[^0]STATUTORY RULES OF NORTHERN IRELAND

## 2006 No. 251

FOOD

# The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2006 

Made - - -<br>Coming into operation<br>5th June 2006<br>30th June 2006

The Department of Health, Social Services and Public Safety(1) makes the following Regulations in exercise of the powers conferred on it by Articles 15(2), 16(1) and (2), 25(1)(a) and (3), 32 and 47(2) of the Food Safety (Northern Ireland) Order 1991(2).
In accordance with Article 47(3A) of the said Order it has taken into account relevant advice given by the Food Standards Agency.
As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council 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(3), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

## PART 1

Preliminary

## Citation and commencement

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2006 and come into operation on 30th June 2006.

## Commencement Information

I1 Reg. 1 in operation at 30.6.2006, see reg. 1

[^1]
## Interpretation

2.-(1) In these Regulations -
"authorised officer" means any person, whether or not an officer of the district council, who is authorised by it in writing to act in matters arising under these Regulations;
"BADGE" has the meaning given in Article 1(1)(a) of Regulation 1895/2005;
"BFDGE" has the meaning given in Article 1(1)(b) of Regulation 1895/2005;
"business" is to be construed in accordance with Article 2(2) of the Order;
"capable" means capable as established under regulation 11;
"Directive $82 / 711 "$ means Council Directive 82/711/EEC(4) laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs, as last amended by Commission Directive 97/48/EC(5);
"Directive 85/572" means Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs $(\mathbf{6})$;
"Directive $88 / 388$ " means Council Directive $88 / 388 /$ EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production(7);
"Directive 89/107" means Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised in foodstuffs intended for human consumption(8);
"the Directive" means Commission Directive 2002/72/EC(9) relating to plastic materials and articles intended to come into contact with foodstuffs, as last amended by Commission Directive 2004/19/EC(10);
"EEA State" means a Member State (other than the United Kingdom), Norway, Iceland and Liechtenstein;
"EFSA" means the European Food Safety Authority;
"food" is to be construed in accordance with Article 15(5) of the Order;
"good technical quality" means good technical quality as regards the purity criteria;
"handling of food" means use in connection with the storage, preparation, packaging, sale or serving of food;
"import" means import in the course of a business;
"material or article" means a material or article falling within the definition of materials and articles in Article 1(2) of Regulation 1895/2005;
"monomer" means any substance which is included for the purposes of the Directive among monomers and other starting substances;
"NOGE" has the meaning given in Article 1(1)(c) of Regulation 1895/2005;
"the Order" means the Food Safety (Northern Ireland) Order1991;

[^2]"the 1998 Regulations" means the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998(11);
"the 2005 Regulations" means the Materials and Articles in Contact with Food Regulations (Northern Ireland) 2005(12);
"plastic material or article" means anything which for the purposes of the Directive is included among those plastic materials and articles and parts thereof to which the Directive applies;
"the Purity Directives" means Commission Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs(13), Commission Directive 95/45/EC laying down purity criteria concerning colours for use in foodstuffs(14) and Commission Directive 96/77/EC laying down specific purity criteria for food additives other than colours or sweeteners(15);
"Regulation 1895/2005" means Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food(16);
(2) For the purposes of these Regulations the supply otherwise than on sale, in the course of a business, of any material or article is deemed to be a sale.
(3) Any other expression used in these Regulations and in the Directive, Directive 82/711, Directive 85/572 or Regulation 1895/2005 bears the same meaning in these Regulations as it bears in that Directive or Regulation.

## Commencement Information

I2 Reg. 2 in operation at 30.6.2006, see reg. 1

## PART 2

## Requirements for Materials and Articles

## Restriction on the use, sale or import of plastic materials and articles

3.-(1) No person may -
(a) use for the handling of food in the course of a business;
(b) sell for the purpose of handling of food; or
(c) import from anywhere other than an EEA State for the purpose of handling of food, a plastic material or article which fails to meet the required standard.
(2) For the purposes of this regulation a plastic material or article fails to meet the required standard if -
(a) it has been manufactured with a prohibited monomer as described in regulation 4(2) or a prohibited additive as described in regulation 5(2); or
(b) it does not meet the required standards set out in regulation $6,7,8,9$ or 10 .

[^3]
## Commencement Information

I3 Reg. 3 in operation at 30.6.2006, see reg. 1

## Restriction on the use of monomers in the manufacture of plastic materials and articles

4.-(1) Subject to paragraphs (3), (4) and (5), no person may use any prohibited monomer in the manufacture of any plastic material or article.
(2) A prohibited monomer is any monomer which is not -
(a) of good technical quality;
(b) identified by PM/REF no, CAS no (if any) and name in columns 1, 2 and 3 respectively of the relevant section of Part 1 of Schedule 1; and
(c) used in accordance with any restrictions and specifications for that monomer set out or referred to in column 4 of that Schedule.
(3) Paragraph (1) does not apply to the use of a monomer in the manufacture of any -
(a) surface coatings obtained from resinous of polymerised products in liquid, powder or dispersion form, including but not limited to varnishes, lacquers and paints;
(b) epoxy resins;
(c) adhesives and adhesion promoters; or
(d) printing inks.
(4) Paragraph (1) shall not be taken to prohibit the manufacture of any plastic material or article with any substance if the substance in question is a mixture which falls within paragraph 3(c) (relating to mixtures of authorised substances) of Annex II to the Directive and is of good technical quality.
(5) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with paragraph (1) because it was manufactured with any monomer (whether or not of good technical quality) other than one mentioned in paragraph (2)(b) it shall a be defence for the person accused to prove that -
(a) each monomer is present in the finished plastic material as an impurity, a reaction intermediate or a decomposition product which falls within paragraph 3(a) of Annex II to the Directive,
(b) each such monomer is an oligomer or a natural or synthetic macromolecular substance or a mixture thereof which falls within paragraph 3(b) of that Annex, or
(c) each monomer falls within either sub-paragraph (a) or (b)of these Regulations, and is of good technical quality.
(6) Part 2 of Schedule 1 has effect to supplement this regulation and Part 1 of that Schedule.

## Commencement Information

I4 Reg. 4 in operation at 30.6.2006, see reg. 1

## Restriction on the use of additives in the manufacture of plastic materials and articles

5.-(1) Subject to paragraph (3) no person may use in the manufacture of any plastic material or article any prohibited additive.
(2) A prohibited additive is -
(a) any additive identified by PM/REF No, CAS No (if any) and name in columns 1, 2 and 3 respectively of Part 1 or Part 2 of Schedule 2 which -
(i) is not of good technical quality, or
(ii) is not used in accordance with any restrictions and specifications for that additive set out in the corresponding entry in column 4 of Part 1 or Part 2 of that Schedule; or
(b) any food additive authorised by Directive $89 / 107$ or any flavouring authorised by Directive 88/388 that migrates into food -
(i) in a quantity that has a technical function in the final food product, or
(ii) where the food is of a type for which the use of any such food additive or flavouring is so authorised, in quantities exceeding the limits provided for in Directive 89/107 or Directive $88 / 388$ as appropriate, or in Schedule 2, whichever is the lower.
(3) In any proceedings for an offence under these Regulations where it is alleged that the commission of the offence is due to the manufacture of a plastic material or article with any additive identified in Part 1 or Part 2 of Schedule 2 which is not of good technical quality, it shall be a defence for the person accused to prove that each such additive is present in the finished plastic material or article as an impurity, a reaction intermediate or a decomposition product.
(4) Part 3 of Schedule 2 has effect to supplement this regulation and Parts 1 and 2 of that Schedule.

## Commencement Information

I5 Reg. 5 in operation at 30.6.2006, see reg. 1

## Required standard for non-migration of constituents of monomers

6.-(1) Subject to paragraph (2), where a migration limit expressed in $\mathrm{mg} / \mathrm{kg}$ is indicated in column 4 of the relevant section of Part 1 of Schedule 1 in relation to any monomer, a plastic material or article manufactured from that monomer meets the required standard under this regulation if it is not capable of transferring constituents of that monomer to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is -
(a) the number of milligrams expressed in column 4 released per kilogram of food in the case of any plastic material or article other than one specified in sub-paragraph (b); and
(b) one sixth of the number of milligrams expressed in column 4 per square decimetre of surface area of the plastic material or article if the plastic material or article comprises -
(i) an article which is a container or is comparable to a container or can be filled, having a capacity of less than 500 millilitres or more than 10 litres, or
(ii) sheet, film or other plastic material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the material or article in question and the quantity of food in contact with that surface area.
(2) A plastic material or article manufactured from any monomer for which a migration limit in $\mathrm{mg} / \mathrm{kg}$ is expressed in column 4 of the relevant section of Part 1 of Schedule 1 is not deemed to be capable of transferring constituents of that monomer to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (1) if the only food with which that plastic material or article may come into contact is food to which regulation 9(3) applies.

