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*Status: Point in time view as at 26/02/2015.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)*

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Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance)

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## ANNEX I

### Substances

1. Union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids

Table 1 contains the following information:

Column 1 (FCM substance No): the unique identification number of the substance

Column 2 (Ref. No): the EEC packaging material reference number

Column 3 (CAS No): the Chemical Abstracts Service (CAS) registry number

Column 4 (Substance Name): the chemical name

Column 5 (Use as additive or polymer production aid (PPA) (yes/no)): an indication if the substance is authorised to be used as additive or polymer production aid (yes) or if the substance is not authorised to be used as additive or polymer production aid (no). If the substance is only authorised as PPA it is indicated (yes) and in the specifications the use is restricted to PPA.

Column 6 (Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)): an indication if the substance is authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes) or if the substance is not authorised to be used as monomer or other starting substance or macromolecule obtained from microbial fermentation (no). If the substance is authorised as macromolecule obtained from microbial fermentation it is indicated (yes) and in the specifications it is indicated that the substance is a macromolecule obtained from microbial fermentation.

Column 7 (FRF applicable (yes/no)): an indication if for the substance the migration results can be corrected by the Fat Consumption Reduction Factor (FRF) (yes) or if they cannot be corrected by the FRF (no).

Column 8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is indicated ND if the substance shall not migrate in detectable quantities.

Column 9 (SML(T) [mg/kg] (group restriction No)): contains the identification number of the group of substances for which the group restriction in Column 1 in Table 2 of this Annex applies.

Column 10 (Restrictions and specifications): contains other restrictions than the specific migration limit specifically mentioned and it contains specifications related to the substance. In case detailed specifications are set out a reference to Table 4 is included.

Column 11 (Notes on verification of compliance): contains the Notes number which refers to the detailed rules applicable for verification of compliance for this substance included in Column 1 in Table 3 of this Annex.

If a substance appearing on the list as an individual compound is also covered by a generic term, the restrictions applying to this substance shall be those indicated for the individual compound.

If in Column 8 the specific migration limit is non-detectable (ND) a detection limit of 0,01 mg substance per kg food is applicable unless specified differently for an individual substance.

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TABLE 1

| (1)              | (2)     | (3)     | (4)  | (5)   | (6)   | (7)                 | (8)         | (9)                                    | (10)                                  | (11)                                 |
|------------------|---------|---------|--|---|---|---------------------|-------------|--|---------------------------------------|--------------------------------------|
| FCM substance No | Ref. No | CAS No  | Substance name   | Use as additive or polymer product aid (yes/no) | Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no) | FRF applicable (no) | SML [mg/kg] | SML (T) [mg/kg] (Group restriction No) | Restrictions and specifications       | Notes on certification of compliance |
| 1                | 12310   | 0266309 | albumin  | no  | yes   | no                  |             |  |                                       |                                      |
| 2                | 12340   | —       | albumin coagulated by formaldehyde   | no  | yes   | no                  |             |  |                                       |                                      |
| 3                | 12375   | —       | alcohols, aliphatic, monohydric, saturated, linear, primary (C <sub>4</sub> -C <sub>22</sub> ) | no  | yes   | no                  |             |  |                                       |                                      |
| 4                | 22332   | —       | mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate                                   | no  | yes   | no                  |             | (17)                                   | 1 mg/kg in final product expressed as | (10)                                 |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>OJ L 83, 22.3.2012, p. 1.]

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|   |       |   |   |     |     |    |      |  |   |
|---|-------|---|---|-----|-----|----|------|--|---|
|   |       |   | and<br>(60 %<br>w/w)<br>2,4,4-<br>trimethylhexane-1,6-<br>diisocyanate                        |     |     |    |      |  | isocyanate<br>moiety.   |
| 5 | 25360 | — | trialkyl(C <sub>6</sub> -<br>C <sub>15</sub> )acetic<br>acid,<br>2,3-<br>epoxypropyl<br>ester | yes | no  | ND |      |  | 1 mg/<br>kg in<br>final<br>product<br>expressed<br>as<br>epoxygroup.<br>Molecular<br>weight<br>is 43<br>Da. |
| 6 | 25380 | — | trialkyl<br>acetic<br>acid<br>(C <sub>7</sub> -<br>C <sub>17</sub> ),<br>vinyl<br>esters      | no  | yes | no | 0,05 |  | (1)   |
| 7 | 30370 | — | acetylates<br>acid,<br>salts  | no  | no  |    |      |  |   |
| 8 | 30401 | — | acetylates<br>mono-<br>and<br>diglycerides<br>of<br>fatty<br>acids                            | no  | no  |    | (32) |  |   |
| 9 | 30610 | — | acids,<br>C <sub>2</sub> -<br>C <sub>24</sub> ,   | yes | no  | no |      |  |   |

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**b** [OJ L 330, 5.12.1998, p. 32.](#)

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|    |       |   |   |     |    |    |  |  |  |
|----|-------|---|---|-----|----|----|--|--|--|
|    |       |   | aliphatic,<br>linear,<br>monocarboxylic<br>from<br>natural<br>oils<br>and<br>fats,<br>and<br>their<br>mono-,<br>di- and<br>triglycerol<br>esters<br>(branched<br>fatty<br>acids<br>at<br>naturally<br>occurring<br>levels<br>are<br>included) |     |    |    |  |  |  |
| 10 | 30612 | — | acids, C <sub>2</sub> -<br>C <sub>24</sub> ,<br>aliphatic,<br>linear,<br>monocarboxylic,<br>synthetic<br>and<br>their<br>mono-,<br>di- and<br>triglycerol<br>esters   | yes | no | no |  |  |  |
| 11 | 30960 | — | acids,<br>aliphatic,<br>monocarboxylic  | yes | no | no |  |  |  |

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|----|-------|---|--|-----|----|-----|----|--|--|--|
|    |       |   | (C <sub>6</sub> -C <sub>22</sub> ), esters with polyglycerol                                   |     |    |     |    |  |  |  |
| 12 | 31328 | — | acids, fatty, from animal or vegetable food fats and oils                                      | yes | no | no  |    |  |  |  |
| 13 | 33120 | — | alcohols, aliphatic, monohydric, saturated, linear, primary (C <sub>4</sub> -C <sub>24</sub> ) | yes | no | no  |    |  |  |  |
| 14 | 33801 | — | n-alkyl (C <sub>10</sub> -C <sub>13</sub> ) benzenesulphonic acid                              | yes | no | no  | 30 |  |  |  |
| 15 | 34130 | — | alkyl, linear with even number of carbon atoms (C <sub>12</sub> -                              | yes | no | yes | 30 |  |  |  |

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|    |       |   |   |     |    |    |   |     |   |
|----|-------|---|---|-----|----|----|---|-----|---|
|    |       |   | C <sub>20</sub> )<br>dimethylamines   |     |    |    |   |     |   |
| 16 | 34230 | — | alkyl(C <sub>8</sub> -<br>C <sub>22</sub> )sulphonic<br>acids   | yes | no | no | 6 |     |   |
| 17 | 34281 | — | alkyl(C <sub>8</sub> -<br>C <sub>22</sub> )sulphuric<br>acids,<br>linear,<br>primary<br>with<br>an<br>even<br>number<br>of<br>carbon<br>atoms | yes | no | no |   |     |   |
| 18 | 34475 | — | aluminium<br>calcium<br>hydroxide<br>phosphite,<br>hydrate  | yes | no | no |   |     |   |
| 19 | 39090 | — | N,N-<br>bis(2-<br>hydroxyethyl)<br>alkyl(C <sub>8</sub> -<br>C <sub>18</sub> )amine   | yes | no | no |   | (7) |   |
| 20 | 39120 | — | N,N-<br>bis(2-<br>hydroxyethyl)<br>alkyl(C <sub>8</sub> -<br>C <sub>18</sub> )amine<br>hydrochlorides   | yes | no | no |   | (7) | SML(T)<br>expressed<br>excluding<br>HCl |
| 21 | 42500 | — | carbonic<br>acid,<br>salts  | yes | no | no |   |     |   |

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|----|-------|---|---|-----|----|----|-----|--|--|-----|
| 22 | 43200 | — | castor oil, mono- and diglycerides  | yes | no | no |     |  |  |     |
| 23 | 43515 | — | chlorides of choline esters of coconut oil fatty acids  | yes | no | no | 0,9 |  |  | (1) |
| 24 | 45280 | — | cotton fibers   | yes | no | no |     |  |  |     |
| 25 | 45440 | — | cresols, butylated, styrenated  | yes | no | no | 12  |  |  |     |
| 26 | 46700 | — | 5,7-di-tert-butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing:<br>a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80 to | yes | no | no | 5   |  |  |     |

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|----|-------|---|---|-----|----|----|---|------|--|--|
|    |       |   | 100 %<br>w/w)<br>and b)<br>5,7-di-<br>tert-<br>butyl-3-<br>(2,3-<br>dimethylphenyl)-3H-<br>benzofuran-2-<br>one (0<br>to 20<br>% w/<br>w) |     |    |    |   |      |  |  |
| 27 | 48960 | — | 9,10-<br>dihydroxy<br>stearic<br>acid<br>and its<br>oligomers   | yes | no | no | 5 |      |  |  |
| 28 | 50160 | — | di-n-<br>octyltin<br>bis(n-<br>alkyl(C <sub>10</sub> -<br>C <sub>16</sub> )<br>mercaptoacetate)   | yes | no | no |   | (10) |  |  |
| 29 | 50360 | — | di-n-<br>octyltin<br>bis(ethyl<br>maleate)  | yes | no | no |   | (10) |  |  |
| 30 | 50560 | — | di-n-<br>octyltin<br>1,4-<br>butanediol<br>bis(mercaptoacetate)   | yes | no | no |   | (10) |  |  |
| 31 | 50800 | — | di-n-<br>octyltin   | yes | no | no |   | (10) |  |  |

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|----|-------|---|--|-----|----|----|--|------|--|--|
|    |       |   | dimaleate,<br>esterified   |     |    |    |  |      |  |  |
| 32 | 50880 | — | di-n-octyltin dimaleate, polymers (n = 2-4)                        | yes | no | no |  | (10) |  |  |
| 33 | 51120 | — | di-n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate            | yes | no | no |  | (10) |  |  |
| 34 | 54270 | — | ethylhydroxymethylcellulose  | yes | no | no |  |      |  |  |
| 35 | 54280 | — | ethylhydroxypropylcellulose  | yes | no | no |  |      |  |  |
| 36 | 54450 | — | fats and oils, from animal or vegetable food sources               | yes | no | no |  |      |  |  |
| 37 | 54480 | — | fats and oils, hydrogenated, from animal or vegetable food sources | yes | no | no |  |      |  |  |

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|----|-------|---|---|-----|----|----|--|--|--|--|
| 38 | 55520 | — | glass fibers  | yes | no | no |  |  |  |  |
| 39 | 55600 | — | glass microballs  | yes | no | no |  |  |  |  |
| 40 | 56360 | — | glycerol esters with acetic acid  | yes | no | no |  |  |  |  |
| 41 | 56486 | — | glycerol esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C <sub>14</sub> -C <sub>18</sub> ) and with acids, aliphatic, unsaturated, linear, with an even number of carbon atoms | yes | no | no |  |  |  |  |

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|    |       |   | (C <sub>16</sub> -<br>C <sub>18</sub> )                     |     |    |    |  |  |  |  |
|----|-------|---|---|-----|----|----|--|--|--|--|
| 42 | 56487 | — | glycerol<br>esters<br>with<br>butyric<br>acid               | yes | no | no |  |  |  |  |
| 43 | 56490 | — | glycerol<br>esters<br>with<br>erucic<br>acid                | yes | no | no |  |  |  |  |
| 44 | 56495 | — | glycerol<br>esters<br>with<br>12-<br>hydroxystearic<br>acid | yes | no | no |  |  |  |  |
| 45 | 56500 | — | glycerol<br>esters<br>with<br>lauric<br>acid                | yes | no | no |  |  |  |  |
| 46 | 56510 | — | glycerol<br>esters<br>with<br>linoleic<br>acid              | yes | no | no |  |  |  |  |
| 47 | 56520 | — | glycerol<br>esters<br>with<br>myristic<br>acid              | yes | no | no |  |  |  |  |
| 48 | 56535 | — | glycerol<br>esters<br>with                                  | yes | no | no |  |  |  |  |

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|----|-------|---|---|----|----|--|--|--|--|
|    |       |   | nonanoic acid   |    |    |  |  |  |  |
| 49 | 56540 | — | glycerol, yes<br>esters with<br>oleic acid                  | no | no |  |  |  |  |
| 50 | 56550 | — | glycerol, yes<br>esters with<br>palmitic acid               | no | no |  |  |  |  |
| 51 | 56570 | — | glycerol, yes<br>esters with<br>propionic acid              | no | no |  |  |  |  |
| 52 | 56580 | — | glycerol, yes<br>esters with<br>ricinoleic acid             | no | no |  |  |  |  |
| 53 | 56585 | — | glycerol, yes<br>esters with<br>stearic acid                | no | no |  |  |  |  |
| 54 | 57040 | — | glycerol, yes<br>monooleate,<br>ester with<br>ascorbic acid | no | no |  |  |  |  |
| 55 | 57120 | — | glycerol, yes<br>monooleate,<br>ester                       | no | no |  |  |  |  |

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|    |       |   |   |     |    |    |  |  |  |
|----|-------|---|---|-----|----|----|--|--|--|
|    |       |   | with<br>citric<br>acid  |     |    |    |  |  |  |
| 56 | 57200 | — | glycerol<br>monopalmitate,<br>ester<br>with<br>ascorbic<br>acid | yes | no | no |  |  |  |
| 57 | 57280 | — | glycerol<br>monopalmitate,<br>ester<br>with<br>citric<br>acid   | yes | no | no |  |  |  |
| 58 | 57600 | — | glycerol<br>monostearate,<br>ester<br>with<br>ascorbic<br>acid  | yes | no | no |  |  |  |
| 59 | 57680 | — | glycerol<br>monostearate,<br>ester<br>with<br>citric<br>acid    | yes | no | no |  |  |  |
| 60 | 58300 | — | glycine,<br>salts   | yes | no | no |  |  |  |
| 62 | 64500 | — | lysine,<br>salts  | yes | no | no |  |  |  |
| 63 | 65440 | — | manganese<br>pyrophosphite                                      | yes | no | no |  |  |  |
| 64 | 66695 | — | methyl<br>hydroxymethyl<br>cellulose                            | yes | no | no |  |  |  |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|    |       |   |  |     |    |    |  |      |  |
|----|-------|---|--|-----|----|----|--|------|--|
| 65 | 67155 | — | mixture of 4-(2-benzoxazolyl)-4-(5-methyl-2-benzoxazolyl)stilbene, 4,4'-bis(2-benzoxazolyl) stilbene and 4,4'-bis(5-methyl-2-benzoxazolyl)stilbene | yes | no | no |  |      | Not more than 0,05 % (w/w) (quantity of substance used/ quantity of the formulation). Mixture obtained from the manufacturing process in the typical ratio of (58-62 %): (23-27 %): (13-17 %). |
| 66 | 67600 | — | mono-n-octyltin tris(alkyl(C <sub>10</sub> -C <sub>16</sub> ) mercaptoacetate)   | yes | no | no |  | (11) |  |
| 67 | 67840 | — | montanic acids and/or their  | yes | no | no |  |      |  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|    |       |   |   |     |    |     |      |  |  |
|----|-------|---|---|-----|----|-----|------|--|--|
|    |       |   | esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol          |     |    |     |      |  |  |
| 68 | 73160 | — | phosphoric acid, mono- and di-n-alkyl (C <sub>16</sub> and C <sub>18</sub> ) esters | yes | no | yes | 0,05 |  |  |
| 69 | 74400 | — | phosphoric acid, tris(nonyl- and/or dinonylphenyl) ester                            | yes | no | yes | 30   |  |  |
| 70 | 76463 | — | polyacrylic acid, salts   | yes | no | no  | (22) |  |  |
| 71 | 76730 | — | polydimethylsiloxane, $\gamma$ -hydroxypropylated                                   | yes | no | no  | 6    |  |  |
| 72 | 76815 | — | polyester of adipic acid with glycerol  | yes | no | no  | (32) | The fraction with molecular weight below |  |

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**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|    |       |   | or<br>pentaerythritol,<br>esters<br>with<br>even<br>numbered,<br>unbranched<br>C <sub>12</sub> -<br>C <sub>22</sub><br>fatty<br>acids   |     |    |     |              | 1 000<br>Da<br>should<br>not<br>exceed<br>5 %<br>(w/w) |
|----|-------|---|---|-----|----|-----|--------------|--|
| 73 | 76866 | — | polyesters<br>of 1,2-<br>propanediol<br>and/<br>or 1,3-<br>and/<br>or 1,4-<br>butanediol<br>and/or<br>polypropyleneglycol<br>with<br>adipic<br>acid,<br>which<br>may<br>be<br>end-<br>capped<br>with<br>acetic<br>acid or<br>fatty<br>acids<br>C <sub>12</sub> -<br>C <sub>18</sub><br>or n-<br>octanol<br>and/ | yes | no | yes | (31)<br>(32) |  |

**a** OJ L 302, 19.11.2005, p. 28.

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**c** OJ L 253, 20.9.2008, p. 1.

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|    |       |   |   |     |    |     |      |  |                     |
|----|-------|---|---|-----|----|-----|------|--|---------------------|
|    |       |   | or n-decanol  |     |    |     |      |  |                     |
| 74 | 77440 | — | polyethylene glycol dibenzoate  | yes | no | yes | 42   |  |                     |
| 75 | 77702 | — | polyethylene glycol esters of aliph. monocarb. acids (C <sub>6</sub> -C <sub>22</sub> ) and their ammonium and sodium sulphates | yes | no | no  |      |  |                     |
| 76 | 77732 | — | polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate                      | yes | no | no  | 0,05 |  | Only for use in PET |
| 77 | 77733 | — | polyethylene glycol (EO = 1-30, typically 5)  | yes | no | no  | 0,05 |  | Only for use in PET |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

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|    |       |   |   |     |    |    |  |  |  |
|----|-------|---|---|-----|----|----|--|--|--|
|    |       |   | ether<br>of<br>butyl-2-<br>cyano-3-<br>(4-<br>hydroxyphenyl)<br>acrylate  |     |    |    |  |  |  |
| 78 | 77897 | — | polyethylene glycol<br>(EO =<br>1-50)<br>monoalkylether<br>(linear<br>and<br>branched,<br>C <sub>8</sub> -<br>C <sub>20</sub> )<br>sulphate,<br>salts | yes | no | 5  |  |  |  |
| 79 | 80640 | — | polyoxyalkyl<br>(C <sub>2</sub> -<br>C <sub>4</sub> )<br>dimethylpolysiloxane   | no  | no |    |  |  |  |
| 80 | 81760 | — | powders<br>flakes<br>and<br>fibres<br>of<br>brass,<br>bronze,<br>copper,<br>stainless<br>steel,<br>tin,<br>iron<br>and<br>alloys<br>of<br>copper,     | yes | no | no |  |  |  |

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**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|    |       |   |  |     |    |    |   |     |  |
|----|-------|---|--|-----|----|----|---|-----|--|
|    |       |   | tin and iron   |     |    |    |   |     |  |
| 81 | 83320 | — | propylhydroxyethylcellulose                                    | yes | no | no |   |     |  |
| 82 | 83325 | — | propylhydroxyethylcellulose                                    | yes | no | no |   |     |  |
| 83 | 83330 | — | propylhydroxypropylcellulose                                   | yes | no | no |   |     |  |
| 84 | 85601 | — | silicates, natural (with the exception of asbestos)            | yes | no | no |   |     |  |
| 85 | 85610 | — | silicates, natural, silanated (with the exception of asbestos) | yes | no | no |   |     |  |
| 86 | 86000 | — | silicic acid, silylated  | yes | no | no |   |     |  |
| 87 | 86285 | — | silicon dioxide, silanated                                     | yes | no | no |   |     |  |
| 88 | 86880 | — | sodium monoalkyl dialkylphenoxybenzenedisulphonate             | yes | no | no | 9 |     |  |
| 89 | 89440 | — | stearic acid, esters with ethyleneglycol                       | yes | no | no |   | (2) |  |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

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|    |       |   |   |     |    |     |      |  |   |
|----|-------|---|---|-----|----|-----|------|--|---|
| 90 | 92195 | — | taurine, salts  | yes | no | no  |      |  |   |
| 91 | 92320 | — | tetradecyl polyethyleneglycol ether of glycolic acid (EO = 3-8)   | yes | no | yes | 15   |  |   |
| 92 | 93970 | — | tricyclohexylbis(phthalate)   | yes | no | no  | 0,05 |  |   |
| 93 | 95858 | — | waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity | yes | no | no  | 0,05 |  | Not to be used for articles in contact with fatty foods for which simulant D is laid down. Average molecular weight not less than 350 Da. Viscosity at 100 °C not |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|    |       |   |  |     |    |    |  |  |  |
|----|-------|---|--|-----|----|----|--|--|--|
|    |       |   |  |     |    |    |  |  | less than 2,5 cSt (2,5 × 10 <sup>-6</sup> m <sup>2</sup> /s). Content of hydrocarbons with Carbon number less than 25, not more than 40 % (w/w). |
| 94 | 95859 | — | waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity | yes | no | no |  |  | Average molecular weight not less than 500 Da. Viscosity at 100 °C not less than 11 cSt (11 × 10 <sup>-6</sup> m <sup>2</sup> /s). Content of    |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

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|          |   |   |   |     |    |    |  |  |   |
|----------|---|---|---|-----|----|----|--|--|---|
|          |   |   |   |     |    |    |  |  | mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).  |
| 95       | 95883   | — | white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks | yes | no | no |  |  | Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt (8,5 × 10 <sup>-6</sup> m <sup>2</sup> /s). Content of mineral hydrocarbons with Carbon number less than 25, not |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |   |   |     |    |    |  |  |   |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |   |   |     |    |    |  |  |   |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |   |   |     |    |    |  |  |   |
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|----------|---|---|---|-----|----|----|--|--|---|
|          |   |   |   |     |    |    |  |  | more than 5 % (w/w).  |
| 96       | 95920   | — | wood flour and fibers, untreated            | yes | no | no |  |  |   |
| 97       | 72081/10  | — | petroleum hydrocarbon resins (hydrogenated) | yes | no | no |  |  | Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermal polymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |   |   |     |    |    |  |  |   |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |   |   |     |    |    |  |  |   |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |   |   |     |    |    |  |  |   |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |   |   |     |    |    |  |  |   |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |   |   |     |    |    |  |  |   |
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| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |   |   |     |    |    |  |  |   |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |   |   |     |    |    |  |  |   |



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|          |   |  |  |  |  |  |  |  |
|----------|---|--|--|--|--|--|--|--|
|          |   |  |  |  |  |  |  | greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing.<br>Properties:<br>— Viscosity at 120 °C:<br>> 3 Pa.s,<br>— Softening point:<br>> 95 °C as determined by ASTM Method |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |  |  |  |  |  |  |  |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |  |  |  |  |  |  |  |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |  |  |  |  |  |  |  |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |  |  |  |  |  |  |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |  |  |  |  |  |  |  |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |  |  |  |  |  |  |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |  |  |  |  |  |  |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |  |  |  |  |  |  |

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|     |       |         |              |     |     |    |      |  |   |   |
|-----|-------|---------|--------------|-----|-----|----|------|--|---|---|
|     |       |         |              |     |     |    |      |  | — | E<br>28-67,<br>Bromine<br>number:<br><<br>40<br>(ASTM<br>D1159),<br>The<br>colour<br>of<br>a<br>50<br>%<br>solution<br>in<br>toluene<br><<br>11<br>on<br>the<br>Gardner<br>scale,<br>Residual<br>aromatic<br>monomer<br>≤<br>50<br>ppm, |
| 98  | 17260 | 0000050 | formaldehyde | yes | no  |    | (15) |  |   |   |
|     | 54880 |         |              |     |     |    |      |  |   |   |
| 99  | 19460 | 0000050 | lactic acid  | yes | yes | no |      |  |   |   |
|     | 62960 |         |              |     |     |    |      |  |   |   |
| 100 | 24490 | 0000050 | sorbitol     | yes | yes | no |      |  |   |   |
|     | 88320 |         |              |     |     |    |      |  |   |   |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

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|     |       |         |                                |     |     |    |   |  |  |
|-----|-------|---------|--------------------------------|-----|-----|----|---|--|--|
| 101 | 36000 | 0000050 | asorbic acid                   | yes | no  | no |   |  |  |
| 102 | 17530 | 0000050 | geose                          | no  | yes | no |   |  |  |
| 103 | 18100 | 0000056 | glycerol                       | yes | yes | no |   |  |  |
|     | 55920 |         |                                |     |     |    |   |  |  |
| 104 | 58960 | 0000057 | decyltrimethylammonium bromide |     |     |    | 6 |  |  |
| 105 | 22780 | 0000057 | phthalic acid                  | yes | yes | no |   |  |  |
|     | 70400 |         |                                |     |     |    |   |  |  |
| 106 | 24550 | 0000057 | stearic acid                   | yes | yes | no |   |  |  |
|     | 89040 |         |                                |     |     |    |   |  |  |
| 107 | 25960 | 0000057 | uracil                         | no  | yes | no |   |  |  |
| 108 | 24880 | 0000057 | uracil                         | no  | yes | no |   |  |  |
| 109 | 23740 | 0000057 | propanediol                    | yes | yes | no |   |  |  |
|     | 81840 |         |                                |     |     |    |   |  |  |
| 110 | 93520 | 0000059 | hydrophol                      | yes | no  | no |   |  |  |
| 111 | 53600 | 0000060 | benzylamine                    | no  | no  | no |   |  |  |
| 112 | 64015 | 0000060 | lactic acid                    | yes | no  | no |   |  |  |
| 113 | 16780 | 0000064 | thanol                         | yes | yes | no |   |  |  |
|     | 52800 |         |                                |     |     |    |   |  |  |
| 114 | 55040 | 0000064 | formic acid                    | yes | no  | no |   |  |  |
| 115 | 10090 | 0000064 | acetic acid                    | yes | yes | no |   |  |  |
|     | 30000 |         |                                |     |     |    |   |  |  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [F<sup>1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

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|     |       |              |                              |     |     |    |    |     |                                    |
|-----|-------|--------------|------------------------------|-----|-----|----|----|-----|------------------------------------|
| 116 | 13090 | 000006585-0  | 585-0<br>benzoic acid        | yes | yes | no |    |     |                                    |
|     | 37600 |              |                              |     |     |    |    |     |                                    |
| 117 | 21550 | 000006756-0  | 756-0<br>ethanol             | no  | yes | no |    |     |                                    |
| 118 | 23830 | 0000067263-0 | 263-0<br>propanol            | yes | yes | no |    |     |                                    |
|     | 81882 |              |                              |     |     |    |    |     |                                    |
| 119 | 30295 | 000006766-0  | 66-0<br>ethene               | yes | no  | no |    |     |                                    |
| 120 | 49540 | 0000067468-0 | 468-0<br>ethyl sulphoxide    | yes | no  | no |    |     |                                    |
| 121 | 24270 | 000006957-0  | 57-0<br>fattylic acid        | yes | yes | no |    |     |                                    |
|     | 84640 |              |                              |     |     |    |    |     |                                    |
| 122 | 23800 | 0000071423-8 | 1423-8<br>propanol           | no  | yes | no |    |     |                                    |
| 123 | 13840 | 0000071436-3 | 1436-3<br>butanol            | no  | yes | no |    |     |                                    |
| 124 | 22870 | 0000071441-0 | 1441-0<br>pentanol           | no  | yes | no |    |     |                                    |
| 125 | 16950 | 000007485-0  | 485-0<br>ethylene            | no  | yes | no |    |     |                                    |
| 126 | 10210 | 000007486-2  | 486-2<br>ethylene            | no  | yes | no |    |     |                                    |
| 127 | 26050 | 000007501-4  | 501-4<br>vinyl chloride      | no  | yes | no | ND |     | 1 mg/<br>kg in<br>final<br>product |
| 128 | 10060 | 000007507-0  | 507-0<br>aldehyde            | yes | yes | no |    | (1) |                                    |
| 129 | 17020 | 000007521-0  | 521-0<br>ethylene oxide      | no  | yes | no | ND |     | 1 mg/<br>kg in<br>final<br>product |
| 130 | 26110 | 000007535-4  | 535-4<br>vinylidene chloride | no  | yes | no | ND |     | (1)                                |

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**b** OJ L 330, 5.12.1998, p. 32.

