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► **B****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)****(OJ L 12, 15.1.2011, p. 1)**Amended by:

|                     |   | Official Journal |      |            |
|---------------------|---|------------------|------|------------|
|                     |   | No               | page | date       |
| ► <b><u>M1</u></b>  | Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 | L 87             | 1    | 2.4.2011   |
| ► <b><u>M2</u></b>  | Commission Regulation (EU) No 1282/2011 of 28 November 2011         | L 328            | 22   | 10.12.2011 |
| ► <b><u>M3</u></b>  | Commission Regulation (EU) No 1183/2012 of 30 November 2012         | L 338            | 11   | 12.12.2012 |
| ► <b><u>M4</u></b>  | Commission Regulation (EU) No 202/2014 of 3 March 2014              | L 62             | 13   | 4.3.2014   |
| ► <b><u>M5</u></b>  | Commission Regulation (EU) No 865/2014 of 8 August 2014             | L 238            | 1    | 9.8.2014   |
| ► <b><u>M6</u></b>  | Commission Regulation (EU) 2015/174 of 5 February 2015              | L 30             | 2    | 6.2.2015   |
| ► <b><u>M7</u></b>  | Commission Regulation (EU) 2016/1416 of 24 August 2016              | L 230            | 22   | 25.8.2016  |
| ► <b><u>M8</u></b>  | Commission Regulation (EU) 2017/752 of 28 April 2017                | L 113            | 18   | 29.4.2017  |
| ► <b><u>M9</u></b>  | Commission Regulation (EU) 2018/79 of 18 January 2018               | L 14             | 31   | 19.1.2018  |
| ► <b><u>M10</u></b> | Commission Regulation (EU) 2018/213 of 12 February 2018             | L 41             | 6    | 14.2.2018  |
| ► <b><u>M11</u></b> | Commission Regulation (EU) 2018/831 of 5 June 2018                  | L 140            | 35   | 6.6.2018   |
| ► <b><u>M12</u></b> | Commission Regulation (EU) 2019/37 of 10 January 2019               | L 9              | 88   | 11.1.2019  |
| ► <b><u>M13</u></b> | Commission Regulation (EU) 2019/988 of 17 June 2019                 | L 160            | 10   | 18.6.2019  |
| ► <b><u>M14</u></b> | Commission Regulation (EU) 2019/1338 of 8 August 2019               | L 209            | 5    | 9.8.2019   |
| ► <b><u>M15</u></b> | Commission Regulation (EU) 2020/1245 of 2 September 2020            | L 288            | 1    | 3.9.2020   |

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- **C1** Corrigendum, OJ L 349, 19.12.2012, p. 77 (1183/2012)



**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)

CHAPTER I  
**GENERAL PROVISIONS**

*Article 1*

**Subject matter**

1. This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004.
2. This Regulation establishes specific requirements for the manufacture and marketing of plastic materials and articles:
  - (a) intended to come into contact with food; or
  - (b) already in contact with food; or
  - (c) which can reasonably be expected to come into contact with food.

*Article 2*

**Scope**

1. This Regulation shall apply to materials and articles which are placed on the EU market and fall under the following categories:
  - (a) materials and articles and parts thereof consisting exclusively of plastics;
  - (b) plastic multi-layer materials and articles held together by adhesives or by other means;
  - (c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating;
  - (d) plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;
  - (e) plastic layers in multi-material multi-layer materials and articles.
2. This Regulation shall not apply to the following materials and articles which are placed on the EU market and are intended to be covered by other specific measures:
  - (a) ion exchange resins;
  - (b) rubber;
  - (c) silicones.

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3. This Regulation shall be without prejudice to the EU or national provisions applicable to printing inks, adhesives or coatings.

*Article 3***Definitions**

For the purpose of this Regulation, the following definitions shall apply:

- (1) ‘plastic materials and articles’ means:
  - (a) materials and articles referred to in points (a), (b) and (c) of Article 2(1); and
  - (b) plastic layers referred to in Article 2(1)(d) and (e);
- (2) ‘plastic’ means polymer to which additives or other substances may have been added, which is capable of functioning as a main structural component of final materials and articles;
- (3) ‘polymer’ means any macromolecular substance obtained by:
  - (a) a polymerisation process such as polyaddition or polycondensation, or by any other similar process of monomers and other starting substances; or
  - (b) chemical modification of natural or synthetic macromolecules; or
  - (c) microbial fermentation;
- (4) ‘plastic multi-layer’ means a material or article composed of two or more layers of plastic;
- (5) ‘multi-material multi-layer’ means a material or article composed of two or more layers of different types of materials, at least one of them a plastic layer;
- (6) ‘monomer or other starting substance’ means:
  - (a) a substance undergoing any type of polymerisation process to manufacture polymers; or
  - (b) a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or
  - (c) a substance used to modify existing natural or synthetic macromolecules;
- (7) ‘additive’ means a substance which is intentionally added to plastics to achieve a physical or chemical effect during processing of the plastic or in the final material or article; it is intended to be present in the final material or article;

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- (8) ‘polymer production aid’ means any substance used to provide a suitable medium for polymer or plastic manufacturing; it may be present but is neither intended to be present in the final materials or articles nor has a physical or chemical effect in the final material or article;
- (9) ‘non-intentionally added substance’ means an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product;
- (10) ‘aid to polymerisation’ means a substance which initiates polymerisation and/or controls the formation of the macromolecular structure;
- (11) ‘overall migration limit’ (OML) means the maximum permitted amount of non-volatile substances released from a material or article into food simulants;
- (12) ‘food simulant’ means a test medium imitating food; in its behaviour the food simulant mimics migration from food contact materials;
- (13) ‘specific migration limit’ (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants;
- (14) ‘total specific migration limit’ (SML(T)) means the maximum permitted sum of particular substances released in food or food simulants expressed as total of moiety of the substances indicated;
- (15) ‘functional barrier’ means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation;

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- (16) ‘non-fatty food’ means a food for which in migration testing only food simulants other than food simulants D1 or D2 are laid down in Table 2 of Annex III to this Regulation;

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- (17) ‘restriction’ means limitation of use of a substance or migration limit or limit of content of the substance in the material or article;

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- (18) ‘specification’ means composition of a substance, purity criteria for a substance, physico-chemical characteristics of a substance, details concerning the manufacturing process of a substance or further information concerning the expression of migration limits;

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- (19) ‘hot-fill’ means the filling of any article with a food with a temperature not exceeding 100 °C at the moment of filling, after which the food cools down to 50 °C or below within 60 minutes, or to 30 °C or below within 150 minutes.

**▼B***Article 4***Placing on the market of plastic materials and articles**

Plastic materials and articles may only be placed on the market if they:

- (a) comply with the relevant requirements set out in Article 3 of Regulation (EC) No 1935/2004 under intended and foreseeable use; and
- (b) comply with the labelling requirements set out in Article 15 of Regulation (EC) No 1935/2004; and
- (c) comply with the traceability requirements set out in Article 17 of Regulation (EC) No 1935/2004; and
- (d) are manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006 <sup>(1)</sup>; and
- (e) comply with the compositional and declaration requirements set out in Chapters II, III and IV of this Regulation.

## CHAPTER II

## COMPOSITIONAL REQUIREMENTS

## SECTION 1

*Authorised substances**Article 5***Union list of authorised substances**

1. Only the substances included in the Union list of authorised substances (hereinafter referred to as the Union list) set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.
2. The Union list shall contain:
  - (a) monomers or other starting substances;
  - (b) additives excluding colorants;
  - (c) polymer production aids excluding solvents;
  - (d) macromolecules obtained from microbial fermentation.

<sup>(1)</sup> OJ L 384, 29.12.2006, p. 75.

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3. The Union list may be amended in accordance with the procedure established by Articles 8 to 12 of Regulation (EC) No 1935/2004.

*Article 6***Derogations for substances not included in the Union list**

1. By way of derogation from Article 5, substances other than those included in the Union list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles subject to national law.

2. By way of derogation from Article 5, colorants and solvents may be used in the manufacture of plastic layers in plastic materials and articles subject to national law.

3. The following substances not included in the Union list are authorised subject to the rules set out in Articles 8, 9, 10, 11 and 12:

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(a) all salts of substances for which 'yes' is indicated in column 2 in Table 1 of Annex II of authorised acids, phenols or alcohols, and subject to the restrictions set out in column 3 and 4 of that table;

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(b) mixtures obtained by mixing authorised substances without a chemical reaction of the components;

(c) when used as additives, natural or synthetic polymeric substances of a molecular weight of at least 1 000 Da, except macromolecules obtained from microbial fermentation, complying with the requirements of this Regulation, if they are capable of functioning as the main structural component of final materials or articles;

(d) when used as monomer or other starting substance, pre-polymers and natural or synthetic macromolecular substances, as well as their mixtures, except macromolecules obtained from microbial fermentation, if the monomers or starting substances required to synthesise them are included in the Union list.

4. The following substances not included in the Union list may be present in the plastic layers of plastic materials or articles:

(a) non-intentionally added substances;

(b) aids to polymerisation.

5. By derogation from Article 5, additives not included in the Union list may continue to be used subject to national law after 1 January 2010 until a decision is taken to include or not to include them in the Union list provided they are included in the provisional list referred to in Article 7.

**▼B***Article 7***Establishment and management of the provisional list**

1. The provisional list of additives that are under evaluation by the European Food Safety Authority (hereinafter referred to as the Authority) that was made public by the Commission in 2008 shall be regularly updated.
2. An additive shall be removed from the provisional list:
  - (a) when it is included in the Union list set out in Annex I; or
  - (b) when a decision is taken by the Commission not to include it in the Union list; or
  - (c) if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.

*SECTION 2****General requirements, restrictions and specifications****Article 8***General requirement on substances**

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

*Article 9***Specific requirements on substances**

1. Substances used in the manufacture of plastic layers in plastic materials and articles shall be subject to the following restrictions and specifications:
  - (a) the specific migration limit set out in Article 11;
  - (b) the overall migration limit set out in Article 12;
  - (c) the restrictions and specifications set out in column 10 of Table 1 of point 1 of Annex I;
  - (d) the detailed specifications set out in point 4 of Annex I.
2. Substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications in Annex I.

**▼B***Article 10***General restrictions on plastic materials and articles**

General restrictions related to plastic materials and articles are laid down in Annex II.

*Article 11***Specific migration limits**

1. Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).

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3. By derogation from paragraph 1, additives which are also authorised as food additives by Regulation (EC) No 1333/2008 or as flavourings by Regulation (EC) No 1334/2008 shall not migrate into foods in quantities having a technical effect in the final foods and shall not:

- (a) exceed the restrictions provided for in Regulation (EC) No 1333/2008 or in Regulation (EC) No 1334/2008 or in Annex I to this Regulation for foods for which their use is authorised as food additive or flavouring substances; or
- (b) exceed the restrictions set out in Annex I to this Regulation in foods for which their use is not authorised as food additive or flavouring substances.

4. Where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods selected in accordance with Article 11 of Regulation (EC) No 882/2004 that can confirm the absence of migration above a specified limit of detection.

For the purposes of the first subparagraph, unless specific detection limits have been set for particular substances or groups of substances, a detection limit of 0,01 mg/kg shall apply.

**▼B***Article 12***Overall migration limit**

1. Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm<sup>2</sup> of food contact surface (mg/dm<sup>2</sup>).



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2. By derogation from paragraph 1, plastic materials and articles intended to be brought into contact with food intended for infants and young children, as defined by Commission Directives 2006/141/EC <sup>(1)</sup> and 2006/125/EC <sup>(2)</sup>, shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

## CHAPTER III

## SPECIFIC PROVISIONS FOR CERTAIN MATERIALS AND ARTICLES

*Article 13***Plastic multi-layer materials and articles**

1. In a plastic multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.

2. By derogation from paragraph 1, a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may:

- (a) not comply with the restrictions and specifications set out in this Regulation except for vinyl chloride monomer as provided in Annex I; and/or
- (b) be manufactured with substances not listed in the Union list or in the provisional list.

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3. Substances under paragraph 2(b) shall not migrate into food or food simulant, in accordance with Article 11(4). The detection limit set out in the second subparagraph of Article 11(4) shall apply to groups of substances if they are structurally and toxicologically related, including isomers or substances with the same relevant functional group, or to individual substances that are not related, and shall include possible set-off transfer.

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4. The substances not listed in the Union list or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories:

- (a) substances classified as ‘mutagenic’, ‘carcinogenic’ or ‘toxic to reproduction’ in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and the Council <sup>(3)</sup>;
- (b) substances in nanoform.

<sup>(1)</sup> OJ L 401, 30.12.2006, p. 1.

<sup>(2)</sup> OJ L 339, 6.12.2006, p. 16.

<sup>(3)</sup> OJ L 353, 31.12.2008, p. 1.

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5. The final plastic multi-layer material or article shall comply with the specific migration limits set out in Article 11 and the overall migration limit set out in Article 12 of this Regulation.

*Article 14***Multi-material multi-layer materials and articles**

1. In a multi-material multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.

2. By derogation from paragraph 1, in a multi-material multi-layer material or article a plastic layer which is not in direct contact with food and is separated from the food by a functional barrier, may be manufactured with substances not listed in the Union list or the provisional list.

3. The substances not listed in the Union list or provisional list referred to in paragraph 2 shall not belong to either of the following categories:

(a) substances classified as ‘mutagenic’, ‘carcinogenic’ or ‘toxic to reproduction’ in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008;

(b) substances in nanoform.

4. By derogation from paragraph 1, Articles 11 and 12 of this Regulation do not apply to plastic layers in multi-material multi-layer materials and articles.

5. The plastic layers in a multi-material multi-layer material or article shall always comply with the restrictions for vinyl chloride monomer laid down in Annex I to this Regulation.

6. In a multi-material multi-layer material or article, specific and overall migration limits for plastic layers and for the final material or article may be established by national law.

## CHAPTER IV

**DECLARATION OF COMPLIANCE AND DOCUMENTATION***Article 15***Declaration of compliance**

1. At the marketing stages other than at the retail stage, a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 shall be available for plastic materials and articles, products from intermediate stages of their manufacturing as well as for the substances intended for the manufacturing of those materials and articles.

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2. The written declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex IV.

3. The written declaration shall permit an easy identification of the materials, articles or products from intermediate stages of manufacture or substances for which it is issued. It shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available.

*Article 16***Supporting documents**

1. Appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Regulation shall be made available by the business operator to the national competent authorities on request.

2. That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in Chapter V.

## CHAPTER V

**COMPLIANCE***Article 17***Expression of migration test results**

1. To check the compliance, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use.

2. By derogation from paragraph 1 for:

(a) containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres,

(b) materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith,

(c) sheets and films that are not yet in contact with food,

(d) sheets and films containing less than 500 millilitres or grams or more than 10 litres,

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the value of migration shall be expressed in mg/kg applying a surface to volume ratio of 6 dm<sup>2</sup> per kg of food.

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 2006/141/EC and 2006/125/EC.

3. By derogation from paragraph 1, for caps, gaskets, stoppers and similar sealing articles the specific migration value shall be expressed in:

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(a) mg/kg using the actual content of the container for which the closure is intended applying the total contact surface of sealing article and sealed container if the intended use of the article is known, while taking into account the provisions of paragraph 2;

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(b) mg/article if the intended use of the article is unknown.

4. For caps, gaskets, stoppers and similar sealing articles the overall migration value shall be expressed in:

(a) mg/dm<sup>2</sup> applying the total contact surface of sealing article and sealed container if the intended use of the article is known;

(b) mg/article if the intended use of the article is unknown.

*Article 18***Rules for assessing compliance with migration limits**

1. For materials and articles already in contact with food verification of compliance with specific migration limits shall be carried out in accordance with the rules set out in Chapter 1 of Annex V.

2. For materials and articles not yet in contact with food verification of compliance with specific migration limits shall be carried out in food or in food simulants set out in Annex III in accordance with the rules set out in Chapter 2, Section 2.1 of Annex V.

3. For materials and articles not yet in contact with food screening of compliance with the specific migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 2, Section 2.2 of Annex V. If a material or article fails to comply with the migration limits in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 2.

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4. For materials and articles not yet in contact with food verification of compliance with the overall migration limit shall be carried out in food simulants as set out in Annex III in accordance with the rules set out in Chapter 3 of Annex V.

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5. For materials and articles not yet in contact with food screening of compliance with the overall migration limit can be performed applying screening approaches in accordance with the rules set out in Chapter 3, Section 3.4 of Annex V. If a material or article fails to comply with the migration limit in the screening approach a conclusion of non-compliance has to be confirmed by verification of compliance in accordance with paragraph 4.

6. The results of specific migration testing obtained in food shall prevail over the results obtained in food simulant. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches.

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7. Before comparing specific and overall migration test results with the migration limits the correction factors set out in point 3 of Annex III and Chapter 4 of Annex V shall be applied in accordance with the rules set out therein.

**▼B***Article 19***Assessment of substances not included in the Union list**

Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.

## CHAPTER VI

**FINAL PROVISIONS***Article 20***Amendments of EU acts**

The Annex to Council Directive 85/572/EEC <sup>(1)</sup> is replaced by the following:

‘The food simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with a single food or specific groups of foods are set out in point 3 of Annex III to Commission Regulation (EU) No 10/2011.’

<sup>(1)</sup> OJ L 372, 31.12.1985, p. 14.



### *Article 21*

#### **Repeal of EU acts**

Directives 80/766/EEC, 81/432/EEC, and 2002/72/EC are hereby repealed with effect from 1 May 2011.

References to the repealed Directives shall be construed as references to this Regulation and shall be read in accordance with the correlation tables in Annex VI.

### *Article 22*

#### **Transitional provisions**

1. Until 31 December 2012 the supporting documents referred to in Article 16 shall be based on the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

2. As from 1 January 2013 the supporting documents referred to in Article 16 for materials, articles and substances placed on the market until 31 December 2015, may be based on:

- (a) the rules for migration testing set out in Article 18 of this Regulation; or
- (b) the basic rules for overall and specific migration testing set out in the Annex to Directive 82/711/EEC.

3. As from 1 January 2016, the supporting documents referred to in Article 16 shall be based on the rules for migration testing set out in Article 18, without prejudice to paragraph 2 of this Article.

4. Until 31 December 2015 additives used in glass fibre sizing for glass fibre reinforced plastics which are not listed in Annex I have to comply with the risk assessment provisions set out in Article 19.

5. Materials and articles that have been lawfully placed on the market before 1 May 2011 may be placed on the market until 31 December 2012.

### *Article 23*

#### **Entry into force and application**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 May 2011.

The provision of Article 5 as regards the use of additives, others than plasticisers, shall apply for plastic layers or plastic coatings in caps and closures referred to in Article 2(1)(d), as from 31 December 2015.

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The provision of Article 5 as regards the use of additives used in glass fibre sizing for glass fibre reinforced plastics, shall apply from 31 December 2015.

The provisions of Articles 18(2), 18(4) and 20 shall apply from 31 December 2012.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

**▼B***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).

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Column 8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is marked as ND ('not-detectable') if the substance is one in respect of which no migration is permitted, to be determined in accordance with Article 11(4).

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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.

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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 production aid (yes/no) | Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no) | FRF applicable (yes/no) | SML [mg/kg] | SML(T) [mg/kg] (Group restriction No) | Restrictions and specifications  | Notes on verification of compliance |
| 1                | 12310   | 0266309-43-7 | 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 and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate | no   | yes   | no                      |             | (17)                                  | 1 mg/kg in final product expressed as isocyanate moiety.                     | (10)                                |
| 5                | 25360   | —            | trialkyl(C <sub>5</sub> -C <sub>15</sub> )acetic acid, 2,3-epoxypropyl ester                                       | no   | yes   | no                      | ND          |                                       | 1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da. |                                     |
| 6                | 25380   | —            | trialkyl acetic acid (C <sub>7</sub> -C <sub>17</sub> ), vinyl esters  | no   | yes   | no                      | 0,05        |                                       |  | (1)                                 |
| 7                | 30370   | —            | acetylacetic acid, salts   | yes  | no  | no                      |             |                                       |  |                                     |
| 8                | 30401   | —            | acetylated mono- and diglycerides of fatty acids   | yes  | no  | no                      |             | (32)                                  |  |                                     |

## ▼B

| (1) | (2)   | (3) | (4)  | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|-----|--|-----|-----|-----|-----|-----|------|------|
| 9   | 30610 | —   | acids, C <sub>2</sub> -C <sub>24</sub> , aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included) | yes | no  | no  |     |     |      |      |
| 10  | 30612 | —   | acids, C <sub>2</sub> -C <sub>24</sub> , aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters  | yes | no  | no  |     |     |      |      |
| 11  | 30960 | —   | acids, aliphatic, monocarboxylic (C <sub>6</sub> -C <sub>22</sub> ), esters with polyglycerol  | yes | no  | no  |     |     |      |      |
| 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> -C <sub>20</sub> ) dimethylamines  | yes | no  | yes | 30  |     |      |      |
| 16  | 34230 | —   | alkyl(C <sub>8</sub> -C <sub>22</sub> )sulphonic acids   | yes | no  | no  | 6   |     |      |      |
| 17  | 34281 | —   | alkyl(C <sub>8</sub> -C <sub>22</sub> )sulphuric acids, linear, primary with an even number of carbon atoms  | yes | no  | no  |     |     |      |      |

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| (1) | (2)   | (3) | (4)   | (5) | (6) | (7) | (8) | (9)  | (10)                           | (11) |
|-----|-------|-----|---|-----|-----|-----|-----|------|--------------------------------|------|
| 18  | 34475 | —   | aluminium calcium hydroxide phosphite, hydrate  | yes | no  | no  |     |      |                                |      |
| 19  | 39090 | —   | N,N-bis(2-hydroxyethyl)alkyl (C <sub>8</sub> -C <sub>18</sub> )amine  | yes | no  | no  |     | (7)  |                                |      |
| 20  | 39120 | —   | N,N-bis(2-hydroxyethyl)alkyl (C <sub>8</sub> -C <sub>18</sub> )amine hydrochlorides   | yes | no  | no  |     | (7)  | SML(T) expressed excluding HCl |      |
| 21  | 42500 | —   | carbonic acid, salts  | yes | no  | no  |     |      |                                |      |
| 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: a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80 to 100 % w/w) and b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0 to 20 % w/w) | yes | no  | no  | 5   |      |                                |      |
| 27  | 48960 | —   | 9,10-dihydroxy stearic acid and its oligomers   | yes | no  | no  | 5   |      |                                |      |
| 28  | 50160 | —   | di-n-octyltin bis(n-alkyl(C <sub>10</sub> -C <sub>16</sub> )mercaptoacetate)  | yes | no  | no  |     | (10) |                                |      |

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| (1) | (2)   | (3) | (4)  | (5) | (6) | (7) | (8) | (9)  | (10) | (11) |
|-----|-------|-----|--|-----|-----|-----|-----|------|------|------|
| 29  | 50360 | —   | di-n-octyltin bis(ethyl maleate)                                   | yes | no  | no  |     | (10) |      |      |
| 30  | 50560 | —   | di-n-octyltin 1,4-butanediol bis(mercaptoacetate)                  | yes | no  | no  |     | (10) |      |      |
| 31  | 50800 | —   | di-n-octyltin dimaleate, esterified                                | yes | no  | no  |     | (10) |      |      |
| 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  |     |      |      |      |
| 38  | 55520 | —   | glass fibers   | yes | no  | no  |     |      |      |      |
| 39  | 55600 | —   | glass microballs   | yes | no  | no  |     |      |      |      |
| 40  | 56360 | —   | glycerol, esters with acetic acid                                  | yes | no  | no  |     |      |      |      |

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| (1) | (2)   | (3) | (4)  | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|-----|--|-----|-----|-----|-----|-----|------|------|
| 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 (C <sub>16</sub> -C <sub>18</sub> ) | yes | no  | no  |     |     |      |      |
| 42  | 56487 | —   | glycerol, esters with butyric acid   | yes | no  | no  |     |     |      |      |
| 43  | 56490 | —   | glycerol, esters with erucic acid  | yes | no  | no  |     |     |      |      |
| 44  | 56495 | —   | glycerol, esters with 12-hydroxystearic acid   | yes | no  | no  |     |     |      |      |
| 45  | 56500 | —   | glycerol, esters with lauric acid  | yes | no  | no  |     |     |      |      |
| 46  | 56510 | —   | glycerol, esters with linoleic acid  | yes | no  | no  |     |     |      |      |
| 47  | 56520 | —   | glycerol, esters with myristic acid  | yes | no  | no  |     |     |      |      |
| 48  | 56535 | —   | glycerol, esters with nonanoic acid  | yes | no  | no  |     |     |      |      |
| 49  | 56540 | —   | glycerol, esters with oleic acid   | yes | no  | no  |     |     |      |      |
| 50  | 56550 | —   | glycerol, esters with palmitic acid  | yes | no  | no  |     |     |      |      |

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| (1) | (2)   | (3) | (4)  | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|-----|--|-----|-----|-----|-----|-----|------|------|
| 51  | 56570 | —   | glycerol, esters with propionic acid             | yes | no  | no  |     |     |      |      |
| 52  | 56580 | —   | glycerol, esters with ricinoleic acid            | yes | no  | no  |     |     |      |      |
| 53  | 56585 | —   | glycerol, esters with stearic acid               | yes | no  | no  |     |     |      |      |
| 54  | 57040 | —   | glycerol monooleate, ester with ascorbic acid    | yes | no  | no  |     |     |      |      |
| 55  | 57120 | —   | glycerol monooleate, ester with citric acid      | yes | no  | no  |     |     |      |      |
| 56  | 57200 | —   | glycerol monopalmitate, ester with ascorbic acid | yes | no  | no  |     |     |      |      |
| 57  | 57280 | —   | glycerol monopalmitate, ester with citric acid   | yes | no  | no  |     |     |      |      |
| 58  | 57600 | —   | glycerol monostearate, ester with ascorbic acid  | yes | no  | no  |     |     |      |      |
| 59  | 57680 | —   | glycerol monostearate, ester with citric acid    | yes | no  | no  |     |     |      |      |
| 60  | 58300 | —   | glycine, salts                                   | yes | no  | no  |     |     |      |      |
| 62  | 64500 | —   | lysine, salts                                    | yes | no  | no  |     |     |      |      |
| 63  | 65440 | —   | manganese pyrophosphite                          | yes | no  | no  |     |     |      |      |
| 64  | 66695 | —   | methylhydroxymethylcellulose                     | yes | no  | no  |     |     |      |      |

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| (1) | (2)   | (3) | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|-----|---|-----|-----|-----|------|------|--|------|
| 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 esters with ethyleneglycol and/or with 1,3-butanediol and/or with glycerol  | yes | no  | no  |      |      |  |      |
| 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 | —   | phosphorous acid, tris(nonyl-and/ or dinonylphenyl) ester   | yes | no  | yes | 30   |      |  |      |
| 70  | 76463 | —   | polyacrylic acid, salts   | yes | no  | no  |      | (22) |  |      |
| 71  | 76730 | —   | polydimethylsiloxane, $\gamma$ -hydroxy-propylated  | yes | no  | no  | 6    |      |  |      |
| 72  | 76815 | —   | polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered, unbranched C <sub>12</sub> -C <sub>22</sub> fatty acids       | yes | no  | no  |      | (32) | The fraction with molecular weight below 1 000 Da ► <b>M7</b> shall ◀ not exceed 5 % (w/w)   |      |

