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)

## COMMISSION REGULATION (EU) No 10/2011

of 14 January 2011

on plastic materials and articles intended to come into contact with food

(Text with EEA relevance)

## THE EUROPEAN COMMISSION,

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

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

After consulting the European Food Safety Authority,

#### Whereas:

- (1) Regulation (EC) No 1935/2004 lays down the general principles for eliminating the differences between the laws of the Member States as regards food contact materials. Article 5(1) of that Regulation provides for the adoption of specific measures for groups of materials and articles and describes in detail the procedure for the authorisation of substances at EU level when a specific measure provides for a list of authorised substances.
- (2) This Regulation is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use and repeal Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs<sup>(2)</sup>.
- (3) Directive 2002/72/EC sets out basic rules for the manufacture of plastic materials and articles. The Directive has been substantially amended 6 times. For reasons of clarity the text should be consolidated and redundant and obsolete parts removed.
- (4) In the past Directive 2002/72/EC and its amendments have been transposed into national legislation without any major adaptation. For transposition into national law usually a time period of 12 months is necessary. In case of amending the lists of monomers and additives in order to authorise new substances this transposition time leads to a retardation of the authorisation and thus slows down innovation. Therefore it seems appropriate to adopt rules on plastic materials and articles in form of a Regulation directly applicable in all Member States.

- Directive 2002/72/EC applies to materials and articles purely made of plastics and to plastic gaskets in lids. In the past these were the main use of plastics on the market. However, in recent years, besides materials and articles purely made of plastics, plastics are also used in combination with other materials in so called multi-material multi-layers. Rules on the use of vinyl chloride monomer laid down in Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs<sup>(3)</sup> already apply to all plastics. Therefore it seems appropriate to extend the scope of this Regulation to plastic layers in multi-material multi-layers.
- (6) Plastic materials and articles may be composed of different layers of plastics held together by adhesives. Plastic materials and articles may also be printed or coated with an organic or inorganic coating. Printed or coated plastic materials and articles as well as those held together by adhesives should be within the scope of the Regulation. Adhesives, coatings and printing inks are not necessarily composed of the same substances as plastics. Regulation (EC) No 1935/2004 foresees that for adhesives, coatings and printing inks specific measures can be adopted. Therefore plastic materials and articles that are printed, coated or held together by adhesives should be allowed to contain in the printing, coating or adhesive layer other substances than those authorised at EU level for plastics. Those layers may be subject to other EU or national rules.
- (7) Plastics as well as ion exchange resins, rubbers and silicones are macromolecular substances obtained by polymerisation processes. Regulation (EC) No 1935/2004 foresees that for ion exchange resins, rubbers and silicones specific measures can be adopted. As those materials are composed of different substances than plastics and have different physico-chemical properties specific rules for them need to apply and it should be made clear that they are not within the scope of this Regulation.
- (8) Plastics are made of monomers and other starting substances which are chemically reacted to a macromolecular structure, the polymer, which forms the main structural component of the plastics. To the polymer additives are added to achieve defined technological effects. The polymer as such is an inert high molecular weight structure. As substances with a molecular weight above 1 000 Da usually cannot be absorbed in the body the potential health risk from the polymer itself is minimal. Potential health risk may occur from non- or incompletely reacted monomers or other starting substances or from low molecular weight additives which are transferred into food via migration from the plastic food contact material. Therefore monomers, other starting substances and additives should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.
- (9) The risk assessment of a substance to be performed by the European Food Safety Authority (hereinafter the Authority) should cover the substance itself, relevant impurities and foreseeable reaction and degradation products in the intended use. The risk assessment should cover the potential migration under worst foreseeable conditions of use and the toxicity. Based on the risk assessment the authorisation should if

- necessary set out specifications for the substance and restrictions of use, quantitative restrictions or migration limits to ensure the safety of the final material or article.
- (10) No rules have yet been set out at EU level for the risk assessment and use of colorants in plastics. Therefore their use should remain subject to national law. That situation should be reassessed at a later stage.
- (11) Solvents used in the manufacture of plastics to create a suitable reaction environment are expected to be removed in the manufacturing process as they are usually volatile. No rules have yet been set out at EU level for the risk assessment and use of solvents in the manufacture of plastics. Therefore their use should remain subject to national law. That situation should be reassessed at a later stage.
- (12) Plastics can also be made of synthetic or natural occurring macromolecular structures which are chemically reacted with other starting substances to create a modified macromolecule. Synthetic macromolecules used are often intermediate structures which are not fully polymerised. Potential health risk may occur from the migration of non-or incompletely reacted other starting substances used to modify the macromolecule or an incompletely reacted macromolecule. Therefore the other starting substances as well as the macromolecules used in the manufacture of modified macromolecules should be risk assessed and authorised before their use in the manufacture of plastic materials and articles.
- (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.
- 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.

- 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.
- When an additive included in the provisional list is inserted in the Union list or when it is decided not to include it in the Union list, that additive should be removed from the provisional list of additives.
- (23) New technologies engineer substances in particle size that exhibit chemical and physical properties that significantly differ from those at a larger scale, for example, nanoparticles. These different properties may lead to different toxicological properties and therefore these substances should be assessed on a case-by-case basis by the Authority as regards their risk until more information is known about such new technology. Therefore it should be made clear that authorisations which are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles.
- (24)Based on the risk assessment the authorisation should if necessary set out specific migration limits to ensure the safety of the final material or article. If an additive that is authorised for the manufacture of plastic materials and articles is at the same time authorised as food additive or flavouring substance it should be ensured that the release of the substance does not change the composition of the food in an unacceptable way. Therefore the release of such a dual use additive or flavouring should not exhibit a technological function on the food unless such a function is intended and the food contact material complies with the requirements on active food contact materials set out in Regulation (EC) No 1935/2004 and Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food<sup>(4)</sup>. The requirements of Regulations (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives<sup>(5)</sup> or (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC<sup>(6)</sup> should be respected where applicable.
- (25) According to Article 3(1)(b) of Regulation (EC) No 1935/2004 the release of substances from food contact materials and articles should not bring about unacceptable changes in the composition of the food. According to good manufacturing practice it is feasible to manufacture plastic materials in such a way that they are not releasing more than 10 mg of substances per 1 dm<sup>2</sup> of surface area of the plastic material. If the risk

assessment of an individual substance is not indicating a lower level, this level should be set as a generic limit for the inertness of a plastic material, the overall migration limit. In order to achieve comparable results in the verification of compliance with the overall migration limit, testing should be performed under standardised test conditions including testing time, temperature and test medium (food simulant) representing worst foreseeable conditions of use of the plastic material or article.

- The overall migration limit of 10 mg per 1 dm<sup>2</sup> 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<sup>(7)</sup> requires the food business operator to verify that foods are compliant with the rules applicable to them. To this end and subject to the requirement of confidentiality, food business operators should be given access to the relevant information to enable them to ensure that the migration from the materials and articles to food complies with the specifications and restrictions laid down in food legislation.
- (32) At each stage of manufacture, supporting documentation, substantiating the declaration of compliance, should be kept available for the enforcement authorities. Such demonstration of compliance may be based on migration testing. As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculations, including modelling, other analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing. Test results should be regarded as valid as long as formulations and processing conditions remain constant as part of a quality assurance system.
- (33) When testing articles not yet in contact with food, for certain articles, such as films or lids, it is often not feasible to determine the surface area that is in contact with a defined volume of food. For these articles specific rules should be set out for verification of compliance.
- (34) The setting of migration limits takes into account a conventional assumption that 1kg of food is consumed daily by a person of 60 kg bodyweight and that the food is packaged in a cubic container of 6 dm<sup>2</sup> surface area releasing the substance. For very small and very large containers the real surface area to volume of packaged food is varying a lot

- from the conventional assumption. Therefore, their surface area should be normalised before comparing testing results with migration limits. These rules should be reviewed when new data on food packaging uses become available.
- (35) The specific migration limit is a maximum permitted amount of a substance in food. This limit should ensure that the food contact material does not pose a risk to health. It should be ensured by the manufacturer that materials and articles not yet in contact with food will respect these limits when brought into contact with food under the worst foreseeable contact conditions. Therefore compliance of materials and articles not yet in contact with food should be assessed and the rules for this testing should be set out.
- (36) Food is a complex matrix and therefore the analysis of migrating substances in food may pose analytical difficulties. Therefore test media should be assigned that simulate the transfer of substances from the plastic material into food. They should represent the major physico-chemical properties exhibited by food. When using food simulants standard testing time and temperature should reproduce, as far as possible, the migration which may occur from the article into the food.
- (37) For determining the appropriate food simulant for certain foods the chemical composition and the physical properties of the food should be taken into account. Research results are available for certain representative foods comparing migration into food with migration into food simulants. On the basis of the results, food simulants should be assigned. In particular, for fat containing foods the result obtained with food simulant may in certain cases significantly overestimate migration into food. In these cases it should be foreseen that the result in food simulant is corrected by a reduction factor.
- (38) The exposure to substances migrating from food contact materials was based on the conventional assumption that a person consumes daily 1 kg of food. However, a person ingests at most 200 g of fat on a daily basis. For lipophilic substances that only migrate into fat this should be taken into consideration. Therefore a correction of the specific migration by a correction factor applicable to lipophilic substances in accordance with the opinion of the Scientific Committee on Food (SCF)<sup>(8)</sup> and the opinion of the Authority<sup>(9)</sup> should be foreseen.
- (39) Official control should establish testing strategies which allow the enforcement authorities to perform controls efficiently making best use of available resources. Therefore it should be admissible to use screening methods for checking compliance under certain conditions. Non-compliance of a material or article should be confirmed by a verification method.
- (40) Basic rules on migration testing should be set out in this Regulation. As migration testing is a very complex issue, these basic rules can, however, not cover all foreseeable cases and details necessary for performing the testing. Therefore a EU guidance document should be established, dealing with more detailed aspects of the implementation of the basic migration testing rules.
- (41) The updated rules on food simulants and migration testing provided by this Regulation will supersede those in Directive 78/142/EEC and the Annex to Council Directive

- 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs<sup>(10)</sup>.
- (42) Substances present in the plastic but not listed in Annex I to this Regulation have not necessarily been risk assessed as they had not been subject to an authorisation procedure. Compliance with Article 3 of Regulation (EC) No 1935/2004 for these substances should be assessed by the relevant business operator in accordance with internationally recognised scientific principles taking into account exposure from food contact materials and other sources.
- (43) Recently additional monomers, other starting substances and additives have received a favourable scientific evaluation by the Authority and should now be added to the Union list.
- (44) As new substances are added to the Union list the Regulation should apply as soon as possible to allow for manufacturers to adapt to technical progress and allow for innovation.
- (45) Certain migration testing rules should be updated in view of new scientific knowledge. Enforcement authorities and industry need to adapt their current testing regime to these updated rules. To allow for this adaptation it seems appropriate that the updated rules only apply 2 years after the adoption of the Regulation.
- (46) Business operators are currently basing their declaration of compliance on supporting documentation following the requirements set out in Directive 2002/72/EC. Declaration of compliance need, in principle, only to be updated when substantial changes in the production bring about changes in the migration or when new scientific data are available. In order to limit the burden to business operators, materials which have been lawfully placed on the market based on the requirements set out in Directive 2002/72/EC should be able to be placed on the market with a declaration of compliance based on supporting documentation in accordance with Directive 2002/72/EC until 5 years after the adoption of the Regulation.
- (47) Analytical methods for testing migration and residual content of vinyl chloride monomer as described in Commission Directives 80/766/EEC of 8 July 1980 laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs<sup>(11)</sup> and 81/432/EEC of 29 April 1981 laying down the Community method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs<sup>(12)</sup> are outdated. Analytical methods should comply with the criteria set out in Article 11 of Regulation (EC) No 882/2004<sup>(13)</sup> of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Therefore Directives 80/766/EEC and 81/432/EEC should be repealed.
- (48) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

## HAS ADOPTED THIS REGULATION:

CHAPTER I U.K.

## **GENERAL PROVISIONS**

Article 1 U.K.

## **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.

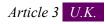


## Scope

- 1 This Regulation shall apply to materials and articles which are placed on the F1... 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.
- This Regulation shall not apply to the following materials and articles which are placed on the F1... market and are intended to be covered by other specific measures:
  - a ion exchange resins;
  - b rubber;
  - c silicones.
- This Regulation shall be without prejudice to the <sup>F2</sup>... provisions applicable to printing inks, adhesives or coatings.

#### **Textual Amendments**

- Word in Art. 2 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 66(b); 2020 c. 1, Sch. 5 para. 1(1)
- F2 Words in Art. 2(3) omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 66(a); 2020 c. 1, Sch. 5 para. 1(1)



#### **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;
- [F3° non-fatty food' means a food for which in migration testing only food simulants other than food simulants D1 or D2 are laid down in Table 2 of Annex III to this Regulation;]
- (17) 'restriction' means limitation of use of a substance or migration limit or limit of content of the substance in the material or article;
- [F3'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;]
- (19) [F4'hot-fill' means the filling of any article with a food with a temperature not exceeding 100 °C at the moment of filling, after which the food cools down to 50 °C or below within 60 minutes, or to 30 °C or below within 150 minutes.]

#### **Textual Amendments**

- **F3** Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F4** Inserted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).



## 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

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

- (c) comply with the traceability requirements set out in Article 17 of Regulation (EC) No 1935/2004; and
- (d) are manufactured according to good manufacturing practice as set out in Commission Regulation (EC) No 2023/2006<sup>(14)</sup>; and
- (e) comply with the compositional and declaration requirements set out in Chapters II, III and IV of this Regulation.

CHAPTER II U.K.

## **COMPOSITIONAL REQUIREMENTS**

SECTION 1 U.K.

### **Authorised substances**

Article 5 U.K.

## F5... List of authorised substances

- Only the substances included in the <sup>F6</sup>... list of authorised substances (hereinafter referred to as the <sup>F6</sup>... list) set out in Annex I may be intentionally used in the manufacture of plastic layers in plastic materials and articles.
- The F6... 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.
- [F73] The appropriate authority may prescribe amendments to the list.]

## **Textual Amendments**

- F5 Word in Art. 5 heading omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 67(a); 2020 c. 1, Sch. 5 para. 1(1)
- Word in Art. 5 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 67(a); 2020 c. 1, Sch. 5 para. 1(1)
- F7 Art. 5(3) substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 67(b); 2020 c. 1, Sch. 5 para. 1(1)

[F8 Article 5A U.K.

## Regulations and devolved powers

- 1. Any power to make regulations under this Regulation
  - a so far as exercisable by a Minister of the Crown, is exercisable by statutory instrument;

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

- b so far as exercisable by the Welsh Ministers, is exercisable by statutory instrument.
- 2. For regulations made under this Regulation by the Scottish Ministers, see also section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).
- 3. Any power to make regulations under this Regulation includes power
  - a to make different provision in relation to different cases or classes of case (including different provision for different areas or different classes of business); and
  - b to provide for such exceptions, limitations and conditions, and to make such supplementary, incidental, consequential or transitional provisions, as the appropriate authority considers necessary or expedient.
- 4. Any statutory instrument or Scottish statutory instrument containing regulations made under this Regulation is subject to annulment in pursuance of a resolution
  - a in the case of England, of either House of Parliament;
  - b in the case of Wales, of Senedd Cymru;
  - c in the case of Scotland, of the Scottish Parliament.
- 5. In this Regulation, any power
  - a of the Secretary of State to make regulations is limited to regulations which apply in relation to England only;
  - b of the Welsh Ministers to make regulations is limited to regulations which apply in relation to Wales only;
  - of the Scottish Ministers to make regulations is limited to regulations which apply in relation to Scotland only.]

#### **Textual Amendments**

F8 Art. 5A inserted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 68; 2020 c. 1, Sch. 5 para. 1(1) (as amended by S.I. 2020/1504, regs. 1(2), 16(7))

# Article 6 U.K.

## Derogations for substances not included in the F9... list

- 1 By way of derogation from Article 5, substances other than those included in the F10... list may be used as polymer production aids in the manufacture of plastic layers in plastic materials and articles subject to [F11 any relevant enactment].
- [F122] By way of derogation from Article 5, colorants and solvents which were capable of lawful use in the manufacture of plastic layers in plastic materials and articles prior to adoption of the list may continue to be so used subject to any relevant enactment.]
- The following substances not included in the <sup>F10</sup>... list are authorised subject to the rules set out in Articles 8, 9, 10, 11 and 12:
  - [F13a all salts of substances for which 'yes' is indicated in column 2 in Table 1 of Annex II of authorised acids, phenols or alcohols, and subject to the restrictions set out in column 3 and 4 of that table;]
    - b mixtures obtained by mixing authorised substances without a chemical reaction of the components;

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- 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 <sup>F10</sup>... list.
- The following substances not included in the <sup>F10</sup>... list may be present in the plastic layers of plastic materials or articles:
  - a non-intentionally added substances;
  - b aids to polymerisation.
- By derogation from Article 5, additives not included in the <sup>F10</sup>... 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 <sup>F10</sup>... list provided they are included in the provisional list referred to in Article 7.

#### **Textual Amendments**

- F9 Word in Art. 6 heading omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 69(a); 2020 c. 1, Sch. 5 para. 1(1)
- F10 Word in Art. 6 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 69(a); 2020 c. 1, Sch. 5 para. 1(1)
- F11 Words in Art. 6(1) substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 69(b); 2020 c. 1, Sch. 5 para. 1(1)
- F12 Art. 6(2) substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 69(c); 2020 c. 1, Sch. 5 para. 1(1)
- F13 Substituted by Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

# [F14Article 7 U.K.

## Establishment and management of the provisional list

- 1. The appropriate authority must regularly prescribe updates to the provisional list of additives that that was published by the European Commission in 2008.
- 2. An additive must be removed from the provisional list
  - a when it is included in the list set out in Annex 1;
  - b when a decision is taken by the appropriate authority not to include it in the list; or
  - c if during the examination of the data, the appropriate authority calls for supplementary information and that information is not submitted within the time limits specified by the appropriate authority.]

#### **Textual Amendments**

F14 Art. 7 substituted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 70; 2020 c. 1, Sch. 5 para. 1(1)

SECTION 2 U.K.

## General requirements, restrictions and specifications

Article 8 U.K.

## 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 U.K.

## 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 U.K.

## General restrictions on plastic materials and articles

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

Article 11 U.K.

## **Specific migration limits**

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

F152 ......

- [F3] By derogation from paragraph 1, additives which are also authorised as food additives by Regulation (EC) No 1333/2008 or as flavourings by Regulation (EC) No 1334/2008 shall not migrate into foods in quantities having a technical effect in the final foods and shall not:
  - a exceed the restrictions provided for in Regulation (EC) No 1333/2008 or in Regulation (EC) No 1334/2008 or in Annex I to this Regulation for foods for which their use is authorised as food additive or flavouring substances; or
  - b exceed the restrictions set out in Annex I to this Regulation in foods for which their use is not authorised as food additive or flavouring substances.]
- [F44] Where it is specified that no migration of a particular substance is permitted, compliance shall be established using appropriate migration test methods selected in accordance with Article 11 of Regulation (EC) No 882/2004 that can confirm the absence of migration above a specified limit of detection.

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

#### **Textual Amendments**

- **F3** Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F4** Inserted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F15 Deleted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

# Article 12 U.K.

#### **Overall migration limit**

- 1 Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm<sup>2</sup> of food contact surface (mg/dm<sup>2</sup>).
- By derogation from paragraph 1, plastic materials and articles intended to be brought into contact with food intended for infants and young children, as defined by Commission Directives 2006/141/EC<sup>(15)</sup> and 2006/125/EC<sup>(16)</sup>, shall not transfer their constituents to food simulants in quantities exceeding 60 milligrams of total of constituents released per kg of food simulant.

# CHAPTER III U.K.

## SPECIFIC PROVISIONS FOR CERTAIN MATERIALS AND ARTICLES

# Article 13 U.K.

## 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 F16... list or in the provisional list.
- [F33] Substances under paragraph 2(b) shall not migrate into food or food simulant, in accordance with Article 11(4). The detection limit set out in the second subparagraph of Article 11(4) shall apply to groups of substances if they are structurally and toxicologically related, including isomers or substances with the same relevant functional group, or to individual substances that are not related, and shall include possible set-off transfer.]
- The substances not listed in the <sup>F16</sup>... list or provisional list referred to in paragraph 2(b) shall not belong to either of the following categories:
  - a substances classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and the Council<sup>(17)</sup>;
  - b substances in nanoform.
- 5 The final plastic multi-layer material or article shall comply with the specific migration limits set out in Article 11 and the overall migration limit set out in Article 12 of this Regulation.

### **Textual Amendments**

- **F3** Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- F16 Word in Art. 13 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 71; 2020 c. 1, Sch. 5 para. 1(1)

# Article 14 U.K.

## 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.
- 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 F17... list or the provisional list.

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

- The substances not listed in the <sup>F17</sup>... 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.
- 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.

F186																																
U	٠	٠	٠	•	٠	٠	•	٠	٠	٠	•	٠	٠	٠	٠	٠	•	٠	•	•	٠	•	٠	٠	•	•	٠	٠	٠	٠	•	•

#### **Textual Amendments**

- F17 Word in Art. 14 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 72(a); 2020 c. 1, Sch. 5 para. 1(1)
- F18 Art. 14(6) omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 72(b); 2020 c. 1, Sch. 5 para. 1(1)

# CHAPTER IV U.K.

## DECLARATION OF COMPLIANCE AND DOCUMENTATION

Article 15 U.K.