## Commencement Information

I6 Reg. 6 in operation at 30.6.2006, see reg. 1

## Required standard for non-migration of constituents of additives

7.-(1) Subject to paragraph (2), where a migration limit expressed in $\mathrm{mg} / \mathrm{kg}$ is indicated in column 4 of Part 1 or 2 of Schedule 2 in relation to any additive, a plastic material or article manufactured containing that additive meets the required standard under this regulation if it is not capable of transferring constituents of that additive to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is -
(a) the number of milligrams indicated in column 4 released per kilogram of food in the case of any plastic material or article other than one specified in sub-paragraph (b); and
(b) one sixth of the number of milligrams expressed in column 4 per square decimetre of surface area of the plastic material or article if the plastic material or article comprises -
(i) an article which is a container or is comparable to a container or can be filled, having a capacity of less than 500 millilitres or more than 10 litres, or
(ii) sheet, film or other plastic material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the material or article in question and the quantity of food in contact with that surface area.
(2) A plastic material or article manufactured containing an additive for which a migration limit in $\mathrm{mg} / \mathrm{kg}$ is expressed in column 4 of Part 1 or Part 2 of Schedule 2 is not deemed to be capable of transferring constituents of that additive to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (1) if the only food with which that plastic material or article may come into contact is food to which regulation $9(3)$ applies.

## Commencement Information

I7 Reg. 7 in operation at 30.6.2006, see reg. 1

## Required standard for products obtained by bacterial fermentation

8. A product obtained by bacterial fermentation meets the required standard under this regulation if it is -
(a) of good technical quality;
(b) identified by PM/REF No, CAS No and name in columns 1, 2 and 3 respectively of Schedule 3: and
(c) in compliance with the restrictions and specifications set out in column 4 of that Schedule.

## Commencement Information

I8 Reg. 8 in operation at 30.6 .2006 , see reg. 1

## Required standards relating to overall migration limits

9.-(1) Subject to paragraph (3), a plastic material or article meets the required standard under this regulation if it is not capable of transferring its constituents to food with which it may come into contact in quantities exceeding the appropriate limit specified in paragraph (2).
(a) (2) (a) In the case of any plastic material or article comprising -
(i) an article which is a container or comparable to a container or can be filled, with a capacity of not less than 500 millilitres and not more than 10 litres;
(ii) an article which can be filled and for which it is impracticable to estimate the surface area in contact with food; or
(iii) a cap, gasket, stopper or similar device for sealing
the appropriate limit is an overall migration limit of 60 milligrams of constituents released per kilogram of food.
(b) In the case of any other plastic material or article, the appropriate limit is an overall migration limit of 10 milligrams per square decimetre of the surface area of the plastic material or article.
(3) For the purposes of this regulation a plastic material or article is not deemed to fail to meet the required standard under paragraph (1) if the only food with which that material or article may come into contact is food -
(a) which is specified in the table to Part 4 of Schedule 6; and
(b) where there is no " X " placed anywhere in the group of columns headed "Simulants to be used" opposite that food.
(4) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with this regulation, the defences available in paragraph 6(2) and $7(2)$ of Schedule 5 shall be available as specified in those paragraphs.

## Commencement Information

I9 Reg. 9 in operation at 30.6.2006, see reg. 1

## Required standard for non-migration of primary aromatic amines

10.-(1) Subject to paragraph (3), a plastic material or article manufactured using isocyanates or colourants prepared by diazo-coupling meets the required standard under this regulation if it is not capable of transferring in a detectable quantity primary aromatic amines (expressed as aniline), not being primary aromatic amines listed in these Regulations, to food with which that plastic material or article may come into contact.
(2) Schedule 4 has effect for the purpose of prescribing, for certain items listed in Part 1 of Schedule 1, Part 1 or 2 of Schedule 2, or Schedule 3, the specifications for those items that are referred to in column 4 of the Part or Schedule concerned.
(3) In paragraph (1) a detectable quantity means a quantity which can be determined with an analytical method capable of achieving a detection limit of at least 0.02 milligrams per kilogram of food or food simulant (including analytical tolerance).

## Commencement Information

I10 Reg. 10 in operation at 30.6 .2006 , see reg. 1

## Method of testing the capability of plastic materials or articles to transfer constituents, and methods of analysis

11.-(1) A plastic material or article shall be treated as capable of transferring constituents to food with which it may come into contact to the extent that such capability is established -
(a) in any case other than one to which sub-paragraph (b) applies, and subject to Article 8.4 of the Directive (which may be applied on compliance with the conditions stated therein), by the verification methods specified in Schedule 5 (including the analytical tolerances referred to in paragraph 8 of that Schedule) and Schedule 6;
(b) in any case where the extent to which vinyl chloride, as identified in Part 1 of Schedule 1, is capable of such transfer falls to be established, by the method referred to in regulation 7(2) of the 2005 Regulations.
(2) In Schedules 5 and 6, references to migration or release of a substance are to be construed as references to the transfer of constituents to the simulant representing the food or, as the case may be, food with which it may come into contact.
(3) The specific migration of a constituent from a plastic material or article shall where applicable be determined in the manner specified in the relevant sub-paragraph of paragraph 8 of Annex II to the Directive.
(4) The quantity of a constituent in a plastic material or article shall where applicable be determined in the manner specified in the sub-paragraph of paragraph 8 of Annex II to the Directive relating to the term " $\mathrm{QM}(\mathrm{T})$ ", " QMA " or " $\mathrm{QMA}(\mathrm{T})$ ", as the case may be.

## Commencement Information

I11 Reg. 11 in operation at 30.6 .2006, see reg. 1

## Labelling

12.-(1) At marketing stages other than the retail stage a person who is in possession of any plastic material or article must ensure that the plastic material or article is accompanied by a written declaration which -
(a) attests that it complies with the legislation applicable to it; and
(b) provides, in respect of substances that are subject to a restriction on quantities migrating into food, information obtained from experimental data or theoretical calculation concerning -
(i) the levels of migration specific to those substances;
(ii) where appropriate, purity criteria in accordance with the purity Directives.
(2) In establishing which descriptions of food a material or article may come into contact with, it is to be assumed until the contrary is proved that, for the purposes of these Regulations, if particulars are shown in relation to that material or article in accordance with Regulation (EC) No. 1935/2004 of the European Parliament and of the Council(17), those particulars are accurate and that unless the particulars so indicate, there are no restrictions on the intended conditions of contact.

## Commencement Information

I12 Reg. 12 in operation at 30.6 .2006 , see reg. 1

[^4]
## Provisions relating to the use of certain epoxy derivatives (BADGE, BFDGE and NOGE)

13.-(1) In this regulation -
(a) any reference to a numbered Article is a reference to that Article in Regulation1895/2005;
(b) paragraphs (2) to (5) are subject to Article 1(3) (exception relating to certain storage containers and pipelines);
(c) for the purpose of Article 6(4) the competent authority is the authority identified in regulation 14.
(2) Subject to Article 6(1), (2) (transitional provisions) and (4) (labelling requirements), no person may -
(a) manufacture,
(b) use for the handling of food in the course of a business,
(c) sell for the purpose of the handling of food, or
(d) import for the purpose of the handling of food
any material or article in contravention of Article 3 or Article 4 (prohibitions relating to BFDGE and NOGE respectively).
(3) No person may manufacture any material or article in such a way as to contravene the requirements of Article 2 (controls on the migration of BADGE from materials and articles).
(4) Subject to Article 6(1), no person may -
(a) use for the handling of food in the course of a business,
(b) sell for the purpose of the handling of food, or
(c) import for the purpose of the handling of food
any material or article that has been manufactured in such a way as to contravene the requirements of Article 2.
(5) Subject to Article 6(3) (transitional provisions relating to materials and articles brought into contact with food before 1st January 2007), no person shall contravene the requirements of Article 5 (obligations regarding the provision of a written statement when marketing materials or articles containing BADGE or its derivatives).
(6) No person shall without reasonable excuse fail to comply with a request made under Article $6(4)$ (requirement to disclose date of filling to competent authority).

