

## II

*(Non-legislative acts)*

## REGULATIONS

## 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)*

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC <sup>(1)</sup>, and in particular Article 5(1)(a), (c), (d), (e), (f), (h), (i) and (j) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1935/2004 lays down the general principles for eliminating the differences between the laws of the Member States as regards food contact materials. Article 5(1) of that Regulation provides for the adoption of specific measures for groups of materials and articles and describes in detail the procedure for the authorisation of substances at EU level when a specific measure provides for a list of authorised substances.

(2) This Regulation is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use and repeal Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs <sup>(2)</sup>.

(3) Directive 2002/72/EC sets out basic rules for the manufacture of plastic materials and articles. The Directive has been substantially amended 6 times. For reasons of clarity the text should be consolidated and redundant and obsolete parts removed.

(4) In the past Directive 2002/72/EC and its amendments have been transposed into national legislation without any major adaptation. For transposition into national law usually a time period of 12 months is necessary. In case of amending the lists of monomers and additives in order to authorise new substances this transposition time leads to a retardation of the authorisation and thus slows down innovation. Therefore it seems appropriate to adopt rules on plastic materials and articles in form of a Regulation directly applicable in all Member States.

<sup>(1)</sup> OJ L 338, 13.11.2004, p. 4.

<sup>(2)</sup> OJ L 220, 15.8.2002, p. 18.

- (5) Directive 2002/72/EC applies to materials and articles purely made of plastics and to plastic gaskets in lids. In the past these were the main use of plastics on the market. However, in recent years, besides materials and articles purely made of plastics, plastics are also used in combination with other materials in so called multi-material multi-layers. Rules on the use of vinyl chloride monomer laid down in Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs <sup>(1)</sup> already apply to all plastics. Therefore it seems appropriate to extend the scope of this Regulation to plastic layers in multi-material multi-layers.
- (6) Plastic materials and articles may be composed of different layers of plastics held together by adhesives. Plastic materials and articles may also be printed or coated with an organic or inorganic coating. Printed or coated plastic materials and articles as well as those held together by adhesives should be within the scope of the Regulation. Adhesives, coatings and printing inks are not necessarily composed of the same substances as plastics. Regulation (EC) No 1935/2004 foresees that for adhesives, coatings and printing inks specific measures can be adopted. Therefore plastic materials and articles that are printed, coated or held together by adhesives should be allowed to contain in the printing, coating or adhesive layer other substances than those authorised at EU level for plastics. Those layers may be subject to other EU or national rules.
- (7) Plastics as well as ion exchange resins, rubbers and silicones are macromolecular substances obtained by polymerisation processes. Regulation (EC) No 1935/2004 foresees that for ion exchange resins, rubbers and silicones specific measures can be adopted. As those materials are composed of different substances than plastics and have different physico-chemical properties specific rules for them need to apply and it should be made clear that they are not within the scope of this Regulation.
- (8) Plastics are made of monomers and other starting substances which are chemically reacted to a macromolecular structure, the polymer, which forms the main structural component of the plastics. To the polymer additives are added to achieve defined technological effects. The polymer as such is an inert high molecular weight structure. As substances with a molecular weight above 1 000 Da usually cannot be absorbed in the body the potential health risk from the polymer itself is minimal. Potential health risk may occur from non- or incompletely reacted monomers or other starting substances or from low molecular weight additives which are transferred into food via migration from the plastic food contact material. Therefore monomers, other starting substances and additives should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.
- (9) The risk assessment of a substance to be performed by the European Food Safety Authority (hereinafter the Authority) should cover the substance itself, relevant impurities and foreseeable reaction and degradation products in the intended use. The risk assessment should cover the potential migration under worst foreseeable conditions of use and the toxicity. Based on the risk assessment the authorisation should if necessary set out specifications for the substance and restrictions of use, quantitative restrictions or migration limits to ensure the safety of the final material or article.
- (10) No rules have yet been set out at EU level for the risk assessment and use of colorants in plastics. Therefore their use should remain subject to national law. That situation should be reassessed at a later stage.
- (11) Solvents used in the manufacture of plastics to create a suitable reaction environment are expected to be removed in the manufacturing process as they are usually volatile. No rules have yet been set out at EU level for the risk assessment and use of solvents in the manufacture of plastics. Therefore their use should remain subject to national law. That situation should be reassessed at a later stage.
- (12) Plastics can also be made of synthetic or natural occurring macromolecular structures which are chemically reacted with other starting substances to create a modified macromolecule. Synthetic macromolecules used are often intermediate structures which are not fully polymerised. Potential health risk may occur from the migration of non- or incompletely reacted other starting substances used to modify the macromolecule or an incompletely reacted macromolecule. Therefore the other starting substances as well as the macromolecules used in the manufacture of modified macromolecules should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.

<sup>(1)</sup> OJ L 44, 15.2.1978, p. 15.

- (13) Plastics can also be made by micro-organisms that create macromolecular structures out of starting substances by fermentation processes. The macromolecule is then either released to a medium or extracted. Potential health risk may occur from the migration of non- or incompletely reacted starting substances, intermediates or by-products of the fermentation process. In this case the final product should be risk assessed and authorised before its use in the manufacture of plastic materials and articles.
- (14) Directive 2002/72/EC contains different lists for monomers or other starting substances and for additives authorised for the manufacture of plastic materials and articles. For monomers, other starting substances and additives the Union list is now complete, this means that only substances authorised at EU level may be used. Therefore a separation of monomers or other starting substances and of additives in separate lists due to their authorisation status is no longer necessary. As certain substances can be used both as monomer or other starting substances and as additive for reasons of clarity they should be published in one list of authorised substances indicating the authorised function.
- (15) Polymers can not only be used as main structural component of plastics but also as additives achieving defined technological effects in the plastic. If such a polymeric additive is identical to a polymer that can form the main structural component of a plastic material the risk from polymeric additive can be regarded as evaluated if the monomers have already been evaluated and authorised. In such a case it should not be necessary to authorise the polymeric additive but it could be used on the basis of the authorisation of its monomers and other starting substances. If such a polymeric additive is not identical to a polymer that can form the main structural component of a plastic material then the risk of the polymeric additive can not be regarded as evaluated by evaluation of the monomers. In such a case the polymeric additive should be risk assessed as regards its low molecular weight fraction below 1 000 Da and authorised before its use in the manufacture of plastic materials and articles.
- (16) In the past no clear differentiation has been made between additives that have a function in the final polymer and polymer production aids (PPA) that only exhibit a function in the manufacturing process and are not intended to be present in the final article. Some substances acting as PPA had already been included in the incomplete list of additives in the past. These PPA should remain in the Union list of authorised substances. However, it should be made clear that the use of other PPA will remain possible, subject to national law. That situation should be reassessed at a later stage.
- (17) The Union list contains substances authorised to be used in the manufacture of plastics. Substances such as acids, alcohols and phenols can also occur in form of salts. As the salts usually are transformed in the stomach to acid, alcohol or phenol the use of salts with cations that have undergone a safety evaluation should in principle be authorised together with the acid, alcohol or phenol. In certain cases, where the safety assessment indicates concerns on the use of the free acids, only the salts should be authorised by indicating in the list the name as '... acid(s), salts'.
- (18) Substances used in the manufacture of plastic materials or articles may contain impurities originating from their manufacturing or extraction process. These impurities are non-intentionally added together with the substance in the manufacture of the plastic material (non-intentionally added substance – NIAS). As far as they are relevant for the risk assessment the main impurities of a substance should be considered and if necessary be included in the specifications of a substance. However it is not possible to list and consider all impurities in the authorisation. Therefore they may be present in the material or article but not included in the Union list.
- (19) In the manufacture of polymers substances are used to initiate the polymerisation reaction such as catalysts and to control the polymerisation reaction such as chain transfer, chain extending or chain stop reagents. These aids to polymerisation are used in minute amounts and are not intended to remain in the final polymer. Therefore they should at this point of time not be subject to the authorisation procedure at EU level. Any potential health risk in the final material or article arising from their use should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment.
- (20) During the manufacture and use of plastic materials and articles reaction and degradation products can be formed. These reaction and degradation products are non-intentionally present in the plastic material (NIAS). As far as they are relevant for the risk assessment the main reaction and degradation products of the intended application of a substance should be considered and included in the restrictions of the substance. However it is not possible to list and consider all reaction and degradation products in the authorisation. Therefore they should not be listed as single entries in the Union list. Any potential health risk in the final material or article arising from reaction and degradation products should be assessed by the manufacturer in accordance with internationally recognised scientific principles on risk assessment.