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|     |       |              |  |     |     |    |    |  |      |
|-----|-------|--------------|--|-----|-----|----|----|--|------|
| 131 | 48460 | 0000075137-6 | yes<br>difluoroethane  | no  | no  |    |    |  |      |
| 132 | 26140 | 0000075387-6 | yes<br>fluoride  | no  | yes | no | 5  |  |      |
| 133 | 14380 | 0000075416-6 | no<br>chloride   | yes | no  | ND |    | 1 mg/<br>kg in<br>final<br>product   | (10) |
|     | 23155 |              |  |     |     |    |    |  |      |
| 134 | 43680 | 0000075456-6 | yes<br>chlorofluoromethane   | no  | no  | 6  |    | Content<br>of<br>chlorofluoromethane<br>less<br>than 1<br>mg/kg<br>of the<br>substance |      |
| 135 | 24010 | 0000075569-6 | yes<br>oxide   | no  | yes | no | ND | 1 mg/<br>kg in<br>final<br>product   |      |
| 136 | 41680 | 0000076221-6 | yes<br>phoryl  | no  | no  | no |    |  | (3)  |
| 137 | 66580 | 0000077262-3 | yes<br>methylenebis(4-<br>methyl-6-<br>(1-<br>methylcyclohexyl)phenol) | no  | yes | no |    | (5)  |      |
| 138 | 93760 | 0000077407-6 | yes<br>butyl<br>acetyl<br>citrate                                      | no  | no  | no |    | (32)   |      |
| 139 | 14680 | 0000077921-9 | yes<br>acid  | yes | yes | no |    |  |      |
|     | 44160 |              |  |     |     |    |    |  |      |
| 140 | 44640 | 0000077931-0 | yes<br>acid,   | no  | no  | no |    | (32)   |      |

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|     |       |              |                             |     |     |      |    |   |     |
|-----|-------|--------------|-----------------------------|-----|-----|------|----|---|-----|
|     |       |              | triethyl ester              |     |     |      |    |   |     |
| 141 | 13380 | 0000077199-6 | yes                         | yes | no  | 6    |    |   |     |
|     | 25600 |              | trimethylolpropane          |     |     |      |    |   |     |
|     | 94960 |              |                             |     |     |      |    |   |     |
| 142 | 26305 | 0000078081-0 | triethoxysilanes            | yes | no  | 0,05 |    | Only to be used as a surface treatment agent          | (1) |
| 143 | 62450 | 0000078158-4 | pentanes                    | yes | no  | no   |    |   |     |
| 144 | 19243 | 0000078279-5 | no                          | yes | no  | ND   |    | 1 mg/kg in final product                              |     |
|     | 21640 |              | methyl-1,3-butadiene        |     |     |      |    |   |     |
| 145 | 10630 | 0000079006-1 | amide                       | yes | no  | ND   |    |   |     |
| 146 | 23890 | 0000079009-1 | ionic acid                  | yes | yes | no   |    |   |     |
|     | 82000 |              |                             |     |     |      |    |   |     |
| 147 | 10690 | 0000079101-1 | acrylic acid                | no  | yes | no   |    | (22)  |     |
| 148 | 14650 | 0000079188-0 | trifluoroethylene           | yes | no  | no   | ND |   | (1) |
| 149 | 19990 | 0000079201-0 | methacrylamide              | yes | yes | no   | ND |   |     |
| 150 | 20020 | 0000079211-0 | methacrylic acid            | yes | yes | no   |    | (23)  |     |
| 151 | 13480 | 0000080205-7 | no                          | yes | no  | 0,6  |    | [ <sup>F2</sup> Not to be used for the manufacture of |     |
|     | 13607 |              | bis(4-hydroxyphenyl)propane |     |     |      |    |   |     |

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|     |       |              |                                     |     |    |      |      |                                       | polycarbonate infant <sup>f</sup> feeding bottles <sup>g</sup> .]   |  |
|-----|-------|--------------|-------------------------------------|-----|----|------|------|---------------------------------------|---|--|
| 152 | 15610 | 0000080407-9 | no<br>dichlorodiphenyl sulphone     | yes | no | 0,05 |      |                                       |   |  |
| 153 | 15267 | 0000080408-0 | no<br>diaminodiphenyl sulphone      | yes | no | 5    |      |                                       |   |  |
| 154 | 13617 | 0000080409-1 | no<br>dihydroxydiphenyl sulphone    | yes | no | 0,05 |      |                                       |   |  |
|     | 16090 |              |                                     |     |    |      |      |                                       |   |  |
| 155 | 23470 | 0000080456-8 | no<br>pinene                        | yes | no |      |      |                                       |   |  |
| 156 | 21130 | 0000080462-6 | no<br>acrylic acid, methyl ester    | yes | no |      | (23) |                                       |   |  |
| 157 | 74880 | 0000080474-4 | yes<br>phthalic acid, dibutyl ester | yes | no | 0,3  | (32) | Only to be used as:<br>(a)<br><br>(b) | (7)<br><br>plasticiser in repeated use materials and articles contacting non-fatty foods; technical support |  |

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|     |                |         |                                   |     |     |    |    |      |                                       | agent<br>in<br>polyolefins<br>in<br>concentrations<br>up<br>to<br>0,05<br>%<br>in<br>the<br>final<br>product.                                     |
|-----|----------------|---------|-----------------------------------|-----|-----|----|----|------|---------------------------------------|---|
| 158 | 23380<br>76320 | 0000085 | phthalic anhydride                | yes | yes | no |    |      |                                       |   |
| 159 | 74560          | 0000085 | phthalic acid, benzyl butyl ester | yes | no  | no | 30 | (32) | Only to be used as:<br>(a)<br><br>(b) | (7)<br><br>plasticiser in repeated use materials and articles; plasticiser in single-use materials and articles contacting non-fatty foods except |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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|                     |                |         |  |     |     |     |      |      |   | %<br>in<br>the<br>final<br>product. |
|---------------------|----------------|---------|--|-----|-----|-----|------|------|---|-------------------------------------|
| 160                 | 84800          | 0000087 | salicylic acid, 4-tert-butylphenyl ester       | yes | no  | yes | 12   |      |   |                                     |
| [ <sup>F4</sup> 161 | 92160          | 0000087 | (4)-tartaric acid                              | yes | no  | no  |      |      |   | ]                                   |
| 162                 | 65520          | 0000087 | nitro  | yes | no  | no  |      |      |   |                                     |
| 163                 | 66400          | 0000088 | 2,2'-methylene bis(4-ethyl-6-tert-butylphenol) | yes | no  | yes |      | (13) |   |                                     |
| 164                 | 34895          | 0000088 | 2,6-aminobenzamide                             | yes | no  | no  | 0,05 |      | Only for use in PET for water and beverages |                                     |
| 165                 | 23200<br>74480 | 0000088 | phthalic acid                                  | yes | yes | no  |      |      |   |                                     |
| 166                 | 24057          | 0000089 | phthalic anhydride                             | yes | yes | no  | 0,05 |      |   |                                     |
| 167                 | 25240          | 0000091 | toluene diisocyanate                           | no  | yes | no  |      | (17) | 1 mg/kg in final product                    | (10)                                |

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|     |                |        |  |     |     |    |      |      | expressed as isocyanate moiety                          |      |
|-----|----------------|--------|--|-----|-----|----|------|------|---|------|
| 168 | 13075<br>15310 | 000009 | 1276-9<br>diamino-6-phenyl-1,3,5-triazine    | no  | yes | no | 5    |      |   | (1)  |
| 169 | 16240          | 000009 | 1397-4<br>dimethyl-4,4'-diisocyanatobiphenyl | no  | yes | no |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 170 | 16000          | 000009 | 2488-6<br>dihydroxybiphenyl                  | no  | yes | no | 6    |      |   |      |
| 171 | 38080          | 000009 | 3588-2<br>benzoic acid, methyl ester         | yes | no  | no |      |      |   |      |
| 172 | 37840          | 000009 | 3589-0<br>benzoic acid, ethyl ester          | yes | no  | no |      |      |   |      |
| 173 | 60240          | 000009 | 4413-3<br>hydroxybenzoic acid, propyl ester  | yes | no  | no |      |      |   |      |
| 174 | 14740          | 000009 | 5048-7<br>cresol                             | no  | yes | no |      |      |   |      |
| 175 | 20050          | 000009 | 6051-9<br>methacrylic acid,                  | no  | yes | no | 0,05 |      |   |      |

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|     |       |         |  |     |     |     |      |      |   |  |
|-----|-------|---------|--|-----|-----|-----|------|------|---|--|
|     |       |         | allyl ester  |     |     |     |      |      |   |  |
| 176 | 11710 | 0000096 | 633-11-01<br>acetic acid, methyl ester             | no  | yes | no  |      | (22) |   |  |
| 177 | 16955 | 0000096 | 49-1-01<br>ethylene carbonate                      | no  | yes | no  | 30   |      | SML expressed as ethyleneglycol. Residual content of 5 mg ethylene carbonate per kg of hydrogel with max 10 g of hydrogel in contact with 1 kg of food. |  |
| 178 | 92800 | 0000096 | 49-5-01<br>thiobis(6-tert-butyl-3-methylphenol)    | yes | no  | yes | 0,48 |      |   |  |
| 179 | 48800 | 0000097 | 22-4-01<br>dihydroxy--5,5'-dichlorodiphenylmethane | yes | no  | yes | 12   |      |   |  |

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|---------------------|-------|-------------|---|-----|-----|----|------|------|--|---|
| [ <sup>F5</sup> 180 | 17160 | 000009753-0 | phenol                                    | no  | yes | no |      | (33) |  | ] |
| 181                 | 20890 | 000009760-2 | acrylic acid, ethyl ester                 |     | yes | no |      | (23) |  |   |
| 182                 | 19270 | 000009765-4 | ascorbic acid                             | no  | yes | no |      |      |  |   |
| 183                 | 21010 | 000009784-0 | acrylic acid, isobutyl ester              |     | yes | no |      | (23) |  |   |
| 184                 | 20110 | 000009788-1 | acrylic acid, butyl ester                 |     | yes | no |      | (23) |  |   |
| 185                 | 20440 | 000009790-5 | acrylic acid, diester with ethyleneglycol |     | yes | no | 0,05 |      |  |   |
| 186                 | 14020 | 000009845-4 | tert-butylphenol                          | no  | yes | no | 0,05 |      |  |   |
| 187                 | 22210 | 000009868-3 | 9-methylstyrene                           | no  | yes | no | 0,05 |      |  |   |
| 188                 | 19180 | 000009916-3 | phthalic acid dichloride                  |     | yes | no |      | (27) |  |   |
| 189                 | 60200 | 000009947-3 | 3-hydroxybenzoic acid, methyl ester       | yes | no  | no |      |      |  |   |

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|     |       |         |   |    |     |    |      |   |      |
|-----|-------|---------|---|----|-----|----|------|---|------|
| 190 | 18880 | 0000099 | 96-7<br>hydroxybenzoic acid                 | no | yes | no |      |   |      |
| 191 | 24940 | 0000100 | 100-9<br>phthalic acid dichloride           | no | yes | no | (28) |   |      |
| 192 | 23187 | —       | phthalic acid                               | no | yes | no | (28) |   |      |
| 193 | 24610 | 0000100 | 042-9<br>styrene                            | no | yes | no |      |   |      |
| 194 | 13150 | 0000100 | 051-6<br>benzyl alcohol                     | no | yes | no |      |   |      |
| 195 | 37360 | 0000100 | 052-7<br>benzaldehyde                       | no | no  | no |      |   | (3)  |
| 196 | 18670 | 0000100 | 070-0<br>hexamethylene tetramine            | no | no  | no | (15) |   |      |
|     | 59280 |         |   |    |     |    |      |   |      |
| 197 | 20260 | 0000101 | 140-9<br>methacrylic acid, cyclohexyl ester | no | yes | no | 0,05 |   |      |
| 198 | 16630 | 0000101 | 160-8<br>diphenylmethane 4,4'-diisocyanate  | no | no  | no | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 199 | 24073 | 0000101 | 190-6<br>bisphenol diglycidyl ether         | no | yes | no | ND   | Not to be used for articles in contact with             | (8)  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|     |                |              |   |     |     |     |      |  |  |
|-----|----------------|--------------|---|-----|-----|-----|------|--|--|
|     |                |              |   |     |     |     |      |  | fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer. |
| 200 | 51680          | 000010220819 | 409-diphenylthiourea                              | yes | no  | yes | 3    |  |  |
| 201 | 16540          | 000010220910 | 409-phenyl carbonate                              | no  | yes | no  | 0,05 |  |  |
| 202 | 23070          | 00001022136  | 409-phenylenedioxy acid                           | no  | yes | no  | 0,05 |  | (1)  |
| 203 | 13323          | 00001022149  | 409-bis(2-hydroxyethoxy)benzene                   | no  | yes | no  | 0,05 |  |  |
| 204 | 25180<br>92640 | 00001022603  | 409-N,N'-tetrakis(2-hydroxypropyl)ethylenediamine | yes | yes | no  |      |  |  |
| 205 | 25385          | 000010227015 | 409-amine   | yes | no  |     |      |  | 40 mg/kg hydrogel at a ratio of 1 kg food  |

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|     |       |         |                                      |     |     |     |      |      |   |     |
|-----|-------|---------|--------------------------------------|-----|-----|-----|------|------|---|-----|
|     |       |         |                                      |     |     |     |      |      | to a maximum of 1,5 grams of hydrogel. Only to be used in hydrogels intended for non-direct food contact use. |     |
| 206 | 11500 | 0000103 | adipic acid, 2-ethylhexyl ester      | no  | yes | no  | 0,05 |      |   |     |
| 207 | 31920 | 0000103 | adipic acid, bis(2-ethylhexyl) ester | yes | no  | yes | 18   | (32) |   | (2) |
| 208 | 18898 | 0000103 | 4-(2-hydroxyphenyl) acetamide        | no  | yes | no  | 0,05 |      |   |     |
| 209 | 17050 | 0000104 | 276-7 ethyl-1-hexanol                | no  | yes | no  | 30   |      |   |     |
| 210 | 13390 | 0000105 | 408-8 bis(hydroxymethyl)cyclohexane  | no  | yes | no  |      |      |   |     |
|     | 14880 |         |                                      |     |     |     |      |      |   |     |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|-----|-------|--------------|-------------------------------------|-----|-----|----|------|------|--------------------------|------|
| 211 | 23920 | 0000105384   | phthalic acid, vinyl ester          | no  | yes | no |      | (1)  |                          |      |
| 212 | 14200 | 000010560    | ε-caprolactam                       | yes | yes | no |      | (4)  |                          |      |
|     | 41840 |              |                                     |     |     |    |      |      |                          |      |
| 213 | 82400 | 0000105162-4 | propyleneglycol dioleate            | yes | no  | no |      |      |                          |      |
| 214 | 61840 | 0000106124-9 | hydroxystearic acid                 | yes | no  | no |      |      |                          |      |
| 215 | 14170 | 000010616    | butyric anhydride                   | no  | yes | no |      |      |                          |      |
| 216 | 14770 | 000010644-5  | resol                               | no  | yes | no |      |      |                          |      |
| 217 | 15565 | 000010646-7  | dichlorobenzene                     | no  | yes | no | 12   |      |                          |      |
| 218 | 11590 | 000010667    | isobutylic acid, isobutyl ester     | no  | yes | no |      | (22) |                          |      |
| 219 | 14570 | 000010689    | chlorohydrin                        | yes | yes | no | ND   |      | 1 mg/kg in final product | (10) |
|     | 16750 |              |                                     |     |     |    |      |      |                          |      |
| 220 | 20590 | 0000106912   | acrylic acid, 2,3-epoxypropyl ester | yes | yes | no | 0,02 |      |                          | (10) |
| 221 | 40570 | 000010697    | stearic acid                        | yes | no  | no |      |      |                          |      |

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|     |       |              |                           |     |     |    |    |     |                          |
|-----|-------|--------------|---------------------------|-----|-----|----|----|-----|--------------------------|
| 222 | 13870 | 0000106198-9 | butene                    | no  | yes | no |    |     |                          |
| 223 | 13630 | 0000106000-0 | butadiene                 | no  | yes | no | ND |     | 1 mg/kg in final product |
| 224 | 13900 | 0000107201-7 | butene                    | no  | yes | no |    |     |                          |
| 225 | 12100 | 0000107433-1 | butyrolactone             | yes | yes | no | ND |     |                          |
| 226 | 15272 | 0000107115-1 | butylendiamine            | yes | yes | no | 12 |     |                          |
|     | 16960 |              |                           |     |     |    |    |     |                          |
| 227 | 16990 | 0000107211-1 | ethylene glycol           | yes | yes | no |    | (2) |                          |
|     | 53650 |              |                           |     |     |    |    |     |                          |
| 228 | 13690 | 0000107183-0 | butanediol                | no  | yes | no |    |     |                          |
| 229 | 14140 | 0000107502-6 | butyric acid              | no  | yes | no |    |     |                          |
| 230 | 16150 | 0000108401-1 | butylaminoethanol         | yes | yes | no | 18 |     |                          |
| 231 | 10120 | 0000108051-4 | butyric acid, vinyl ester | no  | yes | no | 12 |     |                          |
| 232 | 10150 | 0000108241-7 | butyric anhydride         | yes | yes | no |    |     |                          |
|     | 30280 |              |                           |     |     |    |    |     |                          |
| 233 | 24850 | 0000108310-5 | butyric anhydride         | no  | yes | no |    |     |                          |
| 234 | 19960 | 0000108311-6 | butyric anhydride         | no  | yes | no |    | (3) |                          |
| 235 | 14710 | 0000108739-4 | cresol                    | no  | yes | no |    |     |                          |

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|                      |                          |              |                               |     |     |    |      |      |      |
|----------------------|--------------------------|--------------|-------------------------------|-----|-----|----|------|------|------|
| 236                  | 23050                    | 0000108145-2 | phenylenediamine              | no  | yes | no | ND   |      |      |
| 237                  | 15910<br>24072           | 0000108146-3 | dihydroxybenzene              | no  | yes | no | 2,4  |      |      |
| 238                  | 18070                    | 0000108554-1 | glutaric anhydride            | no  | yes | no |      |      |      |
| [ <sup>F6</sup> 239] | 19975<br>25420<br>93720] | 0000108274-1 | 2,4,6-triamino-1,3,5-triazine | yes | yes | no | 2,5  |      |      |
| 240                  | 45760                    | 0000108911-8 | hexylamine                    | no  | no  | no |      |      |      |
| [ <sup>F4</sup> 241] | 22960                    | 0000108952-1 | phenol                        | no  | yes | no | 3    |      | I    |
| 242                  | 85360                    | 0000109454-1 | sebacic acid, dibutyl ester   | yes | no  | no |      | (32) |      |
| 243                  | 19060                    | 0000109535-1 | isobutyl vinyl ether          | no  | yes | no | 0,05 |      | (10) |
| 244                  | 71720                    | 0000109661-0 | acetone                       | yes | no  | no |      |      |      |
| 245                  | 22900                    | 0000109167-1 | pentene                       | no  | yes | no | 5    |      |      |
| 246                  | 25150                    | 0000109499-1 | tetrahydrofuran               | yes | no  | no | 0,6  |      |      |
| 247                  | 24820<br>90960           | 0000110156-1 | sulfenic acid                 | yes | yes | no |      |      |      |
| 248                  | 19540<br>64800           | 0000110147-1 | maleic acid                   | yes | yes | no |      | (3)  |      |
| 249                  | 17290<br>55120           | 0000110171-1 | fumaric acid                  | yes | yes | no |      |      |      |

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|                     |       |              |                                  |     |     |    |      |  |   |
|---------------------|-------|--------------|----------------------------------|-----|-----|----|------|--|---|
| 250                 | 53520 | 0000110305   | N,N5<br>ethylenebisstearamide    | yes | no  | no |      |  |   |
| 251                 | 53360 | 0000110306   | N,N6<br>ethylenebisoleamide      | yes | no  | no |      |  |   |
| 252                 | 87200 | 0000110401   | adipic<br>acid                   | yes | no  | no |      |  |   |
| 253                 | 15250 | 0000110401   | 1,4-<br>diaminobutane            | no  | yes | no |      |  |   |
| 254                 | 13720 | 0000110404   | 1,4-<br>butanediol               | yes | yes | no | (30) |  |   |
|                     | 40580 |              |                                  |     |     |    |      |  |   |
| 255                 | 25900 | 0000110403   | 1,4-<br>butane                   | no  | yes | no | 5    |  |   |
| 256                 | 18010 | 0000110909   | Malic<br>acid                    | yes | yes | no |      |  |   |
|                     | 55680 |              |                                  |     |     |    |      |  |   |
| [ <sup>F5</sup> 257 | 13550 | 0000110905   | 1,3-<br>propylene glycol         | yes | yes | no |      |  |   |
|                     | 16660 | 0025265-71-8 |                                  |     |     |    |      |  |   |
|                     | 51760 | ]            |                                  |     |     |    |      |  |   |
| 258                 | 70480 | 0000111008   | Malic<br>acid,<br>butyl<br>ester | yes | no  | no |      |  |   |
| 259                 | 58720 | 0000111008   | Malic<br>acid                    | yes | no  | no |      |  |   |
| 260                 | 24280 | 0000111206   | adipic<br>acid                   | no  | yes | no |      |  |   |
| 261                 | 15790 | 0000111400   | 1,4-<br>diaminobutane            | yes | yes | no | 5    |  |   |
| 262                 | 35284 | 0000111412   | N-(2-<br>aminoethyl)ethanolamine | yes | no  | no | 0,05 |  | Not<br>to be<br>used<br>for<br>articles<br>in |

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|-----|-------|--------------|------------------------|-----|-----|----|------|--|---|
|     |       |              |                        |     |     |    |      |  | contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer. |
| 263 | 13326 | 0000111466-0 | 1466-0 ethylene glycol | yes | no  |    | (2)  |  |   |
|     | 15760 |              |                        |     |     |    |      |  |   |
|     | 47680 |              |                        |     |     |    |      |  |   |
| 264 | 22660 | 0000111466-0 | 1466-0 octene          | no  | yes | no | 15   |  |   |
| 265 | 22600 | 0000111487-5 | 1487-5 octanol         | no  | yes | no |      |  |   |
| 266 | 25510 | 0000112427-6 | 1427-6 ethylene glycol | yes | no  |    |      |  |   |
|     | 94320 |              |                        |     |     |    |      |  |   |
| 267 | 15100 | 0000112430-1 | 1430-1 decanol         | no  | yes | no |      |  |   |
| 268 | 16704 | 0000112441-4 | 1441-4 dodecene        | no  | yes | no | 0,05 |  |   |
| 269 | 25090 | 0000112607-7 | 1607-7 ethylene glycol | yes | no  |    |      |  |   |
|     | 92350 |              |                        |     |     |    |      |  |   |

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|     |       |         |  |     |     |    |      |      |   |      |
|-----|-------|---------|--|-----|-----|----|------|------|---|------|
| 270 | 22763 | 0000112 | 2801 acid  | yes | yes | no |      |      |   |      |
|     | 69040 |         | acid   |     |     |    |      |      |   |      |
| 271 | 52720 | 0000112 | 2845 amides  | yes | no  | no |      |      |   |      |
| 272 | 37040 | 0000112 | 2856 benzoic acid                                    | yes | no  | no |      |      |   |      |
| 273 | 52730 | 0000112 | 2867 acetic acid                                     | yes | no  | no |      |      |   |      |
| 274 | 22570 | 0000112 | 2869 decyl isocyanate                                | no  | yes | no |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 275 | 23980 | 0000115 | 2907 polyethylene                                    | no  | yes | no |      |      |   |      |
| 276 | 19000 | 0000115 | 2918 polybutene                                      | no  | yes | no |      |      |   |      |
| 277 | 18280 | 0000115 | 2927 chloroendomethylenetetrahydrophthalic anhydride | yes | no  | no |      |      |   |      |
| 278 | 18250 | 0000115 | 2928 chloroendomethylenetetrahydrophthalic acid      | yes | no  | no |      |      |   |      |
| 279 | 22840 | 0000115 | 2975 pentaerythritol                                 | yes | no  | no |      |      |   |      |
|     | 71600 |         |  |     |     |    |      |      |   |      |
| 280 | 73720 | 0000115 | 2988 phosphoric acid, trichloroethyl ester           | yes | no  | no | ND   |      |   |      |
| 281 | 25120 | 0000116 | 3143 tetrafluoroethylene                             | yes | no  | no | 0,05 |      |   |      |
| 282 | 18430 | 0000116 | 3154 hexafluoropropylene                             | yes | no  | no | ND   |      |   |      |
| 283 | 74640 | 0000117 | 3171 phthalic acid, bis(2-                           | yes | no  | no | 1,5  | (32) | Only to be  | (7)  |

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|     |       |         |  |     |    |     |     |                 |  |
|-----|-------|---------|--|-----|----|-----|-----|-----------------|--|
|     |       |         | ethylhexyl ester                                 |     |    |     |     | used as:<br>(a) | plasticiser in repeated use materials and articles contacting non-fatty foods; technical support agent in concentrations up to 0,1 % in the final product. |
| 284 | 84880 | 0000119 | salic acid, methyl ester                         | yes | no | no  | 30  |                 |  |
| 285 | 66480 | 0000119 | 247-1 methylene bis(4-methyl-6-tert-butylphenol) | yes | no | yes |     | (13)            |  |
| 286 | 38240 | 0000119 | benzophenone                                     | no  | no | yes | 0,6 |                 |  |

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|     |       |              |                                   |     |     |    |     |      |                              |
|-----|-------|--------------|-----------------------------------|-----|-----|----|-----|------|------------------------------|
| 287 | 60160 | 0000120447-8 | hydroxybenzoic acid, ethyl ester  | yes | no  | no |     |      |                              |
| 288 | 24970 | 0000120614-9 | terephthalic acid, dimethyl ester | yes | no  |    |     |      |                              |
| 289 | 15880 | 0000120180-9 | 1,2-dihydroxybenzene              | no  | yes | no | 6   |      |                              |
|     | 24051 |              |                                   |     |     |    |     |      |                              |
| 290 | 55360 | 0000121701-9 | terephthalic acid, propyl ester   | yes | no  | no |     | (20) |                              |
| 291 | 19150 | 0000121101-5 | isophthalic acid                  | yes | no  |    |     | (27) |                              |
| 292 | 94560 | 0000122410-3 | propylamine                       | yes | no  | no | 5   |      |                              |
| 293 | 23175 | 0000122512-5 | phosphoric acid, triethyl ester   | yes | no  | no | ND  |      | 1 mg/kg in final product (1) |
| 294 | 93120 | 0000123428-4 | propionic acid, didodecyl ester   | no  | yes | no |     | (14) |                              |
| 295 | 15940 | 0000123434-9 | 1,2-dihydroxybenzene              | yes | yes | no | 0,6 |      |                              |
|     | 18867 |              |                                   |     |     |    |     |      |                              |
|     | 48620 |              |                                   |     |     |    |     |      |                              |
| 296 | 23860 | 0000123386-6 | propionaldehyde                   | yes | no  | no |     |      |                              |
| 297 | 23950 | 0000123602-6 | phthalic anhydride                | no  | yes | no |     |      |                              |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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**e** OJ L 158, 18.6.2008, p. 17.

**f** [F<sup>2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

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**h** [F<sup>3</sup>OJ L 83, 22.3.2012, p. 1.]