## ▼B

| (1) | (2)   | (3) | (4)   | (5) | (6) | (7) | (8)  | (9)          | (10)                | (11) |
|-----|-------|-----|---|-----|-----|-----|------|--------------|---------------------|------|
| 73  | 76866 | —   | polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C <sub>12</sub> -C <sub>18</sub> or n-octanol and/or n-decanol | yes | no  | yes |      | (31)<br>(32) |                     |      |
| 74  | 77440 | —   | polyethyleneglycol diricinoleate  | yes | no  | yes | 42   |              |                     |      |
| 75  | 77702 | —   | polyethyleneglycol 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 | —   | polyethyleneglycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate   | yes | no  | no  | 0,05 |              | Only for use in PET |      |
| 78  | 77897 | —   | polyethyleneglycol (EO = 1-50) monoalkylether (linear and branched, C <sub>8</sub> -C <sub>20</sub> ) sulphate, salts   | yes | no  | no  | 5    |              |                     |      |
| 79  | 80640 | —   | polyoxyalkyl (C <sub>2</sub> -C <sub>4</sub> ) dimethyl-polysiloxane  | yes | no  | no  |      |              |                     |      |



▼B

| (1)         | (2)   | (3) | (4)  | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-------------|-------|-----|--|-----|-----|-----|-----|-----|---|------|
| 80          | 81760 | —   | powders, flakes and fibres of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron | yes | no  | no  |     |     |   |      |
| 81          | 83320 | —   | propylhydroxyethylcellulose  | yes | no  | no  |     |     |   |      |
| 82          | 83325 | —   | propylhydroxymethylcellulose   | 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  |     |     |   |      |
| ▼ <u>M7</u> |       |     |  |     |     |     |     |     |   |      |
| 87          | 86285 |     | Silicon dioxide, silanated   | yes | no  | no  |     |     | For synthetic amorphous silicon dioxide, silanated: primary particles of 1–100 nm which are aggregated to a size of 0,1–1 µm and may form agglomerates within the size distribution of 0,3 µm to the mm size. |      |
| ▼ <u>B</u>  |       |     |  |     |     |     |     |     |   |      |
| 88          | 86880 | —   | sodium monoalkyl dialkylphenoxybenzenedisulphonate   | yes | no  | no  | 9   |     |   |      |
| 89          | 89440 | —   | stearic acid, esters with ethylene-glycol  | yes | no  | no  |     | (2) |   |      |
| 90          | 92195 | —   | taurine, salts   | yes | no  | no  |     |     |   |      |

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| (1) | (2)   | (3) | (4)   | (5) | (6) | (7) | (8)  | (9) | (10)  | (11) |
|-----|-------|-----|---|-----|-----|-----|------|-----|---|------|
| 91  | 92320 | —   | tetradecyl-polyethyleneglycol(EO = 3-8) ether of glycolic acid  | yes | no  | yes | 15   |     |   |      |
| 92  | 93970 | —   | tricyclodecanedimethanol bis(hexahydrophthalate)  | 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 ►M7 simulant D1 and/or D2 ◀ is laid down.<br>Average molecular weight not less than 350 Da.<br>Viscosity at 100 °C not less than 2,5 cSt ( $2,5 \times 10^{-6} \text{ m}^2/\text{s}$ ).<br>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.<br>Viscosity at 100 °C not less than 11 cSt ( $11 \times 10^{-6} \text{ m}^2/\text{s}$ ).<br>Content of 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.<br>Viscosity at 100 °C not less than 8,5 cSt ( $8,5 \times 10^{-6} \text{ m}^2/\text{s}$ ).<br>Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).   |      |
| 96  | 95920 | —   | wood flour and fibers, untreated  | yes | no  | no  |      |     |   |      |

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| (1) | (2)      | (3)          | (4)   | (5) | (6) | (7) | (8) | (9)  | (10)   | (11) |
|-----|----------|--------------|---|-----|-----|-----|-----|------|--|------|
| 97  | 72081/10 | —            | petroleum hydrocarbon resins (hydrogenated) | yes | no  | no  |     |      | <p>Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermalpolymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing.</p> <p>Properties:</p> <ul style="list-style-type: none"> <li>— Viscosity at 120 °C: &gt; 3 Pa.s,</li> <li>— Softening point: &gt; 95 °C as determined by ASTM Method E 28-67,</li> <li>— Bromine number: &lt; 40 (ASTM D1159),</li> <li>— The colour of a 50 % solution in toluene &lt; 11 on the Gardner scale,</li> <li>— Residual aromatic monomer ≤ 50 ppm,</li> </ul> |      |
| 98  | 17260    | 0000050-00-0 | formaldehyde                                | yes | yes | no  |     | (15) |  |      |
|     | 54880    |              |   |     |     |     |     |      |  |      |
| 99  | 19460    | 0000050-21-5 | lactic acid                                 | yes | yes | no  |     |      |  |      |
|     | 62960    |              |   |     |     |     |     |      |  |      |

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| (1) | (2)   | (3)                          | (4)                                | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|------------------------------|------------------------------------|-----|-----|-----|-----|-----|------|------|
| 100 | 24490 | 0000050-70-4                 | sorbitol                           | yes | yes | no  |     |     |      |      |
|     | 88320 |                              |                                    |     |     |     |     |     |      |      |
| 101 | 36000 | 0000050-81-7                 | ascorbic acid                      | yes | no  | no  |     |     |      |      |
| 102 | 17530 | 0000050-99-7                 | glucose                            | no  | yes | no  |     |     |      |      |
| 103 | 18100 | 0000056-81-5                 | glycerol                           | yes | yes | no  |     |     |      |      |
|     | 55920 |                              |                                    |     |     |     |     |     |      |      |
| 104 | 58960 | 0000057-09-0                 | hexadecyltrimethylammonium bromide | yes | no  | no  | 6   |     |      |      |
| 105 | 22780 | 0000057-10-3                 | palmitic acid                      | yes | yes | no  |     |     |      |      |
|     | 70400 |                              |                                    |     |     |     |     |     |      |      |
| 106 | 24550 | 0000057-11-4                 | stearic acid                       | yes | yes | no  |     |     |      |      |
|     | 89040 |                              |                                    |     |     |     |     |     |      |      |
| 107 | 25960 | 0000057-13-6                 | urea                               | no  | yes | no  |     |     |      |      |
| 108 | 24880 | 0000057-50-1                 | sucrose                            | no  | yes | no  |     |     |      |      |
| 109 | 23740 | 0000057-55-6                 | 1,2-propanediol                    | yes | yes | no  |     |     |      |      |
|     | 81840 |                              |                                    |     |     |     |     |     |      |      |
| 110 | 93520 | 0000059-02-9<br>0010191-41-0 | $\alpha$ -tocopherol               | yes | no  | no  |     |     |      |      |
| 111 | 53600 | 0000060-00-4                 | ethylenediaminetetraacetic acid    | yes | no  | no  |     |     |      |      |
| 112 | 64015 | 0000060-33-3                 | linoleic acid                      | yes | no  | no  |     |     |      |      |

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| (1) | (2)   | (3)          | (4)                 | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|--------------|---------------------|-----|-----|-----|-----|-----|------|------|
| 113 | 16780 | 0000064-17-5 | ethanol             | yes | yes | no  |     |     |      |      |
|     | 52800 |              |                     |     |     |     |     |     |      |      |
| 114 | 55040 | 0000064-18-6 | formic acid         | yes | no  | no  |     |     |      |      |
| 115 | 10090 | 0000064-19-7 | acetic acid         | yes | yes | no  |     |     |      |      |
|     | 30000 |              |                     |     |     |     |     |     |      |      |
| 116 | 13090 | 0000065-85-0 | benzoic acid        | yes | yes | no  |     |     |      |      |
|     | 37600 |              |                     |     |     |     |     |     |      |      |
| 117 | 21550 | 0000067-56-1 | methanol            | no  | yes | no  |     |     |      |      |
| 118 | 23830 | 0000067-63-0 | 2-propanol          | yes | yes | no  |     |     |      |      |
|     | 81882 |              |                     |     |     |     |     |     |      |      |
| 119 | 30295 | 0000067-64-1 | acetone             | yes | no  | no  |     |     |      |      |
| 120 | 49540 | 0000067-68-5 | dimethyl sulphoxide | yes | no  | no  |     |     |      |      |
| 121 | 24270 | 0000069-72-7 | salicylic acid      | yes | yes | no  |     |     |      |      |
|     | 84640 |              |                     |     |     |     |     |     |      |      |
| 122 | 23800 | 0000071-23-8 | 1-propanol          | no  | yes | no  |     |     |      |      |
| 123 | 13840 | 0000071-36-3 | 1-butanol           | no  | yes | no  |     |     |      |      |
| 124 | 22870 | 0000071-41-0 | 1-pentanol          | no  | yes | no  |     |     |      |      |
| 125 | 16950 | 0000074-85-1 | ethylene            | no  | yes | no  |     |     |      |      |

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| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8) | (9)  | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|-----|------|---|------|
| 126 | 10210 | 0000074-86-2 | acetylene  | no  | yes | no  |     |      |   |      |
| 127 | 26050 | 0000075-01-4 | vinyl chloride   | no  | yes | no  | ND  |      | 1 mg/kg in final product  |      |
| 128 | 10060 | 0000075-07-0 | acetaldehyde   | no  | yes | no  |     | (1)  |   |      |
| 129 | 17020 | 0000075-21-8 | ethylene oxide   | no  | yes | no  | ND  |      | 1 mg/kg in final product  | (10) |
| 130 | 26110 | 0000075-35-4 | vinylidene chloride                                      | no  | yes | no  | ND  |      |   | (1)  |
| 131 | 48460 | 0000075-37-6 | 1,1-difluoroethane                                       | yes | no  | no  |     |      |   |      |
| 132 | 26140 | 0000075-38-7 | vinylidene fluoride                                      | no  | yes | no  | 5   |      |   |      |
| 133 | 14380 | 0000075-44-5 | carbonyl chloride  | no  | yes | no  | ND  |      | 1 mg/kg in final product  | (10) |
|     | 23155 |              |  |     |     |     |     |      |   |      |
| 134 | 43680 | 0000075-45-6 | chlorodifluoromethane                                    | yes | no  | no  | 6   |      | Content of chlorofluoromethane less than 1 mg/kg of the substance |      |
| 135 | 24010 | 0000075-56-9 | propylene oxide  | no  | yes | no  | ND  |      | 1 mg/kg in final product  |      |
| 136 | 41680 | 0000076-22-2 | camphor  | yes | no  | no  |     |      |   | (3)  |
| 137 | 66580 | 0000077-62-3 | 2,2'-methylenebis(4-methyl-6-(1-methylcyclohexyl)phenol) | yes | no  | yes |     | (5)  |   |      |
| 138 | 93760 | 0000077-90-7 | tri-n-butyl acetyl citrate                               | yes | no  | no  |     | (32) |   |      |
| 139 | 14680 | 0000077-92-9 | citric acid  | yes | yes | no  |     |      |   |      |
|     | 44160 |              |  |     |     |     |     |      |   |      |
| 140 | 44640 | 0000077-93-0 | citric acid, triethyl ester                              | yes | no  | no  |     | (32) |   |      |

▼B

| (1)          | (2)   | (3)          | (4)                             | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11)              |
|--------------|-------|--------------|---------------------------------|-----|-----|-----|------|------|--|-------------------|
| 141          | 13380 | 0000077-99-6 | 1,1,1-trimethylolpropane        | yes | yes | no  | 6    |      |  |                   |
|              | 25600 |              |                                 |     |     |     |      |      |  |                   |
|              | 94960 |              |                                 |     |     |     |      |      |  |                   |
| 142          | 26305 | 0000078-08-0 | vinyltriethoxysilane            | no  | yes | no  | 0,05 |      | Only to be used as a surface treatment agent   | ► <u>M8</u> ——— ◀ |
| 143          | 62450 | 0000078-78-4 | isopentane                      | yes | no  | no  |      |      |  |                   |
| 144          | 19243 | 0000078-79-5 | 2-methyl-1,3-butadiene          | no  | yes | no  | ND   |      | 1 mg/kg in final product   |                   |
|              | 21640 |              |                                 |     |     |     |      |      |  |                   |
| 145          | 10630 | 0000079-06-1 | acrylamide                      | no  | yes | no  | ND   |      |  |                   |
| 146          | 23890 | 0000079-09-4 | propionic acid                  | yes | yes | no  |      |      |  |                   |
|              | 82000 |              |                                 |     |     |     |      |      |  |                   |
| 147          | 10690 | 0000079-10-7 | acrylic acid                    | no  | yes | no  |      | (22) |  |                   |
| 148          | 14650 | 0000079-38-9 | chlorotrifluoroethylene         | no  | yes | no  | ND   |      |  | (1)               |
| 149          | 19990 | 0000079-39-0 | methacrylamide                  | no  | yes | no  | ND   |      |  |                   |
| 150          | 20020 | 0000079-41-4 | methacrylic acid                | no  | yes | no  |      | (23) |  |                   |
| ▼ <u>M10</u> | 13480 | 0000080-05-7 | 2,2-bis(4-hydroxyphenyl)propane | no  | yes | no  | 0,05 |      | Not to be used for the manufacture of polycarbonate infant <sup>(6)</sup> feeding bottles <sup>(7)</sup> .<br>Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants <sup>(8)</sup> and young children <sup>(10)</sup> . |                   |
|              | 13607 |              |                                 |     |     |     |      |      |  |                   |
| ▼ <u>B</u>   | 152   | 0000080-07-9 | 4,4'-dichlorodiphenyl sulphone  | no  | yes | no  | 0,05 |      |  |                   |
|              | 153   | 0000080-08-0 | 4,4'-diaminodiphenyl sulphone   | no  | yes | no  | 5    |      |  |                   |

## ▼B

| (1) | (2)   | (3)          | (4)                               | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|-----------------------------------|-----|-----|-----|------|------|--|------|
| 154 | 13617 | 0000080-09-1 | 4,4'-dihydroxydiphenyl sulphone   | no  | yes | no  | 0,05 |      |  |      |
|     | 16090 |              |                                   |     |     |     |      |      |  |      |
| 155 | 23470 | 0000080-56-8 | $\alpha$ -pinene                  | no  | yes | no  |      |      |  |      |
| 156 | 21130 | 0000080-62-6 | methacrylic acid, methyl ester    | no  | yes | no  |      | (23) |  |      |
| 157 | 74880 | 0000084-74-2 | phthalic acid, dibutyl ester      | yes | no  | no  | 0,3  | (32) | Only to be used as:<br>(a) plasticiser in repeated use materials and articles contacting non-fatty foods;<br>(b) technical support agent in polyolefins in concentrations up to 0,05 % in the final product.   | (7)  |
| 158 | 23380 | 0000085-44-9 | phthalic anhydride                | yes | yes | no  |      |      |  |      |
|     | 76320 |              |                                   |     |     |     |      |      |  |      |
| 159 | 74560 | 0000085-68-7 | phthalic acid, benzyl butyl ester | yes | no  | no  | 30   | (32) | Only to be used as:<br>(a) plasticiser in repeated use materials and articles;<br>(b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant 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; | (7)  |



▼ B

| (1) | (2)   | (3)          | (4)                                      | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|-----|-----|---|------|
|     |       |              |  |     |     |     |     |     | (c) technical support agent in concentrations up to 0,1 % in the final product. |      |
| 160 | 84800 | 0000087-18-3 | salicylic acid, 4-tert-butylphenyl ester | yes | no  | yes | 12  |     |   |      |

▼ M6

|     |       |             |                     |     |    |    |  |  |  |  |
|-----|-------|-------------|---------------------|-----|----|----|--|--|--|--|
| 161 | 92160 | 000087-69-4 | L-(+)-tartaric acid | yes | no | no |  |  |  |  |
|-----|-------|-------------|---------------------|-----|----|----|--|--|--|--|

▼ B

|     |       |              |  |     |     |     |      |      |   |                   |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|-------------------|
| 162 | 65520 | 0000087-78-5 | mannitol                                       | yes | no  | no  |      |      |   |                   |
| 163 | 66400 | 0000088-24-4 | 2,2'-methylene bis(4-ethyl-6-tert-butylphenol) | yes | no  | yes |      | (13) |   |                   |
| 164 | 34895 | 0000088-68-6 | 2-aminobenzamide                               | yes | no  | no  | 0,05 |      | Only for use in PET for water and beverages             |                   |
| 165 | 23200 | 0000088-99-3 | o-phthalic acid                                | yes | yes | no  |      |      |   |                   |
|     | 74480 |              |  |     |     |     |      |      |   |                   |
| 166 | 24057 | 0000089-32-7 | pyromellitic anhydride                         | no  | yes | no  | 0,05 |      |   |                   |
| 167 | 25240 | 0000091-08-7 | 2,6-toluene diisocyanate                       | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10)              |
| 168 | 13075 | 0000091-76-9 | 2,4-diamino-6-phenyl-1,3,5-triazine            | no  | yes | no  | 5    |      |   | ▶ <u>M8</u> ——— ◀ |
|     | 15310 |              |  |     |     |     |      |      |   |                   |
| 169 | 16240 | 0000091-97-4 | 3,3'-dimethyl-4,4'-diisocyanato-biphenyl       | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10)              |
| 170 | 16000 | 0000092-88-6 | 4,4'-dihydroxybiphenyl                         | no  | yes | no  | 6    |      |   |                   |
| 171 | 38080 | 0000093-58-3 | benzoic acid, methyl ester                     | yes | no  | no  |      |      |   |                   |
| 172 | 37840 | 0000093-89-0 | benzoic acid, ethyl ester                      | yes | no  | no  |      |      |   |                   |

▼B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|---|------|
| 173 | 60240 | 0000094-13-3 | 4-hydroxybenzoic acid, propyl ester           | yes | no  | no  |      |      |   |      |
| 174 | 14740 | 0000095-48-7 | <i>o</i> -cresol                              | no  | yes | no  |      |      |   |      |
| 175 | 20050 | 0000096-05-9 | methacrylic acid, allyl ester                 | no  | yes | no  | 0,05 |      |   |      |
| 176 | 11710 | 0000096-33-3 | acrylic acid, methyl ester                    | no  | yes | no  |      | (22) |   |      |
| 177 | 16955 | 0000096-49-1 | 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 | 0000096-69-5 | 4,4'-thiobis(6-tert-butyl-3-methylphenol)     | yes | no  | yes | 0,48 |      |   |      |
| 179 | 48800 | 0000097-23-4 | 2,2'-dihydroxy--5,5'-dichlorodiphenylmethane  | yes | no  | yes | 12   |      |   |      |
| 180 | 17160 | 0000097-53-0 | eugenol                                       | no  | yes | no  |      | (33) |   |      |
| 181 | 20890 | 0000097-63-2 | methacrylic acid, ethyl ester                 | no  | yes | no  |      | (23) |   |      |
| 182 | 19270 | 0000097-65-4 | itaconic acid                                 | no  | yes | no  |      |      |   |      |
| 183 | 21010 | 0000097-86-9 | methacrylic acid, isobutyl ester              | no  | yes | no  |      | (23) |   |      |
| 184 | 20110 | 0000097-88-1 | methacrylic acid, butyl ester                 | no  | yes | no  |      | (23) |   |      |
| 185 | 20440 | 0000097-90-5 | methacrylic acid, diester with ethyleneglycol | no  | yes | no  | 0,05 |      |   |      |
| 186 | 14020 | 0000098-54-4 | 4-tert-butylphenol                            | no  | yes | no  | 0,05 |      |   |      |
| 187 | 22210 | 0000098-83-9 | $\alpha$ -methylstyrene                       | no  | yes | no  | 0,05 |      |   |      |

▼M3▼B

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| (1) | (2)   | (3)          | (4)                                 | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11)    |
|-----|-------|--------------|-------------------------------------|-----|-----|-----|------|------|--|---------|
| 188 | 19180 | 0000099-63-8 | isophthalic acid dichloride         | no  | yes | no  |      | (27) |  |         |
| 189 | 60200 | 0000099-76-3 | 4-hydroxybenzoic acid, methyl ester | yes | no  | no  |      |      |  |         |
| 190 | 18880 | 0000099-96-7 | <i>p</i> -hydroxybenzoic acid       | no  | yes | no  |      |      |  |         |
| 191 | 24940 | 0000100-20-9 | terephthalic acid dichloride        | no  | yes | no  |      | (28) |  |         |
| 192 | 23187 | —            | phthalic acid                       | no  | yes | no  |      | (28) |  |         |
| 193 | 24610 | 0000100-42-5 | styrene                             | no  | yes | no  |      |      |  |         |
| 194 | 13150 | 0000100-51-6 | benzyl alcohol                      | no  | yes | no  |      |      |  |         |
| 195 | 37360 | 0000100-52-7 | benzaldehyde                        | yes | no  | no  |      |      |  | (3)     |
| 196 | 18670 | 0000100-97-0 | hexamethylenetetramine              | yes | yes | no  |      | (15) |  |         |
|     | 59280 |              |                                     |     |     |     |      |      |  |         |
| 197 | 20260 | 0000101-43-9 | methacrylic acid, cyclohexyl ester  | no  | yes | no  | 0,05 |      |  |         |
| 198 | 16630 | 0000101-68-8 | diphenylmethane-4,4'-diisocyanate   | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety  | (10)    |
| 199 | 24073 | 0000101-90-6 | resorcinol diglycidyl ether         | no  | yes | no  | ND   |      | Not to be used for articles in contact with fatty foods for which ►M7 simulant D1 and/or D2 ◀ is laid down.<br>For indirect food contact only, behind a PET layer. | (8)     |
| 200 | 51680 | 0000102-08-9 | N,N'-diphenylthiourea               | yes | no  | yes | 3    |      |  |         |
| 201 | 16540 | 0000102-09-0 | diphenyl carbonate                  | no  | yes | no  | 0,05 |      |  |         |
| 202 | 23070 | 0000102-39-6 | (1,3-phenylenedioxy)diacetic acid   | no  | yes | no  | 0,05 |      |  | ►M8 — ◀ |

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| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|--|------|
| 203 | 13323 | 0000102-40-9 | 1,3-bis(2-hydroxyethoxy)benzene                    | no  | yes | no  | 0,05 |      |  |      |
| 204 | 25180 | 0000102-60-3 | N,N,N',N'-tetrakis(2-hydroxypropyl)ethylenediamine | yes | yes | no  |      |      |  |      |
|     | 92640 |              |  |     |     |     |      |      |  |      |
| 205 | 25385 | 0000102-70-5 | triallylamine                                      | no  | yes | no  |      |      | 40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel.<br>Only to be used in hydrogels intended for non-direct food contact use. |      |
| 206 | 11500 | 0000103-11-7 | acrylic acid, 2-ethylhexyl ester                   | no  | yes | no  | 0,05 |      |  |      |
| 207 | 31920 | 0000103-23-1 | adipic acid, bis(2-ethylhexyl) ester               | yes | no  | yes | 18   | (32) |  | (2)  |
| 208 | 18898 | 0000103-90-2 | N-(4-hydroxyphenyl) acetamide                      | no  | yes | no  | 0,05 |      |  |      |
| 209 | 17050 | 0000104-76-7 | 2-ethyl-1-hexanol                                  | no  | yes | no  | 30   |      |  |      |
| 210 | 13390 | 0000105-08-8 | 1,4-bis(hydroxymethyl)cyclohexane                  | no  | yes | no  |      |      |  |      |
|     | 14880 |              |  |     |     |     |      |      |  |      |
| 211 | 23920 | 0000105-38-4 | propionic acid, vinyl ester                        | no  | yes | no  |      | (1)  |  |      |
| 212 | 14200 | 0000105-60-2 | caprolactam  | yes | yes | no  |      |      |  | (4)  |
|     | 41840 |              |  |     |     |     |      |      |  |      |
| 213 | 82400 | 0000105-62-4 | 1,2-propyleneglycol dioleate                       | yes | no  | no  |      |      |  |      |
| 214 | 61840 | 0000106-14-9 | 12-hydroxystearic acid                             | yes | no  | no  |      |      |  |      |

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| (1) | (2)   | (3)          | (4)                                     | (5) | (6) | (7) | (8)  | (9)  | (10)                     | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|--------------------------|------|
| 215 | 14170 | 0000106-31-0 | butyric anhydride                       | no  | yes | no  |      |      |                          |      |
| 216 | 14770 | 0000106-44-5 | <i>p</i> -cresol                        | no  | yes | no  |      |      |                          |      |
| 217 | 15565 | 0000106-46-7 | 1,4-dichlorobenzene                     | no  | yes | no  | 12   |      |                          |      |
| 218 | 11590 | 0000106-63-8 | acrylic acid, isobutyl ester            | no  | yes | no  |      | (22) |                          |      |
| 219 | 14570 | 0000106-89-8 | epichlorohydrin                         | no  | yes | no  | ND   |      | 1 mg/kg in final product | (10) |
|     | 16750 |              |   |     |     |     |      |      |                          |      |
| 220 | 20590 | 0000106-91-2 | methacrylic acid, 2,3-epoxypropyl ester | no  | yes | no  | 0,02 |      |                          | (10) |
| 221 | 40570 | 0000106-97-8 | butane                                  | yes | no  | no  |      |      |                          |      |
| 222 | 13870 | 0000106-98-9 | 1-butene                                | no  | yes | no  |      |      |                          |      |
| 223 | 13630 | 0000106-99-0 | butadiene                               | no  | yes | no  | ND   |      | 1 mg/kg in final product |      |
| 224 | 13900 | 0000107-01-7 | 2-butene                                | no  | yes | no  |      |      |                          |      |
| 225 | 12100 | 0000107-13-1 | acrylonitrile                           | no  | yes | no  | ND   |      |                          |      |
| 226 | 15272 | 0000107-15-3 | ethylenediamine                         | no  | yes | no  | 12   |      |                          |      |
|     | 16960 |              |   |     |     |     |      |      |                          |      |
| 227 | 16990 | 0000107-21-1 | ethyleneglycol                          | yes | yes | no  |      | (2)  |                          |      |
|     | 53650 |              |   |     |     |     |      |      |                          |      |
| 228 | 13690 | 0000107-88-0 | 1,3-butanediol                          | no  | yes | no  |      |      |                          |      |
| 229 | 14140 | 0000107-92-6 | butyric acid                            | no  | yes | no  |      |      |                          |      |