- (21) Prior to the establishment of the Union list of additives, other additives than those authorised at EU level could be used in the manufacture of plastics. For those additives which were permitted in the Member States, the time limit for the submission of data for their safety evaluation by the Authority with a view to their inclusion in the Union list expired on 31 December 2006. Additives for which a valid application was submitted within this time limit were listed in a provisional list. For certain additives on the provisional list a decision on their authorisation at EU level has not yet been taken. For those additives, it should be possible to continue to be used in accordance with national law until their evaluation is completed and a decision is taken on their inclusion in the Union list.
- (22) When an additive included in the provisional list is inserted in the Union list or when it is decided not to include it in the Union list, that additive should be removed from the provisional list of additives.
- (23) New technologies engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles. These different properties may lead to different toxicological properties and therefore these substances should be assessed on a case-by-case basis by the Authority as regards their risk until more information is known about such new technology. Therefore it should be made clear that authorisations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles.
- (24) Based on the risk assessment the authorisation should if necessary set out specific migration limits to ensure the safety of the final material or article. If an additive that is authorised for the manufacture of plastic materials and articles is at the same time authorised as food additive or flavouring substance it should be ensured that the release of the substance does not change the composition of the food in an unacceptable way. Therefore the release of such a dual use additive or flavouring should not exhibit a technological function on the food unless such a function is intended and the food contact material complies with the requirements on active food contact materials set out in Regulation (EC) No 1935/2004 and Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food <sup>(1)</sup>. The requirements of Regulations (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives <sup>(2)</sup> or (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC <sup>(3)</sup> should be respected where applicable.
- (25) According to Article 3(1)(b) of Regulation (EC) No 1935/2004 the release of substances from food contact materials and articles should not bring about unacceptable changes in the composition of the food. According to good manufacturing practice it is feasible to manufacture plastic materials in such a way that they are not releasing more than 10 mg of substances per 1 dm<sup>2</sup> of surface area of the plastic material. If the risk assessment of an individual substance is not indicating a lower level, this level should be set as a generic limit for the inertness of a plastic material, the overall migration limit. In order to achieve comparable results in the verification of compliance with the overall migration limit, testing should be performed under standardised test conditions including testing time, temperature and test medium (food simulant) representing worst foreseeable conditions of use of the plastic material or article.
- (26) The overall migration limit of 10 mg per 1 dm<sup>2</sup> results for a cubic packaging containing 1 kg of food to a migration of 60 mg per kg food. For small packaging where the surface to volume ratio is higher the resulting migration into food is higher. For infants and small children which have a higher consumption of food per kilogram bodyweight than adults and do not yet have a diversified nutrition, special provisions should be set in order to limit the intake of substances migrating from food contact materials. In order to allow also for small volume packaging the same protection as for high volume packaging, the overall migration limit for food contact materials that are dedicated for packaging foods for infants and small children should be linked to the limit in food and not to the surface area of the packaging.
- (27) In recent years plastic food contact materials are being developed that do not only consist of one plastic but combine up to 15 different plastic layers to attain optimum functionality and protection of the food, while reducing packaging waste. In such a plastic multi-layer material or article, layers may be separated from the food by a functional barrier. This barrier is a layer within food contact materials or articles preventing the migration of substances from behind that barrier into the food. Behind a functional barrier, non-authorised substances may be used, provided

<sup>(1)</sup> OJ L 135, 30.5.2009, p. 3.

<sup>(2)</sup> OJ L 354, 31.12.2008, p. 16.

<sup>(3)</sup> OJ L 354, 31.12.2008, p. 34.

they fulfil certain criteria and their migration remains below a given detection limit. Taking into account foods for infants and other particularly susceptible persons, as well as the large analytical tolerance of the migration analysis, a maximum level of 0,01 mg/kg in food should be established for the migration of a non-authorised substance through a functional barrier. Substances that are mutagenic, carcinogenic or toxic to reproduction should not be used in food contact materials or articles without previous authorisation and should therefore not be covered by the functional barrier concept. New technologies that engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles, should be assessed on a case-by-case basis as regards their risk until more information is known about such new technology. Therefore, they should not be covered by the functional barrier concept.

(28) In recent years food contact materials and articles are being developed that consist of a combination of several materials to achieve optimum functionality and protection of the food while reducing packaging waste. In these multi-material multi-layer materials and articles plastic layers should comply with the same compositional requirements as plastic layers which are not combined with other materials. For plastic layers in a multi-material multi-layer which are separated from the food by a functional barrier the functional barrier concept should apply. As other materials are combined with the plastic layers and for these other materials specific measures are not yet adopted at EU level it is not yet possible to set out requirements for the final multi-material multi-layer materials and articles. Therefore specific migration limits and the overall migration limit should not be applicable except for vinyl chloride monomer for which such a restriction is already in place. In the absence of a specific measure at EU level covering the whole multi-material multi-layer material or article Member States may maintain or adopt national provisions for these materials and articles provided they comply with the rules of the Treaty.

(29) Article 16(1) of Regulation (EC) No 1935/2004 provides that materials and articles covered by specific measures be accompanied by a written declaration of compliance stating that they comply with the rules applicable to them. To strengthen the coordination and responsibility of the suppliers at each stage of manufacture, including that of the starting substances, the responsible persons should document the compliance with the relevant rules in a declaration of compliance which is made available to their customers.

(30) Coatings, printing inks and adhesives are not yet covered by a specific EU legislation and therefore not subject to the requirement of a declaration of compliance. However, for

coatings, printing inks and adhesives to be used in plastic materials and articles adequate information should be provided to the manufacturer of the final plastic article that would enable him to ensure compliance for substances for which migration limits have been established in this Regulation.

(31) Article 17(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety <sup>(1)</sup> requires the food business operator to verify that foods are compliant with the rules applicable to them. To this end and subject to the requirement of confidentiality, food business operators should be given access to the relevant information to enable them to ensure that the migration from the materials and articles to food complies with the specifications and restrictions laid down in food legislation.

(32) At each stage of manufacture, supporting documentation, substantiating the declaration of compliance, should be kept available for the enforcement authorities. Such demonstration of compliance may be based on migration testing. As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculations, including modelling, other analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing. Test results should be regarded as valid as long as formulations and processing conditions remain constant as part of a quality assurance system.

(33) When testing articles not yet in contact with food, for certain articles, such as films or lids, it is often not feasible to determine the surface area that is in contact with a defined volume of food. For these articles specific rules should be set out for verification of compliance.

(34) The setting of migration limits takes into account a conventional assumption that 1kg of food is consumed daily by a person of 60 kg bodyweight and that the food is packaged in a cubic container of 6 dm<sup>2</sup> surface area releasing the substance. For very small and very large containers the real surface area to volume of packaged food is varying a lot from the conventional assumption. Therefore, their surface area should be normalised before comparing testing results with migration limits. These rules should be reviewed when new data on food packaging uses become available.

<sup>(1)</sup> OJ L 31, 1.2.2002, p. 1.

