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

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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[(1)], 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[(2)].

(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.

(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[3] 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.

(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[(4)]. The requirements of Regulations (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives[(5)] 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[(6)] 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^2 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^2 results for a cubic packaging containing 1kg 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 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[7] 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^2 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.

(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)[8] and the opinion of the Authority[9] 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[10].

(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.

(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[11] 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[12] are outdated. Analytical methods should comply with the criteria set out in Article 11 of Regulation (EC) No 882/2004[13] 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);

(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[(14)]; 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.

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^2 of food contact surface (mg/dm^2).

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[(15)] and 2006/125/EC[(16)], 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.

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[17];

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.

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^2 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^2 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^2 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[(18)] 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.

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.

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.

For the Commission

The President

José Manuel BARROSO

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	026630-43-7	albumin	no	yes	no				
2	12340	—	albumin, coagulated by formaldehyde	no	yes	no				
3	12375	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{22})	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)

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

5	25360	—	trialkyl(C_{13}-C_{15})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_7-C_{17}), 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_2-C_{24}, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			esters (branched fatty acids at naturally occuring levels are included)						
10	30612	—	acids, C_2-C_{24}, aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	yes	no	no			
11	30960	—	acids, aliphatic, monocarboxylic (C_6-C_{22}), 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,	yes	no	no			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			saturated, linear, primary (C_4-C_{24})							
14	33801	—	n-alkyl(C_{10}-C_{13})benzenesulphonic acid	yes	no	no	30			
15	34130	—	alkyl, linear with even number of carbon atoms (C_{12}-C_{20}) dimethylamines	yes	no	yes	30			
16	34230	—	alkyl(C_8-C_{22})sulphonic acids	yes	no	no	6			
17	34281	—	alkyl(C_8-C_{22})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-	yes	no	no		(7)		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			hydroxyethyl)alkyl(C_8-C_{18})amine							
20	39120	—	N,N-bis(2-hydroxyethyl)alkyl(C_8-C_{18})amine hydrochlorides	yes	no	no		(7)	SML(T) expressed excluding HCl	
21	42500	—	carbonic acid, salts	yes	no	no				
22	43200	—	castor oil, mono- and diglycerides	yes	no	no				
23	43515	—	chlorides of choline esters of coconut oil fatty acids	yes	no	no	0,9			(1)
24	45280	—	cotton fibers	yes	no	no				
25	45440	—	cresols, butylated, styrenated	yes	no	no	12			
26	46700	—	5,7-di-tert-butyl-3-(3,4- and 2,3-dimethylphenyl)-3H-benzofuran-2-one containing: a) 5,7-di-tert-butyl-3-	yes	no	no	5			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			(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)							
27	48960	—	9,10-dihydroxy stearic acid and its oligomers	yes	no	no	5			
28	50160	—	di-n-octyltin bis(n-alkyl(C_{10}-C_{16}) 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)		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			acetic acid							
41	56486	—	glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C_{14}-C_{18}) and with acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C_{16}-C_{18})	yes	no	no				
42	56487	—	glycerol, esters with butyric acid	yes	no	no				
43	56490	—	glycerol, esters with erucic acid	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

52	56580	—	glycerol esters with ricinoleic acid	yes	no	no			
53	56585	—	glycerol esters with stearic acid	yes	no	no			
54	57040	—	glycerol monooleate, ester with ascorbic acid	yes	no	no			
55	57120	—	glycerol monooleate, ester with citric acid	yes	no	no			
56	57200	—	glycerol monopalmitate, ester with ascorbic acid	yes	no	no			
57	57280	—	glycerol monopalmitate, ester with citric acid	yes	no	no			
58	57600	—	glycerol monostearate, ester with ascorbic acid	yes	no	no			
59	57680	—	glycerol monostearate,	yes	no	no			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			ester with citric acid							
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). 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_{10}-C_{16}) mercaptoacetate)	yes	no	no		(11)		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

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	—	phosphonic acid, mono- and di-n-alkyl (C_{16} and C_{18}) 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	—	polyesters of adipic acid with glycerol or pentaerythritol,	yes	no	no		(32)	The fraction with molecular weight below 1 000 Da	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			esters with even numbered, unbranched C_{12}-C_{22} fatty acids						should not exceed 5 % (w/w)	
73	76866	—	polyesters of 1,2-propanediol and/or 1,3-and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic acid or fatty acids C_{12}-C_{18} or n-octanol and/or n-decanol	yes	no	yes		(31) (32)		
74	77440	—	polyethyleneglycol diricinoleate	yes	no	yes	42			
75	77702	—	polyethyleneglycol esters of	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			aliph. monocarb. acids (C_6-C_{22}) and their ammonium and sodium sulphates						
76	77732	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate	no	no	0,05		Only for use in PET	
77	77733	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	no	no	0,05		Only for use in PET	
78	77897	—	polyethylene glycol (EO = 1-50) monoalkylether (linear and branched,	no	no	5			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			C_8-C_{20}) sulphate, salts							
79	80640	—	polyoxyalkyl (C_2-C_4) 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	no	no					
82	83325	—	propylhydroxymethylcellulose	no						
83	83330	—	propylhydroxypropylcellulose	no						
84	85601	—	silicates, natural (with the exception of asbestos)	yes	no	no				
85	85610	—	silicates, natural, silanated (with the exception	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			of asbestos)							
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				
91	92320	—	tetradecyl polyethyleneglycol ether of glycolic acid	yes	no (EO = 3-8)	yes	15			
92	93970	—	tricyclodecanedimethanol bis(hexahydrophthalate)	yes	no	no	0,05			
93	95858	—	waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, low viscosity	yes	no	no	0,05		Not to be used for articles in contact with fatty foods for which simulant D is	

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									laid down. Average molecular weight not less than 350 Da. Viscosity at 100 °C not less than 2,5 cSt (2,5 × 10^{-6} m^2/s). Content of hydrocarbons with Carbon number less than 25, not more than 40 % (w/w).	
94	95859	—	waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity	yes	no	no			Average molecular weight not less than 500 Da. Viscosity at 100 °C not	

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									less than 11 cSt (11×10^{-6} m^2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
95	95883	—	white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	yes	no	no			Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt ($8,5 \times 10^{-6}$ m^2/s). Content of mineral hydrocarbons with Carbon number

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									less than 25, not more than 5 % (w/w).	
96	95920	—	wood flour and fibers, untreated	yes	no	no				
97	72081/10	—	petroleum hydrocarbon resins (hydrogenated)	yes	no	no			Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermalpolymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C,	

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										as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing. Properties: — Viscosity at 120 °C: > 3 Pa.s, — Softening point: > 95 °C as determined by ASTM Method E 28-67, — Bromine number: < 40 (ASTM D1159), — The colour of a 50 % solution in toluene < 11	

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									—	on the Gardner scale, Residual aromatic monomer ≤ 50 ppm,
98	17260 54880	000005	formaldehyde	yes	yes	no		(15)		
99	19460 62960	000005	lactic acid	yes	yes	no				
100	24490 88320	000005	sorbitol	yes	yes	no				
101	36000	000005	ascorbic acid	yes	no	no				
102	17530	000005	glucose	no	yes	no				
103	18100 55920	000005	glycerol	yes	yes	no				
104	58960	000005	hexadecyltrimethylammonium bromide	yes	yes	no	6			
105	22780 70400	000005	palmitic acid	yes	yes	no				
106	24550 89040	000005	stearic acid	yes	yes	no				
107	25960	000005	urea	no	yes	no				
108	24880	000005	sucrose	no	yes	no				
109	23740 81840	000005	1,2-propanediol	yes	yes	no				
110	93520	000005 001019	α-tocopherol	yes	no	no				
111	53600	000006	ethylenediaminetetraacetic acid	yes	yes	no				

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112	64015	000006[illegible]-33-3	linoleic acid	yes	no	no				
113	16780 52800	000006[illegible]-17-5	ethanol	yes	yes	no				
114	55040	000006[illegible]-18-6	formic acid	yes	no	no				
115	10090 30000	000006[illegible]-19-7	acetic acid	yes	yes	no				
116	13090 37600	000006[illegible]-85-0	benzoic acid	yes	yes	no				
117	21550	000006[illegible]-56-1	methanol	no	yes	no				
118	23830 81882	000006[illegible]-63-0	propanol	yes	yes	no				
119	30295	000006[illegible]-64-1	acetone	yes	no	no				
120	49540	000006[illegible]-68-5	dimethyl sulphoxide	yes	no	no				
121	24270 84640	000006[illegible]-72-7	salicylic acid	yes	yes	no				
122	23800	000007[illegible]-23-8	propanol	no	yes	no				
123	13840	000007[illegible]-36-3	butanol	no	yes	no				
124	22870	000007[illegible]-41-0	pentanol	no	yes	no				
125	16950	000007[illegible]-85-1	ethylene	no	yes	no				
126	10210	000007[illegible]-86-2	acetylene	no	yes	no				
127	26050	000007[illegible]-01-4	vinyl chloride	no	yes	no	ND		1 mg/kg in final product	
128	10060	000007[illegible]-07-0	acetaldehyde	no	yes	no		(1)		
129	17020	000007[illegible]-21-8	ethylene oxide	no	yes	no	ND		1 mg/kg in	(10)