▼ B

| (1)          | (2)   | (3)          | (4)                           | (5) | (6) | (7) | (8)  | (9)  | (10) | (11) |
|--------------|-------|--------------|-------------------------------|-----|-----|-----|------|------|------|------|
| 230          | 16150 | 0000108-01-0 | dimethylaminoethanol          | no  | yes | no  | 18   |      |      |      |
| 231          | 10120 | 0000108-05-4 | acetic acid, vinyl ester      | no  | yes | no  | 12   |      |      |      |
| 232          | 10150 | 0000108-24-7 | acetic anhydride              | yes | yes | no  |      |      |      |      |
|              | 30280 |              |                               |     |     |     |      |      |      |      |
| 233          | 24850 | 0000108-30-5 | succinic anhydride            | no  | yes | no  |      |      |      |      |
| 234          | 19960 | 0000108-31-6 | maleic anhydride              | no  | yes | no  |      | (3)  |      |      |
| 235          | 14710 | 0000108-39-4 | <i>m</i> -cresol              | no  | yes | no  |      |      |      |      |
| ▼ <u>M15</u> |       |              |                               |     |     |     |      |      |      |      |
| 236          | 23050 | 0000108-45-2 | 1,3-phenylenediamine          | no  | yes | no  | ND   |      |      | (28) |
| ▼ <u>B</u>   |       |              |                               |     |     |     |      |      |      |      |
| 237          | 15910 | 0000108-46-3 | 1,3-dihydroxybenzene          | no  | yes | no  | 2,4  |      |      |      |
|              | 24072 |              |                               |     |     |     |      |      |      |      |
| 238          | 18070 | 0000108-55-4 | glutaric anhydride            | no  | yes | no  |      |      |      |      |
| ▼ <u>M2</u>  |       |              |                               |     |     |     |      |      |      |      |
| 239          | 19975 | 0000108-78-1 | 2,4,6-triamino-1,3,5-triazine | yes | yes | no  | 2,5  |      |      |      |
|              | 25420 |              |                               |     |     |     |      |      |      |      |
|              | 93720 |              |                               |     |     |     |      |      |      |      |
| ▼ <u>B</u>   |       |              |                               |     |     |     |      |      |      |      |
| 240          | 45760 | 0000108-91-8 | cyclohexylamine               | yes | no  | no  |      |      |      |      |
| ▼ <u>M6</u>  |       |              |                               |     |     |     |      |      |      |      |
| 241          | 22960 | 0000108-95-2 | phenol                        | no  | yes | no  | 3    |      |      |      |
| ▼ <u>B</u>   |       |              |                               |     |     |     |      |      |      |      |
| 242          | 85360 | 0000109-43-3 | sebacic acid, dibutyl ester   | yes | no  | no  |      | (32) |      |      |
| 243          | 19060 | 0000109-53-5 | isobutyl vinyl ether          | no  | yes | no  | 0,05 |      |      | (10) |
| 244          | 71720 | 0000109-66-0 | pentane                       | yes | no  | no  |      |      |      |      |

▼B

| (1) | (2)   | (3)          | (4)                        | (5) | (6) | (7) | (8) | (9)  | (10) | (11) |
|-----|-------|--------------|----------------------------|-----|-----|-----|-----|------|------|------|
| 245 | 22900 | 0000109-67-1 | 1-pentene                  | no  | yes | no  | 5   |      |      |      |
| 246 | 25150 | 0000109-99-9 | tetrahydrofuran            | no  | yes | no  | 0,6 |      |      |      |
| 247 | 24820 | 0000110-15-6 | succinic acid              | yes | yes | no  |     |      |      |      |
|     | 90960 |              |                            |     |     |     |     |      |      |      |
| 248 | 19540 | 0000110-16-7 | maleic acid                | yes | yes | no  |     | (3)  |      |      |
|     | 64800 |              |                            |     |     |     |     |      |      |      |
| 249 | 17290 | 0000110-17-8 | fumaric acid               | yes | yes | no  |     |      |      |      |
|     | 55120 |              |                            |     |     |     |     |      |      |      |
| 250 | 53520 | 0000110-30-5 | N,N'-ethylenebisstearamide | yes | no  | no  |     |      |      |      |
| 251 | 53360 | 0000110-31-6 | N,N'-ethylenebisoleamide   | yes | no  | no  |     |      |      |      |
| 252 | 87200 | 0000110-44-1 | sorbic acid                | yes | no  | no  |     |      |      |      |
| 253 | 15250 | 0000110-60-1 | 1,4-diaminobutane          | no  | yes | no  |     |      |      |      |
| 254 | 13720 | 0000110-63-4 | 1,4-butanediol             | yes | yes | no  |     | (30) |      |      |
|     | 40580 |              |                            |     |     |     |     |      |      |      |
| 255 | 25900 | 0000110-88-3 | trioxane                   | no  | yes | no  | 5   |      |      |      |
| 256 | 18010 | 0000110-94-1 | glutaric acid              | yes | yes | no  |     |      |      |      |
|     | 55680 |              |                            |     |     |     |     |      |      |      |
| 257 | 13550 | 0000110-98-5 | dipropylene glycol         | yes | yes | no  |     |      |      |      |
|     | 16660 | 0025265-71-8 |                            |     |     |     |     |      |      |      |
|     | 51760 |              |                            |     |     |     |     |      |      |      |

▼M3

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| (1) | (2)   | (3)          | (4)                          | (5) | (6) | (7) | (8)  | (9) | (10)   | (11) |
|-----|-------|--------------|------------------------------|-----|-----|-----|------|-----|--|------|
| 258 | 70480 | 0000111-06-8 | palmitic acid, butyl ester   | yes | no  | no  |      |     |  |      |
| 259 | 58720 | 0000111-14-8 | heptanoic acid               | yes | no  | no  |      |     |  |      |
| 260 | 24280 | 0000111-20-6 | sebacic acid                 | no  | yes | no  |      |     |  |      |
| 261 | 15790 | 0000111-40-0 | diethylenetriamine           | no  | yes | no  | 5    |     |  |      |
| 262 | 35284 | 0000111-41-1 | N-(2-aminoethyl)ethanolamine | yes | no  | no  | 0,05 |     | Not to be used for articles in contact with fatty foods for which ►M7 simulant D1 and/or D2 ◀ is laid down.<br>For indirect food contact only, behind a PET layer. |      |
| 263 | 13326 | 0000111-46-6 | diethyleneglycol             | yes | yes | no  |      | (2) |  |      |
|     | 15760 |              |                              |     |     |     |      |     |  |      |
|     | 47680 |              |                              |     |     |     |      |     |  |      |
| 264 | 22660 | 0000111-66-0 | 1-octene                     | no  | yes | no  | 15   |     |  |      |
| 265 | 22600 | 0000111-87-5 | 1-octanol                    | no  | yes | no  |      |     |  |      |
| 266 | 25510 | 0000112-27-6 | triethyleneglycol            | yes | yes | no  |      |     |  |      |
|     | 94320 |              |                              |     |     |     |      |     |  |      |
| 267 | 15100 | 0000112-30-1 | 1-decanol                    | no  | yes | no  |      |     |  |      |
| 268 | 16704 | 0000112-41-4 | 1-dodecene                   | no  | yes | no  | 0,05 |     |  |      |
| 269 | 25090 | 0000112-60-7 | tetraethyleneglycol          | yes | yes | no  |      |     |  |      |
|     | 92350 |              |                              |     |     |     |      |     |  |      |



## ▼B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|---|------|
| 270 | 22763 | 0000112-80-1 | oleic acid  | yes | yes | no  |      |      |   |      |
|     | 69040 |              |   |     |     |     |      |      |   |      |
| 271 | 52720 | 0000112-84-5 | erucamide   | yes | no  | no  |      |      |   |      |
| 272 | 37040 | 0000112-85-6 | behenic acid  | yes | no  | no  |      |      |   |      |
| 273 | 52730 | 0000112-86-7 | erucic acid   | yes | no  | no  |      |      |   |      |
| 274 | 22570 | 0000112-96-9 | octadecyl isocyanate                                | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 275 | 23980 | 0000115-07-1 | propylene   | no  | yes | no  |      |      |   |      |
| 276 | 19000 | 0000115-11-7 | isobutene   | no  | yes | no  |      |      |   |      |
| 277 | 18280 | 0000115-27-5 | hexachloroendomethylenetetrahydrophthalic anhydride | no  | yes | no  | ND   |      |   |      |
| 278 | 18250 | 0000115-28-6 | hexachloroendomethylenetetrahydrophthalic acid      | no  | yes | no  | ND   |      |   |      |
| 279 | 22840 | 0000115-77-5 | pentaerythritol                                     | yes | yes | no  |      |      |   |      |
|     | 71600 |              |   |     |     |     |      |      |   |      |
| 280 | 73720 | 0000115-96-8 | phosphoric acid, trichloroethyl ester               | yes | no  | no  | ND   |      |   |      |
| 281 | 25120 | 0000116-14-3 | tetrafluoroethylene                                 | no  | yes | no  | 0,05 |      |   |      |
| 282 | 18430 | 0000116-15-4 | hexafluoropropylene                                 | no  | yes | no  | ND   |      |   |      |

## ▼B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8) | (9)  | (10)   | (11) |
|-----|-------|--------------|---|-----|-----|-----|-----|------|--|------|
| 283 | 74640 | 0000117-81-7 | phthalic acid, bis(2-ethylhexyl) ester          | yes | no  | no  | 1,5 | (32) | Only to be used as:<br>(a) plasticiser in repeated use materials and articles contacting non-fatty foods;<br>(b) technical support agent in concentrations up to 0,1 % in the final product. | (7)  |
| 284 | 84880 | 0000119-36-8 | salicylic acid, methyl ester                    | yes | no  | no  | 30  |      |  |      |
| 285 | 66480 | 0000119-47-1 | 2,2'-methylene bis(4-methyl-6-tert-butylphenol) | yes | no  | yes |     | (13) |  |      |
| 286 | 38240 | 0000119-61-9 | benzophenone                                    | yes | no  | yes | 0,6 |      |  |      |
| 287 | 60160 | 0000120-47-8 | 4-hydroxybenzoic acid, ethyl ester              | yes | no  | no  |     |      |  |      |
| 288 | 24970 | 0000120-61-6 | terephthalic acid, dimethyl ester               | no  | yes | no  |     |      |  |      |
| 289 | 15880 | 0000120-80-9 | 1,2-dihydroxybenzene                            | no  | yes | no  | 6   |      |  |      |
|     | 24051 |              |   |     |     |     |     |      |  |      |
| 290 | 55360 | 0000121-79-9 | gallic acid, propyl ester                       | yes | no  | no  |     | (20) |  |      |
| 291 | 19150 | 0000121-91-5 | isophthalic acid                                | no  | yes | no  |     | (27) |  |      |
| 292 | 94560 | 0000122-20-3 | triisopropanolamine                             | yes | no  | no  | 5   |      |  |      |
| 293 | 23175 | 0000122-52-1 | phosphorous acid, triethyl ester                | no  | yes | no  | ND  |      | 1 mg/kg in final product   | (1)  |
| 294 | 93120 | 0000123-28-4 | thiodipropionic acid, didodecyl ester           | yes | no  | yes |     | (14) |  |      |

## ▼B

| (1) | (2)   | (3)          | (4)                         | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|--------------|-----------------------------|-----|-----|-----|-----|-----|------|------|
| 295 | 15940 | 0000123-31-9 | 1,4-dihydroxybenzene        | yes | yes | no  | 0,6 |     |      |      |
|     | 18867 |              |                             |     |     |     |     |     |      |      |
|     | 48620 |              |                             |     |     |     |     |     |      |      |
| 296 | 23860 | 0000123-38-6 | propionaldehyde             | no  | yes | no  |     |     |      |      |
| 297 | 23950 | 0000123-62-6 | propionic anhydride         | no  | yes | no  |     |     |      |      |
| 298 | 14110 | 0000123-72-8 | butyraldehyde               | no  | yes | no  |     |     |      |      |
| 299 | 63840 | 0000123-76-2 | levulinic acid              | yes | no  | no  |     |     |      |      |
| 300 | 30045 | 0000123-86-4 | acetic acid, butyl ester    | yes | no  | no  |     |     |      |      |
| 301 | 89120 | 0000123-95-5 | stearic acid, butyl ester   | yes | no  | no  |     |     |      |      |
| 302 | 12820 | 0000123-99-9 | azelaic acid                | no  | yes | no  |     |     |      |      |
| 303 | 12130 | 0000124-04-9 | adipic acid                 | yes | yes | no  |     |     |      |      |
|     | 31730 |              |                             |     |     |     |     |     |      |      |
| 304 | 14320 | 0000124-07-2 | caprylic acid               | yes | yes | no  |     |     |      |      |
|     | 41960 |              |                             |     |     |     |     |     |      |      |
| 305 | 15274 | 0000124-09-4 | hexamethylenediamine        | no  | yes | no  | 2,4 |     |      |      |
|     | 18460 |              |                             |     |     |     |     |     |      |      |
| 306 | 88960 | 0000124-26-5 | stearamide                  | yes | no  | no  |     |     |      |      |
| 307 | 42160 | 0000124-38-9 | carbon dioxide              | yes | no  | no  |     |     |      |      |
| 308 | 91200 | 0000126-13-6 | sucrose acetate isobutyrate | yes | no  | no  |     |     |      |      |

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| (1) | (2)   | (3)          | (4)                                  | (5) | (6) | (7) | (8)  | (9)  | (10) | (11) |
|-----|-------|--------------|--------------------------------------|-----|-----|-----|------|------|------|------|
| 309 | 91360 | 0000126-14-7 | sucrose octaacetate                  | yes | no  | no  |      |      |      |      |
| 310 | 16390 | 0000126-30-7 | 2,2-dimethyl-1,3-propanediol         | no  | yes | no  | 0,05 |      |      |      |
|     | 22437 |              |                                      |     |     |     |      |      |      |      |
| 311 | 16480 | 0000126-58-9 | dipentaerythritol                    | yes | yes | no  |      |      |      |      |
|     | 51200 |              |                                      |     |     |     |      |      |      |      |
| 312 | 21490 | 0000126-98-7 | methacrylonitrile                    | no  | yes | no  | ND   |      |      |      |
| 313 | 16650 | 0000127-63-9 | diphenyl sulphone                    | yes | yes | no  | 3    |      |      |      |
|     | 51570 |              |                                      |     |     |     |      |      |      |      |
| 314 | 23500 | 0000127-91-3 | β-pinene                             | no  | yes | no  |      |      |      |      |
| 315 | 46640 | 0000128-37-0 | 2,6-di-tert-butyl-p-cresol           | yes | no  | no  | 3    |      |      |      |
| 316 | 23230 | 0000131-17-9 | phthalic acid, diallyl ester         | no  | yes | no  | ND   |      |      |      |
| 317 | 48880 | 0000131-53-3 | 2,2'-dihydroxy-4-methoxybenzophenone | yes | no  | yes |      | (8)  |      |      |
| 318 | 48640 | 0000131-56-6 | 2,4-dihydroxybenzophenone            | yes | no  | no  |      | (8)  |      |      |
| 319 | 61360 | 0000131-57-7 | 2-hydroxy-4-methoxybenzophenone      | yes | no  | yes |      | (8)  |      |      |
| 320 | 37680 | 0000136-60-7 | benzoic acid, butyl ester            | yes | no  | no  |      |      |      |      |
| 321 | 36080 | 0000137-66-6 | ascorbyl palmitate                   | yes | no  | no  |      |      |      |      |
| 322 | 63040 | 0000138-22-7 | lactic acid, butyl ester             | yes | no  | no  |      |      |      |      |
| 323 | 11470 | 0000140-88-5 | acrylic acid, ethyl ester            | no  | yes | no  |      | (22) |      |      |

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| (1) | (2)   | (3)          | (4)                         | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|-----------------------------|-----|-----|-----|------|------|--|------|
| 324 | 83700 | 0000141-22-0 | ricinoleic acid             | yes | no  | yes | 42   |      |  |      |
| 325 | 10780 | 0000141-32-2 | acrylic acid, n-butyl ester | no  | yes | no  |      | (22) |  |      |
| 326 | 12763 | 0000141-43-5 | 2-aminoethanol              | yes | yes | no  | 0,05 |      | Not to be used for articles in contact with fatty foods for which ►M7 simulant D1 and/or D2 ◀ is laid down.<br>For indirect food contact only, behind a PET layer. |      |
|     | 35170 |              |                             |     |     |     |      |      |  |      |
| 327 | 30140 | 0000141-78-6 | acetic acid, ethyl ester    | yes | no  | no  |      |      |  |      |
| 328 | 65040 | 0000141-82-2 | malonic acid                | yes | no  | no  |      |      |  |      |
| 329 | 59360 | 0000142-62-1 | hexanoic acid               | yes | no  | no  |      |      |  |      |
| 330 | 19470 | 0000143-07-7 | lauric acid                 | yes | yes | no  |      |      |  |      |
|     | 63280 |              |                             |     |     |     |      |      |  |      |
| 331 | 22480 | 0000143-08-8 | 1-nonanol                   | no  | yes | no  |      |      |  |      |
| 332 | 69760 | 0000143-28-2 | oleyl alcohol               | yes | no  | no  |      |      |  |      |
| 333 | 22775 | 0000144-62-7 | oxalic acid                 | yes | yes | no  | 6    |      |  |      |
|     | 69920 |              |                             |     |     |     |      |      |  |      |
| 334 | 17005 | 0000151-56-4 | ethyleneimine               | no  | yes | no  | ND   |      |  |      |
| 335 | 68960 | 0000301-02-0 | oleamide                    | yes | no  | no  |      |      |  |      |
| 336 | 15095 | 0000334-48-5 | n-decanoic acid             | yes | yes | no  |      |      |  |      |
|     | 45940 |              |                             |     |     |     |      |      |  |      |
| 337 | 15820 | 0000345-92-6 | 4,4'-difluorobenzophenone   | no  | yes | no  | 0,05 |      |  |      |

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| (1) | (2)   | (3)          | (4)              | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|--------------|------------------|-----|-----|-----|-----|-----|------|------|
| 338 | 71020 | 0000373-49-9 | palmitoleic acid | yes | no  | no  |     |     |      |      |
| 339 | 86160 | 0000409-21-2 | silicon carbide  | yes | no  | no  |     |     |      |      |

▼M4

|     |       |              |                |     |    |    |    |  |  |  |
|-----|-------|--------------|----------------|-----|----|----|----|--|--|--|
| 340 | 47440 | 0000461-58-5 | dicyanodiamide | yes | no | no | 60 |  |  |  |
|-----|-------|--------------|----------------|-----|----|----|----|--|--|--|

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|     |       |              |                          |    |     |    |      |      |  |  |
|-----|-------|--------------|--------------------------|----|-----|----|------|------|--|--|
| 341 | 13180 | 0000498-66-8 | bicyclo[2.2.1]hept-2-ene | no | yes | no | 0,05 |      |  |  |
|     | 22550 |              |                          |    |     |    |      |      |  |  |
| 342 | 14260 | 0000502-44-3 | caprolactone             | no | yes | no |      | (29) |  |  |
| 343 | 23770 | 0000504-63-2 | 1,3-propanediol          | no | yes | no | 0,05 |      |  |  |

▼M6

|     |       |              |                       |    |     |    |      |          |  |      |
|-----|-------|--------------|-----------------------|----|-----|----|------|----------|--|------|
| 344 | 13810 | 0000505-65-7 | 1,4-butanediol formal | no | yes | no | 0,05 | 15<br>30 |  | (21) |
|     | 21821 |              |                       |    |     |    |      |          |  |      |

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|     |       |              |                       |     |     |    |  |      |  |  |
|-----|-------|--------------|-----------------------|-----|-----|----|--|------|--|--|
| 345 | 35840 | 0000506-30-9 | arachidic acid        | yes | no  | no |  |      |  |  |
| 346 | 10030 | 0000514-10-3 | abietic acid          | no  | yes | no |  |      |  |  |
| 347 | 13050 | 0000528-44-9 | trimellitic acid      | no  | yes | no |  | (21) |  |  |
|     | 25540 |              |                       |     |     |    |  |      |  |  |
| 348 | 22350 | 0000544-63-8 | myristic acid         | yes | yes | no |  |      |  |  |
|     | 67891 |              |                       |     |     |    |  |      |  |  |
| 349 | 25550 | 0000552-30-7 | trimellitic anhydride | no  | yes | no |  | (21) |  |  |
| 350 | 63920 | 0000557-59-5 | lignoceric acid       | yes | no  | no |  |      |  |  |

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| (1) | (2)   | (3)          | (4)                                | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|------------------------------------|-----|-----|-----|------|------|---|------|
| 351 | 21730 | 0000563-45-1 | 3-methyl-1-butene                  | no  | yes | no  | ND   |      | Only to be used in polypropylene  | (1)  |
| 352 | 16360 | 0000576-26-1 | 2,6-dimethylphenol                 | no  | yes | no  | 0,05 |      |   |      |
| 353 | 42480 | 0000584-09-8 | carbonic acid, rubidium salt       | yes | no  | no  | 12   |      |   |      |
| 354 | 25210 | 0000584-84-9 | 2,4-toluene diisocyanate           | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety                   | (10) |
| 355 | 20170 | 0000585-07-9 | methacrylic acid, tert-butyl ester | no  | yes | no  |      | (23) |   |      |
| 356 | 18820 | 0000592-41-6 | 1-hexene                           | no  | yes | no  | 3    |      |   |      |
| 357 | 13932 | 0000598-32-3 | 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 | 0000599-64-4 | 4-cumylphenol                      | no  | yes | no  | 0,05 |      |   |      |
| 359 | 15970 | 0000611-99-4 | 4,4'-dihydroxybenzophenone         | yes | yes | no  |      | (8)  |   |      |
|     | 48720 |              |                                    |     |     |     |      |      |   |      |
| 360 | 57920 | 0000620-67-7 | glycerol triheptanoate             | yes | no  | no  |      |      |   |      |
| 361 | 18700 | 0000629-11-8 | 1,6-hexanediol                     | no  | yes | no  | 0,05 |      |   |      |
| 362 | 14350 | 0000630-08-0 | carbon monoxide                    | no  | yes | no  |      |      |   |      |
| 363 | 16450 | 0000646-06-0 | 1,3-dioxolane                      | no  | yes | no  | 5    |      |   |      |

▼ B▼ M6

| (1) | (2)            | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|----------------|--------------|--|-----|-----|-----|------|------|--|------|
| 364 | 15404          | 0000652-67-5 | 1,4:3,6-dianhydrosorbitol                        | no  | yes | no  | 5    |      | Only to be used as:<br>(a) a co-monomer in poly (ethylene-co-isosorbide terephthalate);<br>(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 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          | 0000689-12-3 | acrylic acid, isopropyl ester                    | no  | yes | no  |      | (22) |  |      |
| 366 | 22150          | 0000691-37-2 | 4-methyl-1-pentene                               | no  | yes | no  | 0,05 |      |  |      |
| 367 | 16697          | 0000693-23-2 | n-dodecanedioic acid                             | no  | yes | no  |      |      |  |      |
| 368 | 93280          | 0000693-36-7 | thiodipropionic acid, dioctadecyl ester          | yes | no  | yes |      | (14) |  |      |
| 369 | 12761          | 0000693-57-2 | 12-aminododecanoic acid                          | no  | yes | no  | 0,05 |      |  |      |
| 370 | 21460          | 0000760-93-0 | methacrylic anhydride                            | no  | yes | no  |      | (23) |  |      |
| 371 | 11510<br>11830 | 0000818-61-1 | acrylic acid, monoester with ethyleneglycol      | no  | yes | no  |      | (22) |  |      |
| 372 | 18640          | 0000822-06-0 | hexamethylene diisocyanate                       | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety  | (10) |
| 373 | 22390          | 0000840-65-3 | 2,6-naphthalenedicarboxylic acid, dimethyl ester | no  | yes | no  | 0,05 |      |  |      |
| 374 | 21190          | 0000868-77-9 | methacrylic acid, monoester with ethyleneglycol  | no  | yes | no  |      | (23) |  |      |
| 375 | 15130          | 0000872-05-9 | 1-decene   | no  | yes | no  | 0,05 |      |  |      |

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| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11)          |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|---------------|
| 376 | 66905 | 0000872-50-4 | N-methylpyrrolidone  | yes | no  | no  | 60   |      |   |               |
| 377 | 12786 | 0000919-30-2 | 3-aminopropyltriethoxysilane   | no  | yes | no  | 0,05 |      | Residual extractable content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler when used for the reactive surface treatment of inorganic fillers.<br>SML = 0,05 mg/kg when used for the surface treatment of materials and articles. |               |
| 378 | 21970 | 0000923-02-4 | N-methylolmethacrylamide   | no  | yes | no  | 0,05 |      |   |               |
| 379 | 21940 | 0000924-42-5 | N-methylolacrylamide   | no  | yes | no  | ND   |      |   |               |
| 380 | 11980 | 0000925-60-0 | acrylic acid, propyl ester   | no  | yes | no  |      | (22) |   |               |
| 381 | 15030 | 0000931-88-4 | cyclooctene  | no  | yes | no  | 0,05 |      | Only to be used in polymers contacting foods for which simulant A is laid down  |               |
| 382 | 19490 | 0000947-04-6 | lauro lactam   | no  | yes | no  | 5    |      |   |               |
| 383 | 72160 | 0000948-65-2 | 2-phenylindole   | yes | no  | yes | 15   |      |   |               |
| 384 | 40000 | 0000991-84-4 | 2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine | yes | no  | yes | 30   |      |   |               |
| 385 | 11530 | 0000999-61-1 | acrylic acid, 2-hydroxypropyl ester  | no  | yes | no  | 0,05 |      | SML expressed as the sum of acrylic acid, 2-hydroxypropyl ester and acrylic acid, 2-hydroxyisopropyl ester.<br>It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No 0002918-23-2).                                   | (1)           |
| 386 | 55280 | 0001034-01-1 | gallic acid, octyl ester   | yes | no  | no  |      | (20) |   |               |
| 387 | 26155 | 0001072-63-5 | 1-vinylimidazole   | no  | yes | no  | 0,05 |      |   | ► <b>M8</b> ◀ |
| 388 | 25080 | 0001120-36-1 | 1-tetradecene  | no  | yes | no  | 0,05 |      |   |               |

▼B

| (1) | (2)   | (3)          | (4)                              | (5) | (6) | (7) | (8) | (9)  | (10) | (11) |
|-----|-------|--------------|----------------------------------|-----|-----|-----|-----|------|------|------|
| 389 | 22360 | 0001141-38-4 | 2,6-naphthalenedicarboxylic acid | no  | yes | no  | 5   |      |      |      |
| 390 | 55200 | 0001166-52-5 | gallic acid, dodecyl ester       | yes | no  | no  |     | (20) |      |      |

▼M7

|     |       |              |                                      |    |     |    |      |  |  |  |
|-----|-------|--------------|--------------------------------------|----|-----|----|------|--|--|--|
| 391 | 22932 | 0001187-93-5 | perfluoromethyl perfluorovinyl ether | no | yes | no | 0,05 |  | Only to be used in:<br>— anti-stick coatings;<br>— fluoro- and perfluoropolymers intended for repeated use applications where the contact ratio is 1 dm <sup>2</sup> surface in contact with at least 150 kg food. |  |
|-----|-------|--------------|--------------------------------------|----|-----|----|------|--|--|--|