- (35) The specific migration limit is a maximum permitted amount of a substance in food. This limit should ensure that the food contact material does not pose a risk to health. It should be ensured by the manufacturer that materials and articles not yet in contact with food will respect these limits when brought into contact with food under the worst foreseeable contact conditions. Therefore compliance of materials and articles not yet in contact with food should be assessed and the rules for this testing should be set out.
- (36) Food is a complex matrix and therefore the analysis of migrating substances in food may pose analytical difficulties. Therefore test media should be assigned that simulate the transfer of substances from the plastic material into food. They should represent the major physico-chemical properties exhibited by food. When using food simulants standard testing time and temperature should reproduce, as far as possible, the migration which may occur from the article into the food.
- (37) For determining the appropriate food simulant for certain foods the chemical composition and the physical properties of the food should be taken into account. Research results are available for certain representative foods comparing migration into food with migration into food simulants. On the basis of the results, food simulants should be assigned. In particular, for fat containing foods the result obtained with food simulant may in certain cases significantly overestimate migration into food. In these cases it should be foreseen that the result in food simulant is corrected by a reduction factor.
- (38) The exposure to substances migrating from food contact materials was based on the conventional assumption that a person consumes daily 1 kg of food. However, a person ingests at most 200 g of fat on a daily basis. For lipophilic substances that only migrate into fat this should be taken into consideration. Therefore a correction of the specific migration by a correction factor applicable to lipophilic substances in accordance with the opinion of the Scientific Committee on Food (SCF) <sup>(1)</sup> and the opinion of the Authority <sup>(2)</sup> should be foreseen.
- (39) Official control should establish testing strategies which allow the enforcement authorities to perform controls efficiently making best use of available resources. Therefore it should be admissible to use screening methods for checking compliance under certain conditions. Non-compliance of a material or article should be confirmed by a verification method.
- (40) Basic rules on migration testing should be set out in this Regulation. As migration testing is a very complex issue, these basic rules can, however, not cover all foreseeable cases and details necessary for performing the testing. Therefore a EU guidance document should be established, dealing with more detailed aspects of the implementation of the basic migration testing rules.
- (41) The updated rules on food simulants and migration testing provided by this Regulation will supersede those in Directive 78/142/EEC and the Annex to Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs <sup>(3)</sup>.
- (42) Substances present in the plastic but not listed in Annex I to this Regulation have not necessarily been risk assessed as they had not been subject to an authorisation procedure. Compliance with Article 3 of Regulation (EC) No 1935/2004 for these substances should be assessed by the relevant business operator in accordance with internationally recognised scientific principles taking into account exposure from food contact materials and other sources.
- (43) Recently additional monomers, other starting substances and additives have received a favourable scientific evaluation by the Authority and should now be added to the Union list.
- (44) As new substances are added to the Union list the Regulation should apply as soon as possible to allow for manufacturers to adapt to technical progress and allow for innovation.
- (45) Certain migration testing rules should be updated in view of new scientific knowledge. Enforcement authorities and industry need to adapt their current testing regime to these updated rules. To allow for this adaptation it seems appropriate that the updated rules only apply 2 years after the adoption of the Regulation.

<sup>(1)</sup> SCF opinion of 4 December 2002 on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials.

[http://ec.europa.eu/food/fs/sc/scf/out149\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out149_en.pdf)

<sup>(2)</sup> Opinion of the Scientific Panel on Food Additives, Flavours, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to the introduction of a Fat (consumption) Reduction Factor for infants and children, The EFSA Journal (2004) 103, 1-8.

<sup>(3)</sup> OJ L 297, 23.10.1982, p. 26.

(46) Business operators are currently basing their declaration of compliance on supporting documentation following the requirements set out in Directive 2002/72/EC. Declaration of compliance need, in principle, only to be updated when substantial changes in the production bring about changes in the migration or when new scientific data are available. In order to limit the burden to business operators, materials which have been lawfully placed on the market based on the requirements set out in Directive 2002/72/EC should be able to be placed on the market with a declaration of compliance based on supporting documentation in accordance with Directive 2002/72/EC until 5 years after the adoption of the Regulation.

(47) Analytical methods for testing migration and residual content of vinyl chloride monomer as described in Commission Directives 80/766/EEC of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs <sup>(1)</sup> and 81/432/EEC of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs <sup>(2)</sup> are outdated. Analytical methods should comply with the criteria set out in Article 11 of Regulation (EC) No 882/2004 <sup>(3)</sup> of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Therefore Directives 80/766/EEC and 81/432/EEC should be repealed.

(48) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

## 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.

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);

<sup>(1)</sup> OJ L 213, 16.8.1980, p. 42.

<sup>(2)</sup> OJ L 167, 24.6.1981, p. 6.

<sup>(3)</sup> OJ L 165, 30.4.2004, p. 1.

- (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;
- (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;
- (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 V to this Regulation;
- (17) 'restriction' means limitation of use of a substance or migration limit or limit of content of the substance in the material or article;
- (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.

#### 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.

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.

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

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:

- (a) salts (including double salts and acid salts) of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorised acids, phenols or alcohols;
- (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.

#### 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.

## 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).

2. For substances for which no specific migration limit or other restrictions are provided in Annex I, a generic specific migration limit of 60 mg/kg shall apply.

3. By derogation from paragraphs 1 and 2, 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.

## 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>).

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.

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

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

3. The migration of the substances under paragraph 2(b) into food or food simulant shall not be detectable measured with statistical certainty by a method of analysis set out in Article 11 of Regulation (EC) No 882/2004 with a limit of detection of 0,01 mg/kg. That limit shall always be expressed as concentration in foods or food simulants. That limit shall apply to a group of compounds, if they are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group, and shall include possible set-off transfer.

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>(1)</sup>;

(b) substances in nanoform.

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.

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.

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

## 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,

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:
  - (a) mg/kg using the actual content of the container for which the closure is intended or in 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, while taking into account the provisions of paragraph 2;
  - (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.
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 A, B, C, D1 and D2 as set out in Annex III in accordance with the rules set out in Chapter 3, Section 3.1 of Annex V.
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.
7. Before comparing specific and overall migration test results with the migration limits the correction factors in Chapter 4 of Annex V shall be applied in accordance with the rules set out therein.

## 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.'

## 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.

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

Done at Brussels, 14 January 2011.

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.

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.

For the Commission

The President

José Manuel BARROSO

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

## ANNEX I

## Substances

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

Table 1 contains the following information:

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

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

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

Column 4 (Substance Name): the chemical name

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

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

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

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

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

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

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

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

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

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)                                  |  |                                     |
| 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                      |             |                                       |  |                                     |

| (1) | (2)   | (3) | (4)   | (5) | (6) | (7) | (8) | (9) | (10)                           | (11) |
|-----|-------|-----|---|-----|-----|-----|-----|-----|--------------------------------|------|
| 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  |     |     |                                |      |
| 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  |     |                                |      |



| (1) | (2)   | (3) | (4)   | (5) | (6) | (7) | (8) | (9)  | (10) | (11) |
|-----|-------|-----|---|-----|-----|-----|-----|------|------|------|
| 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) |      |      |
| 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  |     |      |      |      |

| (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  |     |     |      |      |
| 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  |     |     |      |      |

| (1) | (2)   | (3) | (4)  | (5) | (6) | (7) | (8)  | (9)          | (10)   | (11) |
|-----|-------|-----|--|-----|-----|-----|------|--------------|--|------|
| 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  |      |              |  |      |
| 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).<br>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, γ-hydroxypropylated  | 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 should not exceed 5 % (w/w)  |      |
| 73  | 76866 | —   | polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropylene-glycol 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) |  |      |

| (1) | (2)   | (3) | (4)  | (5) | (6) | (7) | (8)  | (9) | (10)                | (11) |
|-----|-------|-----|--|-----|-----|-----|------|-----|---------------------|------|
| 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> ) dimethylpolysiloxane  | yes | no  | no  |      |     |                     |      |
| 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  |      |     |                     |      |
| 87  | 86285 | —   | silicon dioxide, silanated   | yes | no  | no  |      |     |                     |      |
| 88  | 86880 | —   | sodium monoalkyl dialkylphenoxybenzenedisulphonate   | yes | no  | no  | 9    |     |                     |      |
| 89  | 89440 | —   | stearic acid, esters with ethyleneglycol   | yes | no  | no  |      | (2) |                     |      |
| 90  | 92195 | —   | taurine, salts   | yes | no  | no  |      |     |                     |      |

| (1) | (2)   | (3) | (4)  | (5) | (6) | (7) | (8)  | (9) | (10)  | (11) |
|-----|-------|-----|--|-----|-----|-----|------|-----|---|------|
| 91  | 92320 | —   | tetradecyl-polyethyleneglycol<br>(EO = 3-8) ether of glycolic acid   | yes | no  | yes | 15   |     |   |      |
| 92  | 93970 | —   | tricyclodecanedimethanol<br>bis(hexahydrophthalate)  | yes | no  | no  | 0,05 |     |   |      |
| 93  | 95858 | —   | waxes, paraffinic, refined,<br>derived from petroleum based<br>or synthetic hydrocarbon<br>feedstocks, low viscosity | yes | no  | no  | 0,05 |     | Not to be used for articles<br>in contact with fatty foods<br>for which simulant D is laid<br>down.<br>Average molecular weight<br>not less than 350 Da.<br>Viscosity at 100 °C not less<br>than 2,5 cSt<br>( $2,5 \times 10^{-6} \text{ m}^2/\text{s}$ ).<br>Content of hydrocarbons<br>with Carbon number less<br>than 25, not more than<br>40 % (w/w). |      |
| 94  | 95859 | —   | waxes, refined, derived from<br>petroleum based or synthetic<br>hydrocarbon feedstocks, high<br>viscosity            | yes | no  | no  |      |     | Average molecular weight<br>not less than 500 Da.<br>Viscosity at 100 °C not less<br>than 11 cSt<br>( $11 \times 10^{-6} \text{ m}^2/\text{s}$ ).<br>Content of mineral hydro-<br>carbons with Carbon num-<br>ber less than 25, not more<br>than 5 % (w/w).   |      |
| 95  | 95883 | —   | white mineral oils, paraffinic,<br>derived from petroleum based<br>hydrocarbon feedstocks                            | yes | no  | no  |      |     | Average molecular weight<br>not less than 480 Da.<br>Viscosity at 100 °C not less<br>than 8,5 cSt<br>( $8,5 \times 10^{-6} \text{ m}^2/\text{s}$ ).<br>Content of mineral hydro-<br>carbons with Carbon num-<br>ber less than 25, not more<br>than 5 % (w/w).   |      |
| 96  | 95920 | —   | wood flour and fibers, untreated   | yes | no  | no  |      |     |   |      |



| (1) | (2)   | (3)                          | (4)                                | (5) | (6) | (7) | (8) | (9) | (10) | (11) |
|-----|-------|------------------------------|------------------------------------|-----|-----|-----|-----|-----|------|------|
| 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  |     |     |      |      |
| 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  |     |     |      |      |