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									final product	
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 23155	0000075-44-5	carbonyl chloride	no	yes	no	ND		1 mg/kg in final product	(10)
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	tributyl acetyl citrate	yes	no	no		(32)		
139	14680 44160	0000077-92-9	citric acid	yes	yes	no				
140	44640	0000077-93-0	citric acid, triethyl ester	yes	no	no		(32)		

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141	13380 25600 94960	00000077-99-6	1,1,1-trimethylolpropane	yes	yes	no	6			
142	26305	00000778-08-0	vinyltriethoxysilane	yes	yes	no	0,05		Only to be used as a surface treatment agent	(1)
143	62450	00000078-78-4	isopentane	yes	no	no				
144	19243 21640	00000078-79-5	2-methyl-1,3-butadiene	no	yes	no	ND		1 mg/kg in final product	
145	10630	00000079-06-1	acrylamide	no	yes	no	ND			
146	23890 82000	00000079-09-4	propionic acid	yes	yes	no				
147	10690	00000079-10-7	acrylic acid	no	yes	no		(22)		
148	14650	00000079-38-9	chlorotrifluoroethylene	yes	yes	no	ND			(1)
149	19990	00000079-39-0	methacrylamide	no	yes	no	ND			
150	20020	00000079-41-4	methacrylic acid	no	yes	no		(23)		
151	13480 13607	00000080-05-7	2,2-bis(4-hydroxyphenyl)propane	no	yes	no	0,6			
152	15610	00000080-07-9	4,4'-dichlorodiphenyl sulphone	no	yes	no	0,05			
153	15267	00000080-08-0	4,4'-diaminodiphenyl sulphone	no	yes	no	5			
154	13617 16090	00000080-09-1	4,4'-dihydroxydiphenyl sulphone	no	yes	no	0,05			

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155	23470	0000080-56-8	α-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: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefins in concentrations up to 0,05 % in the final product.	(7)
158	23380 76320	0000085-44-9	phthalic anhydride	yes	yes	no				
159	74560	0000085-68-7	phthalic acid, benzyl butyl ester	yes	no	no	30	(32)	Only to be used as: (a) plasticiser in	(7)

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									(b)	repeated use materials and articles; 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

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									(c)	Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product.
160	84800	00000087-18-3	salicylic acid, 4-tert-butylphenyl ester	yes	no	yes	12			
161	92160	00000087-69-4	tartaric acid	yes	no	no				
162	65520	00000087-78-5	mannitol	yes	no	no				
163	66400	00000088-24-4	2,2′-methylene bis(4-ethyl-6-tert-butylphenol)	yes	no	yes		(13)		
164	34895	00000088-68-6	2-aminobenzamide	yes	no	no	0,05		Only for use in PET for water and beverages	
165	23200 74480	00000088-99-3	phthalic acid	yes	yes	no				
166	24057	00000089-32-7	pyromellitic anhydride	yes	no	no	0,05			

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167	25240	000009120-8-7	2,6-toluene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
168	13075 15310	000009127-6-9	2,4-diamino-6-phenyl-1,3,5-triazine	no	yes	no	5			(1)
169	16240	000009139-7-4	3,3′-dimethyl-4,4′-diisocyanatobiphenyl	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
170	16000	000009248-8-6	4,4′-dihydroxybiphenyl	no	yes	no	6			
171	38080	000009358-2-3	benzoic acid, methyl ester	yes	no	no				
172	37840	000009389-0-3	benzoic acid, ethyl ester	yes	no	no				
173	60240	000009441-3-3	3-hydroxybenzoic acid, propyl ester	yes	no	no				
174	14740	000009548-7-4	o-cresol	no	yes	no				
175	20050	000009605-9-0	methacrylic acid, allyl ester	yes	no	no	0,05			

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176	11710	00000096-33-3	acrylic acid, methyl ester	no	yes	no		(22)		
177	16955	00000096-49-1	ethylene carbonate	no	yes	no	30		SML expressed as ethyleneglycol. Residual content of 5 mg ethylene carbonate per kg of hydrogel with max 10 g of hydrogel in contact with 1 kg of food.	
178	92800	00000096-69-5	4,4′-thiobis(6-tert-butyl-3-methylphenol)	yes	no	yes	0,48			
179	48800	00000097-23-4	2,2′-dihydroxy-5,5′-dichlorodiphenylmethane	yes	no	yes	12			
180	17160	00000097-53-0	eugenol	no	yes	no	ND			
181	20890	00000097-63-2	methacrylic acid, ethyl ester	no	yes	no		(23)		
182	19270	00000097-65-4	itaconic acid	no	yes	no				

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183	21010	00000097-86-9	methacrylic acid, isobutyl ester	no	yes	no		(23)		
184	20110	00000097-88-1	methacrylic acid, butyl ester	no	yes	no		(23)		
185	20440	00000097-90-5	methacrylic acid, diester with ethyleneglycol	no	yes	no	0,05			
186	14020	00000098-54-4	4-tert-butylphenol	no	yes	no	0,05			
187	22210	00000098-83-9	alpha-methylstyrene	no	yes	no	0,05			
188	19180	00000099-63-8	isophthalic acid dichloride	no	yes	no		(27)		
189	60200	00000099-76-3	4-hydroxybenzoic acid, methyl ester	yes	no	no				
190	18880	00000099-96-7	*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	00001002-42-5	styrene	no	yes	no				
194	13150	00001003-51-6	benzyl alcohol	no	yes	no				
195	37360	00001003-52-7	benzaldehyde	no	no	no				(3)
196	18670	00001007-28-9	hexamethylenetetramine	yes	yes	no		(15)		

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	59280									
197	20260	00001014-43-9	methacrylic acid, cyclohexyl ester	no	yes	no	0,05			
198	16630	00001016-87-8	diphenylmethane-4,4′-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
199	24073	00001017-90-6	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. For indirect food contact only, behind a PET layer.	(8)
200	51680	00001020-81-9	diphenylthiourea	yes	no	yes	3			
201	16540	00001021-09-0	diphenyl carbonate	no	yes	no	0,05			

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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 92640	0000102-60-3	N,N,N′,N′-tetrakis(2-hydroxypropyl)ethylenediamine	yes	yes	no				
205	25385	0000102-70-5	triallylamine	no	yes	no			40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1,5 grams of hydrogel. 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-	yes	no	yes	18	(32)		(2)

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			ethylhexyl) ester							
208	18898	00001039-44-2	N-(4-hydroxyphenyl) acetamide	no	yes	no	0,05			
209	17050	00001042-76-7	2-ethyl-1-hexanol	no	yes	no	30			
210	13390 14880	00001051-48-8	1,4-bis(hydroxymethyl)cyclohexane	no	yes	no				
211	23920	00001052-38-4	3-mercaptopropionic acid, vinyl ester	no	yes	no		(1)		
212	14200 41840	00001052-60-2	caprolactam	yes	yes	no		(4)		
213	82400	00001052-62-4	1,2-propyleneglycol dioleate	yes	no	no				
214	61840	00001061-12-9	12-hydroxystearic acid	yes	no	no				
215	14170	00001063-31-0	isatoic anhydride	no	yes	no				
216	14770	00001064-44-5	*p*-cresol	no	yes	no				
217	15565	00001064-46-7	1,4-dichlorobenzene	no	yes	no	12			
218	11590	00001064-63-3	3-hydroxybutyric acid, isobutyl ester	no	yes	no		(22)		
219	14570 16750	00001064-89-3	epichlorohydrin	yes	no	no	ND		1 mg/kg in final product	(10)
220	20590	00001064-91-2	methacrylic acid,	yes	yes	no	0,02			(10)

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			2,3-epoxypropyl ester							
221	40570	00001067-97-8	butane	yes	no	no				
222	13870	00001067-98-9	butene	no	yes	no				
223	13630	00001069-61-6	butadiene	no	yes	no	ND		1 mg/kg in final product	
224	13900	00001072-01-7	butene	no	yes	no				
225	12100	00001071-13-1	acrylonitrile	yes	no	no	ND			
226	15272	00001071-15-3	ethylenediamine	yes	no	no	12			
	16960									
227	16990	00001071-21-1	ethylene glycol	yes	no			(2)		
	53650									
228	13690	00001071-63-0	1,3-butanediol	no	yes	no				
229	14140	00001071-93-6	benzoic acid	no	yes	no				
230	16150	00001081-01-0	dimethylaminoethanol	no	no	no	18			
231	10120	00001081-05-4	acetic acid, vinyl ester	no	yes	no	12			
232	10150	00001081-24-7	acetic anhydride	yes	yes	no				
	30280									
233	24850	00001081-30-5	succinic anhydride	no	yes	no				
234	19960	00001081-31-6	maleic anhydride	no	yes	no		(3)		
235	14710	00001081-39-4	*m*-cresol	no	yes	no				
236	23050	00001081-45-2	1,3-phenylenediamine	no	yes	no	ND			

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237	15910 24072	000010814-3	1,3-dihydroxybenzene	no	yes	no	2,4			
238	18070	000010855-4	glutaric anhydride	no	yes	no				
239	19975 25420 93720	000010886-1	2,4,6-triamino-1,3,5-triazine	yes	yes	no	30			
240	45760	000010891-8	cyclohexylamine	no	no	no				
241	22960	000010895-2	phenol	no	yes	no				
242	85360	000010943-3	sebacic acid, dibutyl ester	yes	no	no		(32)		
243	19060	000010953-5	isobutyl vinyl ether	no	yes	no	0,05			(10)
244	71720	000010966-0	pentane	yes	no	no				
245	22900	000010967-1	1-pentene	no	yes	no	5			
246	25150	000010999-9	tetrahydrofuran	yes	no	no	0,6			
247	24820 90960	000011056-6	succinic acid	yes	yes	no				
248	19540 64800	000011061-7	maleic acid	yes	yes	no		(3)		
249	17290 55120	000011078-8	fumaric acid	yes	yes	no				
250	53520	000011130-5	N,N-ethylenebisstearamide	yes	no	no				
251	53360	000011131-6	N,N-ethylenebisoleamide	yes	no	no				
252	87200	000011144-1	sorbic acid	yes	no	no				
253	15250	000011160-1	1,4-diaminobutane	no	yes	no				