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|     |       |              |  |     |    |     |     |  |  |  |
|-----|-------|--------------|--|-----|----|-----|-----|--|--|--|
| 392 | 72800 | 0001241-94-7 | phosphoric acid, diphenyl 2-ethylhexyl ester | yes | no | yes | 2,4 |  |  |  |
| 393 | 37280 | 0001302-78-9 | bentonite                                    | yes | no | no  |     |  |  |  |
| 394 | 41280 | 0001305-62-0 | calcium hydroxide                            | yes | no | no  |     |  |  |  |
| 395 | 41520 | 0001305-78-8 | calcium oxide                                | yes | no | no  |     |  |  |  |
| 396 | 64640 | 0001309-42-8 | magnesium hydroxide                          | yes | no | no  |     |  |  |  |
| 397 | 64720 | 0001309-48-4 | magnesium oxide                              | yes | no | no  |     |  |  |  |

▼M15

|     |       |              |                   |     |    |    |  |  |  |     |
|-----|-------|--------------|-------------------|-----|----|----|--|--|--|-----|
| 398 | 35760 | 0001309-64-4 | antimony trioxide | yes | no | no |  |  |  | (6) |
|-----|-------|--------------|-------------------|-----|----|----|--|--|--|-----|

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|     |       |              |                                  |     |     |    |    |  |  |     |
|-----|-------|--------------|----------------------------------|-----|-----|----|----|--|--|-----|
| 399 | 81600 | 0001310-58-3 | potassium hydroxide              | yes | no  | no |    |  |  |     |
| 400 | 86720 | 0001310-73-2 | sodium hydroxide                 | yes | no  | no |    |  |  |     |
| 401 | 24475 | 0001313-82-2 | sodium sulphide                  | no  | yes | no |    |  |  |     |
| 402 | 96240 | 0001314-13-2 | zinc oxide                       | yes | no  | no |    |  |  |     |
| 403 | 96320 | 0001314-98-3 | zinc sulphide                    | yes | no  | no |    |  |  |     |
| 404 | 67200 | 0001317-33-5 | molybdenum disulphide            | yes | no  | no |    |  |  |     |
| 405 | 16690 | 0001321-74-0 | divinylbenzene                   | no  | yes | no | ND |  | SML expressed as the sum of divinylbenzene and ethylvinylbenzene.<br>It may contain up to 45 % (m/m) of ethylvinylbenzene. | (1) |
| 406 | 83300 | 0001323-39-3 | 1,2-propyleneglycol monostearate | yes | no  | no |    |  |  |     |

▼ B

| (1) | (2)   | (3)          | (4)                            | (5) | (6) | (7) | (8) | (9)  | (10) | (11) |
|-----|-------|--------------|--------------------------------|-----|-----|-----|-----|------|------|------|
| 407 | 87040 | 0001330-43-4 | sodium tetraborate             | yes | no  | no  |     | (16) |      |      |
| 408 | 82960 | 0001330-80-9 | 1,2-propyleneglycol monooleate | yes | no  | no  |     |      |      |      |
| 409 | 62240 | 0001332-37-2 | iron oxide                     | yes | no  | no  |     |      |      |      |

▼ M6

|     |       |              |        |     |    |    |  |  |   |  |
|-----|-------|--------------|--------|-----|----|----|--|--|---|--|
| 410 | 62720 | 0001332-58-7 | kaolin | 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 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. |  |
|-----|-------|--------------|--------|-----|----|----|--|--|---|--|

▼ B

|     |       |              |              |     |    |    |  |  |  |  |
|-----|-------|--------------|--------------|-----|----|----|--|--|--|--|
| 411 | 42080 | 0001333-86-4 | carbon black | yes | no | no |  |  | Primary particles of 10 – 300 nm which are aggregated to a size of 100 – 1 200 nm which may form agglomerates within the size distribution of 300 nm – mm.<br>Toluene extractables: maximum 0,1 %, determined according to ISO method 6209.<br>UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis.<br>Benzo(a)pyrene content: max 0,25 mg/kg carbon black.<br>Maximum use level of carbon black in the polymer: 2,5 % w/w. |  |
|-----|-------|--------------|--------------|-----|----|----|--|--|--|--|

▼B

| (1)         | (2)   | (3)          | (4)                                 | (5) | (6) | (7) | (8)  | (9)  | (10)                                  | (11) |
|-------------|-------|--------------|-------------------------------------|-----|-----|-----|------|------|---------------------------------------|------|
| 412         | 45200 | 0001335-23-5 | copper iodide                       | yes | no  | no  |      | (6)  |                                       |      |
| 413         | 35600 | 0001336-21-6 | ammonium hydroxide                  | yes | no  | no  |      |      |                                       |      |
| 414         | 87600 | 0001338-39-2 | sorbitan monolaurate                | yes | no  | no  |      |      |                                       |      |
| 415         | 87840 | 0001338-41-6 | sorbitan monostearate               | yes | no  | no  |      |      |                                       |      |
| 416         | 87680 | 0001338-43-8 | sorbitan monooleate                 | yes | no  | no  |      |      |                                       |      |
| 417         | 85680 | 0001343-98-2 | silicic acid                        | yes | no  | no  |      |      |                                       |      |
| 418         | 34720 | 0001344-28-1 | aluminium oxide                     | yes | no  | no  |      |      |                                       |      |
| 419         | 92150 | 0001401-55-4 | tannic acids                        | yes | no  | no  |      |      | According to the JECFA specifications |      |
| 420         | 19210 | 0001459-93-4 | isophthalic acid, dimethyl ester    | no  | yes | no  | 0,05 |      |                                       |      |
| ▼ <u>M4</u> |       |              |                                     |     |     |     |      |      |                                       |      |
| 421         | 13000 | 0001477-55-0 | 1,3-benzenedimethanamine            | no  | yes | no  |      | (34) |                                       |      |
| ▼ <u>B</u>  |       |              |                                     |     |     |     |      |      |                                       |      |
| 422         | 38515 | 0001533-45-5 | 4,4'-bis(2-benzoxazolyl)stilbene    | yes | no  | yes | 0,05 |      |                                       | (2)  |
| 423         | 22937 | 0001623-05-8 | perfluoropropylperfluorovinyl ether | no  | yes | no  | 0,05 |      |                                       |      |
| 424         | 15070 | 0001647-16-1 | 1,9-decadiene                       | no  | yes | no  | 0,05 |      |                                       |      |

▼ **B**

| (1)         | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-------------|-------|--------------|--|-----|-----|-----|------|------|--|------|
| 425         | 10840 | 0001663-39-4 | acrylic acid, tert-butyl ester                                       | no  | yes | no  |      | (22) |  |      |
| 426         | 13510 | 0001675-54-3 | 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether           | no  | yes | no  |      |      | In compliance with Commission Regulation (EC) No 1895/2005 <sup>(1)</sup>  |      |
|             | 13610 |              |  |     |     |     |      |      |  |      |
| 427         | 18896 | 0001679-51-2 | 4-(hydroxymethyl)-1-cyclohexene                                      | no  | yes | no  | 0,05 |      |  |      |
| 428         | 95200 | 0001709-70-2 | 1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene | yes | no  | no  |      |      |  |      |
| 429         | 13210 | 0001761-71-3 | bis(4-aminocyclohexyl)methane  | no  | yes | no  | 0,05 |      |  |      |
| 430         | 95600 | 0001843-03-4 | 1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane             | yes | no  | yes | 5    |      |  |      |
| 431         | 61600 | 0001843-05-6 | 2-hydroxy-4-n-octyloxybenzophenone                                   | yes | no  | yes |      | (8)  |  |      |
| 432         | 12280 | 0002035-75-8 | adipic anhydride   | no  | yes | no  |      |      |  |      |
| 433         | 68320 | 0002082-79-3 | octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate            | yes | no  | yes | 6    |      |  |      |
| 434         | 20410 | 0002082-81-7 | methacrylic acid, diester with 1,4-butanediol                        | no  | yes | no  | 0,05 |      |  |      |
| 435         | 14230 | 0002123-24-2 | caprolactam, sodium salt   | no  | yes | no  |      | (4)  |  |      |
| 436         | 19480 | 0002146-71-6 | lauric acid, vinyl ester   | no  | yes | no  |      |      |  |      |
| 437         | 11245 | 0002156-97-0 | acrylic acid, dodecyl ester  | no  | yes | no  | 0,05 |      |  | (2)  |
| ▼ <b>M2</b> |       |              |  |     |     |     |      |      |  |      |
| 438         | 13303 | 0002162-74-5 | 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 |      |

▼ B

| (1)         | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-------------|-------|--------------|---|-----|-----|-----|------|------|---|------|
| 439         | 21280 | 0002177-70-0 | methacrylic acid, phenyl ester  | no  | yes | no  |      | (23) |   |      |
| 440         | 21340 | 0002210-28-8 | methacrylic acid, propyl ester  | no  | yes | no  |      | (23) |   |      |
| 441         | 38160 | 0002315-68-6 | benzoic acid, propyl ester  | yes | no  | no  |      |      |   |      |
| 442         | 13780 | 0002425-79-8 | 1,4-butanediol bis(2,3-epoxypropyl)ether                                    | no  | yes | no  | ND   |      | Residual content = 1 mg/kg in final product expressed as epoxy-group.<br>Molecular weight is 43 Da. | (10) |
| 443         | 12788 | 0002432-99-7 | 11-aminoundecanoic acid   | no  | yes | no  | 5    |      |   |      |
| 444         | 61440 | 0002440-22-4 | 2-(2'-hydroxy-5'-methylphenyl)benzotriazole                                 | yes | no  | no  |      | (12) |   |      |
| 445         | 83440 | 0002466-09-3 | pyrophosphoric acid   | yes | no  | no  |      |      |   |      |
| 446         | 10750 | 0002495-35-4 | acrylic acid, benzyl ester  | no  | yes | no  |      | (22) |   |      |
| 447         | 20080 | 0002495-37-6 | methacrylic acid, benzyl ester  | no  | yes | no  |      | (23) |   |      |
| 448         | 11890 | 0002499-59-4 | acrylic acid, n-octyl ester   | no  | yes | no  |      | (22) |   |      |
| ▼ <u>M3</u> |       |              |   |     |     |     |      |      |   |      |
| 449         | 49840 | 0002500-88-1 | dioctadecyl disulphide  | yes | no  | yes | 0,05 |      |   |      |
| ▼ <u>B</u>  |       |              |   |     |     |     |      |      |   |      |
| 450         | 24430 | 0002561-88-8 | sebacic anhydride   | no  | yes | no  |      |      |   |      |
| 451         | 66755 | 0002682-20-4 | 2-methyl-4-isothiazolin-3-one   | yes | no  | no  | 0,5  |      | Only to be used in aqueous polymer dispersions and emulsions  |      |
| ▼ <u>M2</u> |       |              |   |     |     |     |      |      |   |      |
| 452         | 38885 | 0002725-22-6 | 2,4-bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine | yes | no  | no  | 5    |      |   |      |
| ▼ <u>B</u>  |       |              |   |     |     |     |      |      |   |      |
| 453         | 26320 | 0002768-02-7 | vinyltrimethoxysilane   | no  | yes | no  | 0,05 |      |   | (10) |

▼ **B**

| (1)          | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11)          |
|--------------|-------|--------------|--|-----|-----|-----|------|------|---|---------------|
| 454          | 12670 | 0002855-13-2 | 1-amino-3-aminomethyl-3,5,5-trimethylcyclohexane                     | no  | yes | no  | 6    |      |   |               |
| 455          | 20530 | 0002867-47-2 | methacrylic acid, 2-(dimethyl-amino)-ethyl ester                     | no  | yes | no  | ND   |      |   |               |
| 456          | 10810 | 0002998-08-5 | acrylic acid, sec-butyl ester  | no  | yes | no  |      | (22) |   |               |
| 457          | 20140 | 0002998-18-7 | methacrylic acid, sec-butyl ester                                    | no  | yes | no  |      | (23) |   |               |
| 458          | 36960 | 0003061-75-4 | behenamide   | yes | no  | no  |      |      |   |               |
| 459          | 46870 | 0003135-18-0 | 3,5-di-tert-butyl-4-hydroxybenzyl-phosphonic acid, dioctadecyl ester | yes | no  | no  |      |      |   |               |
| 460          | 14950 | 0003173-53-3 | cyclohexyl isocyanate  | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety                 | (10)          |
| 461          | 22420 | 0003173-72-6 | 1,5-naphthalene diisocyanate   | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety                 | (10)          |
| 462          | 26170 | 0003195-78-6 | N-vinyl-N-methylacetamide  | no  | yes | no  | 0,02 |      |   | ► <b>M8</b> ◀ |
| 463          | 25840 | 0003290-92-4 | 1,1,1-trimethylolpropane trimethacrylate                             | no  | yes | no  | 0,05 |      |   |               |
| 464          | 61280 | 0003293-97-8 | 2-hydroxy-4-n-hexyloxybenzophenone                                   | yes | no  | yes |      | (8)  |   |               |
| 465          | 68040 | 0003333-62-8 | 7-[2H-naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin                  | yes | no  | no  |      |      |   |               |
| 466          | 50640 | 0003648-18-8 | di-n-octyltin dilaurate  | yes | no  | no  |      | (10) |   |               |
| ▼ <b>M12</b> | 467   | 3724-65-0    | crotonic acid  | yes | yes | no  |      | (35) |   |               |
|              | 14800 |              |  |     |     |     |      |      |   |               |
|              | 45600 |              |  |     |     |     |      |      |   |               |
| ▼ <b>B</b>   | 468   | 0003825-26-1 | perfluorooctanoic acid, ammonium salt                                | yes | no  | no  |      |      | Only to be used in repeated use articles, sintered at high temperatures |               |

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| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11)          |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|---------------|
| 469 | 60480 | 0003864-99-1 | 2-(2'-hydroxy-3,5'-di-tert-butylphenyl)-5-chlorobenzotriazole          | yes | no  | yes |      | (12) |   |               |
| 470 | 60400 | 0003896-11-5 | 2-(2'-hydroxy-3'-tert-butyl-5'-methylphenyl)-5-chlorobenzotriazole     | yes | no  | yes |      | (12) |   |               |
| 471 | 24888 | 0003965-55-7 | 5-sulphoisophthalic acid, monosodium salt, dimethyl ester              | no  | yes | no  | 0,05 |      |   |               |
| 472 | 66560 | 0004066-02-8 | 2,2'-methylenebis(4-methyl-6-cyclohexylphenol)                         | yes | no  | yes |      | (5)  |   |               |
| 473 | 12265 | 0004074-90-2 | adipic acid, divinyl ester   | no  | yes | no  | ND   |      | 5 mg/kg in final product.<br>Only to be used as co-monomer. | (1)           |
| 474 | 43600 | 0004080-31-3 | 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride             | yes | no  | no  | 0,3  |      |   |               |
| 475 | 19110 | 0004098-71-9 | 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane             | no  | yes | no  |      | (17) | 1 mg/kg in final product<br>expressed as isocyanate moiety  | (10)          |
| 476 | 16570 | 0004128-73-8 | diphenylether-4,4'-diisocyanate  | no  | yes | no  |      | (17) | 1 mg/kg in final product<br>expressed as isocyanate moiety  | (10)          |
| 477 | 46720 | 0004130-42-1 | 2,6-di-tert-butyl-4-ethylphenol  | yes | no  | yes | 4,8  |      |   | (1)           |
| 478 | 60180 | 0004191-73-5 | 4-hydroxybenzoic acid, isopropyl ester                                 | yes | no  | no  |      |      |   |               |
| 479 | 12970 | 0004196-95-6 | azelaic anhydride  | no  | yes | no  |      |      |   |               |
| 480 | 46790 | 0004221-80-1 | 3,5-di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester | yes | no  | no  |      |      |   |               |
| 481 | 13060 | 0004422-95-1 | 1,3,5-benzenetricarboxylic acid trichloride                            | no  | yes | no  | 0,05 |      | SML expressed as 1,3,5-benzenetricarboxylic acid            | ► <b>M8</b> ◀ |



## ▼B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|---|------|
| 482 | 21100 | 0004655-34-9 | methacrylic acid, isopropyl ester   | no  | yes | no  |      | (23) |   |      |
| 483 | 68860 | 0004724-48-5 | n-octylphosphonic acid  | yes | no  | no  | 0,05 |      |   |      |
| 484 | 13395 | 0004767-03-7 | 2,2-bis(hydroxymethyl)propionic acid                                      | no  | yes | no  | 0,05 |      |   | (1)  |
| 485 | 13560 | 0005124-30-1 | dicyclohexylmethane-4,4'-diisocyanate                                     | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
|     | 15700 |              |   |     |     |     |      |      |   |      |
| 486 | 54005 | 0005136-44-7 | ethylene-N-palmitamide-N'-stearamide                                      | yes | no  | no  |      |      |   |      |
| 487 | 45640 | 0005232-99-5 | 2-cyano-3,3-diphenylacrylic acid, ethyl ester                             | yes | no  | no  | 0,05 |      |   |      |
| 488 | 53440 | 0005518-18-3 | N,N'-ethylenebispalmitamide   | yes | no  | no  |      |      |   |      |
| 489 | 41040 | 0005743-36-2 | calcium butyrate  | yes | no  | no  |      |      |   |      |
| 490 | 16600 | 0005873-54-1 | diphenylmethane-2,4'-diisocyanate   | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety | (10) |
| 491 | 82720 | 0006182-11-2 | 1,2-propyleneglycol distearate  | yes | no  | no  |      |      |   |      |
| 492 | 45650 | 0006197-30-4 | 2-cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester                      | yes | no  | no  | 0,05 |      |   |      |
| 493 | 39200 | 0006200-40-4 | bis(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride | yes | no  | no  | 1,8  |      |   |      |
| 494 | 62140 | 0006303-21-5 | hypophosphorous acid  | yes | no  | no  |      |      |   |      |
| 495 | 35160 | 0006642-31-5 | 6-amino-1,3-dimethyluracil  | yes | no  | no  | 5    |      |   |      |

## ▼B

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11)  |
|-----|-------|--------------|--|-----|-----|-----|------|------|--|-------|
| 496 | 71680 | 0006683-19-8 | pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate] | yes | no  | no  |      |      |  |       |
| 497 | 95020 | 0006846-50-0 | 2,2,4-trimethyl-1,3-pentanediol diisobutyrate                              | yes | no  | no  | 5    |      | Only to be used in single-use gloves   |       |
| 498 | 16210 | 0006864-37-5 | 3,3'-dimethyl-4,4'-diaminodicyclohexylmethane                              | no  | yes | no  | 0,05 |      | Only to be used in polyamides  | (5)   |
| 499 | 19965 | 0006915-15-7 | malic 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  |       |
|     | 65020 |              |  |     |     |     |      |      |  |       |
| 500 | 38560 | 0007128-64-5 | 2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene                              | yes | no  | yes | 0,6  |      |  |       |
| 501 | 34480 | —            | aluminium fibers, flakes and powders                                       | yes | no  | no  |      |      |  |       |
| 502 | 22778 | 0007456-68-0 | 4,4'-oxybis(benzenesulphonyl azide)  | no  | yes | no  | 0,05 |      |  | ►M8 ◀ |
| 503 | 46080 | 0007585-39-9 | β-dextrin  | yes | no  | no  |      |      |  |       |
| 504 | 86240 | 0007631-86-9 | 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 | 0007631-90-5 | sodium bisulphite  | yes | no  | no  |      | (19) |  |       |

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| (1) | (2)   | (3)          | (4)                 | (5) | (6) | (7) | (8) | (9)  | (10)                                      | (11) |
|-----|-------|--------------|---------------------|-----|-----|-----|-----|------|---|------|
| 506 | 86920 | 0007632-00-0 | sodium nitrite      | yes | no  | no  | 0,6 |      |   |      |
| 507 | 59990 | 0007647-01-0 | hydrochloric acid   | yes | no  | no  |     |      |   |      |
| 508 | 86560 | 0007647-15-6 | sodium bromide      | yes | no  | no  |     |      |   |      |
| 509 | 23170 | 0007664-38-2 | phosphoric acid     | yes | yes | no  |     |      |   |      |
|     | 72640 |              |                     |     |     |     |     |      |   |      |
| 510 | 12789 | 0007664-41-7 | ammonia             | yes | yes | no  |     |      |   |      |
|     | 35320 |              |                     |     |     |     |     |      |   |      |
| 511 | 91920 | 0007664-93-9 | sulphuric acid      | yes | no  | no  |     |      |   |      |
| 512 | 81680 | 0007681-11-0 | potassium iodide    | yes | no  | no  |     | (6)  |   |      |
| 513 | 86800 | 0007681-82-5 | sodium iodide       | yes | no  | no  |     | (6)  |   |      |
| 514 | 91840 | 0007704-34-9 | sulphur             | yes | no  | no  |     |      |   |      |
| 515 | 26360 | 0007732-18-5 | water               | yes | yes | no  |     |      | In compliance with Directive 98/83/EC (2) |      |
|     | 95855 |              |                     |     |     |     |     |      |   |      |
| 516 | 86960 | 0007757-83-7 | sodium sulphite     | yes | no  | no  |     | (19) |   |      |
| 517 | 81520 | 0007758-02-3 | potassium bromide   | yes | no  | no  |     |      |   |      |
| 518 | 35845 | 0007771-44-0 | arachidonic acid    | yes | no  | no  |     |      |   |      |
| 519 | 87120 | 0007772-98-7 | sodium thiosulphate | yes | no  | no  |     | (19) |   |      |
| 520 | 65120 | 0007773-01-5 | manganese chloride  | yes | no  | no  |     |      |   |      |
| 521 | 58320 | 0007782-42-5 | graphite            | yes | no  | no  |     |      |   |      |

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| (1) | (2)   | (3)          | (4)                     | (5) | (6) | (7) | (8)         | (9)  | (10)   | (11) |
|-----|-------|--------------|-------------------------|-----|-----|-----|-------------|------|--|------|
| 522 | 14530 | 0007782-50-5 | chlorine                | no  | yes | no  |             |      |  |      |
| 523 | 45195 | 0007787-70-4 | copper bromide          | yes | no  | no  |             |      |  |      |
| 524 | 24520 | 0008001-22-7 | soybean oil             | no  | yes | no  |             |      |  |      |
| 525 | 62640 | 0008001-39-6 | japan wax               | yes | no  | no  |             |      |  |      |
| 526 | 43440 | 0008001-75-0 | ceresin                 | yes | no  | no  |             |      |  |      |
| 527 | 14411 | 0008001-79-4 | castor oil              | yes | yes | no  |             |      |  |      |
|     | 42880 |              |                         |     |     |     |             |      |  |      |
| 528 | 63760 | 0008002-43-5 | lecithin                | yes | no  | no  |             |      |  |      |
| 529 | 67850 | 0008002-53-7 | montan wax              | yes | no  | no  |             |      |  |      |
| 530 | 41760 | 0008006-44-8 | candelilla wax          | yes | no  | no  |             |      |  |      |
| 531 | 36880 | 0008012-89-3 | beeswax                 | yes | no  | no  |             |      |  |      |
| 532 | 88640 | 0008013-07-8 | soybean oil, epoxidised | yes | no  | no  | 60<br>30(*) | (32) | (*) In the case of PVC gaskets used to seal glass jars containing infant 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.<br>Oxirane < 8 %, iodine number < 6. |      |

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| (1) | (2)   | (3)          | (4)                                      | (5) | (6) | (7) | (8)  | (9) | (10)   | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|-----|--|------|
| 533 | 42720 | 0008015-86-9 | carnauba wax                             | yes | no  | no  |      |     |  |      |
| 534 | 80720 | 0008017-16-1 | polyphosphoric acids                     | yes | no  | no  |      |     |  |      |
| 535 | 24100 | 0008050-09-7 | rosin                                    | yes | yes | no  |      |     |  |      |
|     | 24130 |              |  |     |     |     |      |     |  |      |
|     | 24190 |              |  |     |     |     |      |     |  |      |
|     | 83840 |              |  |     |     |     |      |     |  |      |
| 536 | 84320 | 0008050-15-5 | rosin, hydrogenated, ester with methanol | yes | no  | no  |      |     |  |      |
| 537 | 84080 | 0008050-26-8 | rosin, ester with pentaerythritol        | yes | no  | no  |      |     |  |      |
| 538 | 84000 | 0008050-31-5 | rosin, ester with glycerol               | yes | no  | no  |      |     |  |      |
| 539 | 24160 | 0008052-10-6 | rosin tall oil                           | no  | yes | no  |      |     |  |      |
| 540 | 63940 | 0008062-15-5 | lignosulphonic acid                      | yes | no  | no  | 0,24 |     | Only to be used as dispersant for plastics dispersions |      |
| 541 | 58480 | 0009000-01-5 | gum arabic                               | yes | no  | no  |      |     |  |      |
| 542 | 42640 | 0009000-11-7 | carboxymethylcellulose                   | yes | no  | no  |      |     |  |      |
| 543 | 45920 | 0009000-16-2 | dammar                                   | yes | no  | no  |      |     |  |      |
| 544 | 58400 | 0009000-30-0 | guar gum                                 | yes | no  | no  |      |     |  |      |
| 545 | 93680 | 0009000-65-1 | tragacanth gum                           | yes | no  | no  |      |     |  |      |
| 546 | 71440 | 0009000-69-5 | pectin                                   | yes | no  | no  |      |     |  |      |

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| (1) | (2)   | (3)                          | (4)                             | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|------------------------------|---------------------------------|-----|-----|-----|-----|-----|---|------|
| 547 | 55440 | 0009000-70-8                 | gelatin                         | yes | no  | no  |     |     |   |      |
| 548 | 42800 | 0009000-71-9                 | casein                          | yes | no  | no  |     |     |   |      |
| 549 | 80000 | 0009002-88-4                 | polyethylene wax                | yes | no  | no  |     |     |   |      |
| 550 | 81060 | 0009003-07-0                 | polypropylene wax               | yes | no  | no  |     |     |   |      |
| 551 | 79920 | 0009003-11-6<br>0106392-12-5 | poly(ethylene propylene) glycol | yes | no  | no  |     |     |   |      |
| 552 | 81500 | 0009003-39-8                 | polyvinylpyrrolidone            | yes | no  | no  |     |     | The substance shall meet the purity criteria as laid down in Commission Directive 2008/84/EC <sup>(3)</sup> |      |
| 553 | 14500 | 0009004-34-6                 | cellulose                       | yes | yes | no  |     |     |   |      |
|     | 43280 |                              |                                 |     |     |     |     |     |   |      |
| 554 | 43300 | 0009004-36-8                 | cellulose acetate butyrate      | yes | no  | no  |     |     |   |      |
| 555 | 53280 | 0009004-57-3                 | ethylcellulose                  | yes | no  | no  |     |     |   |      |
| 556 | 54260 | 0009004-58-4                 | ethylhydroxyethylcellulose      | yes | no  | no  |     |     |   |      |
| 557 | 66640 | 0009004-59-5                 | methylethylcellulose            | yes | no  | no  |     |     |   |      |
| 558 | 60560 | 0009004-62-0                 | hydroxyethylcellulose           | yes | no  | no  |     |     |   |      |
| 559 | 61680 | 0009004-64-2                 | hydroxypropylcellulose          | yes | no  | no  |     |     |   |      |
| 560 | 66700 | 0009004-65-3                 | methylhydroxypropylcellulose    | yes | no  | no  |     |     |   |      |
| 561 | 66240 | 0009004-67-5                 | methylcellulose                 | yes | no  | no  |     |     |   |      |
| 562 | 22450 | 0009004-70-0                 | nitrocellulose                  | no  | yes | no  |     |     |   |      |