## **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.
- 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.
- 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 U.K.

#### **Supporting documents**

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 <sup>F19</sup>... 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.

#### **Textual Amendments**

F19 Word in Art. 16 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 73; 2020 c. 1, Sch. 5 para. 1(1)



Article 17 U.K.

## **Expression of migration test results**

- 1 To check the compliance, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use.
- 2 By derogation from paragraph 1 for:
  - a containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres,
  - b materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith,
  - c sheets and films that are not yet in contact with food,
  - d sheets and films containing less than 500 millilitres or grams or more than 10 litres,

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

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

- 3 By derogation from paragraph 1, for caps, gaskets, stoppers and similar sealing articles the specific migration value shall be expressed in:
  - I<sup>F3</sup>a mg/kg using the actual content of the container for which the closure is intended applying the total contact surface of sealing article and sealed container if the intended use of the article is known, while taking into account the provisions of paragraph 2;]
    - b mg/article if the intended use of the article is unknown.
- 4 For caps, gaskets, stoppers and similar sealing articles the overall migration value shall be expressed in:
  - a mg/dm<sup>2</sup> applying the total contact surface of sealing article and sealed container if the intended use of the article is known;
  - b mg/article if the intended use of the article is unknown.

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

#### **Textual Amendments**

**F3** Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

# Article 18 U.K.

## Rules for assessing compliance with migration limits

- 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.
- 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.
- [F34] For materials and articles not yet in contact with food verification of compliance with the overall migration limit shall be carried out in food simulants as set out in Annex III in accordance with the rules set out in Chapter 3 of Annex V.]
- 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.
- 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.
- [F37] Before comparing specific and overall migration test results with the migration limits the correction factors set out in point 3 of Annex III and Chapter 4 of Annex V shall be applied in accordance with the rules set out therein.]

#### **Textual Amendments**

Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

Article 19 U.K.

# Assessment of substances not included in the F20... 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.

#### **Textual Amendments**

**F20** Word in Art. 19 heading omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 74; 2020 c. 1, Sch. 5 para. 1(1)

CHAPTER VI U.K.

### FINAL PROVISIONS

Article 20 U.K.

### **Amendments of EU acts**

The Annex to Council Directive 85/572/EEC<sup>(18)</sup> is replaced by the following:

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

Article 21 U.K.

## 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 U.K.

## **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.

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

- 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.
- 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 U.K.

## 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.

F21

### **Textual Amendments**

F21 Words in Signature omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 75; 2020 c. 1, Sch. 5 para. 1(1)

# ANNEX I U.K.

#### Substances

1. F22... List of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids U.K.

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).

[F3Column 8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is marked as ND ( 'not-detectable') if the substance is one in respect of which no migration is permitted, to be determined in accordance with Article 11(4).]

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.

F15 ...

TABLE 1

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM	Ref.	CAS	Substa	n <b>Ł</b> ese	Use	FRF	SML[r	n <b>&amp;</b> ML(	Γ)Restri	cti <b>Vat</b> es
substa No	1	No	name	as additiv or polymo produc	as yemonon or erother statartin st substa or macro obtain from microt	applicanero) g nce moleculo	a <b>Hlg(</b> yes/		and specifi p	on cat <b>iv</b> ification of compliance
1	12310	026630	9a <b>413</b> u7inin	no	yes	no				
2	12340	_	albumin coagula by formald	ted	yes	no				
3	12375	_	alcohols aliphatic monohy saturate linear, primary (C <sub>4</sub> - C <sub>22</sub> )	c, dric, d,	yes	no				
4	22332	_	diisocya and (60 % w/w) 2,4,4-	ylhexane inate ylhexane		no		(17)	1 mg/kg in final product express as isocyan moiety.	ed
5	25360	_	trialkyl( C <sub>15</sub> )ace acid, 2,3- epoxyprester	tic	yes	no	ND		1 mg/kg in final product express as epoxygn	ed

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and...

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

									Molecu weight is 43 Da.	lar
6	25380	_	trialkyl acetic acid (C <sub>7</sub> -C <sub>17</sub> ), vinyl esters	no	yes	no	0,05			(1)
7	30370	_	acetylac acid, salts	estės	no	no				
8	30401	_	acetylat mono- and diglycer of fatty acids		no	no		(32)		
9	30610		acids, C <sub>2</sub> -C <sub>24</sub> , aliphatic linear, monoca from natural oils and fats, and their mono-, di- and triglyce esters (branch fatty acids at naturall occuring levels are included	rboxylic rol ed y	no	no				
10	30612		acids, C <sub>2</sub> - C <sub>24</sub> ,	yes	no	no				

			aliphatic linear, monoca syntheti and their mono-, di- and triglyce esters	rboxylic c	,				
11	30960	_	acids, aliphatic monoca (C <sub>6</sub> -C <sub>22</sub> ), esters with polygly	rboxylic	no	no			
12	31328		acids, fatty, from animal or vegetab food fats and oils	yes	no	no			
13	33120	_	alcohols aliphatic monohy saturate linear, primary (C <sub>4</sub> - C <sub>24</sub> )	c, /dric, d,	no	no			
14	33801	_	n- alkyl(C C <sub>13</sub> )ben acid	yes 10 <sup>-</sup> zenesulp	no honic	no	30		
15	34130	_	alkyl, linear with even number of carbon atoms (C <sub>12</sub> -	yes	no	yes	30		

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

			C <sub>20</sub> ) dimethy	lamines						
16	34230	_	alkyl(C <sub>22</sub> )sulpacids		no	no	6			
17	34281	_	alkyl(C <sub>22</sub> )sulpacids, linear, primary with an even number of carbon atoms	huric	no	no				
18	34475	_	alumini calcium hydroxi phosphi hydrate	de	no	no				
19	39090	_	N,N- bis(2- hydroxy C <sub>18</sub> )ami	yes yethyl)all ne	no kyl(C <sub>8</sub> -	no		(7)		
20	39120	_	N,N- bis(2- hydroxy C <sub>18</sub> )ami hydroch		no kyl(C <sub>8</sub> -	no		(7)	SML(T) expresse excludin HCl	ed
21	42500	_	carbonic acid, salts	cyes	no	no				
22	43200		castor oil, mono- and diglycer	yes	no	no				
23	43515	_	chloride of choline esters of coconut oil		no	no	0,9			(1)

			fatty acids						
24	45280	_	cotton	yes	no	no			
25	45440	_	cresols, butylate styrenat	d,	no	no	12		
26	46700		benzofu one containi a) 5,7- di-tert- butyl-3- (3,4- dimethy benzofu one (80 to 100 % w/w) and b) 5,7-di- tert- butyl-3- (2,3-	ran-2- ing: rlphenyl) ran-2-	-3H-	no	5		
27	48960	_	9,10- dihydro stearic acid and its oligome		no	no	5		
28	50160	_	di-n- octyltin bis(n- alkyl(C C <sub>16</sub> ) mercapt		no )	no		(10)	

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29	50360	_	di-n- octyltin bis(ethy maleate	1	no	no	(10)	
30	50560	_	di-n- octyltin 1,4- butaned bis(mer		no tate)	no	(10)	
31	50800		di-n- octyltin dimalea esterifie	te,	no	no	(10)	
32	50880		di-n- octyltin dimalea polyme (n = 2-4)	te,	no	no	(10)	
33	51120		di-n- octyltin thioben: 2- ethylhe: mercapt	zoate	no	no	(10)	
34	54270	_	ethylhy	d <b>yex</b> yme	t <b>hø</b> lcellu	lose		
35	54280	_	ethylhy	d <b>yex</b> ypro	pnydcellu	losse		
36	54450	_	fats and oils, from animal or vegetab food sources	yes le	no	no		
37	54480		fats and oils, hydroge from animal or vegetab food sources	le	no	no		

38	55520	_	glass fibers	yes	no	no		
39	55600	_	glass microba	yes alls	no	no		
40	56360	_	glycero esters with acetic acid	l,yes	no	no		
41	56486		glycero esters with acids, aliphatisaturate linear, with an even number of carbon atoms (C <sub>14</sub> -C <sub>18</sub> ) and with acids, aliphatiunsaturalinear, with an even number of carbon atoms (C <sub>16</sub> -C <sub>18</sub> )	c, d, c, ated,	no	no		
42	56487	_	glycero esters with butyric acid	l,yes	no	no		
43	56490		glycero esters with	l,yes	no	no		

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			erucic acid				
44	56495	_	glycerol,yes esters with 12- hydroxystearic acid	no	no		
45	56500	_	glycerol,yes esters with lauric acid	no	no		
46	56510		glycerol,yes esters with linoleic acid	no	no		
47	56520	_	glycerol,yes esters with myristic acid	no	no		
48	56535	_	glycerol,yes esters with nonanoic acid	no	no		
49	56540	_	glycerol,yes esters with oleic acid	no	no		
50	56550	_	glycerol,yes esters with palmitic acid	no	no		
51	56570	_	glycerol,yes esters with propionic acid	no	no		
52	56580	_	glycerol,yes esters with ricinoleic acid	no	no		

53	56585		glycerol,yes esters with stearic acid	no	no		
54	57040		glycero yes monooleate, ester with ascorbic acid	no	no		
55	57120		glycero yes monooleate, ester with citric acid	no	no		
56	57200		glycero yes monopalmita ester with ascorbic acid	no no	no		
57	57280		glycerol yes monopalmita ester with citric acid	no no	no		
58	57600		glycerol yes monostearate ester with ascorbic acid	no e,	no		
59	57680		glycerol yes monostearate ester with citric acid	e, no	no		
60	58300	_	glycine, yes salts	no	no		
62	64500	_	lysine, yes salts	no	no		
63	65440		manganesses pyrophosphi	te no	no		

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64	66695	_	methylhyddsoxy	m <b>et</b> hylce	llutose			
65	67155		mixture yes of 4- (2- benzoxazolyl)- (5- methyl-2- benzoxazolyl)s 4,4'- bis(2- benzoxazolyl) stilbene and 4,4'- bis(5- methyl-2- benzoxazolyl)s	itilbene,	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- yes n- octyltin tris(alkyl(C <sub>10</sub> - C <sub>16</sub> ) mercaptoacetal	no re)	no		(11)	
67	67840		montanicyes acids and/or their esters with ethyleneglycol and/or with 1,3- butanediol and/or with glycerol	no	no			
68	73160		phosphovies acid, mono- and di-	no	yes	0,05		

69	74400	_	n-alkyl (C <sub>16</sub> and C <sub>18</sub> ) esters phosphoacid, tris(non and/or dinonyl ester	yl-	no	yes	30			
70	76463	_	polyacr acid, salts	ylvies	no	no		(22)		
71	76730		γ-	ı <b>şıtı</b> sylsile propylat		no	6			
72	76815		polyeste of adipic acid with glycero or pentaery esters with even number unbranc $C_{12}$ - $C_{22}$ fatty acids	l ythritol, ed,	no	no		(32)	The fraction with molecul weight below 1 000 Da [F3 shall] not exceed 5 % (w/w)	ar
73	76866		polyeste of 1,2- propane and/ or 1,3- and/ or 1,4- butaned and/or polypro with adipic acid, which may be	diol	no	yes		(31) (32)		

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			end- capped with acetic acid or fatty acids C <sub>12</sub> - C <sub>18</sub> or n- octanol and/ or n- decanol				
74	77440	_	polyethy <b>les</b> egly diricinoleate	cnb	yes	42	
75	77702		polyethylessegly esters of aliph. monocarb. acids (C6-C22) and their ammonium and sodium sulphates	cnb	no		
76	77732		polyethylese 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		polyethylesegly (EO = 1-30, typically 5)	cnb	no	0,05	Only for use in PET

			acrylate	- /phenyl)					
78	77897		(EO = 1-50)		cnb	no	5		
79	80640	_	polyoxy (C <sub>2</sub> - C <sub>4</sub> ) dimethy	a <b>lks</b> yl Ipolysilo	no	no			
80	81760		powders flakes and fibres of brass, bronze, copper, stainless steel, tin, iron and alloys of copper, tin and iron		no	no			
81	83320	_	propylh	ydroxye	thnydcellu	losse			
82	83325	_			etthylcel				
83	83330	_	propylh	yydersoxyp	r <b>op</b> ylcell	ulose			
84	85601		silicates natural (with the exception		no	no			

		of asbestos)					
85	85610 —	silicates, yes natural, silanated (with the exception of asbestos)	no	no			
86	86000 —	silicic yes acid, silylated	no	no			
[F387	86285	Silicon yes dioxide, silanated	no	no			For synthetic amorphous silicon dioxide, silanated: primary particles of 1–100 nm which are aggregated to a size of 0,1–1 µm and may form agglomerates within the size distribution of 0,3 µm to the mm size. ]
88	86880 —	sodium yes monoalkyl dialkylphenox	no vbenzene	no disulpho	9 nate		
89	89440 —	stearic yes acid, esters	no	no		(2)	

			with	eglycol						
90	92195	_	taurine, salts	yes	no	no				
91	92320	_	tetradec polyeth = 3-8) ether of glycolic acid	ylenegly	no col(EO	yes	15			
92	93970	_	tricyclo bis(hexa	d <b>øea</b> nedi ahydropl	mothano thalate)	lno	0,05			
93	95858		waxes, paraffin refined, derived from petrolet based or syntheti hydroca feedstoo low viscosit	ic, ım c ırbon eks,	no	no	0,05	t un final f	Not o be used for articles n contact with fatty foods for which F3simul D1 and/ or D2] s laid lown. Average nolecul weight fot ess han food food food food food food food foo	ar

					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	no	no	Average molecular weight not less than 500 Da. Viscosity at 100 °C not less than 11 cSt (11 × 10-6 m²/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
95	95883 —	white yes mineral oils, paraffinic, derived from	no	no	Average molecular weight not less than

			petroleu based hydroca feedstoo	rbon ks			480 Da. Viscosity at 100 °C not less than 8,5 cSt (8,5 × 10 <sup>-6</sup> m²/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
96	95920	_	wood flour and fibers, untreate	yes ed	no	no	
97	72081/1	θ—	petroleu hydroca resins (hydrog	rbon	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

	1			1				from	
								distillate	20
								of	23
								cracked	
								petroleu	m
								stocks	
								with a	
								boiling	
								range	
								not	
								greater	
								than	
								220 °C,	
								as well	
								as the	
								pure	
								monom	ers
								found	
								in	
								these	
								distillati	on
								streams	
								subsequ	ently
								followe	1
								by	
								distillati	on,
								hydroge	nation
								and	
								addition	al
								process	
								Properti	es.
								Troperti	Viscosity
								_	
									at
									120 °C:
									>
									3
									Pa.s,
									Softening
									point:
									>
									95 °C
									as
									determined
									by ACTM
									ASTM
									Method
									E
									28-67,
								_	Bromine
									number:
									<
									40
I	I	I	I	I	I	ı l	l		

									(ASTM D1159), The colour of a 50 % solution in toluene < 11 on the Gardner scale, Residual aromatic monomer ≤ 50 ppm,
98	17260	000005	Of <b>Orra</b> ld	eshesede	yes	no		(15)	
	54880								
99	19460	000005		yes	yes	no			
	62960		acid						
100	24490	000005	0s <b>∂fb<del>il</del>t</b> ol	yes	yes	no			
	88320								
101	36000	000005	0a8de7bio acid	yes	no	no			
102	17530	000005	0 <b>g90</b> e7se	no	yes	no			
103	18100	000005	6 <b>g&amp;yle6</b> ro	lyes	yes	no			
	55920								
104	58960	000005	7h@9a@lec bromide	yl <b>e</b> simetl	h <b>iyd</b> ammo	o <b>nio</b> im	6		
105	22780	000005	7p <b>hO</b> mitic	yes	yes	no			
	70400		acid						
106	24550	000005		yes	yes	no			
	89040		acid						
107	25960	000005	7ut&a6	no	yes	no			
108	24880	000005	7s <b>ti0rd</b> se	no	yes	no			
109	23740	000005		yes	yes	no			
	81840		propane	dıol					
	*	*				*	*	*	 

110	93520	0000059e02-9 ye 001019 te4dopherol		no				
111	53600	0000060e00ylenegie acid	esminetetraac	eti <b>a</b> o				
112	64015	0000060Hibbleic ye acid	es no	no				
113	16780 52800	0000064ethanol ye	yes yes	no				
114	55040	0000064fd8r6c yeacid	es no	no				
115	10090 30000	0000064a&9tic yeacid	es yes	no				
116	13090 37600	0000065b&fiz@ic ye acid	es yes	no				
117	21550	0000067r56thanoho	yes	no				
118	23830	0000067263-0 ye		no				
	81882	propanol						
119	30295	0000067a <b>64</b> tdne ye	es no	no				
120	49540	0000067d68ethylye sulphoxide		no				
121	24270	0000069salleylic ye	es yes	no				
	84640	acid						
122	23800	000007 1123-8 no propanol	yes	no				
123	13840	000007 1136-3 no butanol	yes	no				
124	22870	0000071141-0 no pentanol	yes	no				
125	16950	0000074ellsylleneno	yes	no				
126	10210	0000074a86tylenero	yes	no				
127	26050	0000075v0rly4 no chloride	yes	no	ND		1 mg/ kg in final product	
128	10060	0000075a07ta0ldelmyo	de yes	no		(1)		
129	17020	0000075eHiykeneno oxide	yes	no	ND		1 mg/ kg in final product	(10)

130	26110	000007	5 <b>v315y4</b> ide chloride		yes	no	ND			(1)
131	48460	000007	51317–6 difluoro	yes ethane	no	no				
132	26140	000007	5 <b>v3</b> ชy1/de fluoride		yes	no	5			
133	14380	000007	5e <b>41</b> b6ny		yes	no	ND		1 mg/	(10)
	23155		chloride						kg in final product	
134	43680	000007	5ellifofod	i <b>ßles</b> srom	e <b>th</b> ane	no	6		Content of chloroff less than 1 mg/ kg of the substant	uoromethan
135	24010	000007	5 <b>p56p</b> 9∫le oxide	ni <del>c</del> o	yes	no	ND		1 mg/ kg in final product	
136	41680	000007	6ea2anpaho	ryes	no	no				(3)
137	66580	000007	methyle methyl- (1-		no yl)pheno	yes		(5)		
138	93760	000007	7t90n7 butyl acetyl citrate	yes	no	no		(32)		
139	14680	000007		yes	yes	no				
	44160		acid							
140	44640	000007	7e93i0 acid, triethyl ester	yes	no	no		(32)		
141	13380	000007	1 / /	yes	yes	no	6			
	25600		trimethy	ylolpropa	ine					
	94960	1								
142	26305	000007	8 <b>v08y0</b> trio	<b>tho</b> xysi	aynæs	no	0,05		Only to be	[F28(1)]

143	62450	000007	8iક <b>િંગન</b> nta	nyes	no	no			used as a surface treatmen agent	nt
144	19243 21640	000007	8279-5 methyl- butadier		yes	no	ND		1 mg/ kg in final product	
145	10630	000007	9 <b>a06yll</b> am	ide	yes	no	ND			
146	23890 82000	000007	9 <b>р00р4</b> оп acid	i <b>y</b> es	yes	no				
147	10690	000007	9a&by17c acid	no	yes	no		(22)		
148	14650	000007	9 <b>eB&amp;</b> Potr	i <b>filo</b> ioroet	hydene	no	ND			(1)
149	19990	000007	9 <b>n3Otl</b> Oaci	<b>yla</b> mide	yes	no	ND			
150	20020	000007	9 <del>r/l</del> dt <del>l/l</del> acr acid	yrlóc	yes	no		(23)		
[F25]151	13480 13607]	000008	bis(4-	no /phenyl)	yes	no	0,05		Not to be used for the manufactof polycarl infant feeding bottles s. Not to be used for the manufactof polycarl drinking cups or bottles which, due to their spill proof characters.	eture conate

152	15610	000008	04047-9	no	yes	no	0,05		are intended for infants and young children i.	
			dichloro sulphon	dipheny e						
153	15267	000008		no dipheny e	yes I	no	5			
154	13617 16090	000008	040 <b>9</b> -1 dihydro sulphon	no xydipher e	yes nyl	no	0,05			
155	23470	000008	0e56-8 pinene	no	yes	no				
156	21130	000008	0n62thacr acid, methyl ester	ydic	yes	no		(23)		
157	74880	000008-	1pMhalic 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; technical support agent in polyolefins in concentrations up to 0,05 % in

										the final product.
158	23380	000008	5p <b>M</b> h9lic	yes	yes	no				
	76320		anhydri	de						
159	74560	000008	5ph8halic acid, benzyl butyl ester	yes	no	no	30	(32)	Only to be used as: (a)	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 or processed cereal-based foods and baby foods for infants

									(c)	and young children as defined by Directive 2006/125/ EC; technical support agent in concentrations up to 0,1 % in the final product.
160	84800	000008	7sa <b>Re3</b> /lic acid, 4-tert- butylpho ester		no	yes	12			
[ <sup>F29</sup> 161	92160	000087-	69(4)- tartaric acid	yes	no	no ]				
162	65520	000008	7 <b>ค728ค5</b> ito	lyes	no	no				
163	66400	000008	82224'-4 methyle bis(4- ethyl-6- tert- butylpho		no	yes		(13)		
164	34895	000008		yes enzamide	no	no	0,05		Only for use in PET for water and beverag	es
165	23200	000008		yes	yes	no				
	74480		phthalic acid							
166	24057	0000089	9 <b>53267</b> ne anhydri	l <b>hti</b> c de	yes	no	0,05			