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|------|
| 125 | 16950 | 0000074-85-1 | ethylene   | no  | yes | no  |      |      |   |      |
| 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) |   |      |
| 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                      | (1)  |
| 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 |              |  |     |     |     |      |      |   |      |



| (1) | (2)   | (3)          | (4)                              | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|----------------------------------|-----|-----|-----|------|------|--|------|
| 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) |  |      |
| 151 | 13480 | 0000080-05-7 | 2,2-bis(4-hydroxyphenyl) propane | no  | yes | no  | 0,6  |      |  |      |
|     | 13607 |              |                                  |     |     |     |      |      |  |      |
| 152 | 15610 | 0000080-07-9 | 4,4'-dichlorodiphenyl sulphone   | no  | yes | no  | 0,05 |      |  |      |
| 153 | 15267 | 0000080-08-0 | 4,4'-diaminodiphenyl sulphone    | no  | yes | no  | 5    |      |  |      |
| 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 |              |                                  |     |     |     |      |      |  |      |

[illegible]

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|--|------|
| 169 | 16240 | 0000091-97-4 | 3,3'-dimethyl-4,4'-diisocyanatobiphenyl       | 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  |      |      |  |      |
| 173 | 60240 | 0000094-13-3 | 4-hydroxybenzoic acid, propyl ester           | yes | no  | no  |      |      |  |      |
| 174 | 14740 | 0000095-48-7 | o-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.<br>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  | ND   |      |  |      |
| 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 | α-methylstyrene                               | no  | yes | no  | 0,05 |      |  |      |
| 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 | p-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  |      |      |  |      |

| (1) | (2)            | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|----------------|--------------|--|-----|-----|-----|------|------|--|------|
| 194 | 13150          | 0000100-51-6 | benzyl alcohol                                     | no  | yes | no  |      |      |  |      |
| 195 | 37360          | 0000100-52-7 | benzaldehyde                                       | yes | no  | no  |      |      |  | (3)  |
| 196 | 18670<br>59280 | 0000100-97-0 | hexamethylenetetramine                             | yes | yes | no  |      | (15) |  |      |
| 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 simulant D 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 |      |  | (1)  |
| 203 | 13323          | 0000102-40-9 | 1,3-bis(2-hydroxyethoxy) benzene                   | no  | yes | no  | 0,05 |      |  |      |
| 204 | 25180<br>92640 | 0000102-60-3 | N,N,N',N'-tetrakis(2-hydroxypropyl)ethylenediamine | yes | yes | no  |      |      |  |      |
| 205 | 25385          | 0000102-70-5 | triallamine  | 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<br>14880 | 0000105-08-8 | 1,4-bis(hydroxymethyl) cyclohexane                 | no  | yes | no  |      |      |  |      |

| (1) | (2)   | (3)          | (4)                                     | (5) | (6) | (7) | (8)  | (9)  | (10)                     | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|--------------------------|------|
| 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  |      |      |                          |      |
| 215 | 14170 | 0000106-31-0 | butyric anhydride                       | no  | yes | no  |      |      |                          |      |
| 216 | 14770 | 0000106-44-5 | p-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  |      |      |                          |      |
| 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 | m-cresol                                | no  | yes | no  |      |      |                          |      |

| (1) | (2)   | (3)          | (4)                           | (5) | (6) | (7) | (8)  | (9)  | (10) | (11) |
|-----|-------|--------------|-------------------------------|-----|-----|-----|------|------|------|------|
| 236 | 23050 | 0000108-45-2 | 1,3-phenylenediamine          | no  | yes | no  | ND   |      |      |      |
| 237 | 15910 | 0000108-46-3 | 1,3-dihydroxybenzene          | no  | yes | no  | 2,4  |      |      |      |
|     | 24072 |              |                               |     |     |     |      |      |      |      |
| 238 | 18070 | 0000108-55-4 | glutaric anhydride            | no  | yes | no  |      |      |      |      |
| 239 | 19975 | 0000108-78-1 | 2,4,6-triamino-1,3,5-triazine | yes | yes | no  | 30   |      |      |      |
|     | 25420 |              |                               |     |     |     |      |      |      |      |
|     | 93720 |              |                               |     |     |     |      |      |      |      |
| 240 | 45760 | 0000108-91-8 | cyclohexylamine               | yes | no  | no  |      |      |      |      |
| 241 | 22960 | 0000108-95-2 | phenol                        | no  | yes | no  |      |      |      |      |
| 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  |      |      |      |      |
| 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 | dipropyleneglycol             | yes | yes | no  |      |      |      |      |
|     | 16660 |              |                               |     |     |     |      |      |      |      |
|     | 51760 |              |                               |     |     |     |      |      |      |      |

| (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 simulant D 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 |              |                              |     |     |     |      |      |   |      |
| 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  |      |      |   |      |

[illegible]



| (1) | (2)   | (3)          | (4)                                  | (5) | (6) | (7) | (8)  | (9) | (10) | (11) |
|-----|-------|--------------|--------------------------------------|-----|-----|-----|------|-----|------|------|
| 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  |      |     |      |      |
| 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) |      |      |

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

| (1) | (2)   | (3)          | (4)                                | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|------------------------------------|-----|-----|-----|------|------|---|------|
| 340 | 47440 | 0000461-58-5 | dicyanodiamide                     | yes | no  | no  |      |      |   |      |
| 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 |      |   |      |
| 344 | 13810 | 0000505-65-7 | 1,4-butanediol formal              | no  | yes | no  | ND   |      |   | (10) |
|     | 21821 |              |                                    |     |     |     |      |      |   |      |
| 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  |      |      |   |      |
| 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 |      |   |      |

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|------|
| 362 | 14350 | 0000630-08-0 | carbon monoxide                                  | no  | yes | no  |      |      |   |      |
| 363 | 16450 | 0000646-06-0 | 1,3-dioxolane                                    | no  | yes | no  | 5    |      |   |      |
| 364 | 15404 | 0000652-67-5 | 1,4:3,6-dianhydrosorbitol                        | no  | yes | no  | 5    |      | Only to be used as a co-monomer in poly(ethylen-co-isosorbide terephthalate)  |      |
| 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 | 0000818-61-1 | acrylic acid, monoester with ethyleneglycol      | no  | yes | no  |      | (22) |   |      |
|     | 11830 |              |  |     |     |     |      |      |   |      |
| 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 |      |   |      |
| 376 | 66905 | 0000872-50-4 | N-methylpyrrolidone                              | yes | no  | no  |      |      |   |      |
| 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   |      |   |      |