## Commencement Information

I13 Reg. 13 in operation at 30.6.2006, see reg. 1

## PART 3

Execution and Enforcement

## Enforcement

14. Each district council in its district shall execute and enforce -
(a) the provisions of Regulation 1895/2005 mentioned in regulation 13, and
(b) these Regulations.

## Commencement Information

I14 Reg. 14 in operation at 30.6 .2006 , see reg. 1

## Offences and Penalties

15.-(1) Any person who -
(a) contravenes regulation $3(1), 4(1), 5(1), 12(1)$ or $13(2)$ to (5);
(b) intentionally obstructs any person acting in the execution of Regulation 1895/2005 or these Regulations;
(c) contravenes regulation 13(6) or, without reasonable excuse, fails to give to any person acting in the execution of Regulation 1895/2005 or these Regulations any assistance or information which that person may reasonably require; or
(d) in purported compliance with any requirement mentioned in sub-paragraph (c), knowingly or recklessly supplies information that is false or misleading in any material particular, is guilty of an offence.
(2) Anyone convicted of an offence under these Regulations is liable -
(a) in the case of an offence under paragraph (1)(a) -
(i) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to a fine or both;
(ii) on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding six months or to both;
(b) in the case of any other offence under these Regulations to a term of imprisonment not exceeding six months or to a fine not exceeding level five on the standard scale or both.
(3) Nothing in paragraph (1)(c) is to be construed as requiring any person to answer any question or give any information if to do so might incriminate him.
(4) No prosecution for an offence under these Regulations shall be begun after the expiry of three years from the commission of the offence or one year from its discovery by the prosecutor, whichever is the earlier.
(5) Where the commission by any person of an offence under these Regulations is due to the act or default of some other person, that other person shall also be guilty of the offence; and a person may be charged with and convicted of the offence whether or not proceedings are taken against the first mentioned person.

## Commencement Information

I15 Reg. 15 in operation at 30.6 .2006 , see reg. 1

## General defences

16.-(1) In any proceedings for an offence under these Regulations it shall, subject to paragraph (5), be a defence for the person accused to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control.
(2) Without prejudice to the generality of paragraph (1), a person accused of an offence under these Regulations who did not -
(a) prepare the plastic material or article or, as the case may be, the material or article in respect of which the offence is alleged to have been committed; nor
(b) import it into the United Kingdom,
shall be taken to have established the defence provided by paragraph (1) if he satisfies the requirements of paragraphs (3) and (4).
(3) A person satisfies the requirements of this paragraph if he proves -
(a) that the commission of the offence was due to the act or default of some other person who was not under his control, or to reliance on information supplied by such a person;
(b) that either -
(i) he carried out all such checks of the plastic material or article or material or article in question as were reasonable in all the circumstances, or
(ii) it was reasonable in all the circumstances for him to rely on checks carried out by the person who supplied him with the plastic material or article or the material or article in question; and
(c) that he did not know and had no reason to suspect at the time the offence was committed that his act or omission would amount to an offence under these Regulations.
(4) A person satisfies the requirements of this paragraph if the offence is one of sale and he proves -
(a) that the commission of the offence was due to the act or default of some other person who was not under his control, or to reasonable reliance on information supplied by such a person;
(b) that the sale of which the alleged offence consisted was not a sale under his name or mark; and
(c) that he did not know and could not reasonably have been expected to know at the time the offence was committed that his act or omission would amount to an offence under these Regulations.
(5) If in any case the defence provided by this regulation involves the allegation that the commission of the offence was due to the act or default of another person, or to reliance on information supplied by another person, the person accused shall not without leave of the court be entitled to rely on that defence unless -
(a) at least seven clear days before and including the date of the hearing; and
(b) where he has previously appeared before the court in connection with the alleged offence, within one month of his first such appearance,
he has served on the prosecutor a written notice giving such information identifying or assisting in the identification of that other person as was then in his possession.

## Commencement Information

I16 Reg. 16 in operation at 30.6 .2006 , see reg. 1

## Transitional defences and savings

17. Not withstanding the revocations made in regulation 23 , in relation to any plastic material or article -
(a) manufactured before the 1st July 1998, the defence in regulation 3(3) of the 1998 Regulations;
(b) manufactured or imported into the European Community before 1st January 2003, the defence in regulation 10(13) of the 1998 Regulations;
(c) put into free circulation in the European Community before 30th November 2002, the defence in regulation 10(14) of the 1998 Regulations;
(d) manufactured or imported into the European Community before 1st March 2004, the defence in regulation 10(19)(a) of the 1998 Regulations as in operation on the 28th February 2003;
(e) manufactured or imported into the European Community before 1st March 2003, the defence in regulation $10(19)$ (b) of the 1998 Regulations as in operation on the 28 th February 2003;
(f) containing azodicarbonamide and brought into contact with food before 2nd August 2005, the defence in regulation $10(23)$ of the 1998 Regulations; or
(g) manufactured or imported into the European Community before 1st March 2006, the defence in regulation $10(25)$ of the 1998 Regulations,
shall apply in relation to offences under these Regulations in like manner as it applied to offences under the equivalent provisions in those Regulations.

## Commencement Information

I17 Reg. 17 in operation at 30.6.2006, see reg. 1

## Procedure where a sample is to be analysed

18.-(1) An authorised officer who has procured a sample under Article 29 of the Order and who considers it should be analysed shall divide the sample into three parts.
(2) If the sample consists of sealed containers and opening them would, in the opinion of the authorised officer, impede a proper analysis, the authorised officer shall divide the sample into parts by putting the containers into three lots, and each lot shall be treated as being a part.
(3) The authorised officer shall -
(a) if necessary place each part in a suitable container and seal it;
(b) mark each part or container;
(c) as soon as reasonably practicable, give one part to the owner and notify him in writing that the sample will be analysed;
(d) submit one part for analysis in accordance with Article 30 of the Order; and
(e) retain one part for future submission under regulation 19.
(4) For the purpose of this regulation and regulation 19 analysis includes examination.

## Commencement Information

I18 Reg. 18 in operation at 30.6 .2006, see reg. 1

## Secondary analysis by the Government Chemist

19.-(1) Where a sample has been retained under regulation 18 and -
(a) proceedings are intended to be or have been commenced against a person for an offence under these Regulations; and
(b) the prosecution intends to adduce as evidence the result of the analysis mentioned in regulation 18 ,
paragraphs (2) to (7) shall apply.
(2) The authorised officer -
(a) may of his own volition;
(b) shall if requested by the prosecutor (if a person other than the authorised officer);
(c) shall if the court so orders; or
(d) shall (subject to paragraph (5)) if requested by the defendant,
send the retained part of the sample to the Government Chemist for analysis.
(3) The Government Chemist shall analyse the part sent to him under paragraph (2) and send to the authorised officer a certificate of analysis;
(4) Any certificate of the results of testing transmitted by the Government Chemist under this regulation shall be signed by or on behalf of him, but the testing may be carried out by any person under the direction of the person who signs the certificate.
(5) The authorised officer shall immediately on receipt supply the prosecutor (if a person other than the authorised officer) and the defendant with a copy of the Government Chemist's certificate of analysis.
(6) Where a request is made under paragraph (2)(d) the authorised officer may give notice in writing to the defendant requesting payment of a fee specified in the notice to defray some or all of the Government Chemist's charges for performing the functions under paragraph (3), and in the absence of agreement by the defendant to pay the fee specified in the notice the authorised officer may refuse to comply with the request.
(7) In this regulation "defendant" includes a prospective defendant.

