ANNEX

Entries 4 to 7 in the table in Annex XIV to Regulation (EC) No 1907/2006 are replaced by the following entries:

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| --- | --- | --- | --- | --- | --- |
| **Entry****Nr** | **Substance** | **Intrinsicproperty(ies) referred to in Article 57** | **Transitional arrangements**  | **Exempted (categories of) uses** | **Review periods** |
| **Latest application date(1)** | **Sunset date(2)** |
| ‘4. | Bis(2-ethylhexyl) phthalate(**DEHP**) EC No: 204-211-0CAS No: 117-81-7 | Toxic for reproduction (category 1B)Endocrine disrupting properties (Article 57(f) - human health)Endocrine disrupting properties (Article 57(f) - environment) | 1. 21 August 2013\*
2. By way of derogation from point (a):

…[OJ please insert the date - 18 months after entry into force of this amending Regulation] for uses in:* food contact materials within the scope of Regulation (EC) No 1935/2004;
* immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC;
* mixtures containing DEHP at or above 0,1% and below 0,3% weight by weight;
1. By derogation of point (a):

27 November 2023 for uses in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC and 98/79/EC. | 1. 21 February 2015\*\*
2. By way of derogation from point (a):

… [OJ please insert the date - 36 months after entry into force of this amending Regulation] for uses in:* food contact materials within the scope of Regulation (EC) No 1935/2004;
* immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC;
* mixtures containing DEHP at or above 0,1% and below 0,3% weight by weight;

(c) By derogation of point (a):27 May 2025 for uses in medical devices within the scope of Directives 90/385/EEC, 93/42/EEC and 98/79/EC. | - | - |
| 5. | Benzyl butyl phthalate(**BBP**) EC No: 201-622-7CAS No:85-68-7 | Toxic for reproduction (category 1B)Endocrine disrupting properties (Article 57(f) - human health) | 1. 21 August 2013\*
2. By way of derogation from point (a):

… [OJ please insert the date 18 months after entry into force of this amending Regulation] for uses in:* immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC;
* mixtures containing BBP at or above 0,1% and below 0,3% weight by weight.
 | 1. 21 February 2015\*\*
2. By way of derogation from point (a):

… [OJ please insert the date 36 months after entry into force of this amending Regulation] for uses in:* immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC;
* mixtures containing BBP at or above 0,1% and below 0,3% weight by weight.
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| 6. | Dibutyl phthalate (**DBP**) EC No: 201-557-4CAS No:84-74-2 | Toxic for reproduction (category 1B)Endocrine disrupting properties (Article 57(f) - human health) | 1. 21 August 2013\*
2. By way of derogation from point (a):

… [OJ please insert the date 18 months after entry into force of this amending Regulation] for uses in:* immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC;
* mixtures containing DBP at or above 0,1% and below 0,3% weight by weight.
 | 1. 21 February 2015\*\*
2. By way of derogation from point (a):

… [OJ please insert the date 36 months after entry into force of this amending Regulation] for uses in:* immediate packaging of medicinal products covered under Regulation (EC) No 726/2004, Directive 2001/82/EC, and/or Directive 2001/83/EC;
* mixtures containing DBP at or above 0,1% and below 0,3% weight by weight.
 | - | - |
| 7. | Diisobutyl phthalate **(DIBP)**EC No: 201-553-2CAS No: 84-69-5 | Toxic for reproduction (category 1B)Endocrine disrupting properties (Article 57(f) - human health) | 1. 21 August 2013\*
2. By way of derogation from point (a):

… [OJ please insert the date - 18 months after entry into force of this amending Regulation] for uses in mixtures containing DIBP at or above 0,1% and below 0,3% weight by weight. | 1. 21 February 2015\*\*
2. By way of derogation from point (a):

… [OJ please insert the date - 36 months after entry into force of this amending Regulation] for uses in mixtures containing DIBP at or above 0,1% and below 0,3% weight by weight. | - | -’ |