

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** | **Intrinsic property(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: 204-211-0  CAS 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: 201-622-7  CAS 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. | - | - |
| 6. | Dibutyl phthalate  (**DBP**)  EC No: 201-557-4  CAS 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: 201-553-2  CAS 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. | - | -’ |