167	25240	000009	1208–7 toluene diisocya	no anate	yes	no		(17)	1 mg/kg in final product expresse as isocyan; moiety	
168	13075 15310	000009	12746-9 diamino phenyl- triazine		yes	no	5			[ <sup>F28</sup> (1)]
169	16240	000009	dimethy	no d-4,4'- natobipl	yes	no		(17)	1 mg/kg in final product expresse as isocyana moiety	
170	16000	0000092		no xybiphei	yes nyl	no	6			
171	38080	0000093	3b <b>58z3</b> ic acid, methyl ester	yes	no	no				
172	37840	0000093	3b891200ic acid, ethyl ester	yes	no	no				
173	60240	0000094		yes benzoic	no	no				
174	14740	000009	5 <i>6</i> 48-7 cresol	no	yes	no				
175	20050	000009	on05thacr acid, allyl ester	yrlóc	yes	no	0,05			
176	11710	000009	6að By lic acid, methyl ester	no	yes	no		(22)		
177	16955	000009	6 <b>e419y 1</b> lend carbona		yes	no	30		SML	ed

								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	000009	thiobis(6- tert- butyl-3- methylphenol)	no	yes	0,48		
179	48800	000009	7223'-4 yes dihydroxy 5,5'- dichlorodipher	no nylmetha	yes ne	12		
[F30180	17160	000009	7efigenol no	yes	no		(33)]	
181	20890	000009	7n6&thacrylic acid, ethyl ester	yes	no		(23)	
182	19270	000009	7ittateothic no acid	yes	no			
183	21010	000009	7n&ctHacrylic acid, isobutyl ester	yes	no		(23)	
184	20110	000009	7n& thac rylic acid, butyl ester	yes	no		(23)	
185	20440	000009	7n90thacrylic acid, diester	yes	no	0,05		

			with ethylen	eglycol						
186	14020	000009	845 <del>ter<b>1</b>-</del> butylph	no enol	yes	no	0,05			
187	22210	000009	8683-9 methyls	no tyrene	yes	no	0,05			
188	19180	000009	9is69pl8th: acid dichlori		yes	no		(27)		
189	60200	000009		yes benzoic	no	no				
190	18880	000009		no vbenzoic	yes	no				
191	24940	000010	Ot 20019htl acid dichlori		yes	no		(28)		
192	23187	_	phthalic acid	no	yes	no		(28)		
193	24610	000010	Os <b>tly2re</b> me	no	yes	no				
194	13150	000010	Ob <b>&amp;hzt</b> yl alcohol	no	yes	no				
195	37360	000010	Ob <b>&amp;A</b> zāld	esheysde	no	no				(3)
196	18670	000010	Oh&XaOne	t <b>lyg</b> kenete	tyresmine	no		(15)		
	59280									
197	20260	000010	lm4&thaci acid, cyclohe ester		yes	no	0,05			
198	16630	000010	1d6p8h8ny diisocya	l <b>no</b> ethan anate	ey <b>4</b> 51'-	no		(17)	1 mg/ kg in final product expresse as isocyana moiety	
199	24073	000010	lr <b>9006</b> cir diglycio ether		yes	no	ND		Not to be used for articles	(8)

						in contact with fatty foods for which [F3 simul D1 and/ or D2] is laid down. For indirect food contact only, behind a PET layer.	ant
200	51680	0000102M0849 yes diphenylthi		yes	3		
201	16540	0000102d09h0nylno carbonate	yes	no	0,05		
202	23070	0000102(3,3-6 no phenylened acid	yes ioxy)diacetic	no	0,05		[F28(1)]
203	13323	0000102 <b>143</b> 0-9 no bis(2- hydroxyeth	yes oxy)benzene	no	0,05		
204	25180	0000102N6N3N yes	yes	no			
	92640	',N'- tetrakis(2- hydroxypro	pyl)ethyleneo	diamine			
205	25385	0000102trī@H5ylarnin	e yes	no		40 mg/kg hydroge at a ratio of 1 kg food to a maximu of 1,5 gran of hydroge	m ns

									Only to be used in hydroge intended for non-direct food contact use.	els 1
206	11500	0000103	Bactylic acid, 2- ethylher ester	no xyl	yes	no	0,05			
207	31920	0000103	Ballspile acid, bis(2- ethylhes ester	yes xyl)	no	yes	18	(32)		(2)
208	18898	0000103		no /phenyl) de	yes	no	0,05			
209	17050	0000104	4276-7 ethyl-1- hexanol	no	yes	no	30			
210	13390 14880	000010		no roxymetl	yes nyl)cyclo	no hexane				
211	23920	000010	5p38p3on acid, vinyl ester	i <b>a</b> o	yes	no		(1)		
212	14200 41840	000010	5 <b>∈6β</b> ғ∂la¢	taera	yes	no		(4)		
213	82400	000010		yes neglycol	no	no				
214	61840	000010	61 <b>2</b> 4-9 hydroxy acid	yes ystearic	no	no				
215	14170	000010	6 <b>5311y0</b> ic anhydri		yes	no				
216	14770	000010	6p44-5 cresol	no	yes	no				

217	15565	00001061446		yes	no	12			
210	11500		nlorobenzene				(22)		
218	11590	0000106a6By acid isob este	l, outyl	yes	no		(22)		
219	14570 16750	0000106e <b>\$9</b>	<b>Blorolo</b> ydrin	yes	no	ND		1 mg/ kg in final	(10)
								product	
220	20590	0000106n9dt acid 2,3- epo este	l, xypropyl	yes	no	0,02			(10)
221	40570	0000106b9a7a	afie yes	no	no				
222	13870	0000106498 bute		yes	no				
223	13630	0000106b99	adienno	yes	no	ND		1 mg/ kg in final product	
224	13900	0000107201 bute		yes	no				
225	12100	0000107a&By	∤llonitmide	yes	no	ND			
226	15272	0000107etlby	Bene <b>dia</b> mine	yes	no	12			
	16960								
227	16990	0000107e <b>2</b> hiy	rllenegybyscol	yes	no		(2)		
	53650								
228	13690	000010718 <b>38</b> - buta	-0 no anediol	yes	no				
229	14140	0000107 <b>b92</b>		yes	no				
230	16150	0000108el0n	Athyl <b>ao</b> ninoe	thyænsol	no	18			
231	10120	0000108a066 acid viny este	l, yl	yes	no	12			
232	10150	0000108a241		yes	no				
	30280	anh	ydride						
233	24850	0000108s <b>30</b> 0	efinic no ydride	yes	no				

234	19960	000010	8 <b>m3ale6c</b> anhydri	no de	yes	no		(3)	
235	14710	000010	8 <b>n3</b> -9-4 cresol	no	yes	no			
[F13236	23050	000010		no nediami	yes ne	no	ND		(28)]
237	15910	000010		no	yes	no	2,4		
	24072		dihydro	xybenze	ne				
238	18070	000010	8 <b>956tat</b> ric anhydri		yes	no			
[F31239	19975	000010		yes	yes	no	2,5		
	25420		triamino triazine	<b>)</b> -1,3,5-					
	93720]		VIIWEIIIV						
240	45760	000010	8 <b>e9&amp;l8</b> he	x <b>yda</b> min	eno	no			
[F29241	22960	000010	8p905en201	no	yes	no	3]		
242	85360	000010	9s4Baðic acid, dibutyl ester	yes	no	no		(32)	
243	19060	000010	Pistobotyl vinyl ether	no	yes	no	0,05		(10)
244	71720	000010	9 <b>p66</b> t <b>0</b> ne	yes	no	no			
245	22900	000010	9467-1 pentene	no	yes	no	5		
246	25150	000010	9t <b>919</b> a¶yd	lmoofuran	yes	no	0,6		
247	24820	000011	Os <b>ílo Set</b> ónic	yes	yes	no			
	90960		acid						
248	19540	000011		yes	yes	no		(3)	
	64800		acid						
249	17290	000011	Of <b>u</b> inatic	yes	yes	no			
	55120		acid						
250	53520	000011		yes ebisstear	no amide	no			
251	53360	000011		yes ebisolear	no nide	no			
252	87200	0000110	Os <b>dabi</b> c acid	yes	no	no			

253	15250	0000110	04640-1	no	yes	no				
200	10200	000011	diamino		yes	110				
254	13720	0000110		yes	yes	no		(30)		
	40580		butaned	101						
255	25900	0000110	Ot <b>isl8x3</b> ane	no	yes	no	5			
256	18010	0000110	og <b>9dta</b> ric acid	yes	yes	no				
	55680		aciu							
[F30257	13550	0000110	) <b>еЮ</b> рг <b>б</b> ру	l <b>øne</b> glyc	oyles	no				
	16660	002526	5-71-8							
	51760 ]									
258	70480	000011	l paden&itic acid, butyl ester	yes	no	no				
259	58720	000011	l hb‡bt&no acid	i <b>y</b> es	no	no				
260	24280	000011	ls <b>20a6</b> ic acid	no	yes	no				
261	15790	000011	l <b>e40</b> t10yle	<b>ma</b> triami	nyees	no	5			
262	35284	000011		yes hyl)etha	no nolamine	no	0,05		Not to be used for articles in contact with fatty foods for which [F3 simul D1 and/ or D2] is laid down. For indirect food contact only, behind	ant

									a PET layer.	
263	13326	000011	l <b>eH6H6</b> yle	nyeegslyco	l yes	no		(2)		
	15760									
	47680									
264	22660	000011	1466-0 octene	no	yes	no	15			
265	22600	000011	1487-5 octanol	no	yes	no				
266	25510	0000112	2 <b>t2l₹t6</b> yle	nyeglyco	lyes	no				
	94320									
267	15100	0000112	2430-1 decanol	no	yes	no				
268	16704	0000112	2441-4 dodecer	no ne	yes	no	0,05			
269	25090	0000112	2 <b>t6t0</b> a <b>7</b> th	y <b>læs</b> egly	c <b>yė</b> s	no				
	92350									
270	22763	0000112		yes	yes	no				
	69040		acid							
271	52720	0000112	2 <b>e&amp;4eā</b> mi	dyces	no	no				
272	37040	0000112	2 <b>b&amp;5neo</b> nic acid	yes	no	no				
273	52730	0000112	2 <b>e86</b> e7c acid	yes	no	no				
274	22570	0000112	2006adec isocyan	ľ	yes	no		(17)	l mg/ kg in final product expresse as isocyana moiety	
275	23980	000011:	5p0dplyle	nico	yes	no				
276	19000	000011:	5iddbūter	neo	yes	no				
277	18280	000011:	5h2xæhl anhydri		mætshylen	<b>ete</b> trahy	d <b>Nap</b> htha	lic		
278	18250	000011:	5 <b>h2∾</b> hl acid	aroendo	mædshylen	etetrahy	d <b>Nip</b> htha	lic		
279	22840	000011:	5p <b>enta</b> ery	ytyhensitol	yes	no				
	71600									

280	73720	0000115p% sphories acid, trichloroethyl ester	no	no	ND			
281	25120	0000116tdtfaBluorcethy	lenæs	no	0,05			
282	18430	0000116hexafluo <b>no</b> pro	pylens	no	ND			
283	74640	0000117phthalic yes acid, bis(2-ethylhexyl) ester	no	no	1,5	(32)	Only to be used as: (a)	plasticiser in repeated use materials and articles contacting nonfatty foods; technical support agent in concentrations up to 0,1 % in the final product.
284	84880	0000119saticslic yes acid, methyl ester	no	no	30			
285	66480	00001192427-1 yes methylene bis(4- methyl-6- tert- butylphenol)	no	yes		(13)		
286	38240	0000119behzophspeone	no	yes	0,6			
287	60160	0000120447-8 yes hydroxybenzo acid,	no	no				

			ethyl ester							
288	24970	000012	Oterbythth acid, dimethy ester		yes	no				
289	15880 24051	000012		no xybenze	yes ne	no	6			
290	55360	000012	lganio acid, propyl ester	yes	no	no		(20)		
291	19150	000012	1 <b>i90lp15</b> tha acid	aho	yes	no		(27)		
292	94560	000012	2ti2l0so3pro	p <b>en</b> olan	nime	no	5			
293	23175	000012	2ph2spho acid, triethyl ester	onous	yes	no	ND		1 mg/ kg in final product	(1)
294	93120	000012	3t226 dipr acid, didodec ester		no	yes		(14)		
295	15940	000012		yes	yes	no	0,6			
	18867		dihydro	xybenze	ne					
	48620									
296	23860	000012	3 <b>p38p6</b> on	anhodehyde	yes	no				
297	23950	000012	3 <b>p62p6</b> on anhydri		yes	no				
298	14110	000012	3 <b>5712y8</b> alo	<b>lelo</b> yde	yes	no				
299	63840	000012	3l <b>∂√o</b> u⊠ni acid	cyes	no	no				
300	30045	000012	3a86ti& acid, butyl ester	yes	no	no				
301	89120	000012	Зя <b>дэнэ</b> с acid, butyl ester	yes	no	no				
302	12820	000012	3a <b>99l</b> 3ic acid	no	yes	no				

303	12130	000012	4a(14b9c	yes	yes	no			
	31730		acid						
304	14320	000012	4e@pr⊋lic	yes	yes	no			
	41960		acid						
305	15274	000012	4 <b>h@9</b> a4me	t <b>hø</b> lened	iamenine	no	2,4		
	18460								
306	88960	000012	4s <b>ใช่งหว</b> ักm	i <b>şte</b> s	no	no			
307	42160	000012	<del>1</del> ଥେଞ୍ଚିଥ dioxide	yes	no	no			
308	91200	000012	osudr <b>o</b> se acetate isobutyi		no	no			
309	91360	000012	6s <b>ılı4r7</b> se octaace		no	no			
310	16390	000012		no	yes	no	0,05		
	22437		dimethy propane						
311	16480	000012	6 <b>d5</b> p8e19tae		yes	no			
	51200								
312	21490	000012	6 <b>n9/8th/</b> acr	y <b>lo</b> nitril	eyes	no	ND		
313	16650	000012	7 <b>d6βh</b> 9ny		yes	no	3		
	51570		sulphon	e					
314	23500	000012	7β91-3 pinene	no	yes	no			
315	46640	000012	8236- <b>©</b> i- tert- butyl- p- cresol	yes	no	no	3		
316	23230	000013	lph7halic acid, diallyl ester	no	yes	no	ND		
317	48880	000013	dihydro	yes xy-4- ybenzop	no henone	yes		(8)	
318	48640	000013		yes xybenzo	no phenone	no		(8)	
319	61360	000013	hydroxy	yes 7-4- ybenzop	no henone	yes		(8)	

320	37680	000013	6b <b>60</b> zbic acid, butyl ester	yes	no	no				
321	36080	000013	7a <b>66</b> 9 <b>6</b> by palmitat		no	no				
322	63040	000013	8la2tid acid, butyl ester	yes	no	no				
323	11470	000014	0a88yfic acid, ethyl ester	no	yes	no		(22)		
324	83700	000014	1 <b>r22n0</b> 1e acid	iges	no	yes	42			
325	10780	000014	lað Dy Ilc acid, n- butyl ester	no	yes	no		(22)		
326	12763 35170	000014	1243-5 aminoet	yes hanol	yes	no	0,05		Not to be used for articles in contact with fatty foods for which [F3 simul D1 and/ or D2] is laid down. For indirect food contact only, behind a PET layer.	ant
327	30140	000014	la <b>78ti6</b> acid,	yes	no	no				

			ethyl ester						
328	65040	000014	l <b>#&amp;ଥି</b> ଠୀic acid	yes	no	no			
329	59360	000014	2 <b>h62</b> ahoi acid	cyes	no	no			
330	19470	000014		yes	yes	no			
	63280		acid						
331	22480	000014	3108-8 nonanol	no	yes	no			
332	69760	000014	3 <b>02&amp;y</b> 2 alcohol	yes	no	no			
333	22775	000014		yes	yes	no	6		
	69920		acid						
334	17005	000015	l <b>efl<del>byll</del>e</b> nd	eimine	yes	no	ND		
335	68960	000030	1 <b>⊝0-2a</b> m∂nid	eyes	no	no			
336	15095	000033		yes	yes	no			
	45940		decanoi acid	c					
337	15820	000034		no benzoph	yes enone	no	0,05		
338	71020	000037	3p49n9to acid	leyies	no	no			
339	86160	000040	9s <b>11le2</b> n carbide	yes	no	no			
[F32340	47440	000046	1 <b>d5&amp;y5</b> no	djesnide	no	no	60]		
341	13180	000049	8 <b>666y8</b> lo	2n@.1]he	pyte2s-	no	0,05		
	22550		ene						
342	14260	000050	2e <b>4∌</b> r∂lao	tone	yes	no		(29)	
343	23770	000050	416 <b>3</b> –2 propane	no diol	yes	no	0,05		
[F29344	13810	000050	1 1	no	yes	no	0,05	15	(21)
	21821]		butaned formal	10l				30	
345	35840	000050	6a <b>3acl9</b> idi acid	ges	no	no			
346	10030	000051	4ab0efic acid	no	yes	no			
347	13050	000052	8 <b>t:14n:0</b> llit acid	i <b>n</b> o	yes	no		(21)	

		٦	I	I	I	1	ı	I	ſ	
	25540									
348	22350	000054	4n63ri8tio acid	yes	yes	no				
	67891		aciu							
349	25550	000055	2 <b>tdîn</b> Əllit anhydri		yes	no		(21)		
350	63920	000055	7li <b>59</b> nocei acid	riges	no	no				
351	21730	000056	3345-1 methyl- butene	no 1-	yes	no	ND		Only to be used in polypro	(1)
352	16360	000057		no lphenol	yes	no	0,05			
353	42480	000058	4e09b8ni acid, rubidiui salt		no	no	12			
354	25210	000058	4284–9 toluene diisocya	no	yes	no		(17)	1 mg/kg in final product express as isocyan moiety	
355	20170	000058	5#007tPaci acid, tert- butyl ester	yrlic	yes	no		(23)		
356	18820	000059	2141-6 hexene	no	yes	no	3			
357	13932	000059	8332-3 buten-2 ol	no	yes	no	ND		Only to be used as a comonom for the preparatof polymer additive	ric
358	14841	000059	9464-4 cumylp	no henol	yes	no	0,05			

359	15970	000061	14949'-4	yes	yes	no		(8)		
	48720		dihydro	xybenzo	phenone					
360	57920	000062	20g <b>6√e</b> erol trihepta	l yes noate	no	no				
361	18700	0000629	291Jd-8 hexaned	no diol	yes	no	0,05			
362	14350	000063	0e01900n monoxi		yes	no				
363	16450	0000640	610 <b>%</b> -0 dioxola	no ne	yes	no	5			
[F29364	15404	0000653	2164:-36- dianhyd	no drosorbito	yes	no	5		Only to be used as: (a)	a co- monomer in poly(ethylene- co- isosorbide terephthalate); a co- monomer at levels of up to 40 mole % of the diol component in combination with ethylene glycol and/ or 1,4- bis(hydroxymethyl)cyclohe for the production

									together with 1,4-	rosorbito	
365	11680	000068	9act2yBc acid, isoprop ester	no yl	yes	no		(22)	-		
366	22150	000069	1437-2 methyl- pentene		yes	no	0,05				
367	16697	000069	3n23-2 dodecar acid	no nedioic	yes	no					-
368	93280	000069	3tBi6d/ipr acid, dioctado ester		no	yes		(14)			
369	12761	000069		no odecanoi	yes c	no	0,05				
370	21460	000076	0 <del>n9&amp;tl0a</del> cı anhydri		yes	no		(23)			
371	11510 11830	000081	8a6ilyllic acid, monoes with ethylend	ter	yes	no		(22)			

372	18640	000082	2h06anne diisocya	t <b>hy</b> lene anate	yes	no		(17)	1 mg/kg in final product express as isocyan moiety	ed	
373	22390	000084	0266-3 naphtha acid, dimethy ester		yes rboxylic	no	0,05				
374	21190	000086	8n76thacr acid, monoes with ethylen	ter	yes	no		(23)			
375	15130	000087	2105-9 decene	no	yes	no	0,05				
[F31376	66905	000087		yes yrrolido	no ne	no	60]				
377	12786	000091	9330-2 aminop	no ropyltrie	yes thoxysila	no	0,05		Residual extractal content of 3-aminopito be less than 3 mg/kg filler when used for the reactive surface treatment of inorgan fillers. SML = 0,05 mg kg when used for the surface	ble ropyltrietl nt ic	noxysilane