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|     |       |             |                               |     |     |    |      |  |
|-----|-------|-------------|-------------------------------|-----|-----|----|------|--|
| 298 | 14110 | 00001235728 | 5728 aldehyde                 | yes | no  |    |      |  |
| 299 | 63840 | 00001235611 | 5611 lnicic acid              | yes | no  | no |      |  |
| 300 | 30045 | 00001238614 | 8614 acid, butyl ester        | yes | no  | no |      |  |
| 301 | 89120 | 00001239515 | 9515 acic acid, butyl ester   | yes | no  | no |      |  |
| 302 | 12820 | 00001239916 | 9916 acic acid                | no  | yes | no |      |  |
| 303 | 12130 | 00001244119 | 4419 acic acid                | yes | yes | no |      |  |
|     | 31730 |             |                               |     |     |    |      |  |
| 304 | 14320 | 00001240721 | 0721 acic acid                | yes | yes | no |      |  |
|     | 41960 |             |                               |     |     |    |      |  |
| 305 | 15274 | 00001240924 | 0924 methylenediamine         | yes | no  | no | 2,4  |  |
|     | 18460 |             |                               |     |     |    |      |  |
| 306 | 88960 | 00001245615 | 5615 amides                   | yes | no  | no |      |  |
| 307 | 42160 | 00001243810 | 3810 lead dioxide             | yes | no  | no |      |  |
| 308 | 91200 | 00001263116 | 3116 acetate isobutyrate      | yes | no  | no |      |  |
| 309 | 91360 | 00001263417 | 3417 octaacetate              | yes | no  | no |      |  |
| 310 | 16390 | 00001262317 | 2317 dimethyl-1,3-propanediol | no  | yes | no | 0,05 |  |
|     | 22437 |             |                               |     |     |    |      |  |
| 311 | 16480 | 00001265819 | 5819 erythritol               | yes | no  |    |      |  |

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|-----|-------|--------------|------------------------------|-----|-----|-----|-----|--|--|
|     | 51200 |              |                              |     |     |     |     |  |  |
| 312 | 21490 | 00001269815  | acrylonitrile                | yes | no  | ND  |     |  |  |
| 313 | 16650 | 00001274639  | phenylsulphone               | yes | no  | 3   |     |  |  |
|     | 51570 |              |                              |     |     |     |     |  |  |
| 314 | 23500 | 0000127991-3 | pinene                       | no  | yes | no  |     |  |  |
| 315 | 46640 | 0000128236-0 | tert-butyl-p-cresol          | yes | no  | no  | 3   |  |  |
| 316 | 23230 | 0000131791   | phthalic acid, diallyl ester | no  | yes | no  | ND  |  |  |
| 317 | 48880 | 0000131253-3 | 4-methoxybenzophenone        | yes | no  | yes | (8) |  |  |
| 318 | 48640 | 0000131256-6 | 4-methoxybenzophenone        | yes | no  | no  | (8) |  |  |
| 319 | 61360 | 0000131257-7 | 4-methoxybenzophenone        | yes | no  | yes | (8) |  |  |
| 320 | 37680 | 0000136607   | azobutyl ester               | yes | no  | no  |     |  |  |
| 321 | 36080 | 0000137660   | butyl palmitate              | yes | no  | no  |     |  |  |
| 322 | 63040 | 0000138121-7 | azobutyl ester               | yes | no  | no  |     |  |  |

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|-----|-------|---------|---------------------------------------|-----|-----|-----|------|------|--|--|
| 323 | 11470 | 0000140 | 088-11<br>Fatty acid,<br>ethyl ester  | no  | yes | no  |      | (22) |  |  |
| 324 | 83700 | 0000141 | 23-01<br>Fatty acid                   | yes | no  | yes | 42   |      |  |  |
| 325 | 10780 | 0000141 | 32-11<br>Fatty acid,<br>n-butyl ester | no  | yes | no  |      | (22) |  |  |
| 326 | 12763 | 0000141 | 243-5<br>aminoethanol                 | yes | yes | no  | 0,05 |      | Not to be used for articles in contact with fatty foods for which simulant D is laid down. For indirect food contact only, behind a PET layer. |  |
|     | 35170 |         |                                       |     |     |     |      |      |  |  |
| 327 | 30140 | 0000141 | 78-11<br>Fatty acid,                  | yes | no  | no  |      |      |  |  |

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|---------------------|-------|----------------------|---------------------------|-----|-----|----|------|--|---|
|                     |       |                      | ethyl ester               |     |     |    |      |  |   |
| 328                 | 65040 | 000014182-1          | undecanoic acid           | yes | no  | no |      |  |   |
| 329                 | 59360 | 000014262-1          | heptanoic acid            | yes | no  | no |      |  |   |
| 330                 | 19470 | 000014310-7<br>63280 | undecanoic acid           | yes | yes | no |      |  |   |
|                     |       |                      |                           |     |     |    |      |  |   |
| 331                 | 22480 | 000014310-8          | nonanol                   | no  | yes | no |      |  |   |
| 332                 | 69760 | 000014328-2          | ethyl alcohol             | yes | no  | no |      |  |   |
| 333                 | 22775 | 000014462-1<br>69920 | undecanoic acid           | yes | yes | no | 6    |  |   |
|                     |       |                      |                           |     |     |    |      |  |   |
| 334                 | 17005 | 000015156-4          | ethyleneimine             | yes | yes | no | ND   |  |   |
| 335                 | 68960 | 000030102-0          | oleamide                  | yes | no  | no |      |  |   |
| 336                 | 15095 | 000033448-5<br>45940 | decanoic acid             | yes | yes | no |      |  |   |
|                     |       |                      |                           |     |     |    |      |  |   |
| 337                 | 15820 | 000034542-6          | 4,4'-difluorobenzophenone | no  | yes | no | 0,05 |  |   |
| 338                 | 71020 | 000037340-1          | undecanoic acid           | yes | no  | no |      |  |   |
| 339                 | 86160 | 000040951-2          | silicon carbide           | yes | no  | no |      |  |   |
| [ <sup>F7</sup> 340 | 47440 | 000046158-5          | diacrylamide              | no  | no  | no | 60   |  | ] |
| 341                 | 13180 | 000049866-8<br>22550 | 1,2-dibromoethane         | no  | no  | no | 0,05 |  |   |
|                     |       |                      |                           |     |     |    |      |  |   |
| 342                 | 14260 | 000050241-1          | ε-caprolactone            | yes | no  |    | (29) |  |   |

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|---------------------|-----------------|--------------|----------------------------------|-----|----|------|----------|---|------|
| 343                 | 23770           | 0000504163-2 | no<br>propanediol                | yes | no | 0,05 |          |   |      |
| [ <sup>F4</sup> 344 | 13810<br>21821] | 0000505165-7 | no<br>butanediol<br>formal       | yes | no | 0,05 | 15<br>30 |   | (21) |
| 345                 | 35840           | 0000506300-9 | yes<br>acid                      | no  | no |      |          |   |      |
| 346                 | 10030           | 0000514100-0 | no<br>acid                       | yes | no |      |          |   |      |
| 347                 | 13050<br>25540  | 0000528410-9 | no<br>acid                       | yes | no |      | (21)     |   |      |
| 348                 | 22350<br>67891  | 0000544162-8 | yes<br>acid                      | yes | no |      |          |   |      |
| 349                 | 25550           | 0000552110-7 | no<br>anhydride                  | yes | no |      | (21)     |   |      |
| 350                 | 63920           | 0000557150-6 | yes<br>acid                      | no  | no |      |          |   |      |
| 351                 | 21730           | 0000563345-1 | no<br>methyl-1-<br>butene        | yes | no | ND   |          | Only<br>to be<br>used<br>in<br>polypropylene    | (1)  |
| 352                 | 16360           | 0000576226-1 | no<br>dimethylphenol             | yes | no | 0,05 |          |   |      |
| 353                 | 42480           | 0000584008-0 | yes<br>acid,<br>rubidium<br>salt | no  | no | 12   |          |   |      |
| 354                 | 25210           | 0000584284-9 | no<br>toluene<br>diisocyanate    | yes | no |      | (17)     | 1 mg/<br>kg in<br>final<br>product<br>expressed | (10) |

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

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|     |                |         |  |     |     |    |      |      | as isocyanate moiety  |     |
|-----|----------------|---------|--|-----|-----|----|------|------|---|-----|
| 355 | 20170          | 0000585 | 0716-0716 acrylic acid, tert-butyl ester | no  | yes | no |      | (23) |   |     |
| 356 | 18820          | 0000592 | 141-6 hexene                             | no  | yes | no | 3    |      |   |     |
| 357 | 13932          | 0000598 | 332-3 buten-2-ol                         | no  | yes | no | ND   |      | Only to be used as a co-monomer for the preparation of polymeric additive | (1) |
| 358 | 14841          | 0000599 | 464-4 cumylphenol                        | no  | yes | no | 0,05 |      |   |     |
| 359 | 15970<br>48720 | 0000614 | 49-4 dihydroxybenzophenone               | yes | yes | no |      | (8)  |   |     |
| 360 | 57920          | 0000620 | 677-7 glycerol triheptanoate             | yes | no  | no |      |      |   |     |
| 361 | 18700          | 0000629 | 11-8 hexanediol                          | no  | yes | no | 0,05 |      |   |     |
| 362 | 14350          | 0000630 | 08-0 carbon monoxide                     | no  | yes | no |      |      |   |     |
| 363 | 16450          | 0000646 | 106-0 dioxolane                          | no  | yes | no | 5    |      |   |     |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|---------------------|---|----------------|----|-----|----|---|--|---------------------|---|
| [ <sup>F4</sup> 364 | 15404   | 0000652167-36- | no | yes | no | 5 |  | Only to be used as: | ] a co-monomer in poly(ethylene-co-isosorbide terephthalate); (b) a co-monomer at levels of up to 40 mole % of the diol component in combination with ethylene glycol and/or 1,4-bis(hydroxymethyl)cyclohexane for the production |
| <b>a</b>            | OJ L 302, 19.11.2005, p. 28.  |                |    |     |    |   |  |                     |   |
| <b>b</b>            | OJ L 330, 5.12.1998, p. 32.   |                |    |     |    |   |  |                     |   |
| <b>c</b>            | OJ L 253, 20.9.2008, p. 1.  |                |    |     |    |   |  |                     |   |
| <b>d</b>            | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |                |    |     |    |   |  |                     |   |
| <b>e</b>            | OJ L 158, 18.6.2008, p. 17.   |                |    |     |    |   |  |                     |   |
| <b>f</b>            | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |                |    |     |    |   |  |                     |   |
| <b>g</b>            | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |                |    |     |    |   |  |                     |   |
| <b>h</b>            | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |                |    |     |    |   |  |                     |   |

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|-----|-------|---------|---|----|-----|----|------|------|--|--|
|     |       |         |   |    |     |    |      |      |  | of polyesters.<br>Polyesters made using dianhydrosorbitol together with 1,4-bis(hydroxymethyl)cyclohexane shall not be used in contact with foods containing more than 15 % alcohol. |
| 365 | 11680 | 0000689 | 142-1-10<br>adipic acid, isopropyl ester    | no | yes | no |      | (22) |  |  |
| 366 | 22150 | 0000691 | 1437-2<br>methyl-1-pentene                  | no | yes | no | 0,05 |      |  |  |
| 367 | 16697 | 0000693 | 1423-2<br>dodecanedioic acid                | no | yes | no |      |      |  |  |
| 368 | 93280 | 0000693 | 1407-1<br>propionic acid, dioctadecyl ester | no | yes | no |      | (14) |  |  |

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|---------------------|-------|---------|--|-----|-----|----|------|------|---|------|
| 369                 | 12761 | 0000693 | 127-2  | no  | yes | no | 0,05 |      |   |      |
|                     |       |         | aminododecanoic acid                             |     |     |    |      |      |   |      |
| 370                 | 21460 | 0000760 | 093-0  | no  | yes | no |      | (23) |   |      |
|                     |       |         | butylacrylic anhydride                           |     |     |    |      |      |   |      |
| 371                 | 11510 | 0000818 | 61-1   | no  | yes | no |      | (22) |   |      |
|                     | 11830 |         | acrylic acid, monoester with ethyleneglycol      |     |     |    |      |      |   |      |
| 372                 | 18640 | 0000822 | 206-0  | no  | yes | no |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
|                     |       |         | hexamethylene diisocyanate                       |     |     |    |      |      |   |      |
| 373                 | 22390 | 0000840 | 266-3  | no  | yes | no | 0,05 |      |   |      |
|                     |       |         | naphthalenedicarboxylic acid, dimethyl ester     |     |     |    |      |      |   |      |
| 374                 | 21190 | 0000868 | 77-0   | no  | yes | no |      | (23) |   |      |
|                     |       |         | butylacrylic acid, monoester with ethyleneglycol |     |     |    |      |      |   |      |
| 375                 | 15130 | 0000872 | 2405-9   | no  | yes | no | 0,05 |      |   |      |
|                     |       |         | decene   |     |     |    |      |      |   |      |
| [ <sup>F6</sup> 376 | 66905 | 0000872 | 250-4  | yes | no  | no | 60   |      |   | I    |
|                     |       |         | methylpyrrolidone                                |     |     |    |      |      |   |      |
| 377                 | 12786 | 0000919 | 330-2  | no  | yes | no | 0,05 |      | Residual extractable content                            |      |
|                     |       |         | aminopropyltriethoxysilane                       |     |     |    |      |      |   |      |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

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|-----|-------|---------|------------------------------------|----|-----|----|------|------|---|
|     |       |         |                                    |    |     |    |      |      | of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler when used for the reactive surface treatment of inorganic fillers. SML = 0,05 mg/kg when used for the surface treatment of materials and articles. |
| 378 | 21970 | 0000923 | 202-4<br>methylmethacrylamide      | no | yes | no | 0,05 |      |   |
| 379 | 21940 | 0000924 | 442-5<br>methylolacrylamide        | no | yes | no | ND   |      |   |
| 380 | 11980 | 0000925 | 66-1<br>acrylic acid, propyl ester | no | yes | no |      | (22) |   |
| 381 | 15030 | 0000931 | 88-4<br>1,8-dioxane                | no | yes | no | 0,05 |      | Only to be  |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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**Status:** Point in time view as at 26/02/2015.

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|     |       |              |  |     |     |     |      |  | used<br>in<br>polymers<br>contacting<br>foods<br>for<br>which<br>simulant<br>A is<br>laid<br>down                              |
|-----|-------|--------------|--|-----|-----|-----|------|--|--|
| 382 | 19490 | 0000947104-6 | 4-oxo-2-oxo-1,2,3,4-tetrahydro-6H-pyridin-6(1H)-one                        | yes | no  | 5   |      |  |  |
| 383 | 72160 | 0000948265-2 | 2-(2-phenylindol-3-yl)propanoic acid                                       | yes | no  | yes | 15   |  |  |
| 384 | 40000 | 0000991284-4 | 4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine | yes | no  | yes | 30   |  |  |
| 385 | 11530 | 0000999a61   | acrylic acid, 2-hydroxypropyl ester  | no  | yes | no  | 0,05 |  | SML (1) expressed as the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester. It may contain |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

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|     |       |         |                                       |     |     |    |      |      |   |     |
|-----|-------|---------|---------------------------------------|-----|-----|----|------|------|---|-----|
|     |       |         |                                       |     |     |    |      |      | up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 0002918-23-2). |     |
| 386 | 55280 | 0001034 | allilic acid, octyl ester             | yes | no  | no |      | (20) |   |     |
| 387 | 26155 | 0001072 | 2163-5 vinylimidazole                 | no  | yes | no | 0,05 |      |   | (1) |
| 388 | 25080 | 0001120 | 436-1 tetradecene                     | no  | yes | no | 0,05 |      |   |     |
| 389 | 22360 | 0001141 | 238-4 naphthalenedicarboxylic acid    | no  | yes | no | 5    |      |   |     |
| 390 | 55200 | 0001166 | 5215 acid, dodecyl ester              | yes | no  | no |      | (20) |   |     |
| 391 | 22932 | 0001187 | 235 fluoromethyl perfluorovinyl ether | yes | no  | no | 0,05 |      | Only to be used in anti-stick coatings  |     |
| 392 | 72800 | 0001241 | 194-7 phosphonic acid,                | no  | yes | no | 2,4  |      |   |     |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|     |       |              |                                       |     |     |    |      |  |  |
|-----|-------|--------------|---------------------------------------|-----|-----|----|------|--|--|
|     |       |              | diphenyl<br>2-<br>ethylhexyl<br>ester |     |     |    |      |  |  |
| 393 | 37280 | 000130257810 | benzoin<br>resin                      | yes | no  | no |      |  |  |
| 394 | 41280 | 000130561210 | barium<br>hydroxide                   | yes | no  | no |      |  |  |
| 395 | 41520 | 000130571810 | barium<br>oxide                       | yes | no  | no |      |  |  |
| 396 | 64640 | 000130914210 | barium<br>hydroxide                   | yes | no  | no |      |  |  |
| 397 | 64720 | 000130914810 | barium<br>oxide                       | yes | no  | no |      |  |  |
| 398 | 35760 | 000130926110 | antimony<br>trioxide                  | yes | no  | no | 0,04 |  | SML (6)<br>expressed<br>as<br>antimony   |
| 399 | 81600 | 000131058310 | potassium<br>hydroxide                | yes | no  | no |      |  |  |
| 400 | 86720 | 000131057110 | potassium<br>hydroxide                | yes | no  | no |      |  |  |
| 401 | 24475 | 000131388110 | zinc<br>sulphide                      | no  | yes | no |      |  |  |
| 402 | 96240 | 000131421110 | zinc<br>oxide                         | yes | no  | no |      |  |  |
| 403 | 96320 | 000131428310 | zinc<br>sulphide                      | yes | no  | no |      |  |  |
| 404 | 67200 | 000131733110 | polybenzen<br>disulphide              | yes | no  | no |      |  |  |
| 405 | 16690 | 000132174110 | styrene<br>monomer                    | yes | no  | no | ND   |  | SML (1)<br>expressed<br>as the<br>sum of |

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**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|                      |       |               |                              |     |    |    |      |  |   |
|----------------------|-------|---------------|------------------------------|-----|----|----|------|--|---|
|                      |       |               |                              |     |    |    |      |  | divinylbenzene and ethylvinylbenzene. It may contain up to 45 % (m/m) of ethylvinylbenzene.                         |
| 406                  | 83300 | 00013323432-3 | propyleneglycol monostearate | yes | no | no |      |  |   |
| 407                  | 87040 | 00013330614   | sodium tetraborate           | yes | no | no | (16) |  |   |
| 408                  | 82960 | 0001330482-9  | propyleneglycol monooleate   | yes | no | no |      |  |   |
| 409                  | 62240 | 0001332137-2  | oxide                        | yes | no | no |      |  |   |
| [ <sup>F4</sup> 410] | 62720 | 000133245817  |                              | yes | no | no |      |  | Particles] can be thinner than 100 nm only if incorporated at a quantity of less than 12 % w/w in an ethylene vinyl |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|-----|-------|---------|--------------|-----|----|----|--|--|--|
|     |       |         |              |     |    |    |  |  | alcohol copolymer (EVOH) inner layer of a multi-layer structure, in which the layer in direct contact with the food provides a functional barrier preventing migration of particles into the food. |
| 411 | 42080 | 0001333 | beaten black | yes | no | no |  |  | Primary particles of 10 – 300 nm which are aggregated to a   |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

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|          |   |  |  |  |  |  |  |  |   |
|----------|---|--|--|--|--|--|--|--|---|
|          |   |  |  |  |  |  |  |  | size of<br>100 –<br>1 200<br>nm<br>which<br>may<br>form<br>agglomerates<br>within<br>the<br>size<br>distribution<br>of 300<br>nm –<br>mm.<br>Toluene<br>extractables:<br>maximum<br>0,1 %,<br>determined<br>according<br>to ISO<br>method<br>6209.<br>UV<br>absorption<br>of<br>cyclohexane<br>extract<br>at 386<br>nm: <<br>0,02<br>AU<br>for a<br>1 cm<br>cell or<br>< 0,1<br>AU<br>for a<br>5 cm |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |  |  |  |  |  |  |  |   |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |  |  |  |  |  |  |  |   |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |  |  |  |  |  |  |  |   |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |  |  |  |  |  |  |   |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |  |  |  |  |  |  |  |   |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |  |  |  |  |  |  |   |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |  |  |  |  |  |  |   |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |  |  |  |  |  |  |   |



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|     |       |         |                         |     |    |    |  |     |  |
|-----|-------|---------|-------------------------|-----|----|----|--|-----|--|
|     |       |         |                         |     |    |    |  |     | cell, determined according to a generally recognised method of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of carbon black in the polymer: 2,5 % w/w. |
| 412 | 45200 | 0001335 | 235 copper iodide       | yes | no | no |  | (6) |  |
| 413 | 35600 | 0001336 | 216 antimony hydroxide  | yes | no | no |  |     |  |
| 414 | 87600 | 0001338 | 061 sodium monolaurate  | yes | no | no |  |     |  |
| 415 | 87840 | 0001338 | 011 sodium monostearate | yes | no | no |  |     |  |
| 416 | 87680 | 0001338 | 011 sodium monooleate   | yes | no | no |  |     |  |

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**c** OJ L 253, 20.9.2008, p. 1.

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|                     |       |         |  |     |     |     |      |      |   |
|---------------------|-------|---------|--|-----|-----|-----|------|------|---|
| 417                 | 85680 | 0001343 | 18-2<br>sulfuric acid                  | yes | no  | no  |      |      |   |
| 418                 | 34720 | 0001344 | 28-1<br>zinc oxide                     | yes | no  | no  |      |      |   |
| 419                 | 92150 | 0001401 | 55-4<br>fatty acids                    | yes | no  | no  |      |      | According to the JECFA specifications                                   |
| 420                 | 19210 | 0001459 | 03-4<br>phthalic acid, dimethyl ester  | yes | no  | no  | 0,05 |      |   |
| [ <sup>F7</sup> 421 | 13000 | 0001477 | 53-0<br>benzenedimethanamine           | no  | yes | no  |      | (34) | I   |
| 422                 | 38515 | 0001533 | 45-5<br>bis(2-benzoxazolyl)stilbene    | yes | no  | yes | 0,05 |      | (2)   |
| 423                 | 22937 | 0001623 | 05-8<br>isopropylperfluorovinyl ether  | yes | no  | no  | 0,05 |      |   |
| 424                 | 15070 | 0001647 | 16-1<br>decadiene                      | no  | yes | no  | 0,05 |      |   |
| 425                 | 10840 | 0001663 | 09-4<br>acrylic acid, tert-butyl ester | no  | yes | no  |      | (22) |   |
| 426                 | 13510 | 0001675 | 21-3<br>bis(4-hydroxyphenyl)propane    | no  | yes | no  |      |      | In compliance with Commission Regulation (EC) No 1895/2005 <sup>a</sup> |
|                     | 13610 |         | bis(2,3-epoxypropyl) ether             |     |     |     |      |      |   |

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**b** OJ L 330, 5.12.1998, p. 32.

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|-----|-------|----------|--|-----|-----|-----|------|-----|--|--|
| 427 | 18896 | 00016794 | 51-2<br>(hydroxymethyl)-1-cyclohexene                      | no  | yes | no  | 0,05 |     |  |  |
| 428 | 95200 | 00017091 | 70-5<br>tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene     | yes | no  | no  |      |     |  |  |
| 429 | 13210 | 00017615 | 73-4<br>aminocyclohexylmethane                             | no  | yes | no  | 0,05 |     |  |  |
| 430 | 95600 | 00018431 | 08-34<br>tris(2-methyl-4-hydroxy-5-tert-butylphenyl)butane | yes | no  | yes | 5    |     |  |  |
| 431 | 61600 | 00018432 | 05-6<br>hydroxy-4-n-octyloxybenzophenone                   | yes | no  | yes |      | (8) |  |  |
| 432 | 12280 | 00020354 | 75-8<br>anhydride  | no  | yes | no  |      |     |  |  |
| 433 | 68320 | 00020826 | 70-1<br>3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate    | yes | no  | yes | 6    |     |  |  |
| 434 | 20410 | 00020828 | 17-1<br>acrylic acid, diester with 1,4-butanediol          | yes | yes | no  | 0,05 |     |  |  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

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|---------------------|-------|----------|--|-----|-----|----|------|------|--|------|
| 435                 | 14230 | 00021232 | 2,4-dichlorobenzaldehyde sodium salt   | no  | yes | no |      | (4)  |  |      |
| 436                 | 19480 | 00021461 | maleic acid, vinyl ester               | no  | yes | no |      |      |  |      |
| 437                 | 11245 | 00021560 | maleic acid, dodecyl ester             | no  | yes | no | 0,05 |      |  | (2)  |
| [ <sup>F6</sup> 438 | 13303 | 00021625 | bis(2,6-diisopropylphenyl)carbodiimide | no  | yes | no | 0,05 |      | Expressed as the sum of bis(2,6-diisopropylphenyl)carbodiimide and its hydrolysis product 2,6-diisopropylaniline |      |
| 439                 | 21280 | 00021777 | methacrylic acid, phenyl ester         | no  | yes | no |      | (23) |  |      |
| 440                 | 21340 | 00022102 | methacrylic acid, propyl ester         | no  | yes | no |      | (23) |  |      |
| 441                 | 38160 | 00023156 | benzoic acid, propyl ester             | yes | no  | no |      |      |  |      |
| 442                 | 13780 | 00024251 | 1,4-butanediol                         | no  | yes | no | ND   |      | Residual content = 1   | (10) |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|                     |       |              | bis(2,3-epoxypropyl)ether             |     |     |    |      | mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da. |   |
|---------------------|-------|--------------|---------------------------------------|-----|-----|----|------|--|---|
| 443                 | 12788 | 0002432199-7 | aminoundecanoic acid                  | no  | yes | no | 5    |  |   |
| 444                 | 61440 | 0002440222-4 | hydroxy-5'-methylphenyl)benzotriazole | yes | no  | no | (12) |  |   |
| 445                 | 83440 | 0002466993   | phosphoric acid                       | no  | yes | no |      |  |   |
| 446                 | 10750 | 0002495354   | acrylic acid, benzyl ester            | no  | yes | no | (22) |  |   |
| 447                 | 20080 | 0002495376   | acrylic acid, benzyl ester            | no  | yes | no | (23) |  |   |
| 448                 | 11890 | 0002499554   | acrylic acid, n-octyl ester           | no  | yes | no | (22) |  |   |
| [ <sup>F5</sup> 449 | 49840 | 0002500886   | octadecyl disulphide                  | no  | yes | no | 0,05 |  | ] |
| 450                 | 24430 | 0002561888   | Basic anhydride                       | no  | yes | no |      |  |   |

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

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|                     |       |         |       |     |     |    |      |      |  |      |
|---------------------|-------|---------|-------|-----|-----|----|------|------|--|------|
| 451                 | 66755 | 0002682 | 220-4 | yes | no  | no | 0,5  |      | Only to be used in aqueous polymer dispersions and emulsions |      |
| [ <sup>F6</sup> 452 | 38885 | 0002725 | 224-6 | yes | no  | no | 5    |      |  | ] ]  |
| 453                 | 26320 | 0002768 | 0027  | no  | yes | no | 0,05 |      |  | (10) |
| 454                 | 12670 | 0002855 | 113-2 | no  | yes | no | 6    |      |  |      |
| 455                 | 20530 | 0002867 | 4512  | yes | no  | no | ND   |      |  |      |
| 456                 | 10810 | 0002998 | 0087  | no  | yes | no |      | (22) |  |      |
| 457                 | 20140 | 0002998 | 1817  | yes | no  | no |      | (23) |  |      |

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

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d [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|     |       |               |  |     |     |     |      |   |   |      |
|-----|-------|---------------|--|-----|-----|-----|------|---|---|------|
|     |       |               | butyl ester  |     |     |     |      |   |   |      |
| 458 | 36960 | 0003061       | benzamide  | no  | no  |     |      |   |   |      |
| 459 | 46870 | 0003135318-01 | tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester | yes | no  | no  |      |   |   |      |
| 460 | 14950 | 00031735313   | hexyl isocyanate   | yes | no  |     | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10)  |      |
| 461 | 22420 | 0003173472-6  | naphthalene diisocyanate                                     | no  | yes | no  |      | (17)  | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 462 | 26170 | 0003195178-6  | vinyl-N-methylacetamide                                      | no  | yes | no  | 0,02 |   |   | (1)  |
| 463 | 25840 | 0003290192-4  | trimethylolpropane trimethacrylate                           | no  | yes | no  | 0,05 |   |   |      |
| 464 | 61280 | 0003293297-8  | hydroxy-4-   | yes | no  | yes |      | (8)   |   |      |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|     |       |              |  |     |     |     |      |      |   |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|
|     |       |              | n-hexyloxybenzophenone   |     |     |     |      |      |   |
| 465 | 68040 | 00033337621  | 1-naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin                | yes | no  | no  |      |      |   |
| 466 | 50640 | 0003648188   | 1-octyltin dilaurate   | yes | no  | no  |      | (10) |   |
| 467 | 14800 | 0003724660   | 4-hydroxybenzoic acid  | yes | yes | no  | 0,05 |      | (1)   |
|     | 45600 |              |  |     |     |     |      |      |   |
| 468 | 71960 | 000382526    | 26-fluorocyclohexanoic acid, ammonium salt                     | no  | no  | no  |      |      | Only to be used in repeated use articles, sintered at high temperatures |
| 469 | 60480 | 000386429021 | 2-hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole      | yes | no  | yes |      | (12) |   |
| 470 | 60400 | 000389621025 | 2-hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole | yes | no  | yes |      | (12) |   |
| 471 | 24888 | 0003965555-7 | 5-sulphoisophthalic  | no  | yes | no  | 0,05 |      |   |

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**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|     |       |               |  |     |     |     |     |      |  |      |
|-----|-------|---------------|--|-----|-----|-----|-----|------|--|------|
|     |       |               | acid,<br>monosodium<br>salt,<br>dimethyl<br>ester        |     |     |     |     |      |  |      |
| 472 | 66560 | 0004066202-8  | methylenebis(4-methyl-6-cyclohexylphenol)                | yes | no  | yes |     | (5)  |  |      |
| 473 | 12265 | 0004074401-2  | acid,<br>divinyl<br>ester                                | no  | yes | no  | ND  |      | 5 mg/<br>kg in<br>final<br>product.<br>Only<br>to be<br>used<br>as co-<br>monomer. | (1)  |
| 474 | 43600 | 000408043(3-3 | chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride    | yes | no  | no  | 0,3 |      |  |      |
| 475 | 19110 | 0004098171-9  | isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane | no  | yes | no  |     | (17) | 1 mg/<br>kg in<br>final<br>product<br>expressed<br>as<br>isocyanate<br>moiety      | (10) |
| 476 | 16570 | 0004128471-8  | diisocyanate   | no  | yes | no  |     | (17) | 1 mg/<br>kg in<br>final<br>product<br>expressed<br>as                              | (10) |

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**c** OJ L 253, 20.9.2008, p. 1.