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254	13720 40580	00001101-63-4	1,3-butanediol	yes	yes	no		(30)		
255	25900	00001101-88-3	tridecane	no	yes	no	5			
256	18010 55680	00001109-94-1	glutaric acid	yes	yes	no				
257	13550 16660 51760	00001110-63-2	hexamethylenediamine	yes	yes	no				
258	70480	00001111-06-8	octanoic acid, butyl ester	yes	no	no				
259	58720	00001111-14-8	heptanoic acid	yes	no	no				
260	24280	00001111-20-6	sebacic acid	no	yes	no				
261	15790	00001112-57-0	triethylenetetramine	yes	yes	no	5			
262	35284	00001113-41-1	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. For indirect food contact only, behind	

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									a PET layer.	
263	13326 15760 47680	0000111-46-6	diethyleneglycol	yes	yes	no		(2)		
264	22660	0000111-66-0	1-octene	no	yes	no	15			
265	22600	0000111-87-5	1-octanol	no	yes	no				
266	25510 94320	0000112-27-6	triethyleneglycol	yes	yes	no				
267	15100	0000112-30-1	1-decanol	no	yes	no				
268	16704	0000112-41-4	1-dodecene	no	yes	no	0,05			
269	25090 92350	0000112-60-7	tetraethyleneglycol	yes	yes	no				
270	22763 69040	0000112-80-1	oleic acid	yes	yes	no				
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				

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277	18280	000011[illegible]	5-norbornene-2,3-dicarboxylic anhydride, 5,6,7,8,9,9-hexachloro-1,4,4a,5,8,8a-hexahydro-1,4-endo-endo-dimethylene-	yes	no	ND			
278	18250	000011[illegible]	5-norbornene-2,3-dicarboxylic acid, 5,6,7,8,9,9-hexachloro-1,4,4a,5,8,8a-hexahydro-1,4-endo-endo-dimethylene-	yes	no	ND			
279	22840 71600	000011[illegible]	pentaerythritol	yes	no				
280	73720	000011[illegible]	phosphoric acid, trichloroethyl ester	yes	no	no	ND			
281	25120	000011[illegible]	tetrafluoroethylene	yes	no	no	0,05			
282	18430	000011[illegible]	hexafluoropropylene	yes	no	no	ND			
283	74640	000011[illegible]	phthalic acid, bis(2-ethylhexyl) ester	yes	no	no	1,5	(32)	Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in concentrations up to 0,1 % in the final product.	(7)
284	84880	000011[illegible]	salicylic acid,	yes	no	no	30			

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			methyl ester							
285	66480	00001192-27-1	2,2'-methylene bis(4-methyl-6-tert-butylphenol)	yes	no	yes		(13)		
286	38240	00001196-01-9	benzophenone	yes	no	yes	0,6			
287	60160	00001204-47-8	4-hydroxybenzoic acid, ethyl ester	yes	no	no				
288	24970	00001206-61-6	terephthalic acid, dimethyl ester		yes	no				
289	15880 24051	00001207-82-9	1,2-dihydroxybenzene	no	yes	no	6			
290	55360	00001217-79-9	3,4,5-trihydroxybenzoic acid, propyl ester	yes	no	no		(20)		
291	19150	00001219-54-5	2-hydroxybenzoic acid	no	yes	no		(27)		
292	94560	00001222-83-3	2,2',2''-nitrilotripropanol	yes	no	no	5			
293	23175	00001224-41-4	phosphorous acid, triethyl ester	no	yes	no	ND		1 mg/kg in final product	(1)
294	93120	00001238-23-8	3,3'-thiodipropionic acid, didodecyl ester	yes	no	yes		(14)		
295	15940 18867 48620	00001243-34-9	1,4-dihydroxybenzene	yes	yes	no	0,6			

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296	23860	00001238-6	propionaldehyde	yes	no					
297	23950	00001263-6	propionic anhydride	yes	no					
298	14110	00001272-8	benzaldehyde	yes	no					
299	63840	00001376-2	levulinic acid	yes	no	no				
300	30045	00001386-4	adipic acid, butyl ester	yes	no	no				
301	89120	00001395-5	stearic acid, butyl ester	yes	no	no				
302	12820	00001491-9	azelaic acid	no	yes	no				
303	12130 31730	00001494-2	adipic acid	yes	yes	no				
304	14320 41960	00001497-5	caprylic acid	yes	yes	no				
305	15274 18460	00001509-4	hexamethylenediamine	yes	no	2,4				
306	88960	00001526-5	stearamide	yes	no	no				
307	42160	00001538-9	carbon dioxide	yes	no	no				
308	91200	00001613-6	sucrose acetate isobutyrate	yes	no	no				
309	91360	00001614-7	sucrose octaacetate	yes	no	no				
310	16390 22437	00001632-7	2,2-dimethyl-1,3-propanediol	no	yes	no	0,05			
311	16480 51200	00001658-9	pentaerythritol	yes	no					

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312	21490	000012698-97-7	methacrylonitrile	yes	no	no	ND			
313	16650 51570	000012736-69-2	diphenyl sulphone	yes	yes	no	3			
314	23500	000012738-91-3	β-pinene	no	yes	no				
315	46640	000012837-19-1	2,6-di-tert-butyl-p-cresol	yes	no	no	3			
316	23230	000013178-17-9	phthalic acid, diallyl ester	no	yes	no	ND			
317	48880	000013126-31-3	2,2′-dihydroxy-4-methoxybenzophenone	yes	no	yes		(8)		
318	48640	000013126-36-6	2,4-dihydroxybenzophenone	yes	no	no		(8)		
319	61360	000013127-57-7	2-hydroxy-4-methoxybenzophenone	yes	no	yes		(8)		
320	37680	000013606-65-7	benzoic acid, butyl ester	yes	no	no				
321	36080	000013718-66-6	ascorbyl palmitate	yes	no	no				
322	63040	000013817-22-7	lactic acid, butyl ester	yes	no	no				
323	11470	000014088-45-5	acrylic acid, ethyl ester	no	yes	no		(22)		
324	83700	000014112-20-0	ricinoleic acid	yes	no	yes	42			

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325	10780	0000141-32-2	acrylic acid, n-butyl ester	no	yes	no		(22)		
326	12763 35170	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. For indirect food contact only, behind a PET layer.	
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 63280	0000143-07-7	lauric acid	yes	yes	no				
331	22480	0000143-08-8	1-nonanol	no	yes	no				

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332	69760	0000143-28-2	oleyl alcohol	yes	no	no				
333	22775 69920	0000144-62-7	oxalic acid	yes	yes	no	6			
334	17005	0000151-56-4	ethyleneimine	no	yes	no	ND			
335	68960	0000301-02-0	oleamide	yes	no	no				
336	15095 45940	0000334-48-5	n-decanoic acid	yes	yes	no				
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				
340	47440	0000461-58-5	dicyanodiamide	yes	no	no				
341	13180 22550	0000498-66-8	bicyclo[2.2.1]hept-2-ene	no	yes	no	0,05			
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 21821	0000505-65-7	1,4-butanediol formal	no	yes	no	ND			(10)
345	35840	0000506-30-9	arachidic acid	yes	no	no				
346	10030	0000514-10-3	abietic acid	no	yes	no				
347	13050 25540	0000528-44-9	trimellitic acid	no	yes	no		(21)		
348	22350 67891	0000544-63-8	myristic acid	yes	yes	no				
349	25550	0000552-30-7	trimellitic anhydride	no	yes	no		(21)		

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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			

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359	15970 48720	00006114-9	4,4′-dihydroxybenzophenone	yes	yes	no		(8)		
360	57920	00006207-7	glyceryl triheptanoate	yes	no	no				
361	18700	00006291-8	1,6-hexanediol	no	yes	no	0,05			
362	14350	00006308-0	carbon monoxide	no	yes	no				
363	16450	00006461-0	1,3-dioxolane	no	yes	no	5			
364	15404	00006521-7	1,4:3,6-dianhydrosorbitol	no	yes	no	5		Only to be used as a co-monomer in poly(ethylene-co-isosorbide terephthalate)	
365	11680	00006899-3	acrylic acid, isopropyl ester	no	yes	no		(22)		
366	22150	00006914-7	2-methyl-1-pentene	no	yes	no	0,05			
367	16697	00006932-3	2-dodecanedioic acid	no	yes	no				
368	93280	00006933-4	3-thiodipropionic acid, dioctadecyl ester	no	no	yes		(14)		
369	12761	00006935-7	12-aminododecanoic acid	no	yes	no	0,05			