378	21970	000092		no Imethac	yes rylamide	no	0,05		treatment of material and articles.	
379	21940	0000924	4 <del>N1</del> 2-5 methylo	no lacrylan	yes iide	no	ND			
380	11980	000092	5a60ylic acid, propyl ester	no	yes	no		(22)		
381	15030	000093	1e <b>§8<del>14</del>0</b> c	tence	yes	no	0,05		Only to be used in polymer contactifoods for which simulan A is laid down	ng
382	19490	000094	71 <b>-00-41-06</b> 1 a c	tam	yes	no	5			
383	72160	000094	8265-2 phenyli	yes ndole	no	yes	15			
384	40000	000099	bis(octy (4- hydroxy di-tert-	ilino)-1,3		yes	30			
385	11530	0000999	9a6ilyllic acid, 2- hydroxy ester	no	yes	no	0,05		SML expressed as the sum of acrylic acid, 2-hydroxy ester and acrylic acid,	

									ester. It may contain up to 25 % (m/m) of acrylic acid, 2-hydroxy ester (CAS No	visopropyl 8-23-2).
386	55280	000103	4galli¢ acid, octyl ester	yes	no	no		(20)		
387	26155	000107	2163-5 vinylim	no idazole	yes	no	0,05			[F28(1)]
388	25080	000112	0436-1 tetradec	no ene	yes	no	0,05			
389	22360	000114		no lenedica	yes rboxylic	no	5			
390	55200	000116	6 <b>g521/i5</b> acid, dodecyl ester	yes	no	no		(20)		
[F3391	22932	000118	7p₩3fKioi perfluoi ether		yes	no	0,05		Only to be used in: —	antistick coatings; fluoroand perfluoropolymers intended for repeated use applications where the contact

								ratio is 1 dm 2 surface in contact with at least 150 kg food. ]
392	72800	000124	lphosphovies acid, diphenyl 2- ethylhexyl ester	no	yes	2,4		
393	37280	000130	2 <b>b₹8ŧ</b> 9niteyes	no	no			
394	41280	000130	5e <b>61</b> cium yes hydroxide	no	no			
395	41520	000130	5eaRei8im yes oxide	no	no			
396	64640	000130	9m42gResinner hydroxide	no	no			
397	64720	000130	9m4&g4esiwers oxide	no	no			
[F13398	35760	000130	9a64ir4onwes trioxide	no	no			(6)]
399	81600	000131	Op58a3siunyes hydroxide	no	no			
400	86720	000131	0sødi@m yes hydroxide	no	no			
401	24475	000131	3s <b>8aia</b> m no sulphide	yes	no			
402	96240	000131	4zln3e2 yes oxide	no	no			
403	96320	000131	4z98e3 yes sulphide	no	no			
404	67200	000131	7 <b>n36</b> ly9bde <b>yæs</b> m disulphide	no	no			
405	16690	000132	ld74in0ylbenozene	yes	no	ND	1	SML (1) expressed

100	02200	000122	2127.2					as the sum of divinylbenzene and ethylvinylbenzene. It may contain up to 45 % (m/m) of ethylvinylbenzene.
406	83300	000132	propyle monoste		no	no		
407	87040	000133	0s <b>4di4</b> m tetrabor		no	no	(16)	
408	82960	000133	01 <b>§2</b> 0–9 propyle monool	yes neglycol eate	no	no		
409	62240	000133	2in367n-2 oxide	yes	no	no		
[F29410	62720	000133	2k <b>5</b> 84ih	yes	no	no		Particles can be thinner than 100 nm only if incorporated at a quantity of less than 12 % w/w in an ethylene vinyl alcohol copolymer (EVOH) inner layer of a multi- layer structure, in which the

								layer in direct contact with the food provides a functiona barrier preventir migration of particles into the food. ]	al ng
411	42080	000133	black	yes	no	no		Primary particles of 10 – 300 nm which are aggregate to a size of 100 – 1 200 nm which may form agglomer within the size distributiof 300 nm – mm. Toluene extractab maximum 0,1 %, determin according to ISO method 6209. UV absorption	rates on oles: n ed

								of cyclohe 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 generall recognism ethod of analysis Benzo(a content max 0,25 mg kg carbon black. Maximuse level of carbon black in the polymer 2,5 % w/w.	ned ng y sed . n)pyrene
412	45200	000133	iodide	yes	no	no	(6)		
413	35600	000133	6 <b>a2⁄1</b> m6on hydroxi		no	no			
414	87600	000133	8s <b>8951</b> tan monola		no	no			
415	87840	000133	8s <b>4:lb/t</b> an monoste		no	no			
416	87680	000133	8s <b>4ßbl</b> tan monool		no	no			

417	85680	000134	3s <b>A&amp;i</b> c acid	yes	no	no				
418	34720	000134	4a <b>2\&amp;</b> mlini oxide	unymes	no	no				
419	92150	000140	ltannic acids	yes	no	no			According to the JECFA specific	
420	19210	000145	9isOpHtha acid, dimethy ester		yes	no	0,05			
[F32421	13000	000147		no dimetha	yes namine	no		(34)]		
422	38515	000153	bis(2-	yes zolyl)sti	no Ibene	yes	0,05			(2)
423	22937	000162	3p@ff8101 ether	oppropyl	o <b>ye</b> Suore	vioyl	0,05			
424	15070	000164	711%-1 decadie	no ne	yes	no	0,05			
425	10840	000166	Bad Dylic acid, tert- butyl ester	no	yes	no		(22)		
426	13510 13610	000167	bis(4-	no yphenyl) ropyl)	yes	no			In complia with Commis Regulat (EC) No 1895/20	ssion ion
427	18896	000167		no ymethyl xene	yes )-1-	no	0,05			
428	95200	000170	trimethy tris(3,5- di-tert- butyl-4-		no	no				
429	13210	000176		no yclohexy	yes l)methai	no ne	0,05			

	1		1			1			T		
430	95600	000184	340B,34 tris(2- methyl- hydroxy tert- butylph butane	y-5-	no	yes	5				
431	61600	000184	hydroxy n-	yes y-4- ybenzopl	no	yes		(8)			
432	12280	000203	5a <b>d5p&amp;</b> anhydri	no de	yes	no					
433	68320	000208	2079adec 3-(3,5- di-tert- butyl-4- hydroxy		no	yes	6				
434	20410	000208	2n&dth/act acid, diester with 1,4- butaned		yes	no	0,05				
435	14230	000212	3eapralae sodium salt	ctaon,	yes	no		(4)			
436	19480	000214	6læuri <b>6</b> acid, vinyl ester	no	yes	no					
437	11245	000215	6a@ffyllc acid, dodecyl ester	no	yes	no	0,05			(2)	
[F31438	13303	000216	2b7s(-25,6- diisopro carbodi	pylphen	yes yl)	no	0,05		and its hydroly product 2,6-	ppylpheny sis	yl)carbodiimide ne
439	21280	000217	7 <b>#7@t40</b> acı acid,	yrlóc	yes	no		(23)			

			phenyl ester							
440	21340	000221	0m2&Hacr acid, propyl ester	yrlóc	yes	no		(23)		
441	38160	000231	5b68zoic acid, propyl ester	yes	no	no				
442	13780	000242	butaned bis(2,3-	no iol ropyl)eth	yes	no	ND		Residua content = 1 mg/ kg in final product expresse as epoxygn Molecu weight is 43 Da.	ed roup.
443	12788	000243		no ndecanoi	yes c	no	5			
444	61440	000244	hydroxy		no nzotriaz	no ole		(12)		
445	83440	000246	6 <b>9999</b> ho	sydsoric	no	no				
446	10750	000249	5aðfyllc acid, benzyl ester	no	yes	no		(22)		
447	20080	000249	5m30thacr acid, benzyl ester	yrlóc	yes	no		(23)		
448	11890	0002499	PassPyHc acid, n-octyl ester	no	yes	no		(22)		
[ <sup>F30</sup> 449	49840	000250	Od&&etlade disulphi		no	yes	0,05]			

450	24430	000256	ls <b>88a8</b> ic anhydri		yes	no				
451	66755	000268	2220-4 methyl- isothiaz one	yes 4- olin-3-	no	no	0,5		Only to be used in aqueous polymer dispersi and emulsio	ons
[ <sup>F31</sup> 452	38885	000272	bis(2,4- dimethy (2- hydroxy n-	yes (lphenyl) y-4- yphenyl)		no	5]			
453	26320	000276	8 <b>v0ı2y1</b> tri	methoxy	s <b>idas</b> ie	no	0,05			(10)
454	12670	000285	amino-3	no 3- nethyl-3,; vlcycloho		no	6			
455	20530	000286	7mlethacr acid, 2- (dimeth ethyl ester	<b>ylic</b> ylamino	yes )-	no	ND			
456	10810	000299	8a08ylic acid, sec- butyl ester	no	yes	no		(22)		
457	20140	000299	8ml&haci acid, sec- butyl ester	yrlic	yes	no		(23)		
458	36960	000306	lb <b>₹5e4</b> haı	nyde	no	no				
459	46870	000313	tert- butyl-4-		no hosphon	no				

			dioctade ester	ecyl						
460	14950	000317.	Be <b>§∂l∂</b> he isocyan		yes	no		(17)	1 mg/kg in final product express as isocyan moiety	
461	22420	000317	3172-6 naphtha diisocya		yes	no		(17)	l mg/kg in final product expresse as isocyan moiety	
462	26170	000319	vinyl- N-	no cetamid	yes	no	0,02			[F28(1)]
463	25840	000329		no dolpropa crylate	yes ane	no	0,05			
464	61280	000329	hydroxy n-	yes 7-4- ybenzop	no henone	yes		(8)		
465	68040	000333	naphtho (1,2- D)triazo yl]-3- phenylo	-	no	no				
466	50640	000364	8 <b>d1-8</b> 1-8 octyltin dilaurat		no	no		(10)		
[ <sup>F33</sup> 467	14800 45600]	-	Orotonic acid	yes	yes	no		(35)		
468	71960	000382	5p <b>26</b> fluor acid, ammon salt	oostano: ium	mo	no			Only to be used in repeated use articles,	

									sintered at high tempera	
469	60480	0003864	hydroxy di-tert- butylph	yes y-3,5'- enyl)-5- enzotriaz	no	yes		(12)		
470	60400	000389	hydroxy tert- butyl-5' methylp			yes		(12)		
471	24888	000396.			yes c	no	0,05			
472	66560	000406	methyle methyl-	yes nebis(4- 6- xylphen		yes		(5)		
473	12265	000407-	າສ <b>ຝ</b> າວາເ acid, divinyl ester	no	yes	no	ND		5 mg/kg in final product Only to be used as comonom	
474	43600	000408	chloroa triaza-1	damanta		no	0,3			
475	19110	000409	isocyan isocyan	no ato-3- atomethy vlcycloho	yes v1-3,5,5- exane	no		(17)	1 mg/kg in final product expresse as isocyana moiety	

476	16570	000412	8d <b>7βh8</b> ny diisocya		4yes	no		(17)	1 mg/kg in final product expresse as isocyan moiety	ed
477	46720	000413	024⁄2-di- tert- butyl-4- ethylphe	yes	no	yes	4,8			(1)
478	60180	000419	hydroxy acid, isopropy ester		no	no				
479	12970	000419	6a <b>26k6</b> ic anhydrio	no de	yes	no				
480	46790	000422	1380-di- tert- butyl-4- hydroxy acid, 2,4-di- tert- butylphe ester		no	no				
481	13060	000442	21935,51- benzene acid trichlori		yes xylic	no	0,05		SML expressor as 1,3,5-benzene acid	[F28(1)] ed etricarboxylid
482	21100	000465	5m3ettPacr acid, isopropy ester	-	yes	no		(23)		
483	68860	000472	4n48-5 octylpho acid	yes osphonic	no	no	0,05			
484	13395	000476		no oxymetl	yes nyl)propi	no onic	0,05			(1)
485	13560 15700	000512	4d30y&lol diisocya		th <b>xers</b> e-4,4	'no		(17)	1 mg/ kg in final product	(10)

									expresso as isocyana moiety	
486	54005	p N	May Tene N- palmitar N'- tearami	mide-	no	no				
487	45640	d a e	yano-3	yes ,3- lacrylic	no	no	0,05			
488	53440	0005518N		yes ebispalm	no itamide	no				
489	41040	0005743ea	altoilum outyrate		no	no				
490	16600	0005873d	ნ¤heny liisocya		еу∕ся'-	no		(17)	l mg/ kg in final product expresse as isocyana moiety	
491	82720	00061824 p		yes neglycol te	no	no				
492	45650	d a 2 e	yano-3 lipheny icid,	lacrylic	no	no	0,05			
493	39200	h (c	ıydroxy ıydroxy			no onium	1,8			
494	62140	0006303ki	ß≱bofpho icid	o <b>sph</b> orou	isno	no				
495	35160		31-5 mino-1 limethy		no	no	5			

496	71680	000668	BptAt8er; tetrakis (3,5- di-tert- butyl-4- hydroxy propion	[3- yphenyl)	no	no			
497	95020	000684	62510,40 trimethy pentane diisobu	diol	no	no	5	Only to be used in single-use gloves	
498	16210	000686	dimethy	no /l-4,4'- odicycloł	yes nexylmet	no hane	0,05	Only to be used in polyamic	(5) les
499	19965	000691		yes	yes	no		In case	
	65020		acid					of use as a monomer only to be used as a commonomer in aliphatic polyester up to maximur level of 1 % on a molar basis	r
500	38560	000712	bis(5- tert- butyl-2-	yes azolyl)th	no	yes	0,6		
501	34480	_	alumini fibers, flakes and powder		no	no			

502	22778	000745		no benzenes	yes sulphony	no I	0,05			[F28(1)]
503	46080	000758		yes	no	no				
504	86240	000763	Is H 60 m dioxide	yes	no	no			For synthetiamorph silicon dioxide primary particles of 1 – 100 nm which are aggregato a size of 0,1 – 1 µm which may form agglom within the size distribu of 0,3 µm to the mm size.	ous s ted
505	86480	000763	ls <b>00i6</b> m bisulphi		no	no		(19)		
506	86920	000763	2s <b>0d+0</b> m nitrite	yes	no	no	0,6			
507	59990	000764	<b>7h%tlr0</b> cl acid	llocisc	no	no				
508	86560	000764	7s <b>øði6</b> m bromide		no	no				
509	23170 72640	000766	<b>4թՖ&amp;ֆ</b> ին acid	nies	yes	no				
510	12789 35320	000766	<b>4a41</b> 1170n	ayes	yes	no				

511	91920	0007664s@RpDuriges	no	no		
512	81680	acid 0007681pbta0siumes	no	no	(6)	
312	81080	iodide	110	IIO	(0)	
513	86800	000768 Is8 <b>@io</b> dide yes	no	no	(6)	
514	91840	0007704sa4pbur yes	no	no		
515	26360 95855	0007732wlates yes	yes	no		In compliance with Directive 98/83/EC <sup>b</sup>
516	86960	0007757s8dium yes sulphite	no	no	(19)	
517	81520	0007758p@2a3siumes bromide	no	no		
518	35845	000777 lastate bid on its acid	no	no		
519	87120	0007772s98iam yes thiosulphate	no	no	(19)	
520	65120	0007773m0dnganeses chloride	no	no		
521	58320	0007782g42phite yes	no	no		
522	14530	0007782 <b>сБО</b> біпе по	yes	no		
523	45195	0007787eØpper yes bromide	no	no		
524	24520	000800 Isagbean no oil	yes	no		
525	62640	000800 lj <b>apa6</b> yes	no	no		
526	43440	000800 le <b>&amp;fes</b> in yes	no	no		
527	14411	000800 le <b>ā9toi</b> r yes	yes	no		
	42880	oil				
528	63760	0008002lek@ithin yes	no	no		
529	67850	0008002n53n7an yes wax	no	no		
530	41760	0008006c44ckelillæes wax	no	no		
531	36880	0008012b <b>&amp;9</b> s <b>3</b> vaxyes	no	no		

	1	1	1		i .	1	1	1		
532	88640	000801	3 <b>s6ÿb&amp;</b> an oil,	yes	no	no	60 30(*)	(32)	(*)	In
			epoxidi	sed						the
			1							case
										of
										PVC
										gaskets
										used to
										seal
										glass
										jars
										containing
										infant
										formulae
										and
										follow-
										on
										formulae
										as
										defined
										by
										Directive
										2006/141/
										EC or
										processed
										cereal-
										based
										foods
										and
										baby
										foods
										for
										infants
										and
										young
										children
										as
										defined
										by Directive
										2006/125/
										EC,
										the
										SML
										is
										lowered
										to
									m	g/30
										kg.
									Oxirane	
									< 8 %,	

								iodine number < 6.	
533	42720	000801	5 <b>e&amp;6n&amp;</b> ub wax	ayes	no	no			
534	80720	000801	7pb6yphc acids	spelsoric	no	no			
535	24100	000805	0 <b>r09</b> in7	yes	yes	no			
	24130								
	24190								
	83840								
536	84320	000805	Ord Sith, hydroge ester with methan		no	no			
537	84080	000805	Orasins, ester with pentaery	yes ythritol	no	no			
538	84000	000805	Orðsliff, ester with glycero	yes	no	no			
539	24160	000805	2 <b>rd Di</b> t6 tall oil	no	yes	no			
540	63940	000806	2H <b>gno</b> sul acid	phesnic	no	no	0,24	Only to be used as dispersa for plastics dispersi	
541	58480	000900	0g01m5 arabic	yes	no	no			
542	42640	000900	Oe <b>a</b> ilbōxy	nynesthylc	e <b>tla</b> lose	no			
543	45920	000900	0 <b>da6n2</b> nai	yes	no	no			
544	58400	000900	O <b>gMar</b> O gum	yes	no	no			
545	93680	000900	O <b>tılooğal</b> caı gum	ntshes	no	no			
546	71440	000900	0 <b>p69ti</b> n	yes	no	no			

	1						 	
547	55440	0009000g <b>₹0a8</b> n ye	es no	0	no			
548	42800	0009000easeth ye	es no	0	no			
549	80000	0009002p88y4thyle wax	esse no	0	no			
550	81060	0009003p <b>07</b> y <b>p</b> rop <b>y</b> s	dene no	0	no			
551	79920	0009003pbly(ethyk 0106392pt3p\$lene) glycol		0	no			
552	81500	0009003p&9y&inyyg	<b>əy</b> rroli <b>d</b>	one	no		The substant shall meet the purity criteria as laid down in Commis Directiv 2008/84	ssion e
553	14500 43280	000900 <mark>4е<b>3</b>Инб</mark> оѕеуе	es ye	es	no			
554	43300	000900 4e3fl+floseye acetate butyrate	es no	0	no			
555	53280	0009004eff7yRcellyd	bosse no	0	no			
556	54260	0009004ef8ylhydyc	exyethydo	œllulos	3 <b>(C</b> O			
557	66640	0009004n5@tlfylethe	ysicellu luo	<b>s</b> e	no			
558	60560	0009004h6/2h0xye/t	hsylcellul	<b>o</b> se	no			
559	61680	0009004h6y4hr2xypyr	aspylcetto	alose	no			
560	66700	0009004n65th3ylhyd	esoxypnog	pylcell	unlose			
561	66240	0009004n6@tlfsylcesld	bslose no	0	no			
562	22450	0009004n7@e@elluk	ose ye	es	no			
563	78320	0009004p@Tyethyle monoricin		b	yes	42		
564	24540 88800	0009005s2fresh, edible	es ye	es	no			

565	61120	0009005h27dr0xy5tesyl starch	no	no		
566	33350	0009005aBgiнЛс yes acid	no	no		
567	82080	00090051327-2 yes propyleneglycol alginate	no	no		
568	79040	0009005p64y5thylesegly sorbitan monolaurate	cnb	no		
569	79120	0009005p65y6thylæseglyd sorbitan monooleate	cnb	no		
570	79200	0009005p66y2thylæseglydsorbitan monopalmitate	cnb	no		
571	79280	0009005p67y8thylæsegly sorbitan monostearate	cnb	no		
572	79360	0009005p70y2thyJessegly sorbitan trioleate	cnb	no		
573	79440	0009005poly4thylæseglydsorbitan tristearate	enb	no		
574	24250 84560	0009006F0l4b6r, yes natural	yes	no		
575	76721	0063148p62ydimentsylsilo (Mw > 6 800 Da)	ane	no		Viscosity at 25 °C not less than 100 cSt (100 × 10 <sup>-6</sup> m <sup>2</sup> /s)
576	60880	0009032h4/2lr2xyettsylme	thølcellu	lnse		
577	62280	0009044islobuty leres- butene copolymer	no	no		
578	79600	0009046p@ly@thylessegly.tridecyl	cnb	no	5	For materials and

			ether						(EO ≤ 11) tridecyl ether phospha (monoand dialkyl ester) with a maximu 10 % content of	yleneglycol ate
579	61800	000904	9 <b>hyd</b> røxy starch	/ <b>pas</b> pyl	no	no				
580	46070	001001	6e20-3 dextrin	yes	no	no				
581	36800	001002	2batikam nitrate	yes	no	no				
582	50240	001003	9d3-15 octyltin bis(2- ethylher maleate	kyl	no	no		(10)		
583	40400	001004	3bbtesn nitride	yes	no	no		(16)		
584	13620 40320	001004	3bari3 acid	yes	yes	no		(16)		
585	41120	001004	3e <b>51</b> c <del>il</del> ım chloride		no	no				
586	65280	001004	3 <b>n&amp;4n</b> 2an hypopho		no	no				
587	68400	001009	10 <b>4 fa8</b> ec	y <b>yes</b> ucan	ide	yes	5			