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|--|------|
| 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. 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 |      |  | (1)  |
| 388 | 25080 | 0001120-36-1 | 1-tetradecene  | no  | yes | no  | 0,05 |      |  |      |
| 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) |  |      |
| 391 | 22932 | 0001187-93-5 | perfluoromethyl perfluorovinyl ether   | no  | yes | no  | 0,05 |      | Only to be used in anti-stick coatings   |      |
| 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  |      |      |  |      |
| 398 | 35760 | 0001309-64-4 | antimony trioxide  | yes | no  | no  | 0,04 |      | SML expressed as antimony  | (6)  |
| 399 | 81600 | 0001310-58-3 | potassium hydroxide  | yes | no  | no  |      |      |  |      |
| 400 | 86720 | 0001310-73-2 | sodium hydroxide   | yes | no  | no  |      |      |  |      |

| (1) | (2)   | (3)          | (4)                              | (5) | (6) | (7) | (8) | (9)  | (10)  | (11) |
|-----|-------|--------------|----------------------------------|-----|-----|-----|-----|------|---|------|
| 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  |     |      |   |      |
| 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  |     |      |   |      |
| 410 | 62720 | 0001332-58-7 | kaolin                           | yes | no  | no  |     |      |   |      |
| 411 | 42080 | 0001333-86-4 | carbon black                     | yes | no  | no  |     |      | <p>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.</p> <p>Toluene extractables: maximum 0,1 %, determined according to ISO method 6209.</p> <p>UV absorption of cyclohexane extract at 386 nm:<br/>&lt; 0,02 AU for a 1 cm cell<br/>or &lt; 0,1 AU for a 5 cm cell,<br/>determined according to a generally recognised method of analysis.</p> <p>Benzo(a)pyrene content:<br/>max 0,25 mg/kg carbon black.</p> <p>Maximum use level of carbon black in the polymer:<br/>2,5 % w/w.</p> |      |
| 412 | 45200 | 0001335-23-5 | copper iodide                    | yes | no  | no  |     | (6)  |   |      |
| 413 | 35600 | 0001336-21-6 | ammonium hydroxide               | yes | no  | no  |     |      |   |      |

| (1) | (2)            | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|----------------|--------------|---|-----|-----|-----|------|------|--|------|
| 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 |      |  |      |
| 421 | 13000          | 0001477-55-0 | 1,3-benzenedimethanamine  | no  | yes | no  | 0,05 |      |  |      |
| 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 |      |  |      |
| 425 | 10840          | 0001663-39-4 | acrylic acid, tert-butyl ester  | no  | yes | no  |      | (22) |  |      |
| 426 | 13510<br>13610 | 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 (1) |      |
| 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)  |

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|---|------|
| 438 | 38875 | 0002162-74-5 | bis(2,6-diisopropylphenyl)carbodiimide                                      | yes | no  | no  | 0,05 |      | For indirect food contact only, behind a PET layer  |      |
| 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 epoxygroup. 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) |   |      |
| 449 | 49840 | 0002500-88-1 | dioctadecyl disulphide  | yes | no  | yes | 3    |      |   |      |
| 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                                    |      |
| 452 | 38885 | 0002725-22-6 | 2,4-bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine | yes | no  | no  | 0,05 |      | Only to be used in aqueous foods  |      |
| 453 | 26320 | 0002768-02-7 | vinyltrimethoxysilane   | no  | yes | no  | 0,05 |      |   | (10) |
| 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-(dimethylamino)-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  |      |      |   |      |



| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|---|------|
| 459 | 46870 | 0003135-18-0 | 3,5-di-tert-butyl-4-hydroxybenzylphosphonic 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 |      |   | (1)  |
| 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) |   |      |
| 467 | 14800 | 0003724-65-0 | crotonic acid   | yes | yes | no  | 0,05 |      |   | (1)  |
|     | 45600 |              |   |     |     |     |      |      |   |      |
| 468 | 71960 | 0003825-26-1 | perfluorooctanoic acid, ammonium salt                               | yes | no  | no  |      |      | Only to be used in repeated use articles, sintered at high temperatures |      |
| 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. 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 expressed as isocyanate moiety                 | (10) |

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|------|
| 476 | 16570 | 0004128-73-8 | diphenylether-4,4'-diisocyanate  | no  | yes | no  |      | (17) | 1 mg/kg in final product 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        | (1)  |
| 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    |      |   |      |
| 496 | 71680 | 0006683-19-8 | pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate] | yes | no  | no  |      |      |   |      |

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|------|--|------|
| 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 |      |  | (1)  |
| 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) |  |      |
| 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  |      |      |  |      |

| (1) | (2)   | (3)          | (4)                     | (5) | (6) | (7) | (8)         | (9)  | (10)   | (11) |
|-----|-------|--------------|-------------------------|-----|-----|-----|-------------|------|--|------|
| 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  |             |      |  |      |
| 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 gas-kets 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. Oxirane < 8 %, iodine number < 6. |      |

| (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  |      |     |  |      |
| 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 (*) |      |

| (1) | (2)   | (3)          | (4)                                       | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|-----|-----|---|------|
| 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  |     |     |   |      |
| 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 |              |   |     |     |     |     |     |   |      |
| 575 | 76721 | 0063148-62-9 | polydimethylsiloxane (Mw > 6 800 Da)      | yes | no  | no  |     |     | Viscosity at 25 °C not less than 100 cSt (100 × 10 <sup>-6</sup> m <sup>2</sup> /s) |      |

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8) | (9)  | (10)   | (11) |
|-----|-------|--------------|---|-----|-----|-----|-----|------|--|------|
| 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. 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  |     |      |  |      |
| 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  |     |      |  |      |

| (1) | (2)   | (3)                          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|------------------------------|---|-----|-----|-----|------|------|--|------|
| 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  |      |      |  |      |
| 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) |  |      |
| 620 | 50720 | 0015571-60-5                 | di-n-octyltin dimaleate   | yes | no  | no  |      | (10) |  |      |



| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|------|
| 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   |      |   |      |
| 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 simulant D 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 |      |   |      |

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)   | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|--|------|
| 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 |      |  | (10) |
| 642 | 64990 | 0025736-61-2 | maleic anhydride-styrene, copolymer, sodium salt   | yes | no  | no  |      |      | The fraction with molecular weight below 1 000 Da should not exceed 0,05 % (w/w) |      |
| 643 | 87760 | 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) |  |      |
| 647 | 56720 | 0026402-23-3 | glycerol monohexanoate   | yes | no  | no  |      |      |  |      |
| 648 | 56880 | 0026402-26-6 | glycerol mono-octanoate  | yes | no  | no  |      |      |  |      |
| 649 | 47210 | 0026427-07-6 | dibutylthiostannic acid polymer  | yes | no  | no  |      |      | Molecular unit = $(C_8H_{18}S_3Sn_2)_n$ (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 |      |  |      |

| (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-hydroxyphenol) ethane  | no  | yes | no  | 0,005 |              | Only to be used in polycarbonates   | (1)  |
| 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 monobenhenate  | 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 should not exceed 0,5 % (w/w) |      |
| 673 | 53670 | 0032509-66-3 | ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]                  | yes | no  | yes | 6     |              |   |      |
| 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     |              |   |      |

| (1) | (2)            | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9) | (10)  | (11) |
|-----|----------------|--------------|---|-----|-----|-----|------|-----|---|------|
| 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. |      |
| 686 | 61390          | 0037353-59-6 | hydroxymethylcellulose  | yes | no  | no  |      |     |   |      |
| 687 | 13530<br>13614 | 0038103-06-9 | 2,2-bis(4-hydroxyphenyl) propane bis(phthalic anhydride)                                    | no  | yes | no  | 0,05 |     |   |      |
| 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  |      |     |   |      |

| (1) | (2)       | (3)          | (4)   | (5) | (6) | (7) | (8) | (9)  | (10) | (11) |
|-----|-----------|--------------|---|-----|-----|-----|-----|------|------|------|
| 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)  |      |      |
| 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 | 0061788-89-4 | acids, fatty, unsaturated (C <sub>18</sub> ), dimers, non hydrogenated, distilled and non-distilled | no  | yes | no  |     | (18) |      | (1)  |
|     | 10599/91  |              |   |     |     |     |     |      |      |      |
| 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  |      |      |      |
| 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  |     |      |      |      |