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|     |       |            |  |     |     |     |      |      | isocyanate moiety                                |     |
|-----|-------|------------|--|-----|-----|-----|------|------|--|-----|
| 477 | 46720 | 0004130246 | 2,4-di-tert-butyl-4-ethylphenol  | yes | no  | yes | 4,8  |      |  | (1) |
| 478 | 60180 | 0004191473 | 5-hydroxybenzoic acid, isopropyl ester                                 | yes | no  | no  |      |      |  |     |
| 479 | 12970 | 0004196261 | 6-aminocaproic anhydride   | no  | yes | no  |      |      |  |     |
| 480 | 46790 | 0004221380 | 2,4-di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester | yes | no  | no  |      |      |  |     |
| 481 | 13060 | 0004422195 | 5-benzenetricarboxylic acid trichloride                                | no  | yes | no  | 0,05 |      | SML expressed as 1,3,5-benzenetricarboxylic acid | (1) |
| 482 | 21100 | 0004655349 | methacrylic acid, isopropyl ester                                      | yes | no  | no  |      | (23) |  |     |
| 483 | 68860 | 0004724448 | 5-octylphosphonic acid   | yes | no  | no  | 0,05 |      |  |     |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|     |       |              |   |     |     |    |      |      |   |      |
|-----|-------|--------------|---|-----|-----|----|------|------|---|------|
| 484 | 13395 | 0004767203-7 | bis(hydroxymethyl)propionic acid            | no  | yes | no | 0,05 |      |   | (1)  |
| 485 | 13560 | 000512430-1  | 4,4'-dihydroxydiphenylmethane diisocyanate  | no  | no  | no |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
|     | 15700 |              |   |     |     |    |      |      |   |      |
| 486 | 54005 | 000513644-1  | N-palmitamide-N'-stearamide                 | yes | no  | no |      |      |   |      |
| 487 | 45640 | 000523229-5  | cyano-3,3-diphenylacrylic acid, ethyl ester | yes | no  | no | 0,05 |      |   |      |
| 488 | 53440 | 000551818-3  | ethylenebispalmitamide                      | yes | no  | no |      |      |   |      |
| 489 | 41040 | 000574346-2  | butyrate                                    | yes | no  | no |      |      |   |      |
| 490 | 16600 | 000587345-1  | 4,4'-dihydroxydiphenylmethane diisocyanate  | no  | no  | no |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |

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|     |       |          |      |   |    |    |      |  |  |                                      |
|-----|-------|----------|------|---|----|----|------|--|--|--------------------------------------|
| 491 | 82720 | 00061824 | 11-2 | yes<br>propyleneglycol distearate   | no | no |      |  |  |                                      |
| 492 | 45650 | 00061972 | 30-4 | yes<br>cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester                       | no | no | 0,05 |  |  |                                      |
| 493 | 39200 | 00062004 | 40-2 | yes<br>hydroxyethyl-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride       | no | no | 1,8  |  |  |                                      |
| 494 | 62140 | 00063033 | 1-5  | no<br>hypophosphorous acid  | no | no |      |  |  |                                      |
| 495 | 35160 | 00066426 | 31-5 | yes<br>amino-1,3-dimethyluracil   | no | no | 5    |  |  |                                      |
| 496 | 71680 | 00066831 | 10-8 | no<br>pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate] | no | no |      |  |  |                                      |
| 497 | 95020 | 00068462 | 50-4 | yes<br>trimethyl-1,3-pentandiol diisobutyrate                                   | no | no | 5    |  |  | Only to be used in single-use gloves |

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|     |                |              |   |     |     |     |      |  |   |     |
|-----|----------------|--------------|---|-----|-----|-----|------|--|---|-----|
| 498 | 16210          | 0006864337-5 | dimethyl-4,4'-diaminodicyclohexylmethane  | no  | yes | no  | 0,05 |  | Only to be used in polyamides   | (5) |
| 499 | 19965<br>65020 | 0006915117   | maleic acid                               | yes | yes | no  |      |  | In case of use as a monomer only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis |     |
| 500 | 38560          | 0007128261-5 | bis(5-tert-butyl-2-benzoxazolyl)thiophene | yes | no  | yes | 0,6  |  |   |     |
| 501 | 34480          | —            | aluminium fibers, flakes and powders      | yes | no  | no  |      |  |   |     |

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|     |       |              |                                |     |     |    |      |      |  |     |
|-----|-------|--------------|--------------------------------|-----|-----|----|------|------|--|-----|
| 502 | 22778 | 0007456468-0 | oxybis(benzenesulphonyl azide) | no  | yes | no | 0,05 |      |  | (1) |
| 503 | 46080 | 000758539-9  | dextrin                        | yes | no  | no |      |      |  |     |
| 504 | 86240 | 0007631860-0 | silicon dioxide                | yes | no  | no |      |      | For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size. |     |
| 505 | 86480 | 0007631800-0 | disodium bisulphite            | yes | no  | no |      | (19) |  |     |

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**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|     |       |               |                     |     |     |    |     |      |  |  |
|-----|-------|---------------|---------------------|-----|-----|----|-----|------|--|--|
| 506 | 86920 | 0007632s00i0m | nitrite             | yes | no  | no | 0,6 |      |  |  |
| 507 | 59990 | 0007647h01i0  | hydrochloric acid   | yes | no  | no |     |      |  |  |
| 508 | 86560 | 0007647s0i0m  | bromide             | yes | no  | no |     |      |  |  |
| 509 | 23170 | 0007664p0s0   | phosphoric acid     | yes | yes | no |     |      |  |  |
|     | 72640 |               |                     |     |     |    |     |      |  |  |
| 510 | 12789 | 0007664a0i0m  | ammonia             | yes | yes | no |     |      |  |  |
|     | 35320 |               |                     |     |     |    |     |      |  |  |
| 511 | 91920 | 0007664s0p0   | perboric acid       | yes | no  | no |     |      |  |  |
| 512 | 81680 | 0007681p0i0m  | potassium iodide    | yes | no  | no |     | (6)  |  |  |
| 513 | 86800 | 0007681s0i0m  | sodium iodide       | yes | no  | no |     | (6)  |  |  |
| 514 | 91840 | 0007704s0p0   | sulphur             | yes | no  | no |     |      |  |  |
| 515 | 26360 | 0007732w0t0   | water               | yes | yes | no |     |      |  | In compliance with Directive 98/83/EC <sup>b</sup> |
|     | 95855 |               |                     |     |     |    |     |      |  |  |
| 516 | 86960 | 0007757s0i0m  | sodium sulphite     | yes | no  | no |     | (19) |  |  |
| 517 | 81520 | 0007758p0i0m  | potassium bromide   | yes | no  | no |     |      |  |  |
| 518 | 35845 | 0007771a0i0m  | ascorbic acid       | yes | no  | no |     |      |  |  |
| 519 | 87120 | 0007772s0i0m  | sodium thiosulphate | yes | no  | no |     | (19) |  |  |

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**b** OJ L 330, 5.12.1998, p. 32.

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|-----|-------|---------|-------|-------------------------|-----|-----|----|-------------|------|-----|--|
| 520 | 65120 | 0007773 | 30015 | mercuric chloride       | yes | no  | no |             |      |     |  |
| 521 | 58320 | 0007782 | 4241  | zinc white              | yes | no  | no |             |      |     |  |
| 522 | 14530 | 0007782 | 505   | zinc white              | no  | yes | no |             |      |     |  |
| 523 | 45195 | 0007787 | 7004  | copper bromide          | yes | no  | no |             |      |     |  |
| 524 | 24520 | 0008001 | 3217  | lanolin oil             | no  | yes | no |             |      |     |  |
| 525 | 62640 | 0008001 | 3016  | Japan wax               | yes | no  | no |             |      |     |  |
| 526 | 43440 | 0008001 | 1756  | linseed oil             | yes | no  | no |             |      |     |  |
| 527 | 14411 | 0008001 | 1794  | castor oil              | yes | yes | no |             |      |     |  |
|     | 42880 |         |       |                         |     |     |    |             |      |     |  |
| 528 | 63760 | 0008002 | 1435  | linseed oil             | yes | no  | no |             |      |     |  |
| 529 | 67850 | 0008002 | 1507  | lanolin wax             | yes | no  | no |             |      |     |  |
| 530 | 41760 | 0008006 | 418   | beeswax                 | yes | no  | no |             |      |     |  |
| 531 | 36880 | 0008012 | 1893  | beeswax                 | yes | no  | no |             |      |     |  |
| 532 | 88640 | 0008013 | 3078  | lanolin oil, epoxidised | yes | no  | no | 60<br>30(*) | (32) | (*) | In the case of PVC gaskets used to seal glass jars containing infant |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|          |   |  |  |  |  |  |  |  |  |  |
|----------|---|--|--|--|--|--|--|--|--|--|
|          |   |  |  |  |  |  |  |  |  | formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC, the SML is lowered to 30 mg/kg. |
|          |   |  |  |  |  |  |  |  |  | Oxirane < 8 %,   |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |  |  |  |  |  |  |  |  |  |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |  |  |  |  |  |  |  |  |  |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |  |  |  |  |  |  |  |  |  |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |  |  |  |  |  |  |  |  |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |  |  |  |  |  |  |  |  |  |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |  |  |  |  |  |  |  |  |
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| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |  |  |  |  |  |  |  |  |

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|     |       |            |                                   |     |     |    |      |  | iodine number < 6.                                     |
|-----|-------|------------|-----------------------------------|-----|-----|----|------|--|--|
| 533 | 42720 | 0008015869 | sebacic wax                       | yes | no  | no |      |  |  |
| 534 | 80720 | 0008017061 | phosphoric acids                  | yes | no  | no |      |  |  |
| 535 | 24100 | 0008050097 |                                   | yes | yes | no |      |  |  |
|     | 24130 |            |                                   |     |     |    |      |  |  |
|     | 24190 |            |                                   |     |     |    |      |  |  |
|     | 83840 |            |                                   |     |     |    |      |  |  |
| 536 | 84320 | 0008050456 | hydrogenated, ester with methanol | yes | no  | no |      |  |  |
| 537 | 84080 | 0008050268 | ester with pentaerythritol        | yes | no  | no |      |  |  |
| 538 | 84000 | 0008050316 | ester with glycerol               | yes | no  | no |      |  |  |
| 539 | 24160 | 0008052106 | tall oil                          | no  | yes | no |      |  |  |
| 540 | 63940 | 0008062155 | phosphonic acid                   | yes | no  | no | 0,24 |  | Only to be used as dispersant for plastics dispersions |

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**c** OJ L 253, 20.9.2008, p. 1.

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|-----|-------|--------------|---------------------------|-----|-----|----|--|--|--|---|
| 541 | 58480 | 000900000115 | gum arabic                | yes | no  | no |  |  |  |   |
| 542 | 42640 | 000900000117 | cellulose methylcellulose | yes | no  | no |  |  |  |   |
| 543 | 45920 | 000900000118 | cellulose                 | yes | no  | no |  |  |  |   |
| 544 | 58400 | 000900000119 | gum                       | yes | no  | no |  |  |  |   |
| 545 | 93680 | 000900000120 | gum                       | yes | no  | no |  |  |  |   |
| 546 | 71440 | 000900000121 | gum                       | yes | no  | no |  |  |  |   |
| 547 | 55440 | 000900000122 | gum                       | yes | no  | no |  |  |  |   |
| 548 | 42800 | 000900000123 | gum                       | yes | no  | no |  |  |  |   |
| 549 | 80000 | 000900000124 | polyethylene wax          | yes | no  | no |  |  |  |   |
| 550 | 81060 | 000900000125 | polypropylene wax         | yes | no  | no |  |  |  |   |
| 551 | 79920 | 000900000126 | poly(ethylene glycol)     | yes | no  | no |  |  |  |   |
| 552 | 81500 | 000900000127 | polyvinylpyrrolidone      | yes | no  | no |  |  |  | The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC <sup>c</sup> |
| 553 | 14500 | 000900000128 | cellulose                 | yes | yes | no |  |  |  |   |

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|-----|----------------|-------------|--|-----|-----|-----|----|--|--|
|     | 43280          |             |  |     |     |     |    |  |  |
| 554 | 43300          | 00090043118 | acetate butyrate                       | yes | no  | no  |    |  |  |
| 555 | 53280          | 0009004677  | cellulose                              | yes | no  | no  |    |  |  |
| 556 | 54260          | 0009004684  | hydroxyethylcellulose                  | yes | no  | no  |    |  |  |
| 557 | 66640          | 00090045015 | ethylcellulose                         | yes | no  | no  |    |  |  |
| 558 | 60560          | 0009004620  | hydroxyethylcellulose                  | yes | no  | no  |    |  |  |
| 559 | 61680          | 0009004642  | propylcellulose                        | yes | no  | no  |    |  |  |
| 560 | 66700          | 0009004653  | hydroxypropylcellulose                 | yes | no  | no  |    |  |  |
| 561 | 66240          | 0009004675  | cellulose                              | yes | no  | no  |    |  |  |
| 562 | 22450          | 0009004700  | cellulose                              | yes | yes | no  |    |  |  |
| 563 | 78320          | 0009004907  | ethylsuccinylsuccinate monoricinoleate | yes | no  | yes | 42 |  |  |
| 564 | 24540<br>88800 | 0009005268  | edible                                 | yes | yes | no  |    |  |  |
| 565 | 61120          | 0009005370  | hydroxyethyl starch                    | yes | no  | no  |    |  |  |
| 566 | 33350          | 0009005421  | lactic acid                            | yes | no  | no  |    |  |  |
| 567 | 82080          | 0009005137  | propyleneglycol alginate               | yes | no  | no  |    |  |  |
| 568 | 79040          | 0009005645  | sorbitan monolaurate                   | yes | no  | no  |    |  |  |
| 569 | 79120          | 0009005656  | sorbitan monooleate                    | yes | no  | no  |    |  |  |

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**c** OJ L 253, 20.9.2008, p. 1.

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|-----|----------------|-------------|--|-----|-----------|----|---|--|--|
| 570 | 79200          | 00090056067 | polyethyl-<br>sorbitan<br>monopalmitate      | yes | glycol    | no |   |  |  |
| 571 | 79280          | 00090056078 | polyethyl-<br>sorbitan<br>monostearate       | yes | glycol    | no |   |  |  |
| 572 | 79360          | 00090056073 | polyethyl-<br>sorbitan<br>trioleate          | yes | glycol    | no |   |  |  |
| 573 | 79440          | 00090056074 | polyethyl-<br>sorbitan<br>tristearate        | yes | glycol    | no |   |  |  |
| 574 | 24250<br>84560 | 00090060166 | polybut-<br>natural                          | yes | yes       | no |   |  |  |
| 575 | 76721          | 00631486029 | polydimethyl-<br>(Mw ><br>6 800<br>Da)       | yes | siloxane  | no |   |  | Viscosity<br>at 25<br>°C not<br>less<br>than<br>100<br>cSt<br>(100<br>× 10 <sup>-6</sup><br>m <sup>2</sup> /s) |
| 576 | 60880          | 00090324212 | hydroxyethyl-<br>methylcellulose             | yes | cellulose | no |   |  |  |
| 577 | 62280          | 00090441576 | isobutylene-<br>butene<br>copolymer          | yes | no        | no |   |  |  |
| 578 | 79600          | 00090460190 | polyethyl-<br>tridecyl<br>ether<br>phosphate | yes | glycol    | no | 5 |  | For<br>materials<br>and<br>articles<br>intended<br>for   |

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|-----|-------|-------------|------------------------------------|-----|----|----|------|--|---|
|     |       |             |                                    |     |    |    |      |  | contact with aqueous foods only. Polyethyleneglycol (EO ≤ 11) tridecyl ether phosphate (mono- and dialkyl ester) with a maximum 10 % content of polyethyleneglycol (EO ≤ 11) tridecylether. |
| 579 | 61800 | 00090491747 | hydroxypropyl starch               | yes | no | no |      |  |   |
| 580 | 46070 | 00100166203 | dextrin                            | yes | no | no |      |  |   |
| 581 | 36800 | 00100226118 | barium nitrate                     | yes | no | no |      |  |   |
| 582 | 50240 | 00100394335 | octyltin bis(2-ethylhexyl maleate) | yes | no | no | (10) |  |   |
| 583 | 40400 | 00100436665 | boron nitride                      | yes | no | no | (16) |  |   |

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|-----|-------|----------|-----------------------------------|-----|-----|-----|----|------|--|-----|
| 584 | 13620 | 00100435 | 3503                              | yes | yes | no  |    | (16) |  |     |
|     | 40320 |          | acid                              |     |     |     |    |      |  |     |
| 585 | 41120 | 00100435 | 5104                              | yes | no  | no  |    |      |  |     |
|     |       |          | chloride                          |     |     |     |    |      |  |     |
| 586 | 65280 | 00100435 | 8402                              | yes | no  | no  |    |      |  |     |
|     |       |          | hypophosphite                     |     |     |     |    |      |  |     |
| 587 | 68400 | 00100944 | 4508                              | yes | no  | yes | 5  |      |  |     |
|     |       |          | succinimide                       |     |     |     |    |      |  |     |
| 588 | 64320 | 00103771 | 1102                              | yes | no  | no  |    | (6)  |  |     |
|     |       |          | iodide                            |     |     |     |    |      |  |     |
| 589 | 52645 | 00104360 | 0815                              | yes | no  | no  |    |      |  |     |
|     |       |          | eicosenamide                      |     |     |     |    |      |  |     |
| 590 | 21370 | 00105955 | 8010                              | yes | no  | no  | ND |      |  | (1) |
|     |       |          | acrylic acid, 2-sulphoethyl ester |     |     |     |    |      |  |     |
| 591 | 36160 | 00106055 | 0011                              | yes | no  | no  |    |      |  |     |
|     |       |          | stearate                          |     |     |     |    |      |  |     |
| 592 | 34690 | 00110975 | 0909                              | yes | no  | no  |    |      |  |     |
|     |       |          | magnesium carbonate hydroxide     |     |     |     |    |      |  |     |
| 593 | 44960 | 00111040 | 0011                              | yes | no  | no  |    |      |  |     |
|     |       |          | oxide                             |     |     |     |    |      |  |     |
| 594 | 65360 | 00111290 | 0015                              | yes | no  | no  |    |      |  |     |
|     |       |          | oxide                             |     |     |     |    |      |  |     |
| 595 | 19510 | 00111321 | 2003                              | yes | no  | no  |    |      |  |     |
|     |       |          | cellulose                         |     |     |     |    |      |  |     |
| 596 | 95935 | 00111380 | 0011                              | yes | no  | no  |    |      |  |     |
|     |       |          | gum                               |     |     |     |    |      |  |     |
| 597 | 67120 | 00120011 | 2002                              | yes | no  | no  |    |      |  |     |
|     |       |          | lactate                           |     |     |     |    |      |  |     |

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|-----|-------|--------------------|----------------|--|-----|-----|-----|------|------|--|
| 598 | 41600 | 0012004<br>0037293 | 441-7<br>321-4 | lead-<br>sulfate   | yes | no  | no  |      |      |  |
| 599 | 36840 | 0012007            | 551-7          | tetraborate  | yes | no  | no  |      | (16) |  |
| 600 | 60030 | 0012072            | 901-8          | zinc   | yes | no  | no  |      |      |  |
| 601 | 35440 | 0012124            | 071-9          | bromide  | yes | no  | no  |      |      |  |
| 602 | 70240 | 0012198            | 231-5          | zinc   | yes | no  | no  |      |      |  |
| 603 | 83460 | 0012269            | 781-2          | phthalate  | yes | no  | no  |      |      |  |
| 604 | 60080 | 0012304            | 611-3          | phthalate  | yes | no  | no  |      |      |  |
| 605 | 11005 | 0012542            | 201-1          | acid,<br>dicyclopentenyl<br>ester                                | no  | yes | no  | 0,05 |      | (1)  |
| 606 | 65200 | 0012626            | 881-9          | hydroxide  | yes | no  | no  |      |      |  |
| 607 | 62245 | 0012751            | 221-3          | phosphide  | yes | no  | no  |      |      | Only to be used in PET polymers and copolymers |
| 608 | 40800 | 0013003            | 411-8          | butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite) | yes | no  | yes | 6    |      |  |
| 609 | 83455 | 0013445            | 561-2          | phosphorous<br>acid  | yes | no  | no  |      |      |  |

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|-----|-------|---------|-------|---|-----|-----|----|------|------|------|
| 610 | 93440 | 0013463 | 1677  | tin dioxide   | yes | no  | no |      |      |      |
| 611 | 35120 | 0013560 | 349-1 | aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether | yes | no  | no |      |      |      |
| 612 | 16694 | 0013811 | 502   | divinyl-2-imidazolidinone                                       | no  | yes | no | 0,05 |      | (10) |
| 613 | 95905 | 0013983 | 1710  | histidine   | yes | no  | no |      |      |      |
| 614 | 45560 | 0014464 | 461   | calcium lactate   | yes | no  | no |      |      |      |
| 615 | 92080 | 0014807 | 16-6  | tin   | yes | no  | no |      |      |      |
| 616 | 83470 | 0014808 | 607z  | tin   | yes | no  | no |      |      |      |
| 617 | 10660 | 0015214 | 289-8 | acrylamido-2-methylpropanesulphonic acid                        | no  | yes | no | 0,05 |      |      |
| 618 | 51040 | 0015535 | 179-2 | octyltin mercaptoacetate  | yes | no  | no |      | (10) |      |
| 619 | 50320 | 0015571 | 158-1 | octyltin bis(2-ethylhexyl mercaptoacetate)                      | yes | no  | no |      | (10) |      |
| 620 | 50720 | 0015571 | 160-5 | octyltin dimaleate  | yes | no  | no |      | (10) |      |

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|-----|-------|--------------|--|-----|-----|-----|------|--|--|-----|
| 621 | 17110 | 0016219575-3 | ethylidenebicyclo[2,2,1]hept-2-ene                                   | no  | yes | no  | 0,05 |  |  | (9) |
| 622 | 69840 | 0016260009-6 | palmitamide  | no  | yes | yes | 5    |  |  |     |
| 623 | 52640 | 0016389488-1 | zinc stearate  | yes | no  | no  |      |  |  |     |
| 624 | 18897 | 0016712664-4 | hydroxy-2-naphthalenecarboxylic acid                                 | no  | yes | no  | 0,05 |  |  |     |
| 625 | 36720 | 0017194400-2 | zinc hydroxide   | yes | no  | no  |      |  |  |     |
| 626 | 57800 | 0018641574-1 | glycerol tribehenate   | yes | no  | no  |      |  |  |     |
| 627 | 59760 | 0019569411-2 | zinc stearate  | yes | no  | no  |      |  |  |     |
| 628 | 96190 | 0020427388-1 | zinc hydroxide   | yes | no  | no  |      |  |  |     |
| 629 | 34560 | 0021645411-2 | zinc hydroxide   | yes | no  | no  |      |  |  |     |
| 630 | 82240 | 0022788412-8 | propyleneglycol dilaurate  | yes | no  | no  |      |  |  |     |
| 631 | 59120 | 0023128176-7 | hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide) | yes | no  | yes | 45   |  |  |     |
| 632 | 52880 | 0023676409-7 | ethoxybenzoic acid, ethyl ester                                      | yes | no  | no  | 3,6  |  |  |     |

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|-----|-------|---------|--------------------------|---|-----|-----|----|------|------|---|
| 633 | 53200 | 0023949 | 266-8                    | yes   | no  | yes | 30 |      |      |   |
|     |       |         | ethoxy-2'-ethyloxanilide |   |     |     |    |      |      |   |
| 634 | 25910 | 0024800 | 44-0                     | polypropylene glycols                                   |     | no  |    |      |      |   |
| 635 | 40720 | 0025013 | 6-5                      | butyl-4-hydroxyanisole                                  | yes | no  | no | 30   |      |   |
| 636 | 31500 | 0025134 | 51-4                     | fatty acid, acrylic acid, 2-ethylhexyl ester, copolymer | yes | no  | no | 0,05 | (22) | SML expressed as acrylic acid, 2-ethylhexyl ester   |
| 637 | 71635 | 0025151 | 26-6                     | polybutyl diolate                                       |     | no  | no | 0,05 |      | Not to be used for articles in contact with fatty foods for which simulant D is laid down |
| 638 | 23590 | 0025322 | 68-3                     | polyethylene glycols                                    |     | yes | no |      |      |   |
|     | 76960 |         |                          |   |     |     |    |      |      |   |
| 639 | 23651 | 0025322 | 69-4                     | polypropylene glycol                                    |     | yes | no |      |      |   |
|     | 80800 |         |                          |   |     |     |    |      |      |   |

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**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

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|-----|-------|----------|--|-----|-----|------|------|--|------|
| 640 | 54930 | 00253599 | Formaldehyde-1-naphthol, copolymer   | no  | no  | 0,05 |      |  |      |
| 641 | 22331 | 00255136 | Mixture of (35-45 % w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65 % w/w) 1,6-diamino-2,4,4-trimethylhexane | no  | yes | no   | 0,05 |  | (10) |
| 642 | 64990 | 00257366 | Maleic anhydride-styrene, copolymer, sodium salt   | yes | no  | no   |      | The fraction with molecular weight below 1 000 Da should not exceed 0,05 % (w/w) |      |
| 643 | 87760 | 00262665 | Dan monopalmitate  | yes | no  | no   |      |  |      |
| 644 | 88080 | 00262665 | Dan trioleate  | yes | no  | no   |      |  |      |
| 645 | 67760 | 00264018 | n-octyltin   | yes | no  | no   |      | (11)   |      |

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|-----|-------|--------------|--|-----|-----|-----|-----|------|--|------|
|     |       |              | tris(isooctyl mercaptoacetate)                               |     |     |     |     |      |  |      |
| 646 | 50480 | 0026401497-8 | 1,4-bis(isooctyl mercaptoacetate)tin                         | yes | no  | no  |     | (10) |  |      |
| 647 | 56720 | 0026402236-3 | glycerol monohexanoate                                       | yes | no  | no  |     |      |  |      |
| 648 | 56880 | 0026402236-6 | glycerol mono-octanoate                                      | yes | no  | no  |     |      |  |      |
| 649 | 47210 | 0026427407-6 | polythiostannic acid polymer                                 | no  | no  | no  |     |      | Molecular unit = (C <sub>8</sub> H <sub>18</sub> S <sub>3</sub> Sn <sub>2</sub> ) <sub>n</sub> (n = 1,5-2) |      |
| 650 | 49600 | 0026636401-1 | dimethyltin bis(isooctyl mercaptoacetate)                    | yes | no  | no  |     | (9)  |  |      |
| 651 | 88240 | 0026658501-1 | soybean tristearate  | yes | no  | no  |     |      |  |      |
| 652 | 38820 | 0026741532-4 | 1,5-bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite | yes | no  | yes | 0,6 |      |  |      |
| 653 | 25270 | 0026747290-0 | toluene diisocyanate dimer                                   | no  | yes | no  |     | (17) | 1 mg/kg in final product expressed as isocyanate moiety  | (10) |
| 654 | 88600 | 0026836471-1 | olefin monostearate  | yes | no  | no  |     |      |  |      |

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|-----|-------|-------------|---|-----|-----|-----|-------|------|-----------------------------------|-----|
| 655 | 25450 | 002689648-0 | 1,4-bis(4-chlorophenyl)ethane   | no  | no  | no  | 0,05  |      |                                   |     |
| 656 | 24760 | 002691433-2 | 4-sulphonic acid  | yes | no  | no  | 0,05  |      |                                   |     |
| 657 | 67680 | 002710780-7 | n-octyltris(2-ethylhexyl mercaptoacetate)                                     | yes | no  | no  |       | (11) |                                   |     |
| 658 | 52000 | 002717687-0 | dodecylbenzenesulphonic acid  | no  | no  | no  | 30    |      |                                   |     |
| 659 | 82800 | 002719472-7 | propyleneglycol monolaurate   | yes | no  | no  |       |      |                                   |     |
| 660 | 47540 | 002745840-8 | dodecyl disulphide  | yes | no  | yes | 0,05  |      |                                   |     |
| 661 | 95360 | 002767642-5 | tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione | yes | no  | yes | 5     |      |                                   |     |
| 662 | 25927 | 002795549-8 | tris(4-hydroxyphenyl)ethane   | no  | yes | no  | 0,005 |      | Only to be used in polycarbonates | (1) |
| 663 | 64150 | 002829070-1 | trifluoroacetic acid  | yes | no  | no  |       |      |                                   |     |
| 664 | 95000 | 002893167-6 | trimethylpropylmethacrylate   | no  | no  | no  |       |      |                                   |     |