589	52645	0010436	iodide e0&45 - eicosena	yes mide	no	no				
590	21370	0010595		yrlóc	yes	no	ND			(1)
591	36160	0010605	a00oilbyl stearate	yes	no	no				
592	34690		a59n9init magnesi carbonat hydroxid	um e	no	no				
593	44960	0011104	e6balt oxide	yes	no	no				
594	65360	0011129	ห <b>6ญกฐ</b> and oxide	eys <b>e</b> s	no	no				
595	19510	0011132	ligh&cell	<b>n</b> bose	yes	no				
596	95935	0011138	x <b>66+12</b> an gum	yes	no	no				
597	67120	0012001	m2i6e2	yes	no	no				
598	41600	0012004 0037293			no	no				
599	36840	0012007	b <b>абня</b> т tetrabora		no	no		(16)		
600	60030	0012072	h <b>9⁄0</b> lrbma	ngensesite	no	no				
601	35440	0012124	anneonide		no	no				
602	70240	0012198	e <b>23</b> k&erit	eyes	no	no				
603	83460	0012269	<b>₱₮%⊖₽</b> hy	lyietse	no	no				
604	60080	0012304	h <b>6</b> 5dr&tal	gite	no	no				
605	11005		aðflyDc acid, dicyclop ester	no entenyl	yes	no	0,05			(1)
606	65200	00126261	n&&n&an hydroxio		no	no				
607	62245	0012751	ii2211-3 phosphic	yes de	no	no			Only to be used	

									in PET polymer and copolyn	
608	40800	001300	butylide bis(6- tert- butyl-3- methylp ditridec phosphi	henyl- yl	no	yes	6			
609	83455	001344	5 <b>p5/602</b> ho acid	<b>syds</b> orou	sno	no				
610	93440	001346	3 <b>ti6</b> 2n7um dioxide	ıyes	no	no				
611	35120	001356	0349-1 aminoci acid, diester with thiobis (2- hydroxy ether		no	no				
612	16694	001381	divinyl-	no 2- lidinone	yes	no	0,05			(10)
613	95905	001398	3wlo7H@sto	nite	no	no				
614	45560	001446	<del>le<b>⁄li⁄s</b>ŧ</del> øba	l <b>ite</b> s	no	no				
615	92080	001480	7 <b>t-216</b> -6	yes	no	no				
616	83470	001480	8q <b>610.117</b> z	yes	no	no				
617	10660	0015214	acrylam		yes ılphonic	no	0,05			
618	51040	001553	octyltin	yes oacetate	no	no		(10)		
619	50320	001557	octyltin bis(2- ethylhex		no )	no		(10)		

620	50720	001557	1 <b>d60n-</b> 5 octyltin	yes	no	no		(10)	
			dimalea	te					
621	17110	001621		no nebicycl	yes o[2,2,1]l	no nept-2-	0,05		(9)
622	69840	001626	0 <b>009</b> fpal	n <b>nėt</b> samid	eno	yes	5		
623	52640	001638	9 <b>d&amp;&amp;</b> e1mit	eyes	no	no			
624	18897	001671	2664-4 hydroxy naphtha acid		yes oxylic	no	0,05		
625	36720	001719	4 <b>b@0iv2</b> m hydroxi		no	no			
626	57800	001864	lg\$ye&rol tribehen		no	no			
627	59760	001956	9h2tht2te	yes	no	no			
628	96190	002042	7 <b>z518</b> c-1 hydroxi	yes de	no	no			
629	34560	002164	5a5dn2ini hydroxi		no	no			
630	82240	002278	81 J <b>2</b> –8 propyle dilaurate		no	no			
631	59120	002312	hexame bis(3- (3,5- di-tert- butyl-4-		no	yes mide)	45		
632	52880	002367	6409-7 ethoxyb acid, ethyl ester	yes enzoic	no	no	3,6		
633	53200	002394	9266-8 ethoxy- ethyloxa		no	yes	30		
634	25910	002480	0 <b>t<del>r1ф</del>ғ0</b> ру	l <b>en</b> eglyc	oyles	no			
635	40720	002501	8 <b>td16</b> -5 butyl-4- hydroxy		no	no	30		

636	31500	002513	4a5ilyHc	yes	no	no	0,05	(22)	SML	
			acid, acrylic						express	ed
			acid,						acrylic acid,	
			ethylhe	xyl					2-	
			ester, copolyn	ner					ethylhe: ester	kyl
637	71635	002515	l <b>p&amp;nŧ6</b> ery dioleate	ythesitol	no	no	0,05		Not to be used for articles in contact with fatty foods for which [F3 simul D1 and/ or D2] is laid down	ant
638	23590	002532	2 <b>p68y3</b> th	y <b>læs</b> egly	cyes	no				
	76960									
639	23651	002532	2 <b>p69y</b> ptro	p <b>yds</b> negl	yyocol	no				
	80800									
640	54930	002535	9f0thrfald naphtho copolyn	l,	no	no	0,05			
[ <sup>F3</sup> 641	22331	002551	and (55-65 9 w/ w)1,6- diamino	% -2,2,4- ylhexane %		no	0,05 ]			
642	64990	002573	6 <b>n6</b> dle2c anhydri	yes de-	no	no			The fraction	

			styrene, copolymer sodium salt	.,,					with molecul weight below 1 000 Da [F3 shall] not exceed 0,05 % (w/w)	
643	87760	002626	6s <b>67</b> bHan ye monopalm		no	no				
644	88080	002626	6s <b>6&amp;At</b> an ye trioleate	es	no	no				
645	67760	002640	In86n5- ye n- octyltin tris(isoocty mercaptoa	yl	no )	no		(11)		
646	50480	002640	octyltin bis(isoocty mercaptoa	<sub>1</sub> 1	no )	no		(10)		
647	56720	002640	2g <b>1</b> 3e8rol ye monohexa		no	no				
648	56880	002640	2 <b>g2%e6</b> rol ye monooctar		no	no				
649	47210	002642	7 <b>ฝ07น6</b> ylth <b>ye</b> acid polymer	stann	onic	no			Molecu unit = (C <sub>8</sub> H <sub>18</sub> S (n = 1,5-2)	
650	49600	002663	bis(isoocty	/1	no )	no		(9)		
651	88240	002665	8ร <b>ง</b> ยิงสิลก ye tristearate	es	no	no				
652	38820	002674	lb5s(27,4- ye di-tert- butylpheny pentaeryth diphosphit	yl) ritol	no	yes	0,6			
653	25270	002674	7290-0 no toluene diisocyana dimer		yes	no		(17)	1 mg/ kg in final product	(10)

									expresse as isocyana moiety	
654	88600	0026836s	470ttol nonoste	•	no	no				
655	25450	0026896ы	<b>48y0</b> lod	<b>œo</b> anedi	n <b>aes</b> hano	lno	0,05			
656	24760	0026914s	###Prenesi	<b>mp</b> honic	yes	no	0,05			
657	67680	tı e	1.		no )	no		(11)		
658	52000	0027176d	<b>87</b> 0cylb	<b>yen</b> zene:	s <b>ul</b> phonic	eno	30			
659	82800		7 <b>2</b> 1-7 propylen nonolau		no	no				
660	47540		190e8t- lodecyl lisulphic	yes de	no	yes	0,05			
661	95360	d b h tt	ris(3,5- li-tert- outyl-4- nydroxyl		no -1,3,5- I,3H,5H)	yes	5			
662	25927		94,48 ris(4- nydroxy)	no phenol)	yes	no	0,005		Only to be used in polycarl	[F28(1)]
663	64150	0028290H	i7001enic	yes	no	no				
664	95000	n	nondthy rimethac nethyl nethacry copolym	crylate- /late	imæ)	no				
665	83120		228-3 propylen nonopal		no	no				

666	87280	0029110	6s <b>98</b> 5 <b>i</b> ltan dioleate		no	no				
667	55190	0029204	4 <b>g@2l@1</b> eio acid	eyes	no	no				
668	80240	0029894	4p&5ygly ricinole		no	no				
669	56610	003023	3g <b>6√le8</b> ro] monobe		no	no				
670	56800	0030899	9 <b>g62e8</b> rol monola diacetat	urate	no	no		(32)		
671	74240	0031570	Op <b>0.4</b> s/pho acid, tris(2,4- di-tert- butylpho		no	no				
672	76845	003183	lpm3y5ste of 1,4- butaned with caprolac	iol	no	no		(29) (30)	The fraction with molecula weight below 1 000 Da [F3 shall] not exceed 0,5 % (w/w)	ar
673	53670	0032509	glycol bis[3,3- bis(3- tert- butyl-4- hydroxy		no butyrate]	yes	6			
674	46480	003264	7 <b>d617e9</b> 1zy sorbitol		no	no				
675	38800	003268	bis(3- (3,5- di-tert- butyl-4-		no	yes l)hydraz	15			
676	50400	0033568	8d99n-9 octyltin	yes	no	no		(10)		

			bis(isoo maleate						
677	82560	003358		yes neglycol tate	no	no			
678	59200	003507	hexame bis(3- (3,5- di-tert- butyl-4-		no	yes te)	6		
679	39060	003595	bis(2- hydroxy di-tert-	yes y-3,5- enyl)etha	no	yes	5		
680	94400	003644	bis[3- (3-tert- butyl-4- hydroxy methylp propion	y-5- henyl)	lno	no	9		
681	18310	003665	3482-4 hexadeo	no anol	yes	no			
682	53270	003720			thnyolcellu	lousce			
683	66200		-		nentohylcel				
684	68125		4n <b>26</b> tælin syenite	-	no	no			
685	85950	003729	6s A Well acid, magnes sodium- fluoride salt		no	no	0,15	SML expressed as fluorided Only to be used in layers of multilayer material not coming into direct contact	

									with food.	
686	61390	003735	3h <b>5/9</b> l+66xy	nnesthylc	enhulose	no				
687	13530 13614	0038103	bis(4-		yes	no	0,05			
688	92560	0038613	di-tert- butyl- phenyl) bipheny diphosp	-4,4'- dylene	no	yes	18			
689	95280	004060	tris(4- tert- butyl-3- hydroxy dimethy	/-2,6- lbenzyl)	no -1,3,5- I,3H,5H)	yes	6			
690	92880	0041484	dtBiodiet bis(3- (3,5- di-tert- butyl-4- hydroxy phenyl) propion	,	no	yes	2,4			
691	13600	004746	bis(3- methyl-	phenyl)	yes 2-	no	1,8			
692	52320	005204		yes phenyl)i	no ndole	yes	0,06			
693	88160	0054140	Os <b>&amp;fbit</b> an tripalmi		no	no				
694	21400	0054270	acid, sulphop ester		yes	no	0,05			(1)
695	67520	0054849	9 <b>n3&amp;n6</b> m tris(isoc mercapt		no )	no		(9)		

					1			1	T	
696	92205	005756	etal@plhth acid, diester with 2,2'- methyle methyl- tert- butylph	nebis(4- 6-	no	no				
697	67515	005758	B <b>n3dn3</b> m tris(ethy mercap		no )	no		(9)		
698	49595	005758	Belsmethy bis(ethy mercap		no )	no		(9)		
699	90720	005844	6s <b>te2н%</b> уl	byeenszoylı	methane	no				
700	31520	006116	acid, 2-tert- butyl-6- (3-tert- butyl-2- hydroxy	y-5- enzyl)-4	no	yes	6			
701	40160	006126	bis(2,2, tetrame piperidy	thyl-4- /l)hexam oethane,	no ethylene	no diamine-	2,4			
702	87920	006175	2s68ə9tar tetrastea	-	no	no				
703	17170	006178	8f <b>a</b> t/Ty4 acids, coco	no	yes	no				
704	77600	006178	8p&5y0th ester of hydroge castor oil	y <b>læs</b> egly enated	cnb	no				
705	10599/9	<b>000</b> 6178		no	yes	no		(18)		(1)
	10599/9	1	fatty, unsatura (C <sub>18</sub> ), dimers,							

706	17230	006179	non hydroged distilled and non- distilled Ofaty3 acids, tall oil		yes	no			
707	46375	006179	Odsatolma earth	cyccosus	no	no			
708	77520	006179	lpb2y6th ester of castor oil	y <b>les</b> egly	cnb	no	42		
709	87520	006256	8s <b>ø</b> #b@an monobe	yes henate	no	no			
710	38700	006339	carbobu bis(isoo	yes toxyethy ctyl oacetate		yes	18		
711	42000	006343	carbobu tris(isoc	yes toxyethy ctyl oacetate		yes	30		
712	42960	006414	7 <b>e49t6r</b> oil, dehydra	yes .ted	no	no			
[F29713	43480	006436	5e <b>ha</b> rðoa activate 0-44-0]	lyes d	no	no		Only for use in PET at maximu 10 mg/kg of polymer Same purity requirer as for Vegetab Carbon (E 153) set out by Commis	nents le

								Regulat (EU) No 231/201  d with exception of ash content which can be up to 10 % (w/w).	2
714	84400	006436.	hydroge ester with pentaery		no	no			
715	46880	0065140	tert- butyl-4-	benzylp hyl	no	no	6		
716	60800	006544	hydroxy	ne- }	no	no	30		
717	84210	006599	7 <b>r0s</b> i+0, hydroge	yes nated	no	no			
718	84240	006599	7rdSirQ hydroge ester with glycerol		no	no			
719	65920	006682		yes yloyloxy ·l-	no vethyl-	no			

			carboxy chloride sodium salt - octadec methacr ethyl methacr cyclohe methacr N- vinyl-2- pyrrolid copolyn	yl ylate- ylate- xyl ylate- one,	mmoniui	n			
720	67360	006764	n- dodecyl tris(isoc		no )	no	(25)		
721	46800	006784	tert- butyl-4-	benzoic	no	no			
722	17200	006830	8 <b>f5tfy</b> 2 acids, soya	no	yes	no			
723	88880	006841	2s <b>2æ€h</b> , hydroly	yes sed	no	no			
724	24903	006842	5syfugs, hydroly starch, hydroge	sed	yes	no		In complia with the purity criteria for maltitol syrup E 965(ii) as laid down in Commis Directiv 2008/60 EC°	ssion re

F34									
726	83599	006844	products of oleic acid, 2- mercapt ester, with dichloro sodium sulphide and trichloro	oethyl odimethy		yes	(9)		
727	43360	006844	2 <b>c8 ก็</b> เมื่อร regenera		no	no			
728	75100	006851	5p48h@lic 3ac2d.0 diesters with primary saturate C <sub>8</sub> -C <sub>10</sub> branche alcohols more than 60 % C <sub>9</sub>	, d	no	no	(26) (32)	Only to be used as: (a)	plasticises in repeated use materials and articles; plasticises in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive

								(c)	2006/141/ EC 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.
729	75105	006851 002676	5p49halic lad0d0 diesters with primary saturate C9-C <sub>11</sub> alcohols more than 90 % C <sub>10</sub>	, d	no	no	(26) (32)	Only to be used as: (a)	plasticiser in repeated use materials and articles; plasticiser in single- use materials and articles contacting

								(c)	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; technical support agent in concentrations up to 0,1 % in the final product.
730	66930	0068554	4 <b>n7Cthl</b> yls	i <b>lses</b> squic	xxane	no		Residua monomo in methylsi	

		00.50.7.5					0.05		kg of	rimethox ilsesquio	-
731	18220	006856		no ninound	yes ecanoic	no	0,05			(2)	
732	45450	006861	cresol-		no ne-	yes	5				
733	10599/9	<b>20a</b> 6878		no	yes	no		(18)		(1)	
	10599/9	3	fatty, unsatura (C <sub>18</sub> ), dimers, hydroge distilled and non-distilled	enated,							
734	46380	006885	earth, soda ash flux- calcined		no	no					
735	40120	006895	1 <b>Ыऽ≲(</b> p‰ly	e <b>stes</b> ylene	glycol)h	yadroxym	etl6ylpho	sphonat	e		
736	50960	006922	octyltin ethylene	yes eglycol captoace	no tate)	no		(10)			
737	77370	007014	2p34y6th; dipolyh	y <b>læs</b> egly ydroxyst	earate	no					
738	60320	007032	hydroxy bis(1,1-	yes 7-3,5- Ylbenzyl)	no phenyl]b	yes enzotria:	1,5 zole				
739	70000	007033	oxamide (3,5- di-tert- butyl-4-	yes obis[ethy phenyl)- ate]		no					

	1	T	ı	I	T	1	T			
740	81200	007187	8 <b>рbФу&amp;6-</b> [(1,1,3,:		no	yes	3			
					)amino]-	1,3,5-				
			triazine	2,4-						
			diyl]- [(2,2,6,6	 						
			tetrame							
			piperidy	1)-						
					ylene[(2	2,6,6-				
			tetrame piperidy							
			imino]							
741	24070	007313	_	yes	yes	no				
	83610	_	acids							
	05010		and rosin							
			acids							
742	92700	007830	12423,464-		no	yes	5			
			tetrame	thyl-20-						
			(2,3- enoxypi	 ropyl)-7-						
			oxa-3,2							
			diazadis							
			[5.1.11. heneico							
			one,	Sa11-21-						
			polyme	r						
743	38950	007907		yes nzyliden	no e)sorbito	no I				
[F33744	18888	080181		no	yes	no		(35)	The	
•				butanoi	\$				substan	ee
			acid-3-	mantana					is used	
			acid,	pentano	IC				as product	
			copolyn	ner					obtained	i
									by	
									bacteria ferment	
									In	ation.
									complia	nce
									with	
									the	otions
									specific mention	
									in the	.cu
									Table	
									4 of	
									Annex I.]	
									1. J	

745	68145	0080410	0232'-92'- nitrilo(t tris(3,3' tetra- tert- butyl-1, bi- phenyl-1	riethyl ,5,5'- 1'- 2,2'-	no	yes	5		SML expresse as sum of phosphi and phospha	te
746	38810	008069	3500(21,6- di-tert- butyl-4- methylp diphosp	henyl)pe	no	yes ritol	5		SML expresse as sum of phosphi and phospha	te
747	47600	008403	dodecyl bis(isoo		no )	yes		(25)		
748	12765	008443	4N-228 aminoet β- alanine, sodium salt	,	yes	no	0,05			
749	66360	0085209	9292'-2 methyle bis(4,6- di-tert- butylph sodium phospha	enyl)	no	yes	5			
750	66350	0085209			no 6-	no	5			
751	81515	0087189	9 <b>p2/5y(</b> zir glycerol		no	no				
[F3752	39890	0087820 0069153 4 0054686 008154	6 <b>b4s</b> (+13et) 8-41- 6-97-4		lindene)so	o <b>nlo</b> it <b>l</b> ol				
753	62800	009270	4k4blin, calcined	yes I	no	no				

		1							
754	56020	009988	0g <b>6</b> 4e <b>6</b> rol yes dibehenate	no	no				
755	21765	010624	6434/-7 no methylenebis(3 chloro-2,6- diethylaniline)	yes -	no	0,05			(1)
756	40020	011055	322/4-0 yes bis(octylthiome methylphenol	no ethyl)-6-	yes		(24)		
757	95725	011063	reaction product with citric acid, lithium salt	no	no				
758	38940	011067	52246-8 yes bis(dodecylthic methylphenol	no omethyl)-6	yes -		(24)		
759	54300	011833	72097-0 yes ethylidenebis(4 di-tert- butylphenyl) fluorophosphor		yes	6			
760	83595	011934	product of ditert-butylphosphoniwith biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	no	no	18		Compo	sition:  4,4'- biphenylene- bis[0,0- bis(2,4- di- tert- butylphenyl)phosphonite (CAS No 0038613-77-3) (36-46 % w/ w (*)), 4,3'- biphenylene- bis[0,0- bis(2,4- di- tert- butylphenyl)phosphonite (CAS No

					0118421-00-4) (17-23 % w/ w
				_	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) (9-18 % w/
				_	w (*)), 4,4'- biphenylene-0,0-
					bis(2,4- di- tert- butylphenyl)phosphonate-0
					bis(2,4- di- tert- butylphenyl)phosphonite

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								(*) Other specifica	(CAS No 0112949-97-0) (< 5 % w/ w (*)) Quantity of substance used/ quantity of formulation  ations: Phosphor content of min. 5,4 % to max. 5,9 %, Acid value of max. 10 mg KOH per gram, Melt range of 85- 110 °C,
761	92930	012021	dimethy	ycarbony 1-1,4- pyridine-	1-2,6-	no	6		
762	31530	012396	8a2fyIlc acid, 2,4-di- tert- pentyl-6 (1- (3,5- di-tert-	yes	no	yes	5		

			pentyl-2 hydroxy ester		ethyl)phe	enyl			
763	39925	012922	bis(met	yes hoxymet lhexane	no hyl)-2,5-	yes	0,05		
764	13317	013245	bis[4- (ethoxy	no carbonyl lenetetra	yes )phenyl] carboxyo	no -1,4,5,8- diimide	0,05	Purity > 98,1 % (w/w). Only to be used as comonom (max 4 %) for polyeste (PET, PBT).	
765	49485	013470	dimethy (1-		no yl)pheno	yes	1		
766	38879	013586	16 <b>5%</b> (-22,4- dimethy		no dene)sor	no bitol			
767	38510	013650	bis(3-	2,6,6- thyl-4- namine	no	no mine,	5		
768	34850	014392	5a92i+tes, bis(hyd tallow alkyl) oxidised	rogenate	no d	no		Not to be used for articles in contact with fatty foods	(1)