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| (1) | (2)   | (3)          | (4)                                       | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|--------------|---|-----|-----|-----|-----|-----|------|------|
| 563 | 78320 | 0009004-97-1 | polyethyleneglycol monoricinoleate        | yes | no  | yes | 42  |     |      |      |
| 564 | 24540 | 0009005-25-8 | starch, edible                            | yes | yes | no  |     |     |      |      |
|     | 88800 |              |   |     |     |     |     |     |      |      |
| 565 | 61120 | 0009005-27-0 | hydroxyethyl starch                       | yes | no  | no  |     |     |      |      |
| 566 | 33350 | 0009005-32-7 | alginic acid                              | yes | no  | no  |     |     |      |      |
| 567 | 82080 | 0009005-37-2 | 1,2-propyleneglycol alginate              | yes | no  | no  |     |     |      |      |
| 568 | 79040 | 0009005-64-5 | polyethyleneglycol sorbitan monolaurate   | yes | no  | no  |     |     |      |      |
| 569 | 79120 | 0009005-65-6 | polyethyleneglycol sorbitan monooleate    | yes | no  | no  |     |     |      |      |
| 570 | 79200 | 0009005-66-7 | polyethyleneglycol sorbitan monopalmitate | yes | no  | no  |     |     |      |      |
| 571 | 79280 | 0009005-67-8 | polyethyleneglycol sorbitan monostearate  | yes | no  | no  |     |     |      |      |
| 572 | 79360 | 0009005-70-3 | polyethyleneglycol sorbitan trioleate     | yes | no  | no  |     |     |      |      |
| 573 | 79440 | 0009005-71-4 | polyethyleneglycol sorbitan tristearate   | yes | no  | no  |     |     |      |      |
| 574 | 24250 | 0009006-04-6 | rubber, natural                           | yes | yes | no  |     |     |      |      |
|     | 84560 |              |   |     |     |     |     |     |      |      |

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| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8) | (9)  | (10)   | (11) |
|-----|-------|--------------|---|-----|-----|-----|-----|------|--|------|
| 575 | 76721 | 0063148-62-9 | polydimethylsiloxane (Mw > 6 800 Da)        | yes | no  | no  |     |      | Viscosity at 25 °C not less than 100 cSt ( $100 \times 10^{-6} \text{ m}^2/\text{s}$ )   |      |
| 576 | 60880 | 0009032-42-2 | hydroxyethylmethylcellulose                 | yes | no  | no  |     |      |  |      |
| 577 | 62280 | 0009044-17-1 | isobutylene-butene copolymer                | yes | no  | no  |     |      |  |      |
| 578 | 79600 | 0009046-01-9 | polyethyleneglycol tridecyl ether phosphate | yes | no  | no  | 5   |      | For materials and articles intended for contact with aqueous foods only.<br>Polyethyleneglycol (EO ≤ 11) tridecyl ether phosphate (mono- and dialkyl ester) with a maximum 10 % content of polyethyleneglycol (EO ≤ 11) tridecylether. |      |
| 579 | 61800 | 0009049-76-7 | hydroxypropyl starch                        | yes | no  | no  |     |      |  |      |
| 580 | 46070 | 0010016-20-3 | α-dextrin                                   | yes | no  | no  |     |      |  |      |
| 581 | 36800 | 0010022-31-8 | barium nitrate                              | yes | no  | no  |     |      |  |      |
| 582 | 50240 | 0010039-33-5 | di-n-octyltin bis(2-ethylhexyl maleate)     | yes | no  | no  |     | (10) |  |      |
| 583 | 40400 | 0010043-11-5 | boron nitride                               | yes | no  | no  |     | (16) |  |      |
| 584 | 13620 | 0010043-35-3 | boric acid                                  | yes | yes | no  |     | (16) |  |      |
|     | 40320 |              |   |     |     |     |     |      |  |      |
| 585 | 41120 | 0010043-52-4 | calcium chloride                            | yes | no  | no  |     |      |  |      |
| 586 | 65280 | 0010043-84-2 | manganese hypophosphite                     | yes | no  | no  |     |      |  |      |



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| (1) | (2)   | (3)                          | (4)                                     | (5) | (6) | (7) | (8) | (9)  | (10) | (11) |
|-----|-------|------------------------------|---|-----|-----|-----|-----|------|------|------|
| 587 | 68400 | 0010094-45-8                 | octadecylceramide                       | yes | no  | yes | 5   |      |      |      |
| 588 | 64320 | 0010377-51-2                 | lithium iodide                          | yes | no  | no  |     | (6)  |      |      |
| 589 | 52645 | 0010436-08-5                 | cis-11-eicosenamide                     | yes | no  | no  |     |      |      |      |
| 590 | 21370 | 0010595-80-9                 | methacrylic acid, 2-sulphoethyl ester   | no  | yes | no  | ND  |      |      | (1)  |
| 591 | 36160 | 0010605-09-1                 | ascorbyl stearate                       | yes | no  | no  |     |      |      |      |
| 592 | 34690 | 0011097-59-9                 | aluminium magnesium carbonate hydroxide | yes | no  | no  |     |      |      |      |
| 593 | 44960 | 0011104-61-3                 | cobalt oxide                            | yes | no  | no  |     |      |      |      |
| 594 | 65360 | 0011129-60-5                 | manganese oxide                         | yes | no  | no  |     |      |      |      |
| 595 | 19510 | 0011132-73-3                 | lignocellulose                          | no  | yes | no  |     |      |      |      |
| 596 | 95935 | 0011138-66-2                 | xanthan gum                             | yes | no  | no  |     |      |      |      |
| 597 | 67120 | 0012001-26-2                 | mica                                    | yes | no  | no  |     |      |      |      |
| 598 | 41600 | 0012004-14-7<br>0037293-22-4 | calcium sulphoaluminate                 | yes | no  | no  |     |      |      |      |
| 599 | 36840 | 0012007-55-5                 | barium tetraborate                      | yes | no  | no  |     | (16) |      |      |
| 600 | 60030 | 0012072-90-1                 | hydromagnesite                          | yes | no  | no  |     |      |      |      |
| 601 | 35440 | 0012124-97-9                 | ammonium bromide                        | yes | no  | no  |     |      |      |      |
| 602 | 70240 | 0012198-93-5                 | ozokerite                               | yes | no  | no  |     |      |      |      |
| 603 | 83460 | 0012269-78-2                 | pyrophyllite                            | yes | no  | no  |     |      |      |      |
| 604 | 60080 | 0012304-65-3                 | hydrotalcite                            | yes | no  | no  |     |      |      |      |

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| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|--|------|
| 605 | 11005 | 0012542-30-2 | acrylic acid, dicyclopentenyl ester                                   | no  | yes | no  | 0,05 |      |  | (1)  |
| 606 | 65200 | 0012626-88-9 | manganese hydroxide   | yes | no  | no  |      |      |  |      |
| 607 | 62245 | 0012751-22-3 | iron phosphide  | yes | no  | no  |      |      | Only to be used in PET polymers and copolymers |      |
| 608 | 40800 | 0013003-12-8 | 4,4'-butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite) | yes | no  | yes | 6    |      |  |      |
| 609 | 83455 | 0013445-56-2 | pyrophosphorous acid  | yes | no  | no  |      |      |  |      |
| 610 | 93440 | 0013463-67-7 | titanium dioxide  | yes | no  | no  |      |      |  |      |
| 611 | 35120 | 0013560-49-1 | 3-aminocrotonic acid, diester with thiobis (2-hydroxyethyl) ether     | yes | no  | no  |      |      |  |      |
| 612 | 16694 | 0013811-50-2 | N,N'-divinyl-2-imidazolidinone  | no  | yes | no  | 0,05 |      |  | (10) |
| 613 | 95905 | 0013983-17-0 | wollastonite  | yes | no  | no  |      |      |  |      |
| 614 | 45560 | 0014464-46-1 | crystalite  | yes | no  | no  |      |      |  |      |
| 615 | 92080 | 0014807-96-6 | talc  | yes | no  | no  |      |      |  |      |
| 616 | 83470 | 0014808-60-7 | quartz  | yes | no  | no  |      |      |  |      |
| 617 | 10660 | 0015214-89-8 | 2-acrylamido-2-methylpropanesulphonic acid                            | no  | yes | no  | 0,05 |      |  |      |
| 618 | 51040 | 0015535-79-2 | di-n-octyltin mercaptoacetate   | yes | no  | no  |      | (10) |  |      |
| 619 | 50320 | 0015571-58-1 | di-n-octyltin bis(2-ethylhexyl mercaptoacetate)                       | yes | no  | no  |      | (10) |  |      |

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| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10) | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|------|------|
| 620 | 50720 | 0015571-60-5 | di-n-octyltin dimaleate  | yes | no  | no  |      | (10) |      |      |
| 621 | 17110 | 0016219-75-3 | 5-ethylidenebicyclo[2,2,1]hept-2-ene                                     | no  | yes | no  | 0,05 |      |      | (9)  |
| 622 | 69840 | 0016260-09-6 | oleylpalmitamide   | yes | no  | yes | 5    |      |      |      |
| 623 | 52640 | 0016389-88-1 | dolomite   | yes | no  | no  |      |      |      |      |
| 624 | 18897 | 0016712-64-4 | 6-hydroxy-2-naphthalenecarboxylic acid                                   | no  | yes | no  | 0,05 |      |      |      |
| 625 | 36720 | 0017194-00-2 | barium hydroxide   | yes | no  | no  |      |      |      |      |
| 626 | 57800 | 0018641-57-1 | glycerol tribehenate   | yes | no  | no  |      |      |      |      |
| 627 | 59760 | 0019569-21-2 | huntite  | yes | no  | no  |      |      |      |      |
| 628 | 96190 | 0020427-58-1 | zinc hydroxide   | yes | no  | no  |      |      |      |      |
| 629 | 34560 | 0021645-51-2 | aluminium hydroxide  | yes | no  | no  |      |      |      |      |
| 630 | 82240 | 0022788-19-8 | 1,2-propyleneglycol dilaurate  | yes | no  | no  |      |      |      |      |
| 631 | 59120 | 0023128-74-7 | 1,6-hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide) | yes | no  | yes | 45   |      |      |      |
| 632 | 52880 | 0023676-09-7 | 4-ethoxybenzoic acid, ethyl ester  | yes | no  | no  | 3,6  |      |      |      |
| 633 | 53200 | 0023949-66-8 | 2-ethoxy-2'-ethyloxanilide   | yes | no  | yes | 30   |      |      |      |

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| (1)         | (2)   | (3)          | (4)   | (5)  | (6) | (7) | (8)  | (9)  | (10)   | (11)  |
|-------------|-------|--------------|---|--|-----|-----|------|------|--|---|
| 634         | 25910 | 0024800-44-0 | tripropyleneglycol  | no   | yes | no  |      |      |  |   |
| 635         | 40720 | 0025013-16-5 | tert-butyl-4-hydroxyanisole                               | yes  | no  | no  | 30   |      |  |   |
| 636         | 31500 | 0025134-51-4 | acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer | yes  | no  | no  | 0,05 | (22) | SML expressed as acrylic acid, 2-ethylhexyl ester  |   |
| 637         | 71635 | 0025151-96-6 | pentaerythritol dioleate                                  | yes  | no  | no  | 0,05 |      | Not to be used for articles in contact with fatty foods for which ► <u>M7</u> simulant D1 and/or D2 ◀ is laid down |   |
| 638         | 23590 | 0025322-68-3 | polyethyleneglycol  | yes  | yes | no  |      |      |  |   |
|             | 76960 |              |   |  |     |     |      |      |  |   |
| 639         | 23651 | 0025322-69-4 | polypropyleneglycol                                       | yes  | yes | no  |      |      |  |   |
|             | 80800 |              |   |  |     |     |      |      |  |   |
| 640         | 54930 | 0025359-91-5 | formaldehyde-1-naphthol, copolymer                        | yes  | no  | no  | 0,05 |      |  |   |
| ▼ <u>M7</u> | 641   | 22331        | 0025513-64-8  | 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 |  |   |
| ▼ <u>B</u>  | 642   | 64990        | 0025736-61-2  | maleic anhydride-styrene, copolymer, sodium salt   | yes | no  | no   |      |  | The fraction with molecular weight below 1 000 Da ► <u>M7</u> shall ◀ not exceed 0,05 % (w/w) |
|             | 643   | 87760        | 0026266-57-9  | sorbitan monopalmitate   | yes | no  | no   |      |  |   |
|             | 644   | 88080        | 0026266-58-0  | sorbitan trioleate   | yes | no  | no   |      |  |   |
|             | 645   | 67760        | 0026401-86-5  | mono-n-octyltin tris(isooctyl mercaptoacetate)   | yes | no  | no   |      | (11)   |   |
|             | 646   | 50480        | 0026401-97-8  | di-n-octyltin bis(isooctyl mercaptoacetate)  | yes | no  | no   |      | (10)   |   |

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| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|------|
| 647 | 56720 | 0026402-23-3 | glycerol monohehexanoate                                 | yes | no  | no  |      |      |   |      |
| 648 | 56880 | 0026402-26-6 | glycerol monohehexanoate                                 | yes | no  | no  |      |      |   |      |
| 649 | 47210 | 0026427-07-6 | dibutylthiostannoic acid polymer                         | yes | no  | no  |      |      | Molecular unit = (C <sub>8</sub> H <sub>18</sub> S <sub>3</sub> Sn <sub>2</sub> ) <sub>n</sub><br>(n = 1,5-2) |      |
| 650 | 49600 | 0026636-01-1 | dimethyltin bis(isooctyl mercaptoacetate)                | yes | no  | no  |      | (9)  |   |      |
| 651 | 88240 | 0026658-19-5 | sorbitan tristearate                                     | yes | no  | no  |      |      |   |      |
| 652 | 38820 | 0026741-53-7 | bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite | yes | no  | yes | 0,6  |      |   |      |
| 653 | 25270 | 0026747-90-0 | 2,4-toluene diisocyanate dimer                           | no  | yes | no  |      | (17) | 1 mg/kg in final product expressed as isocyanate moiety   | (10) |
| 654 | 88600 | 0026836-47-5 | sorbitol monostearate                                    | yes | no  | no  |      |      |   |      |
| 655 | 25450 | 0026896-48-0 | tricyclodecanedimethanol                                 | no  | yes | no  | 0,05 |      |   |      |
| 656 | 24760 | 0026914-43-2 | styrenesulphonic acid                                    | no  | yes | no  | 0,05 |      |   |      |
| 657 | 67680 | 0027107-89-7 | mono-n-octyltin tris(2-ethylhexyl mercaptoacetate)       | yes | no  | no  |      | (11) |   |      |
| 658 | 52000 | 0027176-87-0 | dodecylbenzenesulphonic acid                             | yes | no  | no  | 30   |      |   |      |
| 659 | 82800 | 0027194-74-7 | 1,2-propyleneglycol monolaurate                          | yes | no  | no  |      |      |   |      |
| 660 | 47540 | 0027458-90-8 | di-tert-dodecyl disulphide                               | yes | no  | yes | 0,05 |      |   |      |

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| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)   | (9)          | (10)   | (11)    |
|-----|-------|--------------|---|-----|-----|-----|-------|--------------|--|---------|
| 661 | 95360 | 0027676-62-6 | 1,3,5-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 | 0027955-94-8 | 1,1,1-tris(4-hydroxyphenyl)ethane   | no  | yes | no  | 0,005 |              | Only to be used in polycarbonates  | ►M8 — ◀ |
| 663 | 64150 | 0028290-79-1 | linolenic acid  | yes | no  | no  |       |              |  |         |
| 664 | 95000 | 0028931-67-1 | trimethylolpropane trimethacrylate-methyl methacrylate copolymer                    | yes | no  | no  |       |              |  |         |
| 665 | 83120 | 0029013-28-3 | 1,2-propyleneglycol monopalmitate   | yes | no  | no  |       |              |  |         |
| 666 | 87280 | 0029116-98-1 | sorbitan dioleate   | yes | no  | no  |       |              |  |         |
| 667 | 55190 | 0029204-02-2 | gadoleic acid   | yes | no  | no  |       |              |  |         |
| 668 | 80240 | 0029894-35-7 | polyglycerol ricinoleate  | yes | no  | no  |       |              |  |         |
| 669 | 56610 | 0030233-64-8 | glycerol monobehenate   | yes | no  | no  |       |              |  |         |
| 670 | 56800 | 0030899-62-8 | glycerol monolaurate diacetate  | yes | no  | no  |       | (32)         |  |         |
| 671 | 74240 | 0031570-04-4 | phosphorous acid, tris(2,4-di-tert-butylphenyl)ester                                | yes | no  | no  |       |              |  |         |
| 672 | 76845 | 0031831-53-5 | polyester of 1,4-butanediol with caprolactone                                       | yes | no  | no  |       | (29)<br>(30) | The fraction with molecular weight below 1 000 Da<br>►M7 shall ◀ not exceed 0,5 %<br>(w/w) |         |
| 673 | 53670 | 0032509-66-3 | ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]                  | yes | no  | yes | 6     |              |  |         |

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| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|------|
| 674 | 46480 | 0032647-67-9 | dibenzylidene sorbitol   | yes | no  | no  |      |      |   |      |
| 675 | 38800 | 0032687-78-8 | N,N'-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide          | yes | no  | yes | 15   |      |   |      |
| 676 | 50400 | 0033568-99-9 | di-n-octyltin bis(isooctyl maleate)  | yes | no  | no  |      | (10) |   |      |
| 677 | 82560 | 0033587-20-1 | 1,2-propyleneglycol dipalmitate  | yes | no  | no  |      |      |   |      |
| 678 | 59200 | 0035074-77-2 | 1,6-hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)     | yes | no  | yes | 6    |      |   |      |
| 679 | 39060 | 0035958-30-6 | 1,1-bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane                           | yes | no  | yes | 5    |      |   |      |
| 680 | 94400 | 0036443-68-2 | triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl)propionate] | yes | no  | no  | 9    |      |   |      |
| 681 | 18310 | 0036653-82-4 | 1-hexadecanol  | no  | yes | no  |      |      |   |      |
| 682 | 53270 | 0037205-99-5 | ethylcarboxymethylcellulose  | yes | no  | no  |      |      |   |      |
| 683 | 66200 | 0037206-01-2 | methylcarboxymethylcellulose   | yes | no  | no  |      |      |   |      |
| 684 | 68125 | 0037244-96-5 | nepheline syenite  | yes | no  | no  |      |      |   |      |
| 685 | 85950 | 0037296-97-2 | silicic 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. |      |

## ▼B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9) | (10) | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|-----|------|------|
| 686 | 61390 | 0037353-59-6 | hydroxymethylcellulose  | yes | no  | no  |      |     |      |      |
| 687 | 13530 | 0038103-06-9 | 2,2-bis(4-hydroxyphenyl)propane bis(phthalic anhydride)                                     | no  | yes | no  | 0,05 |     |      |      |
|     | 13614 |              |   |     |     |     |      |     |      |      |
| 688 | 92560 | 0038613-77-3 | tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite                           | yes | no  | yes | 18   |     |      |      |
| 689 | 95280 | 0040601-76-1 | 1,3,5-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 | 0041484-35-9 | thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)                        | yes | no  | yes | 2,4  |     |      |      |
| 691 | 13600 | 0047465-97-4 | 3,3-bis(3-methyl-4-hydroxyphenyl)2-indolinone   | no  | yes | no  | 1,8  |     |      |      |
| 692 | 52320 | 0052047-59-3 | 2-(4-dodecylphenyl)indole   | yes | no  | yes | 0,06 |     |      |      |
| 693 | 88160 | 0054140-20-4 | sorbitan tripalmitate   | yes | no  | no  |      |     |      |      |
| 694 | 21400 | 0054276-35-6 | methacrylic acid, sulphopropyl ester  | no  | yes | no  | 0,05 |     |      | (1)  |
| 695 | 67520 | 0054849-38-6 | monomethyltin tris(isooctyl mercaptoacetate)  | yes | no  | no  |      | (9) |      |      |
| 696 | 92205 | 0057569-40-1 | terephthalic acid, diester with 2,2'-methylenebis(4-methyl-6-tert-butylphenol)              | yes | no  | no  |      |     |      |      |
| 697 | 67515 | 0057583-34-3 | monomethyltin tris(ethylhexyl mercaptoacetate)  | yes | no  | no  |      | (9) |      |      |
| 698 | 49595 | 0057583-35-4 | dimethyltin bis(ethylhexyl mercaptoacetate)   | yes | no  | no  |      | (9) |      |      |



## ▼B

| (1) | (2)                   | (3)          | (4)   | (5) | (6) | (7) | (8) | (9)  | (10) | (11) |
|-----|-----------------------|--------------|---|-----|-----|-----|-----|------|------|------|
| 699 | 90720                 | 0058446-52-9 | stearoylbenzoylmethane  | yes | no  | no  |     |      |      |      |
| 700 | 31520                 | 0061167-58-6 | acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester           | yes | no  | yes | 6   |      |      |      |
| 701 | 40160                 | 0061269-61-2 | N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer          | yes | no  | no  | 2,4 |      |      |      |
| 702 | 87920                 | 0061752-68-9 | sorbitan tetrastearate  | yes | no  | no  |     |      |      |      |
| 703 | 17170                 | 0061788-47-4 | fatty acids, coco   | no  | yes | no  |     |      |      |      |
| 704 | 77600                 | 0061788-85-0 | polyethyleneglycol ester of hydrogenated castor oil   | yes | no  | no  |     |      |      |      |
| 705 | 10599/90A<br>10599/91 | 0061788-89-4 | acids, fatty, unsaturated (C <sub>18</sub> ), dimers, non hydrogenated, distilled and non-distilled | no  | yes | no  |     | (18) |      | (1)  |
| 706 | 17230                 | 0061790-12-3 | fatty acids, tall oil   | no  | yes | no  |     |      |      |      |
| 707 | 46375                 | 0061790-53-2 | diatomaceous earth  | yes | no  | no  |     |      |      |      |
| 708 | 77520                 | 0061791-12-6 | polyethyleneglycol ester of castor oil  | yes | no  | no  | 42  |      |      |      |
| 709 | 87520                 | 0062568-11-0 | sorbitan monobehenate   | yes | no  | no  |     |      |      |      |
| 710 | 38700                 | 0063397-60-4 | bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)  | yes | no  | yes | 18  |      |      |      |

▼ B

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|--------------|--|-----|-----|-----|-----|-----|------|------|
| 711 | 42000 | 0063438-80-2 | (2-carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate) | yes | no  | yes | 30  |     |      |      |
| 712 | 42960 | 0064147-40-6 | castor oil, dehydrated                                 | yes | no  | no  |     |     |      |      |

▼ M6

|     |       |              |                     |     |    |    |  |  |  |  |
|-----|-------|--------------|---------------------|-----|----|----|--|--|--|--|
| 713 | 43480 | 0064365-11-3 | charcoal, 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>(4)</sup> with exception of ash content which can be up to 10 % (w/w). |  |
|     |       | 0007440-44-0 |                     |     |    |    |  |  |  |  |

▼ B

|     |       |              |   |     |    |    |    |  |  |  |
|-----|-------|--------------|---|-----|----|----|----|--|--|--|
| 714 | 84400 | 0064365-17-9 | rosin, hydrogenated, ester with pentaerythritol   | yes | no | no |    |  |  |  |
| 715 | 46880 | 0065140-91-2 | 3,5-di-tert-butyl-4-hydroxybenzyl-phosphonic acid, monoethyl ester, calcium salt  | yes | no | no | 6  |  |  |  |
| 716 | 60800 | 0065447-77-0 | 1-(2-hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer  | yes | no | no | 30 |  |  |  |
| 717 | 84210 | 0065997-06-0 | rosin, hydrogenated   | yes | no | no |    |  |  |  |
| 718 | 84240 | 0065997-13-9 | rosin, hydrogenated, ester with glycerol  | yes | no | no |    |  |  |  |
| 719 | 65920 | 0066822-60-4 | N-methacryloyloxyethyl-N,N-dimethyl-N-carboxymethyl-ammonium chloride, sodium salt -octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers | yes | no | no |    |  |  |  |

▼B

| (1)         | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8) | (9)  | (10)   | (11) |
|-------------|-------|--------------|--|-----|-----|-----|-----|------|--|------|
| 720         | 67360 | 0067649-65-4 | mono-n-dodecyltin tris(isooctyl mercaptoacetate)   | yes | no  | no  |     | (25) |  |      |
| 721         | 46800 | 0067845-93-6 | 3,5-di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester   | yes | no  | no  |     |      |  |      |
| 722         | 17200 | 0068308-53-2 | fatty acids, soya  | no  | yes | no  |     |      |  |      |
| 723         | 88880 | 0068412-29-3 | starch, hydrolysed   | yes | no  | no  |     |      |  |      |
| 724         | 24903 | 0068425-17-2 | 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>(5)</sup> |      |
| ▼ <u>M6</u> |       |              |  |     |     |     |     |      |  |      |
| ▼ <u>B</u>  |       |              |  |     |     |     |     |      |  |      |
| 726         | 83599 | 0068442-12-6 | reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin | yes | no  | yes |     | (9)  |  |      |
| 727         | 43360 | 0068442-85-3 | cellulose, regenerated   | yes | no  | no  |     |      |  |      |

## ▼B

| (1) | (2)   | (3)                          | (4)  | (5) | (6) | (7) | (8) | (9)          | (10)  | (11) |
|-----|-------|------------------------------|--|-----|-----|-----|-----|--------------|---|------|
| 728 | 75100 | 0068515-48-0<br>0028553-12-0 | phthalic acid, diesters with primary, saturated C <sub>8</sub> -C <sub>10</sub> branched alcohols, more than 60 % C <sub>9</sub> | yes | no  | no  |     | (26)<br>(32) | Only to be used as:<br>(a) plasticiser in repeated use materials and articles;<br>(b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant 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;<br>(c) technical support agent in concentrations up to 0,1 % in the final product. | (7)  |
| 729 | 75105 | 0068515-49-1<br>0026761-40-0 | phthalic acid, diesters with primary, saturated C <sub>9</sub> -C <sub>11</sub> alcohols more than 90 % C <sub>10</sub>          | yes | no  | no  |     | (26)<br>(32) | Only to be used as:<br>(a) plasticiser in repeated use materials and articles;<br>(b) plasticiser in single-use materials and articles contacting non-fatty foods except for infant 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;<br>(c) technical support agent in concentrations up to 0,1 % in the final product. | (7)  |