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|-----|-------|--------------|--|----|----|--|--------------|---|--|
|     |       |              | methacrylate copolymer                                     |    |    |  |              |   |  |
| 665 | 83120 | 0029013428-3 | yes<br>propyleneglycol<br>monopalmitate                    | no | no |  |              |   |  |
| 666 | 87280 | 0029116508-1 | yes<br>diolate   | no | no |  |              |   |  |
| 667 | 55190 | 0029204021-1 | yes<br>acid  | no | no |  |              |   |  |
| 668 | 80240 | 0029894017-1 | yes<br>ricinoleate   | no | no |  |              |   |  |
| 669 | 56610 | 0030233648-1 | yes<br>monobehenate  | no | no |  |              |   |  |
| 670 | 56800 | 0030899628-1 | yes<br>monolaurate<br>diacetate                            | no | no |  | (32)         |   |  |
| 671 | 74240 | 0031570146-1 | yes<br>acid,<br>tris(2,4-<br>di-tert-<br>butylphenyl)ester | no | no |  |              |   |  |
| 672 | 76845 | 0031831615-1 | yes<br>of 1,4-<br>butanediol<br>with<br>caprolactone       | no | no |  | (29)<br>(30) | The<br>fraction<br>with<br>molecular<br>weight<br>below<br>1 000<br>Da<br>should<br>not<br>exceed<br>0,5 %<br>(w/w) |  |

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|-----|-------|---------|---|-----|----|-----|----|------|--|--|
| 673 | 53670 | 0032509 | 166-1<br>ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate] | yes | no | yes | 6  |      |  |  |
| 674 | 46480 | 0032647 | 167-1<br>azylidene sorbitol   | yes | no | no  |    |      |  |  |
| 675 | 38800 | 0032687 | 178-1<br>bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide       | yes | no | yes | 15 |      |  |  |
| 676 | 50400 | 0033568 | 199-9<br>octyltin bis(isooctyl maleate)                                     | yes | no | no  |    | (10) |  |  |
| 677 | 82560 | 0033587 | 201-1<br>propyleneglycol dipalmitate  | yes | no | no  |    |      |  |  |
| 678 | 59200 | 0035074 | 176-2<br>hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate) | yes | no | yes | 6  |      |  |  |
| 679 | 39060 | 0035958 | 130-6<br>bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane                       | yes | no | yes | 5  |      |  |  |
| 680 | 94400 | 0036443 | 168-2<br>ethylene glycol bis[3-   | yes | no | no  | 9  |      |  |  |

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**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|-----|-------|--------------|--|-----|-----|----|------|--|---|
|     |       |              | (3-tert-butyl-4-hydroxy-5-methylphenyl propionate] |     |     |    |      |  |   |
| 681 | 18310 | 0036653482-4 | hexadecanol  | no  | yes | no |      |  |   |
| 682 | 53270 | 0037205601-2 | 5-hydroxymethylcellulose                           | yes | yes | no |      |  |   |
| 683 | 66200 | 0037206011-2 | hydroxymethylcellulose                             | no  | yes | no |      |  |   |
| 684 | 68125 | 0037244061-5 | ephalinesyenite                                    | yes | no  | no |      |  |   |
| 685 | 85950 | 0037296517-2 | fluoride acid, magnesium-sodium-fluoride salt      | yes | no  | no | 0,15 |  | SML expressed as fluoride. Only to be used in layers of multi-layer materials not coming into direct contact with food. |
| 686 | 61390 | 0037353591-6 | hydroxymethylcellulose                             | no  | yes | no |      |  |   |
| 687 | 13530 | 0038103206-9 | bis(4-hydroxyphenyl)propane                        | no  | yes | no | 0,05 |  |   |
|     | 13614 |              |  |     |     |    |      |  |   |

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|     |       |            |   |     |     |     |      |  |     |
|-----|-------|------------|---|-----|-----|-----|------|--|-----|
|     |       |            | bis(phthalic anhydride)   |     |     |     |      |  |     |
| 688 | 92560 | 0038613677 | bis(3,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite                          | yes | no  | yes | 18   |  |     |
| 689 | 95280 | 0040601176 | tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione | yes | no  | yes | 6    |  |     |
| 690 | 92880 | 0041484654 | bis(2-ethylbis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)                       | no  | no  | yes | 2,4  |  |     |
| 691 | 13600 | 0047465397 | bis(3-methyl-4-hydroxyphenyl)2-indolinone   | no  | yes | no  | 1,8  |  |     |
| 692 | 52320 | 0052047250 | 1,3-bis(dodecylphenyl)indole  | yes | no  | yes | 0,06 |  |     |
| 693 | 88160 | 0054140361 | soybean tripalmitate  | yes | no  | no  |      |  |     |
| 694 | 21400 | 0054276356 | methacrylic acid,   | yes | yes | no  | 0,05 |  | (1) |

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|-----|-------|---------|--|-----|----|-----|-----|--|--|
|     |       |         | sulphopropyl ester   |     |    |     |     |  |  |
| 695 | 67520 | 0054849 | 2,2,6-trimethyltris(isooctyl mercaptoacetate)  | no  | no |     | (9) |  |  |
| 696 | 92205 | 0057569 | terephthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)             | no  | no |     |     |  |  |
| 697 | 67515 | 0057583 | 2,2,6-trimethyltris(ethylhexyl mercaptoacetate)  | no  | no |     | (9) |  |  |
| 698 | 49595 | 0057583 | 2,2,6-trimethylbis(ethylhexyl mercaptoacetate)   | no  | no |     | (9) |  |  |
| 699 | 90720 | 0058446 | 2,2,4,4-tetrahydro-2H-pyran  | no  | no |     |     |  |  |
| 700 | 31520 | 0061167 | ascorbic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester | yes | no | yes | 6   |  |  |
| 701 | 40160 | 0061269 | N,N-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-                          | yes | no | no  | 2,4 |  |  |

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|-----|----------------------|---------|--|----|-----|----|----|------|-----|
|     |                      |         | dibromoethane, copolymer   |    |     |    |    |      |     |
| 702 | 87920                | 0061752 | 6814<br>sorbitan yes<br>tetrastearate  | no | no  |    |    |      |     |
| 703 | 17170                | 0061788 | 474<br>fatty<br>acids,<br>coco   | no | yes | no |    |      |     |
| 704 | 77600                | 0061788 | 850<br>polyethylene glycol<br>ester<br>of<br>hydrogenated<br>castor<br>oil   | no | no  |    |    |      |     |
| 705 | 10599/90<br>10599/91 | 0061788 | 8014<br>fatty,<br>unsaturated<br>(C <sub>18</sub> ),<br>dimers,<br>non<br>hydrogenated,<br>distilled<br>and<br>non-<br>distilled | no | yes | no |    | (18) | (1) |
| 706 | 17230                | 0061790 | 0423<br>fatty<br>acids,<br>tall oil  | no | yes | no |    |      |     |
| 707 | 46375                | 0061790 | 520<br>diatomaceous<br>earth   | no | no  |    |    |      |     |
| 708 | 77520                | 0061791 | 1626<br>polyethylene glycol<br>ester<br>of<br>castor<br>oil  | no | no  |    | 42 |      |     |

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|---------------------|-------|--------------------|---|-----|----|-----|----|--|--|
| 709                 | 87520 | 0062568            | solbutan<br>monobenate                              | yes | no | no  |    |  |  |
| 710                 | 38700 | 0063397            | carbutoxyethyl<br>bis(isooctyl<br>mercaptoacetate)  | yes | no | yes | 18 |  |  |
| 711                 | 42000 | 0063438            | carbutoxyethyl<br>tris(isooctyl<br>mercaptoacetate) | yes | no | yes | 30 |  |  |
| 712                 | 42960 | 0064147            | oil,<br>dehydrated                                  | yes | no | no  |    |  |  |
| [ <sup>F4</sup> 713 | 43480 | 0064365<br>0007440 | hard coal<br>activated                              | yes | no | no  |    |  | Only for use in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Regulation (EU) No 231/2012 <sup>d</sup> with |

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|     |       |         |  |     |    |    |    |  | exception<br>of ash<br>content<br>which<br>can be<br>up to<br>10 %<br>(w/w). |
|-----|-------|---------|--|-----|----|----|----|--|--|
| 714 | 84400 | 0064365 | FD 519<br>hydrogenated,<br>ester<br>with<br>pentaerythritol  | yes | no | no |    |  |  |
| 715 | 46880 | 0065140 | 391-01<br>tert-<br>butyl-4-<br>hydroxybenzylphosphonic<br>acid,<br>monoethyl<br>ester,<br>calcium<br>salt                                | yes | no | no | 6  |  |  |
| 716 | 60800 | 0065447 | 720<br>(2-<br>hydroxyethyl)-4-<br>hydroxy-2,2,6,6-<br>tetramethyl<br>piperidine-<br>succinic<br>acid,<br>dimethyl<br>ester,<br>copolymer | yes | no | no | 30 |  |  |
| 717 | 84210 | 0065997 | 0610<br>hydrogenated   | yes | no | no |    |  |  |
| 718 | 84240 | 0065997 | FD 319<br>hydrogenated,<br>ester   | yes | no | no |    |  |  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

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**h** [<sup>F3</sup>OJ L 83, 22.3.2012, p. 1.]

*Status: Point in time view as at 26/02/2015.*

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|     |       |         |   |     |     |    |      |  |  |
|-----|-------|---------|---|-----|-----|----|------|--|--|
|     |       |         | with glycerol   |     |     |    |      |  |  |
| 719 | 65920 | 0066822 | 260-4<br>yes<br>no<br>no<br>methacryloyloxyethyl-<br>N,N-dimethyl-<br>N-carboxymethylammonium<br>chloride,<br>sodium salt -<br>octadecyl methacrylate-<br>ethyl methacrylate-<br>cyclohexyl methacrylate-<br>N-vinyl-2-pyrrolidone,<br>copolymers | yes | no  | no |      |  |  |
| 720 | 67360 | 0067649 | 604-<br>n-dodecyltin tris(isooctyl mercaptoacetate)   | yes | no  | no | (25) |  |  |
| 721 | 46800 | 0067845 | 395-6-<br>tert-butyl-4-hydroxybenzoic acid,<br>hexadecyl ester  | yes | no  | no |      |  |  |
| 722 | 17200 | 0068308 | 651-2<br>acids,<br>soya   | no  | yes | no |      |  |  |

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|     |       |         |   |     |     |    |  |  |  |
|-----|-------|---------|---|-----|-----|----|--|--|--|
| 723 | 88880 | 0068412 | 2026, starch, hydrolysed                      | yes | no  | no |  |  |  |
| 724 | 24903 | 0068425 | 1726, syrups, hydrolysed starch, hydrogenated | no  | yes | no |  |  | In compliance with the purity criteria for maltitol syrup E 965(ii) as laid down in Commission Directive 2008/60/EC <sup>e</sup> |

[<sup>F8</sup>]

|     |       |         |   |     |    |     |  |     |  |
|-----|-------|---------|---|-----|----|-----|--|-----|--|
| 726 | 83599 | 0068442 | 2226, products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin | yes | no | yes |  | (9) |  |
| 727 | 43360 | 0068442 | 2811, dextrose regenerated  | yes | no | no  |  |     |  |

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**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|  |       |                    |   |     |    |    |  |              |  |  |
|--|-------|--------------------|---|-----|----|----|--|--------------|--|--|
| 728  | 75100 | 0068515<br>0028553 | phthalic<br>diesters<br>with<br>primary,<br>saturated<br>C <sub>8</sub> -C <sub>10</sub><br>branched<br>alcohols,<br>more<br>than<br>60 %<br>C <sub>9</sub> | yes | no | no |  | (26)<br>(32) | Only<br>to be<br>used<br>as:<br>(a)<br><br>(b) | (7)<br><br>plasticiser<br>in<br>repeated<br>use<br>materials<br>and<br>articles;<br>plasticiser<br>in<br>single-<br>use<br>materials<br>and<br>articles<br>contacting<br>non-<br>fatty<br>foods<br>except<br>for<br>infant<br>formulae<br>and<br>follow-<br>on<br>formulae<br>as<br>defined<br>by<br>Directive<br>2006/141/<br>EC<br>or<br>processed<br>cereal-<br>based |
| <b>a</b> OJ L 302, 19.11.2005, p. 28.  |       |                    |   |     |    |    |  |              |  |  |
| <b>b</b> OJ L 330, 5.12.1998, p. 32.   |       |                    |   |     |    |    |  |              |  |  |
| <b>c</b> OJ L 253, 20.9.2008, p. 1.  |       |                    |   |     |    |    |  |              |  |  |
| <b>d</b> [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |       |                    |   |     |    |    |  |              |  |  |
| <b>e</b> OJ L 158, 18.6.2008, p. 17.   |       |                    |   |     |    |    |  |              |  |  |
| <b>f</b> [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |       |                    |   |     |    |    |  |              |  |  |
| <b>g</b> This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |       |                    |   |     |    |    |  |              |  |  |
| <b>h</b> [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |       |                    |   |     |    |    |  |              |  |  |

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|     |       |                    |   |     |    |    |              |                            |     |  |
|-----|-------|--------------------|---|-----|----|----|--------------|----------------------------|-----|--|
|     |       |                    |   |     |    |    |              |                            |     | foods and baby foods for infants and young children as defined by Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product. |
| 729 | 75105 | 0068515<br>0026761 | Phthalic acid diesters with primary, saturated C <sub>9</sub> -C <sub>11</sub> alcohols more than | yes | no | no | (26)<br>(32) | Only to be used as:<br>(a) | (c) | (7)<br><br>plasticiser in repeated use materials and articles;   |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

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|          |   |  |                         |  |  |  |  |     |  |
|----------|---|--|-------------------------|--|--|--|--|-----|--|
|          |   |  | 90 %<br>C <sub>10</sub> |  |  |  |  | (b) | plasticiser<br>in<br>single-<br>use<br>materials<br>and<br>articles<br>contacting<br>non-<br>fatty<br>foods<br>except<br>for<br>infant<br>formulae<br>and<br>follow-<br>on<br>formulae<br>as<br>defined<br>by<br>Directive<br>2006/141/<br>EC<br>or<br>processed<br>cereal-<br>based<br>foods<br>and<br>baby<br>foods<br>for<br>infants<br>and<br>young<br>children<br>as<br>defined |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |  |                         |  |  |  |  |     |  |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |  |                         |  |  |  |  |     |  |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |  |                         |  |  |  |  |     |  |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |                         |  |  |  |  |     |  |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |  |                         |  |  |  |  |     |  |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |                         |  |  |  |  |     |  |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |                         |  |  |  |  |     |  |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |                         |  |  |  |  |     |  |

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|     |          |         |  |     |     |     |      |  |      | (c) | by Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product. |
|-----|----------|---------|--|-----|-----|-----|------|--|------|-----|---|
| 730 | 66930    | 0068554 | 47011<br>methylsilsesquioxane                            | no  | yes | no  |      |  |      |     | Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane    |
| 731 | 18220    | 0068564 | 488-5<br>heptylaminoundecanoic acid                      | no  | yes | no  | 0,05 |  |      |     | (2)   |
| 732 | 45450    | 0068610 | 051-5<br>cresol-dicyclopentadiene-isobutylene, copolymer | yes | no  | yes | 5    |  |      |     |   |
| 733 | 10599/92 | 0068783 | 4115<br>fatty, unsaturated (C <sub>18</sub> ), dimers,   | no  | yes | no  |      |  | (18) |     | (1)   |
|     | 10599/93 |         |  |     |     |     |      |  |      |     |   |

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**c** OJ L 253, 20.9.2008, p. 1.

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|     |       |         |  |     |    |     |     |      |  |
|-----|-------|---------|--|-----|----|-----|-----|------|--|
|     |       |         | hydrogenated,<br>distilled<br>and<br>non-<br>distilled   |     |    |     |     |      |  |
| 734 | 46380 | 0068855 | 544-0<br>calcium<br>earth,<br>soda<br>ash<br>flux-<br>calcined   | no  | no |     |     |      |  |
| 735 | 40120 | 0068951 | 551-8<br>bis(2-ethylhexyloxy)ethylene glycol hydroxymethylphosphonate  | no  | no |     |     |      |  |
| 736 | 50960 | 0069226 | 44-4<br>octyltin<br>ethylene glycol<br>bis(mercaptoacetate)  | yes | no | no  |     | (10) |  |
| 737 | 77370 | 0070142 | 204-6<br>polyethylene glycol-30<br>dipolyhydroxystearate   | yes | no | no  |     |      |  |
| 738 | 60320 | 0070321 | 282-7<br>hydroxy-3,5-<br>bis(1,1-<br>dimethylbenzyl)phenyl]benzotriazole   | yes | no | yes | 1,5 |      |  |
| 739 | 70000 | 0070331 | 292-1<br>oxamidobis[ethyl-3-<br>(3,5-<br>di-tert-<br>butyl-4-<br>hydroxyphenyl)-<br>propionate]                  | yes | no | no  |     |      |  |
| 740 | 81200 | 0071878 | 309-6<br>[(1,1,3,3-<br>tetramethylbutyl)amino]-1,3,5-<br>triazine-2,4-<br>diyl]-<br>[(2,2,6,6-<br>tetramethyl-4- | yes | no | yes | 3   |      |  |

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**b** OJ L 330, 5.12.1998, p. 32.

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|     |                |                          |   |     |     |     |   |  |  |
|-----|----------------|--------------------------|---|-----|-----|-----|---|--|--|
|     |                |                          | piperidyl)-<br>imino]hexamethylene[(2,2,6,6-<br>tetramethyl-4-<br>piperidyl)<br>imino]  |     |     |     |   |  |  |
| 741 | 24070<br>83610 | 0073138-83610            | acids<br>and<br>rosin<br>acids  | yes | yes | no  |   |  |  |
| 742 | 92700          | 007830124,4-<br>2,3,6,4- | tetramethyl-20-<br>(2,3-<br>epoxypropyl)-7-<br>oxa-3,20-<br>diazadispiro-<br>[5.1.11.2]-<br>heneicosan-21-<br>one,<br>polymer | yes | no  | yes | 5 |  |  |
| 743 | 38950          | 007907259(4-             | ethylbenzylidene)sorbitol   | yes | no  | no  |   |  |  |
| 744 | 18888          | 0080181331-3             | hydroxybutanoic<br>acid-3-<br>hydroxypentanoic<br>acid,<br>copolymer  | no  | yes | no  |   |  | The<br>substance<br>is used<br>as<br>product<br>obtained<br>by<br>bacterial<br>fermentation.<br>In<br>compliance<br>with<br>the<br>specifications<br>mentioned<br>in the |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|     |       |            |  |     |     |     |      |      | Table<br>4 of<br>Annex<br>I                     |
|-----|-------|------------|--|-----|-----|-----|------|------|---|
| 745 | 68145 | 0080410237 | 2,2',3,3'-nitri(triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-bi-phenyl-2,2'-diyl)phosphite) | yes | no  | yes | 5    |      | SML expressed as sum of phosphite and phosphate |
| 746 | 38810 | 0080693606 | 2,6-di-tert-butyl-4-methylphenyl)pentacerythritol diphosphite                                | yes | no  | yes | 5    |      | SML expressed as sum of phosphite and phosphate |
| 747 | 47600 | 0084030461 | 5-dodecyltin bis(isooctyl mercaptoacetate)   | yes | no  | yes |      | (25) |   |
| 748 | 12765 | 0084434128 | (N-2-aminoethyl)- $\beta$ -alanine, sodium salt  | no  | yes | no  | 0,05 |      |   |
| 749 | 66360 | 0085209221 | 2-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate                                    | yes | no  | yes | 5    |      |   |

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**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [F<sup>1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|     |       |                 |  |     |     |      |      |  |     |
|-----|-------|-----------------|--|-----|-----|------|------|--|-----|
| 750 | 66350 | 0085209293-4    | yes  | no  | no  | 5    |      |  |     |
|     |       |                 | methylenebis(4,6-di-tert-butylphenyl) lithium phosphate        |     |     |      |      |  |     |
| 751 | 81515 | 0087189251      | yes  | no  | no  |      |      |  |     |
|     |       |                 | poly(zinc glycerolate)   |     |     |      |      |  |     |
| 752 | 39890 | 008782644-1     | yes  | yes | no  |      |      |  |     |
|     |       |                 | bis(methylene)adipate sorbitol                                 |     |     |      |      |  |     |
|     |       | – 30069158-41   |  |     |     |      |      |  |     |
|     |       | – 40054686-97   |  |     |     |      |      |  |     |
|     |       | – 40081541-12-0 |  |     |     |      |      |  |     |
| 753 | 62800 | 0092704401      | yes  | no  | no  |      |      |  |     |
|     |       |                 | calcined kaolin  |     |     |      |      |  |     |
| 754 | 56020 | 0099880545      | yes  | no  | no  |      |      |  |     |
|     |       |                 | polyester dibehenate   |     |     |      |      |  |     |
| 755 | 21765 | 010624643-7     | no   | yes | no  | 0,05 |      |  | (1) |
|     |       |                 | methylenebis(3-chloro-2,6-diethylaniline)                      |     |     |      |      |  |     |
| 756 | 40020 | 011055327-0     | yes  | no  | yes |      | (24) |  |     |
|     |       |                 | bis(octylthiomethyl)-6-methylphenol                            |     |     |      |      |  |     |
| 757 | 95725 | 0110638716      | yes  | no  | no  |      |      |  |     |
|     |       |                 | functionalized reaction product with citric acid, lithium salt |     |     |      |      |  |     |

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|     |       |              |   |     |    |     |    |      |              |  |
|-----|-------|--------------|---|-----|----|-----|----|------|--------------|--|
| 758 | 38940 | 011067524-8  | 24-8  | yes | no | yes |    | (24) |              |  |
|     |       |              | bis(dodecylthiomethyl)-6-methylphenol   |     |    |     |    |      |              |  |
| 759 | 54300 | 0118337209-0 | 209-0   | yes | no | yes | 6  |      |              |  |
|     |       |              | ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite  |     |    |     |    |      |              |  |
| 760 | 83595 | 0119345701-0 | 701-0   | yes | no | no  | 18 |      | Composition: |  |
|     |       |              | Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl |     |    |     |    |      | —            | 4,4'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0038613-77-3) (36-46 % w/w (*)), |
|     |       |              |   |     |    |     |    |      | —            | 4,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)), |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>OJ L 83, 22.3.2012, p. 1.]

*Status: Point in time view as at 26/02/2015.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)*

|          |   |  |  |  |  |  |  |  |   |  |
|----------|---|--|--|--|--|--|--|--|---|--|
|          |   |  |  |  |  |  |  |  | — | 3,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)), |
|          |   |  |  |  |  |  |  |  | — | 4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)),       |
|          |   |  |  |  |  |  |  |  | — | tris(2,4-di-tert-butylphenyl)phosphite (CAS No 0031570-04-4) (9-18 % w/w                                 |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |  |  |  |  |  |  |  |   |  |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |  |  |  |  |  |  |  |   |  |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |  |  |  |  |  |  |  |   |  |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |  |  |  |  |  |  |   |  |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |  |  |  |  |  |  |  |   |  |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |  |  |  |  |  |  |   |  |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |  |  |  |  |  |  |   |  |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |  |  |  |  |  |  |   |  |

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|          |   |  |  |  |  |  |  |  |                               |  |
|----------|---|--|--|--|--|--|--|--|-------------------------------|--|
|          |   |  |  |  |  |  |  |  | —                             | w<br>(*),<br>4,4'-<br>biphenylene-0,0-<br>bis(2,4-<br>di-<br>tert-<br>butylphenyl)phosphonate-0<br>bis(2,4-<br>di-<br>tert-<br>butylphenyl)phosphonite<br>(CAS<br>No<br>0112949-97-0)<br>(<br>5<br>%<br>w/<br>w<br>(*) |
|          |   |  |  |  |  |  |  |  | (*)                           | Quantity<br>of<br>substance<br>used/<br>quantity<br>of<br>formulation  |
|          |   |  |  |  |  |  |  |  | Other<br>specifications:<br>— | Phosphor<br>content<br>of<br>min.<br>5,4<br>%<br>to<br>max.  |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |  |  |  |  |  |  |  |                               |  |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |  |  |  |  |  |  |  |                               |  |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |  |  |  |  |  |  |  |                               |  |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |  |  |  |  |  |  |                               |  |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |  |  |  |  |  |  |  |                               |  |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |  |  |  |  |  |  |                               |  |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |  |  |  |  |  |  |                               |  |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |  |  |  |  |  |  |                               |  |

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|     |       |         |  |     |     |     |      |  |                  |   |
|-----|-------|---------|--|-----|-----|-----|------|--|------------------|---|
|     |       |         |  |     |     |     |      |  |                  | 5,9<br>%,<br>Acid<br>value<br>of<br>max.<br>10<br>mg<br>KOH<br>per<br>gram,<br>Melt<br>range<br>of<br>85–<br>110<br>°C, |
| 761 | 92930 | 0120218 | Bis[4-(diethylamino)bis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)] | no  | no  | yes | 6    |  |                  |   |
| 762 | 31530 | 0123968 | 2,5-Di-tert-pentyl-6-(1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl)phenyl ester             | yes | no  | yes | 5    |  |                  |   |
| 763 | 39925 | 0129228 | 2,3-bis(methoxymethyl)-2,5-dimethylhexane  | yes | no  | yes | 0,05 |  |                  |   |
| 764 | 13317 | 0132459 | 5,4,2-bis[4-   | no  | yes | no  | 0,05 |  | Purity<br>> 98,1 |   |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [F<sup>1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

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|     |       |              |   |     |    |     |   |  |   |     |
|-----|-------|--------------|---|-----|----|-----|---|--|---|-----|
|     |       |              | (ethoxycarbonyl)phenyl]-1,4,5,8-naphthalenetetracarboxydiimide  |     |    |     |   |  | % (w/w). Only to be used as co-monomer (max 4 %) for polyesters (PET, PBT). |     |
| 765 | 49485 | 0134701220-5 | dimethyl-6-(1-methylpentadecyl)phenol   | yes | no | yes | 1 |  |   |     |
| 766 | 38879 | 013586156-2  | dimethylbenzylidene)sorbitol  | yes | no | no  |   |  |   |     |
| 767 | 38510 | 0136504195-6 | bis(3-aminopropyl)ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine | yes | no | no  | 5 |  |   |     |
| 768 | 34850 | 014392501-2  | bis(hydrogenated tallow alkyl) oxidised   | yes | no | no  |   |  | Not to be used for articles in contact                                      | (1) |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [F<sup>1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

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|     |       |         |  |     |    |     |      |  |   |  |
|-----|-------|---------|--|-----|----|-----|------|--|---|--|
|     |       |         |  |     |    |     |      |  | with fatty foods for which simulant D is laid down. Only to be used in: |  |
|     |       |         |  |     |    |     |      |  | (a)   | polyolefins at 0,1 % (w/w) concentration and in PET at 0,25 % (w/w) concentration. |
| 769 | 74010 | 0145650 | phosphoric acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester | yes | no | yes | 5    |  | SML expressed as sum of phosphite and phosphate                         |  |
| 770 | 51700 | 0147315 | 2,4,6-tri-tert-butyl-1,3,5-triphenyl                               | yes | no | no  | 0,05 |  |   |  |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.]