## Commencement Information

I19 Reg. 19 in operation at 30.6.2006, see reg. 1

## PART 4

## Application for Authorisation

## Applications for inclusion of an additive in the Community list of authorised additives

20.-(1) This regulation applies where a person wishes to make an application for the inclusion of an eligible additive in the Community list referred to in Article 4 of the Directive.
(2) The application mentioned in paragraph (1), including supporting data, must be made to EFSA before 1st January 2007.
(3) If during examination of the data referred to in paragraph (2), EFSA calls for supplementary information, the eligible additive may, if otherwise permitted to be used under the law of Northern Ireland, continue to be so used until EFSA has issued an opinion, provided the supplementary opinion is submitted within the time limits specified by EFSA.
(4) For the purposes of this regulation, an eligible additive is one whose use is permitted in one or more member states before 1st January 2007.

## Commencement Information

I20 Reg. 20 in operation at 30.6.2006, see reg. 1

## PART 5

## General and Supplementary

## Application of provisions of the Order

21.-(1) The following provisions of the Order shall apply for the purposes of these Regulations as they apply for the purposes of the Order-
(a) Article 4 (presumption that food is intended for human consumption);
(b) Article 30(8) (relating to documentary evidence);
(2) Article 33(1) of the Order (powers of entry) shall be read as if it included reference to contravention of those provisions of Regulation 1895/2005 mentioned in regulation 13.

## Commencement Information

I21 Reg. 21 in operation at 30.6.2006, see reg. 1

## Amendment of the Food Safety (Sampling and Qualifications) Regulations (NI) 1991

22. In the Food Safety (Sampling and Qualifications) Regulations (Northern Ireland) 1991(18), in Schedule 1 (provisions to which those Regulations do not apply) for the title and reference of the 1998 Regulations substitute the title and reference of these Regulations.

## Commencement Information

I22 Reg. 22 in operation at 30.6 .2006 , see reg. 1

## Amendments to the Materials and Articles in Contact with Food Regulations (Northern Ireland) 2005

23.-(1) The 2005 Regulations are amended in accordance with paragraphs (2) to (6).
(2) In regulation 2(1) -
(a) omit the definition of "the 1998 Regulations";
(b) after the definition of "sell" add the following definition -
""the 2006 Regulations" means the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2006(19)."
(3) In regulation 8(4), for the expression "Schedules 1, 2 or 2A to the 1998 Regulations" substitute "Schedules 1, 2 or 3 to the 2006 Regulations".
(4) In regulation 9(3) -
(18) S.R. 1991 No. 198
(19) S.R. 2006 No.
(a) for the expression "Part I of Schedule 1 to the 1998 Regulations" substitute "Part 1 of Schedule 1 to the 2006 Regulations"; and
(b) in sub-paragraph (b) for "Part II" substitute "Part 2".
(5) In regulation 9(5), for the expression "Schedules 3 and 4 of the 1998 Regulations as read with regulation 6 of those Regulations" substitute "Schedules 5 and 6 of the 2006 Regulations as read with regulation 11 of those Regulations".
(6) In regulation $10(2)$, for the expression "proceedings for an offence under regulation" substitute "proceedings for an offence of contravening regulation".

## Commencement Information

I23 Reg. 23 in operation at 30.6.2006, see reg. 1

## Revocations

24. The following Regulations are revoked -
(a) the 1998 Regulations;
(b) the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2000(20);
(c) the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2002(21);
(d) the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2003(22);
(e) the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2004(23); and
(f) the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2005(24).
(g) Regulation 15 of the 2005 Regulations.

## Commencement Information

I24 Reg. 24 in operation at 30.6 .2006, see reg. 1

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 5th June 2006.

## L.S.

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## PART 1

## List of Monomers with Restrictions and Specifications

| Commencement Information |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
| 125 | Sch. 1 Pt. 1 in operation at 30. | 06, see reg. 1 |  |  |
|  | 1 | 2 | 3 | 4 |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 1 | 10030 | 000514-10-3 | Abietic acid |  |
| 2 | 10060 | 00075-07-0 | Acetaldehyde | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=6 \mathrm{mg} / \\ & \operatorname{kg}(2) \end{aligned}$ |
| 3 | 10090 | 000064-19-7 | Acetic acid |  |
| 4 | 10120 | 000108-05-4 | Acetic acid, vinyl ester | The specific migration of this substance shall not exceed 12 mg / kg |
| 5 | 10150 | 000108-24-7 | Acetic anhydride |  |
| 6 | 10210 | 000074-86-2 | Acetylene |  |
| 6A | 10599/90A | 061788-89-4 | Acids, fatty, unsaturated ( $\mathrm{C}_{18}$ ), dimers, distilled | $\begin{aligned} & \mathrm{QMA}(\mathrm{~T})=0.05 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2}\left({ }^{27}\right) \end{aligned}$ |
| 6B | 10599/91 | 061788-89-4 | Acids, fatty, unsaturated ( $\mathrm{C}_{18}$ ), dimers, non distilled | $\begin{aligned} & \mathrm{QMA}(\mathrm{~T})=0.05 \\ & \mathrm{Mg} / 6 \mathrm{dm}^{2}(27) \end{aligned}$ |
| 6C | 10599/92A | 068783-41-5 | Acids, fatty, unsaturated ( $\mathrm{C}_{18}$ ), dimers, hydrogenated, distilled | $\begin{aligned} & \mathrm{QMA}(\mathrm{~T})=0.05 \\ & \mathrm{Mg} / 6 \mathrm{dm}^{2}(27) \end{aligned}$ |
| 6D | 10599/93 | 068783-41-5 | Acids, fatty, unsaturated ( $\mathrm{C}_{18}$ ), dimers, hydrogenated, distilled | $\begin{aligned} & \mathrm{QMA}(\mathrm{~T})=0.05 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2}(27) \end{aligned}$ |
| 7 | 10630 | 000079-06-1 | Acrylamide | The specific migration of this substance shall |

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|  | PM/REF No | CAS No | Name | Restrictions and <br> specifications |

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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
|  |  |  |  | hydroxyisopropyl ester and in compliance with the specifications laid down in Schedule 4 |
| 16 | 11590 | 000106-63-8 | Acrylic acid, asobutyl ester |  |
| 17 | 11680 | 000689-12-3 | Acrylic acid, isopropyl ester |  |
| 18 | 11710 | 000096-33-3 | Acrylic acid, methyl ester |  |
| 19 | 11830 | 000818-61-1 | Acrylic acid, monoester with ethylene gylcol |  |
| 20 | 11890 | 002499-59-4 | Acrylic acid, noctyl ester |  |
| 21 | 11980 | 000925-60-0 | Acrylic acid, propyl ester |  |
| 22 | 12100 | 000104-13-1 | Acrylonitrile | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 $\mathrm{mg} / \mathrm{kg}$, analytical tolerance included) |
| 23 | 12130 | 000124-04-9 | Adipic acid |  |
| 23A | 12265 | 004074-90-2 | Adipic acid, divinyl ester | The quantity of this substance in the finished plastic material or article shall not exceed $5 \mathrm{mg} / \mathrm{kg}$. For use only as comonomer |
| 24 | 12280 | 002035-75-8 | Adipic anhydride |  |
| 25 | 12310 | - | Albumin |  |

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| :--- | :--- | :--- | :--- | :--- |
|  | PM/REF No | CAS No | Name | Restrictions and <br> specifications |
| 26 | 12340 | - | Albumin, <br> coagulated by <br> formaldehyde |  |

