EU Phthalates Directive 2005/84/EC

Update

Requirements

Under the EU Phthalates Directive 2005/84/EC\(^1\) from 16 January 2007, DEHP, DBP and BBP will be banned for use in PVC and other plasticized materials in all toys and childcare articles. Similarly, DINP, DIDP and DNOP will be banned for those toys and child care articles (referred to hereafter as “articles”), which can be placed in the mouth by children of all ages\(^2\) even if these parts are unlikely to be mouthed. Limits of 0.1 % by mass have been specified for the sum of the three phthalates in each group, to permit unavoidable traces, while effectively banning their intentional use, per the table below.

The Directive defines childcare articles as any products, “intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children” (e.g. dummies/pacifiers, feeding teats, etc).

Pyjamas are not covered by the Directive, as they merely dress the child while sleeping, rather than facilitate sleep (and are treated as textile articles).

Sleeping bags, pushchairs, car seats, bicycle seats, cots, cribs and mattresses are all deemed to facilitate sleep and relaxation and therefore are covered by the Directive.

<table>
<thead>
<tr>
<th>Phthalates</th>
<th>CAS Nos</th>
<th>EINECS Nos</th>
<th>Restrictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>bis (2-ethylhexyl) phthalate (DEHP)</td>
<td>117-81-7</td>
<td>204-211-0</td>
<td>Sum of DEHP+DBP+BBP: 0.1 % by mass of the plasticized material in toys and childcare articles, as the sum of the three phthalates.</td>
</tr>
<tr>
<td>dibutyl phthalate (DBP)</td>
<td>84-74-2</td>
<td>201-557-4</td>
<td>Sum of DINP+DIDP+DNOP: 0.1 % by mass of the plasticized material in toys and childcare articles which can be placed in the mouth by children, as the sum of the three phthalates.</td>
</tr>
<tr>
<td>benzyl butyl phthalate (BBP)</td>
<td>85-68-7</td>
<td>201-622-7</td>
<td>Sum of DINP+DIDP+DNOP: 0.1 % by mass of the plasticized material in toys and childcare articles which can be placed in the mouth by children, as the sum of the three phthalates.</td>
</tr>
<tr>
<td>di-&quot;isononyl&quot; phthalate (DINP)</td>
<td>28553-12-0</td>
<td>249-079-5</td>
<td>Sum of DEHP+DBP+BBP: 0.1 % by mass of the plasticized material in toys and childcare articles, as the sum of the three phthalates.</td>
</tr>
<tr>
<td></td>
<td>68515-48-0</td>
<td>271-090-9</td>
<td>Sum of DEHP+DBP+BBP: 0.1 % by mass of the plasticized material in toys and childcare articles, as the sum of the three phthalates.</td>
</tr>
<tr>
<td>di-&quot;isodecyl&quot; phthalate (DIDP)</td>
<td>26761-40-0</td>
<td>247-977-1</td>
<td>Sum of DINP+DIDP+DNOP: 0.1 % by mass of the plasticized material in toys and childcare articles which can be placed in the mouth by children, as the sum of the three phthalates.</td>
</tr>
<tr>
<td></td>
<td>68515-49-1</td>
<td>271-091-4</td>
<td>Sum of DINP+DIDP+DNOP: 0.1 % by mass of the plasticized material in toys and childcare articles which can be placed in the mouth by children, as the sum of the three phthalates.</td>
</tr>
<tr>
<td>dioctyl phthalate (DNOP)</td>
<td>117-84-0</td>
<td>204-214-7</td>
<td>Sum of DEHP+DBP+BBP: 0.1 % by mass of the plasticized material in toys and childcare articles, as the sum of the three phthalates.</td>
</tr>
</tbody>
</table>

\(^{1}\) OJ L 344, 27.12.2005, p. 40

\(^{2}\) The former rolling EU phthalates ban under the repeatedly amended Decision 1999/815/EC only covered toys and childcare articles intended to be placed in the mouth by children less than three years of age.

