by the manufacturer for a child <u>12 years</u> of age or younger for use by the child when the child plays. AB 1108 defines toy as all products designed or intended by the manufacturer to be used by children <u>of any age</u> when they play.
Definition of childcare articles	Any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children. For reference. Examples <ul style="list-style-type: none"> • Cribs • Soothers and soother holders • Carrycots and stands • Sleeping bags <p>Note: The Commission states that the main purpose of pyjamas is to dress children when sleeping and not to facilitate sleep. Pyjamas should therefore be regarded as textiles and, therefore, like other textiles, do not fall under the scope of the restriction cited by REACH.</p>	The CPSIA defines a childcare article as a consumer product designed or intended by the manufacturer to facilitate sleep or the feeding of children age 3 and younger or to help such children with sucking or teething. For reference. AB 1108 defines child care article as all products designed or intended by the manufacturer to facilitate sleep, relaxation, the feeding of children or to help children with sucking or teething. Examples <ul style="list-style-type: none"> • Pacifiers/ teethers • Bibs • Crib mattresses and crib sheets • Pajamas with plastic on the feet

UPCOMING REGULATIONS

A proposed regulation on phthalates in children's toys and childcare articles is currently under consideration in Canada. The regulation, if adopted, will place a ban on DEHP, DBP and BBP in the vinyl of all toys and childcare articles with a limit of 0.1 percent. Under the Canadian proposal, DINP, DIDP and DnOP would also be restricted in the vinyl of toys and childcare articles that in a reasonably foreseeable manner can be placed in the mouth of a child under the age of four. This would include any children's toy with one dimension of 5 cm or less.

The Canadian proposal would also add a new definition for "toy," expanding the term to include products intended for use by children not only in the context of play but also during learning. The definition of the childcare article under the Canadian proposal would be fairly consistent with the EU definition covering products intended to facilitate the relaxation, sleep, hygiene, feeding, sucking or teething of children under the age of four.



INFORMATION ON ALTERNATIVES

- Alternative substances.

There are various commercial proprietary compounds available for phthalates substitution:

- Citrates
- DINCH (Di-(isononyl)-cyclohexan-1,2-dicarboxylate)
- Adipates
- Phosphates

- Alternative techniques

An alternative technique to produce a flexible product might include co-polymerisation with a "softener" (special monomers, like vinyl acetate and maleic acid). For example, vinyl chloride (the monomer of PVC) can be co-polymerised with a certain amount of vinyl acetate to produce a permanently soft plastic.

Throughout our global network of laboratories, we are able to provide a range of services, including analytical testing and consultancy for lead, phthalates and other heavy metals in a comprehensive range of children's products and other consumer products.

Please do not hesitate to contact us for further information.

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