



TÜV Rheinland LGA Products – Information

New Phthalates Restriction – Amendment of Regulation (EC)
No 1907/2006 (REACH) Annex XVII entry 51

1. SUMMARY

REACH Annex XVII already bans the placing on the market of toys and childcare articles containing DEHP, DBP and BBP. As DIBP has a similar hazard profile to the other 3 phthalates and can be used as a substitute for DBP in

production, DIBP should also be included in the restriction. For toys, this amendment to the phthalates restriction widens the scope of products and this results in stricter legal requirements for DIBP and the sum of the 4 phthalates.

2. COMMISSION REGULATION (EU) NO 2018/2005 OF 17 DECEMBER 2018

Modifications to the entry 51 of Annex XVII to Regulation (EC) No 1907/2006:

A) PROHIBITION OF USE (AS SUBSTANCES OR IN MIXTURES)

	ORIGINAL RESTRICTION	AMENDED RESTRICTION
Scope	Toys and childcare articles	Toys and childcare articles
Parameters	DEHP, DBP, BBP	DEHP, DBP, BBP, DIBP
Limits	Sum of the 3 phthalates ≤ 0.1 % by weight of the material	Sum of the 4 phthalates ≤ 0.1 % by weight of the material

The new requirements are effective from 7 January 2019 (date directive entered into force).

B) PROHIBITION OF PLACING ON THE MARKET IN ARTICLES

	ORIGINAL RESTRICTION	AMENDED RESTRICTION
Scope	Toys and childcare articles	Articles in general*
Parameters	DEHP, DBP, BBP	DEHP, DBP, BBP, DIBP
Limits	Sum of the 3 phthalates ≤ 0.1 % by weight of the material	Sum of the 4 phthalates < 0.1 % by weight of the material

* including toys, childcare articles and various other consumer goods

* exclusions for some products covered by other regulations, e.g. food contact materials, electrical and electronic equipment, aircraft and motor vehicles, measuring devices for laboratory use, Medical devices, Immediate packaging of medicinal products as well as articles exclusively for industrial or agricultural use or use in the open air provided that no plasticised material comes into contact with human mucous membranes or prolonged contact with human skin (i.e. continuous contact of more than 10 minutes duration or intermittent contact throughout 30 minutes, per day) as well as articles placed on the market before 7 July 2020

The new requirements becomes effective after 7 July 2020.

3. BACKGROUND AND RATIONALES

3.1. PHTHALATES AS HARMFUL SUBSTANCES

Some phthalates are endocrine disrupting and are suspected of being toxic to reproduction or development. Among those are DEHP, DBP, BBP and DIBP. They are included as harmful CMR-substances reprotoxic category 1B in Annex VI Part 3 table 3.1 of Regulation (EC) No 1272/2008 (CLP) on classification, labelling and packaging of substances and mixtures and have been identified as substances of very high concern (SVHC) in 2008 respectively 2011.

3.2. MEASURES FOR CONSUMER PROTECTION

The European Chemicals Agency (ECHA) consider the use of 'the four phthalates' DEHP, DBP, BBP and DIBP in articles poses a risk to human health or the environment that is not adequately controlled. By considering DIBP has a similar hazard profile to the other 3 phthalates and DIBP can replace DBP, DIBP should also be restricted.

Following the opinion of ECHA's scientific committees RAC and SEAC, the Commission concluded that the four phthalates pose an unacceptable risk to human health when present in any plasticised material in articles at a

concentration, individually or in any combination, equal to or greater than 0.1 % by weight of any of such material. Further, a wider scope of products should be covered.

4. CURRENTLY EXISTING REGULATIONS

4.1. SUBJECT TO AUTHORIZATION WITHIN REACH ANNEX XIV

In 2011, DEHP, DBP, BBP and DIBP were included in Annex XIV to REACH regulation as substances toxic for reproduction, category 1B, with a sunset date of 21 February 2015. Following this, those substances may only be used after prior approval (specific for the intended purpose and linked with preconditions).