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370	21460	000076[illegible]-93-0	methacrylic anhydride	no	yes	no		(23)		
371	11510 11830	000081[illegible]-61-1	acrylic acid, monoester with ethyleneglycol	no	yes	no		(22)		
372	18640	000082[illegible]-06-0	hexamethylene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
373	22390	000084[illegible]-66-3	2,6-naphthalenedicarboxylic acid, dimethyl ester	no	yes	no	0,05			
374	21190	000086[illegible]-77-9	methacrylic acid, monoester with ethyleneglycol	no	yes	no		(23)		
375	15130	000087[illegible]-05-9	1-decene	no	yes	no	0,05			
376	66905	000087[illegible]-50-4	N-methylpyrrolidone	yes	no	no				
377	12786	000091[illegible]-33-0	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	

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									reactive surface treatment of inorganic fillers. SML = 0,05 mg/kg when used for the surface treatment of materials and articles.	
378	21970	00009230-2	N-4-methylolmethacrylamide	no	yes	no	0,05			
379	21940	00009244-2	N-5-methylolacrylamide	no	yes	no	ND			
380	11980	00009255-60-1	acrylic acid, propyl ester	no	yes	no		(22)		
381	15030	00009318-8	ε-caprolactam	no	yes	no	0,05		Only to be used in polymers contacting foods for which simulant A is laid down	
382	19490	00009474-6	lauryllactam	no	yes	no	5			
383	72160	00009482-6	2-phenylindole	yes	no	yes	15			

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384	40000	00009912-84-4	2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	yes	no	yes	30			
385	11530	00009999-61-1	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	00010342-01-1	gallic acid, octyl ester	yes	no	no		(20)		
387	26155	00010724-63-5	1-vinylimidazole	no	yes	no	0,05			(1)
388	25080	00011201-36-1	1-tetradecene	no	yes	no	0,05			

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389	22360	000114[illegible]-4	2,6-naphthalenedicarboxylic acid	no	yes	no	5			
390	55200	000116[illegible]-5	2-hydroxypropanoic acid, dodecyl ester	yes	no	no		(20)		
391	22932	000118[illegible]-5	perfluoromethyl perfluorovinyl ether	no	yes	no	0,05		Only to be used in anti-stick coatings	
392	72800	000124[illegible]-7	phosphoric acid, diphenyl 2-ethylhexyl ester	yes	no	yes	2,4			
393	37280	000130[illegible]-0	chromonitrite	yes	no	no				
394	41280	000130[illegible]-0	calcium hydroxide	yes	no	no				
395	41520	000130[illegible]-8	calcium oxide	yes	no	no				
396	64640	000130[illegible]-8	magnesium hydroxide	yes	no	no				
397	64720	000130[illegible]-4	magnesium oxide	yes	no	no				
398	35760	000130[illegible]-4	antimony trioxide	yes	no	no	0,04		SML expressed as antimony	(6)
399	81600	000131[illegible]-3	potassium hydroxide	yes	no	no				
400	86720	000131[illegible]-2	sodium hydroxide	yes	no	no				
401	24475	000131[illegible]-2	sodium sulphide	no	yes	no				

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402	96240	00013142-13-2	zinc oxide	yes	no	no				
403	96320	00013463-41-7	zinc sulphide	yes	no	no				
404	67200	00013176-33-5	molybdenum disulphide	yes	no	no				
405	16690	00013216-74-0	ethylvinylbenzene	yes	no	ND		SML expressed as the sum of divinylbenzene and ethylvinylbenzene. It may contain up to 45 % (m/m) of ethylvinylbenzene.	(1)	
406	83300	00013233-32-3	propyleneglycol monostearate	yes	no	no				
407	87040	00013300-42-4	sodium tetraborate	yes	no	no		(16)		
408	82960	00013308-20-9	propyleneglycol monooleate	yes	no	no				
409	62240	00013327-43-2	iron oxide	yes	no	no				
410	62720	00013332-58-7	kaolin	yes	no	no				
411	42080	00013393-86-4	carbon black	yes	no	no		Primary particles of 10 – 300 nm which are aggregated to a size of 100		

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									– 1 200 nm which may form agglomerates within the size distribution of 300 nm – mm. Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method

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									of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of carbon black in the polymer: 2,5 % w/w.	
412	45200	00013356-23-5	copper iodide	yes	no	no		(6)		
413	35600	00013362-21-6	ammonium hydroxide	yes	no	no				
414	87600	00013382-39-2	sorbitan monolaurate	yes	no	no				
415	87840	00013381-27-6	sorbitan monostearate	yes	no	no				
416	87680	00013377-03-8	sorbitan monooleate	yes	no	no				
417	85680	00013432-03-2	succinic acid	yes	no	no				
418	34720	00013444-28-1	aluminium oxide	yes	no	no				
419	92150	00014014-55-4	tannic acids	yes	no	no			According to the JECFA specifications	
420	19210	00014591-93-4	isophthalic acid, dimethyl ester	yes	no	0,05				

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421	13000	000147-53-0	benzenedimethanamine	no	yes	no	0,05			
422	38515	000153-44-5	4,4'-bis(2-benzoxazolyl)stilbene	yes	no	yes	0,05			(2)
423	22937	000623-05-8	perfluoropropylperfluorovinyl ether	no	yes	no	0,05			
424	15070	000647-19-1	1,9-decadiene	no	yes	no	0,05			
425	10840	000663-39-4	abietic acid, tert-butyl ester	no	yes	no		(22)		
426	13510 13610	000675-22-3	bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether	no	yes	no			In compliance with Commission Regulation (EC) No 1895/2005[a]	
427	18896	000679-51-2	1-(hydroxymethyl)-1-cyclohexene	no	yes	no	0,05			
428	95200	000709-78-0	1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl)benzene	yes	no	no				
429	13210	000761-71-8	tris(4-aminocyclohexyl)methane	no	yes	no	0,05			
430	95600	001843-03-4	tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane	yes	no	yes	5			
431	61600	001843-22-5	6-hydroxy-4-	yes	no	yes		(8)		

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			n-octyloxybenzophenone							
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	0002156-97-1	acrylic acid, dodecyl ester	no	yes	no	0,05			(2)
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,	no	yes	no		(23)		

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			propyl ester							
441	38160	000231568-6	benzoic acid, propyl ester	yes	no	no				
442	13780	000242517-8	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	000243219-7	11-aminoundecanoic acid	no	yes	no	5			
444	61440	000244022-4	2-(2′-hydroxy-5′-methylphenyl)benzotriazole	yes	no	no		(12)		
445	83440	000246609-3	pyrophosphoric acid	yes	no	no				
446	10750	000249535-4	2-butenoic acid, benzyl ester	no	yes	no		(22)		
447	20080	000249537-6	2-methacrylic acid, benzyl ester	no	yes	no		(23)		
448	11890	000249959-4	2-butenoic acid, n-octyl ester	no	yes	no		(22)		
449	49840	000250088-1	2-dodecanethiol, disulphide	yes	no	yes	3			

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450	24430	000256[illegible]-88-8	ic anhydride	no	yes	no				
451	66755	000268[illegible]-20-4	methyl-4-isothiazolin-3-one	yes	no	no	0,5		Only to be used in aqueous polymer dispersions and emulsions	
452	38885	000272[illegible]-22-6	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	000276[illegible]-02-7	vinyltrimethoxysilane	yes	no	no	0,05			(10)
454	12670	000285[illegible]-13-2	amino-3-aminomethyl-3,5,5-trimethylcyclohexane	no	yes	no	6			
455	20530	000286[illegible]-47-2	methacrylic acid, 2-(dimethylamino)-ethyl ester	no	yes	no	ND			
456	10810	000299[illegible]-08-5	acrylic acid, sec-butyl ester	no	yes	no		(22)		
457	20140	000299[illegible]-18-7	methacrylic acid, sec-butyl ester	no	yes	no		(23)		
458	36960	000306[illegible]-75-4	erucamide	yes	no	no				

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459	46870	00031353-18-0	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	yes	no	no				
460	14950	00031739-53-3	cyclohexyl isocyanate	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)	
461	22420	00031717-7-6	naphthalene diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
462	26170	00031957-78-6	N-vinyl-N-methylacetamide	no	yes	no	0,02			(1)
463	25840	00032901-71-1	2,2,4-trimethylolpropane trimethacrylate	no	yes	no	0,05			
464	61280	00032932-97-8	2-hydroxy-4-n-hexyloxybenzophenone	yes	no	yes		(8)		
465	68040	00033376-20-8	2-[2-H-naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin	yes	no	no				

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466	50640	000364818-8	di-n-octyltin dilaurate	yes	no	no		(10)		
467	14800 45600	000372466-0	ecotonic acid	yes	yes	no	0,05			(1)
468	71960	000382526-1	perfluorooctanoic acid, ammonium salt	no	no	no			Only to be used in repeated use articles, sintered at high temperatures	
469	60480	000386429-1	2-(2′-hydroxy-3,5′-di-tert-butylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)		
470	60400	000389621-25	2-(2′-hydroxy-3′-tert-butyl-5′-methylphenyl)-5-chlorobenzotriazole	yes	no	yes		(12)		
471	24888	000396555-7	5-sulphoisophthalic acid, monosodium salt, dimethyl ester	no	yes	no	0,05			
472	66560	000406622-8	2,2′-methylenebis(4-methyl-6-cyclohexylphenol)	yes	no	yes		(5)		
473	12265	000407490-2	adipic acid, divinyl ester	no	yes	no	ND		5 mg/kg in final product.	(1)