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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 33 | 13000 | 001477-55-0 | 1,3-Benzenedimethanamine | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 33 A | 13060 | 004422-95-1 | 1,3,5- <br> Benzenetricarboxylic acid trichloride | The quantity of this substance in the finished plastic material or article shall not exceed $0.05 \mathrm{mg} / 6$ $\mathrm{m}^{2}$ (measured as $1,3,5-$ benzenetricarboxylic acid) |
| 33B | 13075 | 00091-76-9 | Benzoguanamine | (see "2,4- <br> Diamino-6- <br> Phenyl-1,3,5- <br> Triazine" |
| 34 | 13090 | 000065-85-0 | Benzoic acid |  |
| 35 | 13150 | 000100-51-6 | Benzyl alcohol |  |
| 35A | 13180 | 000498-66-8 | $\begin{aligned} & \text { Bicyclo [2.2.1] } \\ & \text { hept-2-ene (= } \\ & \text { norbornene) } \end{aligned}$ | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 35B | 13210 | 001761-71-3 | Bis (4aminocyclohexyl) methane | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 36 | As item 79 | 000111-46-6 | Bis (2hydroxyethyl) ether | As item 79 |
| 37 | As item 217 | 000077-99-6 | $2,2-\mathrm{Bis}$ <br> (hydroxymethylbu ol) | $\begin{aligned} & \text { As item } 217 \\ & \text { tan-1- } \end{aligned}$ |
| 37A | 13323 | 000102-40-9 | ```1,3-Bis (2- hydroxyethoxy) benzene``` | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 38 | 13390 | 000105-08-8 | $\begin{aligned} & \text { 1,4-Bis } \\ & \text { (hydroxymethyl) } \\ & \text { - cyclohexane } \end{aligned}$ |  |


|  | 1 | 2 | 3 | 4 |
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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 38A | 13395 | 04767-03-7 | $\begin{aligned} & \text { 2,2-Bis } \\ & \text { (hydroxymethyl) } \\ & \text { propionic acid } \end{aligned}$ | $\begin{aligned} & \mathrm{QMA}=0.05 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2} \end{aligned}$ |
| 39 | 13480 | 000080-05-7 | 2,2-Bis (4- <br> hydroxyphenyl) <br> propane | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.6 \\ & \mathrm{mg} / \mathrm{kg}(28) \end{aligned}$ |
| 40 | 13510 | 001675-54-3 | 2,2-Bis (4hydroxyphenyl) propane bis (2,3epoxypropyl) ether | Use must be in accordance with Regulation 1895/2005 |
| 41 | 13530 | 038103-06-9 | 2,2-Bis (4- <br> hydroxyphenyl) <br> propane bis <br> (phthalic <br> anhydride) | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 42 | As item 93 | 000110-98-5 | Bis <br> (hydroxypropyl) ether |  |
| 43 | 13560 | 005124-30-1 | Bis(4isocyanatocyclohe methane | As item 78 xyl) |
| 44 | 13600 | 047465-97-4 | $\begin{aligned} & \text { 3,3-Bis (3- } \\ & \text { methyl-4- } \\ & \text { hydroxyphenyl) - } \\ & \text { indolin-2-one } \end{aligned}$ | The specific migration of this substance shall not exceed 1.8 $\mathrm{mg} / \mathrm{kg}$ |
| 45 | As item 39 | 000080-05-7 | Bisphenol A | As item 39 |
| 46 | As item 40 | 001675-54-3 | Bisphenol A bis (2,3-epoxypropyl) ether | As item 40 |
| 47 | 13614 | 038103-06-9 | Bisphenol A bis (phthalic anhydride) | As item 41 |
| 47A | 13617 | 00080-09-1 | Bisphenol S | As item 86A |
| 47B | 13620 | 10043-35-3 | Boric acid | SML(T) - 6 <br> $\mathrm{mg} / \mathrm{kg}(22)$ <br> (expressed as boron) without prejudice to the provisions of Directive 98/93/EC on |

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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
|  |  |  |  | water for human consumption |
| 48 | 13630 | 000106-99-9 | Butadiene | The quantity of this substance in the finished plastic material or article shall not exceed 1 mg / kg or the specific migration of this substance shall not be detectable (when measured by a method with a limit of detection of $0.02 \mathrm{mg} /$ kg , analytical tolerance included) |
| 49 | 13690 | 000107-88-0 | 1,3 Butandiol |  |
| 49A | 13720 | 00110-63-4 | 1,4-Butanediol | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.05 \\ & \mathrm{mg} / \mathrm{kg}(23) \end{aligned}$ |
| 49B | 13780 | 002425-79-8 | 1,4-Butanediol bis 2,3epoxypropyl) ether | The quantity of this substance in the finished plastic material or article shall not exceed 1 mg / kg (expressed as epoxy group, molecular weight equal to 43) |
| 49C | 13810 | 00505-65-7 | 1,4-Butanediol formal | $\begin{aligned} & \mathrm{QMA}=0.05 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2} \end{aligned}$ |
| 50 | 13840 | 000071-36-3 | Butan-1-ol |  |
| 51 | 13870 | 000106-98-9 | But-1-ene |  |
| 52 | 13900 | 000107-01-7 | Bit-2-ene |  |
| 52A | 13932 | 00598-32-3 | 3-Buten-2-ol | $\begin{aligned} & \mathrm{QMA}=\mathrm{ND}(\mathrm{DL} \\ & =0.02 \mathrm{mg} / 6 \\ & \left.\mathrm{dm}^{2}\right) . \text { To be used } \\ & \text { only as a co- } \\ & \text { monomer for } \\ & \text { the preparation } \end{aligned}$ |


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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
|  |  |  |  | of polymeric additive |
| 52B | 14020 | 000098-54-4 | 4-tert- <br> Butylphenol | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 53 | 14110 | 000123-72-8 | Butyraldehyde |  |
| 54 | 14140 | 000107-92-6 | Butyric acid |  |
| 55 | 14170 | 000106-31-0 | Butyric acid anhydride |  |
| 56 | 14200 | 000105-60-2 | Caprolactam | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=15 \mathrm{mg} / \\ & \operatorname{kg}(5) \end{aligned}$ |
| 57 | 14230 | 002123-24-2 | Caprolactam, sodium salt | $\operatorname{SML}(\mathrm{T})=15 \mathrm{mg} /$ kg (5) (expressed as caprolactam) |
| 58 | 14320 | 000124-07-2 | Caprylic acid |  |
| 59 | 14350 | 000630-80-0 | Carbon monoxide |  |
| 60 | 14380 | 000075-44-5 | Carbonyl chloride | The quantity of this substance in the finished plastic material or article shall not exceed $1 \mathrm{mg} / \mathrm{kg}$ |
| 61 | 14411 | 008001-79-4 | Caster oil |  |
| 62 | 14500 | 009004-34-6 | Cellulose |  |
| 63 | 14530 | 007782-50-5 | Chlorine |  |
| 63A | 14650 | 000079-38-9 | Chlorotrifluorethyl | $\begin{aligned} & \mathrm{eQMA}=0.5 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2} \end{aligned}$ |
| 64 | As item 94 | 000106-89-8 | 1-Chloro-2,3epoxypropane | As item 94 |
| 65 | 14680 | 000077-92-9 | Citric acid |  |
| 66 | 14710 | 000108-39-4 | $m$-Cresol |  |
| 67 | 14740 | 000095-48-7 | $o$-Cresol |  |
| 68 | 14770 | 000106-44-5 | p-Cresol |  |
| 68 MA | 14800 | 003724-65-0 | Crotonic acid | $\begin{aligned} & \mathrm{QMA}(\mathrm{~T})=0.05 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2} /(33) \end{aligned}$ |

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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 68A | 14841 | 000599-64-4 | 4-Cumylphenol | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 69 | As item 38 | 000105-08-8 | $1,4-$ <br> Cyclohexanedime | hanol |
| 70 | 14950 | 003173-53-3 | Cyclohexyl isocyanate | $\begin{aligned} & \mathrm{QM}(\mathrm{~T})=1 \mathrm{mg} / \mathrm{kd} \\ & \text { in } \mathrm{FP}(\text { expressed } \\ & \text { as } \mathrm{NCO})(26) \end{aligned}$ |
| 70A | 15030 | 00931-88-4 | Cyclooctene | SML $=(0.05$ <br> $\mathrm{mg} / \mathrm{kg}$. For use only in polymers contacting foods for which simulant A is laid down in Council Directive 85/572/ EEC |
| 71 | 15070 | 001647-16-1 | Dec-1, 9-diene | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 72 | 15095 | 000334-48-5 | Decanoic acid |  |
| 73 | 15100 | 000112-30-1 | Decan-1-ol |  |
| 73A | 15130 | 000872-05-9 | 1-Decene | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 74 | 15250 | 000110-60-1 | 1,4- <br> Diaminobutane |  |
| 75 | As item 97 | 000107-15-3 | $1,2-$ <br> Diaminoethane | As item 97 |
| 76 | As item 116 | 000124-09-4 | $1,6-$ <br> Diaminohexane | As item 116 |
| 76A | 15310 | 00091-76-9 | $\begin{aligned} & \text { 2,4-Diamino-6- } \\ & \text { phenyl-1,3,5- } \\ & \text { triazine } \end{aligned}$ | $\mathrm{QMA}=5 \mathrm{mg} / 6^{2}$ |
| 77 | 15565 | 000106-46-7 | 1,4.- <br> Dichlorobenzene | The specific migration of this |