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							for which [F3 simul D1 and/ or D2] is laid down. Only to be used in: (a)	polyolefins at 0,1 % (w/ w) concentration and in PET at 0,25 % (w/ w) concentration.
769	74010	0145650	Ophosphowas acid, bis(2,4- di-tert- butyl-6- methylphenyl) ethyl ester	no	yes	5	SML expresse as sum of phosphi and phospha	te
770	51700	014731:	525(4.26- yes diphenyl-1,3,5- triazin-2- yl)-5- (hexyloxy)phen	no ol	no	0,05		
771	34650	015184	latuminiumes hydroxybis [2,2'- methylenebis (4,6- di-tert- butylphenyl) phosphate]	no	no	5		
772	47500	0153250	0M,2N3 yes dicyclohexyl-2,	no 6-	no	5		

			naphtha							
773	38840	015486	2548(-234- dicumy diphosp	phenyl)	no pentaeryt	yes hritol-	5		phosphi and its hydroly product (2,4-	ce d lphenyl)pentaerythritol- ate sis
774	95270	016171	tris(tert-	nenyl-2- 3- diol	no	yes	2		SML express as sum of phosph and the hydroly product = TTBP	ite, ate sis
775	45705	016641	2172-8 cyclohe acid, diisonor ester		no irboxylic	no		(32)		
776	76723	016788	3- aminop termina polyme with dicyclol diisocya	ropyl ted, r hexylme	mane, thane-4,4	no			The fraction with molecu weight below 1 000 Da [F3 shall not exceed 1,5 % (w/w)	lar

777	31542	017425	4a2Bylic acid, methyl ester, telomer with 1-dodecar $C_{16}$ - $C_{18}$ alkyl esters	yes	no	no		0,5 % in final product	(1)
778	71670	017867	lp&8t4ery tetrakis (2- cyano-3 dipheny		no e)	yes	0,05		
[F3779	39815	018212		yes hoxymet	no hyl)fluoi	yes ene	0,05		[F28(2)]]
780	81220	019226	[[6- [N- (2,2,6,6 tetrame piperidi n- butylam triazine diyl] [(2,2,6,6 tetrame piperidi α- [N,N,N ',N'- tetrabut N"- (2,2,6,6 tetrame piperidi N"-[6- (2,2,6,6 tetrame	thyl-4- nyl)- nino]-1,3 -2,4- 5- thyl-4- nyl)imin liyl[(2,2, thyl-4- nyl)imin yl- - thyl-4- nyl)- - thyl-4- nyl)-	o]-1,6- 6,6- o]]-	no	5		

781	95265	022709	triazine- diamine 916 <b>0</b> ,57- tris(4-	yes	no	no	0,05			
			benzoyl benzene							
782	76725	0661470	6phlydlim 3- aminopa termina polymen with 1- isocyana isocyana	ngtebsylsild ropyl ted,	y1-3,5,5-	no			The fraction with molecul weight below 1 000 Da [F3shall] not exceed 1 % (w/w)	ar
783	55910	0736150	Ogbyeðrið castor- oil mono-, hydroge acetates	nated,	no	no		(32)		
[ <sup>F29</sup> 784	95420	0745070	tris (2,2- di-	yes	no nido)	no	5]			
785	24910	000010	0 <b>t2rb₁0</b> hth acid	adic	yes	no		(28)		
786	14627	0000117	7321-5 chlorop anhydri		yes	no	0,05		SML expresse as 3-chloroptacid	
787	14628	0000118	8445-6 chlorop anhydri		yes	no	0,05		SML expresse as 4- chloropt acid	

788	21498	0002530	0 <b>[%</b> 5-0 (methac	no rvloxv)r	yes ropylltri	no methoxy	0,05 silane	Only (1) to be (11)
				-JJ)F				used as a surface treatment agent of inorganic
790	60027		hardesse					fillers
789	60027		hydroge homopo and/or copolyn made of 1- hexene and/ or 1- octene and/ or 1- decene and/ or 1- tetradec (Mw: 440– 12 000)	ners ne	no	no		Average (2) molecular weight not less than 440 Da. Viscosity at 100 °C not less than 3,8 cSt (3,8 × 10 <sup>-6</sup> m <sup>2</sup> /s).
790	80480	009075 008245	triazine diyl)- [(2,2,6,0 tetrame: piperidy hexa- methyle [(2,2,6,0 tetrame:	lino-1,3, -2,4- 6- thyl-4- yl)imino) sne- 5-	]	no	5	Average (16) molecular weight not less than 2 400 Da. Residual content of morpholine ≤ 30 mg/ kg, of N,N'- bis(2,2,6,6- tetramethylpiperidin

							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	tetrame yl)amir yl)-4,7-	2,2,6,6- thylpiper o)triazin cane-1,1	-2-	no	0,05	
792	92475	cyclic ester with [3-(3- tert- butyl-4 hydrox	(tert- 2,2'- xybiphei		yes /phospho	5 onous	SML expressed as the sum of phosphite and phosphate form of the substance and the hydrolysis products
793	94000	0000102tr7tetH6an	oyæmine	no	no	0,05	SML expressed as the sum of triethanolamine and the hydrochloride adduct expressed

								as triethan	olamine
[F31794	18117	0000079	9g <b>ly</b> eolic acid	no	yes	no		Only to be used for manufact of polygly acid (PGA) for (i) indirect food contact behind polyestes such as polyethy terephth (PET) or polylact acid (PLA); and (ii) direct food contact of a blend of PGA up to 3 % w/ w in PET or PLA. ]	ers ylene alate
795	40155	012417	bis(2,2,4) tetrament piperidy N,N'-	thyl-4- rl)-	no thylened	no	0,05		(2) (12)
796	72141	001860	(1,4-	yes ne)bis[4]	no H-3,1-	yes	0,05	SML including the sum	g

[F31797	76807	007301	benzoxa one]  8p26y5ste of adipic acid with 1,3- butaned 1,2- propane and 2- ethyl-1- hexanol	eryes	no	yes		(31) (32) ]	of its hydroly product:	
798	92200	0006422	2t&&phth acid, bis(2- ethylhes	a <b>dės</b> kyl)ester	no	no	60	(32)		
[F29799	77708		(EO = 1-50) ethers of linear and branche primary (C 8 - C 22 ) alcohols	5	cnb	no	1,8		In complia with the maximu ethylene oxide content as laid down in the purity criteria for food additive in Commis Regulat (EU) No 231/201 l	s ssion ion
800	94425	000086	7tnfi8t10yl phospho	yes onoaceta	no te	no			Only for use in PET	
801	30607	_	acids, C <sub>2</sub> - C <sub>24</sub> , aliphatic linear,	yes c,	no	no				

802	33105	from natural oils and fats, lithium salt	rboxylic	no	no	5		(12)
302	33103	$C_{12}$ - $C_{14}$ seconda $\beta$ -(2-	ry, vethoxy),		no			(12)
803	33535	alkeness C <sub>24</sub> ) copolyn with maleic anhydric reaction product with 4- amino-2 tetramet	de, 2,2,6,6- chylpiper	no	no		Not to be used for articles in contact with fatty foods for which [F3 simu D1 and/ or D2] is laid down. Not to be used in contact with alcohol foods.	lant
804	80510	nonyl-1 dioxo-1 thioprop diyl)- block- poly(x- oleyl-7- hydroxy	,1- - oane-1,3-		no		Only to be used as polyme product aid in polyeth (PE), polypro	ion ylene

			diyl), process mixture with $x = 1$ and/ or 5, neutrali with dodecyl acid		sulfonic			(PP) and polystyr (PS)	rene
805	93450		and	ner chlorosila	no ane ylenepho	no		The content of the surface treatmer copolyr of the coated titanium dioxide is less than 1 % w/w	nt ner
806	14876	000107	61947–7 cyclohe acid	no xanedica	yes rboxylic	no	5	Only to be used for manufa- of polyeste	
[F30807	93485		titanium nitride, nanopar		no	no		No migration of titanium nitride nanopar Only to be used in polyethy terephth (PET) up to 20 mg/kg. In the PET, the	ticles.

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									agglome have a diamete of 100-500 consisti of primary titanium nitride nanopar particles have a diamete of approxii 20 nm. ]	r ) nm ng ticles;
808	38550	088207		yes enzylide	no ne)propy	no Isorbitol	5		SML including the sum of its hydroly product.	sis
809	49080	085228	(2,6-disopro [4- (1,1,3,3) tetramet	hylbutyl	no yl)-6- )phenox nolin-1,3		0,05		Only for use in PET	(6) (14) (15)
810	68119		neopent glycol, diesters and monoes with benzoic acid and 2- ethylhes acid	ters	no	no	5	(32)	Not to be used for articles in contact with fatty foods for which [F3 simul D1 and/ or D2]	ant

811	80077	006844	lpb7y8thylæse	no	no	60		is laid down.	
011			waxes, oxidised						
[F31812	80350	012457	8pb1y(12-yes hydroxysteariacid)- polyethylenein copolymer		no			Only to be used in plastics up to 0,1 % w/w. Prepared by the reaction of poly(12 hydroxy acid) with polyethy l	
813	91530	_	sulphosuyesinicacid alkyl (C <sub>4</sub> - C <sub>20</sub> ) or cyclohexyl diesters, salts	c no	no	5			
814	91815		sulphosuyesniacid monoalkyl (C <sub>10</sub> -C <sub>16</sub> ) polyethyleneg esters, salts		no	2			
815	94985		trimethy lods romixed triesters and diesters with benzoic acid and 2-ethylhexanoic acid		no	5	(32)	Not to be used for articles in contact with fatty foods for	

							which  [F3 simu D1 and/ or D2] is laid down	lant
816	45704	 cis-1,2- cyclohe acid, salts	yes xanedica	no rboxylic	no	5		
817	38507	cis- endo- bicyclol dicarbo acid, salts	yes [2.2.1]he xylic	no ptane-2,î	no 3-	5	Not to be used with polyeth in contact with acidic foods. Purity $\geq$ 96 %.	
818	21530	 methally acid, salts	y <b>hsu</b> lphoi	nives	no	5		
819	68110	neodeca acid, salts	nywisc	no	no	0,05	Not to be used in polyme contact fatty foods. Not to be used for articles in contact with fatty foods for which [F3 simu D1 and/	ing

820	76420		pimelic	Ves	no	no		or D2 is laid down. SML expres as neode acid.	
	70420		acid, salts	yes	ПО	ПО			
821	90810		stearoyl lactylic acid, salts	- <b>y</b> es	no	no			
[ <sup>F35</sup> 822	71938		Perchlo acid, salts	riyoes	no	no	0,002		(4)]
823	24889	_	5- Sulphoi acid, salts	no sophthal	yes ic	no	5		
854	71943	032923	8p24f6001 acetic acid, α- substitu with the copolyr of perfluor propyle glycol and perfluor ethylene glycol, termina with chloroh groups	ted ner ro-1,2- ne ro-1,1-	ppropylo	no		up to 0,5 % w/w in the polym of fluoro that are proces	polymers ssed eratures

[ <sup>F36</sup> 855	40560		(butadiestyrene, methyl methacic copolyr crosslinked with 1,3-butaned dimethal	rylate) ner liol	no	no		Only to be used in rigid poly(vin chloride (PVC) at a maximulevel of 12 % at room tempera or below.	am
[ <sup>F37</sup> 856	40563	25101-2	styrene, methyl methaci butyl acrylate copolyr cross-linked with divinyll or 1,3-butaned dimetha	rylate, ner penzene	no	no		Only to be used in: —	rigid poly(vinyl chloride) (PVC) at a maximum level of 12 % at room temperature or below; or at up to 40 % w/ w in blends of styrene acrylonitrile copolymer (SAN)/ poly(methyl methacrylate) (PMMA)

0.57	((7))	002705	2(21,0-1						repeatuse articles at room temperature or below, and when either in contact only with aqueous, acidic and/ or low alcoholic (< 20 %) foodstuffs for less than 1 day, or when in contact only with dry foodstuffs for any duration of time. I
857	66765	003795	acrylate styrene, glycidyl methacr copolyn	ylate, , l ylate)	no	no		Only to be used in rigid poly(vir chloride (PVC) at a maximu level	

							of
							2 % at
							room
							temperature
							or
							below.
							1
[F26[X185\858565	009049	R3000_1	yes	no	yes	0,05	SML (2)]]
[ [ 8386363	007047	bis[2-	yes	110	yes	0,03	expressed
		(3-(3-					as the
		tert-					sum
		butyl-4					of the
							substance
		hydroxy		العسامين	1 1		
		meunyip	henyl)pi	opionyio	)XY)-1,1-	1	and its
		aimeiny	lethyl]-2	,4,8,10-			oxidation
		tetraoxa	spiro[5,	Junaeca	ne		product
							3-[(3-
							(3-tert-
							butyl-4-
							hydroxy-5-
							methylphenyl)prop-2-
							enoyloxy)-1,1-
							dimethylethyl]-9-
							[(3-(3-
							tert-
							butyl-4-
							hydroxy-5-
							methylphenyl)propionyloxy)-1,1-
							dimethylethyl]-2,4,8,10-
							tetraoxaspiro[5,5]-
							undecane
							in
							equilibrium
							with
							its
							para
							para quinone
							methid
							tautomer.
[F23859		(butadie	nves	no	no		Only
1 037		ethyl	)	-			to be
		acrylate	,				used
		methyl	7				as
		methaci	vlate				particles
		styrene)	) 1410,				in
		copolyr					non-
		crosslin	ked				plasticised
		with					PVC
			enzene,				up to
		in	, chizche,				10 %
		nanofor	m				w/w in
		nanoioi	111				contact
I	1	l	I		l		Contact

all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 9988 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by			1	İ		with	1
food types at room temperature or below including long-term storage. When used together with the substance with FCM No 998 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by							
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the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by						No	
the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by						1043,	
of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by							
10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by						restricti	on
10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by						of	
w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by							
applies to the sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by							
to the sum of those substances.  The diameter of particles shall be > 20 nm, and for at least 95 % by							
sum of those substances. The diameter of particles shall be > 20 nm, and for at least 95 % by						to the	
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							it shall be > 40 nm.
860	71980	005179	8pæðffsioi (poly(n- propoxy acid]	ojæs v))propar	no	no	Only to be used in the polymerisation of fluoropolymers that are processed at temperatures at or above 265 °C and are intended for use in repeated use articles
861	71990	001325	2ptsHaoi (n- propoxy acid]	oj@s	no oic	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

		,			,	·		
[ <sup>F31</sup> 862	15180	0018083	53042–4 diacetox butene	no sy-1-	yes	no	0,05	SML (17) includin (19)] the hydrolysis product 3,4- dihydroxy-1- butene Only to be used as a co- monomer for ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers.
[F36863	15260	000064	6121503 decaned	no liamine	yes	no	0,05	Only to be used as a comonomer for manufacturing polyamide articles for repeated use in contact with aqueous, acidic and dairy foodstuffs at room temperature or for short term contact up to 150 °C. l

864	46330	000005		yes	no	no	5	Only	
			diamino hydroxy	o-6- pyrimid	ine			to be used in rigid poly(vir chloride (PVC) in contact with non-acidic and non-alcoholiaqueous food	с
[F30865	40619	002532	2(9919) acrylate methyl methaci butyl methaci copolyn	ylate, ylate)	no	no		Only to be used in: (a)	rigid poly(vinyl chloride) (PVC) at a maximum level of 1 % w/ w; polylactic acid (PLA) at a maximum level of 5 % w/
866	40620		(butyl acrylate methyl methaci copolyr	ylate)	no	no		Only to be used in rigid	w. 1

			cross- linked with allyl methaci	ylate			poly(vin chloride (PVC) at a maximu level of 7 %	;)
867	40815	004047	I(bbtgl methacr ethyl acrylate methyl methacr copolyn	, ylate)	no	no	Only to be used in rigid poly(vin chloride (PVC) at a maximulevel of 2 %	;)
[F30868	53245	000901	acrylate methyl methacr copolyn	ylate)	no	no	Only to be used in: (a)	rigid poly(vinyl chloride) (PVC) at a maximum level of 2 % w/ w; polylactic acid (PLA) at a maximum level of 5 % w/ w; polyethylene terephthalate (PET) at a maximum

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869	66763	0027130	acrylate methyl methaci styrene) copolyn	ylate,	no	no		Only to be used in rigid poly( chlori (PVC at a maxil level of 3 %	de) ) num
870	95500	016053:	',N"- tris(2-	-	no yl)-1,2,3-	no	5		
[F4871		0287910	belode ar acid, 12- amino-, polymer with ethene, 2,5- furandia α- hydro-ω- hydroxy (oxy-1, 2 ethaned and 1- propene	one, poly 2- iyl)	no	no		at levels of up to 20 weigh %. These	lefins

								assigns food simulant E, at ambient temperature or below, and when migration of the total oligomeric fraction of less than 1 000 Da does not exceed 50 µg/kg food.
[F38872		000660	phenyl- bis(4-		yes	no	0,05	To be used only as a co-monomer in polycarbonate copolymers
[F36873	93460		titanium dioxide reacted with octyltrie	ethoxysil	no	no		Reaction product of titanium dioxide with up to 2 % w/w surface treatment substance octyltriethoxysilane processed at high temperatures.

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[F26874	16265	015606	dimethy (4'- hydroxy methox; ω-3- dimethy (4'- hydroxy methox)	y-3'- yphenyl) yl-3- y-3'-	propylsil propylsil pxane		0,05	(33)	Only to be used as comono in siloxane modifie polycarl. The oligome mixture shall be characte by the formula C 24 H 38 Si 2 O 5 (SiOC 2 H 6 )n (50 > n ≥ 26). ]	d d ponate. eric
875	80345	005812	8p22y612 hydroxy acid) stearate	stearic	no	yes	5			
878	31335		acids, fatty (C <sub>8</sub> -C <sub>22</sub> ) from animal or vegetab fats and oils, esters with branche alcohols aliphatimonohy saturate primary	d s, c, rdric, d,	no	no				

			$\begin{pmatrix} (C_3 - C_{22}) \end{pmatrix}$						
879	31336		acids, fatty (C <sub>8</sub> -C <sub>22</sub> ) from animal or vegetab fats and oils, esters with alcohols linear, aliphatic monohy saturate primary (C <sub>1</sub> -C <sub>22</sub> )	s, c, ydric,	no	no			
[ <sup>F29</sup> 880	31348		acids, fatty (C 8 - C 22 ), esters with pentaer	yes	no	no			
881	25187	000301	02926,454- tetrame diol	no	yes butane-	no 1,3-	5	Only for: (a)	repeated use articles for long term storage at room temperature or below and hotfill; single use materials and articles

									as
									a
									co-
									monomer
									at
									a .
									maximum
									use
									level
									of
									35
									mole
									%
									of
									the
									diol
									component
									of
									polyesters,
									and
									if
									such
									materials
									and
									articles
									are
									for
									long
									term
									storage
									at
									room
									temperature
									or
									below
									of
									food
									types which
									WIIICII boxro
									have
									an
									alcohol
									content
									of
									up
									to
									10 %
									and
									for
									which
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									2
									of
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									Annex III does not assign simulant D2. Hot fill conditions are allowed for such single use materials and articles. I
882	25872	000241		no /lphenol	yes	no	0,05		
883	22074	000445	methyl- pentane	diol	yes	no	0,05	Only to be used in material in contact with food at a surface to mass ratio up to 0,5 dm²/kg	S
884	34240	009108	2alky (C C <sub>21</sub> ) sulp acid, esters with phenol		no	no	0,05	Not to be used for articles in contact with fatty foods for	

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								which [F3 simul D1 and/ or D2] is laid down.	ant
885	45676	026324	leyelle oligome of (butyler terephth	ne	no	no		Only to be used in poly(eth terephth (PET), poly(but terephth (PBT), polycarl (PC), polystyr (PS) and rigid poly(vir chloride (PVC) plastics in concent up to 1 % w/ w, in contact with aqueous acidic and alcoholi foods, for long term storage at room tempera	tylene talate) tylene talate) conate rene  rene  retions
[ <sup>F36</sup> 894	93360	001654	5tbibdipr acid, ditetradester		no	no	(14)	_	

895	47060	0171090 <b>39</b> 0	3,55- yes tert-	no	no	0,05	Only to be	
			yl-4-				used	
		hve	droxypheny	Doronan	oic		in	
		aci		i)propun			polyole	fins
		est					in	
		wit					contact	
		C1					with	
		C1					foods	
			nched				other	
		and					than	
		line					fatty/	
		alc	ohols				high-	
							alcohol	ic
							and	
							dairy	
							product	s.
896	71958	0958445344	⊢8 yes	no	no		Only	
			fluoro-3-				to be	
		[(3					used	
		me	thoxy-				in the	
		pro	poxy)propa	noic			polyme	risation
		aci	d],				of	
			monium				fluorop	olymers
		sal	t				when:	
								processed
								at
								temperatur
								higher than
								280 °C
								for
								at
								least
								10
								minutes,
								processed
								at
								temperatur
								higher
								than
								190 °C
								up
								to
								30 %
								w/
								W
								for
								use
								in
								blends
								with

								polyoxymethylene polymers and intended for repeated use articles.
[F26902	000012	benziso one 1,1- dioxide sodium salt	yes thiazol-3	no (2H)-	no		The substant shall comply with the specific purity criteria as set out in Commis Regulat (EU) No 231/201	esion
[ <sup>F23</sup> 903	37486-6	perfluor [(5,8,11 tetramet	,14-	no	no		Only to be used as a polymer producti aid in the polymer of fluoropo intended for: (a)	isation olymers

	20150							(b)	temperatures at or above 360 °C for at least 10 minutes or at higher temperatures for equivalent shorter times; repeated use materials and articles when processed (non-sintered) at temperatures from 300 °C and up to 360 °C for at least 10 minutes. I
923	39150	0000120	bis(2-	yes vethyl)do	no	no	5	The residual amount of diethand in plastics, as an impurity and decomp	olamine

							product of the substance, [F3 shall] not result in a migration of diethanolamine higher than 0,3 mg/kg food.
924	94987	mix tries and dies with n- octa and	ters noic n-	a mec,	no	0,05	Only for use in PET in contact with all types of foods other than fatty, high- alcoholic and dairy products.
926	71955	etho acid	loxy- xy)acetic	no	no		Only to be used in the polymerisation of fluoropolymers that are processed at temperatures higher than 300 °C for at least

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and...