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									Only to be used as co-monomer.	
474	43600	000408013-3	1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	yes	no	no	0,3			
475	19110	000409817-9	1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
476	16570	000412873-8	4-phenylether-4,4'-diisocyanate	yes	no			(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
477	46720	000413024-2	2,6-di-tert-butyl-4-ethylphenol	yes	no	yes	4,8			(1)
478	60180	000419147-5	hydroxybenzoic acid, isopropyl ester	yes	no	no				
479	12970	000419625-6	azelaic anhydride	no	yes	no				
480	46790	000422138-0	3,5-di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-	yes	no	no				

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			tert-butylphenyl ester							
481	13060	000442-95-1	1,3,5-benzenetricarboxylic acid trichloride	no	yes	no	0,05		SML expressed as 1,3,5-benzenetricarboxylic acid	(1)
482	21100	000465-34-9	methacrylic acid, isopropyl ester	yes	no	no		(23)		
483	68860	000724-48-5	octylphosphonic acid	yes	no	no	0,05			
484	13395	000767-03-7	2,2-bis(hydroxymethyl)propionic acid	no	yes	no	0,05			(1)
485	13560 15700	000822-06-0	1,6-hexamethylene diisocyanate	yes	no	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
486	54005	000866-21-4	ethylene-N-palmitamide-N′-stearamide	yes	no	no				
487	45640	000952-28-4	2-cyano-3,3-diphenylacrylic acid, ethyl ester	yes	no	no	0,05			
488	53440	000950-99-2	N,N′-ethylenebispalmitamide	yes	no	no				

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489	41040	000574	3-chloro-2-hydroxypropyl butyrate	yes	no	no				
490	16600	000587	4,4′-diphenylmethanediisocyanate	no	2,4′-diisocyanate	no		(17)	1 mg/kg in final product expressed as isocyanate moiety	(10)
491	82720	000618	1,2-propyleneglycol distearate	yes	no	no				
492	45650	000619	2-cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	yes	no	no	0,05			
493	39200	000620	3-(2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy)methylammonium chloride	yes	no	no	1,8			
494	62140	000630	Hypophosphorous acid	yes	no	no				
495	35160	000664	6-amino-1,3-dimethyluracil	yes	no	no	5			
496	71680	000668	pentaerythritol tetrakis[3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no				
497	95020	000684	2,2,4-trimethyl-1,3-pentanediol diisobutyrate	yes	no	no	5		Only to be used in single-	

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									use gloves	
498	16210	000686433-5	3,3′-dimethyl-4,4′-diaminodicyclohexylmethane	no	yes	no	0,05		Only to be used in polyamides	(5)
499	19965 65020	000691515-7	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	
500	38560	000712826-4	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	000745648-0	4,4′-oxybis(benzenesulphonyl azide)	no	yes	no	0,05			(1)
503	46080	000758539-9	β-dextrin	yes	no	no				

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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 72640	0007664-38-2	phosphoric acid	yes	yes	no				
510	12789 35320	0007664-41-7	ammonia	yes	yes	no				

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511	91920	0007664-93-9	sulphuric acid	yes	no	no				
512	81680	0007681-11-0	potassium iodide	yes	no	no		(6)		
513	86800	0007681-82-5	sodium iodide	yes	no	no		(6)		
514	91840	0007704-34-9	sulphur	yes	no	no				
515	26360 95855	0007732-18-5	water	yes	yes	no			In compliance with Directive 98/83/EC[b]	
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	ascorbic 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	lecithin	yes	no	no				
527	14411 42880	0008001-79-4	castor oil	yes	yes	no				
528	63760	0008002-43-5	lecithin	yes	no	no				

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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 30(*)	(32)	(*)	In the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 2006/141/EC or processed cereal-based foods and baby foods for infants and young children as defined

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									Oxirane < 8 %, iodine number < 6.	by Directive 2006/125/EC, the SML is lowered to 30 mg/kg.
533	42720	000801[illegible]	[illegible]-86-9 carnauba wax	yes	no	no				
534	80720	000801[illegible]	[illegible]-06-1 polyphosphoric acids	yes	no	no				
535	24100 24130 24190 83840	000805[illegible]	[illegible]-09-7 rosin	yes	yes	no				
536	84320	000805[illegible]	[illegible]-15-5 rosin, hydrogenated, ester with methanol	yes	no	no				
537	84080	000805[illegible]	[illegible]-26-8 rosin, ester with pentaerythritol	yes	no	no				
538	84000	000805[illegible]	[illegible]-31-5 rosin, ester with glycerol	yes	no	no				
539	24160	000805[illegible]	[illegible]-10-6 rosin tall oil	no	yes	no				

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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	0009004-67-7	carboxymethylcellulose	no	no	no			
543	45920	0009005-16-2	laminar	yes	no	no			
544	58400	0009005-30-0	guar gum	yes	no	no			
545	93680	0009005-65-1	tragacanth gum	yes	no	no			
546	71440	0009005-69-5	pectin	yes	no	no			
547	55440	0009005-70-8	gellan	yes	no	no			
548	42800	0009005-71-9	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 0106392-12-5	poly(ethylene-co-propylene) glycol	yes	no	no			
552	81500	0009003-39-8	polyvinylpyrrolidone	no	no	no			The substance shall meet the purity criteria as laid down in Commission Directive

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									2008/84/EC[c]	
553	14500 43280	0009004-34-6	cellulose	yes	yes	no				
554	43300	0009004-35-7	cellulose acetate butyrate	yes	no	no				
555	53280	0009004-57-3	ethylcellulose	yes	no	no				
556	54260	0009004-58-4	hydroxyethylcellulose	no	no					
557	66640	0009004-59-5	methylethylcellulose	yes	no					
558	60560	0009004-62-0	hydroxyethylcellulose	no	no					
559	61680	0009004-64-2	hydroxypropylcellulose	no	no					
560	66700	0009004-65-3	methylhydroxypropylcellulose	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 88800	0009005-25-8	starch, edible	yes	yes	no				
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	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				

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571	79280	0009005-67-8	polyethylene glycol sorbitan monostearate	yes	no	no				
572	79360	0009005-70-3	polyethylene glycol sorbitan trioleate	yes	no	no				
573	79440	0009005-71-4	polyethylene glycol sorbitan tristearate	yes	no	no				
574	24250 84560	0009006-04-6	rubber, natural	yes	yes	no				
575	76721	0063148-62-9	polydimethylsiloxane (Mw > 6 800 Da)	yes	no	no			Viscosity at 25 °C not less than 100 cSt (100 × 10^{-6} m^2/s)	
576	60880	0009032-42-2	hydroxyethylmethylcellulose	yes	no	no				
577	62280	0009044-13-1	isobutylene-cis-butene copolymer	yes	no	no				
578	79600	0009046-01-9	polyethylene glycol tridecyl ether phosphate	yes	no	no	5		For materials and articles intended for contact with aqueous foods only. Polyethyleneglycol (EO ≤ 11) tridecyl	

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									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 40320	0010043-35-3	boric acid	yes	yes	no		(16)		
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	octadecyl erucamide	yes	yes	no	5			
588	64320	0010377-51-2	lithium iodide	yes	no	no		(6)		
589	52645	0010436-08-1	cis-13-eicosenamide	yes	no	no				

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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	0011104-61-7	cobalt oxide	yes	no	no				
594	65360	0011129-60-5	manganese oxide	yes	no	no				
595	19510	0011132-73-3	hydrocellulose	no	yes	no				
596	95935	0011138-66-2	xanthan gum	yes	no	no				
597	67120	0012001-26-2	mica	yes	no	no				
598	41600	0012004-14-7 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	zeolite	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	abietic acid, dicyclopentenyl ester	no	yes	no	0,05			(1)
606	65200	0012626-88-9	manganese hydroxide	yes	no	no				
607	62245	0012751-22-3	zinc phosphide	yes	no	no			Only to be	

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									used in PET polymers and copolymers	
608	40800	00130034-2	4,4'-butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	yes	no	yes	6			
609	83455	00134455-6	pyrophosphorous acid	yes	no	no				
610	93440	00134637-7	titanium dioxide	yes	no	no				
611	35120	00135603-1	4-aminocrotonic acid, diester with thiobis(2-hydroxyethyl) ether	yes	no	no				
612	16694	00138115-2	1,3-divinyl-2-imidazolidinone	no	yes	no	0,05			(10)
613	95905	00139837-0	wollastonite	yes	no	no				
614	45560	00144641-1	cristobalite	yes	no	no				
615	92080	00148071-6	talc	yes	no	no				
616	83470	00148085-7	quartz	yes	no	no				
617	10660	00152142-8	2-acrylamido-2-methylpropanesulphonic acid	no	yes	no	0,05			
618	51040	00155357-9	di-n-octyltin mercaptoacetate	yes	no	no		(10)		

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619	50320	00155716-58-1	di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	yes	no	no		(10)		
620	50720	00155760-00-5	di-n-octyltin dimaleate	yes	no	no		(10)		
621	17110	00162195-75-3	5-ethylidenebicyclo[2,2,1]hept-2-ene	no	yes	no	0,05			(9)
622	69840	00162609-96-6	oleylpalmitamide	no	yes	5				
623	52640	00163894-68-1	dolomite	yes	no	no				
624	18897	00167126-64-4	6-hydroxy-2-naphthalenecarboxylic acid	no	yes	no	0,05			
625	36720	00171947-00-2	barium hydroxide	yes	no	no				
626	57800	00186411-57-1	glycerol tribehenate	yes	no	no				
627	59760	00195697-21-2	lithium hydroxide	yes	no	no				
628	96190	00204275-58-1	zinc hydroxide	yes	no	no				
629	34560	00216450-51-2	aluminium hydroxide	yes	no	no				
630	82240	00227881-12-8	propyleneglycol dilaurate	yes	no	no				
631	59120	00231281-76-7	hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)	yes	no	yes	45			
632	52880	00236740-79-7	ethoxybenzoic acid,	yes	no	no	3,6			