|  | 1 | 2 | 3 | 4 |
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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
|  |  |  |  | substance shall not exceed 12 $\mathrm{mg} / \mathrm{kg}$ |
| 77A | 15610 | 00080-07-9 | 4,4'- <br> Dichlorodiphenyl sulphone | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 78 | 15700 | 005124-30-1 | Dicyclohexylmetha <br> - diisocyanate | $\begin{aligned} & \operatorname{aget}(4)=1 \mathrm{mg} / \\ & \mathrm{kg}(\text { expressed as } \\ & \mathrm{NCO}(25) \end{aligned}$ |
| 79 | 15760 | 000111-46-6 | Diethylene glycol | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=30 \mathrm{mg} / \\ & \operatorname{kg}(3) \end{aligned}$ |
| 80 | 15790 | 000111-40-0 | Diethylenetriamine | The specific migration of this substance shall not exceed 5 mg / kg |
| 81 | 15820 | 000345-92-6 | 4,4'- <br> Difluorobenzophen | The specific onigration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 82 | 15880 | 000120-80-9 | 1,2- <br> Dihydroxybenzene | The specific migration of this substance shall not exceed 6 mg / kg |
| 83 | 15910 | 000108-46-3 | 1,3- <br> Dihydroxybenzene | The specific migration of this shall not exceed $2.4 \mathrm{mg} / \mathrm{kg}$ |
| 84 | 15940 | 000123-31-9 | 1,4- <br> Dihydroxybenzene | The specific migration of this shall not exceed $0.6 \mathrm{mg} / \mathrm{kg}$ |
| 85 | 15970 | 000611-99-4 | 4,4'- <br> Dihydroxybenzoph | $\begin{aligned} & \text { (SML(T) - } 6 \mathrm{mg} / \\ & \text { Advgonk4) } \end{aligned}$ |
| 86 | 16000 | 000092-88-6 | 4,4'- <br> Dihydroxybipheny | The specific lmigration of this substance shall not exceed 6 mg / kg |

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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 86A | 16090 | 00080-09-01 | $4,4 \text { '- }$ <br> Dihydroxydiphenyl sulphone | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & 1 \mathrm{~kg} \end{aligned}$ |
| 87 | 16150 | 000108-01-0 | Dimethylaminoeth | aithe specific migration of this substance shall not exceed 18 $\mathrm{mg} / \mathrm{kg}$ |
| 87A | 16210 | 006864-37-5 | 3,3'- <br> Dimethyl-4,4'diaminodicyclohex methane | $\mathrm{SML}=0.05$ <br> $\mathrm{mg} / \mathrm{kg}$ (32). To yde used only in polyamides |
| 88 | 16240 | 000091-97-4 | 3,3'- <br> Dimethyl-4,4'diisocyanatobiphen | $\mathrm{QM}(\mathrm{T})=1 \mathrm{mg} /$ kg (expressed as NCO (25) |
| 88A | 16360 | 000576-26-1 | $2,6-$ <br> Dimethylphenol | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 88B | 16390 | 00126-30-7 | 2,2-Dimethyl-1,3- <br> propanediol | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 88C | 16450 | 000646-06-0 | 1,3-Dioxolane | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 89 | 16480 | 000126-58-9 | Dipentaerythritol |  |
| 89A | 16540 | 000102-09-0 | Diphenyl carbonate | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 90 | 16570 | 004128-73-8 | Diphenylether-4,4'diisocyanate | $-\mathrm{QM}(\mathrm{~T})=1 \mathrm{mg} /$ <br> kg (expressed as NCO) (25) |
| 91 | 16660 | 005873-54-1 | Diphenylmethane-2 diisocyanate | $\begin{aligned} & 24 \mathrm{M}(\mathrm{~T})=1 \mathrm{mg} / \\ & \mathrm{kg}(\text { expressed as } \\ & \mathrm{NCO})(25) \end{aligned}$ |
| 92 | 16630 | 000101-68-8 | Diphenylmethane-4 diisocyanate | $4 \mathrm{M}(\mathrm{T})-1 \mathrm{mg} /$ kg (expressed as NCO) (25) |
| 92 A | 16650 | 00127-63-9 | Diphenyl sulphone | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=3 \mathrm{mg} / \\ & \mathrm{kg}(24) \end{aligned}$ |
| 93 | 16660 | 000110-98-5 | Dipropyleneglycol |  |

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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 93A | 16690 | 01321-74-0 | Divinylbenzene | $\mathrm{QMA}=0.01$ $\mathrm{mg} / 6 \mathrm{dm} 2$ of SML = ND ( $\mathrm{DL}=0.02 \mathrm{mg} /$ kg , analytical tolerance included) for the sum of divinylbenzene and ethylvinylbenzene and in compliance with the specifications laid down in Schedule 4 |
| 93B | 16694 | 013811-50-2 | N,N'-Divinly-2imidazolidinone | The quantity of this substance in the finished plastic material or article shall not exceed $5 \mathrm{mg} / \mathrm{kg}$ |
| 93C | 16697 | 00693-23-2 | n-Dodecanedioic Acid |  |
| 93D | 16704 | 000112-41-4 | 1-Dodecene | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 94 | 16750 | 000106-89-8 | Epichlorohydrin | The quantity of this substance in the finished plastic material or article shall not exceed $1 \mathrm{mg} / \mathrm{kg}$ |
| 95 | 16780 | 000064-17-5 | Ethanol |  |
| 96 | 16950 | 000074-85-1 | Ethylene |  |
| 97 | 16960 | 000107-15-3 | Ethylenediamine | The specific migration of this substance shall not exceed 12 $\mathrm{mg} / \mathrm{kg}$ |
| 98 | 16990 | 000107-21-1 | Ethylene glycol | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=30 \mathrm{mg} / \\ & \operatorname{kg}(3) \end{aligned}$ |

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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 99 | 17005 | 000151-56-4 | Ethyleneimine | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 $\mathrm{mg} / \mathrm{kg}$ ) |
| 100 | 17020 | 000075-21-8 | Ethylene oxide | The quantity of this substance in the finished plastic material or article shall not exceed $1 \mathrm{mg} / \mathrm{kg}$ |
| 101 | 17050 | 00104-76-7 | 2-Ethylhexan-1-ol | The specific migration of this substance shall not exceed 30 $\mathrm{mg} / \mathrm{kg}$ |
| 101A | 17110 | 016219-75-3 | 5- <br> Ethylidenebicyclo hept-2-ene | QMA $=0.05$ 2 2 2g $16 \mathrm{dm}^{2}$. The ratio surface/ quantity of food shall be lower than $2 \mathrm{dm}^{2} / \mathrm{kg}$ |
| 102 | 17160 | 000097-53-0 | Eugenol | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 $\mathrm{mg} / \mathrm{kg}$, analytical tolerance included) |
| 103 | 17170 | 061688-47-4 | Fatty acids, coco |  |
| 104 | 17200 | 068308-53-2 | Fatty acids, soya |  |
| 105 | 17230 | 061790-12-3 | Fatty acids, tall oil |  |
| 106 | 17260 | 000050-00-0 | Formaldehyde | $\operatorname{SML}(T)=15 \mathrm{mg} /$ |

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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 107 | 17290 | 000110-17-8 | Fumaric acid |  |
| 108 | 17530 | 000050-99-7 | Glucose |  |
| 109 | 18010 | 000110-94-1 | Glutaric acid |  |
| 110 | 18070 | 000108-55-4 | Glutaric anhydride |  |
| 111 | 18100 | 000056-81-5 | Glycerol |  |
| 111 A | 18220 | 068564-88-5 | N- <br> Heptylaminoundecanoic acid | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 112 | 18250 | 000115-28-6 | Hexachloroendom tetrahydrophthalic acid | ffliydespecific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 $\mathrm{mg} / \mathrm{kg}$ ) |
| 113 | 18280 | 000115-27-5 | Hexachloroendom tetrahydrophthalic anhydride | ffliydespecific migration of this substance shall not be detectable (when measured by a method with a limit of detection of 0.01 $\mathrm{mg} / \mathrm{kg}$ ) |
| 114 | 18310 | 036653-82-4 | Hexadecan-1-ol |  |
| 115 | 18430 | 000116-15-4 | Hexafluoropropy | nEhe specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 $\mathrm{mg} / \mathrm{kg}$ ) |
| 116 | 18460 | 000124-09-4 | Hexamethylenedi | mihe specific migration of this substance shall |