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8) | (9)  | (10)   | (11) |
|-----|-------|--------------|--|-----|-----|-----|-----|------|--|------|
| 713 | 43480 | 0064365-11-3 | charcoal, activated  | yes | no  | no  |     |      | Only for use in PET at maximum 10 mg/kg of polymer.<br>Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC <sup>(4)</sup> with exception of ash content which can be up to 10 % (w/w). |      |
| 714 | 84400 | 0064365-17-9 | rosin, hydrogenated, ester with pentaerythritol  | yes | no  | no  |     |      |  |      |
| 715 | 46880 | 0065140-91-2 | 3,5-di-tert-butyl-4-hydroxybenzylphosphonic 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-carboxymethylammonium chloride, sodium salt -octadecyl methacrylate-ethyl methacrylate-cyclohexyl methacrylate-N-vinyl-2-pyrrolidone, copolymers | yes | no  | no  |     |      |  |      |
| 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  |     |      |  |      |

| (1) | (2)   | (3)                          | (4)  | (5) | (6) | (7) | (8)  | (9)          | (10)  | (11) |
|-----|-------|------------------------------|--|-----|-----|-----|------|--------------|---|------|
| 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>  |      |
| 725 | 77895 | 0068439-49-6                 | polyethyleneglycol (EO = 2-6) monoalkyl (C <sub>16</sub> -C <sub>18</sub> ) ether  | yes | no  | no  | 0,05 |              | The composition of this mixture is as follows:<br>— polyethyleneglycol (EO = 2-6) monoalkyl (C <sub>16</sub> -C <sub>18</sub> ) ether (approximately 28 %),<br>— fatty alcohols (C <sub>16</sub> -C <sub>18</sub> ) (approximately 48 %),<br>— ethyleneglycol monoalkyl (C <sub>16</sub> -C <sub>18</sub> ) ether (approximately 24 %),   |      |
| 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  |      |              |   |      |
| 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)  |

| (1) | (2)                   | (3)                          | (4)   | (5) | (6) | (7) | (8)  | (9)          | (10)  | (11) |
|-----|-----------------------|------------------------------|---|-----|-----|-----|------|--------------|---|------|
| 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)  |
| 730 | 66930                 | 0068554-70-1                 | methylsilsesquioxane  | yes | no  | no  |      |              | Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane  |      |
| 731 | 18220                 | 0068564-88-5                 | N-heptylaminoundecanoic acid  | no  | yes | no  | 0,05 |              |   | (2)  |
| 732 | 45450                 | 0068610-51-5                 | p-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)hydroxymethylphosphonate   | yes | no  | no  | 0,6  |              |   |      |
| 736 | 50960                 | 0069226-44-4                 | di-n-octyltin ethyleneglycol bis-(mercaptoacetate)  | yes | no  | no  |      | (10)         |   |      |



| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|-----|-----|---|------|
| 737 | 77370 | 0070142-34-6 | polyethyleneglycol-30<br>dipolyhydroxystearate   | yes | no  | no  |     |     |   |      |
| 738 | 60320 | 0070321-86-7 | 2-[2-hydroxy-3,5-bis(1,1-<br>dimethylbenzyl)phenyl]<br>benzotriazole   | yes | no  | yes | 1,5 |     |   |      |
| 739 | 70000 | 0070331-94-1 | 2,2'-oxamidobis[ethyl-3-(3,5-<br>di-tert-butyl-4-hydroxyphenyl)-<br>propionate]  | yes | no  | no  |     |     |   |      |
| 740 | 81200 | 0071878-19-8 | poly[6-[(1,1,3,3-<br>tetramethylbutyl)amino]-1,3,5-<br>triazine-2,4-diyl]-[(2,2,6,6-<br>tetramethyl-4-piperidyl)imino]<br>hexamethylene[(2,2,6,6-<br>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-<br>epoxypropyl)-7-oxa-3,20-<br>diazadispiro-[5.1.11.2]-<br>heneicosan-21-one, polymer   | yes | no  | yes | 5   |     |   |      |
| 743 | 38950 | 0079072-96-1 | bis(4-ethylbenzylidene)sorbitol  | yes | no  | no  |     |     |   |      |
| 744 | 18888 | 0080181-31-3 | 3-hydroxybutanoic<br>acid-3-hydroxypentanoic acid,<br>copolymer  | no  | yes | no  |     |     | The substance is used as<br>product obtained by<br>bacterial fermentation. In<br>compliance with the<br>specifications mentioned in<br>the Table 4 of Annex 1 |      |
| 745 | 68145 | 0080410-33-9 | 2,2',2'-nitrilo(triethyl<br>tris(3,3',5,5'-tetra-tert-<br>butyl-1,1'-bi-phenyl-2,2'-<br>diyl)phosphite)  | yes | no  | yes | 5   |     | SML expressed as sum of<br>phosphite and phosphate  |      |
| 746 | 38810 | 0080693-00-1 | bis(2,6-di-tert-butyl-4-<br>methylphenyl)pentacrythritol<br>diphosphite  | yes | no  | yes | 5   |     | SML expressed as sum of<br>phosphite and phosphate  |      |

| (1) | (2)   | (3)   | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10) | (11) |
|-----|-------|---|---|-----|-----|-----|------|------|------|------|
| 747 | 47600 | 0084030-61-5  | di-n-dodecyltin bis(isooctyl mercaptoacetate)                 | yes | no  | yes |      | (25) |      |      |
| 748 | 12765 | 0084434-12-8  | N-(2-aminoethyl)- $\beta$ -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  |      |      |      |      |
| 752 | 39890 | 0087826-41 –<br>30069158-41 –<br>40054686-97 –<br>40081541-12-0 | bis(methylbenzylidene)sorbitol                                | yes | no  | no  |      |      |      |      |
| 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    |      |      |      |

| (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> |      |

| (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). 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 simulant D 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 |     |  |      |
| 771 | 34650 | 0151841-65-5 | aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert-butylphenyl) phosphate]  | yes | no  | no  | 5    |     |  |      |

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|------|---|------|
| 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-diphosphite   | 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 should 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 |      |   | (1)  |
| 780 | 81220 | 0192268-64-7 | poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]-1,3,5-triazine-2,4-diyl][(2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanediyl[(2,2,6,6-tetramethyl-4-piperidinyl)imino]]-α-[N,N,N',N'-tetrabutyl-N''-(2,2,6,6-tetramethyl-4-piperidinyl)-N''-[6-(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl]-[1,3,5-triazine-2,4,6-triamine]-ω-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine] | yes | no  | no  | 5    |      |   |      |

| (1) | (2)   | (3)                          | (4)  | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11)        |
|-----|-------|------------------------------|--|-----|-----|-----|------|------|---|-------------|
| 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 should not exceed 1 % (w/w)   |             |
| 783 | 55910 | 0736150-63-3                 | glycerides, castor-oil mono-, hydrogenated, acetates   | yes | no  | no  |      | (32) |   |             |
| 784 | 95420 | 0745070-61-5                 | 1,3,5-tris (2,2-dimethylpropanamido) benzene   | yes | no  | no  | 0,05 |      |   |             |
| 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) |
| 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. 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-methylen-[(2,2,6,6-tetramethyl-4-piperidyl)imino]           | yes | no  | no  | 5    |      | Average molecular weight not less than 2 400 Da. 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)        |

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)          | (10)  | (11)        |
|-----|-------|--------------|---|-----|-----|-----|------|--------------|---|-------------|
| 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  |      |              | For indirect food contact only, behind a PET layer  |             |
| 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  |             |
| 797 | 76807 | 0007328-26-5 | polyester of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol   | yes | no  | yes |      | (31)<br>(32) |   |             |
| 798 | 92200 | 0006422-86-2 | terephthalic acid, bis(2-ethylhexyl)ester   | yes | no  | no  | 60   | (32)         |   |             |
| 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 purity criteria for ethylene oxide as laid down in Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ L 253, 20.9.2008, p. 1) |             |
| 800 | 94425 | 0000867-13-0 | triethyl phosphonoacetate   | yes | no  | no  |      |              | Only for use in PET   |             |

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|--------------|--|-----|-----|-----|-----|-----|---|------|
| 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 simulant D is laid down.<br>Not to be used in contact with alcoholic foods.   | (13) |
| 804 | 80510 | 1010121-89-7 | poly(3-nonyl-1,1-dioxo-1-thiopropene-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic 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-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]   | yes | no  | no  |     |     | The content of the surface treatment copolymer of the coated titanium dioxide is less than 1 % w/w  |      |
| 806 | 14876 | 0001076-97-7 | 1,4-cyclohexanedicarboxylic acid   | no  | yes | no  | 5   |     | Only to be used for manufacture of polyesters   |      |
| 807 | 93485 | —            | titanium nitride, nanoparticles  | yes | no  | no  |     |     | No migration of titanium nitride nanoparticles.<br>Only to be used in PET bottles 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. |      |
| 808 | 38550 | 0882073-43-0 | bis(4-propylbenzylidene) propylsorbitol  | yes | no  | no  | 5   |     | SML including the sum of its hydrolysis products  |      |



| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9)  | (10)  | (11)                |
|-----|-------|--------------|---|-----|-----|-----|------|------|---|---------------------|
| 809 | 49080 | 0852282-89-4 | N-(2,6-diisopropylphenyl)-6-[4-(1,1,3,3-tetramethylbutyl)phenoxy]-1H-benzo[de]isoquinolin-1,3(2H)-dione | yes | no  | yes | 0,05 |      | Only 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 simulant D is laid down.  |                     |
| 811 | 80077 | 0068441-17-8 | polyethylene waxes, oxidised  | yes | no  | no  | 60   |      |   |                     |
| 812 | 80350 | 0124578-12-7 | poly(12-hydroxystearic acid)-polyethyleneimine copolymer  | yes | no  | no  |      |      | Only to be used in polyethylene terephthalate (PET), polystyrene (PS), high impact polystyrene (HIPS) and polyamide (PA) up to 0,1 % w/w.<br>Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine. |                     |
| 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 simulant D 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    |      |   |                     |