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			ethyl ester							
633	53200	002394926-8	6-ethoxy-2′-ethyloxanilide	yes	no	yes	30			
634	25910	002480044-0	tripropyleneglycol	yes	no					
635	40720	002501316-5	tert-butyl-4-hydroxyanisole	yes	no	no	30			
636	31500	002513451-4	acrylic acid, acrylic acid, 2-ethylhexyl ester, copolymer	yes	no	no	0,05	(22)	SML expressed as acrylic acid, 2-ethylhexyl ester	
637	71635	002515196-6	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 76960	002532268-3	polyethyleneglycol	yes	no					
639	23651 80800	002532269-4	polypropyleneglycol	yes	no					
640	54930	002535901-5	formaldehyde-1-naphthol, copolymer	yes	no	no	0,05			

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641	22331	00255134-64-8	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	00257364-42-2	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	00262665-09-9	sorbitan monopalmitate	yes	no	no				
644	88080	00262666-08-0	sorbitan trioleate	yes	no	no				
645	67760	00264013-86-5	mono-n-octyltin tris(isooctyl mercaptoacetate)	yes	no	no		(11)		
646	50480	00264016-97-8	di-n-octyltin bis(isooctyl mercaptoacetate)	yes	no	no		(10)		
647	56720	00264027-23-3	glycerol monohexanoate	yes	no	no				

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648	56880	0026402-26-6	glycerol monooctanoate	yes	no	no				
649	47210	0026427-07-6	dibutylthiostannoic 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			

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659	82800	00271941-72-7	propyleneglycol monolaurate	yes	no	no				
660	47540	00274588-90-8	di-tert-dodecyl disulphide	yes	no	yes	0,05			
661	95360	00276761-23-6	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	00279519-11-8	1,1,1-tris(4-hydroxyphenol)ethane	no	yes	no	0,005		Only to be used in polycarbonates	(1)
663	64150	00282990-79-1	linolenic acid	yes	no	no				
664	95000	00289316-67-1	trimethylolpropane trimethacrylate-methyl methacrylate copolymer	no	no	no				
665	83120	00290131-28-3	propyleneglycol monopalmitate	yes	no	no				
666	87280	00291163-98-1	sorbitan dioleate	yes	no	no				
667	55190	00292040-02-2	gadoleic acid	yes	no	no				
668	80240	00298943-35-7	polyglycerol ricinoleate	yes	no	no				
669	56610	00302332-64-8	glycerol monobehenate	yes	no	no				
670	56800	00308996-52-8	glycerol monolaurate diacetate	yes	no	no		(32)		

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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) (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	bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide	yes	no	yes	15			
676	50400	0033568-99-9	octyltin bis(isooctyl maleate)	yes	no	no		(10)		
677	82560	0033587-20-1	propyleneglycol dipalmitate	yes	no	no				
678	59200	0035074-77-2	hexamethylene-	yes	no	yes	6			

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			bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)							
679	39060	00359581-30-6	bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane	yes	no	yes	5			
680	94400	00364431-68-2	bis[3-(3-tert-butyl-4-hydroxy-5-methylphenyl) propionate]	yes	no	no	9			
681	18310	00366531-82-4	hexadecanol	no	yes	no				
682	53270	00372059-09-5	ethylcarboxymethylcellulose	yes	no	no				
683	66200	00372061-01-2	methylcarboxymethylcellulose	yes	no	no				
684	68125	00372440-96-5	nepheline syenite	yes	no	no				
685	85950	00372961-27-2	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	

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									with food.	
686	61390	003735[illegible]	hydroxyethylcellulose	yes	no	no				
687	13530 13614	003810[illegible]	2,2-bis(4-hydroxyphenyl)propane bis(phthalic anhydride)	no	yes	no	0,05			
688	92560	003861[illegible]	tetrakis(2,4-di-tert-butyl-phenyl)-4,4′-biphenylylene diphosphonite	yes	no	yes	18			
689	95280	004060[illegible]	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	004148[illegible]	thiodiethylene bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)	yes	no	yes	2,4			
691	13600	004746[illegible]	3,3′-bis(3-methyl-4-hydroxyphenyl)-2-indolinone	no	yes	no	1,8			
692	52320	005204[illegible]	2-(4-dodecylphenyl)indole	yes	no	yes	0,06			
693	88160	005414[illegible]	sorbitan tripalmitate	yes	no	no				
694	21400	005427[illegible]	methacrylic acid,	yes	no	no	0,05			(1)

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			sulphopropyl ester							
695	67520	0054849-38-6	monomethyltin tris(isooctyl mercaptoacetate)		no	no		(9)		
696	92205	0057569-40-1	terephthalic acid, diester with 2,2′-methylenebis(4-methyl-6-tert-butylphenol)		no	no				
697	67515	0057583-34-3	monomethyltin tris(ethylhexyl mercaptoacetate)		no	no		(9)		
698	49595	0057583-35-4	dimethyltin bis(ethylhexyl mercaptoacetate)		no	no		(9)		
699	90720	0058446-52-9	stearoylbenzoylmethane		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	0061269-64-2	N,N′-bis(2,2,6,6-tetramethyl-4-piperidyl)hexamethylenediamine-1,2-dibromoethane, copolymer	yes	no	no	2,4			
702	87920	0061752-68-2	sorbitan tetrastearate	yes	no	no				

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703	17170	00617884-47-4	fatty acids, coco	no	yes	no				
704	77600	00617888-85-0	polyethyleneglycol ester of hydrogenated castor oil	no	no	no				
705	10599/90 10599/91	00617888-89-4	acids, fatty, unsaturated (C_{18}), dimers, non hydrogenated, distilled and non-distilled	no	yes	no		(18)		(1)
706	17230	00617900-12-3	fatty acids, tall oil	no	yes	no				
707	46375	00617900-53-2	diatomaceous earth	yes	no	no				
708	77520	00617911-12-6	polyethyleneglycol ester of castor oil	no	no	no	42			
709	87520	00625681-10-0	sorbitan monobehenate	yes	no	no				
710	38700	00633976-60-2	bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)	yes	no	yes	18			
711	42000	00634380-20-2	bis(2-carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)	yes	no	yes	30			

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712	42960	00641474-48-6	castor oil, dehydrated	yes	no	no				
713	43480	00643654-21-3	charcoal, activated	yes	no	no			Only for use in PET at maximum 10 mg/kg of polymer. Same purity requirements as for Vegetable Carbon (E 153) set out by Commission Directive 95/45/EC[d] with exception of ash content which can be up to 10 % (w/w).	
714	84400	00643655-17-9	rosin, hydrogenated, ester with pentaerythritol	yes	no	no				
715	46880	00651403-95-2	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid,	yes	no	no	6			

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			monoethyl ester, calcium salt							
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	0066822-56-4	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	yes	no	no		(25)		

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			tris(isooctyl mercaptoacetate)							
721	46800	006784539-6	3,5-di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	yes	no	no				
722	17200	006830853-2	Fatty acids, soya	no	yes	no				
723	88880	006841229-3	Starch, hydrolysed	yes	no	no				
724	24903	006842517-2	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[e]	
725	77895	006843940-6	Polyethyleneglycol (EO = 2-6) monoalkyl (C_{16}-C_{18}) ether	yes	no	no	0,05		The composition of this mixture is as follows: — polyethyleneglycol (EO = 2-6)monoalkyl (C_{16}-C_{18})	

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									—	ether (approximately 28 %), fatty alcohols (C_{16}-C_{18}) (approximately 48 %),
									—	ethyleneglycol monoalkyl (C_{16}-C_{18}) 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	0068442-85-1	cellulose, regenerated	yes	no	no				
728	75100	0068515-48-0 0028553-12-0	phthalic acid, diesters with primary, saturated C_8-C_{10} branched alcohols, more than	yes	no	no		(26) (32)	Only to be used as: (a)	(7) plasticiser in repeated use materials and articles;

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			60 % C_9						(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;
									(c)	technical support

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										agent in concentrations up to 0,1 % in the final product.
729	75105	006851-49-1 002676-40-0	phthalic acid, diesters with primary, saturated C_9-C_{11} alcohols more than 90 % C_{10}	yes	no	no		(26) (32)	Only to be used as: (a) (b)	(7) plasticiser in repeated use materials and articles; 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

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									(c)	or processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC; technical support agent in concentrations up to 0,1 % in the final product.
730	66930	006854-70-1	methylsilsesquioxane			no			Residual monomer in methylsilsesquioxane: < 1 mg methyltrimethoxysilane/kg of methylsilsesquioxane	
731	18220	006856-88-5	7-heptylaminoundecanoic acid	no	yes	no	0,05			(2)
732	45450	006610-51-5	*p*-cresol-dicyclopentadiene-	yes	no	yes	5			

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			isobutylene, copolymer							
733	10599/90A 10599/93	0068783-41-5	acids, fatty, unsaturated (C_{18}), 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)		
737	77370	0070142-34-6	polyethyleneglycol-30 dipolyhydroxystearate	yes	no	no				
738	60320	0070321-86-7	2-[2-hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole	yes	no	yes	1,5			
739	70000	0070331-94-1	2,2′-oxamidobis[ethyl-3-(3,5-di-tert-butyl-4-hydroxyphenyl)-propionate]	yes	no	no				
740	81200	0071878-19-8	poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-	yes	no	yes	3			