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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
|  |  |  |  | not exceed 2.4 $\mathrm{mg} / \mathrm{kg}$ |
| 117 | 18640 | 000822-06-0 | Hexamethylene diisocyanate | $\mathrm{QM}(\mathrm{T})=1 \mathrm{mg} /$ kg (expressed as NCO) (25) |
| 118 | 18670 | 000100-97-0 | Hexamethylenet | asidife $(T)=15 \mathrm{mg} /$ kg (expressed as formaldehyde) (21) |
| 118MA | 18700 | 000629-11-8 | 1,6-Hexanediol | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 118A | 18820 | 000592-41-6 | 1-Hexene | The specific migration of this substance shall not exceed 3 mg / kg |
| 119 | As item 84 | 000123-31-9 | Hydroquinone | As item 84 |
| 120 | 18880 | 000099-96-7 | p- <br> Hydroxybenzoic acid |  |
| 120ZA | 18896 | 001679-51-2 | 4(Hydroxymethyl) cyclohexene | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & 1 \mathrm{~kg} \end{aligned}$ |
| 120A | 18897 | 16712-64-4 | 6-Hydroxy-2naphthalenecarbo acid | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \text { sylkig } \end{aligned}$ |
| 120B | 18898 | 000103-90-2 | N-(4- <br> Hydroxyphenyl) acetamide | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 121 | 19000 | 000115-11-7 | Isobutene |  |
| 121A | 19060 | 000109-53-5 | Isobutyl vinyl ether | The quantity of this substance in the finished plastic material or article shall not exceed $5 \mathrm{mg} / \mathrm{kg}$ |
| 121B | 19110 | 04098-71-9 | 1-Isocyanato-3isocyanantometh trimethylcyclohe | $\mathrm{QM}(\mathrm{T})=1 \mathrm{mg} /$ <br> -kg(5xpressed as añeCO (25) |
| 121C | 19150 | 000121-91-5 | Isophthalic acid | The specific migration of this substance shall |


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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
|  |  |  |  | not exceed $5 \mathrm{mg} /$ kg |
| 122 | 19210 | 001459-93-4 | Isophthalic acid, dimethyl ester | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 122A | 19243 | 000780-79-5 | Isoprene | As item 145A |
| 123 | 19270 | 000097-65-4 | Itaconic acid |  |
| 124 | 19460 | 000050-21-5 | Lactic acid |  |
| 125 | 19470 | 000143-07-7 | Lauric acid |  |
| 126 | 19480 | 002146-71-6 | Lauric acid, vinyl ester |  |
| 126A | 19490 | 00947-04-6 | Laurolactam | $\mathrm{SML}=5 \mathrm{mg} / \mathrm{kg}$ |
| 127 | 19510 | 011132-73-3 | Lignocellulose |  |
| 128 | 19540 | 000110-16-7 | Maleic acid | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=30 \mathrm{mg} / \\ & \mathrm{kg}(4) \end{aligned}$ |
| 129 | 19960 | 000108-31-6 | Maleic anhydride | $\operatorname{SML}(\mathrm{T})=30 \mathrm{mg} /$ kg (4) (expressed as maleic acid) |
| 130 | As item 215 | 000108-78-1 | Melamine | As item 215 |
| 130A | 19990 | 000079-39-0 | Methacrylamide | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 $\mathrm{mg} / \mathrm{kg}$, analytical tolerance included) |
| 131 | 20020 | 000079-41-4 | Methacrylic acid |  |
| 131A | 20050 | 000096-05-9 | Methacrylic acid, allyl ester | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 132 | 20080 | 002495-37-6 | Methacrylic acid, benzyl ester |  |


|  | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 133 | 20110 | 000097-88-1 | Methacrylic acid, butyl ester |  |
| 134 | 20140 | 002998-18-7 | Methacrylic acid, sec-butyl ester |  |
| 135 | 20170 | 000585-07-9 | Methacrylic acid, tert-butyl ester |  |
| 135A | 20260 | 00101-43-9 | Methacrylic acid, cyclohexyl ester | $\begin{aligned} & \mathrm{SML}=0.05 \\ & \text { mg.kg } \end{aligned}$ |
| 135B | 20410 | 02082-81-7 | Methacrylic acid, diester with 1,4butanediol | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 135BM | 20440 | 000097-90-5 | Methacrylic acid, diester with ethylenegycol | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 135C | 20530 | 002867-47-2 | Methacrylic acid, 2(dimethylamino) ethyl ester | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 $\mathrm{mg} / \mathrm{kg}$, analytical tolerance included) |
| 135D | 20590 | 00106-91-2 | Methacrylic acid, 2,3-epoxypropyl ester | $\begin{aligned} & \mathrm{QMA}=0.02 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2} \end{aligned}$ |
| 136 | 20890 | 000097-63-2 | Methacrylic acid, ethyl ester |  |
| 137 | 21010 | 000097-86-9 | Methacrylic acid, isobutyl ester |  |
| 138 | 21100 | 004655-34-9 | Methacrylic acid, isopropyl ester |  |
| 139 | 21130 | 000080-62-6 | Methacrylic acid, methyl ester |  |
| 140 | 21190 | 000868-77-9 | Methacrylic acid, monoester with ethyleneglycol |  |
| 141 | 21280 | 002177-70-0 | Methacrylic acid, phenyl ester |  |

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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 142 | 21340 | 002210-28-8 | Methacrylic acid, propyl ester |  |
| 142A | 21400 | 054276-35-6 | Methacrylic acid, sulphopropyl ester | $\begin{aligned} & \mathrm{QMA}=0.05 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2} \end{aligned}$ |
| 143 | 21460 | 000760-93-0 | Methacrylic anhydride |  |
| 144 | 21490 | 000126-98-7 | Methacrylonitrile | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 $\mathrm{mg} / \mathrm{kg}$., analytical tolerance included) |
| 144A | 21520 | 01561-92-8 | Methallylsulphonic acid, sodium salt | $\mathrm{c} \text { SML }=5 \mathrm{mg} / \mathrm{kg}$ |
| 145 | 21550 | 000067-56-1 | Methanol |  |
| 145A | 21640 | 00078-79-5 | 2-Methyl-1,3- butadiene | $\begin{aligned} & \mathrm{QM}=1 \mathrm{mg} / \mathrm{kg} \text { in } \\ & \mathrm{FP} \text { or } \mathrm{SML}=\mathrm{ND} \end{aligned}$ |
|  |  |  |  | $(\mathrm{DL}=0.02 \mathrm{mg} /$ <br> kg , analytical tolerance included) |
| 145B | 21730 | 000563-45-1 | 3-Methyl-1- <br> butene | The quantity of this substance in the finished plastic material or article shall not exceed 0.006 $\mathrm{mg} / 6 \mathrm{dm}^{2}$. For use only in polypropylene |
| 145C | 21765 | 106246-33-7 | 4,4'-Methylenebis (3-chloro-2,6diethylaniline) | $\begin{aligned} & \mathrm{QMA}=0.05 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2} \end{aligned}$ |
| 145D | 21821 | 00505-65-7 | 1,4- <br> (Methylenedioxy) <br> butane | As item 49B |