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8)  | (9) | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|------|-----|---|------|
| 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 simulant D is laid down.<br>SML expressed as neodecanoic acid.            |      |
| 820 | 76420 | —            | pimelic acid, salts   | yes | no  | no  |      |     |   |      |
| 821 | 90810 | —            | stearoyl-2-lactylic acid, salts   | yes | no  | no  |      |     |   |      |
| 822 | 71938 | —            | perchloric acid, salts  | yes | no  | no  | 0,05 |     |   | (4)  |
| 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 |      |
| 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                                   |      |
| 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 for use as a co-monomer for ethyl vinyl alcohol copolymers.  |      |

| (1) | (2)   | (3)          | (4)   | (5) | (6) | (7) | (8) | (9) | (10)  | (11) |
|-----|-------|--------------|---|-----|-----|-----|-----|-----|---|------|
| 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 |      |
| 865 | 40619 | 0025322-99-0 | (butyl acrylate, methyl methacrylate, butyl methacrylate) copolymer   | yes | no  | no  |     |     | Only to be used in rigid poly(vinyl chloride) (PVC) at a maximum level of 1 %                                 |      |
| 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 rigid poly(vinyl chloride) (PVC) at a maximum level of 2 %                                 |      |
| 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   |     |   |      |
| 875 | 80345 | 0058128-22-6 | poly(12-hydroxystearic acid) stearate   | yes | no  | yes | 5   |     |   |      |
| 878 | 31335 | —            | acids, fatty (C <sub>8</sub> -C <sub>22</sub> ) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C <sub>3</sub> -C <sub>22</sub> ) | yes | no  | no  |     |     |   |      |
| 879 | 31336 | —            | acids, fatty (C <sub>8</sub> -C <sub>22</sub> ) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C <sub>1</sub> -C <sub>22</sub> )  | yes | no  | no  |     |     |   |      |

| (1) | (2)   | (3)          | (4)  | (5) | (6) | (7) | (8)  | (9) | (10)   | (11) |
|-----|-------|--------------|--|-----|-----|-----|------|-----|--|------|
| 880 | 31348 | 0085116-93-4 | 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 repeated use articles for long term storage at room temperature or below and hotfill  |      |
| 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 simulant D 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. |      |

(<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.

(<sup>4</sup>) OJ L 226, 22.9.1995, p. 1.

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

## 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                       | 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                       |

| (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  |
| 14  | 294<br>368   | 5     | expressed as the sum of the substances  |
| 15  | 98<br>196  | 15    | expressed as formaldehyde   |
| 16  | 407<br>583<br>584<br>599   | 6     | expressed as boron<br>Without prejudice to the provisions of Directive 98/83/EC |
| 17  | 4<br>167<br>169<br>198<br>274<br>354<br>372<br>460<br>461<br>475<br>476<br>485<br>490<br>653 | ND    | expressed as isocyanate moiety  |
| 18  | 705<br>733   | 0,05  | expressed as the sum of the substances  |
| 19  | 505<br>516<br>519  | 10    | expressed as SO <sub>2</sub>  |
| 20  | 290<br>386<br>390  | 30    | expressed as the sum of the substances  |
| 21  | 347<br>349   | 5     | expressed as trimellitic acid   |

| (1) | (2)  | (3)  | (4)   |
|-----|--|------|---|
| 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   |
| 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   |
| 30  | 254<br>672   | 5    | expressed as 1,4-butanediol   |
| 31  | 73<br>797  | 30   | expressed as the sum of the substances  |
| 32  | 8<br>72<br>73<br>138<br>140<br>157<br>159<br>207<br>242<br>283<br>532<br>670<br>728<br>729<br>775<br>783<br>797<br>798<br>810<br>815 | 60   | expressed as the sum of the substances  |

### 3. Notes on verification of compliance

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

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

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

Table 3

| (1)     | (2)  |
|---------|--|
| 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. |
| (4)     | Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.   |
| (5)     | Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D2 (unstable).  |
| (6)     | Migration limit might be exceeded at very high temperature.  |
| (7)     | If testing in food is performed, Annex V 1.4 shall be taken into account.  |
| (8)     | Verification of compliance by residual content per food contact surface area (QMA); QMA = 0,005 mg/6 dm <sup>2</sup> .   |
| (9)     | Verification of compliance by residual content per food contact surface area (QMA) pending the availability of analytical method for migration testing. The ratio surface to quantity of food shall be lower than 2dm <sup>2</sup> /kg.      |
| (10)    | Verification of compliance by residual content per food contact surface area (QMA) in case of reaction with food or simulant.  |
| (11)    | Only a method of analysis for the determination of the residual monomer in the treated filler is available.  |
| (12)    | There is a risk that the SML could be exceeded from polyolefins.   |
| (13)    | Only a method for determination of the content in polymer and a method for determination of the starting substances in food simulants are available.   |
| (14)    | There is a risk that the SML could be exceeded from plastics containing more than 0,5 % w/w of the substance.  |
| (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   |

### 4. Detailed specification on substances

Table 4 on detailed specifications on substances contains the following information

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

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



Table 4

| (1)              | (2)                                      |  |
|------------------|--|--|
| FCM substance No | Detailed specification on the substance  |  |
| 744              | Definition                               | The copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wildtype organism <i>Alcaligenes eutrophus</i> strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications |
|                  | Chemical name                            | Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)  |
|                  | CAS number                               | 0080181-31-3   |
|                  | Structural formula                       | $  \begin{array}{ccccccc}  & & & & \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>   |
|                  | Average molecular weight                 | Not less than 150 000 Daltons (measured by gel permeation chromatography)  |
|                  | Assay                                    | Not less than 98 % poly(3-D-hydroxybutanoate-co-3-D-hydroxy-pentanoate) analysed after hydrolysis as a mixture of 3-D-hydro-xybutanoic and 3-D-hydroxypentanoic acids  |
|                  | Description                              | White to off-white powder after isolation  |
|                  | Characteristics<br>Identification tests: |  |
|                  | Solubility                               | Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water  |
|                  | Restriction                              | QMA for crotonic acid is 0,05 mg/6 dm <sup>2</sup>   |
|                  | Purity                                   | Prior to granulation the raw material copolymer powder must contain:   |
|                  | — nitrogen,                              | Not more than 2 500 mg/kg of plastic   |
|                  | — zinc,                                  | Not more than 100 mg/kg of plastic   |
|                  | — copper,                                | Not more than 5 mg/kg of plastic   |
|                  | — lead,                                  | Not more than 2 mg/kg of plastic   |
|                  | — arsenic,                               | Not more than 1 mg/kg of plastic   |
|                  | — chromium,                              | Not more than 1 mg/kg of plastic   |

## ANNEX II

**Restrictions on materials and articles**

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

Barium = 1 mg/kg food or food simulant.

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

Copper = 5 mg/kg food or food simulant.

Iron = 48 mg/kg food or food simulant.

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

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

Zinc = 25 mg/kg food or food simulant.

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

## ANNEX III

## Food simulants

## 1. Food simulants

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

Table 1

List of food simulants

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

(\*) This may be any vegetable oil with a fatty acid distribution of

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

## 2. General assignment of food simulants to foods

Food simulants A, B and C are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances. Food simulant B shall be used for those foods which have a pH below 4.5. Food simulant C shall be used for alcoholic foods with an alcohol content of up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic.