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			tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl) imino]							
741	24070 83610	007313[illegible]	resin acids and rosin acids	yes	yes	no				
742	92700	007830[illegible]	2,2,6,6-tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, polymer	yes	no	yes	5			
743	38950	007907[illegible]	bis(4-ethylbenzylidene)sorbitol	yes	no	no				
744	18888	008018[illegible]	3-hydroxybutanoic acid-3-hydroxypentanoic acid, copolymer	no	yes	no			The substance is used as product obtained by bacterial fermentation. In compliance with the specifications mentioned in the Table 4 of Annex I	
745	68145	008041[illegible]	2,2′,2″-nitrilo(triethyl	yes	no	yes	5		SML expressed	

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			tris(3,3′,5,5′-tetra-tert-butyl-1,1′-bi-phenyl-2,2′-diyl)phosphite)					as sum of phosphite and phosphate	
746	38810	00806931-00-2	bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite	yes	no	yes	5	SML expressed as sum of phosphite and phosphate	
747	47600	00840301-61-5	di-n-dodecyltin bis(isooctyl mercaptoacetate)	yes	no	yes	(25)		
748	12765	00844341-22-8	N-(2-aminoethyl)-β-alanine, sodium salt	no	yes	no	0,05		
749	66360	00852092-21-2	2,2′-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	yes	no	yes	5		
750	66350	00852092-22-4	2,2′-methylenebis(4,6-di-tert-butylphenyl) lithium phosphate	yes	no	no	5		
751	81515	00871892-25-1	bis[2-(zinc glycerolate)	yes	no	no			
752	39890	00878264-34-9 – 30069158-41-7 –	bis(methylbenzylidene)sorbitol	yes	no	no			

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		40054686-97- – 40081541-12-0								
753	62800	009270[illegible]	kaolin, calcined	yes	no	no				
754	56020	009988[illegible]	glycerol dibehenate	yes	no	no				
755	21765	010624[illegible]	4,4′-methylenebis(3-chloro-2,6-diethylaniline)	no	yes	no	0,05			(1)
756	40020	011055[illegible]	2,4-bis(octylthiomethyl)-6-methylphenol	yes	no	yes		(24)		
757	95725	011063[illegible]	reaction product with citric acid, lithium salt	yes	no	no				
758	38940	011067[illegible]	2,4-bis(dodecylthiomethyl)-6-methylphenol	yes	no	yes		(24)		
759	54300	011833[illegible]	2,2′-ethylidenebis(4,6-di-tert-butylphenyl) fluorophosphonite	yes	no	yes	6			
760	83595	011934[illegible]	reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-	yes	no	no	18		Composition: —	4,4′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0038613-77-3) (36-46 % w/

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e OJ L 158, 18.6.2008, p. 17.

			butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl							w (*)), — 4,3′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)), — 3,3′-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)), — 4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)), — tris(2,4-di-tert-butylphenyl)phosphite (CAS No 0031570-04-4)

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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										(9-18 % w/ w (*)),
									—	4,4′-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0 bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0112949-97-0) (< 5 % w/ w (*))
									(*)	Quantity of substance used/ quantity of formulation
										Other specifications:
									—	Phosphor content of min. 5,4 % to max. 5,9 %,
									—	Acid value of max. 10 mg KOH per gram,

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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									—	Melt range of 85–110 °C,
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			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

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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. Only to be used in: (a) polyolefins at 0,1 % (w/w) concentration and (b) in PET at	(1)

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

										0,25 % (w/w) concentration.
769	74010	01456[illegible]	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	01473152[illegible]	2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol	yes	no	no	0,05			
771	34650	01518[illegible]	aluminium hydroxybis [2,2′-methylenebis (4,6-di-tert-butylphenyl) phosphate]	yes	no	no	5			
772	47500	01532501[illegible]	N,N′-dicyclohexyl-2,6-naphthalene dicarboxamide	yes	no	no	5			
773	38840	01548621[illegible]	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	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

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									(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	0167883-16-8	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_{16}-C_{18} alkyl esters	yes	no	no			0,5 % in final product	(1)

a	OJ L 302, 19.11.2005, p. 28.
b	OJ L 330, 5.12.1998, p. 32.
c	OJ L 253, 20.9.2008, p. 1.
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778	71670	01786715-58-4	pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	yes	no	yes	0,05			
779	39815	01821219-12-6	9,9-bis(methoxymethyl)fluorene	yes	no	yes	0,05			(1)
780	81220	01922689-64-7	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			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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781	95265	022709916-8	1,3,5-tris(4-benzoylphenyl) benzene	yes	no	no	0,05			
782	76725	066147644-3	poly(dimethylsiloxane), 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	073615063-3	glycerides, castor-oil mono-, hydrogenated, acetates	yes	no	no		(32)		
784	95420	074507016-5	1,3,5-tris (2,2-dimethylpropanamido)benzene	yes	no	no	0,05			
785	24910	000010021-0	terephthalic acid	no	yes	no		(28)		
786	14627	000011732-1	3-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 3-chlorophthalic acid	
787	14628	000011844-5	4-chlorophthalic anhydride	no	yes	no	0,05		SML expressed as 4-chlorophthalic acid	
788	21498	000253035-0	[3-(methacryloxy)propyl]trimethoxysilane	no	yes	no	0,05		Only to be used	(1) (11)

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

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									as a surface treatment agent of inorganic fillers	
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 × 10^{-6} m^2/s).	(2)
790	80480	0090751-07-8 0082451-48-7	poly(6-morpholino-1,3,5-triazine-2,4-diyl)-[(2,2,6,6-tetramethyl-4-piperidyl)imino)] hexa-methylene-[(2,2,6,6-tetramethyl-4-piperidyl)imino)]	yes	no	no	5		Average molecular weight not less than 2 400 Da. Residual content of morpholine ≤ 30 mg/kg, of N,N′-	(16)

a	OJ L 302, 19.11.2005, p. 28.
b	OJ L 330, 5.12.1998, p. 32.
c	OJ L 253, 20.9.2008, p. 1.
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									bis(2,2,6,6-tetramethylpiperidin-4-yl)hexane-1,6-diamine < 15 000 mg/kg, and of 2,4-dichloro-6-morpholino-1,3,5-triazine ≤ 20 mg/kg.	
791	92470	01069904-53-6	N4,N6′,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	02032553-83-5	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	00001024-71-6	2-ethylhexanoic acid	yes	no	no	0,05		SML expressed as the sum of	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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e OJ L 158, 18.6.2008, p. 17.

									triethanolamine and the hydrochloride adduct expressed as triethanolamine	
794	18117	0000079-41-4	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) (12)
796	72141	0018600-22-4	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	0007328-23-5	polyesters of adipic acid with 1,3-butanediol, 1,2-propanediol and 2-ethyl-1-hexanol	yes	no	yes		(31) (32)		
798	92200	0006422-86-2	terephthalic acid,	yes	no	no	60	(32)		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			bis(2-ethylhexyl)ester							
799	77708	—	polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C_8-C_{22}) 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	
801	30607	—	acids, C_2-C_{24}, aliphatic, linear, monocarboxylic, from natural oils	yes	no	no				

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			and fats, lithium salt							
802	33105	0146340-15-0	alcohols, C_{12}-C_{14} secondary, β-(2-hydroxyethoxy), ethoxylated	yes	no	no	5			(12)
803	33535	0152261-33-1	alkenes(C_{20}-C_{24}) 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. Not to be used in contact with alcoholic foods.	(13)
804	80510	1010121-89-7	poly(3-nonyl-1,1-dioxo-1-thiopropane-1,3-diyl)-block-poly(x-oleyl-7-hydroxy-1,5-diiminooctane-1,8-	yes	no	no			Only to be used as polymer production aid in polyethylene (PE), polypropylene	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			diyl), process mixture with x = 1 and/or 5, neutralised with dodecylbenzenesulfonic acid						(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	00010761-97-7	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. Only to be used in PET bottles up to	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

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									20 mg/kg. 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	088207-38-4	bis(4-propylbenzylidene)propylsorbitol	yes	no	no	5		SML including the sum of its hydrolysis products	
809	49080	852282-89-4	4-(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) (14) (15)
810	68119		neopentyl glycol, diesters and monoesters with	yes	no	no	5	(32)	Not to be used for articles in	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

			benzoic acid and 2-ethylhexanoic acid						contact with fatty foods for which simulant D is laid down.
811	80077	006844[illegible]	poly(ethylene waxes, oxidised	yes	no	no	60		
812	80350	012457[illegible]	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. Prepared by the reaction of poly(12-hydroxystearic acid) with polyethyleneimine.
813	91530	—	sulphosuccinic acid alkyl (C_4-	yes	no	no	5		

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			C_{20}) or cyclohexyl diesters, salts							
814	91815	—	sulphosuccinic acid monoalkyl (C_{10}-C_{16}) 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. Purity ≥ 96 %.	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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818	21530	—	methallylsulphonic acid, salts	yes	yes	no	5			
819	68110	—	neodecanoic acid, salts	yes	no	no	0,05		Not to be used in polymers contacting fatty foods. Not to be used for articles in contact with fatty foods for which simulant D is laid down. SML expressed 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)