## ▼B

| (1) | (2)                   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-----------------------|--------------|---|-----|-----|-----|------|------|---|------|
| 730 | 66930                 | 0068554-70-1 | methylsilsesquioxane  | yes | no  | no  |      |      | Residual monomer in methylsil-sesquioxane: < 1 mg methyl-trimethoxysilane/kg of methylsil-sesquioxane |      |
| 731 | 18220                 | 0068564-88-5 | N-heptylaminoundecanoic acid  | no  | yes | no  | 0,05 |      |   | (2)  |
| 732 | 45450                 | 0068610-51-5 | <i>p</i> -cresol-dicyclopentadiene-isobutylene, copolymer                                       | yes | no  | yes | 5    |      |   |      |
| 733 | 10599/92A<br>10599/93 | 0068783-41-5 | acids, fatty, unsaturated (C <sub>18</sub> ), dimers, hydrogenated, distilled and non-distilled | no  | yes | no  |      | (18) |   | (1)  |
| 734 | 46380                 | 0068855-54-9 | diatomaceous earth, soda ash flux-calcined  | yes | no  | no  |      |      |   |      |
| 735 | 40120                 | 0068951-50-8 | bis(polyethyleneglycol)hydroxy-methylphosphonate  | yes | no  | no  | 0,6  |      |   |      |
| 736 | 50960                 | 0069226-44-4 | di-n-octyltin ethyleneglycol bis(mercaptoacetate)   | yes | no  | no  |      | (10) |   |      |
| 737 | 77370                 | 0070142-34-6 | polyethyleneglycol-30 dipolyhydroxystearate   | yes | no  | no  |      |      |   |      |
| 738 | 60320                 | 0070321-86-7 | 2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzo-triazole                                   | yes | no  | yes | 1,5  |      |   |      |
| 739 | 70000                 | 0070331-94-1 | 2,2'-oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]                         | yes | no  | no  |      |      |   |      |

▼B

| (1)          | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8) | (9)  | (10)  | (11) |
|--------------|-------|--------------|---|-----|-----|-----|-----|------|---|------|
| 740          | 81200 | 0071878-19-8 | poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl) imino] | yes | no  | yes | 3   |      |   |      |
| 741          | 24070 | 0073138-82-6 | resin acids and rosin acids   | yes | yes | no  |     |      |   |      |
|              | 83610 |              |   |     |     |     |     |      |   |      |
| 742          | 92700 | 0078301-43-6 | 2,2,4,4-tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro[5.1.1.2]-heneicosan-21-one, polymer  | yes | no  | yes | 5   |      |   |      |
| 743          | 38950 | 0079072-96-1 | bis(4-ethylbenzylidene)sorbitol   | yes | no  | no  |     |      |   |      |
| ▼ <u>M12</u> |       |              |   |     |     |     |     |      |   |      |
| 744          | 18888 | 080181-31-3  | 3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer   | no  | yes | no  |     | (35) | The substance is used as product obtained by bacterial fermentation. In compliance with the specifications mentioned in the Table 4 of Annex I. |      |
| ▼ <u>B</u>   |       |              |   |     |     |     |     |      |   |      |
| 745          | 68145 | 0080410-33-9 | 2,2',2'-nitriolo(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 | 0080693-00-1 | bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite  | yes | no  | yes | 5   |      | SML expressed as sum of phosphite and phosphate   |      |
| 747          | 47600 | 0084030-61-5 | di-n-dodecyltin bis(isooctyl mercaptoacetate)   | yes | no  | yes |     | (25) |   |      |

▼ **B**

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9) | (10) | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|-----|------|------|
| 748 | 12765 | 0084434-12-8 | N-(2-aminoethyl)-β-alanine, sodium salt                      | no  | yes | no  | 0,05 |     |      |      |
| 749 | 66360 | 0085209-91-2 | 2,2'-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate | yes | no  | yes | 5    |     |      |      |
| 750 | 66350 | 0085209-93-4 | 2,2'-methylenebis(4,6-di-tert-butylphenyl) lithium phosphate | yes | no  | no  | 5    |     |      |      |
| 751 | 81515 | 0087189-25-1 | poly(zinc glycerolate)                                       | yes | no  | no  |      |     |      |      |

▼ **M7**

|     |       |  |                                |     |    |    |  |  |  |  |
|-----|-------|--|--------------------------------|-----|----|----|--|--|--|--|
| 752 | 39890 | 0087826-41-3<br>0069158-41-4<br>0054686-97-4<br>0081541-12-0 | bis(methylbenzylidene)sorbitol | yes | no | no |  |  |  |  |
|-----|-------|--|--------------------------------|-----|----|----|--|--|--|--|

▼ **B**

|     |       |              |   |     |     |     |      |      |  |     |
|-----|-------|--------------|---|-----|-----|-----|------|------|--|-----|
| 753 | 62800 | 0092704-41-1 | kaolin, calcined  | yes | no  | no  |      |      |  |     |
| 754 | 56020 | 0099880-64-5 | glycerol dibehenate   | yes | no  | no  |      |      |  |     |
| 755 | 21765 | 0106246-33-7 | 4,4'-methylenebis(3-chloro-2,6-diethylaniline)                | no  | yes | no  | 0,05 |      |  | (1) |
| 756 | 40020 | 0110553-27-0 | 2,4-bis(octylthiomethyl)-6-methylphenol                       | yes | no  | yes |      | (24) |  |     |
| 757 | 95725 | 0110638-71-6 | vermiculite, reaction product with citric acid, lithium salt  | yes | no  | no  |      |      |  |     |
| 758 | 38940 | 0110675-26-8 | 2,4-bis(dodecylthiomethyl)-6-methylphenol                     | yes | no  | yes |      | (24) |  |     |
| 759 | 54300 | 0118337-09-0 | 2,2'-ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite | yes | no  | yes | 6    |      |  |     |

## ▼B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8) | (9) | (10)   | (11) |
|-----|-------|--------------|---|-----|-----|-----|-----|-----|--|------|
| 760 | 83595 | 0119345-01-6 | 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 | yes | no  | no  | 18  |     | <p>Composition:</p> <ul style="list-style-type: none"> <li>— 4,4'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0038613-77-3) (36-46 % w/w (*)),</li> <li>— 4,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)),</li> <li>— 3,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)),</li> <li>— 4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)),</li> <li>— tris(2,4-di-tert-butylphenyl)phosphite (CAS No 0031570-04-4) (9-18 % w/w (*)),</li> <li>— 4,4'-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0112949-97-0) (&lt; 5 % w/w (*))</li> </ul> <p>(*) Quantity of substance used/ quantity of formulation</p> <p>Other specifications:</p> <ul style="list-style-type: none"> <li>— Phosphor content of min. 5,4 % to max. 5,9 %,</li> <li>— Acid value of max. 10 mg KOH per gram,</li> <li>— Melt range of 85– 110 °C,</li> </ul> |      |



## ▼B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9) | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|-----|---|------|
| 761 | 92930 | 0120218-34-0 | thiodiethanolbis(5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropyridine-3-carboxylate)  | yes | no  | no  | 6    |     |   |      |
| 762 | 31530 | 0123968-25-2 | acrylic acid, 2,4-di-tert-pentyl-6-(1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl)phenyl ester  | yes | no  | yes | 5    |     |   |      |
| 763 | 39925 | 0129228-21-3 | 3,3-bis(methoxymethyl)-2,5-dimethylhexane   | yes | no  | yes | 0,05 |     |   |      |
| 764 | 13317 | 0132459-54-2 | N,N'-bis[4-(ethoxycarbonyl)phenyl]-1,4,5,8-naphthalenetetracarboxydiimide   | no  | yes | no  | 0,05 |     | Purity > 98,1 % (w/w).<br>Only to be used as co-monomer (max 4 %) for polyesters (PET, PBT).  |      |
| 765 | 49485 | 0134701-20-5 | 2,4-dimethyl-6-(1-methylpentadecyl)phenol   | yes | no  | yes | 1    |     |   |      |
| 766 | 38879 | 0135861-56-2 | bis(3,4-dimethylbenzylidene)sorbitol  | yes | no  | no  |      |     |   |      |
| 767 | 38510 | 0136504-96-6 | 1,2-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 | 0143925-92-2 | amines, bis(hydrogenated tallow alkyl) oxidised   | yes | no  | no  |      |     | Not to be used for articles in contact with fatty foods for which ►M7 simulant D1 and/or D2 ◀ is laid down.<br>Only to be used in:<br>(a) polyolefins at 0,1 % (w/w) concentration and in<br>(b) PET at 0,25 % (w/w) concentration. | (1)  |
| 769 | 74010 | 0145650-60-8 | phosphorous 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 | 0147315-50-2 | 2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol  | yes | no  | no  | 0,05 |     |   |      |

## ▼B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11)  |
|-----|-------|--------------|---|-----|-----|-----|------|------|--|-------|
| 771 | 34650 | 0151841-65-5 | aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert-butylphenyl) phosphate]                            | yes | no  | no  | 5    |      |  |       |
| 772 | 47500 | 0153250-52-3 | N,N'-dicyclohexyl-2,6-naphthalene dicarboxamide   | yes | no  | no  | 5    |      |  |       |
| 773 | 38840 | 0154862-43-8 | bis(2,4-dicumylphenyl)pentaerythritol-diphosphate   | yes | no  | yes | 5    |      | SML expressed as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol) |       |
| 774 | 95270 | 0161717-32-4 | 2,4,6-tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite                                  | yes | no  | yes | 2    |      | SML expressed as sum of phosphite, phosphate and the hydrolysis product = TTBP   |       |
| 775 | 45705 | 0166412-78-8 | 1,2-cyclohexanedicarboxylic acid, diisononyl ester  | yes | no  | no  |      | (32) |  |       |
| 776 | 76723 | 0167883-16-1 | polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclohexylmethane-4,4'-diisocyanate      | yes | no  | no  |      |      | The fraction with molecular weight below 1 000 Da<br>►M7 shall ◀ not exceed 1,5 % (w/w)  |       |
| 777 | 31542 | 0174254-23-0 | acrylic 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 | 0178671-58-4 | pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)   | yes | no  | yes | 0,05 |      |  |       |
| 779 | 39815 | 0182121-12-6 | 9,9-bis(methoxymethyl)fluorene  | yes | no  | yes | 0,05 |      |  | ►M8 ◀ |

## ▼M7

▼B

| (1)         | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11)        |
|-------------|-------|--------------|---|-----|-----|-----|------|------|---|-------------|
| 780         | 81220 | 0192268-64-7 | poly-[[[6-[N-(2,2,6,6-tetramethyl-4-piperidiny)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidiny)imino]-1,6-hexanediy]l[(2,2,6,6-tetramethyl-4-piperidiny)imino]]-α-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidiny)-N''-[6-(2,2,6,6-tetramethyl-4-piperidiny-lamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-ω-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine] | yes | no  | no  | 5    |      |   |             |
| 781         | 95265 | 0227099-60-7 | 1,3,5-tris(4-benzoylphenyl) benzene   | yes | no  | no  | 0,05 |      |   |             |
| 782         | 76725 | 0661476-41-1 | polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane   | yes | no  | no  |      |      | The fraction with molecular weight below 1 000 Da<br>► <b>M7</b> shall ◀ not exceed 1 % (w/w) |             |
| 783         | 55910 | 0736150-63-3 | glycerides, castor-oil mono-, hydrogenated, acetates  | yes | no  | no  |      | (32) |   |             |
| ▼ <u>M6</u> |       |              |   |     |     |     |      |      |   |             |
| 784         | 95420 | 0745070-61-5 | 1,3,5-tris (2,2-di-methylpropanamido) benzene   | yes | no  | no  | 5    |      |   |             |
| ▼ <u>B</u>  |       |              |   |     |     |     |      |      |   |             |
| 785         | 24910 | 0000100-21-0 | terephthalic acid   | no  | yes | no  |      | (28) |   |             |
| 786         | 14627 | 0000117-21-5 | 3-chlorophthalic anhydride  | no  | yes | no  | 0,05 |      | SML expressed as 3-chlorophthalic acid  |             |
| 787         | 14628 | 0000118-45-6 | 4-chlorophthalic anhydride  | no  | yes | no  | 0,05 |      | SML expressed as 4-chlorophthalic acid  |             |
| 788         | 21498 | 0002530-85-0 | [3-(methacryloxy)propyl]trimethoxysilane  | no  | yes | no  | 0,05 |      | Only to be used as a surface treatment agent of inorganic fillers                             | (1)<br>(11) |

## ▼B

| (1) | (2)   | (3)                          | (4)  | (5) | (6) | (7) | (8)  | (9) | (10)   | (11) |
|-----|-------|------------------------------|--|-----|-----|-----|------|-----|--|------|
| 789 | 60027 | —                            | hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440–12 000) | yes | no  | no  |      |     | Average molecular weight not less than 440 Da.<br>Viscosity at 100 °C not less than 3,8 cSt ( $3,8 \times 10^{-6} \text{ m}^2/\text{s}$ ).   | (2)  |
| 790 | 80480 | 0090751-07-8<br>0082451-48-7 | poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino] hexa-methylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino]          | yes | no  | no  | 5    |     | Average molecular weight not less than 2 400 Da.<br>Residual content of morpholine $\leq 30 \text{ mg/kg}$ , of N,N'-bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine $< 15 000 \text{ mg/kg}$ , and of 2,4-dichloro-6-morpholino-1,3,5-triazine $\leq 20 \text{ mg/kg}$ . | (16) |
| 791 | 92470 | 0106990-43-6                 | N,N',N'',N'''-tetrakis(4,6-bis(N-butyl-(N-methyl-2,2,6,6-tetramethylpiperidin-4-yl)amino)triazin-2-yl)-4,7-diazadecane-1,10-diamine                  | yes | no  | no  | 0,05 |     |  |      |
| 792 | 92475 | 0203255-81-6                 | 3,3',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 | 0000102-71-6                 | triethanolamine  | yes | no  | no  | 0,05 |     | SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed as triethanolamine  |      |
| 794 | 18117 | 0000079-14-1                 | glycolic acid  | no  | yes | no  |      |     | Only to be used 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.                          |      |

## ▼M2

▼ **B**

| (1)         | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)          | (10)   | (11)        |
|-------------|-------|--------------|---|-----|-----|-----|------|--------------|--|-------------|
| 795         | 40155 | 0124172-53-8 | N,N'-bis(2,2,6,6-tetramethyl-4-piperidyl)-N,N'-diformylhexamethylenediamine   | yes | no  | no  | 0,05 |              |  | (2)<br>(12) |
| 796         | 72141 | 0018600-59-4 | 2,2'-(1,4-phenylene)bis[4H-3,1-benzoxazin-4-one]  | yes | no  | yes | 0,05 |              | SML including the sum of its hydrolysis products   |             |
| ▼ <b>M2</b> |       |              |   |     |     |     |      |              |  |             |
| 797         | 76807 | 0073018-26-5 | polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol   | yes | no  | yes |      | (31)<br>(32) |  |             |
| ▼ <b>B</b>  |       |              |   |     |     |     |      |              |  |             |
| 798         | 92200 | 0006422-86-2 | terephthalic acid, bis(2-ethylhexyl)ester   | yes | no  | no  | 60   | (32)         |  |             |
| ▼ <b>M6</b> |       |              |   |     |     |     |      |              |  |             |
| 799         | 77708 |              | polyethyleneglycol (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 for food additives in Commission Regulation (EU) No 231/2012.                |             |
| ▼ <b>B</b>  |       |              |   |     |     |     |      |              |  |             |
| 800         | 94425 | 0000867-13-0 | triethyl 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 | 0146340-15-0 | alcohols, C <sub>12</sub> -C <sub>14</sub> secondary, β-(2-hydroxyethoxy), ethoxylated  | yes | no  | no  | 5    |              |  | (12)        |
| 803         | 33535 | 0152261-33-1 | α-alkenes(C <sub>20</sub> -C <sub>24</sub> ) copolymer with maleic anhydride, reaction product with 4-amino-2,2,6,6-tetramethylpiperidine | yes | no  | no  |      |              | Not to be used for articles in contact with fatty foods for which ► <b>M7</b> simulant D1 and/or D2 ◀ is laid down.<br>Not to be used in contact with alcoholic foods. | (13)        |

## ▼B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11)                |
|-----|-------|--------------|---|-----|-----|-----|------|------|--|---------------------|
| 804 | 80510 | 1010121-89-7 | poly(3-nonyl-1,1-dioxo-1-thio-propane-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diimi-nooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzene-sulfonic acid | yes | no  | no  |      |      | Only to be used as polymer production aid in polyethylene (PE), polypropylene (PP) and polystyrene (PS)  |                     |
| 805 | 93450 | —            | titanium dioxide, coated with a copolymer of n-octyltrichloro-silane and [aminotris(methylenep-hosphonic 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 | 0001076-97-7 | 1,4-cyclohexanedicarboxylic acid  | no  | yes | no  | 5    |      | Only to be used for manufacture of polyesters  |                     |
| ▼M3 |       |              |   |     |     |     |      |      |  |                     |
| 807 | 93485 | —            | titanium nitride, nanoparticles   | yes | no  | no  |      |      | No migration of titanium nitride nanoparticles.<br>Only to be used in polyethylene terephthalate (PET) up to 20 mg/kg.<br>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. |                     |
| ▼B  |       |              |   |     |     |     |      |      |  |                     |
| 808 | 38550 | 0882073-43-0 | bis(4-propylbenzylidene)propylsorbitol  | yes | no  | no  | 5    |      | SML including the sum of its hydrolysis products   |                     |
| 809 | 49080 | 0852282-89-4 | N-(2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethyl-butyl)phenoxy]-1H-benzo[de]iso-quinolin-1,3(2H)-dione   | yes | no  | yes | 0,05 |      | Only for use in PET  | (6)<br>(14)<br>(15) |
| 810 | 68119 |              | neopentyl glycol, diesters and monoesters with benzoic acid and 2-ethylhexanoic acid  | yes | no  | no  | 5    | (32) | Not to be used for articles in contact with fatty foods for which ►M7 simulant D1 and/or D2 ◀ is laid down.  |                     |

▼ B

| (1) | (2)   | (3)          | (4)                          | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|--------------|------------------------------|-----|-----|-----|-----|-----|------|------|
| 811 | 80077 | 0068441-17-8 | polyethylene waxes, oxidised | yes | no  | no  | 60  |     |      |      |

▼ M2

|     |       |              |  |     |    |    |  |  |  |  |
|-----|-------|--------------|--|-----|----|----|--|--|--|--|
| 812 | 80350 | 0124578-12-7 | poly(12-hydroxystearic acid)-polyethyleneimine copolymer | yes | no | no |  |  | Only to be used in plastics up to 0,1 % w/w.<br>Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine. |  |
|-----|-------|--------------|--|-----|----|----|--|--|--|--|

▼ B

|     |       |   |  |     |     |    |      |      |   |  |
|-----|-------|---|--|-----|-----|----|------|------|---|--|
| 813 | 91530 | — | sulphosuccinic acid alkyl (C <sub>4</sub> -C <sub>20</sub> ) or cyclohexyl diesters, salts         | yes | no  | no | 5    |      |   |  |
| 814 | 91815 | — | sulphosuccinic acid monoalkyl (C <sub>10</sub> -C <sub>16</sub> ) polyethyleneglycol esters, salts | yes | no  | no | 2    |      |   |  |
| 815 | 94985 | — | trimethylolpropane, mixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid        | yes | no  | no | 5    | (32) | Not to be used for articles in contact with fatty foods for which ► <u>M7</u> simulant D1 and/or D2 ◀ is laid down  |  |
| 816 | 45704 | — | cis-1,2-cyclohexanedicarboxylic acid, salts  | yes | no  | no | 5    |      |   |  |
| 817 | 38507 | — | cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts  | yes | no  | no | 5    |      | Not to be used with polyethylene in contact with acidic foods.<br>Purity ≥ 96 %.  |  |
| 818 | 21530 | — | methallylsulphonic acid, salts   | no  | yes | no | 5    |      |   |  |
| 819 | 68110 | — | neodecanoic acid, salts  | yes | no  | no | 0,05 |      | Not to be used in polymers contacting fatty foods.<br>Not to be used for articles in contact with fatty foods for which ► <u>M7</u> simulant D1 and/or D2 ◀ is laid down.<br>SML expressed as neodecanoic acid. |  |

▼ B

| (1) | (2)   | (3) | (4)                             | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|-----|---------------------------------|-----|-----|-----|-----|-----|------|------|
| 820 | 76420 | —   | pimelic acid, salts             | yes | no  | no  |     |     |      |      |
| 821 | 90810 | —   | stearoyl-2-lactylic acid, salts | yes | no  | no  |     |     |      |      |

▼ M11

|     |       |  |                        |     |    |    |       |  |  |     |
|-----|-------|--|------------------------|-----|----|----|-------|--|--|-----|
| 822 | 71938 |  | Perchloric acid, salts | yes | no | no | 0,002 |  |  | (4) |
|-----|-------|--|------------------------|-----|----|----|-------|--|--|-----|

▼ B

|     |       |   |                                 |    |     |    |   |  |  |  |
|-----|-------|---|---------------------------------|----|-----|----|---|--|--|--|
| 823 | 24889 | — | 5-Sulphoisophthalic acid, salts | no | yes | no | 5 |  |  |  |
|-----|-------|---|---------------------------------|----|-----|----|---|--|--|--|

|     |       |              |   |     |    |    |  |  |   |  |
|-----|-------|--------------|---|-----|----|----|--|--|---|--|
| 854 | 71943 | 0329238-24-6 | perfluoro acetic acid, $\alpha$ -substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropoxy groups | yes | no | no |  |  | Only to be used in concentrations up to 0,5 % w/w in the polymerisation of fluoropolymers that are processed at temperatures at or above 340 °C and are intended for use in repeated use articles |  |
|-----|-------|--------------|---|-----|----|----|--|--|---|--|

▼ M2

|     |       |  |   |     |    |    |  |  |  |  |
|-----|-------|--|---|-----|----|----|--|--|--|--|
| 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. |  |
|-----|-------|--|---|-----|----|----|--|--|--|--|

▼ M9

|     |       |            |   |     |    |    |  |  |   |  |
|-----|-------|------------|---|-----|----|----|--|--|---|--|
| 856 | 40563 | 25101-28-4 | (butadiene, styrene, methyl methacrylate, butyl acrylate) copolymer cross-linked with divinylbenzene or 1,3-butanediol dimethacrylate | yes | no | no |  |  | Only to be used in:<br>— rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below; or<br>— at up to 40 % w/w in blends of styrene acrylonitrile copolymer (SAN)/ poly(methyl methacrylate) (PMMA) repeat-use articles at room temperature or below, and when either in contact only with aqueous, acidic and/ or low alcoholic (< 20 %) foodstuffs for less than 1 day, |  |
|-----|-------|------------|---|-----|----|----|--|--|---|--|



▼ M9

| (1)                        | (2) | (3)   | (4)          | (5)  | (6) | (7) | (8) | (9)  | (10)   | (11) |
|----------------------------|-----|-------|--------------|--|-----|-----|-----|------|--|------|
|                            |     |       |              |  |     |     |     |      | or when in contact only with dry foodstuffs for any duration of time.  |      |
| ▼ <u>M2</u>                | 857 | 66765 | 0037953-21-2 | (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.  |      |
| ▼ <u>M3</u><br>▼ <u>C1</u> | 858 | 38565 | 0090498-90-1 | 3,9-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 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-hydroxy-5-methylphenyl)propionyloxy)-1,1-dimethylethyl]-2,4,8,10-tetraoxaspiro[5,5]-undecane in equilibrium with its para quinone methid tautomer.  | (2)  |
| ▼ <u>M6</u>                | 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. 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 it shall be > 40 nm. |      |

▼B

| (1)         | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9) | (10)   | (11)             |
|-------------|-------|--------------|--|-----|-----|-----|------|-----|--|------------------|
| 860         | 71980 | 0051798-33-5 | perfluoro[2-(poly(n-propoxy))propanoic acid] | yes | 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 | 0013252-13-6 | perfluoro[2-(n-propoxy)propanoic acid]       | yes | 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  |                  |
| ▼ <u>M2</u> |       |              |  |     |     |     |      |     |  |                  |
| 862         | 15180 | 0018085-02-4 | 3,4-diacetoxy-1-butene                       | no  | yes | no  | 0,05 |     | SML including the hydrolysis product 3,4-dihydroxy-1-butene<br>Only to be used as a co-monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers.                                    | (17)<br><br>(19) |
| 863         | 15260 | 0000646-25-3 | 1,10-decanediamine                           | no  | yes | no  | 0,05 |     | Only to be used as a co-monomer for 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. |                  |
| ▼ <u>B</u>  |       |              |  |     |     |     |      |     |  |                  |
| 864         | 46330 | 0000056-06-4 | 2,4-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 aqueous food  |                  |

▼ B▼ M3▼ B▼ M3▼ B

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|-----|-----|---|------|
| 865 | 40619 | 0025322-99-0 | (butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer                   | yes | no  | no  |     |     | Only to be used in:<br>(a) rigid poly(vinyl chloride) (PVC) at a maximum level of 1 % w/w;<br>(b) polylactic acid (PLA) at a maximum level of 5 % w/w.  |      |
| 866 | 40620 | —            | (butyl acrylate, methyl methacrylate) copolymer, cross-linked with allyl methacrylate | yes | no  | no  |     |     | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 7 %   |      |
| 867 | 40815 | 0040471-03-2 | (butyl methacrylate, ethyl acrylate, methyl methacrylate) copolymer                   | yes | no  | no  |     |     | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %   |      |
| 868 | 53245 | 0009010-88-2 | (ethyl acrylate, methyl methacrylate) copolymer                                       | yes | 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 level of 5 % w/w;<br>(c) polyethylene terephthalate (PET) at a maximum level of 5 % w/w. |      |
| 869 | 66763 | 0027136-15-8 | (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 | 0160535-46-6 | N,N',N''-tris(2-methylcyclohexyl)-1,2,3-propane-tricarboxamide                        | yes | no  | no  | 5   |     |   |      |

▼ **B**▼ **M7**▼ **M4**▼ **M2**▼ **M3**▼ **B**

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|--|------|
| 871 |       | 0287916-86-3 | dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, $\alpha$ -hydro- $\omega$ -hydroxypoly (oxy-1,2-ethanediyl) and 1-propene             | yes | no  | no  |      |      | Only to be used in polyolefins at levels of up to 20 weight %. These polyolefins shall only be used in contact with foods for which Table 2 of Annex III assigns food simulant E, at ambient temperature or below, and when migration of the total oligomeric fraction of less than 1 000 Da does not exceed 50 $\mu$ g/kg food. | (23) |
| 872 |       | 0006607-41-6 | 2-phenyl-3,3-bis(4-hydroxyphenyl)phthalimidine   | no  | yes | no  | 0,05 |      | To be used only as a co-monomer in polycarbonate copolymers  | (20) |
| 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.  |      |
| 874 | 16265 | 0156065-00-8 | $\alpha$ -dimethyl-3-(4'-hydroxy-3'-methoxyphenyl)propylsilyloxy, $\omega$ -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 $C_{24}H_{38}Si_2O_5(SiOC_2H_6)_n$ ( $50 > n \geq 26$ ).   |      |
| 875 | 80345 | 0058128-22-6 | poly(12-hydroxystearic acid) stearate  | yes | no  | yes | 5    |      |  |      |