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**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|     |       |        |   |    |     |   |  |  |  |  |
|-----|-------|--------|---|----|-----|---|--|--|--|--|
|     |       |        | triazin-2-yl)-5-(hexyloxy)phenol  |    |     |   |  |  |  |  |
| 771 | 34650 | 015184 | 55111-yes<br>bis(hydroxybis[2,2'-methylenebis(4,6-di-tert-butylphenyl)phosphate]) | no | no  | 5 |  |  |  |  |
| 772 | 47500 | 015325 | 05213-yes<br>bis(2,6-dicyclohexyl-2,6-naphthalene dicarboxamide)                  | no | no  | 5 |  |  |  |  |
| 773 | 38840 | 015486 | 21424-yes<br>bis(2,4-dicumylphenyl)phosphite                                      | no | yes | 5 |  |  | SML expressed as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)phosphite and its hydrolysis product (2,4-dicumylphenol) |  |
| 774 | 95270 | 016171 | 72464-yes<br>tris(tert-butylphenyl)-2-butyl-2-ethyl-1,3-                          | no | yes | 2 |  |  | SML expressed as sum of phosphite, phosphate   |  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|     |       |              |  |     |     |     |      |      |   |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|
|     |       |              | propanediol phosphite  |     |     |     |      |      | and the hydrolysis product = TTBP   |
| 775 | 45705 | 0166412478-8 | cyclohexanedicarboxylic acid, diisononyl ester   | yes | no  | no  |      | (32) |   |
| 776 | 76723 | 0167883664-3 | polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4'-diisocyanate     | no  | no  | no  |      |      | The fraction with molecular weight below 1 000 Da should not exceed 1,5 % (w/w) |
| 777 | 31542 | 0174254231-4 | adipic acid, methyl ester, telomer with 1-dodecanethiol, C <sub>16</sub> -C <sub>18</sub> alkyl esters | yes | no  | no  |      |      | 0,5 % in final product (1)  |
| 778 | 71670 | 0178671684-5 | pentacerythritol tetrakis  | no  | yes | yes | 0,05 |      |   |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|     |       |              |  |     |    |     |      |  |  |     |
|-----|-------|--------------|--|-----|----|-----|------|--|--|-----|
|     |       |              | (2-cyano-3,3-diphenylacrylate)   |     |    |     |      |  |  |     |
| 779 | 39815 | 0182121912-6 | bis(methoxymethyl)fluorene   | yes | no | yes | 0,05 |  |  | (1) |
| 780 | 81220 | 01922686017  | [[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-α-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidinyl)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-ω-N,N,N | yes | no | no  | 5    |  |  |     |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|                     |       |          |   |     |     |    |      |      |   |
|---------------------|-------|----------|---|-----|-----|----|------|------|---|
|                     |       |          | [N'-tetrabutyl-1,3,5-triazine-2,4-diamine]  |     |     |    |      |      |   |
| 781                 | 95265 | 02270991 | tris(4-benzoylphenyl)benzene  | yes | no  | no | 0,05 |      |   |
| 782                 | 76725 | 0661476  | polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane |     |     | no |      |      | The fraction with molecular weight below 1 000 Da should not exceed 1 % (w/w) |
| 783                 | 55910 | 0736150  | glycerides, castor-oil mono-, hydrogenated, acetates  |     | no  | no |      | (32) |   |
| [ <sup>F4</sup> 784 | 95420 | 0745070  | tris(2,2-dimethylpropanamido)benzene  | yes | no  | no | 5    |      | ]   |
| 785                 | 24910 | 0000100  | terephthalic acid   |     | yes | no |      | (28) |   |

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|     |       |         |   |     |     |    |      |  |  |  |
|-----|-------|---------|---|-----|-----|----|------|--|--|--|
| 786 | 14627 | 0000117 | 321-5<br>chlorophthalic<br>anhydride  | no  | yes | no | 0,05 |  | SML<br>expressed<br>as 3-<br>chlorophthalic<br>acid  |  |
| 787 | 14628 | 0000118 | 445-6<br>chlorophthalic<br>anhydride  | no  | yes | no | 0,05 |  | SML<br>expressed<br>as 4-<br>chlorophthalic<br>acid  |  |
| 788 | 21498 | 0002530 | 185-0<br>(methacryloxy)propyl]trimethoxysilane  | no  | yes | no | 0,05 |  | Only (1)<br>to be (11)<br>used<br>as a<br>surface<br>treatment<br>agent<br>of<br>inorganic<br>fillers  |  |
| 789 | 60027 | —       | hydrogenated<br>homopolymers<br>and/or<br>copolymers<br>made<br>of 1-<br>hexene<br>and/<br>or 1-<br>octene<br>and/<br>or 1-<br>decene<br>and/<br>or 1-<br>dodecene<br>and/<br>or 1- | yes | no  | no |      |  | Average (2)<br>molecular<br>weight<br>not<br>less<br>than<br>440<br>Da.<br>Viscosity<br>at 100<br>°C not<br>less<br>than<br>3,8 cSt<br>(3,8<br>× 10 <sup>-6</sup><br>m <sup>2</sup> /s). |  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|     |       |                  |   |     |    |    |      |  |  |  |
|-----|-------|------------------|---|-----|----|----|------|--|--|--|
|     |       |                  | tetradecene<br>(Mw:<br>440–<br>12<br>000)   |     |    |    |      |  |  |  |
| 790 | 80480 | 009075<br>008245 | poly-<br>1,3,5-<br>triazine-2,4-<br>diyl)-<br>[(2,2,6,6-<br>tetramethyl-4-<br>piperidyl)imino]<br>hexa-<br>methylene-<br>[(2,2,6,6-<br>tetramethyl-4-<br>piperidyl)imino] | yes | no | no | 5    |  |  | Average (16)<br>molecular<br>weight<br>not<br>less<br>than<br>2 400<br>Da.<br>Residual<br>content<br>of<br>morpholine<br>≤ 30<br>mg/<br>kg, of<br>N,N'-<br>bis(2,2,6,6-<br>tetramethylpiperidin-4-<br>yl)hexane-1,6-<br>diamine<br>< 15<br>000<br>mg/kg,<br>and of<br>2,4-<br>dichloro-6-<br>morpholino-1,3,5-<br>triazine<br>≤ 20<br>mg/kg. |
| 791 | 92470 | 0106990          | N,N'-<br>,N<br>,N''-<br>tetrakis(4,6-   | yes | no | no | 0,05 |  |  |  |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.]

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**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

*Status: Point in time view as at 26/02/2015.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)*

|                     |       |             |  |     |     |     |      |  |   |
|---------------------|-------|-------------|--|-----|-----|-----|------|--|---|
|                     |       |             | bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine                                 |     |     |     |      |  |   |
| 792                 | 92475 | 0203255383  | 5,5'-tetrakis(tert-butyl)-2,2'-dihydroxybiphenyl, cyclic ester with [3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propyl]oxyphosphonous acid | yes | no  | yes | 5    |  | SML expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products |
| 793                 | 94000 | 00001026716 | triethanolamine  | yes | no  | no  | 0,05 |  | SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine |
| [ <sup>F6</sup> 794 | 18117 | 000007914   | glycolic acid  | no  | yes | no  |      |  | Only to be used   |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|     |       |  |     |    |    |      |  |  |   |             |
|-----|-------|--|-----|----|----|------|--|--|---|-------------|
|     |       |  |     |    |    |      |  |  | for manufacture of polyglycolic acid (PGA) for (i) indirect food contact behind polyesters such as polyethylene terephthalate (PET) or polylactic acid (PLA); and (ii) direct food contact of a blend of PGA up to 3 % w/w in PET or PLA. |             |
| 795 | 40155 | 01241725, 01241726, 01241727, 01241728 | yes | no | no | 0,05 |  |  |   | (2)<br>(12) |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|                     |       |              |   |     |    |     |      |              |   |
|---------------------|-------|--------------|---|-----|----|-----|------|--------------|---|
|                     |       |              | N,N'-diformylhexamethylenediamine   |     |    |     |      |              |   |
| 796                 | 72141 | 0018600257-4 | (1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]   | yes | no | yes | 0,05 |              | SML including the sum of its hydrolysis products  |
| [ <sup>F6</sup> 797 | 76807 | 0073018265   | Diethyl ester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol                           | yes | no | yes |      | (31)<br>(32) | I   |
| 798                 | 92200 | 000642286    | terephthalic acid, bis(2-ethylhexyl)ester   | no  | no | no  | 60   | (32)         |   |
| [ <sup>F4</sup> 799 | 77708 |              | polyethylene glycol (EO = 1-50) ethers of linear and branched primary (C <sub>8</sub> -C <sub>22</sub> ) alcohols | yes | no | no  | 1,8  |              | In compliance with the maximum ethylene oxide content as laid down in the purity criteria |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|     |       |         |  |     |    |    |   |  | for food additives in Commission Regulation (EU) No 231/2012. |      |
|-----|-------|---------|--|-----|----|----|---|--|---|------|
| 800 | 94425 | 0000867 | tributyl phosphonoacetate  | yes | no | no |   |  | Only for use in PET   |      |
| 801 | 30607 | —       | acids, C <sub>2</sub> -C <sub>24</sub> , aliphatic, linear, monocarboxylic, from natural oils and fats, lithium salt | yes | no | no |   |  |   |      |
| 802 | 33105 | 0146340 | alcohols C <sub>12</sub> -C <sub>14</sub> secondary, β-(2-hydroxyethoxy), ethoxylated                                | yes | no | no | 5 |  |   | (12) |
| 803 | 33535 | 0152261 | 3-1 alkenes (C <sub>20</sub> -C <sub>24</sub> ) copolymer with   | yes | no | no |   |  | Not to be used for articles                                   | (13) |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|          |   |        |  |     |    |    |  |  |  |
|----------|---|--------|--|-----|----|----|--|--|--|
|          |   |        | maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine  |     |    |    |  | in contact with fatty foods for which simulant D is laid down. Not to be used in contact with alcoholic foods. |  |
| 804      | 80510   | 101012 | poly(7-nonyl-1,1-dioxo-1-thiopropyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctyl), process mixture with x = 1 and/or 5, neutralised with | yes | no | no |  | Only to be used as polymer production aid in polyethylene (PE), polypropylene (PP) and polystyrene (PS)        |  |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |        |  |     |    |    |  |  |  |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |        |  |     |    |    |  |  |  |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |        |  |     |    |    |  |  |  |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |        |  |     |    |    |  |  |  |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |        |  |     |    |    |  |  |  |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |        |  |     |    |    |  |  |  |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |        |  |     |    |    |  |  |  |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |        |  |     |    |    |  |  |  |

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|                     |       |              |  |     |     |    |   |  |   |
|---------------------|-------|--------------|--|-----|-----|----|---|--|---|
|                     |       |              | dodecylbenzenesulfonic acid  |     |     |    |   |  |   |
| 805                 | 93450 | —            | titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt] | yes | no  | no |   |  | The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/w                  |
| 806                 | 14876 | 0001076197-7 | cyclohexanedicarboxylic acid   | no  | yes | no | 5 |  | Only to be used for manufacture of polyesters   |
| [ <sup>F5</sup> 807 | 93485 | —            | titanium nitride, nanoparticles  | yes | no  | no |   |  | No migration of titanium nitride nanoparticles. Only to be used in polyethylene terephthalate (PET) up to 20 mg/kg. |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

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|     |       |         |   |     |    |     |      |  |  |
|-----|-------|---------|---|-----|----|-----|------|--|--|
|     |       |         |   |     |    |     |      |  | In the PET, the agglomerates have a diameter of 100-500 nm consisting of primary titanium nitride nanoparticles; primary particles have a diameter of approximately 20 nm. |
| 808 | 38550 | 0882073 | bis(4-propylbenzylidene)propylsorbitol  | yes | no | no  | 5    |  | SML including the sum of its hydrolysis products   |
| 809 | 49080 | 0852282 | (2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione | yes | no | yes | 0,05 |  | Only (6) for use (14) in PET (15)  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|                      |       |         |  |    |    |    |      |   |   |
|----------------------|-------|---------|--|----|----|----|------|---|---|
| 810                  | 68119 |         | neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid | no | no | 5  | (32) | Not to be used for articles in contact with fatty foods for which simulant D is laid down.                                    |   |
| 811                  | 80077 | 006844  | polyethylene waxes, oxidised   | no | no | 60 |      |   |   |
| [ <sup>F6</sup> 812] | 80350 | 0124578 | poly(12-hydroxystearic acid)-polyethyleneimine copolymer                             | no | no |    |      | Only to be used in plastics up to 0,1 % w/w. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine. | ] |
| 813                  | 91530 | —       | sulphosuccinic acid  | no | no | 5  |      |   |   |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|     |       |   |   |     |    |   |      |   |  |  |
|-----|-------|---|---|-----|----|---|------|---|--|--|
|     |       |   | alkyl (C <sub>4</sub> -C <sub>20</sub> ) or cyclohexyl diesters, salts            |     |    |   |      |   |  |  |
| 814 | 91815 | — | monoalkyl (C <sub>10</sub> -C <sub>16</sub> ) polyethyleneglycol esters, salts    | no  | no | 2 |      |   |  |  |
| 815 | 94985 | — | trimethyl mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid | no  | no | 5 | (32) | Not to be used for articles in contact with fatty foods for which simulant D is laid down |  |  |
| 816 | 45704 | — | cis-1,2-cyclohexanedicarboxylic acid, salts                                       | yes | no | 5 |      |   |  |  |
| 817 | 38507 | — | cis-endo-bicyclo[2.2.1]heptane-2,3-   | yes | no | 5 |      | Not to be used  |  |  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|     |       |   |                                 |     |    |      |  |  |   |
|-----|-------|---|---------------------------------|-----|----|------|--|--|---|
|     |       |   | dicarboxylic acid, salts        |     |    |      |  |  | with polyethylene in contact with acidic foods. Purity $\geq 96$ %.   |
| 818 | 21530 | — | methallyl sulphonic acid, salts | yes | no | 5    |  |  |   |
| 819 | 68110 | — | neodecanoic acid, salts         | no  | no | 0,05 |  |  | Not to be used in polymers contacting fatty foods. Not to be used for articles in contact with fatty foods for which simulant D is laid down. SML expressed |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|     |       |   |  |     |     |    |      |  |   |     |
|-----|-------|---|--|-----|-----|----|------|--|---|-----|
|     |       |   |  |     |     |    |      |  | as<br>neodecanoic<br>acid.  |     |
| 820 | 76420 | —   | pimelic<br>acid,<br>salts  | yes | no  | no |      |  |   |     |
| 821 | 90810 | —   | stearoyl-<br>lactic<br>acid,<br>salts  | yes | no  | no |      |  |   |     |
| 822 | 71938 | —   | perchloric<br>acid,<br>salts   | yes | no  | no | 0,05 |  |   | (4) |
| 823 | 24889 | —   | 5-<br>Sulpho-<br>isophthalic<br>acid,<br>salts   | no  | yes | no | 5    |  |   |     |
| 854 | 71943 | 0329238 <sup>a</sup><br>2416 <sup>b</sup> | perfluoro-<br>acetic<br>acid,<br>α-<br>substituted<br>with<br>the<br>copolymer<br>of<br>perfluoro-1,2-<br>propylene<br>glycol<br>and<br>perfluoro-1,1-<br>ethylene<br>glycol,<br>terminated<br>with<br>chlorohexafluoropropoxy<br>groups | yes | no  | no |      |  | Only<br>to be<br>used<br>in<br>concentrations<br>up to<br>0,5 %<br>w/w<br>in the<br>polymerisation<br>of<br>fluoropolymers<br>that<br>are<br>processed<br>at<br>temperatures<br>at or<br>above<br>340 |     |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

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|                     |       |  |   |     |    |    |  | °C and are intended for use in repeated use articles   |
|---------------------|-------|--|---|-----|----|----|--|--|
| [ <sup>F9</sup> 855 | 40560 |  | (butadiene, styrene, methyl methacrylate) copolymer cross-linked with 1,3-butanediol dimethacrylate                                   | yes | no | no |  | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below. |
| 856                 | 40563 |  | (butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate | yes | no | no |  | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room                       |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

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|  |   |              |  |     |    |     |      |  |  |
|--|---|--------------|--|-----|----|-----|------|--|--|
|  |   |              |  |     |    |     |      |  | temperature or below.  |
| 857                                      | 66765   | 0037953      | (2) methyl methacrylate, butyl acrylate, styrene, glycidyl methacrylate) copolymer                                   | yes | no | no  |      |  | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % at room temperature or below.  |
| [ <sup>F3</sup> [ <sup>X1</sup> 85838565 |   | 0090498390-1 | bis[2-(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionyloxy)-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]undecane | yes | no | yes | 0,05 |  | SML (2)] expressed as the sum of the substance and its oxidation product 3-[(3-(3-tert-butyl-4-hydroxy-5-methylphenyl)prop-2-enoyloxy)-1,1-dimethylethyl]-9-[(3-(3-tert-butyl-4- |
| <b>a</b>                                 | OJ L 302, 19.11.2005, p. 28.  |              |  |     |    |     |      |  |  |
| <b>b</b>                                 | OJ L 330, 5.12.1998, p. 32.   |              |  |     |    |     |      |  |  |
| <b>c</b>                                 | OJ L 253, 20.9.2008, p. 1.  |              |  |     |    |     |      |  |  |
| <b>d</b>                                 | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |              |  |     |    |     |      |  |  |
| <b>e</b>                                 | OJ L 158, 18.6.2008, p. 17.   |              |  |     |    |     |      |  |  |
| <b>f</b>                                 | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |              |  |     |    |     |      |  |  |
| <b>g</b>                                 | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |              |  |     |    |     |      |  |  |
| <b>h</b>                                 | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |              |  |     |    |     |      |  |  |

*Status: Point in time view as at 26/02/2015.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)*

|                     |   |  |  |     |    |    |  |   |
|---------------------|---|--|--|-----|----|----|--|---|
|                     |   |  |  |     |    |    |  | hydroxy-5-methylphenyl)propionyloxy)-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]-undecane in equilibrium with its para quinone methid tautomer.          |
| [ <sup>F1</sup> 859 |   |  | (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with divinylbenzene, in nanoform | yes | no | no |  | Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. |
| <b>a</b>            | OJ L 302, 19.11.2005, p. 28.  |  |  |     |    |    |  |   |
| <b>b</b>            | OJ L 330, 5.12.1998, p. 32.   |  |  |     |    |    |  |   |
| <b>c</b>            | OJ L 253, 20.9.2008, p. 1.  |  |  |     |    |    |  |   |
| <b>d</b>            | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |  |     |    |    |  |   |
| <b>e</b>            | OJ L 158, 18.6.2008, p. 17.   |  |  |     |    |    |  |   |
| <b>f</b>            | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |  |     |    |    |  |   |
| <b>g</b>            | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |  |     |    |    |  |   |
| <b>h</b>            | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |  |     |    |    |  |   |

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|          |   |  |  |  |  |  |  |  |  |   |
|----------|---|--|--|--|--|--|--|--|--|---|
|          |   |  |  |  |  |  |  |  |  | When used together with the substance with FCM No 998 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |  |  |  |  |  |  |  |  |   |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |  |  |  |  |  |  |  |  |   |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |  |  |  |  |  |  |  |  |   |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |  |  |  |  |  |  |  |   |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |  |  |  |  |  |  |  |  |   |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |  |  |  |  |  |  |  |   |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |  |  |  |  |  |  |  |   |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |  |  |  |  |  |  |  |   |

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|     |       |         |  |    |    |  |  |  |   |
|-----|-------|---------|--|----|----|--|--|--|---|
|     |       |         |  |    |    |  |  |  | it shall be > 40 nm.  |
| 860 | 71980 | 0051798 | pebF0r0e-<br>(poly(n-propoxy)propanoic acid] | no | no |  |  |  | Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles |
| 861 | 71990 | 0013252 | pebF0r0e-<br>(n-propoxy)propanoic acid]      | no | no |  |  |  | Only to be used in the polymerisation of fluoropolymers that are processed at temperatures  |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|                     |       |              |                       |     |    |      |  |  |   |
|---------------------|-------|--------------|-----------------------|-----|----|------|--|--|---|
|                     |       |              |                       |     |    |      |  |  | at or above 265 °C and are intended for use in repeated use articles  |
| [ <sup>F6</sup> 862 | 15180 | 0018085302-4 | no diacetoxy-1-butene | yes | no | 0,05 |  |  | SML (17) including (19)] the hydrolysis product 3,4-dihydroxy-1-butene Only to be used as a co-monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers. |
| [ <sup>F9</sup> 863 | 15260 | 000064642503 | no decanediamine      | yes | no | 0,05 |  |  | Only to be used as a co-monomer for   |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

*Status: Point in time view as at 26/02/2015.*

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|     |       |              |                                      |     |    |    |   |  |  |
|-----|-------|--------------|--------------------------------------|-----|----|----|---|--|--|
|     |       |              |                                      |     |    |    |   |  | manufacturing polyamide articles for repeated use in contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact up to 150 °C. |
| 864 | 46330 | 0000056206-4 | 206-4<br>diamino-6-hydroxypyrimidine | yes | no | no | 5 |  | Only to be used in rigid poly(vinyl chloride) (PVC) in contact with non-acidic and non-alcoholic   |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>OJ L 83, 22.3.2012, p. 1.]

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|                     |       |               |   |     |    |    |  |  |   |  |
|---------------------|-------|---------------|---|-----|----|----|--|--|---|--|
|                     |       |               |   |     |    |    |  |  | aqueous food  |  |
| [ <sup>F5</sup> 865 | 40619 | 0025322(00-01 | (butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer | yes | no | no |  |  | Only to be used in:<br>(a)<br><br>(b)               | ] rigid poly(vinyl chloride) (PVC) at a maximum level of 1 % w/w; polylactic acid (PLA) at a maximum level of 5 % w/w. |
| 866                 | 40620 | —             | (butyl acrylate, methyl methacrylate) copolymer, cross-linked with  | yes | no | no |  |  | Only to be used in rigid poly(vinyl chloride) (PVC) |  |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|                     |       |         |  |    |    |  |  |  |  |
|---------------------|-------|---------|--|----|----|--|--|--|--|
|                     |       |         | allyl methacrylate   |    |    |  |  |  | at a maximum level of 7 %  |
| 867                 | 40815 | 0040471 | (b) yes methacrylate, ethyl acrylate, methyl methacrylate) copolymer | no | no |  |  |  | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %  |
| [ <sup>F5</sup> 868 | 53245 | 0009010 | (b) yes acrylate, methyl methacrylate) copolymer                     | no | no |  |  |  | Only to be used in:<br>(a) rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % w/w;<br>(b) polylactic acid (PLA) at a maximum |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]



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|                      |       |              |  |     |     |    |      |  |   |   |
|----------------------|-------|--------------|--|-----|-----|----|------|--|---|---|
|                      |       |              |  |     |     |    |      |  | (c)   | level of 5 % w/w; polyethylene terephthalate (PET) at a maximum level of 5 % w/w. |
| 869                  | 66763 | 00271364558  | (butyl acrylate, methyl methacrylate, styrene) copolymer   | yes | no  | no |      |  | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 3 % |   |
| 870                  | 95500 | 0160535466   | N,N'-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide | yes | no  | no | 5    |  |   |   |
| [ <sup>F10</sup> 872 |       | 0006607241-6 | phenyl-3,3-  | no  | yes | no | 0,05 |  | To be used  | (20)]   |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|                     |       |              |   |     |     |    |      |      |   |
|---------------------|-------|--------------|---|-----|-----|----|------|------|---|
|                     |       |              | bis(4-hydroxyphenyl)phthalimidine   |     |     |    |      |      | only as a co-monomer in polycarbonate copolymers  |
| [ <sup>F9</sup> 873 | 93460 |              | titanium dioxide reacted with octyltriethoxysilane  | yes | no  | no |      |      | Reaction product of titanium dioxide with up to 2 % w/w surface treatment substance octyltriethoxysilane, processed at high temperatures. |
| [ <sup>F3</sup> 874 | 16265 | 0156065600-8 | no dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyloxy, ω-3-dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyl polydimethylsiloxane | no  | yes | no | 0,05 | (33) | Only to be used as comonomer in siloxane modified polycarbonate. The oligomeric mixture shall be characterised by the formula             |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|     |       |                |   |     |    |     |   |  |  | $C_{24}H_{38}Si_2O_5(SiOC_2H_6)_n$<br>(50<br>> n ≥<br>26). |
|-----|-------|----------------|---|-----|----|-----|---|--|--|--|
| 875 | 80345 | 0058128p01y612 | poly(12-hydroxystearic acid) stearate   | yes | no | yes | 5 |  |  |  |
| 878 | 31335 | —              | acids, fatty (C <sub>8</sub> -C <sub>22</sub> ) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C <sub>3</sub> -C <sub>22</sub> ) | yes | no | no  |   |  |  |  |
| 879 | 31336 | —              | acids, fatty (C <sub>8</sub> -C <sub>22</sub> ) from animal or vegetable fats   | yes | no | no  |   |  |  |  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

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**h** [<sup>F3</sup>OJ L 83, 22.3.2012, p. 1.]

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|                     |       |              |  |     |     |    |   |       |  |
|---------------------|-------|--------------|--|-----|-----|----|---|-------|--|
|                     |       |              | and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C <sub>1</sub> -C <sub>22</sub> ) |     |     |    |   |       |  |
| [ <sup>F4</sup> 880 | 31348 |              | acids, fatty (C <sub>8</sub> -C <sub>22</sub> ), esters with pentaerythritol'  | yes | no  | no |   |       |  |
| 881                 | 25187 | 000301029644 | no tetramethylcyclobutane-1,3-diol   | no  | yes | no | 5 | 29644 | Only for:<br>(a) repeated use articles for long term storage at room temperature or below and hotfill;<br>(b) single use materials |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

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**h** [<sup>F3</sup>OJ L 83, 22.3.2012, p. 1.]

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|          |   |  |  |  |  |  |  |   |
|----------|---|--|--|--|--|--|--|---|
|          |   |  |  |  |  |  |  | and articles as a co-monomer at a maximum use level of 35 mole % of the diol component of polyesters, and if such materials and articles are for long term storage at room temperature or below of food types |
| <b>a</b> | <a href="#">OJ L 302, 19.11.2005, p. 28.</a>  |  |  |  |  |  |  |   |
| <b>b</b> | <a href="#">OJ L 330, 5.12.1998, p. 32.</a>   |  |  |  |  |  |  |   |
| <b>c</b> | <a href="#">OJ L 253, 20.9.2008, p. 1.</a>  |  |  |  |  |  |  |   |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ( <a href="#">OJ L 83, 22.3.2012, p. 1.</a> )] |  |  |  |  |  |  |   |
| <b>e</b> | <a href="#">OJ L 158, 18.6.2008, p. 17.</a>   |  |  |  |  |  |  |   |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |  |  |  |  |  |   |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |  |  |  |  |  |   |
| <b>h</b> | [ <sup>F3</sup> <a href="#">OJ L 83, 22.3.2012, p. 1.</a> ]   |  |  |  |  |  |  |   |

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|          |   |              |                    |    |     |    |      |  |  |   |
|----------|---|--------------|--------------------|----|-----|----|------|--|--|---|
|          |   |              |                    |    |     |    |      |  |  | which have an alcohol content of up to 10 % and for which Table 2 of Annex III does not assign simulant D2. Hot fill conditions are allowed for such single use materials and articles. |
| 882      | 25872   | 000241629346 | no trimethylphenol | no | yes | no | 0,05 |  |  |   |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |              |                    |    |     |    |      |  |  |   |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |              |                    |    |     |    |      |  |  |   |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |              |                    |    |     |    |      |  |  |   |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |              |                    |    |     |    |      |  |  |   |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |              |                    |    |     |    |      |  |  |   |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |              |                    |    |     |    |      |  |  |   |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |              |                    |    |     |    |      |  |  |   |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |              |                    |    |     |    |      |  |  |   |

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|     |       |         |   |     |     |    |      |  |  |
|-----|-------|---------|---|-----|-----|----|------|--|--|
| 883 | 22074 | 0004457 | 371-0<br>methyl-1,5-pentanediol                           | no  | yes | no | 0,05 |  | Only to be used in materials in contact with food at a surface to mass ratio up to 0,5 dm <sup>2</sup> /kg |
| 884 | 34240 | 0091082 | alkyl(C <sub>21</sub> )sulphonic acid, esters with phenol | yes | no  | no | 0,05 |  | Not to be used for articles in contact with fatty foods for which simulant D is laid down.                 |
| 885 | 45676 | 0263244 | oligomers of  | yes | no  | no |      |  | Only to be used in   |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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**Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)

|                     |   |         |   |    |    |  |      |  |   |
|---------------------|---|---------|---|----|----|--|------|--|---|
|                     |   |         | (butylene terephthalate)                  |    |    |  |      |  | poly(ethylene terephthalate) (PET), poly(butylene terephthalate) (PBT), polycarbonate (PC), polystyrene (PS) and rigid poly(vinyl chloride) (PVC) plastics in concentrations up to 1 % w/w, in contact with aqueous, acidic and alcoholic foods, for long term storage at room temperature. |
| [ <sup>F9</sup> 894 | 93360   | 0016545 | 554 of propionic acid, ditetradecyl ester | no | no |  | (14) |  |   |
| <b>a</b>            | OJ L 302, 19.11.2005, p. 28.  |         |   |    |    |  |      |  |   |
| <b>b</b>            | OJ L 330, 5.12.1998, p. 32.   |         |   |    |    |  |      |  |   |
| <b>c</b>            | OJ L 253, 20.9.2008, p. 1.  |         |   |    |    |  |      |  |   |
| <b>d</b>            | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |         |   |    |    |  |      |  |   |
| <b>e</b>            | OJ L 158, 18.6.2008, p. 17.   |         |   |    |    |  |      |  |   |
| <b>f</b>            | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |         |   |    |    |  |      |  |   |
| <b>g</b>            | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |         |   |    |    |  |      |  |   |
| <b>h</b>            | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |         |   |    |    |  |      |  |   |



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*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)*

|     |       |             |   |     |    |    |      |  |   |  |
|-----|-------|-------------|---|-----|----|----|------|--|---|--|
| 895 | 47060 | 01710903965 | 3965-<br>di-tert-<br>butyl-4-<br>hydroxyphenyl)propanoic<br>acid,<br>esters<br>with<br>C13-<br>C15<br>branched<br>and<br>linear<br>alcohols | yes | no | no | 0,05 |  | Only<br>to be<br>used<br>in<br>polyolefins<br>in<br>contact<br>with<br>foods<br>other<br>than<br>fatty/<br>high-<br>alcoholic<br>and<br>dairy<br>products.  |  |
| 896 | 71958 | 0958445341  | 341-8<br>perfluoro-3-<br>[(3-<br>methoxy-<br>propoxy)propanoic<br>acid],<br>ammonium<br>salt  | yes | no | no |      |  | Only<br>to be<br>used<br>in the<br>polymerisation<br>of<br>fluoropolymers<br>when:<br>— processed<br>at<br>temperatures<br>higher<br>than<br>280<br>°C<br>for<br>at<br>least<br>10<br>minutes,<br>processed<br>at |  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>OJ L 83, 22.3.2012, p. 1.]