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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823	24889	—	5-Sulphoisophthalic acid, salts	no	yes	no	5			
854	71943	032923-24-6	perfluoro acetic acid, α-substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1-ethylene glycol, terminated with chlorohexafluoropropyloxy 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	005179-8-23-5	perfluoro [2-(poly(n-propoxy))propanoic acid]	no	no	no			Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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									above 265 °C and are intended for use in repeated use articles
861	71990	0013252-13-6	perfluoro[2-(n-propoxy)propanoic acid]	no	no				Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles
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. Only for use as a co-

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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									monomer for ethyl vinyl alcohol copolymers.
864	46330	00000562-46-4	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	00253220-90-0	(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	yes	no	no			Only to be used in rigid poly(vinyl chloride) (PVC) at a

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

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			allyl methacrylate						maximum level of 7 %	
867	40815	00404716-03-2	(tert-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	00090104-88-1	(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	00271366-15-8	(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	01605351-46-6	N,N′,N″-tris(2-methylcyclohexyl)-1,2,3-	yes	no	no	5			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			propane-tricarboxamide						
875	80345	0058128-21-6	poly(12-hydroxystearic acid) stearate	yes	no	yes	5		
878	31335	—	acids, fatty (C_8-C_{22}) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C_3-C_{22})	yes	no	no			
879	31336	—	acids, fatty (C_8-C_{22}) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric,	yes	no	no			

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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			saturated, primary (C_1-C_{22})							
880	31348	00851164-93-4	azelaic, fatty (C_8-C_{22}), esters with pentaerythritol	yes	no	no				
881	25187	00030102-26-6	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	00024167-81-6	2,4,6-trimethylphenol	no	yes	no	0,05			
883	22074	00044737-10-0	2-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	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

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									0,5 dm^2/ kg	
884	34240	0091082-17-6	alkyl(C_{10}-C_{21})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	

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e OJ L 158, 18.6.2008, p. 17.

										with aqueous, acidic and alcoholic foods, for long term storage at room temperature.

a OJ L 302, 19.11.2005, p. 28.

b OJ L 330, 5.12.1998, p. 32.

c OJ L 253, 20.9.2008, p. 1.

d OJ L 226, 22.9.1995, p. 1.

e 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	128 211	6	expressed as acetaldehyde
2	89 227 263	30	expressed as ethyleneglycol
3	234 248	30	expressed as maleic acid

4	212 435	15	expressed as caprolactam
5	137 472	3	expressed as the sum of the substances
6	412 512 513 588	1	expressed as iodine
7	19 20	1,2	expressed as tertiary amine
8	317 318 319 359 431 464	6	expressed as the sum of the substances
9	650 695 697 698 726	0,18	expressed as tin
10	28 29 30 31 32 33 466 582 618 619 620 646 676 736	0,006	expressed as tin
11	66 645 657	1,2	expressed as tin
12	444 469 470	30	expressed as the sum of the substances
13	163 285	1,5	expressed as the sum of the substances
14	294 368	5	expressed as the sum of the substances

15	98 196	15	expressed as formaldehyde
16	407 583 584 599	6	expressed as boron Without prejudice to the provisions of Directive 98/83/EC
17	4 167 169 198 274 354 372 460 461 475 476 485 490 653	ND	expressed as isocyanate moiety
18	705 733	0,05	expressed as the sum of the substances
19	505 516 519	10	expressed as SO_2
20	290 386 390	30	expressed as the sum of the substances
21	347 349	5	expressed as trimellitic acid
22	70 147 176 218 323 325 365 371 380 425 446 448 456 636	6	expressed as acrylic acid
23	150 156 181 183	6	expressed as methacrylic acid

	184 355 370 374 439 440 447 457 482		
24	756 758	5	expressed as the sum of the substances
25	720 747	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	728 729	9	expressed as the sum of the substances
27	188 291	5	expressed as isophthalic acid
28	191 192 785	7,5	expressed as terephthalic acid
29	342 672	0,05	expressed as the sum of 6-hydroxyhexanoic acid and caprolactone
30	254 672	5	expressed as 1,4-butanediol
31	73 797	30	expressed as the sum of the substances
32	8 72 73 138 140 157 159 207 242 283 532	60	expressed as the sum of the substances

	670 728 729 775 783 797 798 810 815		

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^2.
(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^2/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

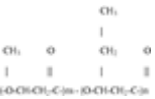
Table 4 on detailed specifications on substances contains the following information

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 Alcaligenes eutrophus 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 Alcaligenes eutrophus 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	 where n/(m + n) greater than 0 and less or equal to 0,25

	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-hydoxy-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	
	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^2
	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

a 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

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

a 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	**Beverages**						
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:						
	A. Clear drinks: Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars,		X(*)	X			

	lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract						
	B. cloudy drinks: juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate		X(*)		X		
01.02	Alcoholic beverages of an alcoholic strength of between 6 %vol and 20 %.			X			
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors				X		

01.04	Miscellaneous: undenaturated ethyl alcohol		X(*)			Substitute 95 % ethanol	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**						
02.01	Starches						X
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)						X
02.03	Cereal flour and meal						X
02.04	Dry pasta e.g. macaroni, spaghetti and similar products and fresh pasta						X
02.05	Pastry, biscuits, cakes, bread, and other bakers' wares, dry:						
	A.	With fatty substances on				X/3	

		the surface					
	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	**Chocolate, sugar and products thereof Confectionery products**						
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				X/3	

		the surface					
	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	**Fruit, vegetables and products thereof**						
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	
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	X				

		or cut					
	C.	Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine)	X(*)	X			
	D.	Preserved vegetables:					
	I.	In an oily medium	X			X	
	II.	In an alcoholic medium			X		
05	**Fats and oils**						
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	**Animal products and eggs**						
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		
07	**Milk products**						
07.01	Milk						
	A.	Milk and milk based drinks whole, partly dried and skimmed			X		

		or partly skimmed					
	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, mozarella, and similar)	X(*)		X		
08	**Miscellaneous products**						
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/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	X(*)			X	

		creams and other oil/ water mixtures e.g. coconut based sauces					
08.05	Mustard (except powdered mustard under heading 08.14)	X	X(*)			X/3(**)	
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff						
	A.	With fatty substances on the surface	X			X/5	
	B.	Other					X
08.07	Ice-creams			X			
08.08	Dried foods:						
	A.	With fatty substances on the surface				X/5	
	B.	Other					X

08.09	Frozen or deep-frozen foods						X
08.10	Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.		X(*)		X		
08.11	Cocoa:						
	A.	Cocoa powder, including fat-reduced and highly fat reduced					X
	B.	Cocoa paste				X/3	
08.12	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered						X
08.13	Aromatic herbs and other herbs such as camomile, mallow, mint, tea, lime blossom						X

	and others						
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.

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 ≤ 5 min	5 min
5 min < t ≤ 0,5 hour	0,5 hour
0,5 hours < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 6 hours	6 hours
6 hours < t ≤ 24 hours	24 hours
1 day < t ≤ 3 days	3 days
3 days < t ≤ 30 days	10 days
Above 30 days	See specific conditions

TABLE 2

Contact temperature

Conditions of contact in worst foreseeable use	**Test conditions**
Contact temperature	**Test temperature**
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C
20 °C < T ≤ 40 °C	40 °C
40 °C < T ≤ 70 °C	70 °C

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

70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C[a]
121 °C < T ≤ 130 °C	130 °C[a]
130 °C < T ≤ 150 °C	150 °C[a]
150 °C < T < 175 °C	175 °C[a]
T > 175 °C	Adjust the temperature to the real temperature at the interface with the food[a]

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

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

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

t2 = t1 * Exp ((-Ea/R) * (1/T1-1/T2))

Ea is the worst case activation energy 80kJ/mol

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

Exp -9627 * (1/T1-1/T2)

t1 is the contact time

t2 is the testing time

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

T2 is the testing temperature in Kelvin.

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

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

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

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

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

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

2.1.5. Specific conditions for combinations of contact times and temperature

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

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

2.1.6. Repeated use articles

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

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

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

2.1.7. Analysis of migrating substances

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

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^2 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^2 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	High temperature applications	OM1, OM2, OM3, OM4, OM5 and OM6

	food simulant D2 for 10 days at 40 °C	including long term storage at room temperature	

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 fat in food/kg of food)/200 = (% fat × 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^2/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

(**1**) OJ L 338, 13.11.2004, p. 4.

(**2**) OJ L 220, 15.8.2002, p. 18.

(**3**) OJ L 44, 15.2.1978, p. 15.

(**4**) OJ L 135, 30.5.2009, p. 3.

(**5**) OJ L 354, 31.12.2008, p. 16.

(**6**) OJ L 354, 31.12.2008, p. 34.

(**7**) OJ L 31, 1.2.2002, p. 1.

(**8**) 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

(**9**) Opinion of the Scientific Panel on Food Additives, Flavourings, 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.

(**10**) OJ L 297, 23.10.1982, p. 26.

(**11**) OJ L 213, 16.8.1980, p. 42.

(**12**) OJ L 167, 24.6.1981, p. 6.

(**13**) OJ L 165, 30.4.2004, p. 1.

(**14**) OJ L 384, 29.12.2006, p. 75.

(**15**) OJ L 401, 30.12.2006, p. 1.

(**16**) OJ L 339, 6.12.2006, p. 16.

(**17**) OJ L 353, 31.12.2008, p. 1.

(**18**) OJ L 372, 31.12.1985, p. 14.