

TÜV Rheinland LGA Products – Information

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US-Market: New Requirements for Phthalates in Toys

CPSC expands national regulation

On the 18th of October 2017, the U.S. Consumer Product Safety Commission (CPSC) accepted a final rule to change the restriction of phthalates in toys and childcare articles. This regulation was published in the Federal Register under the designation “**Consumer Product Safety Improvement Act (CPSIA), Prohibition of Children’s Toys and Child Care Articles Containing Specified Phthalates, Final Rule, 16 CFR 1307, October 2017**” on the 27th of October 2017 and will be effective on the 25th of April 2018, 180 days after its publishing. It will be applicable for all toys (intended for children up to 12 years and childcare articles (intended for children up to 3 years) that have been manufactured or imported after this date.

According to the upcoming law 16 CFR 1307, the 8 phthalates **DEHP, BBP, DBP, DINP, DIBP, DPENP, DHEXP (DnHP) and DCHP** are permanently forbidden in all **accessible materials of toys and childcare articles** (independently if the material can be placed in a child’s mouth), the requirement is **≤ 0.1 % per phthalate**.

The current regulation of the Consumer Product Safety Improvement Act of 2008 (CPSIA) Section 108(a) and (b) includes with DEHP, BBP and DBP 3 permanent and with DINP, DNOP and DIDP 3 interim prohibitions of phthalates. This rule should be adapted following long-term-studies on the health effects of exposure to phthalates. A draft of this law has been planned and discussed over several years; CPSC accepted comments until the 16th of March 2015.

This new regulation is based on the recommendation of the scientific panel „Chronic Hazard Advisory Panel (CHAP)“, to ban the 5 phthalates DINP, DIBP, DPENP, DHEXP (DnHP) and DCHP. Those were shown to have negative effects on development and reproduction of mammals. Originally, also the phthalate DIOP had been discussed but this substance was shown to be less harmful.

The congress also prolonged the permanent prohibition of the 3 phthalates DEHP, BBP and DBP according to CPSIA Section 108(a).

The phthalates DNOP and DIDP, which have been permanently prohibited, were removed because the CPSC decided that those phthalates do not affect the reproducibility of mammals and other risks concerning their use are low.

In comparison with the current regulation of CPSIA Section 108(a) and (b) the following changes arise:

Phthalate	CAS-No.	Kind of Change
Di(2-ethyhexyl) phthalate DEHP	117-81-7	-
Dibutyl phthalate (DBP)	84-74-2	-
Benzyl butyl phthalate (BBP)	85-68-7	-
Diisononyl phthalate (DINP)	28553-12-0, 68515-48-0	up to now only toys that can be placed into the child's mouth
Di-n-octyl phthalate (DnOP)	117-84-0	deleted
Diisodecyl phthalate (DIDP)	26761-40-0, 68515-49-1	deleted
Di-n-pentyl phthalate (DPENP)	131-18-0	added
Di-n-hexyl phthalate (DHEXP)	84-75-3	added
Dicyclohexyl phthalate (DCHP)	84-61-7	added
Diisobutyl phthalaet (DIBP)	84-69-5	added

Update of the testing method for phthalates

The current test method for phthalates, CPSC-CH-C1001-09.3 (2010), as prescribed by the CPSC will be actualized to the test method **CPSC-CH-C1001-09.4 (2017)**. This will be nearly identical to the current version; the only changes will be the adaptation of the list of forbidden phthalates as well as the actualization of the references to current (ASTM) standards.

On the 27th of October 2017 the CPSC published the draft version as „notice of proposed rulemaking“; comments may be submitted until the 10th of January 2018. Thus, preliminary the current version has to be performed for analysis, whereas in the test report already “16 CFR part 1307” has to be cited.

For phthalates in toys and childcare articles, according to CPSA Section 14(a), there is a mandatory testing in a „Third Party Laboratory“ that has been accredited by the CPSC. The laboratories of TÜV Rheinland have been accredited for CPSC-CH-C1001-09.3 (2010) and we are able to test the whole spectrum of phthalates according to 16 CFR part 1307 since many years. As soon as the final version has been published in the Federal Register; we are going to apply for accreditation of CPSC-CH-C1001-09.4 (2017). Nevertheless, as a laboratory that is already accredited, we will keep our permission for 2 years after announcement of the final version of CPSC-CH-C1001-09.4 (2017).

Materials with an obligation for phthalate testing

Principally the law is valid for any plasticized component as well as other components that consist of materials that may possibly contain phthalates. Minor amounts are not intended.

A guide to select the testing materials is given in the „**Statement of Policy: Testing of Component Parts with Respect to Section 108 of the Consumer Product Safety Improvement Act**”

- Materials, for which a phthalate testing has to be taken into account:
 - ✓ PVC and related polymers: PVDC, PVA
 - ✓ soft or flexible plastics, except polyolefins
 - ✓ elastomers (rubber like materials), except silicone rubber and natural latex
 - ✓ rubber foams or foamed plastics like PU
 - ✓ surface coatings, non-slip coatings, lacquer finishings and imprinted designs
 - ✓ sticker
 - ✓ elastic fibers and textiles as well as elastic imprints on textiles
 - ✓ glues and sealing agents
 - ✓ electrical insulation materials
- Materials, for which a phthalate testing has NOT to be taken into account:
 - crude metals
 - pure natural woods (without coatings and glues)
 - uncoated and unprinted textiles made of natural fibers like cotton and wool as well as synthetic fibers like polyester, acryl and nylon
 - plastics of the olefin group (e.g. polyethylene and polypropylene)
 - silicone rubber and natural latex
 - mineral products like play-sand, glass and crystal

Further on, there are **4 plastic types with special additives** that are officially excluded from third party testing of phthalates acc. to **16 CFR 1308**: The Consumer Product Safety Commission (CPSC) investigated, if special plastics with clearly defined additives may contain phthalates in amounts of more than 0.1% (1000 ppm). On the 16th of August 2017, the CPSC proposed a new rule according to that the following plastics are excluded from mandatory phthalate testing:

- Polypropylene (PP)
- Polyethylene (PE)
- General purpose polystyrene (GPPS), medium-impact polystyrene (MIPS), high-impact polystyrene (HIPS), and super high-impact polystyrene (SHIPS)
- Acrylonitrile butadiene styrene (ABS)

This rule entered into force on the 29th of September 2017 as new chapter 16 CFR 1308.

Our Services

The TÜV Rheinland laboratories are accredited for chemical testing of phthalates with the official method CPSC-CH-C1001-09.3 (2010). This has to be used either for determining the 6 phthalates according to CPSIA Section 108(a) and (b) as well as for the 8 phthalates according to 16 CFR 1307. Alternatively, we can offer a test on phthalates and other softeners with an accredited in-house-method. As the new regulation has been discussed since 2015, our test reports for the USA contain an evaluation of the current 6 phthalates as well as the new added 4 phthalates

Further on, TÜV Rheinland is accredited as third party laboratory for various US-requirements. This implements among others the chemical test of the total lead content acc. to Public Law 110-314 (HR 4040; CPSIA), Section 101 und 16 CFR 1303.1 as well as the migration of certain elements according to ASTM F 963-16.

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