ANNEX I

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

	I	1 1		ı	i i	1	 110
							10 minutes.
-							minutes.
[F23969		24937-7	<b>%</b> tBylene	yes	no	no	Only
			vinyl				to be
			acetate				used
			copolyn	ner			as a
			wax				polymeric
							additive
							up to
							2 % w/
							w in
							polyolefins. The
							migration
							of low
							molecular
							weight
							oligomeric
							fraction
							below
							1 000
							Da
							shall
							not
							exceed
							5 mg/
							kg
							food. ]
971	25885	0002459	9 <b>trlifhd</b> thy	ho	yes	no	Only (17)
			trimellit	ate			to be
							used
							as a
							co-
							monomer
							up to
							0,35 %
							w/w to produce
							modified
							polyesters
							intended
							to be
							used
							in
							contact
							with
							aqueous
							and
							dry
							foodstuffs
							containing
							no free

972	45197	001215	Be <b>ōֆբ</b> ær hydroxi phospha	yes de ate	no	no		1	fat at the surface.	
973	22931	0019430	O <del>(p</del> 3r4uc	norbutyl)	e <b>the</b> slene	no			Only to be used as a co- monome up to 0,1 % w/w in the polymer of fluoropo sintered at high tempera	isation olymers,
[F35974	74050	939402-	and 4- (1,1-	·lpropyl) ·lpropyl)		yes	10		SML expresse as the sum of the phosphi and phospha forms of the substance 4-tert- amylphe and 2,4-di- tert- amylphe di-tert- amylphe shall not exceed 1 mg/ kg food. ll	te te te ee, enol enol.

[F26979	79987		(polyeth	<b>vk</b> ene	no	no		Only
			terephth hydroxy polybut pyrome anhydri copolyn	alate, rlated adiene, llitic de)				to be used in polyethylene terephthalate (PET) at a maximum level of 5 % w/w. ]
[ <sup>F38</sup> 988		3634-83		no yanatom	yes ethyl)ber	no nzene	(34)	SML(T) applies to the migration of its hydrolysis product, 1,3- benzenedimethanamine To be used only as co- monomer in the manufacture of a middle layer coating on a poly(ethylene terephthalate) polymer film in a multilayer film
[F23998			(butadie ethyl acrylate methyl methacr styrene) copolyn not cross- linked,	ylate,	no	no		Only to be used as particles in non-plasticised PVC up to 10 %

or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,	 1.	1 1	1	
with all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
all food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,	nanoform			
food types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				with
types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
types at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				food
at room temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
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temperature or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
or below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
below including long-term storage. When used together with the substance with FCM No 859 and/ or the substance with FCM No 1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
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1043, the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				No
the restriction of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				1043,
of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
of 10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				restriction
10 % w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
w/w applies to the sum of those substances. The diameter of particles shall be > 20 nm,				10 %
applies to the sum of those substances. The diameter of particles shall be > 20 nm,				
to the sum of those substances. The diameter of particles shall be > 20 nm,				
sum of those substances. The diameter of particles shall be > 20 nm,				to the
those substances. The diameter of particles shall be > 20 nm,				
substances. The diameter of particles shall be > 20 nm,				
The diameter of particles shall be > 20 nm,				
diameter of particles shall be > 20 nm,				
of particles shall be > 20 nm,				
particles shall be > 20 nm,				
shall be > 20 nm,				
be > 20 nm,				shall
20 nm,				
				and
for at				
least				
95 %				
	1		I I	/3 /0

							by number it shall be > 40 nm.	
[F391007	976-56-	tiethyl[bis(1,1-dimethy)hydroxy	lethyl)-4	yes 1- methyl]p	hosphon	ate	Only to be used up to 0,2 % w/w based on the final polymer weight in the polymer to manufactory poly(eth terephth (PET).	risation cture tylene
1016		(methac acid, ethyl acrylate n- butyl acrylate methyl methac and butadien copolyn in nanofor	, ylate ne) ner	no	no		Only to be used up to: (a)  (b)  The final	10 % w/ w in non- plasticised PVC; 15 % w/ w in non- plasticised PLA.
							material shall be used at room tempera or	

			below.
1017	25618-5 polyglycyeol	no no	To be processed under conditions preventing the decomposition of the substance and up to a maximum temperature of 275 °C.
[F391030	montmonite clay modified by dimethyldialkyl( C18)ammonium chloride	C16-	Only to be used up to 12 % (w/ w) in polyolefins in contact with dry foods to which simulant E is assigned in table 2 of Annex III at room temperature or below. The sum of the specific migration of 1-chlorohexadecane and 1-

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						chlorooctadecane shall not exceed 0,05 mg/kg food. Can contain platelets in the nanoform that are only in one dimension thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer. I
[F41031	3238-40	Haran-2, dicarbo acid	yes	no	5	Only (22) to be (23) used as a monomer in the production of polyethylene furanoate. The migration of the oligomeric fraction

							of less than 1 000 Da shall not exceed 50 µg/kg food (expressed as furan-2,5-dicarboxylic acid).
1034	3710-30	O-B37- octadier	no ne	yes	no	0,05	Only to be used as a crosslinking co- monomer in the manufacture of polyolefins for contact with any type of foods for long term storage at room temperature, including when packaged under hot-fill conditions. ]
1043		(butadie ethyl acrylate methyl methacr styrene)	, ylate,	no	no		Only to be used as particles in

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copolyn	her				1	non-	1
crosslin	ked					plasticis	sed
with						PVC	
1,3-						up to	
butaned	iol					10 %	
dimetha						w/w in	
in						contact	
nanofor	m					with	
						all	
						food	
						types	
						at	
						room	
						tempera	ture
						or	
						below	
						includin	g
						long-	
						term	
						storage.	
						When	
						used	
						together with	
						the	
						substan	re
						with	
						FCM	
						No	
						859	
						and/	
						or the	
						substan	ce
						with	
						FCM	
						No	
						998,	
						the	
						restriction of	on
						10 %	
						W/W	
						applies	
						to the	
						sum of	
						those	
						substan	ces.
						The	
						diamete	r
						of	
						particles	\$
						shall	
						be >	
	•	,	,	,	•		

							20 nm, and for at least 95 % by number it shall be > 40 nm.	
[F41045	119093	lp27flhor acid, 2-[(5- methox dioxolar yl)oxy] ammon salt	y-1,3- n-4- },	no	no		Only to be used as a polymer product aid during the manufact of fluorope under high tempera condition of at least 370 °C.	ion cture olymers ture
1046		zinc oxide, nanopar coated with [3- (methac trimetho (FCM No 788)	yes ticles, ryloxy)p oxysilane	no propyl]	no		Only to be used in unplasti polymer. The restriction and specific specific for FCM substant No 788 shall be respected.	rs. ons ations d

1048	624-03-æthyl glycc dipal		no	no		(2)	Only to be used when produce from a fatty acid precurse that is obtained from edible fats or oils.	or
1050	zinc oxide nano unco	particles,	no	no			Only to be used in unplasti polyme	
1051	tetrar piper	yes ,2,6,6- nethyl-4- idinyl) thalamide	no	no	5			
1052	dieth	,10-no oxaspiro[5, anol,β3,β3 nethyl-	yes 5]undeca ,β9,β9-	no ne-3,9-	5		Only to be used as a monom in the product of polyeste The migratio of oligome of less than 1 000 Da shall not exceed 50 µg/kg food (express)	ion ers. on ers

							as SPG).	
1053		fatty acids, C16– 18 saturate esters with dipentae	yes d, erythritol	no	no		Only to be used when produce from a fatty acid precurse that is obtained from edible fats or oils ]	or
[F391055	7695-91 58-95-7	€ tocophe acetate	yes rol	no	no		Only to be used as antioxid in polyole	
[F401059	147398-	co- (R)-3-	)n&- /butyrate /hexanoa		no	(35)	Only to be used either alone or blended with other polymer in contact with all foods under contact condition of up to 6 month and/or 6 month and more, at room	ons as

							tempera	ture
							or	
							below,	
							includin	g
							hot fill	
							or a	
							short	
							heating	
							up	
							phase.	
							The	
							migratio	n
							of all	
							oligome	ers
							with a	
							molecul	ar
							weight	
							below	
							1 000	
							Da	
							shall	
							not	
							exceed	
							5,0 mg/	
							kg	
							food.	
1060		ground	yes	no	no		Only	
1060		sunflow	yes	no	no		Only to be	
1060		sunflow seed	yes	no	no		Only to be used at	
1060		sunflow	yes	no	no		Only to be used at room	ture
1060		sunflow seed	yes	no	no		Only to be used at room tempera	ture
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or	ture
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below	ture
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in	ture
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact	ture
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with	ture
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods	ture
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with	ture
1060		sunflow seed	yes eer	no	no		Only to be used at room tempera or below in contact with foods for which Table 2	ture
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of	
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I	
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I assigns	
1060		sunflow seed	yes	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I assigns food	11
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I assigns food simulan	11
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I assigns food simulan The	11
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I assigns food simulan The seed	11
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I assigns food simulan The seed hulls	11
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I assigns food simulan The seed hulls shall	11
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I assigns food simulan The seed hulls shall be	II t E.
1060		sunflow seed	yes er	no	no		Only to be used at room tempera or below in contact with foods for which Table 2 of Annex I assigns food simulan The seed hulls shall	II t E.

					sunflower seeds that are fit for human consumption. The processing temperature of the plastic containing the additive shall not exceed 240 °C.
[ <sup>F41</sup> 1061	80512-4	12,3,4'- no trifluorobenzo	yes phenone	no	Only to be used as a comonomer in the manufacture of polyether ether ketone plastics up to 0,3 % w/w of the final material.
1062		mixture no composed of 97 % tetraethyl orthosilicate (TEOS) with CAS No 78-10-4 and 3 % hexamethyldis	yes	no	Only to be used for the production of recycled PET and at up to 0,12 % (w/w). ]

	(HMI with CAS No 99	OS) 99-97-3				
[F411063	1547-26-283,3, hepta pente	fluoro-1-	yes	no		Only to be used together with tetrafluoroethylene and/or ethylene co-monomers to manufacture fluorocopolymers for application as polymer processing aid at up to 0,2 % w/ w of the food contact material, and when the low-molecular mass fraction below 1 500 Da in the fluorocopolymer does not exceed 30 mg/ kg.
1064	39318-18u8gs oxide		no	no	0,05	Stoichio (25) y: WO n = 2,72-2,90
1065	85711-28a0xtu	re yes	no	no	5	Only to be (26)]

		methylbranche and linear C 14 - C 18 alkanan derived from fatty acids					used in the manufactor of articles made of polyolef and which do not come into contact with foods for which food simulant is assigned in Table 2 of Annex I	ĭns, t D2
[F331066	23985-7	75,3,3,4- tetrahyd dicarbon acid, dimethy ester	lronaphtl xylic	yes halene-2,	no 6-	0,05	Only to be used as a comonome in the manufact of a polyeste nonfood contact layer in a plastic multilay material which is to be used only in contact with foods	eture er

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							for which food simulan A, B, C and/ or D1 are assigned in Table 2 of Annex III. The specific migration limit in column 8 refers to the sum of the substant and of its dimers (cyclic and open chain).	l on
[F421067	616-38-	dimethy carbona	lno te	yes	no		Only to be used: a)	with 1,6- hexanediol in the manufacture of polycarbonate pre- polymers that are used at up

1		1		1	1				
									to
									30 %
									to
									manufacture
									thermoplastic
									polyurethanes
									with
									4,4'-
									methylenediphenyldiisocya
									and
									diols,
									such
									as
									polypropylene
									glycol
									and
									1,4-
									butanediol.
									UUIAHEUIUI.
									The
									resulting
									material
									shall
									only
									be
									applied
									in
									repeated
									use
									articles
									interests
									intended
									to
									come
									into
									short-
									term
									contact
									(≤ 30 min
									at
									room
									temperature)
									with
									food
									for
									which
									simulants
									A
									and/
									or
									В
									are
									assigned
									in
									Table
1	I	I	I	I	I		l	ı	14010

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		b)	of Annex III; or for the production of other polycarbonates and/ or under other conditions provided that the migration of dimethyl carbonate does not exceed 0,05 mg/
			kg food and that the migration of all polycarbonate oligomers with a molecular weight below 1 000 Da together does not exceed 0,05 mg/ kg food.

T33   1068   2530-83   18							 
(2,3- epoxypropoxy)propyl]trimethoxy silane  to be used as a component of a sizing agent to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0.01 mg/ kg for	I <sup>F33</sup> 1068	2530-83	<del>1</del> 8-	no	yes	no	Only
epoxypropoxy)propyl]trimethoxy silane  used as a component of a sizing agent to treat glass fibres to be embedded in glass- fibre- reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							
silane  as a component of a sizing agent to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polyearbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for				ropoxy)p	ropyl]tri	methoxy	used
of a sizing agent to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for			silane	1 2/1	1.0 -		as a
of a sizing agent to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							component
agent to treat glass fibres to be embedded in glass-fibre-reinforced low difffusivity plastics (polyethylene terephthalate (PET), polyearbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							
agent to treat glass fibres to be embedded in glass-fibre-reinforced low difffusivity plastics (polyethylene terephthalate (PET), polyearbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							sizing
to treat glass fibres to be embedded in glass-fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polyearbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							
fibres to be embedded in glass- fibre- reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							
fibres to be embedded in glass- fibre- reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							glass
embedded in glass- fibre- reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							fibres
in glass- fibre- reinforced low diffusivity plastics (polyethylene terephthalate (PET), polyearbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							
glass-fibre- reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							
fibre-reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/kg for							
reinforced low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/kg for							
low diffusivity plastics (polyethylene terephthalate (PET), polycarbonate (PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/kg for							
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(PC), polybutylene terephthalate (PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/kg for							(PEI),
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(PBT), thermoset polyesters and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/ kg for							terenhthalate
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and epoxy bisphenol vinylester) in contact with all foodstuffs. In treated glass fibres, residues of the substance must not be detectable at 0,01 mg/kg for							
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							substandand 0,06 mg kg for each of the reaction products (hydroly monomand epoxy- containic cyclic dimer, trimer and tetramer	s ysed ers
[ <sup>F42</sup> 1069	75-28-5	isobutar	nges	no	no		Only to be used as a blowing agent.	,
[F431075		clay modifie with	yltrimet	hylammo	no		Only to be used as additive at up to 4,0 % w/ w in polylact acid plastics intended for long-term storage of water at ambient tempera or below. Can form	iic d

							platelets in the nanoform that are in one or two dimensions than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedd in the polymer.	ons
1076	122793	7P46spho acid, tripheny ester, polymer with alpha- hydro- omega- hydroxy ethaned C10-16 alkyl ester	/l r /poly[ox;	no y(methyl	no -1,2-	0,05	Only to be used as an additive at up to 0,2 % w/w in high impact polystyr material and articles intended contact with food at room tempera and below, includin hot-fill	ene s

							and/or heating up to 100 °C for up to 2 hours. It shall not be used in contact with foods for which simulan C and/ or D1 is assigned in Annex III.	
1077		Titaniur dioxide surface- treated with fluoride modifie alumina	- d	no	no		Only to be used at up to 25,0 % w/w, including in the nanofor	

- **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 [F23Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).]
- e OJ L 158, 18.6.2008, p. 17.
- f [F<sup>24</sup>[F<sup>25</sup>Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).]
- g This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.]
- $\textbf{h} \qquad [^{\text{F26}}\mathrm{OJ} \; L \; 83, \, 22.3.2012, \, p. \; 1 \; .]$
- i [F27]Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013.
- j Young children as defined in Article 2(2)(b) of Regulation (EU) No 609/2013.]

#### **Editorial Information**

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

### **Textual Amendments**

- **F23** Inserted by Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F24** Inserted by Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles (Text with EEA relevance).
- **F25** Substituted by Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials (Text with EEA relevance).
- **F26** Inserted by Commission Regulation (EU) No 1183/2012 of 30 November 2012 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F27** Inserted by Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials (Text with EEA relevance).
- **F28** Deleted by Commission Regulation (EU) 2017/752 of 28 April 2017 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F29** Substituted by Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F30** Substituted by Commission Regulation (EU) No 1183/2012 of 30 November 2012 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F31** Substituted by Commission Regulation (EU) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F32** Substituted by Commission Regulation (EU) No 202/2014 of 3 March 2014 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F33** Substituted by Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F34** Deleted by Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F35** Substituted by Commission Regulation (EU) 2018/831 of 5 June 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F36** Inserted by Commission Regulation (EU) No 1282/2011 of 28 November 2011 amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F37** Substituted by Commission Regulation (EU) 2018/79 of 18 January 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

- **F38** Inserted by Commission Regulation (EU) No 202/2014 of 3 March 2014 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F39** Inserted by Commission Regulation (EU) 2017/752 of 28 April 2017 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F40** Substituted by Commission Regulation (EU) 2019/1338 of 8 August 2019 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F41** Inserted by Commission Regulation (EU) 2018/79 of 18 January 2018 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F42** Inserted by Commission Regulation (EU) 2019/37 of 10 January 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).
- **F43** Inserted by Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

#### **Textual Amendments**

F22 Word in Annex 1 point 1 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 76; 2020 c. 1, Sch. 5 para. 1(1)

### 2. Group restriction of substances U.K.

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
[ <sup>F3</sup> 2	89 227	30	expressed as ethyleneglycol]

	263   1048		
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

	294	5	avaraged as the sum
[ <sup>F31</sup> 14	368		expressed as the sum of the substances
	894]		and their oxidation products
[F2915	98 196 344	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 <sub>2</sub>
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	6	expressed as acrylic acid

	636		
23	150 156 181 183 184 355 370 374 439 440 447 457 482	6	expressed as methacrylic acid
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
[ <sup>F29</sup> 30	254 344 672	5	expressed as 1,4-butanediol]
31	73 797	30	expressed as the sum of the substances
32	8 72 73 138	60	expressed as the sum of the substances

	140 157 159		
	207		
	242		
	283		
	532		
	670 728		
	729		
	775 783		
	797		
	798		
	810		
	815		
[ <sup>F26</sup> 33	180 874	ND	expressed as eugenol]
[ <sup>F38</sup> 34	421 988	0,05	Expressed as 1,3-benzenedimethanamine]
[ <sup>F42</sup> 35	467 744 1059	0,05	expressed as crotonic acid]

## 3. Notes on verification of compliance U.K.

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.
[F30(4)	Compliance testing when there is a fat contact [F3 shall] be performed using saturated fatty food simulants as simulant D2.]
(5)	Compliance testing when there is a fat contact [F3 shall] be performed using isooctane as substitute of simulant D2 (unstable).
(6)	Migration limit might be exceeded at very high temperature.
(7)	If testing in food is performed, Annex V 1.4 shall be taken into account.
(8)	Verification of compliance by residual content per food contact surface area (QMA); QMA = 0,005 mg/6 dm <sup>2</sup> .
(9)	Verification of compliance by residual content per food contact surface area (QMA) pending the availability of analytical method for migration testing. The ratio surface to quantity of food shall be lower than 2dm²/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
[F36(18)	polymer is available  There is a risk that the SML could be exceeded from low-density polyethylene (LDPE)
(19)	There is a risk that the OML could be exceeded in direct contact with aqueous foods from ethylvinylalcohol (EVOH) and polyvinylalcohol (PVOH) copolymers]
[F38(20)	The substance contains aniline as an impurity; verification of compliance with the restriction set for primary aromatic amines in Annex II (2) is necessary]
[ <sup>F23</sup> (21)	In case of reaction with foods or simulants verification of compliance shall include verification that the migration limits of the hydrolysis products, formaldehyde and 1,4-butanediol, are not exceeded.]
[ <sup>F4</sup> (22)	When used in contact with non-alcoholic foods for which Table 2 of Annex III assigns food simulant D1, food simulant C shall be used for verification of compliance instead of food simulant D1.
(23)	When a final material or article containing this substance is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.]
[F39(24)	The substance or its hydrolysis products are authorised food additives and compliance with Article 11(3) shall be verified.]
[ <sup>F41</sup> (25)	When used as reheat agent in polyethylene terephthalate (PET) verification of compliance with the specific migration limit is not required; in all other cases compliance with the specific migration limit shall be verified in accordance with Article 18; the

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

	specific migration limit is expressed as mg tungsten/kg food.
(26)	Migration of stearamide, listed in Table 1 under FCM substance No 306 to which no specific migration limit applies, shall be excluded from verification of the compliance of the migration of the mixture with the specific migration limit laid down for the mixture.]
[F42(27)	When a final material or article containing this substance and produced under conditions other than those described in point (a) column 10 of Table 1 is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in point (b) column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.]
[F43(28)	A detection limit of 0,002 mg/kg food or food simulant applies
(29)	In polar polymers which swell in contact with foods for which simulant B is assigned in Annex III, there is a risk that under severe contact conditions the migration limits for aluminium and fluoride are exceeded. Under contact conditions above 4 hours at 100 °C this exceedance can be high.]