4.2. PROHIBITION OF CMR-SUBSTANCES SUBSTANCES OR IN MIXTURES

According to REACH Annex XVII entries 28, 29 and 30, substances or mixtures classified as carcinogenic category 1A or 1B, mutagenic category 1A or 1B and reprotoxic category 1A or 1B may not be placed on the market for the general public. Thus, mixtures containing 0.3 % (w/w) or more of each DEHP, DBP, BBP or DIBP are prohibited.

4.3. BAN OF CMR-SUBSTANCES INACCESSIBLE TOY MATERIALS

The toy safety directive 2009/48/EC prohibits the use of CMR-substances of the category 1A, 1B or 2. Under point 4(a) of Part III of Annex II, accessible toy materials may not contain reprotoxic phthalates like DIBP in concentrations of 0.3 % (w/w) or more.

4.4. PRODUCT-SPECIFIC PROHIBITIONS FOR TOYS AND CHILDCARE ARTICLES

Some phthalates are banned for toys and childcare articles since 2005 (Directive 2005/84/EC). In 2009, those prohibitions were transformed into REACH Annex XVII entries 51 & 52.

Entry 51 sets up a general ban for DEHP, DBP and BBP. Toys and childcare articles containing DEHP, BBP or DBP in a concentration greater than 0.1 % by weight of the plasticised material, calculated for the three phthalates cumulatively, cannot be placed on the EU market.

Entry 52 defines a ban for DINP, DIDP and DNOP in toys and childcare articles, which can be placed in the mouth by children. The sum of them may not exceed 0.1 % by weight of the plasticized material.

4.5. UPCOMING PROHIBITION FOR ELECTRICAL APPLIANCES WITHIN ROHS

Annex II to Directive 2011/65/EU (RoHS II) on the restriction of the use of certain hazardous substances in electrical and electronic equipment lists various substances that are

forbidden in electrical appliances. Directive 2015/863/EU amending RoHS II extends the existing list with prohibitions for DEHP, BBP, DBP and DIBP in individual concentrations greater than 0.1% of the homogenous material.

This restriction is generally applicable from 22 July 2019 (for medical devices, including in vitro medical devices, and monitoring and control instruments from 22 July 2021). The restriction of DEHP, BBP and DBP shall not apply to toys, which are already subject to the restriction by entry 51 of Annex XVII to Regulation (EC) No 1907/2006. Nevertheless, toys have to fulfil the additional requirement for DIBP (applicable also for inaccessible materials).

4.6 UPCOMING PROHIBITION IN CLOTHING, RELATED ACCESSORIES, TEXTILES OR FOOTWEAR

Commission Regulation (EU) 2018/1513 will be regulating the following Phthalates, amongst other substances, from November 2020 onwards.

The Regulation is amending Annex XVII to Regulation No 1907/2006 (REACH) with certain CMR substances applicable to clothing, related accessories, textiles in contact with human skin and footwear. The objective of this Regulation is to protect consumers from long-term exposure to substances being classified as carcinogenic, mutagenic or toxic to reproduction (CMR), category 1A or 1B.

1,2-Benzenedi-carboxylic acid; di-C 6-8-branched alkylesters, C 7-rich	71888-89-6	1000 mg/kg (individually or in combination with other phthalates)
Bis(2-methoxyethyl) phthalate (DEHP)	117-82-8	
Diisopentylphthalate (DIPP)	605-50-5	
Di-n-pentyl phthalate (DPP)	131-18-0	
Di-n-hexyl phthalate (DnHP)	84-75-3	

The following exceptions apply:

- Clothing, related accessories, textiles or footwear within the scope of EU Regulation No 2016/425 on Personal Protective Equipment (PPE)
- Clothing, related accessories, textiles or footwear within the scope EU Regulation No 2017/745 on medical devices
- Clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide
- Non-textile fasteners and non-textile decorative attachments
- Second-hand clothing, related accessories, textiles other than clothing or footwear

CONTACT PERSON

The experts at TÜV Rheinland have experience in the testing of consumer products, toys, electrical products, textiles and footwear. We are your contact persons in test questions. Please do not hesitate to contact us if you have any questions.

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