Disclaimer

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Guidance – Accessibility

Technically, the total DEHP/DBP/BBP ban applies throughout the construction of the article by default, as the Directive does not limit these requirements to accessible materials. In this way, the Directive’s restrictions go beyond the hazard being addressed, as inaccessible plasticized materials containing DEHP/DBP/BBP (e.g. inaccessible PVC wire covering inside a battery-powered toy) will be banned.

The absence of a mention in the Directive to “accessible” or similar hazard-based focusing of the DEHP/DBP/BBP restrictions is understood to be intentional, as the Council and European Parliament wanted to completely ban the use of these three phthalates in toys and childcare articles.

However, we understand the UK view to be that the DEHP/DBP/BBP restrictions should only apply to accessible materials. However, the Commission does not share this risk-based interpretation.

Guidance – Which Can Be Placed in the Mouth

In support of the Directive, the Commission has issued a non-legally binding guidance document\(^2\) but it only addresses the concept of “which can be placed in the mouth”, relating only to DINP/DIDP/DNOP. These requirements cover plasticized materials that could possibly be placed in the mouth, regardless of the likelihood.

*Articles* “which can be placed in the mouth” include:
- All parts of *articles* both accessible and small enough to be brought to and kept in the child’s mouth.
- Any parts of *articles* that could be sucked and/or chewed, regardless of the likelihood that the child will do so.
- Inflatable *articles* in an “empty” (uninflated) state, for which mouthpieces are deemed to be intended to be placed in the mouth.

The following are not regarded as *articles* “can be placed in the mouth” (but are still subject to the DEHP/DBP/BBP restrictions):
- Any part of an *article* larger than 5 cm in all three dimensions.
  - For example, a part 10 cm x 10 cm x 4 cm is covered, as the 5 cm threshold is only exceeded in two of the three dimensions.
- Inaccessible parts of *articles*.
- Parts of *articles* only accessible to licking (as they are “placed in the mouth”).

Placed on the Market

In the absence of clear guidance, the Directive’s application from when articles are placed on the market has led to significant differences in interpretation.

Some Member States are expected to implement a ban on the retail sale of non-compliant articles from 16 January 2007 (rendering non-compliant stock illegal for sale).

Other Member States have taken their interpretation from the Commission’s Blue Book guide to the New and Global Approach Directives. That is, only applying the Directive to those articles first made available on the EU market after 16 January 2007, by transfer from the stage of manufacturer to an importer, distributor or the final consumer. In this case, articles “transferred” before 16 January 2006 will not be covered and would be allowed to sell-through at retail, although no period is defined.

Where available, details of the Member States’ approaches are listed below. Those countries flagged as “likely” are based on informal information, subject to confirmation.

Member States expected to implement a retail ban from 16 January 2007

- Austria
- Czech Republic (likely)
- Denmark
- Estonia (likely)
- Finland (likely)
- Germany
- Greece
- Hungary (likely)
- Lithuania (likely)
- Netherlands
- Norway
- Poland
- Slovakia (likely)
- Slovenia (likely)

Member States expected to follow the Blue Book definition of “placed on the market”:

- Belgium
- France
- Ireland
- Italy
- Latvia
- Malta
- Portugal
- Spain
- Sweden
- United Kingdom

Member States for which information is not available.

- Cyprus
- Iceland
- Luxembourg
Recommendations

- Identify which *articles* contain any of the six restricted phthalates.
  - Suppliers should confirm the presence/absence of the six restricted phthalates in all toys and childcare articles.
  - Parts of toys or childcare articles containing DINP, DIDP or DNOP must be identified, to permit an assessment to be made as to whether they can be placed in the mouth. Parts that are accessible to mouthing, but are unlikely to be mouthed are still covered.
- What are the stock levels, locations, outstanding orders, delivery dates and markets for any non-compliant *articles*?
- Non-compliant *articles* currently in the supply chain or due to enter it before 16 January 2007 need to be clearly identified and distinguishable from their modified, compliant versions.

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