# 4. Detailed specification on substances U.K.

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

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and...

ANNEX I

Document Generated: 2023-12-17

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

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
[F33Restriction	Specific migration limit for crotonic acid is 0,05 mg/kg food]
Purity	Prior to granulation the raw material copolymer powder must contain:
— nitrogen,	Not more than 2 500 mg/kg of plastic
zinc,	Not more than 100 mg/kg of plastic
— copper,	Not more than 5 mg/kg of plastic
— lead,	Not more than 2 mg/kg of plastic
— arsenic,	Not more than 1 mg/kg of plastic
— chromium,	Not more than 1 mg/kg of plastic



### Restrictions on plastic materials and articles

The following restrictions on plastic materials and articles apply:

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

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

Table 1  General list of migration limits for substances migrating from plastic materials and articles			
Name	Salts allowed in accordance with Article 6(3)(a)	SML [mg/kg food or food simulant]	Remark
Aluminium	yes	1	
Ammonium	yes		(1)
Antimony	no	0,04	(2)
Arsenic	no	ND	
Barium	yes	1	
Cadmium	no	ND (LOD 0,002)	
Calcium	yes		(1)
Chromium	no	ND	(3)
Cobalt	yes	0,05	
Copper	yes	5	
Europium	yes	0,05	(4)
Gadolinium	yes	0,05	(4)
Iron	yes	48	
Lanthanum	yes	0,05	(4)
Lead	no	ND	
Lithium	yes	0,6	
Magnesium	yes		(1)
Manganese	yes	0,6	
Mercury	no	ND	

#### Table 1

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

Nickel	no	0,02	
Potassium	yes		(1)
Sodium	yes		(1)
Terbium	yes	0,05	(4)
Zinc	yes	5	

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

#### Remarks

(1) The migration is subject to Article 11(3) and Article 12

(2) The note in Annex I, Table 1, FCM No 398 applies: SML might be exceeded at very high temperature

(3)To verify compliance with the Regulation, the detection limit of 0,01 mg/kg shall apply for total chromium. However if the operator that placed the material on the market can prove on the basis of pre-existing documentary evidence that the presence of hexavalent chromium in the material is excluded because it is not used or formed or during the entire production process, a limit for the total chromium of 3,6 mg/kg food shall apply.

(4) The lanthanide substances europium, gadolinium, lanthanum, and/or terbium can be used in accordance with

- (a)
- The sum of all lanthanide substances migrating to the food or food simulant does not exceed the specific migration limit of 0,05 mg/kg; and analytical evidence using a well described methodology demonstrating (b) that the lanthanide substance(s) used are present in dissociated ionic form in the food or the food simulant, forms part of the documentation referred to in Article 16.
- 2. Primary aromatic amines ('PAAs') listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council and for which no migration limit is specified in Table 1 of Annex I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant. They shall not be detectable using analytical equipment with a limit of detection of 0,002 mg/kg food or food simulant applied to each individual primary aromatic amine ('PAA'), in accordance with Article 11(4).

For PAAs not listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006, but for which no specific migration limit is specified in Annex I, compliance with Article 3 of Regulation (EC) No 1935/2004 shall be verified in accordance with Article 19. The sum of those PAAs shall however not exceed 0,01 mg/ kg in food or food simulant.]

ANNEX III U.K.

#### Food simulants

Food simulants U.K. 1.

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.

### **I**F3 TABLE 1

#### List of food simulants

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E]

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

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.

# [F33. Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food U.K.

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

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

Table 2 contains the following information:

- Column 1 (Reference number): contains the reference number of the food category
- Column 2 (Description of food): contains a description of the foods covered by the food category
- Column 3 (Food simulants): contains sub-columns for each of the food simulants

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

For food categories where in sub-column D2 or E the cross is followed by an oblique stroke and a figure, the migration test result shall be corrected by dividing the result by this figure. The corrected test result shall then be compared to the migration limit to establish compliance. The

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test results for substances that shall not migrate in detectable quantities shall not be corrected in this way.

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

For food categories where in sub-column B the cross is followed by (\*) the testing in food simulant B can be omitted if the food has a pH of more than 4,5.

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

TABLE 2 food category specific assignment of food simulants

(1)	(2)	(3)					
Reference	e Description						
number	of food	A	В	С	D1	D2	E
1	Beverages						
1.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to						
			X(*)	X			

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	tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract						
	B. cl juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate	oudy rinks:	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	Miscellane undenatura ethyl alcohol		X(*)			Substitute 95 % ethanol	
02	Cereals, cereal						

	products, pastry, biscuits, cakes and other bakers' wares				
02.01	Starches				X
02.02	Cereals, unprocesse 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:				
	fa St Oi th	Vith atty abstances n ne arface		X/3	
	B. O	ther			X
02.06	Pastry, cakes,				

	bread, dough and other bakers' wares, fresh:				
	fa si o th	Vith atty ubstances n ne urface		X/3	
	B. C	ther			X
03	Chocolate sugar and products thereof Confection products				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes			X/3	
03.02	Confection products:	ery			
	A. In	n olid orm:			
	fa sv o th	Vith atty ubstances n ne urface		X/3	
	II. C	ther			X

		In paste form:				
		With fatty substances on the surface			X/2	
	II.	Moist		X		
03.03	Sugar and sugar products					
		In solid form: crystal or powder				X
		X Molasses, sugar syrups, honey and the like				
04	Fruit, vegetable and products thereof					
[F304.01	Fruit, fresh or chilled:					
		unpeeled and uncut				X/10
		X peeled and/ or cut	X (*)			1

04.02	Processed fruit:						
	o d fi w s f	ehydrated ruits, vhole, liced, lour					X
	in the first section of the fi	he orm of furée, oreserves, astes or n ts own uice	X(*)	X			
	p ii a li	Fruit reserved n iquid nedium:					
	a	n n ily nedium				X	
	II. In a	n n			X		

		lcoholic nedium				
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):					
	f	Shelled, Iried, laked or owdered				X
	a r	Shelled and oasted				X
	r c	X n paste or pream form			X	
[ <sup>F3</sup> 04.04	Vegetables fresh or chilled:	5,				
	a	inpeeled ind incut				X/10
	a	X peeled and/ or cut	X (*)			1
[F304.05	V V S					X

		the form of flour or powder.					
	B.	(obsolete)					
		Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine).	X (*)	X			
	D.	Preserved vegetables:					
		X In an oily medium				X	
	II.	In an alcoholic medium			X		1
05	Fats and oils						
05.01	Animals and vegetable fats and oils, whether natural or treated (including	1				X	

	cocoa butter, lard, resolidified butter)					
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:					
	c p s o s iii	X resh, hilled, rocessed, alted r moked neluding ish ggs			X/3(**)	
		reserved ish:				
	o	X n ily nedium			X	
	a	n n queous nedium	X(*)	X		
06.02	Crustacear and molluscs (including oysters, mussels, snails)					

		Fresh within the shell				
		Shell removed, processed, preserved or cooked with the shell				
		X In an oily medium			X	
		In an aqueous medium	X(*)	X		
06.03	Meat of all zoologica species (including poultry and game):					
		X Fresh, chilled, salted, smoked			X/4(**)	
		X Processed meat products (such as ham, salami, bacon, sausages, and other) or			X/4(**)	

	1	:.1	1	ı	1	I	I
		in the					
		form					
		of					
		paste,					
		creams					
	C.	X. Marinated				X	
		meat products					
		in					
		an oily					
		medium					
06.04	Dunggamya						
06.04	Preserved meat:	u					
	A.	X In				X/3	
	11.	an					
		fatty					
		or					
		oily medium					
		incurum	TT (de)				
	B.	In	X(*)		X		
		an					
		aqueous					
		medium					
06.05	Whole						
	eggs, egg	g					
	eggs, egg yolk, egg white	5					
	wnite						
	A.	Powdered					X
	11.	or					
		dried					
		or					
		frozen					
	B.	Liquid			X		
	D.	and					
		cooked					
07	Milk						
	products	8					
07.01	Milk						
		N C:11-			X		
	A.	Milk and					
		milk					
	1		1	I	I	1	I

	d v p d a s o	ased rinks whole, artly ried nd kimmed artly kimmed				
	p ii ff ( o v	Ailk bowder ncluding nfant ormula based on whole nilk owder)				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:					
	n e	Whole, vith ot dible ind				X
	c v r o v e r (,	Vatural heese vithout ind r vith dible ind gouda, amembert, nd			X/3(**)	

		the like) and melting cheese				
	C.	Processed cheese (soft cheese, cottage cheese and similar)	X(*)	X		
	D.	Preserved cheese:				
	I.	In an oily medium			X	
	II.	In an aqueous medium (feta, mozarella, and similar)	X(*)	X		
08	Miscella product					
08.01	Vinegar		X			
08.02	Fried or roasted foods:					
	A.	X Fried potatoes, fritters and the like			X/5	
	B.	Of animal origin			X/4	

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00.02	ъ	.· I					
08.03	Prepara	tions					
	for soup	os,					
	broths,						
	sauces,						
	in liquio	d,					
	solid or						
	powder						
	form						
	(extract	s,					
	concent						
	homoge	enised					
	compos	site					
	food						
	prepara	tions					
	prepare	d ,					
	dishes	u					
	includir	າσ					
	yeast ar	nd					
	raising	iu					
	agents						
	agents						
	A.	Powdered					
		or					
		dried:					
	-	*****				X/5	
	I.	With					
		fatty					
		character					
	II.	Other					X
	11.	Other					
	B.	any					
	В.	other					
		form					
		than					
		novydorod					
		powdered					
		or dried:					
	T	X With	X(*)			X/3	
	I.						
		fatty					
		character					
_			X(*)	X			
	II.	Other	1-( )				
08.04	Sauces:						
		XX7*.1	X(*)	X			
	A.	With					
		aqueous					
		character					
					,	'	

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

	fa si o th	Vith atty ubstances n ne urface			X/5	
	B. C	ther				X
08.09	Frozen or deep- frozen foods					X
08.10	Concentrate extracts of an alcoholic strength equal to or exceeding 6 % vol.	ed	X(*)	X		
08.11	Cocoa:					
	p ir fa re ar h fa	ocoa owder, icluding it- educed id ighly it				X
	B. C	ocoa aste			X/3	
08.12	Coffee, whether or not roasted, decaffeinat or soluble, coffee substitutes, granulated or powdered					X
08.13	Aromatic herbs					X

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	and other herbs such as camomile, mallow, mint, tea, lime blossom 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	

#### [F444. Food simulant assignment for testing overall migration U.K.

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

### TABLE 3

Foods covered	g compliance with the overall migration limit Food simulants in which testing shall be performed
all types of food	distilled water or water of equivalent quality or food simulant A;

	<ul><li>food simulant B; and</li><li>food simulant D2.</li></ul>
all types of food except for acidic foods	distilled water or water of equivalent quality or food simulant A; and
	2. food simulant D2.
$\[ \]^{F33}$ all aqueous and alcoholic foods and milk products with a pH $\geq 4.5$	food simulant D1
all aqueous and alcoholic foods and milk products with a pH < 4,5	food simulant D1 and food simulant B]
all aqueous foods and alcoholic foods up to an alcohol content of 20 %	food simulant C
all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 %	1. food simulant C; and
	2. food simulant B.]

#### **Textual Amendments**

**F44** Substituted by Commission Regulation (EU) 2017/752 of 28 April 2017 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

# [F45. General derogation to the assignment of food simulants U.K.

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

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

# ANNEX IV U.K.

#### 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) [F3 confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004;]
- [F13] adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

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

- that are subject to restrictions in Annex II, or
- for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant;]
- (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 F45... 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) [F44the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Article 17 and 18 or equivalent information;]
- (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.

#### **Textual Amendments**

F45 Words in Annex 4 para. 7 omitted (31.12.2020) by virtue of The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), regs. 1, 77; 2020 c. 1, Sch. 5 para. 1(1)

# ANNEX V U.K.

#### **COMPLIANCE TESTING**

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

# CHAPTER 1 U.K.

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

# 1.1. Sample preparation U.K.

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 U.K.

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 U.K.

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.

# [F31.4. Account of substances originating from other sources U.K.

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

# CHAPTER 2 U.K.

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

# 2.1. Verification method U.K.

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 U.K.

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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 U.K.

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 U.K.

[F3 The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2.

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

- (i) If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place;
- (ii) if the material or article during it intended use is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment;
- (iii) if the material or article is intended to be employed only for hot-fill conditions, only a 2-hour test at 70 °C shall be carried out. However, if the material or article is intended to be used also for storage at room temperature or below, the test conditions set out in Tables 1 and 2 of this Section or in Section 2.1.4 of this Chapter apply depending on the duration of storage.
- (iv) [F43if the plastic material or article intended to come into contact with food of which the compliance must be verified becomes in its final application part of a food processing equipment or an appliance, or a part thereof, the migration tests may be carried out by determining the specific migration into the food or food simulant produced or processed by the whole equipment or appliance, or the part thereof, as appropriate, subject to the following conditions:
  - the food or food simulant is processed during testing by the equipment or part thereof in accordance with the worst foreseeable conditions that can be achieved if the equipment or its part is operated in accordance with its operating instructions, and
  - the migration from parts used for storage such as from reservoirs, containers, or capsules or pads which are part of the equipment during the processing of

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the food, is determined using conditions representative for their use, unless the applied testing conditions for the whole tested equipment or appliance are representative also of their use.

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

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

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

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

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

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

TABLE 1

#### [F3Selection of test time]

Contact time in worst foreseeable use	[F3Time to be selected for testing]
$t \le 5 \text{ min}$	5 min
$5 \min < t \le 0.5 \text{ hour}$	0,5 hour
$0.5 \text{ hours} < t \le 1 \text{ hour}$	1 hour
1 hour $\leq t \leq 2$ hours	2 hours
2 hours $< t \le 6$ hours	6 hours
6 hours < t ≤ 24 hours	24 hours

$1 \text{ day} < t \le 3 \text{ days}$	3 days
$3 \text{ days} < t \le 30 \text{ days}$	10 days
Above 30 days	See specific conditions

### J<sup>F3</sup>TABLE 2

### Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C
20 °C < T ≤ 40 °C	40 °C
40 °C < T ≤ 70 °C	70 °C
70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C <sup>a</sup>
121 °C < T ≤ 130 °C	130 °C <sup>a</sup>
130 °C < T ≤ 150 °C	150 °Cª
150 °C < T < 175 °C	175 °C <sup>a</sup>
175 °C < T ≤ 200 °C	200 °Cª
T > 200 °C	225 °Ca

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.]

# [F32.1.4. Specific conditions for contact times above 30 days at room temperature and below U.K.

For contact times above 30 days (long term) at room temperature and below, the specimen shall be tested in accelerated test conditions at elevated temperature for a maximum of 10 days at  $60 \, {}^{\circ}\text{C}^{(20)}$ .

- (a) Testing for 10 days at 20 °C shall cover all storage times at frozen condition. This test can include the freezing and defrosting processes if labelling or other instructions ensure that 20 °C is not exceeded and the total time above 15 °C does not exceed 1 day in total during the foreseeable intended use of the material or article.
- (b) Testing for 10 days at 40 °C shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to 70 °C  $\leq$  T  $\leq$  100 °C for maximum t =  $120/2^{\circ}((T-70)/10)$  minutes.
- (c) Testing for 10 days at 50 °C shall cover all storage times of up to 6 months at room temperature, including hot-fill conditions and/or heating up to 70 °C  $\leq$  T  $\leq$  100 °C for maximum t = 120/2^((T-70)/10) minutes.

- (d) Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to 70 °C  $\leq$  T  $\leq$  100 °C for maximum t = 120/2^((T-70)/10) minutes.
- (e) For storage at room temperature the testing conditions can be reduced to 10 days at 40 °C if it is shown by scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.
- (f) For worst foreseeable conditions of intended use not covered by the test conditions set out in points (a) to (e), the testing time and temperature conditions shall be based on the following formula:

t2 = t1 \* Exp (9627 \* (1/T2 - 1/T1))

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 298K (25 °C). For refrigerated conditions it is set at 278K (5 °C). For frozen storage it is set at 258 K (– 15 °C).

T2 is the testing temperature in Kelvin.]

2.1.5. Specific conditions for combinations of contact times and temperature U.K.

[F3] If a material or article is intended for different applications covering different combinations of contact time and temperature the testing shall be restricted to the test conditions which are recognised to be the most severe on the basis of scientific evidence.]

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.

[F132.1.6. Repeated use materials and articles] U.K.

If the material or article is intended to come into repeated contact with foods, the migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. The specific migration in the second test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test.

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

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

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

2.1.7. Analysis of migrating substances U.K.

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

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) U.K.

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

2.2. Screening approaches U.K.

[F3To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered at least as severe as the verification method described in section 2.1.]

2.2.1. Replacing specific migration by overall migration U.K.

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 U.K.

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.

[F32.2.3. Migration modelling U.K.

To screen for specific migration, the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed in a way that must never underestimate real levels of migration.]

[F32.2.4. Food simulant substitutes U.K.

To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Section 2.1.2.]

[F42.2.5. Single test for successive combinations of time and temperature U.K.

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

# CHAPTER 3 U.K.

#### 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 U.K.

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.

### **I**<sup>F13</sup>TABLE 3

Standardised conditions for testing the overall migration

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C] for testing	Intended food contact conditions
OM0	30 min at 40 °C	Any food contact at cold or ambient temperatures and for a short duration ( $\leq$ 30 minutes).
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions
OM2	10 d at 40 °C	Any long-term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C $\leq$ T $\leq$ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes.
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C $\leq$ T $\leq$ 100 °C for maximum of t = 120/2^((T-70)/10) minutes, which are not followed by

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		long-term room temperature or refrigerated storage.
OM4	1 h at 100 °C or at reflux	High temperature applications for all types of food at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.

Test OM 7 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in paragraph 3.2.

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

Test OM 5 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM 2 covers also food contact conditions described for OM0, OM1 and OM3.]

# [F33.2. Substitute overall migration tests for tests with food simulant D2 U.K.

[F13] If it is not technically feasible to perform one or more of the tests OM0 to OM6 in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a test shall be done using food simulant E in case the worst foreseeable conditions of use exceed 100 °C. The test that results in the highest overall migration shall be used to establish compliance with the Regulation.

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

Test number Test conditions	Intended food contact conditions	Covers the intended food contact conditions described in
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OM8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C	High temperature applications only	OM1, OM3, OM4, OM5 and OM6
OM9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C	High temperature applications including long term storage at room temperature	OM1, OM2, OM3, OM4, OM5 and OM6]

# [F33.3. Verification of compliance U.K.

### 3.3.1. *Single use articles and materials* U.K.

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

# [F133.3.2. Repeated use articles and materials U.K.

The applicable overall migration test shall be carried out three times on a single sample using another portion of food simulant on each occasion. The migration shall be determined using an analytical method in accordance with the requirements of Article 34 of Regulation (EU) 2017/625 of the European Parliament and of the Council<sup>(21)</sup>. The overall migration in the second test shall be lower than in the first test, and the overall migration in the third test shall be lower than in the second test. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found in the third test.

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

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

# 3.4. Screening approaches U.K.

[F3 To screen if a material or article complies with the migration limits, any of the following approaches can be applied which are considered at least as severe as the verification method described in Sections 3.1 and 3.2.]

# 3.4.1. Residual content U.K.

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.

# [F33,4,2] Food simulant substitutes U.K.

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

To screen for overall migration, food simulants can be replaced if based on scientific evidence the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Annex III.]

### CHAPTER 4 U.K.

#### 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) U.K.

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

The FRF shall be applied according to the following rules.

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

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

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

[F3The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.]

[F4When testing is performed in food simulant D2 or E and when the test results are corrected in application of the correction factor laid down in Table 2 of Annex III this correction may be applied in combination with the FRF by multiplying both factors. The combined correction factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.]

F154.2.	Correction of migration into food simulant D2	U.K.
<sup>F15</sup> 4.3.	Combination of correction factors 4.1 and 4.2.	U.K.
	ANNEX VI U.K.	

Directive 2002/72/EC This Regulation

Correlation tables

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

- (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.
- (19) [F13Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1)...]
- (20) [F3When testing at these accelerated test conditions the test specimen shall not undergo any physical or other changes compared to the real conditions of use, including a phase transition of the material.]
- (21) [Fi3[Fi3]Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).]]

#### **Textual Amendments**

F3 Substituted by Commission Regulation (EU) 2016/1416 of 24 August 2016 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

**F13** Substituted by Commission Regulation (EU) 2020/1245 of 2 September 2020 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Text with EEA relevance).

# **Changes to legislation:**

There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011.