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

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

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

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

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

Table 2 contains the following information:

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

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

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

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

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

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

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

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

Table 2  
food category specific assignment of food simulants

| (1)              | (2)   | (3)            |      |   |    |    |   |
|------------------|---|----------------|------|---|----|----|---|
| Reference number | Description of food   | 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><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<br><br>B. cloudy drinks:<br><br>juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate |                | X(*) | X |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |
|                  |   |                |      |   |    |    |   |

| (1)              | (2)  | (3)            |      |   |    |     |   |
|------------------|--|----------------|------|---|----|-----|---|
| Reference number | Description of food  | Food simulants |      |   |    |     |   |
|                  |  | A              | B    | C | D1 | D2  | E |
| 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</b>   |                |      |   |    |     |   |
|                  | <b>Confectionery products</b>  |                |      |   |    |     |   |
| 03.01            | Chocolate, chocolate-coated products, substitutes and products coated with substitutes                                       |                |      |   |    | X/3 |   |
| 03.02            | Confectionery products:  |                |      |   |    |     |   |
|                  | A. In solid form:  |                |      |   |    |     |   |
|                  | I. With fatty substances on the surface  |                |      |   |    | X/3 |   |
|                  | II. Other  |                |      |   |    |     | X |
|                  | B. In paste form:  |                |      |   |    |     |   |
|                  | I. With fatty substances on the surface  |                |      |   |    | X/2 |   |
|                  | II. Moist  |                |      | X |    |     |   |
| 03.03            | Sugar and sugar products   |                |      |   |    |     |   |
|                  | A. In solid form: crystal or powder  |                |      |   |    |     | X |
|                  | B. Molasses, sugar syrups, honey and the like  | X              |      |   |    |     |   |
| 04               | <b>Fruit, vegetables and products thereof</b>  |                |      |   |    |     |   |
| 04.01            | Whole fruit, fresh or chilled, unpeeled  |                |      |   |    |     |   |
| 04.02            | Processed fruit:   |                |      |   |    |     |   |
|                  | A. Dried or dehydrated fruits, whole, sliced, flour or powder  |                |      |   |    |     | X |
|                  | B. Fruit in the form of purée, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products) |                | X(*) | X |    |     |   |
|                  | C. Fruit preserved in a liquid medium:   |                |      |   |    |     |   |
|                  | I. In an oily medium   |                |      |   |    | X   |   |
|                  | II. In an alcoholic medium   |                |      |   | X  |     |   |
| 04.03            | Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):   |                |      |   |    |     |   |
|                  | A. Shelled, dried, flaked or powdered  |                |      |   |    |     | X |
|                  | B. Shelled and roasted   |                |      |   |    |     | X |
|                  | C. In paste or cream form  | X              |      |   |    | X   |   |

| (1)              | (2)   | (3)            |      |   |    |         |   |
|------------------|---|----------------|------|---|----|---------|---|
| Reference number | Description of food   | Food simulants |      |   |    |         |   |
|                  |   | A              | B    | C | D1 | D2      | E |
| 04.04            | Whole vegetables, fresh or chilled, unpeeled  |                |      |   |    |         |   |
| 04.05            | Processed vegetables:   |                |      |   |    |         |   |
|                  | A. Dried or dehydrated vegetables whole, sliced or in the form of flour or powder                                   |                |      |   |    |         | X |
|                  | B. Fresh vegetables, peeled or cut  | X              |      |   |    |         |   |
|                  | 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  |         |   |
| 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)   |                |      |   |    |         |   |
|                  | 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  |         |   |

| (1)              | (2)   | (3)            |      |   |    |         |   |
|------------------|---|----------------|------|---|----|---------|---|
| Reference number | Description of food   | Food simulants |      |   |    |         |   |
|                  |   | A              | B    | C | D1 | D2      | E |
| 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  |         |   |
| 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. 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(**) |   |

| (1)              | (2)   | (3)            |      |   |    |     |   |
|------------------|---|----------------|------|---|----|-----|---|
| Reference number | Description of food   | Food simulants |      |   |    |     |   |
|                  |   | A              | B    | C | D1 | D2  | E |
| 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   |   |

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

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

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

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

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

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

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



## ANNEX IV

**Declaration of compliance**

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

- (1) the identity and address of the business operator issuing the declaration of compliance;
  - (2) the identity and address of the business operator which manufactures or imports the plastic materials or articles or products from intermediate stages of their manufacturing or the substances intended for the manufacturing of those materials and articles;
  - (3) the identity of the materials, the articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;
  - (4) the date of the declaration;
  - (5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) No 1935/2004;
  - (6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to this Regulation to allow the downstream business operators to ensure compliance with those restrictions;
  - (7) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60/EC, 95/45/EC and 2008/84/EC to enable the user of these materials or articles to comply with the relevant EU provisions or, in their absence, with national provisions applicable to food;
  - (8) specifications on the use of the material or article, such as:
    - (i) type or types of food with which it is intended to be put in contact;
    - (ii) time and temperature of treatment and storage in contact with the food;
    - (iii) ratio of food contact surface area to volume used to establish the compliance of the material or article;
  - (9) when a functional barrier is used in a multi-layer material or article, the confirmation that the material or article complies with the requirements of Article 13(2), (3) and (4) or Article 14(2) and (3) of this Regulation.
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## ANNEX V

**COMPLIANCE TESTING**

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

## CHAPTER 1

*Testing for specific migration of materials and articles already in contact with food***1.1. Sample preparation**

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

**1.2. Conditions of testing**

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

**1.3. Analysis of migrated substances**

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

**1.4. Special cases**

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

## CHAPTER 2

*Testing for specific migration of materials and articles not yet in contact with food***2.1. Verification method**

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

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

**2.1.1. Sample preparation**

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

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

2.1.2. *Choice of food simulant*

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

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

2.1.3. *Conditions of contact when using food simulants*

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

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

Table 1  
Contact time

| Contact time in worst foreseeable use       | Test time               |
|---|-------------------------|
| $t \leq 5 \text{ min}$                      | 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 |

Table 2  
Contact temperature

| Conditions of contact in worst foreseeable use                       | Test conditions   |
|--|---|
| Contact temperature  | Test temperature  |
| $T \leq 5 \text{ }^{\circ}\text{C}$                                  | 5 $^{\circ}\text{C}$  |
| $5 \text{ }^{\circ}\text{C} < T \leq 20 \text{ }^{\circ}\text{C}$    | 20 $^{\circ}\text{C}$   |
| $20 \text{ }^{\circ}\text{C} < T \leq 40 \text{ }^{\circ}\text{C}$   | 40 $^{\circ}\text{C}$   |
| $40 \text{ }^{\circ}\text{C} < T \leq 70 \text{ }^{\circ}\text{C}$   | 70 $^{\circ}\text{C}$   |
| $70 \text{ }^{\circ}\text{C} < T \leq 100 \text{ }^{\circ}\text{C}$  | 100 $^{\circ}\text{C}$ or reflux temperature                                      |
| $100 \text{ }^{\circ}\text{C} < T \leq 121 \text{ }^{\circ}\text{C}$ | 121 $^{\circ}\text{C}$ (*)  |
| $121 \text{ }^{\circ}\text{C} < T \leq 130 \text{ }^{\circ}\text{C}$ | 130 $^{\circ}\text{C}$ (*)  |
| $130 \text{ }^{\circ}\text{C} < T \leq 150 \text{ }^{\circ}\text{C}$ | 150 $^{\circ}\text{C}$ (*)  |
| $150 \text{ }^{\circ}\text{C} < T < 175 \text{ }^{\circ}\text{C}$    | 175 $^{\circ}\text{C}$ (*)  |
| $T > 175 \text{ }^{\circ}\text{C}$                                   | Adjust the temperature to the real temperature at the interface with the food (*) |

(\*) 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  $^{\circ}\text{C}$  or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.

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

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

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

$E_a$  is the worst case activation energy 80kJ/mol

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

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

$t_1$  is the contact time

$t_2$  is the testing time

$T_1$  is the contact temperature in Kelvin. For room temperature storage this is set at 298 K (25 °C). For refrigerated and frozen conditions it is set at 278 K (5 °C).

$T_2$  is the testing temperature in Kelvin.

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

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

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

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

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

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

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

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

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

#### 2.1.6. *Repeated use articles*

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

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

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

#### 2.1.7. *Analysis of migrating substances*

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

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

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

### 2.2. **Screening approaches**

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

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

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

#### 2.2.2. *Residual content*

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

#### 2.2.3. *Migration modelling*

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

#### 2.2.4. *Food simulant substitutes*

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

## CHAPTER 3

### ***Testing for overall migration***

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

#### 3.1. **Standardised testing conditions**

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

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

Table 3

**Standardised testing conditions**

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

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

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

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

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

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

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

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

### 3.3. Repeated use articles

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

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

### 3.4. Screening approaches

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

#### 3.4.1. Residual content

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

#### 3.4.2. Food simulant substitutes

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

## CHAPTER 4

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

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

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

The FRF shall be applied according to the following rules.

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

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

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

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

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

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

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

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

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

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



## ANNEX VI

## Correlation tables

| 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         |