▼ **B**

| (1) | (2)   | (3) | (4)   | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|-----|---|-----|-----|-----|-----|-----|------|------|
| 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 and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C <sub>1</sub> -C <sub>22</sub> )  | yes | no  | no  |     |     |      |      |

▼ **M6**

|     |       |              |   |     |     |    |   |  |  |  |
|-----|-------|--------------|---|-----|-----|----|---|--|--|--|
| 880 | 31348 |              | acids, fatty (C <sub>8</sub> -C <sub>22</sub> ), esters with pentaerythritol' | yes | no  | no |   |  |  |  |
| 881 | 25187 | 0003010-96-6 | 2,2,4,4-tetramethylcyclobutane-1,3-diol                                       | no  | yes | no | 5 |  | Only for:<br>(a) repeated use articles for long term storage at room temperature or below and hotfill;<br>(b) single use materials 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 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. |  |

▼**B**

| (1)         | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-------------|-------|--------------|---|-----|-----|-----|------|------|--|------|
| 882         | 25872 | 0002416-94-6 | 2,3,6-trimethylphenol   | no  | yes | no  | 0,05 |      |  |      |
| 883         | 22074 | 0004457-71-0 | 3-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 | 0091082-17-6 | alkyl(C <sub>10</sub> -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 ► <b>M7</b> simulant D1 and/or D2 ◀ is laid down.  |      |
| 885         | 45676 | 0263244-54-8 | cyclic oligomers of (butylene terephthalate)  | yes | no  | no  |      |      | Only to be used in 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. |      |
| ▼ <b>M2</b> |       |              |   |     |     |     |      |      |  |      |
| 894         | 93360 | 0016545-54-3 | thiodipropionic acid, ditetradecyl ester  | yes | no  | no  |      | (14) |  |      |
| 895         | 47060 | 0171090-93-0 | 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propanoic acid, esters with C13-C15 branched and linear alcohols | yes | no  | no  | 0,05 |      | Only to be used in polyolefins in contact with foods other than fatty/high-alcoholic and dairy products.   |      |

▼ M2

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|-----|-----|---|------|
| 896 | 71958 | 0958445-44-8 | 3H-perfluoro-3-[(3-methoxypropoxy)propanoic acid], ammonium salt | yes | no  | no  |     |     | Only to be used in the polymerisation of fluoropolymers when: <ul style="list-style-type: none"> <li>— processed at temperatures higher than 280 °C for at least 10 minutes,</li> <li>— processed at temperatures higher than 190 °C up to 30 % w/w for use in blends with polyoxymethylene polymers and intended for repeated use articles.</li> </ul> |      |

▼ M3

|     |  |              |   |     |    |    |  |  |  |  |
|-----|--|--------------|---|-----|----|----|--|--|--|--|
| 902 |  | 0000128-44-9 | 1,2-benzisothiazol-3(2H)-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) No 231/2012 (8). |  |
|-----|--|--------------|---|-----|----|----|--|--|--|--|

▼ M6

|     |  |            |   |     |    |    |  |  |  |  |
|-----|--|------------|---|-----|----|----|--|--|--|--|
| 903 |  | 37486-69-4 | 2H-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: <ul style="list-style-type: none"> <li>(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 at higher temperatures for equivalent shorter times;</li> <li>(b) repeated use materials and articles when processed (non-sintered) at temperatures from 300 °C and up to 360 °C for at least 10 minutes.</li> </ul> |  |
|-----|--|------------|---|-----|----|----|--|--|--|--|

▼ M2

| (1)         | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9) | (10)  | (11) |
|-------------|-------|--------------|---|-----|-----|-----|------|-----|---|------|
| 923         | 39150 | 0000120-40-1 | N,N-bis(2-hydroxyethyl)dodecanamide   | yes | no  | no  | 5    |     | The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, ► <u>M7</u> shall ◀ not result in a migration of diethanolamine higher than 0,3 mg/kg food. | (18) |
| 924         | 94987 |              | trimethylolpropane, mixed triesters and diesters with n-octanoic and n-decanoic acids | yes | no  | 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 | 0908020-52-0 | perfluoro[(2-ethoxyethoxy)acetic acid], ammonium salt                                 | yes | no  | no  |      |     | Only to be used in the polymerisation of fluoropolymers that are processed at temperatures higher than 300 °C for at least 10 minutes.  |      |
| ▼ <u>M6</u> |       |              |   |     |     |     |      |     |   |      |
| 969         |       | 24937-78-8   | ethylene-vinyl acetate copolymer wax  | yes | no  | no  |      |     | Only to be used as a polymeric additive up to 2 % w/w in polyolefins.<br>The migration of low molecular weight oligomeric fraction below 1 000 Da shall not exceed 5 mg/kg food.                          |      |
| ▼ <u>M2</u> |       |              |   |     |     |     |      |     |   |      |
| 971         | 25885 | 0002459-10-1 | trimethyl trimellitate  | no  | 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) |



▼ **M2**

| (1) | (2)   | (3)          | (4)                        | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|--------------|----------------------------|-----|-----|-----|-----|-----|---|------|
| 972 | 45197 | 0012158-74-6 | copper hydroxide phosphate | yes | no  | no  |     |     |   |      |
| 973 | 22931 | 0019430-93-4 | (perfluorobutyl)ethylene   | no  | yes | no  |     |     | Only to be used as a co-monomer up to 0,1 % w/w in the polymerisation of fluoropolymers, sintered at high temperatures. |      |

▼ **M11**

|     |       |             |  |     |    |     |    |  |  |  |
|-----|-------|-------------|--|-----|----|-----|----|--|--|--|
| 974 | 74050 | 939402-02-5 | phosphorous acid, mixed 2,4-bis(1,1- dimethylpropyl)phenyl and 4-(1,1- dimethylpropyl)phenyl triesters | yes | no | yes | 10 |  | SML expressed as the sum of the phosphite and phosphate forms of the substance, 4-tert-amylphenol and 2,4-di-tert-amylphenol. The migration of 2,4-di-tert-amylphenol shall not exceed 1 mg/kg food. |  |
|-----|-------|-------------|--|-----|----|-----|----|--|--|--|

▼ **M3**

|     |       |   |  |     |    |    |  |  |  |  |
|-----|-------|---|--|-----|----|----|--|--|--|--|
| 979 | 79987 | — | (polyethylene terephthalate, hydroxylated polybutadiene, pyromellitic anhydride) copolymer | yes | no | no |  |  | Only to be used in polyethylene terephthalate (PET) at a maximum level of 5 % w/w. |  |
|-----|-------|---|--|-----|----|----|--|--|--|--|

▼ **M4**

|     |  |           |                                  |    |     |    |  |      |   |  |
|-----|--|-----------|----------------------------------|----|-----|----|--|------|---|--|
| 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<br>To be used only as co-monomer in the manufacture of a middle layer coating on a poly(ethylene terephthalate) polymer film in a multilayer film |  |
|-----|--|-----------|----------------------------------|----|-----|----|--|------|---|--|

▼ **B**▼ **M6**▼ **M8**

| (1)  | (2) | (3)      | (4)   | (5) | (6) | (7) | (8) | (9) | (10)   | (11) |
|------|-----|----------|---|-----|-----|-----|-----|-----|--|------|
| 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/ 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. |      |
| 1007 |     | 976-56-7 | diethyl[[3,5-bis(1,1-dimethyl-ethyl)-4-hydroxyphenyl]methyl]phosphonate                                       | no  | yes | no  |     |     | Only to be used up to 0,2 % w/w based on the final polymer weight in the polymerisation process to manufacture poly(ethylene terephthalate) (PET).   |      |
| 1016 |     |          | (methacrylic acid, ethyl acrylate, n-butyl acrylate, methyl methacrylate and butadiene) copolymer in nanoform | yes | no  | no  |     |     | Only to be used up to:<br>(a) 10 % w/w in non-plasticised PVC;<br>(b) 15 % w/w in non-plasticised PLA.<br>The final material shall be used at room temperature or below.   |      |

▼ M6

| (1)  | (2) | (3)        | (4)          | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|------|-----|------------|--------------|-----|-----|-----|-----|-----|---|------|
| 1017 |     | 25618-55-7 | polyglycerol | yes | no  | no  |     |     | To be processed under conditions preventing the decomposition of the substance and up to a maximum temperature of 275 °C. |      |

▼ M8

|      |  |  |  |     |    |    |  |  |  |  |
|------|--|--|--|-----|----|----|--|--|--|--|
| 1030 |  |  | montmorillonite clay modified by dimethyldialkyl(C16-C18)ammonium chloride | yes | no | no |  |  | <p>Only to be used up to 12 % (w/w) in polyolefins in contact with dry foods to which simulant E is assigned in table 2 of Annex III at room temperature or below.</p> <p>The sum of the specific migration of 1-chlorohexadecane and 1-chlorooctadecane shall not exceed 0,05 mg/kg food.</p> <p>Can contain platelets in the nanoform that are only in one dimension thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer.</p> |  |
|------|--|--|--|-----|----|----|--|--|--|--|

▼ M7

|      |  |           |                             |    |     |    |   |  |   |              |
|------|--|-----------|-----------------------------|----|-----|----|---|--|---|--------------|
| 1031 |  | 3238-40-2 | furan-2,5-dicarboxylic acid | no | yes | no | 5 |  | Only to be used as a monomer in the production of polyethylene furanoate. The migration of the oligomeric fraction of less than 1 000 Da shall not exceed 50 µg/kg food (expressed as furan-2,5-dicarboxylic acid). | (22)<br>(23) |
|------|--|-----------|-----------------------------|----|-----|----|---|--|---|--------------|

▼ M7

| (1)  | (2) | (3)       | (4)           | (5) | (6) | (7) | (8)  | (9) | (10)  | (11) |
|------|-----|-----------|---------------|-----|-----|-----|------|-----|---|------|
| 1034 |     | 3710-30-3 | 1,7-octadiene | no  | yes | no  | 0,05 |     | Only to be used as a crosslinking co-monomer in the manufacture of polyolefins for contact with any type of foods for long term storage at room temperature, including when packaged under hot-fill conditions. |      |

▼ M6

|      |  |  |   |     |    |    |  |  |   |  |
|------|--|--|---|-----|----|----|--|--|---|--|
| 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 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. |  |
|------|--|--|---|-----|----|----|--|--|---|--|

▼ M7

|      |  |              |   |     |    |    |  |  |  |  |
|------|--|--------------|---|-----|----|----|--|--|--|--|
| 1045 |  | 1190931-27-1 | perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt                   | yes | no | no |  |  | Only to be used as a polymer production aid during the manufacture of fluoropolymers under high temperature conditions of at least 370 °C. |  |
| 1046 |  |              | zinc oxide, nanoparticles, coated with [3-(methacryloxy)propyl] trimethoxysilane (FCM No 788) | yes | no | no |  |  | Only to be used in unplasticised polymers. The restrictions and specifications specified for FCM substance No 788 shall be respected.      |  |

▼ **M7**

| (1)          | (2) | (3)                  | (4)  | (5) | (6) | (7) | (8) | (9)  | (10)  | (11)         |
|--------------|-----|----------------------|--|-----|-----|-----|-----|------|---|--------------|
| 1048         |     | 624-03-3             | ethylene glycol dipalmitate  | yes | no  | no  |     | (2)  | Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils.  |              |
| 1050         |     |                      | zinc oxide, nanoparticles, uncoated  | yes | no  | no  |     |      | Only to be used in unplasticised polymers.  |              |
| 1051         |     | 42774-15-2           | N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl) isophthalamide                         | yes | no  | no  | 5   |      |   |              |
| 1052         |     | 1455-42-1            | 2,4,8,10-tetraoxaspiro[5,5]undecane-3,9-diethanol,β3,β3,β9,β9-tetramethyl- ('SPG') | no  | yes | no  | 5   |      | Only to be used as a monomer in the production of polyesters. The migration of oligomers of less than 1 000 Da shall not exceed 50 µg/kg food (expressed as SPG).   | (22)<br>(23) |
| 1053         |     |                      | fatty acids, C16–18 saturated, esters with dipentaerythritol                       | yes | no  | no  |     |      | Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils   |              |
| ▼ <b>M8</b>  |     |                      |  |     |     |     |     |      |   |              |
| 1055         |     | 7695-91-2<br>58-95-7 | α-tocopherol acetate   | yes | no  | no  |     |      | Only to be used as antioxidant in polyolefins.  | (24)         |
| ▼ <b>M14</b> |     |                      |  |     |     |     |     |      |   |              |
| 1059         |     | 147398-31-0          | Poly((R)-3-hydroxybutyrate-co-(R)-3-hydroxyhexanoate)                              | no  | yes | no  |     | (35) | Only to be used either alone or blended with other polymers in contact with all foods under contact conditions of up to 6 months and/or 6 months and more, at room temperature or below, including hot fill or a short heating up phase. The migration of all oligomers with a molecular weight below 1 000 Da shall not exceed 5,0 mg/kg food. | (23)         |

▼ M8

| (1)         | (2) | (3)        | (4)   | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-------------|-----|------------|---|-----|-----|-----|-----|-----|---|------|
| 1060        |     |            | ground sunflower seed hulls   | yes | no  | no  |     |     | Only to be used at room temperature or below in contact with foods for which Table 2 of Annex III assigns food simulant E.<br>The seed hulls shall be obtained from sunflower seeds that are fit for human consumption.<br>The processing temperature of the plastic containing the additive shall not exceed 240 °C. |      |
| ▼ <u>M9</u> |     |            |   |     |     |     |     |     |   |      |
| 1061        |     | 80512-44-3 | 2,4,4'-trifluorobenzophenone  | no  | yes | no  |     |     | Only to be used as a co-monomer in the manufacture of polyether ether ketone plastics up to 0,3 % w/w of the final material.  |      |
| ▼ <u>M8</u> |     |            |   |     |     |     |     |     |   |      |
| 1062        |     |            | mixture composed of 97 % tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3 % hexamethyldisilazane (HMDS) with CAS No 999-97-3 | no  | yes | no  |     |     | Only to be used for the production of recycled PET and at up to 0,12 % (w/w).   |      |
| ▼ <u>M9</u> |     |            |   |     |     |     |     |     |   |      |
| 1063        |     | 1547-26-8  | 2,3,3,4,4,5,5-heptafluoro-1-pentene   | no  | yes | no  |     |     | Only to be used together with tetrafluoroethylene and/or ethylene co-monomers to manufacture fluorocopolymers for application as polymer processing aid at up to 0,2 % w/w of the food contact  |      |

▼ M9

| (1)  | (2) | (3)        | (4)  | (5) | (6) | (7) | (8)  | (9) | (10)  | (11) |
|------|-----|------------|--|-----|-----|-----|------|-----|---|------|
|      |     |            |  |     |     |     |      |     | material, and when the low-molecular mass fraction below 1 500 Da in the fluorocopolymer does not exceed 30 mg/kg.  |      |
| 1064 |     | 39318-18-8 | tungsten oxide   | yes | no  | no  | 0,05 |     | Stoichiometry:<br>WO <sub>n</sub> , n = 2,72-2,90   | (25) |
| 1065 |     | 85711-28-0 | mixture of methyl-branched and linear C <sub>14</sub> -C <sub>18</sub> alkanamides, derived from fatty acids | yes | no  | no  | 5    |     | Only to be used in the manufacture of articles made of polyolefins, and which do not come into contact with foods for which food simulant D2 is assigned in Table 2 of Annex III.   | (26) |
| 1066 |     | 23985-75-3 | 1,2,3,4-tetrahydronaphthalene-2,6-dicarboxylic acid, dimethyl ester  | no  | yes | no  | 0,05 |     | Only to be used as a co-monomer in the manufacture of a polyester non-food contact layer in a plastic multilayer material, which is to be used only in contact with foods for which food simulants A, B, C and/or D1 are assigned in Table 2 of Annex III. The specific migration limit in column 8 refers to the sum of the substance and of its dimers (cyclic and open chain). |      |

▼ M12

▼ M12

| (1)  | (2) | (3)       | (4)   | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|------|-----|-----------|---|-----|-----|-----|-----|-----|---|------|
| 1067 |     | 616-38-6  | dimethyl carbonate                            | no  | yes | no  |     |     | <p>Only to be used:</p> <p>a) with 1,6-hexanediol in the manufacture of polycarbonate pre-polymers that are used at up to 30 % to manufacture thermoplastic polyurethanes with 4,4'-methylenediphenyldiisocyanate and diols, such as polypropylene glycol and 1,4-butanediol. The resulting material shall only be applied in repeated use articles intended to come into short-term contact (<math>\leq 30</math> min at room temperature) with food for which simulants A and/or B are assigned in Table 2 of Annex III; or</p> <p>b) for the production of other polycarbonates and/or under other conditions provided that the migration of dimethyl carbonate does not exceed 0,05 mg/kg food and that the migration of all polycarbonate oligomers with a molecular weight below 1 000 Da together does not exceed 0,05 mg/kg food.</p> | (27) |
| 1068 |     | 2530-83-8 | [3-(2,3-epoxypropoxy)propyl]trimethoxy silane | no  | yes | no  |     |     | <p>Only to be used as a component of a sizing agent to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC),</p>  |      |



▼ **M12**

| (1)  | (2) | (3)     | (4)       | (5) | (6) | (7) | (8) | (9) | (10)   | (11) |
|------|-----|---------|-----------|-----|-----|-----|-----|-----|--|------|
|      |     |         |           |     |     |     |     |     | polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinyl ester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/kg for the substance and 0,06 mg/kg for each of the reaction products (hydrolysed monomers and epoxy-containing cyclic dimer, trimer and tetramer). |      |
| 1069 |     | 75-28-5 | isobutane | yes | no  | no  |     |     | Only to be used as a blowing agent.  |      |

▼ **M15**

|      |  |  |   |     |    |    |  |  |   |  |
|------|--|--|---|-----|----|----|--|--|---|--|
| 1075 |  |  | Montmorillonite clay modified with hexadecyltrimethylammonium bromide | yes | no | no |  |  | Only to be used as additive at up to 4,0 % w/w in polylactic acid plastics intended for long-term storage of water at ambient temperature or below.<br>Can form platelets in the nanoform that are in one or two dimensions thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer. |  |
|------|--|--|---|-----|----|----|--|--|---|--|

▼ **M15**

| (1)  | (2) | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9) | (10)  | (11) |
|------|-----|--------------|--|-----|-----|-----|------|-----|---|------|
| 1076 |     | 1227937-46-3 | Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediy)], C10-16 alkyl ester | yes | no  | no  | 0,05 |     | Only to be used as an additive at up to 0,2 % w/w in high impact polystyrene materials and articles intended contact with food at room temperature and below, including hot-fill and/or heating up to 100 °C for up to 2 hours. It shall not be used in contact with foods for which simulant C and/or D1 is assigned in Annex III. |      |
| 1077 |     |              | Titanium dioxide surface-treated with fluoride-modified alumina  | yes | no  | no  |      |     | Only to be used at up to 25,0 % w/w, including in the nanoform.   | 29   |

▼ **B**

(<sup>1</sup>) OJ L 302, 19.11.2005, p. 28.

(<sup>2</sup>) OJ L 330, 5.12.1998, p. 32.

(<sup>3</sup>) OJ L 253, 20.9.2008, p. 1.

► **M6** (<sup>4</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). ◀

(<sup>5</sup>) OJ L 158, 18.6.2008, p. 17.

► **M1** (<sup>6</sup>) Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

(<sup>7</sup>) 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. ◀

► **M3** (<sup>8</sup>) OJ L 83, 22.3.2012, p. 1. ◀

► **M10** (<sup>9</sup>) Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013.

(<sup>10</sup>) Young children as defined in Article 2(2)(b) of Regulation (EU) No 609/2013. ◀

**▼B****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.

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<br>1048               | 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                       |

**▼M7****▼B**

**▼B**

| (1)               | (2)  | (3)   | (4)   |
|-------------------|--|-------|---|
| 10                | 28<br>29<br>30<br>31<br>32<br>33<br>466<br>582<br>618<br>619<br>620<br>646<br>676<br>736     | 0,006 | expressed as tin  |
| 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  |
| <b>▼<u>M2</u></b> |  |       |   |
| 14                | 294<br>368<br>894  | 5     | expressed as the sum of the substances and their oxidation products             |
| <b>▼<u>M6</u></b> |  |       |   |
| 15                | 98<br>196<br>344   | 15    | expressed as formaldehyde   |
| <b>▼<u>B</u></b>  |  |       |   |
| 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  |

▼B

| (1) | (2)   | (3)  | (4)   |
|-----|---|------|---|
| 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   |
| 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(isooctyl mercaptoacetate), 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   |

**▼B**

| (1) | (2)               | (3)  | (4)   |
|-----|-------------------|------|---|
| 28  | 191<br>192<br>785 | 7,5  | expressed as terephthalic acid                                  |
| 29  | 342<br>672        | 0,05 | expressed as the sum of 6-hydroxyhexanoic acid and caprolactone |

**▼M6**

|    |                   |   |                             |
|----|-------------------|---|-----------------------------|
| 30 | 254<br>344<br>672 | 5 | expressed as 1,4-butanediol |
|----|-------------------|---|-----------------------------|

**▼B**

|    |  |    |  |
|----|--|----|--|
| 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 |

**▼M3**

|    |            |    |                      |
|----|------------|----|----------------------|
| 33 | 180<br>874 | ND | expressed as eugenol |
|----|------------|----|----------------------|

**▼M4**

|    |            |      |                                       |
|----|------------|------|---------------------------------------|
| 34 | 421<br>988 | 0,05 | Expressed as 1,3-benzenedimethanamine |
|----|------------|------|---------------------------------------|

**▼M12**

|    |                    |      |                            |
|----|--------------------|------|----------------------------|
| 35 | 467<br>744<br>1059 | 0,05 | expressed as crotonic acid |
|----|--------------------|------|----------------------------|

**▼B****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.

**▼ B**

Table 3

| (1)         | (2)  |
|-------------|--|
| Note No     | Notes on verification of compliance  |
| (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. |
| <b>▼ M3</b> |  |
| (4)         | Compliance testing when there is a fat contact ► <b>M7</b> shall ◀ be performed using saturated fatty food simulants as simulant D2.   |
| <b>▼ B</b>  |  |
| (5)         | Compliance testing when there is a fat contact ► <b>M7</b> shall ◀ 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.  |

**▼ B**

| (1)  | (2)  |
|------|--|
| (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   |

**▼ M2**

|      |  |
|------|--|
| (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 |

**▼ M4**

|      |   |
|------|---|
| (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 |
|------|---|

**▼ M6**

|      |  |
|------|--|
| (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. |
|------|--|

**▼ M7**

|      |   |
|------|---|
| (22) | When used in contact with non-alcoholic foods for which Table 2 of Annex III assigns food simulant D1, food simulant C shall be used for verification of compliance instead of food simulant D1.  |
| (23) | When a final material or article containing this substance is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request. |

**▼ M8**

|      |   |
|------|---|
| (24) | The substance or its hydrolysis products are authorised food additives and compliance with Article 11(3) shall be verified. |
|------|---|



**▼ B**

| (1)  | (2)   |
|--|---|
| <b>▼ <u>M9</u></b>   | (25) When used as reheat agent in polyethylene terephthalate (PET) verification of compliance with the specific migration limit is not required; in all other cases compliance with the specific migration limit shall be verified in accordance with Article 18; the specific migration limit is expressed as mg tungsten/kg food.   |
|  | (26) Migration of stearamide, listed in Table 1 under FCM substance No 306 to which no specific migration limit applies, shall be excluded from verification of the compliance of the migration of the mixture with the specific migration limit laid down for the mixture.   |
| <b>▼ <u>M12</u></b>  | (27) When a final material or article containing this substance and produced under conditions other than those described in point (a) column 10 of Table 1 is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in point (b) column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request. |
|  | <b>▼ <u>M15</u></b>   |
| (29) In polar polymers which swell in contact with foods for which simulant B is assigned in Annex III, there is a risk that under severe contact conditions the migration limits for aluminium and fluoride are exceeded. Under contact conditions above 4 hours at 100 °C this exceedance can be high. |   |

▼ B

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                              | <p>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 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</p> |
|                  | Chemical name                           | Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)   |
|                  | CAS number                              | 0080181-31-3  |
|                  | Structural formula                      | $  \begin{array}{cccc}  & & \text{CH}_3 & \\  & &   & \\  \text{CH}_3 & \text{O} & \text{CH}_2 & \text{O} \\    &    &   &    \\  (-\text{O}-\text{CH}-\text{CH}_2-\text{C})_m & - & (\text{O}-\text{CH}-\text{CH}_2-\text{C})_n & \\  \end{array}  $ <p>where <math>n/(m + n)</math> greater than 0 and less or equal to 0,25</p>  |

▼ **B**

| (1) | (2)                      |  |
|-----|--------------------------|--|
|     | 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-hydroxybutanoic and 3-D-hydroxypentanoic acids |
|     | 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                          |
|     | ► <b>M12</b> Restriction | Specific migration limit for crotonic acid is 0,05 mg/kg food ◀  |
|     | 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   |

▼ **M15***ANNEX II***Restrictions on plastic materials and articles**

The following restrictions on plastic materials and articles apply:

1. Plastic materials and articles shall not release the substances in Table 1 below in quantities exceeding the specific migration limits expressed in mg/kg food or simulant specified in column (3), and subject to the remarks in Column (4).

Substances listed in Table 1 shall only be used in accordance with the compositional requirements set out in Chapter II. If Chapter II does not provide a basis for the authorised use of such a substance, that substance may only be present as an impurity subject to the restrictions specified in Table 1.

*Table 1*

**General list of migration limits for substances migrating from plastic materials and articles**

| (1)        | (2)  | (3)                               | (4)    |
|------------|--|-----------------------------------|--------|
| Name       | Salts allowed in accordance with Article 6(3)(a) | SML [mg/kg food or food simulant] | Remark |
| Aluminium  | yes  | 1                                 |        |
| Ammonium   | yes  | -                                 | (1)    |
| Antimony   | no   | 0,04                              | (2)    |
| Arsenic    | no   | ND                                |        |
| Barium     | yes  | 1                                 |        |
| Cadmium    | no   | ND (LOD 0,002)                    |        |
| Calcium    | yes  | -                                 | (1)    |
| Chromium   | no   | ND                                | (3)    |
| Cobalt     | yes  | 0,05                              |        |
| Copper     | yes  | 5                                 |        |
| Europium   | yes  | 0,05                              | (4)    |
| Gadolinium | yes  | 0,05                              | (4)    |
| Iron       | yes  | 48                                |        |
| Lanthanum  | yes  | 0,05                              | (4)    |
| Lead       | no   | ND                                |        |
| Lithium    | yes  | 0,6                               |        |
| Magnesium  | yes  | -                                 | (1)    |
| Manganese  | yes  | 0,6                               |        |
| Mercury    | no   | ND                                |        |
| Nickel     | no   | 0,02                              |        |
| Potassium  | yes  | -                                 | (1)    |
| Sodium     | yes  | -                                 | (1)    |

▼ **M15**

| (1)     | (2)  | (3)                               | (4)    |
|---------|--|-----------------------------------|--------|
| Name    | Salts allowed in accordance with Article 6(3)(a) | SML [mg/kg food or food simulant] | Remark |
| Terbium | yes  | 0,05                              | (4)    |
| Zinc    | yes  | 5                                 |        |

ND: Not Detectable; detection limit assigned in accordance with second subparagraph of Article 11(4); LOD: specified Limit of Detection.

