EU Amended Restriction on Phthalates under REACH Annex XVII

On December 17, 2018, the Official Journal of the European Union (OJEU) published Regulation (EU) 2018/2005, amending the REACH Annex XVII Entry 51 on phthalates restrictions. The new amendment increased the number of restricted phthalates from three (DEHP, DBP, BBP) to four by adding diisobutyl phthalate (DIBP), and expanded the scope of products concerned. The additional restrictions on the phthalates under Entry 51 will enter into force from July 7, 2020.

The restricted phthalates should not be present in an article individually or in any combination of the phthalates in a concentration equal to or greater than 0.1% by weight.

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS no.</th>
<th>EC no.</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bis(2-ethylhexyl) phthalate (DEHP)</td>
<td>117-81-7</td>
<td>204-211-0</td>
<td>&lt; 0.1% (individually or in combination)</td>
</tr>
<tr>
<td>Dibutyl phthalate (DBP)</td>
<td>84-74-2</td>
<td>201-557-4</td>
<td>for articles placed on the market after July 7, 2020</td>
</tr>
<tr>
<td>Benzyl butyl phthalate (BBP)</td>
<td>85-68-7</td>
<td>201-622-7</td>
<td></td>
</tr>
<tr>
<td>Diisobutyl phthalate (DIBP)</td>
<td>84-69-5</td>
<td>201-553-2</td>
<td></td>
</tr>
</tbody>
</table>

This law expands the scope from plasticized materials in toys and childcare articles to plasticized materials in articles. It also provides legal definitions for ‘plasticized material’, ‘prolonged contact with human skin’ and ‘childcare article’ as below:

Childcare article means any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.

Plasticized material means the following homogeneous materials:
- Polyvinyl chloride (PVC), polyvinylidene chloride (PVDC), polyvinyl acetate (PVA), polyurethanes;
- Any other polymer (including, inter alia, polymer foams and rubber material) except silicone rubber and natural latex coatings;
- Surface coatings, non-slip coatings, finishes, decals, printed designs;
- Adhesives, sealants, paints and inks

Prolonged contact with human skin is defined as continuous contact of more than 10 minutes or intermittent contact over a period of 30 minutes per day.

For the restricted phthalates (DEHP, DBP, BBP and DIBP) that are used as substances or in mixtures in toys and childcare articles, the new law has been in effect since January 7, 2019, with a limit of less than 0.1% individually or in combination.

STC (The Hong Kong Standards and Testing Centre) is a not-for-profit, independent testing, inspection, and certification organization. With a global network of ISO/IEC 17025 accredited testing laboratories and over 50 years of experience in consumer products testing, we can meet your conformity assessment needs with highly efficient and reliable service.

For more information, please contact our Toys and Children’s Products Department.

Hong Kong: hktcd@stc.group  Dongguan: datcd@stc.group  Shanghai: shhtcd@stc.group
Japan: jpc@stc.group  Vietnam: vnstc@stc.group  USA: usstc@stc.group  Germany: info@pkm.eu.com