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|                     |   |             |   |     |    |    |  |  |   |
|---------------------|---|-------------|---|-----|----|----|--|--|---|
|                     |   |             |   |     |    |    |  |  | temperatures higher than 190 °C up to 30 % w/w for use in blends with polyoxymethylene polymers and intended for repeated use articles. |
| [ <sup>F3</sup> 902 |   | 000012844-9 | benzothiazol-3-one 1,1-dioxide, sodium salt | yes | no | no |  |  | The substance shall comply with the specific purity criteria as set out in Commission Regulation (EU)                                   |
| <b>a</b>            | OJ L 302, 19.11.2005, p. 28.  |             |   |     |    |    |  |  |   |
| <b>b</b>            | OJ L 330, 5.12.1998, p. 32.   |             |   |     |    |    |  |  |   |
| <b>c</b>            | OJ L 253, 20.9.2008, p. 1.  |             |   |     |    |    |  |  |   |
| <b>d</b>            | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |             |   |     |    |    |  |  |   |
| <b>e</b>            | OJ L 158, 18.6.2008, p. 17.   |             |   |     |    |    |  |  |   |
| <b>f</b>            | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |             |   |     |    |    |  |  |   |
| <b>g</b>            | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |             |   |     |    |    |  |  |   |
| <b>h</b>            | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |             |   |     |    |    |  |  |   |

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|                     |   |            |  |     |    |    |  | No 231/2012 <sup>a</sup> .  |     |
|---------------------|---|------------|--|-----|----|----|--|---|-----|
| [ <sup>F1</sup> 903 |   | 37486-624- | perfluoro-[(5,8,11,14-tetramethyl)-tetraethyleneglycol ethyl propyl ether] | yes | no | no |  | Only to be used as a polymer production aid in the polymerisation of fluoropolymers intended for:<br>(a) repeated and single use materials and articles when sintered or processed (non-sintered) at temperatures at or above 360 °C for at least 10 minutes or | ] ] |
| <b>a</b>            | OJ L 302, 19.11.2005, p. 28.  |            |  |     |    |    |  |   |     |
| <b>b</b>            | OJ L 330, 5.12.1998, p. 32.   |            |  |     |    |    |  |   |     |
| <b>c</b>            | OJ L 253, 20.9.2008, p. 1.  |            |  |     |    |    |  |   |     |
| <b>d</b>            | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |            |  |     |    |    |  |   |     |
| <b>e</b>            | OJ L 158, 18.6.2008, p. 17.   |            |  |     |    |    |  |   |     |
| <b>f</b>            | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |            |  |     |    |    |  |   |     |
| <b>g</b>            | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |            |  |     |    |    |  |   |     |
| <b>h</b>            | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |            |  |     |    |    |  |   |     |

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|     |       |         |                                     |     |    |    |   |  |  |   |  |
|-----|-------|---------|-------------------------------------|-----|----|----|---|--|--|---|--|
|     |       |         |                                     |     |    |    |   |  |  |   | at higher temperatures for equivalent shorter times; repeated use materials and articles when processed (non-sintered) at temperatures from 300 °C and up to 360 °C for at least 10 minutes. |
| 923 | 39150 | 0000120 | NON-bis(2-hydroxyethyl)dodecanamide | yes | no | no | 5 |  |  | The residual amount of diethanolamine in plastics, as an impurity and | (18)   |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|     |       |         |   |           |    |      |  |  |  |
|-----|-------|---------|---|-----------|----|------|--|--|--|
|     |       |         |   |           |    |      |  |  | decomposition product of the substance, should not result in a migration of diethanolamine higher than 0,3 mg/kg food. |
| 924 | 94987 |         | trimethyl mixed triesters and diesters with n-octanoic and n-decanoic acids | propylene | no | 0,05 |  |  | Only for use in PET in contact with all types of foods other than fatty, high-alcoholic and dairy products.            |
| 926 | 71955 | 0908020 | propyl (2-ethoxyethoxy)acetic acid],  | no        | no |      |  |  | Only to be used in the polymerisation  |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [F<sup>1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [F<sup>2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

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**h** [F<sup>3</sup>OJ L 83, 22.3.2012, p. 1.]

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|                     |   |          |  |    |    |  |  |   |
|---------------------|---|----------|--|----|----|--|--|---|
|                     |   |          | ammonium salt                          |    |    |  |  | of fluoropolymers that are processed at temperatures higher than 300 °C for at least 10 minutes.  |
| [ <sup>F1</sup> 969 |   | 24937-78 | Styleneyes vinyl acetate copolymer wax | no | no |  |  | Only to be used as a polymeric additive up to 2 % w/w in polyolefins. The migration of low molecular weight oligomeric fraction below 1 000 Da shall not exceed 5 mg/ |
| <b>a</b>            | OJ L 302, 19.11.2005, p. 28.  |          |  |    |    |  |  |   |
| <b>b</b>            | OJ L 330, 5.12.1998, p. 32.   |          |  |    |    |  |  |   |
| <b>c</b>            | OJ L 253, 20.9.2008, p. 1.  |          |  |    |    |  |  |   |
| <b>d</b>            | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |          |  |    |    |  |  |   |
| <b>e</b>            | OJ L 158, 18.6.2008, p. 17.   |          |  |    |    |  |  |   |
| <b>f</b>            | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |          |  |    |    |  |  |   |
| <b>g</b>            | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |          |  |    |    |  |  |   |
| <b>h</b>            | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |          |  |    |    |  |  |   |

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|     |       |         |                                  |     |    |    |  |  |   |      |
|-----|-------|---------|----------------------------------|-----|----|----|--|--|---|------|
|     |       |         |                                  |     |    |    |  |  | kg food.  |      |
| 971 | 25885 | 0002459 | trifluoromethyl trimellitate     | yes | no |    |  |  | Only to be used as a co-monomer up to 0,35 % w/w to produce modified polyesters intended to be used in contact with aqueous and dry foodstuffs containing no free fat at the surface. | (17) |
| 972 | 45197 | 0012158 | 8-cyclohexyl hydroxide phosphate | yes | no | no |  |  |   |      |
| 973 | 22931 | 0019430 | (9-Fluorobutyl)ethylene          | no  | no |    |  |  | Only to be used as a co-monomer   |      |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|     |       |             |   |     |    |     |   |  |  |
|-----|-------|-------------|---|-----|----|-----|---|--|--|
|     |       |             |   |     |    |     |   |  | up to 0,1 % w/w in the polymerisation of fluoropolymers, sintered at high temperatures.  |
| 974 | 74050 | 939402-02-5 | Phosphoric acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters | yes | no | yes | 5 |  | SML   expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis product 4-t-amyphenol. The migration of the hydrolysis product 2,4-di-t-amyphenol should not exceed 0,05 mg/kg. |

**a** OJ L 302, 19.11.2005, p. 28.

**b** OJ L 330, 5.12.1998, p. 32.

**c** OJ L 253, 20.9.2008, p. 1.

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]

**e** OJ L 158, 18.6.2008, p. 17.

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.

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**h** [<sup>F3</sup>OJ L 83, 22.3.2012, p. 1.]



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|                      |   |           |  |    |     |    |      |  |     |
|----------------------|---|-----------|--|----|-----|----|------|--|-----|
| [ <sup>F3</sup> 979  | 79987   | —         | (polyethylene terephthalate, hydroxylated polybutadiene, pyromellitic anhydride) copolymer | no | no  |    |      | Only to be used in polyethylene terephthalate (PET) at a maximum level of 5 % w/w.   | ] ] |
| [ <sup>F10</sup> 988 |   | 3634-83-1 | 1,3-bis(isocyanatomethyl)benzene   | no | yes | no | (34) | SML(T)] applies to the migration of its hydrolysis product, 1,3-benzenedimethanamine. To be used only as co-monomer in the manufacture of a middle layer coating on a poly(ethylene terephthalate) polymer film in a |     |
| <b>a</b>             | OJ L 302, 19.11.2005, p. 28.  |           |  |    |     |    |      |  |     |
| <b>b</b>             | OJ L 330, 5.12.1998, p. 32.   |           |  |    |     |    |      |  |     |
| <b>c</b>             | OJ L 253, 20.9.2008, p. 1.  |           |  |    |     |    |      |  |     |
| <b>d</b>             | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |           |  |    |     |    |      |  |     |
| <b>e</b>             | OJ L 158, 18.6.2008, p. 17.   |           |  |    |     |    |      |  |     |
| <b>f</b>             | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |           |  |    |     |    |      |  |     |
| <b>g</b>             | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |           |  |    |     |    |      |  |     |
| <b>h</b>             | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |           |  |    |     |    |      |  |     |

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|                     |   |  |   |     |    |    |  |  |  |
|---------------------|---|--|---|-----|----|----|--|--|--|
|                     |   |  |   |     |    |    |  |  | multilayer film  |
| [ <sup>F1</sup> 998 |   |  | (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer not cross-linked, in nanoform | yes | no | no |  |  | Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ |
| <b>a</b>            | OJ L 302, 19.11.2005, p. 28.  |  |   |     |    |    |  |  |  |
| <b>b</b>            | OJ L 330, 5.12.1998, p. 32.   |  |   |     |    |    |  |  |  |
| <b>c</b>            | OJ L 253, 20.9.2008, p. 1.  |  |   |     |    |    |  |  |  |
| <b>d</b>            | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |   |     |    |    |  |  |  |
| <b>e</b>            | OJ L 158, 18.6.2008, p. 17.   |  |   |     |    |    |  |  |  |
| <b>f</b>            | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |   |     |    |    |  |  |  |
| <b>g</b>            | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |   |     |    |    |  |  |  |
| <b>h</b>            | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |   |     |    |    |  |  |  |

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|          |   |            |              |    |    |  |  |  |   |
|----------|---|------------|--------------|----|----|--|--|--|---|
|          |   |            |              |    |    |  |  |  | or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm. |
| 1017     |   | 25618-55-7 | polyglycerol | no | no |  |  |  | To be processed under conditions preventing the   |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |            |              |    |    |  |  |  |   |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |            |              |    |    |  |  |  |   |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |            |              |    |    |  |  |  |   |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |            |              |    |    |  |  |  |   |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |            |              |    |    |  |  |  |   |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |            |              |    |    |  |  |  |   |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |            |              |    |    |  |  |  |   |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |            |              |    |    |  |  |  |   |

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|      |  |  |   |     |    |    |  | decomposition of the substance and up to a maximum temperature of 275 °C.   |   |
|------|--|--|---|-----|----|----|--|---|---|
| 1043 |  |  | (butadiene, ethyl acrylate, methyl methacrylate, styrene) copolymer crosslinked with 1,3-butanediol dimethacrylate, in nanoform | yes | no | no |  | Only to be used as particles in non-plasticised PVC up to 10 % w/w in contact with all food types at room temperature or below including long-term storage. When used together with | ] |

**a** [OJ L 302, 19.11.2005, p. 28.](#)

**b** [OJ L 330, 5.12.1998, p. 32.](#)

**c** [OJ L 253, 20.9.2008, p. 1.](#)

**d** [<sup>F1</sup>Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([OJ L 83, 22.3.2012, p. 1.](#))]

**e** [OJ L 158, 18.6.2008, p. 17.](#)

**f** [<sup>F2</sup>Infant as defined in Article 2 of Directive 2006/141/EC.]

**g** This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]

**h** [<sup>F3</sup>[OJ L 83, 22.3.2012, p. 1.](#)]

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|          |   |  |  |  |  |  |  |  |   |
|----------|---|--|--|--|--|--|--|--|---|
|          |   |  |  |  |  |  |  |  | the substance with FCM No 859 and/ or the substance with FCM No 998, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by number it shall be > 40 nm. |
| <b>a</b> | OJ L 302, 19.11.2005, p. 28.  |  |  |  |  |  |  |  |   |
| <b>b</b> | OJ L 330, 5.12.1998, p. 32.   |  |  |  |  |  |  |  |   |
| <b>c</b> | OJ L 253, 20.9.2008, p. 1.  |  |  |  |  |  |  |  |   |
| <b>d</b> | [ <sup>F1</sup> Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).] |  |  |  |  |  |  |  |   |
| <b>e</b> | OJ L 158, 18.6.2008, p. 17.   |  |  |  |  |  |  |  |   |
| <b>f</b> | [ <sup>F2</sup> Infant as defined in Article 2 of Directive 2006/141/EC.  |  |  |  |  |  |  |  |   |
| <b>g</b> | This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]  |  |  |  |  |  |  |  |   |
| <b>h</b> | [ <sup>F3</sup> OJ L 83, 22.3.2012, p. 1.]  |  |  |  |  |  |  |  |   |

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### Editorial Information

- X1** Substituted by [Corrigendum to Commission Regulation \(EU\) No 1183/2012 of 30 November 2012 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Official Journal of the European Union L 338 of 12 December 2012\)](#).

### Textual Amendments

- F1** Inserted by [Commission Regulation \(EU\) 2015/174 of 5 February 2015 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).
- F2** Inserted by [Commission Implementing Regulation \(EU\) No 321/2011 of 1 April 2011 amending Regulation \(EU\) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles \(Text with EEA relevance\)](#).
- F3** Inserted by [Commission Regulation \(EU\) No 1183/2012 of 30 November 2012 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).
- F4** Substituted by [Commission Regulation \(EU\) 2015/174 of 5 February 2015 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).
- F5** Substituted by [Commission Regulation \(EU\) No 1183/2012 of 30 November 2012 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).
- F6** Substituted by [Commission Regulation \(EU\) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).
- F7** Substituted by [Commission Regulation \(EU\) No 202/2014 of 3 March 2014 amending Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).
- F8** Deleted by [Commission Regulation \(EU\) 2015/174 of 5 February 2015 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).
- F9** Inserted by [Commission Regulation \(EU\) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).
- F10** Inserted by [Commission Regulation \(EU\) No 202/2014 of 3 March 2014 amending Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).

## 2. Group restriction of substances

Table 2 on Group restrictions contains the following information:

Column 1 (Group restriction No): contains the identification number of the group of substances for which the group restriction applies. It is the number referred to in Column 9 in Table 1 of this Annex.

Column 2 (FCM substance No): contains the unique identification numbers of the substances for which the group restriction applies. It is the number referred to in Column 1 in Table 1 of this Annex.

Column 3 (SML (T) [mg/kg]): contains the total specific migration limit for the sum of substances applicable to this group. It is expressed in mg substance per kg food. It is indicated ND if the substance shall not migrate in detectable quantities.

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Column 4 (Group restriction specification): contains an indication of the substance whose molecular weight forms the basis for expression of the result.

TABLE 2

| (1)                  | (2)   | (3)            | (4)                                    |
|----------------------|---|----------------|--|
| Group Restriction No | FCM substance No  | SML (T)[mg/kg] | Group restriction specification        |
| 1                    | 128<br>211  | 6              | expressed as acetaldehyde              |
| 2                    | 89<br>227<br>263  | 30             | expressed as ethyleneglycol            |
| 3                    | 234<br>248  | 30             | expressed as maleic acid               |
| 4                    | 212<br>435  | 15             | expressed as caprolactam               |
| 5                    | 137<br>472  | 3              | expressed as the sum of the substances |
| 6                    | 412<br>512<br>513<br>588  | 1              | expressed as iodine                    |
| 7                    | 19<br>20  | 1,2            | expressed as tertiary amine            |
| 8                    | 317<br>318<br>319<br>359<br>431<br>464                              | 6              | expressed as the sum of the substances |
| 9                    | 650<br>695<br>697<br>698<br>726                                     | 0,18           | expressed as tin                       |
| 10                   | 28<br>29<br>30<br>31<br>32<br>33<br>466<br>582<br>618<br>619<br>620 | 0,006          | expressed as tin                       |

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|                    |  |      |   |
|--------------------|--|------|---|
|                    | 646<br>676<br>736  |      |   |
| 11                 | 66<br>645<br>657   | 1,2  | expressed as tin  |
| 12                 | 444<br>469<br>470  | 30   | expressed as the sum of the substances  |
| 13                 | 163<br>285   | 1,5  | expressed as the sum of the substances  |
| [ <sup>F6</sup> 14 | 294  | 5    | expressed as the sum of the substances and their oxidation products             |
|                    | 368  |      |   |
|                    | 894]   |      |   |
| [ <sup>F4</sup> 15 | 98<br>196<br>344   | 15   | expressed as formaldehyde]  |
| 16                 | 407<br>583<br>584<br>599   | 6    | expressed as boron<br>Without prejudice to the provisions of Directive 98/83/EC |
| 17                 | 4<br>167<br>169<br>198<br>274<br>354<br>372<br>460<br>461<br>475<br>476<br>485<br>490<br>653 | ND   | expressed as isocyanate moiety  |
| 18                 | 705<br>733   | 0,05 | expressed as the sum of the substances  |
| 19                 | 505<br>516<br>519  | 10   | expressed as SO <sub>2</sub>  |
| 20                 | 290<br>386<br>390  | 30   | expressed as the sum of the substances  |
| 21                 | 347<br>349   | 5    | expressed as trimellitic acid   |



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|    |   |      |  |
|----|---|------|--|
| 22 | 70<br>147<br>176<br>218<br>323<br>325<br>365<br>371<br>380<br>425<br>446<br>448<br>456<br>636 | 6    | expressed as acrylic acid  |
| 23 | 150<br>156<br>181<br>183<br>184<br>355<br>370<br>374<br>439<br>440<br>447<br>457<br>482       | 6    | expressed as methacrylic acid  |
| 24 | 756<br>758  | 5    | expressed as the sum of the substances   |
| 25 | 720<br>747  | 0,05 | sum of mono-n-dodecyltin tris(isooctylmercaptoacetate), di-n-dodecyltin bis(isooctylmercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride |
| 26 | 728<br>729  | 9    | expressed as the sum of the substances   |
| 27 | 188<br>291  | 5    | expressed as isophthalic acid  |
| 28 | 191<br>192<br>785   | 7,5  | expressed as terephthalic acid   |

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|                     |  |      |   |
|---------------------|--|------|---|
| 29                  | 342<br>672   | 0,05 | expressed as the sum of 6-hydroxyhexanoic acid and caprolactone |
| [ <sup>F4</sup> 30  | 254<br>344<br>672  | 5    | expressed as 1,4-butanediol]                                    |
| 31                  | 73<br>797  | 30   | expressed as the sum of the substances                          |
| 32                  | 8<br>72<br>73<br>138<br>140<br>157<br>159<br>207<br>242<br>283<br>532<br>670<br>728<br>729<br>775<br>783<br>797<br>798<br>810<br>815 | 60   | expressed as the sum of the substances                          |
| [ <sup>F3</sup> 33  | 180<br>874   | ND   | expressed as eugenol]   |
| [ <sup>F10</sup> 34 | 421<br>988   | 0,05 | Expressed as 1,3-benzenedimethanamine]                          |

### 3. Notes on verification of compliance

Table 3 on notes on verification of compliance contains the following information:

Column 1 (Note No): contains the identification number of the Note. It is the number referred to in Column 11 in Table 1 of this Annex.

Column 2 (Notes on verification of compliance): contains rules that shall be respected when testing for compliance of the substance with specific migration limits or other restrictions or it contains remarks on situations where there is a risk of non-compliance.

TABLE 3

|                |  |
|----------------|--|
| (1)            | (2)  |
| <b>Note No</b> | <b>Notes on verification of compliance</b> |

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|                     |  |
|---------------------|--|
| (1)                 | Verification of compliance by residual content per food contact surface area (QMA) pending the availability of an analytical method.   |
| (2)                 | There is a risk that the SML or OML could be exceeded in fatty food simulants.   |
| (3)                 | There is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the final product does not comply with Article 3(1) c of the Framework Regulation (EC) No 1935/2004. |
| [ <sup>F5</sup> (4) | Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D2.]   |
| (5)                 | Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D2 (unstable).  |
| (6)                 | Migration limit might be exceeded at very high temperature.  |
| (7)                 | If testing in food is performed, Annex V 1.4 shall be taken into account.  |
| (8)                 | Verification of compliance by residual content per food contact surface area (QMA); QMA = 0,005 mg/6 dm <sup>2</sup> .   |
| (9)                 | Verification of compliance by residual content per food contact surface area (QMA) pending the availability of analytical method for migration testing. The ratio surface to quantity of food shall be lower than 2dm <sup>2</sup> /kg.      |
| (10)                | Verification of compliance by residual content per food contact surface area (QMA) in case of reaction with food or simulant.  |
| (11)                | Only a method of analysis for the determination of the residual monomer in the treated filler is available.  |
| (12)                | There is a risk that the SML could be exceeded from polyolefins.   |
| (13)                | Only a method for determination of the content in polymer and a method for determination of the starting substances in food simulants are available.   |
| (14)                | There is a risk that the SML could be exceeded from plastics containing more than 0,5 % w/w of the substance.  |

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|                       |   |
|-----------------------|---|
| (15)                  | There is a risk that the SML could be exceeded in contact with foods with high alcoholic content.   |
| (16)                  | There is a risk that the SML could be exceeded from low-density polyethylene (LDPE) containing more than 0,3 % w/w of the substance when in contact with fatty foods  |
| (17)                  | Only a method for determination of the residual content of the substance in the polymer is available  |
| [ <sup>F9</sup> (18)  | There is a risk that the SML could be exceeded from low-density polyethylene (LDPE)   |
| (19)                  | There is a risk that the OML could be exceeded in direct contact with aqueous foods from ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers]   |
| [ <sup>F10</sup> (20) | The substance contains aniline as an impurity; verification of compliance with the restriction set for primary aromatic amines in Annex II (2) is necessary]  |
| [ <sup>F1</sup> (21)  | In case of reaction with foods or simulants verification of compliance shall include verification that the migration limits of the hydrolysis products, formaldehyde and 1,4-butanediol, are not exceeded.] |

#### 4. Detailed specification on substances

Table 4 on detailed specifications on substances contains the following information

Column 1 (FCM substance No): contains the unique identification number of the substances referred to in Column 1 in Table 1 of Annex I to which the specification applies.

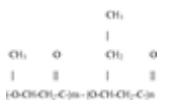
Column 2 (Detailed specification on the substance): contains the specification on the substance.

TABLE 4

| (1)              | (2)                                     |   |
|------------------|---|---|
| FCM substance No | Detailed specification on the substance |   |
| 744              | Definition                              | The copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been |

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|  |                          |  |
|--|--------------------------|--|
|  |                          | genetically engineered and has been derived from a single wildtype organism <i>Alcaligenes eutrophus</i> strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications |
|  | Chemical name            | Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)  |
|  | CAS number               | 0080181-31-3   |
|  | Structural formula       |  <p>where n/(m + n) greater than 0 and less or equal to 0,25</p>   |
|  | Average molecular weight | Not less than 150 000 Daltons (measured by gel permeation chromatography)  |
|  | Assay                    | Not less than 98 % poly(3-D-hydroxybutanoate-co-3-D-hydroxy-pentanoate) analysed after hydrolysis as a mixture of 3-D-hydro-xybutanoic and 3-D-hydroxypentanoic acids  |

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|  |                       |   |
|--|-----------------------|---|
|  | Description           | White to off-white powder after isolation   |
|  | Characteristics       |   |
|  | Identification tests: |   |
|  | Solubility            | Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water |
|  | Restriction           | QMA for crotonic acid is 0,05 mg/6 dm <sup>2</sup>  |
|  | Purity                | Prior to granulation the raw material copolymer powder must contain:  |
|  | — nitrogen,           | Not more than 2 500 mg/kg of plastic  |
|  | — zinc,               | Not more than 100 mg/kg of plastic  |
|  | — copper,             | Not more than 5 mg/kg of plastic  |
|  | — lead,               | Not more than 2 mg/kg of plastic  |
|  | — arsenic,            | Not more than 1 mg/kg of plastic  |
|  | — chromium,           | Not more than 1 mg/kg of plastic  |

## ANNEX II

### Restrictions on materials and articles

1. Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

Barium = 1 mg/kg food or food simulant.

Cobalt = 0,05 mg/kg food or food simulant.

Copper = 5 mg/kg food or food simulant.

Iron = 48 mg/kg food or food simulant.

Lithium = 0,6 mg/kg food or food simulant.

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Manganese = 0,6 mg/kg food or food simulant.

Zinc = 25 mg/kg food or food simulant.

2. Plastic materials and articles shall not release primary aromatic amines, excluding those appearing in Table 1 of Annex I, in a detectable quantity into food or food simulant. The detection limit is 0,01 mg of substance per kg of food or food simulant. The detection limit applies to the sum of primary aromatic amines released.

## ANNEX III

### Food simulants

#### 1. Food simulants

For demonstration of compliance for plastic materials and articles not yet in contact with food the food simulants listed in Table 1 below are assigned.

TABLE 1

#### List of food simulants

| Food simulant   | Abbreviation     |
|---|------------------|
| Ethanol 10 % (v/v)  | Food simulant A  |
| Acetic acid 3 % (w/v)   | Food simulant B  |
| Ethanol 20 % (v/v)  | Food simulant C  |
| Ethanol 50 % (v/v)  | Food simulant D1 |
| Vegetable oil <sup>a</sup>  | Food simulant D2 |
| poly(2,6-diphenyl-p-phenylene oxide),<br>particle size 60-80 mesh, pore size 200 nm | Food simulant E  |

<sup>a</sup> This may be any vegetable oil with a fatty acid distribution of

|  |      |     |        |      |       |      |       |
|--|------|-----|--------|------|-------|------|-------|
| No of carbon atoms in fatty acid chain: No of unsaturation                               | 6-12 | 14  | 16     | 18:0 | 18:1  | 18:2 | 18:3  |
| Range of fatty acid composition expressed % (w/w) of methyl esters by Gas chromatography | < 1  | < 1 | 1,5-20 | < 7  | 15-85 | 5-70 | < 1,5 |

#### 2. General assignment of food simulants to foods

Food simulants A, B and C are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances. Food simulant B shall be used for those foods which have a pH below 4.5. Food simulant C shall be used for alcoholic foods with an alcohol content of

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up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic.

Food simulants D1 and D2 are assigned for foods that have a lipophilic character and are able to extract lipophilic substances. Food simulant D1 shall be used for alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions. Food simulant D2 shall be used for foods which contain free fats at the surface.

Food simulant E is assigned for testing specific migration into dry foods.

3. Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food

For testing migration from materials and articles not yet in contact with food the food simulants that corresponds to a certain food category shall be chosen according Table 2 below.

For testing overall migration from materials and articles intended to come into contact with different food categories or a combination of food categories the food simulant assignment in point 4 is applicable.

Table 2 contains the following information:

Column 1 (Reference number): contains the reference number of the food category.

Column 2 (Description of food): contains a description of the foods covered by the food category

Column 3 (Food simulants): contains sub-columns for each of the food simulants

The food simulant for which a cross is contained in the respective sub-column of column 3 shall be used when testing migration of materials and articles not yet in contact with food.

For food categories where in sub-column D2 the cross is followed by an oblique stroke and a figure, the migration test result shall be divided by this figure before comparing the result with the migration limit. The figure is the correction factor referred to in point 4.2 of Annex V to this Regulation.

For food category 01.04 food simulant D2 shall be replaced by 95 % ethanol.

For food categories where in sub-column B the cross is followed by (\*) the testing in food simulant B can be omitted if the food has a pH of more than 4.5.

For food categories where in sub-column D2 the cross is followed by (\*\*) the testing in food simulant D2 can be omitted if it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic food contact material.