**Remarks**

- (1) The migration is subject to Article 11(3) and Article 12
  - (2) The note in Annex I, Table 1, FCM No 398 applies: SML might be exceeded at very high temperature
  - (3) To verify compliance with the Regulation, the detection limit of 0,01 mg/kg shall apply for total chromium. However if the operator that placed the material on the market can prove on the basis of pre-existing documentary evidence that the presence of hexavalent chromium in the material is excluded because it is not used or formed or during the entire production process, a limit for the total chromium of 3,6 mg/kg food shall apply.
  - (4) The lanthanide substances europium, gadolinium, lanthanum, and/or terbium can be used in accordance with Article 6(3)(a) provided that:
    - (a) The sum of all lanthanide substances migrating to the food or food simulant does not exceed the specific migration limit of 0,05 mg/kg; and
    - (b) analytical evidence using a well described methodology demonstrating that the lanthanide substance(s) used are present in dissociated ionic form in the food or the food simulant, forms part of the documentation referred to in Article 16.
2. Primary aromatic amines ('PAAs') listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>(1)</sup> and for which no migration limit is specified in Table 1 of Annex I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant. They shall not be detectable using analytical equipment with a limit of detection of 0,002 mg/kg food or food simulant applied to each individual primary aromatic amine ('PAA'), in accordance with Article 11(4).
- For PAAs not listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006, but for which no specific migration limit is specified in Annex I, compliance with Article 3 of Regulation (EC) No 1935/2004 shall be verified in accordance with Article 19. The sum of those PAAs shall however not exceed 0,01 mg/kg in food or food simulant.

<sup>(1)</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).;

**▼B***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.

**▼M7***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 |
| Any vegetable oil containing less than 1 % unsaponifiable matter                 | Food simulant D2 |
| poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm | Food simulant E  |

**▼B****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 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.

**▼M7****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 to Table 2 below.

For testing migration from materials and articles intended to come into contact with foods not listed in Table 2 below, or a combination of foods, the general food simulant assignments in point 2 shall be used for specific migration testing, and for overall migration testing the food simulant assignments in point 4 shall be applicable.

**▼M7**

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 or E the cross is followed by an oblique stroke and a figure, the migration test result shall be corrected by dividing the result by this figure. The corrected test result shall then be compared to the migration limit to establish compliance. The test results for substances that shall not migrate in detectable quantities shall not be corrected in this way.

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 that there is no 'fatty contact' with the plastic food contact material.

**▼B**

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 alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:<br><br>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

| (1)              | (2)  | (3)            |      |   |    |                         |   |
|------------------|--|----------------|------|---|----|-------------------------|---|
| Reference number | Description of food  | Food simulants |      |   |    |                         |   |
|                  |  | A              | B    | C | D1 | D2                      | E |
|                  | B. cloudy drinks:<br>juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate |                | X(*) |   | X  |                         |   |
| 01.02            | Alcoholic beverages of an alcoholic strength of between 6 %vol and 20 %.   |                |      | X |    |                         |   |
| 01.03            | Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors  |                |      |   | X  |                         |   |
| 01.04            | Miscellaneous: undenaturated ethyl alcohol   |                | X(*) |   |    | Substitute 95 % ethanol |   |
| 02               | <b>Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares</b>   |                |      |   |    |                         |   |
| 02.01            | Starches   |                |      |   |    |                         | X |
| 02.02            | Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)  |                |      |   |    |                         | X |
| 02.03            | Cereal flour and meal  |                |      |   |    |                         | X |
| 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<br/>Confectionery products</b>  |                |      |   |    |                         |   |
| 03.01            | Chocolate, chocolate-coated products, substitutes and products coated with substitutes                                       |                |      |   |    | X/3                     |   |



▼ B

| (1)<br>Reference number | (2)<br>Description of food  | (3)<br>Food simulants |   |   |    |     |      |
|-------------------------|---|-----------------------|---|---|----|-----|------|
|                         |   | A                     | B   | C | D1 | D2  | E    |
|                         |   | 03.02                 | Confectionery products:<br>A. In solid form:<br>I. With fatty substances on the surface<br>II. Other<br>B. In paste form:<br>I. With fatty substances on the surface<br>II. Moist |   |    |     |      |
| 03.03                   | Sugar and sugar products<br>A. In solid form: crystal or powder<br>B. Molasses, sugar syrups, honey and the like  | X                     |   |   |    | X/2 | X    |
| 04                      | <b>Fruit, vegetables and products thereof</b>   |                       |   |   |    |     |      |
| ▼ <u>M7</u>             |   |                       |   |   |    |     |      |
| 04.01                   | Fruit, fresh or chilled:<br>A. unpeeled and uncut<br>B. peeled and/or cut   |                       |   |   |    |     | X/10 |
| ▼ <u>B</u>              |   |                       |   |   |    |     |      |
| 04.02                   | Processed fruit:<br>A. Dried or dehydrated fruits, whole, sliced, flour or powder<br>B. Fruit in the form of purée, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products)<br>C. Fruit preserved in a liquid medium:<br>I. In an oily medium<br>II. In an alcoholic medium | X                     | X (*)   | X |    |     | X    |
| 04.03                   | Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):<br>A. Shelled, dried, flaked or powdered   |                       |   |   |    |     | X    |

▼ B

| (1)<br>Reference number | (2)<br>Description of food  | (3)<br>Food simulants |       |   |    |         |      |
|-------------------------|---|-----------------------|-------|---|----|---------|------|
|                         |   | A                     | B     | C | D1 | D2      | E    |
|                         |   |                       |       |   |    |         |      |
|                         | B. Shelled and roasted  |                       |       |   |    |         | X    |
|                         | C. In paste or cream form   | X                     |       |   |    | X       |      |
|                         | <b>▼ <u>M7</u></b>  |                       |       |   |    |         |      |
| 04.04                   | Vegetables, fresh or chilled:   |                       |       |   |    |         |      |
|                         | A. unpeeled and uncut   |                       |       |   |    |         | X/10 |
|                         | B. peeled and/or cut  | X                     | X (*) |   |    |         |      |
| 04.05                   | Processed vegetables:   |                       |       |   |    |         | X    |
|                         | A. Dried or dehydrated vegetables whole, sliced or in the form of flour or powder.                                  |                       |       |   |    |         |      |
|                         | B. ( <i>obsolete</i> )  |                       |       |   |    |         |      |
|                         | 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. In an oily medium  | X                     |       |   |    | X       |      |
|                         | II. In an alcoholic medium  |                       |       |   | X  |         |      |
|                         | <b>▼ <u>B</u></b>   |                       |       |   |    |         |      |
| 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. Fresh, chilled, processed, salted or smoked including fish eggs  | X                     |       |   |    | X/3(**) |      |
|                         | B. Preserved fish:  |                       |       |   |    |         |      |
|                         | I. In an oily medium  | X                     |       |   |    | X       |      |
|                         | II. In an aqueous medium  |                       | X(*)  | X |    |         |      |
| 06.02                   | Crustaceans and molluscs (including oysters, mussels, snails)   |                       |       |   |    |         |      |

## ▼B

| (1)<br>Reference number | (2)<br>Description of food   | (3)<br>Food simulants |      |   |    |         |   |
|-------------------------|--|-----------------------|------|---|----|---------|---|
|                         |  | A                     | B    | C | D1 | D2      | E |
|                         |  |                       |      |   |    |         |   |
|                         | A. Fresh within the shell  |                       |      |   |    |         |   |
|                         | B. Shell removed, processed, preserved or cooked with the shell  |                       |      |   |    |         |   |
|                         | I. In an oily medium   | X                     |      |   |    | X       |   |
|                         | II. In an aqueous medium   |                       | X(*) | X |    |         |   |
| 06.03                   | Meat of all zoological species (including poultry and game):   |                       |      |   |    |         |   |
|                         | A. Fresh, chilled, salted, smoked  | X                     |      |   |    | X/4(**) |   |
|                         | B. Processed meat products (such as ham, salami, bacon, sausages, and other) or in the form of paste, creams | X                     |      |   |    | X/4(**) |   |
|                         | C. Marinated meat products in an oily medium   | X                     |      |   |    | X       |   |
| 06.04                   | Preserved meat:  |                       |      |   |    |         |   |
|                         | A. In an fatty or oily medium  | X                     |      |   |    | X/3     |   |
|                         | B. In an aqueous medium  |                       | X(*) |   | X  |         |   |
| 06.05                   | Whole eggs, egg yolk, egg white  |                       |      |   |    |         |   |
|                         | A. Powdered or dried or frozen   |                       |      |   |    |         | X |
|                         | B. Liquid and cooked   |                       |      |   | X  |         |   |
| 07                      | <b>Milk products</b>   |                       |      |   |    |         |   |
| 07.01                   | Milk   |                       |      |   |    |         |   |
|                         | A. Milk and milk based drinks whole, partly dried and skimmed or partly skimmed                              |                       |      |   | X  |         |   |
|                         | B. Milk powder including infant formula (based on whole milk powder)   |                       |      |   |    |         | X |
| 07.02                   | Fermented milk such as yoghurt, buttermilk and similar products  |                       | X(*) |   | X  |         |   |
| 07.03                   | Cream and sour cream   |                       | X(*) |   | X  |         |   |

## ▼B

| (1)<br>Reference number | (2)<br>Description of food  | (3)<br>Food simulants |          |   |    |         |   |
|-------------------------|---|-----------------------|----------|---|----|---------|---|
|                         |   | A                     | B        | C | D1 | D2      | E |
|                         |   | 07.04                 | Cheeses: |   |    |         |   |
|                         | A. Whole, with not edible rind  |                       |          |   |    |         | X |
|                         | B. Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese  |                       |          |   |    | X/3(**) |   |
|                         | C. Processed cheese (soft cheese, cottage cheese and similar)   |                       | X(*)     |   | X  |         |   |
|                         | D. Preserved cheese:  |                       |          |   |    |         |   |
|                         | I. In an oily medium  | X                     |          |   |    | X       |   |
|                         | II. In an aqueous medium (feta, mozzarella, and similar)  |                       | X(*)     |   | X  |         |   |
| 08                      | <b>Miscellaneous products</b>   |                       |          |   |    |         |   |
| 08.01                   | Vinegar   |                       | X        |   |    |         |   |
| 08.02                   | Fried or roasted foods:   |                       |          |   |    |         |   |
|                         | A. Fried potatoes, fritters and the like  | X                     |          |   |    | X/5     |   |
|                         | B. Of animal origin   | X                     |          |   |    | 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 or dried:   |                       |          |   |    |         |   |
|                         | I. With fatty character   | X                     | X(*)     |   |    | X/3     |   |
|                         | II. Other   |                       | X(*)     | X |    |         |   |
| 08.04                   | Sauces:   |                       |          |   |    |         |   |
|                         | A. With aqueous character   |                       | X(*)     | X |    |         |   |

▼B

| (1)              | (2)  | (3)            |      |   |    |         |   |
|------------------|--|----------------|------|---|----|---------|---|
| Reference number | Description of food  | Food simulants |      |   |    |         |   |
|                  |  | A              | B    | C | D1 | D2      | E |
|                  | B. With fatty character e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/water mixtures e.g. coconut based sauces | X              | X(*) |   |    | X       |   |
| 08.05            | Mustard (except powdered mustard under heading 08.14)  | X              | X(*) |   |    | X/3(**) |   |
| 08.06            | Sandwiches, toasted bread pizza and the like containing any kind of foodstuff  |                |      |   |    |         |   |
|                  | A. With fatty substances on the surface  | X              |      |   |    | X/5     |   |
|                  | B. Other   |                |      |   |    |         | X |
| 08.07            | Ice-creams   |                |      | X |    |         |   |
| 08.08            | Dried foods:   |                |      |   |    |         |   |
|                  | A. With fatty substances on the surface  |                |      |   |    | X/5     |   |
|                  | B. Other   |                |      |   |    |         | X |
| 08.09            | Frozen or deep-frozen foods  |                |      |   |    |         | X |
| 08.10            | Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.  |                | X(*) |   | X  |         |   |
| 08.11            | Cocoa:   |                |      |   |    |         |   |
|                  | A. Cocoa powder, including fat-reduced and highly fat reduced  |                |      |   |    |         | X |
|                  | B. Cocoa paste   |                |      |   |    | X/3     |   |
| 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       |   |

**▼ M8****4. Food simulant assignment for testing overall migration**

For tests to demonstrate compliance with the overall migration limit food simulants shall be chosen as set out in Table 3:

*Table 3*

**Food simulant assignment for demonstrating compliance with the overall migration limit**

| Foods covered  | Food simulants in which testing shall be performed   |
|--|--|
| all types of food  | 1. distilled water or water of equivalent quality or food simulant A;<br>2. food simulant B; and<br>3. food simulant D2. |
| all types of food except for acidic foods  | 1. distilled water or water of equivalent quality or food simulant A; and<br>2. food simulant D2.                        |
| <b>▼ M12</b><br>all aqueous and alcoholic foods and milk products with a pH $\geq$ 4,5 | food simulant D1   |
| all aqueous and alcoholic foods and milk products with a pH < 4,5                      | food simulant D1 and food simulant B   |
| <b>▼ M8</b><br>all aqueous foods and alcoholic foods up to an alcohol content of 20 %  | food simulant C  |
| all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 %      | 1. food simulant C; and<br>2. food simulant B.   |

**▼ M7****5. General derogation to the assignment of food simulants**

By derogation from the assignments of food simulants in points 2 to 4 of this Annex, where testing with several food simulants is required, a single food simulant shall be sufficient if on the basis of evidence acquired using generally recognised scientific methods this food simulant is shown to be the most severe food simulant for the particular material or article being tested under the applicable time and temperature conditions selected in accordance with Chapters 2 and 3 of Annex V.

The scientific basis on which this derogation is used shall in such cases form part of the documentation required under Article 16 of this Regulation.

**▼ B***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;

**▼ M7**

- (5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004;

**▼ M15**

- (6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

At intermediate stages, this information shall include the identification and amount of substances in the intermediate material,

- that are subject to restrictions in Annex II, or
- for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant;

**▼ B**

- (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 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;

**▼ M8**

- (iii) the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information;

**▼ B**

- (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.

**▼B**

## 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.

**▼M7****1.4. Account of substances originating from other sources**

In case there is evidence linked to the food sample that a substance partially or wholly originates from a source or sources other than the material or article for which the test is being carried out, the test results shall be corrected for the amount of that substance originating from the other source or sources before comparing the test results to the applicable specific migration limit.

**▼B**

## 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.



**▼ B**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***▼ M7**

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.

By way of derogation to the conditions set out in Tables 1 and 2, the following rules apply:

- (i) 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;
- (ii) if the material or article during its intended use is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment;
- (iii) if the material or article is intended to be employed only for hot-fill conditions, only a 2-hour test at 70 °C shall be carried out. However, if the material or article is intended to be used also for storage at room temperature or below, the test conditions set out in Tables 1 and 2 of this Section or in Section 2.1.4 of this Chapter apply depending on the duration of storage.

**▼ M15**

(iv) if the plastic material or article intended to come into contact with food of which the compliance must be verified becomes in its final application part of a food processing equipment or an appliance, or a part thereof, the migration tests may be carried out by determining the specific migration into the food or food simulant produced or processed by the whole equipment or appliance, or the part thereof, as appropriate, subject to the following conditions:

- the food or food simulant is processed during testing by the equipment or part thereof in accordance with the worst foreseeable conditions that can be achieved if the equipment or its part is operated in accordance with its operating instructions, and
- the migration from parts used for storage such as from reservoirs, containers, or capsules or pads which are part of the equipment during the processing of the food, is determined using conditions representative for their use, unless the applied testing conditions for the whole tested equipment or appliance are representative also of their use.

When migration testing is done under the above conditions, and the transfer of constituents from the equipment or appliance as a whole does not exceed the migration limits, the plastic parts or materials present in the equipment or appliance shall be considered to comply with Article 11(1).

The testing of the parts used for storage or supply such as reservoirs, containers, capsules or pads shall be under conditions representative of their use, and shall include the foreseeable storage conditions of the food in these parts.

The supporting documentation referred to in Article 16 shall clearly document the testing on the whole food processing and/or food producing equipment or appliance, or on parts thereof. It shall demonstrate that the testing was representative of its foreseeable use, and shall indicate for which substances migration testing was carried out and provide all testing results. The manufacturer of individual plastic parts shall ensure the absence of migration for substances for which the Regulation specifies that their migration shall not be detectable at a specified level of detection in accordance with Article 11(4).

Compliance documentation supplied in accordance with the Regulation to the producer of the final equipment or appliance, or part thereof, shall list all substances subject to migration limits that might be exceeded under the foreseeable use of the supplied part or material.

When the result is not in compliance with the Regulation it shall be determined whether the source of the non-compliance is a plastic part subject to the Regulation or a part made from another material not subject to the Regulation on the basis of documentary evidence or analytical testing. Without prejudice to Article 3 of Regulation (EU) No 1935/2004, non-compliance to the Regulation shall only be established if the migration originates from a plastic part.

▼ M7

If the testing conditions representative for the worst foreseeable conditions of intended use of the material or article, are not technically feasible in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a migration test shall be done using food simulant E if the temperature under the worst foreseeable conditions of intended use exceeds 100 °C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation.

▼ B

Table 1

▼ M7

## Selection of test time

▼ B

| Contact time in worst foreseeable use       | ► <u>M7</u> Time to be selected for testing ◀ |
|---|---|
| $t \leq 5 \text{ min}$                      | 5 min   |
| $5 \text{ min} < t \leq 0,5 \text{ hour}$   | 0,5 hour                                      |
| $0,5 \text{ hours} < t \leq 1 \text{ hour}$ | 1 hour  |
| $1 \text{ hour} < t \leq 2 \text{ hours}$   | 2 hours                                       |
| $2 \text{ hours} < t \leq 6 \text{ hours}$  | 6 hours                                       |
| $6 \text{ hours} < t \leq 24 \text{ hours}$ | 24 hours                                      |
| $1 \text{ day} < t \leq 3 \text{ days}$     | 3 days  |
| $3 \text{ days} < t \leq 30 \text{ days}$   | 10 days                                       |
| Above 30 days                               | See specific conditions                       |

▼ M7

Table 2

## Selection of test temperature

| Worst foreseeable contact temperature    | Contact temperature to be selected for testing |
|--|--|
| $T \leq 5 \text{ °C}$                    | 5 °C   |
| $5 \text{ °C} < T \leq 20 \text{ °C}$    | 20 °C  |
| $20 \text{ °C} < T \leq 40 \text{ °C}$   | 40 °C  |
| $40 \text{ °C} < T \leq 70 \text{ °C}$   | 70 °C  |
| $70 \text{ °C} < T \leq 100 \text{ °C}$  | 100 °C or reflux temperature                   |
| $100 \text{ °C} < T \leq 121 \text{ °C}$ | 121 °C (*)                                     |
| $121 \text{ °C} < T \leq 130 \text{ °C}$ | 130 °C (*)                                     |
| $130 \text{ °C} < T \leq 150 \text{ °C}$ | 150 °C (*)                                     |
| $150 \text{ °C} < T < 175 \text{ °C}$    | 175 °C (*)                                     |
| $175 \text{ °C} < T \leq 200 \text{ °C}$ | 200 °C (*)                                     |
| $T > 200 \text{ °C}$                     | 225 °C (*)                                     |

(\*) 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.

▼ **M7**2.1.4. *Specific conditions for contact times above 30 days at room temperature and below*

For contact times above 30 days (long term) at room temperature and below, the specimen shall be tested in accelerated test conditions at elevated temperature for a maximum of 10 days at 60 °C <sup>(1)</sup>.

- (a) Testing for 10 days at 20 °C shall cover all storage times at frozen condition. This test can include the freezing and defrosting processes if labelling or other instructions ensure that 20 °C is not exceeded and the total time above – 15 °C does not exceed 1 day in total during the foreseeable intended use of the material or article.
- (b) Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum  $t = 120/2^{((T-70)/10)}$  minutes.
- (c) Testing for 10 days at 50 °C shall cover all storage times of up to 6 months at room temperature, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum  $t = 120/2^{((T-70)/10)}$  minutes.
- (d) Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum  $t = 120/2^{((T-70)/10)}$  minutes.
- (e) For storage at room temperature the testing conditions can be reduced to 10 days at 40 °C if it is shown by scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.
- (f) For worst foreseeable conditions of intended use not covered by the test conditions set out in points (a) to (e), the testing time and temperature conditions shall be based on the following formula:

$$t_2 = t_1 * \text{Exp} (9627 * (1/T_2 - 1/T_1))$$

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

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

T<sub>1</sub> is the contact temperature in Kelvin. For room temperature storage this is set at 298K (25 °C). For refrigerated conditions it is set at 278K (5 °C). For frozen storage it is set at 258 K (– 15 °C).

T<sub>2</sub> is the testing temperature in Kelvin.

<sup>(1)</sup> When testing at these accelerated test conditions the test specimen shall not undergo any physical or other changes compared to the real conditions of use, including a phase transition of the material.

**▼ B**2.1.5. *Specific conditions for combinations of contact times and temperature***▼ M7**

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

**▼ B**

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.

**▼ M15**2.1.6. *Repeated use materials and 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. The specific migration in the second test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test.

Compliance of the material or article shall than be verified on the basis of the level of the migration found in the third test and on the basis of the stability of the material or article from the first to the third migration test. The stability of the material shall be considered insufficient if migration is observed above the level of detection in any of the three migration tests, and increases from the first migration test to the third migration test. In case of insufficient stability, compliance of the material shall not be established even in case the specific migration limit is not exceeded in any of the three tests.

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

Irrespective of the above rules, a material or article shall never be considered to comply with this Regulation if in the first test a substance that is prohibited from migrating or from being released in detectable quantities under Article 11(4) is detected.

**▼ B**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.

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.

**▼ B****2.2. Screening approaches****▼ M7**

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

**▼ B****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.

**▼ M7****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 in a way that must never underestimate real levels of 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 result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Section 2.1.2.

**2.2.5. *Single test for successive combinations of time and temperature***

If the material or article is intended for a food contact application where it is successively subject to two or more time and temperature combinations, a single migration contact test time can be defined based on the highest contact test temperature from Section 2.1.3 and/or 2.1.4 by using the equation as described in point (f) of Section 2.1.4. The reasoning justifying that the resulting single test is at least as severe as the combined time and temperature combinations shall be documented in the supporting documentation provided for in Article 16.

**▼ B**

## 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.

**▼B**

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

**▼M15**

Table 3

**Standardised conditions for testing the overall migration**

| Column 1    | Column 2   | Column 3  |
|-------------|--|---|
| Test number | Contact time in days [d] or hours [h] at Contact temperature in [°C] for testing | Intended food contact conditions  |
| OM0         | 30 min at 40 °C  | Any food contact at cold or ambient temperatures and for a short duration ( $\leq 30$ minutes).   |
| 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 when packaged under hot-fill conditions, and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.                        |
| OM3         | 2 h at 70 °C   | Any food contact conditions that include hot-fill and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum of $t = 120/2^{((T-70)/10)}$ minutes, which are not followed by long-term room temperature or refrigerated storage. |
| OM4         | 1 h at 100 °C or at reflux   | High temperature applications for all types of food 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 at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.  |
| 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 OM0, 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.

**▼ M15**

Test OM 6 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.

Test OM 5 covers also food contact conditions described for OM0, 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 OM0, OM1 and OM3.

**▼ M7****3.2. Substitute overall migration tests for tests with food simulant D2****▼ M15**

If it is not technically feasible to perform one or more of the tests OM0 to OM6 in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a test shall be done using food simulant E in case the worst foreseeable conditions of use exceed 100 °C. The test that results in the highest overall migration shall be used to establish compliance with the Regulation.

In case it is technically not feasible to perform OM7 with food simulant D2, either test OM8 or test OM9 shall be selected as a replacement test by selecting the most appropriate of these two tests on the basis of the intended and the foreseeable use of the material or article that is being tested. Subsequently, a migration test shall be done at each of the two test conditions specified for the selected test, using a new test sample for each test condition. The test condition that results in the higher overall migration shall be used to establish compliance with the Regulation.

**▼ M7**

| Test number | Test conditions  | Intended food contact conditions  | Covers the intended food contact conditions described in |
|-------------|--|---|--|
| OM8         | 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                               |
| OM9         | 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. Verification of compliance****3.3.1. Single use articles and materials**

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



**▼ M15**3.3.2. *Repeated use articles and materials*

The applicable overall migration test shall be carried out three times on a single sample using another portion of food simulant on each occasion. The migration shall be determined using an analytical method in accordance with the requirements of Article 34 of Regulation (EU) 2017/625 of the European Parliament and of the Council <sup>(1)</sup>. The overall migration in the second test shall be lower than in the first test, and the overall migration in the third test shall be lower than in the second test. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found in the third test.

If it is not technically feasible to test the same sample three times, such as when testing in vegetable oil, the overall migration test can be carried out by testing different samples for three different periods of time lasting one, two and three times the applicable contact test time. The difference between the third and the second test results shall be considered to represent the overall migration. Compliance shall be verified on the basis of this difference, which shall not exceed the overall migration limit. In addition, the difference between the second and the first test results shall be lower than the first test results and the difference between the third and the second test results shall be lower than the difference between the second and the first test results.

By derogation from the first paragraph, if, on the basis of scientific evidence, it is established that for the material or article being tested the overall migration decreases in the second and third tests and if the overall migration limit is not exceeded in the first test, the first test alone shall be sufficient.

**▼ B**3.4. **Screening approaches****▼ M7**

To screen if a material or article complies with the migration limits, any of the following approaches can be applied which are considered at least as severe as the verification method described in Sections 3.1 and 3.2.

**▼ B**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.

**▼ M7**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 result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Annex III.

<sup>(1)</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

**▼B**

## 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  $FRF = (\text{g fat in food/kg of food})/200 = (\% \text{ fat} \times 5)/100$ .

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.

**▼M7**

The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.

When testing is performed in food simulant D2 or E and when the test results are corrected in application of the correction factor laid down in Table 2 of Annex III this correction may be applied in combination with the FRF by multiplying both factors. The combined correction factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.

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## ANNEX VI

## Correlation tables

| Directive 2002/72/EC  | This Regulation |
|---|-----------------|
| 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         |

  

| Directive 93/8/EEC | This Regulation |
|--------------------|-----------------|
| Article 1          | Article 11      |
| Article 1          | Article 12      |
| Article 1          | Article 18      |
| Annex              | Annex III       |
| Annex              | Annex V         |

  

| Directive 97/48/EC | This Regulation |
|--------------------|-----------------|
| Annex              | Annex III       |
| Annex              | Annex V         |