TABLE 2

food category specific assignment of food simulants

| (1)<br>Reference number | (2)<br>Description of food | (3)<br>Food simulants |   |   |    |    |   |
|-------------------------|----------------------------|-----------------------|---|---|----|----|---|
|                         |                            | A                     | B | C | D1 | D2 | E |
| 01                      | <b>Beverages</b>           |                       |   |   |    |    |   |
| 01.01                   | Non-alcoholic beverages or |                       |   |   |    |    |   |



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|    |   |      |   |   |  |  |  |
|----|---|------|---|---|--|--|--|
|    | alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:   |      |   |   |  |  |  |
| A. | Clear drinks:<br>Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract | X(*) | X |   |  |  |  |
| B. | cloudy drinks:<br>juices and nectars and soft drinks containing fruit pulp, musts containing  | X(*) |   | X |  |  |  |

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|       |  |  |      |   |   |                               |   |
|-------|--|--|------|---|---|-------------------------------|---|
|       | fruit pulp,<br>liquid<br>chocolate   |  |      |   |   |                               |   |
| 01.02 | Alcoholic<br>beverages<br>of an<br>alcoholic<br>strength<br>of<br>between 6<br>%vol and<br>20 %.                     |  |      | X |   |                               |   |
| 01.03 | Alcoholic<br>beverages<br>of an<br>alcoholic<br>strength<br>above 20<br>% and<br>all cream<br>liquors                |  |      |   | X |                               |   |
| 01.04 | Miscellaneous:<br>undenaturated<br>ethyl<br>alcohol  |  | X(*) |   |   | Substitute<br>95 %<br>ethanol |   |
| 02    | <b>Cereals,<br/>cereal<br/>products,<br/>pastry,<br/>biscuits,<br/>cakes<br/>and<br/>other<br/>bakers'<br/>wares</b> |  |      |   |   |                               |   |
| 02.01 | Starches   |  |      |   |   |                               | X |
| 02.02 | Cereals,<br>unprocessed,<br>puffed,<br>in flakes<br>(including<br>popcorn,<br>corn<br>flakes and<br>the like)        |  |      |   |   |                               | X |
| 02.03 | Cereal<br>flour and<br>meal  |  |      |   |   |                               | X |

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|       |   |  |  |  |  |     |   |
|-------|---|--|--|--|--|-----|---|
| 02.04 | Dry pasta e.g. macaroni, spaghetti and similar products and fresh pasta |  |  |  |  |     | X |
| 02.05 | Pastry, biscuits, cakes, bread, and other bakers' wares, dry:           |  |  |  |  |     |   |
|       | A. With fatty substances on the surface                                 |  |  |  |  | X/3 |   |
|       | B. Other  |  |  |  |  |     | X |
| 02.06 | Pastry, cakes, bread, dough and other bakers' wares, fresh:             |  |  |  |  |     |   |
|       | A. With fatty substances on the surface                                 |  |  |  |  | X/3 |   |
|       | B. Other  |  |  |  |  |     | X |
| 03    | <b>Chocolate, sugar and products thereof Confectionery products</b>     |  |  |  |  |     |   |

*Status: Point in time view as at 26/02/2015.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011. (See end of Document for details)*

|       |  |  |  |   |  |     |   |
|-------|--|--|--|---|--|-----|---|
| 03.01 | Chocolate, chocolate-coated products, substitutes and products coated with substitutes |  |  |   |  | X/3 |   |
| 03.02 | Confectionery products:  |  |  |   |  |     |   |
|       | A. In solid form:  |  |  |   |  |     |   |
|       | I. With fatty substances on the surface  |  |  |   |  | X/3 |   |
|       | II. Other  |  |  |   |  |     | X |
|       | B. In paste form:  |  |  |   |  |     |   |
|       | I. With fatty substances on the surface  |  |  |   |  | X/2 |   |
|       | II. Moist  |  |  | X |  |     |   |
| 03.03 | Sugar and sugar products   |  |  |   |  |     |   |
|       | A. In solid form: crystal or powder  |  |  |   |  |     | X |

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|       |   |  |      |   |  |  |   |
|-------|---|--|------|---|--|--|---|
|       | B.  | X<br>Molasses,<br>sugar<br>syrops,<br>honey<br>and<br>the<br>like  |      |   |  |  |   |
| 04    | <b>Fruit,<br/>vegetables<br/>and<br/>products<br/>thereof</b> |  |      |   |  |  |   |
| 04.01 | Whole<br>fruit,<br>fresh or<br>chilled,<br>unpeeled           |  |      |   |  |  |   |
| 04.02 | Processed<br>fruit:   |  |      |   |  |  |   |
|       | A.  | Dried<br>or<br>dehydrated<br>fruits,<br>whole,<br>sliced,<br>flour<br>or<br>powder   |      |   |  |  | X |
|       | B.  | Fruit<br>in<br>the<br>form<br>of<br>purée,<br>preserves,<br>pastes<br>or<br>in<br>its<br>own<br>juice<br>or<br>in<br>sugar<br>syrup<br>(jams,<br>compote,<br>and | X(*) | X |  |  |   |

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|       |     |  |  |  |   |   |   |
|-------|-----|--|--|--|---|---|---|
|       |     | similar products)  |  |  |   |   |   |
|       | C.  | Fruit preserved in a liquid medium:  |  |  |   |   |   |
|       | I.  | In an oily medium  |  |  |   | X |   |
|       | II. | In an alcoholic medium   |  |  | X |   |   |
| 04.03 |     | Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others): |  |  |   |   |   |
|       | A.  | Shelled, dried, flaked or powdered   |  |  |   |   | X |
|       | B.  | Shelled and roasted  |  |  |   |   | X |
|       | C.  | X<br>In paste or cream form  |  |  |   | X |   |
| 04.04 |     | Whole vegetables, fresh or chilled, unpeeled                                     |  |  |   |   |   |

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|       |                       |   |      |   |  |   |   |
|-------|-----------------------|---|------|---|--|---|---|
| 04.05 | Processed vegetables: |   |      |   |  |   |   |
|       | A.                    | Dried or dehydrated vegetables whole, sliced or in the form of flour or powder                          |      |   |  |   | X |
|       | B.                    | X<br>Fresh vegetables, peeled or cut  |      |   |  |   |   |
|       | C.                    | Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine) | X(*) | X |  |   |   |
|       | D.                    | Preserved vegetables:   |      |   |  |   |   |
|       | I.                    | X<br>In an oily medium  |      |   |  | X |   |

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|       |   |  |  |  |   |         |  |
|-------|---|--|--|--|---|---------|--|
|       | II.   | In an alcoholic medium   |  |  | X |         |  |
| 05    | <b>Fats and oils</b>  |  |  |  |   |         |  |
| 05.01 | Animals and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter) |  |  |  |   | X       |  |
| 05.02 | Margarine, butter and other fats and oils made from water emulsions in oil  |  |  |  |   | X/2     |  |
| 06    | <b>Animal products and eggs</b>   |  |  |  |   |         |  |
| 06.01 | Fish:   |  |  |  |   |         |  |
|       | A.  | X<br>Fresh, chilled, processed, salted or smoked including fish eggs |  |  |   | X/3(**) |  |
|       | B.  | Preserved fish:  |  |  |   |         |  |
|       | I.  | X<br>In an   |  |  |   | X       |  |



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|       |     |   |      |   |  |         |  |
|-------|-----|---|------|---|--|---------|--|
|       |     | oily medium   |      |   |  |         |  |
|       | II. | In an aqueous medium  | X(*) | X |  |         |  |
| 06.02 |     | Crustaceans and molluscs (including oysters, mussels, snails) |      |   |  |         |  |
|       | A.  | Fresh within the shell  |      |   |  |         |  |
|       | B.  | Shell removed, processed, preserved or cooked with the shell  |      |   |  |         |  |
|       | I.  | X<br>In an oily medium  |      |   |  | X       |  |
|       | II. | In an aqueous medium  | X(*) | X |  |         |  |
| 06.03 |     | Meat of all zoological species (including poultry and game):  |      |   |  |         |  |
|       | A.  | X<br>Fresh, chilled,  |      |   |  | X/4(**) |  |

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|       |  |   |      |  |   |         |   |
|-------|--|---|------|--|---|---------|---|
|       |  | salted,<br>smoked   |      |  |   |         |   |
|       | B.                                       | X<br>Processed<br>meat<br>products<br>(such<br>as<br>ham,<br>salami,<br>bacon,<br>sausages,<br>and<br>other)<br>or<br>in<br>the<br>form<br>of<br>paste,<br>creams |      |  |   | X/4(**) |   |
|       | C.                                       | X<br>Marinated<br>meat<br>products<br>in<br>an<br>oily<br>medium  |      |  |   | X       |   |
| 06.04 | Preserved<br>meat:                       |   |      |  |   |         |   |
|       | A.                                       | X<br>In<br>an<br>fatty<br>or<br>oily<br>medium  |      |  |   | X/3     |   |
|       | B.                                       | In<br>an<br>aqueous<br>medium   | X(*) |  | X |         |   |
| 06.05 | Whole<br>eggs, egg<br>yolk, egg<br>white |   |      |  |   |         |   |
|       | A.                                       | Powdered<br>or<br>dried   |      |  |   |         | X |

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|       |  |  |      |  |   |  |   |
|-------|--|--|------|--|---|--|---|
|       |  | or<br>frozen   |      |  |   |  |   |
|       | B.   | Liquid<br>and<br>cooked  |      |  | X |  |   |
| 07    | <b>Milk<br/>products</b>   |  |      |  |   |  |   |
| 07.01 | Milk   |  |      |  |   |  |   |
|       | A.   | Milk<br>and<br>milk<br>based<br>drinks<br>whole,<br>partly<br>dried<br>and<br>skimmed<br>or<br>partly<br>skimmed |      |  | X |  |   |
|       | B.   | Milk<br>powder<br>including<br>infant<br>formula<br>(based<br>on<br>whole<br>milk<br>powder)                     |      |  |   |  | X |
| 07.02 | Fermented<br>milk<br>such as<br>yoghurt,<br>buttermilk<br>and<br>similar<br>products |  | X(*) |  | X |  |   |
| 07.03 | Cream<br>and sour<br>cream   |  | X(*) |  | X |  |   |
| 07.04 | Cheeses:   |  |      |  |   |  |   |
|       | A.   | Whole,<br>with   |      |  |   |  | X |

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|       |                                   |  |      |  |   |         |  |
|-------|-----------------------------------|--|------|--|---|---------|--|
|       |                                   | not<br>edible<br>rind  |      |  |   |         |  |
|       | B.                                | Natural<br>cheese<br>without<br>rind<br>or<br>with<br>edible<br>rind<br>(gouda,<br>camembert,<br>and<br>the<br>like)<br>and<br>melting<br>cheese |      |  |   | X/3(**) |  |
|       | C.                                | Processed<br>cheese<br>(soft<br>cheese,<br>cottage<br>cheese<br>and<br>similar)  | X(*) |  | X |         |  |
|       | D.                                | Preserved<br>cheese:   |      |  |   |         |  |
|       | I.                                | X<br>In<br>an<br>oily<br>medium  |      |  |   | X       |  |
|       | II.                               | In<br>an<br>aqueous<br>medium<br>(feta,<br>mozzarella,<br>and<br>similar)  | X(*) |  | X |         |  |
| 08    | <b>Miscellaneous<br/>products</b> |  |      |  |   |         |  |
| 08.01 | Vinegar                           |  | X    |  |   |         |  |

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|       |   |  |  |  |  |     |   |
|-------|---|--|--|--|--|-----|---|
| 08.02 | Fried or roasted foods:   |  |  |  |  |     |   |
|       | A.  | X<br>Fried potatoes, fritters and the like |  |  |  | X/5 |   |
|       | B.  | X<br>Of animal origin                      |  |  |  | X/4 |   |
| 08.03 | Preparations for soups, broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents |  |  |  |  |     |   |
|       | A.  | Powdered or dried:                         |  |  |  |     |   |
|       | I.  | With fatty character                       |  |  |  | X/5 |   |
|       | II.   | Other                                      |  |  |  |     | X |
|       | B.  | any other form than powdered               |  |  |  |     |   |

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|       |   |  |      |   |  |         |  |
|-------|---|--|------|---|--|---------|--|
|       |   | or<br>dried:   |      |   |  |         |  |
|       | I.  | X<br>With<br>fatty<br>character  | X(*) |   |  | X/3     |  |
|       | II.   | Other  | X(*) | X |  |         |  |
| 08.04 | Sauces:   |  |      |   |  |         |  |
|       | A.  | With<br>aqueous<br>character   | X(*) | X |  |         |  |
|       | B.  | X<br>With<br>fatty<br>character<br>e.g.<br>mayonnaise,<br>sauces<br>derived<br>from<br>mayonnaise,<br>salad<br>creams<br>and<br>other<br>oil/<br>water<br>mixtures<br>e.g.<br>coconut<br>based<br>sauces | X(*) |   |  | X       |  |
| 08.05 | Mustard<br>(except<br>powdered<br>mustard<br>under<br>heading<br>08.14)                               | X  | X(*) |   |  | X/3(**) |  |
| 08.06 | Sandwiches,<br>toasted<br>bread<br>pizza and<br>the like<br>containing<br>any<br>kind of<br>foodstuff |  |      |   |  |         |  |

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|       |   |   |      |   |   |     |   |
|-------|---|---|------|---|---|-----|---|
|       | A.  | X<br>With<br>fatty<br>substances<br>on<br>the<br>surface                            |      |   |   | X/5 |   |
|       | B.  | Other   |      |   |   |     | X |
| 08.07 | Ice-<br>creams  |   |      | X |   |     |   |
| 08.08 | Dried<br>foods:   |   |      |   |   |     |   |
|       | A.  | With<br>fatty<br>substances<br>on<br>the<br>surface                                 |      |   |   | X/5 |   |
|       | B.  | Other   |      |   |   |     | X |
| 08.09 | Frozen<br>or deep-<br>frozen<br>foods   |   |      |   |   |     | X |
| 08.10 | Concentrated<br>extracts<br>of an<br>alcoholic<br>strength<br>equal<br>to or<br>exceeding<br>6 % vol. |   | X(*) |   | X |     |   |
| 08.11 | Cocoa:  |   |      |   |   |     |   |
|       | A.  | Cocoa<br>powder,<br>including<br>fat-<br>reduced<br>and<br>highly<br>fat<br>reduced |      |   |   |     | X |
|       | B.  | Cocoa<br>paste  |      |   |   | X/3 |   |

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|       |   |  |  |  |  |   |   |
|-------|---|--|--|--|--|---|---|
| 08.12 | Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered                            |  |  |  |  |   | X |
| 08.13 | Aromatic herbs and other herbs such as camomile, mallow, mint, tea, lime blossom and others                                     |  |  |  |  |   | X |
| 08.14 | Spices and seasonings in the natural state such as cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and other |  |  |  |  |   | X |
| 08.15 | Spices and seasoning in oily medium such as pesto, curry paste  |  |  |  |  | X |   |



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#### 4. Food simulant assignment for testing overall migration

To demonstrate compliance with the overall migration limit for all type of foods testing in distilled water or water of equivalent quality or food simulant A and food simulant B and simulant D2 shall be performed.

To demonstrate compliance with the overall migration limit for all types of food except for acidic foods testing in distilled water or water of equivalent quality or food simulant A and food simulant D2 shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous and alcoholic foods and milk products testing in food simulant D1 shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous, acidic and alcoholic foods and milk products testing in food simulant D1 and food simulant B shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous foods and alcoholic foods up to an alcohol content of 20 % testing in food simulant C shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 % testing in food simulant C and food simulant B shall be performed.

## ANNEX IV

### Declaration of compliance

The written declaration referred to in Article 15 shall contain the following information:

- (1) the identity and address of the business operator issuing the declaration of compliance;
- (2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;
- (3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;
- (4) the date of the declaration;
- (5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) No 1935/2004;
- (6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;
- (7) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials

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- or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;
- (8) specifications on the use of the material or article, such as:
- (i) type or types of food with which it is intended to be put in contact;
  - (ii) time and temperature of treatment and storage in contact with the food;
  - (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;
- (9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.

## ANNEX V

### COMPLIANCE TESTING

For testing compliance of migration from plastic food contact materials and articles the following general rules apply.

#### CHAPTER 1

##### **Testing for specific migration of materials and articles already in contact with food**

###### 1.1. Sample preparation

The material or article shall be stored as indicated on the packaging label or under conditions adequate for the packaged food if no instructions are given. The food shall be removed from contact with the material or article before its expiration date or any date by which the manufacturer has indicated the product should be used for reasons of quality or safety.

###### 1.2. Conditions of testing

The food shall be treated in accordance with the cooking instructions on the package if the food is to be cooked in the package. Parts of the food which are not intended to be eaten shall be removed and discarded. The remainder shall be homogenised and analysed for migration. The analytical results shall always be expressed on the basis of the food mass that is intended to be eaten, in contact with the food contact material.

###### 1.3. Analysis of migrated substances

The specific migration is analysed in the food using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

###### 1.4. Special cases

When contamination occurs from sources other than food contact materials this has to be taken into account when testing for compliance of the food contact materials, in particular for phthalates (FCM substance 157, 159, 283, 728, 729) referred to in Annex I.

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## CHAPTER 2

### Testing for specific migration of materials and articles not yet in contact with food

#### 2.1. Verification method

Verification of compliance of migration into foods with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use taking into account paragraphs 1.4, 2.1.1, 2.1.6 and 2.1.7.

Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests according to the rules set out in paragraphs 2.1.1 to 2.1.7.

##### 2.1.1. Sample preparation

The material or article shall be treated as described by accompanying instructions or by provisions given in the declaration of compliance.

Migration is determined on the material or article or, if this is impractical, on a specimen taken from the material or article, or a specimen representative of this material or article. For each food simulant or food type, a new test specimen is used. Only those parts of the sample which are intended to come into contact with foods in actual use shall be placed in contact with the food simulant or the food.

##### 2.1.2. Choice of food simulant

Materials and articles intended for contact with all types of food shall be tested with food simulant A, B and D2. However, if substances that may react with acidic food simulant or foods are not present testing in food simulant B can be omitted.

Materials and articles intended only for specific types of foods shall be tested with the food simulants indicated for the food types in Annex III.

##### 2.1.3. Conditions of contact when using food simulants

The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2.

If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

TABLE 1

Contact time

| Contact time in worst foreseeable use | Test time |
|---------------------------------------|-----------|
| $t \leq 5$ min                        | 5 min     |
| $5$ min $< t \leq 0,5$ hour           | 0,5 hour  |
| $0,5$ hours $< t \leq 1$ hour         | 1 hour    |
| $1$ hour $< t \leq 2$ hours           | 2 hours   |

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|                        |                         |
|------------------------|-------------------------|
| 2 hours < t ≤ 6 hours  | 6 hours                 |
| 6 hours < t ≤ 24 hours | 24 hours                |
| 1 day < t ≤ 3 days     | 3 days                  |
| 3 days < t ≤ 30 days   | 10 days                 |
| Above 30 days          | See specific conditions |

TABLE 2

| Contact temperature                            |  |
|--|--|
| Conditions of contact in worst foreseeable use | Test conditions  |
| Contact temperature                            | Test temperature   |
| T ≤ 5 °C                                       | 5 °C   |
| 5 °C < T ≤ 20 °C                               | 20 °C  |
| 20 °C < T ≤ 40 °C                              | 40 °C  |
| 40 °C < T ≤ 70 °C                              | 70 °C  |
| 70 °C < T ≤ 100 °C                             | 100 °C or reflux temperature   |
| 100 °C < T ≤ 121 °C                            | 121 °C <sup>a</sup>  |
| 121 °C < T ≤ 130 °C                            | 130 °C <sup>a</sup>  |
| 130 °C < T ≤ 150 °C                            | 150 °C <sup>a</sup>  |
| 150 °C < T < 175 °C                            | 175 °C <sup>a</sup>  |
| T > 175 °C                                     | Adjust the temperature to the real temperature at the interface with the food <sup>a</sup> |

<sup>a</sup> This temperature shall be used only for food simulants D2 and E. For applications heated under pressure migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.

#### 2.1.4. Specific conditions for contact times above 30 days at room temperature and below

For contact times above 30 days at room temperature and below the specimen shall be tested in an accelerated test at elevated temperature for a maximum of 10 days at 60 °C. Testing time and temperature conditions shall be based on the following formula.

$$t_2 = t_1 * \text{Exp} ((-E_a/R) * (1/T_1 - 1/T_2))$$

E<sub>a</sub> is the worst case activation energy 80kJ/mol

R is a factor 8,31 J/Kelvin/mol

$$\text{Exp} -9627 * (1/T_1 - 1/T_2)$$

t<sub>1</sub> is the contact time

t<sub>2</sub> is the testing time

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T1 is the contact temperature in Kelvin. For room temperature storage this is set at 298 K (25 °C). For refrigerated and frozen conditions it is set at 278 K (5 °C).

T2 is the testing temperature in Kelvin.

Testing for 10 days at 20 °C shall cover all storage times at frozen condition.

Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

Testing for 10 days at 50 °C shall cover all storage time at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes and storage times of up to 6 months at room temperature.

Testing for 10 days at 60 °C shall cover long term storage above 6 months at room temperature and below including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

The maximum testing temperature is governed by the phase transition temperature of the polymer. At the test temperature the test specimen should not undergo any physical changes.

For storage at room temperature testing time can be reduced to 10 days at 40 °C if there is scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.

#### 2.1.5. Specific conditions for combinations of contact times and temperature

If a material or article is intended for different applications covering different combinations of contact time and temperature the testing should be restricted to the test conditions which are recognised to be the most severe on the basis of scientific evidence.

If the material or article is intended for a food contact application where it is successively subject to a combination of two or more times and temperatures, the migration test shall be carried out subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

#### 2.1.6. Repeated use articles

If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. Its compliance shall be checked on the basis of the level of the migration found in the third test.

However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the migration limits are not exceeded on the first test, no further test is necessary.

The material or article shall respect the specific migration limit already in the first test for substances for which in Annex I Table 1 column 8 or Table 2 column 3 the specific migration limit is set as non-detectable and for non-listed substances used behind a plastic functional barrier covered by the rules of point (b) of Articles 13(2) which should not migrate in detectable amounts.

#### 2.1.7. Analysis of migrating substances

At the end of the prescribed contact time, the specific migration is analysed in the food or food simulant using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

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#### 2.1.8. Verification of compliance by residual content per food contact surface area (QMA)

For substances which are unstable in food simulant or food or for which no adequate analytical method is available it is indicated in Annex I that verification of compliance shall be undertaken by verification of residual content per 6 dm<sup>2</sup> of contact surface. For materials and articles between 500 ml and 10 l the real contact surface is applied. For materials and articles below 500 ml and above 10 l as well as for articles for which it is impractical to calculate the real contact surface the contact surface is assumed to be 6 dm<sup>2</sup> per kg food.

#### 2.2. Screening approaches

To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered more severe than the verification method described in section 2.1.

##### 2.2.1. Replacing specific migration by overall migration

To screen for specific migration of non-volatile substances, determination of overall migration under test conditions at least as severe as for specific migration can be applied.

##### 2.2.2. Residual content

To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration.

##### 2.2.3. Migration modelling

To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed such as to overestimate real migration.

##### 2.2.4. Food simulant substitutes

To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants overestimate migration compared to the regulated food simulants.

## CHAPTER 3

### Testing for overall migration

Overall migration testing shall be performed under the standardised testing conditions set out in this chapter.

#### 3.1. Standardised testing conditions

The overall migration test for materials and articles intended for the food contact conditions described in column 3 of Table 3 shall be performed for the time specified and at the temperature specified in column 2. For test OM5 the test can be performed either for 2 hours at 100 °C (food simulant D2) or at reflux (food simulant A, B, C, D1) or for 1 hour at 121 °C. The food simulant shall be chosen in accordance with Annex III.

If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried

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out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

TABLE 3

Standardised testing conditions

| <b>Column 1</b>    | <b>Column 2</b>   | <b>Column 3</b>  |
|--------------------|---|--|
| <b>Test number</b> | <b>Contact time in days [d] or hours [h] at Contact temperature in [°C]</b> | <b>Intended food contact conditions</b>  |
| OM1                | 10 d at 20 °C   | Any food contact at frozen and refrigerated conditions.  |
| OM2                | 10 d at 40 °C   | Any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.   |
| OM3                | 2 h at 70 °C  | Any contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage. |
| OM4                | 1 h at 100 °C   | High temperature applications for all food simulants at temperature up to 100 °C.  |
| OM5                | 2 h at 100 °C or at reflux or alternatively 1 h at 121 °C                   | High temperature applications up to 121 °C.  |
| OM6                | 4 h at 100 °C or at reflux  | Any food contact conditions with food simulants A, B or C, at temperature exceeding 40 °C.   |
| OM7                | 2 h at 175 °C   | High temperature applications with fatty foods exceeding the conditions of OM5.  |

Test OM 7 covers also food contact conditions described for OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in paragraph 3.2.

Test OM 6 covers also food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.

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Test OM 5 covers also food contact conditions described for OM1, OM2, OM3, OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM 2 covers also food contact conditions described for OM1 and OM3.

### 3.2. Substitute test for OM7 with food simulant D2

In case it is technically NOT feasible to perform OM7 with food simulant D2 the test can be replaced by test OM 8 or OM9. Both test conditions described under the respective test shall be performed with a new test sample.

| Test number | Test conditions  | Intended food contact conditions  | Covers the intended food contact conditions described in |
|-------------|--|---|--|
| OM 8        | Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C | High temperature applications only  | OM1, OM3, OM4, OM5, and OM6                              |
| OM 9        | Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C  | High temperature applications including long term storage at room temperature | OM1, OM2, OM3, OM4, OM5 and OM6                          |

### 3.3. Repeated use articles

Where a material or article is intended to come into repeated contact with foods, the migration test shall be carried out three times on a single sample using another sample of the food simulant on each occasion.

Its compliance shall be checked on the basis of the level of the migration found in the third test. However, if there is conclusive proof that the level of the migration does not increase in the second and third tests and if the overall migration limit is not exceeded on the first test, no further test is necessary.

### 3.4. Screening approaches

To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered more severe than the verification method described in sections 3.1. and 3.2.

#### 3.4.1. Residual content

To screen for overall migration the migration potential can be calculated based on the residual content of migratable substances determined in a complete extraction of the material or article.

#### 3.4.2. Food simulant substitutes

To screen for overall migration food simulants can be replaced if based on scientific evidence the substitute food simulants overestimate migration compared to the regulated food simulants.



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## CHAPTER 4

### **Correction factors applied when comparing migration test results with migration limits**

#### 4.1. Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF)

For lipophilic substances for which in Annex I it is indicated in column 7 that the FRF is applicable the specific migration can be corrected by the FRF. The FRF is determined according to the formula  $FRF = (g \text{ fat in food/kg of food})/200 = (\% \text{ fat} \times 5)/100$ .

The FRF shall be applied according to the following rules.

The migration test results shall be divided by the FRF before comparing with the migration limits.

The correction by the FRF is not applicable in the following cases:

- (a) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 2006/141/EC and 2006/125/EC;
- (b) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm<sup>2</sup>/kg.

The application of the FRF shall not lead to a specific migration exceeding the overall migration limit.

#### 4.2. Correction of migration into food simulant D2

For the food categories where in sub-column D2 of column 3 of Table 2 of Annex III the cross is followed by a figure the migration test result into food simulant D2 shall be divided by this figure.

The migration test results shall be divided by the correction factor before comparing with the migration limits.

The correction is not applicable to the specific migration for substances in the Union list in Annex I for which the specific migration limit in column 8 is 'not detectable' and for non-listed substances used behind a plastic functional barrier covered by the rules of Article 13(2) (b) which should not migrate in detectable amounts.

#### 4.3. Combination of correction factors 4.1 and 4.2.

The correction factors described in 4.1 and 4.2 can be combined for migration of substances for which the FRF is applicable when testing is performed in food simulant D2 by multiplying both factors. The applied maximum factor shall not exceed 5.

## ANNEX VI

### Correlation tables

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**Directive 2002/72/EC**

**This Regulation**

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|   |                        |
|---|------------------------|
| Article 1(1)  | Article 1              |
| Article 1(2), (3) and (4)   | Article 2              |
| Article 1a  | Article 3              |
| Article 3(1), Article 4(1) and Article 5  | Article 5              |
| Article 4(2), Article 4a(1) and (4), Article 4d, Annex II (2) and (3) and Annex III (2) and (3) | Article 6              |
| Article 4a(3) and (6)   | Article 7              |
| Annex II (4) and Annex III (4)  | Article 8              |
| Article 3(1) and Article 4(1)   | Article 9              |
| Article 6   | Article 10             |
| Article 5a(1) and Annex I (8)   | Article 11             |
| Article 2   | Article 12             |
| Article 7a  | Article 13             |
| Article 9(1) and (2)  | Article 15             |
| Article 9(3)  | Article 16             |
| Article 7 and Annex I (5a)  | Article 17             |
| Article 8   | Article 18             |
| Annex II (3) and Annex III (3)  | Article 19             |
| Annex I, Annex II, Annex IV, Annex IVa, Annex V Part B, and Annex VI                            | Annex I                |
| Annex II (2), Annex III (2) and Annex V, Part A   | Annex II               |
| Article 8(5) and Annex VIa  | Annex IV               |
| Annex I   | Annex V                |
| <b>Directive 93/8/EEC</b>   | <b>This Regulation</b> |
| Article 1   | Article 11             |
| Article 1   | Article 12             |
| Article 1   | Article 18             |
| Annex   | Annex III              |
| Annex   | Annex V                |
| <b>Directive 97/48/EC</b>   | <b>This Regulation</b> |
| Annex   | Annex III              |
| Annex   | Annex V                |

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