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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 146 | 21940 | 000924-42-5 | N- <br> Methylolacrylam | The specific emigration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 $\mathrm{mg} / \mathrm{kg}$ ) |
| 147 | 22150 | 000691-37-2 | 4-Methyl-1pentene | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 147A | 22331 | 025513-64-8 | Mixture of (35-45\% w/w) 1,6-diamino-2,2,4trimethylhexane and (55-65\% w/w) 1,6-diamino-2,4,4trimethylhexane | $\begin{aligned} & \mathrm{QMA}=5 \mathrm{mg} / 6 \\ & \mathrm{dm}^{2} \end{aligned}$ |
| 147B | 22332 |  | Mixture of (40\% w/w) 2,,2,4-trimethylhexane-6-diisocyanate and ( $60 \%$ w/w) 2,4,4-trimethylhexanediisocyanate | $\mathrm{QM}(\mathrm{T})=1 \mathrm{mg} /$ kg (expressed as NCO (26) 6- |
| 148 | 22350 | 000544-63-8 | Myristic acid |  |
| 148A | 22360 | 01141-38-4 | 2,6- <br> Naphthalenedicarb acid | $\underset{\text { oxylic }}{\mathrm{SML}}=5 \mathrm{mg} / \mathrm{kg}$ |
| 149 | 22390 | 000840-65-3 | 2,6- <br> Naphthalenedicarb acid, dimethyl ester | The specific oxyygication of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 150 | 22420 | 003173-72-6 | 1,5-Naphthalene diisocyanate | $\mathrm{QM}(\mathrm{~T})=1 \mathrm{mg} /$ <br> kg (expressed as NCO) (25) |
| 150A | 22437 | 00126-30-7 | Neopentylgycol | As item 88B |
| 151 | 22450 | 009004-70-0 | Nitrocellulose |  |
| 152 | 22480 | 000143-08-8 | Nonan-1-ol |  |


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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 152A | 22550 | 000498-66-8 | Norbornene | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 153 | 22570 | 000112-96-9 | Octadecyl isocyanate | $\begin{aligned} & \mathrm{QM}(\mathrm{~T})=1 \mathrm{mg} / \\ & \mathrm{kg}(\text { expressed as } \\ & \mathrm{NCO})(25) \end{aligned}$ |
| 154 | 22600 | 000111-87-5 | Octan-1-ol |  |
| 155 | 22660 | 000111-66-0 | Oct-1-ene | The specific migration of this substance shall not exceed 15 $\mathrm{mg} / \mathrm{kg}$ |
| 156 | 22763 | 000112-80-1 | Oleic acid |  |
| 156XA | 22775 | 000144-62-7 | Oxalic acid | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=6 \mathrm{mg} / \\ & \mathrm{kg}(29) \end{aligned}$ |
| 156A | 22778 | 07456-68-0 | 4,4'-Oxybis (benzenesulphonyl azide | $\begin{aligned} & \mathrm{QMA}=0.05 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2} \end{aligned}$ |
| 157 | 22780 | 000057-10-3 | Palmitic acid |  |
| 158 | 22840 | 000115-77-5 | Pentaerythritol |  |
| 159 | 22870 | 000071-41-0 | Pentan-1-ol |  |
| 159A | 22900 | 00109-67-1 | 1-Pentene | SML $=5 \mathrm{mg} / \mathrm{kg}$ |
| 159B | 22937 | 001623-05-8 | Perfluoropropyl perfluorovinyl ether | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 160 | 22960 | 000108-95-2 | Phenol |  |
| 161 | 23050 | 000108-45-2 | 1,3- <br> Phenylenediamine | $\begin{aligned} & \mathrm{SML}=\mathrm{ND} \\ & (\mathrm{DL}=0.02 \mathrm{mg} / \end{aligned}$ <br> kg. Analytical tolerance included) |
| 161A | 23070 | 000102-39-6 | $(1,3-$ <br> Phenylenedioxy) diacetic acid | $\begin{aligned} & \mathrm{QMA}=0.05 \\ & \mathrm{mg} / 6 \mathrm{dm}^{2} \end{aligned}$ |
| 162 | As item 60 | 000075-44-5 | Phosgene | As item 60 |
| 163 | 23170 | 007665-38-2 | Phosphoric acid |  |

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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 163 A | 23175 | 000122-52-1 | Phosphorous acid, triethyl ester | The quantity of this substance in the finished plastic material or article shall be not detectable (when measured by a method with a detection limit of $1 \mathrm{mg} / \mathrm{kg}$ |
| 164 | As item 204 | - | Phthalic acid | As item 204 |
| 165 | 23200 | 000088-99-3 | o-Phthalic acid |  |
| 166 | 23230 | 000131-17-9 | Phthalic acid, diallyl ester | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 $\mathrm{mg} / \mathrm{kg}$ ) |
| 167 | 23380 | 000085-44-9 | Phthalic anhydride |  |
| 168 | 23470 | 000080-56-8 | Alpha-Pinene |  |
| 169 | 23500 | 000127-91-3 | Beta-Pinene |  |
| 169A | 23547 | $\begin{aligned} & 009016-00-6 \\ & 063148-62-9 \end{aligned}$ | Polydimethylsiloxa <br> ( $\mathrm{Mw}>6800$ ) | aía compliance with the specifications laid down in Schedule 4 |
| 170 | 23590 | 025322-68-3 | Polyethylene glycol |  |
| 171 | 23650 | 025322-69-4 | Polypropylene glycol (molecular weight greater than 400) |  |
| 172 | 23651 | 025322-69-4 | Polypropyleneglyco |  |
| 173 | 23740 | 000057-55-6 | Propan-1,2-diol |  |
| 173A | 23770 | 000504-63-2 | 1,3-Propanediol | The specific migration of this substance shall |


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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
|  |  |  |  | not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 174 | 23800 | 000071-23-8 | Propan-1-ol |  |
| 175 | 23830 | 000067-63-0 | Propan-2-ol |  |
| 176 | 23860 | 000123-38-6 | Propionaldehyde |  |
| 177 | 23890 | 000079-09-4 | Propionic acid |  |
| 177A | 23920 | 000105-38-4 | Propionic acid, vinyl ester | $\operatorname{SML}(\mathrm{T})=6 \mathrm{mg} /$ kg (2) (expressed as acetaldehyde) |
| 178 | 23950 | 000123-62-6 | Propionic anhydride |  |
| 179 | 23980 | 000115-07-1 | Propylene |  |
| 180 | 24010 | 000075-56-9 | Propylene oxide | The quantity of this substance in the finished plastic material or article shall not exceed $1 \mathrm{mg} / \mathrm{kg}$ |
| 181 | As item 82 | 000128-80-9 | Pyrocatechol | As item 82 |
| 182 | 24057 | 000089-32-7 | Pyromellitic anhydride | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ (expressed as pyromellitic acid) |
| 183 | 24070 | 073138-82-6 | Resin acids and rosin acids |  |
| 184 | As item 83 | 000108-46-3 | Resorcinol | As item 83 |
| 184A | 24073 | 000101-90-6 | Resorcinol diglycidyl ether | $\mathrm{QMA}=0.005$ <br> $\mathrm{mg} / \mathrm{g} \mathrm{dm}^{2}$. <br> Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, |


|  | 1 | 2 | 3 | 4 |
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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
|  |  |  |  | behind the PET layer |
| 185 | 24100 | 008050-09-7 | Rosin |  |
| 186 | 24130 | 008050-09-7 | Rosin gum |  |
| 187 | 24160 | 008052-10-6 | Rosin tall oil |  |
| 188 | 24190 | 065997-05-9 | Rosin wood |  |
| 189 | 24250 | 009006-04-6 | Rubber, natural |  |
| 190 | 24270 | 000069-72-7 | Salicylic acid |  |
| 191 | 24280 | 000111-20-6 | Sebacic acid |  |
| 192 | 24430 | 002561-88-8 | Sebacic anhydride |  |
| 193 | 24475 | 001313-82-2 | Sodium sulphide |  |
| 194 | 24490 | 000050-70-4 | Sorbitol |  |
| 195 | 24520 | 008001-22-7 | Soybean oil |  |
| 196 | 24540 | 009005-25-8 | Starch, edible |  |
| 197 | 24550 | 000057-11-4 | Stearic acid |  |
| 198 | 24610 | 000100-42-5 | Styrene |  |
| 198A | 24760 | 026914-43-2 | Styrenesulphonic acid | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 199 | 24820 | 000110-15-6 | Succinic acid |  |
| 200 | 24850 | 000108-30-5 | Succinic anhydride |  |
| 201 | 24880 | 000057-50-1 | Sucrose |  |
| 202 | 24887 | 006362-79-4 | 5- <br> Sulphoisophthalic acid, monosodium salt | The specific migration of this substance shall not exceed 5 mg / kg |
| 203 | 24888 | 003965-55-7 | 5- <br> Sulphoisophthalic acid, monosodium salt, dimethyl ester | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 204 | 24910 | 000100-21-0 | Terephthalic acid | The specific migration of this |

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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
|  |  |  |  | substance alone or together with item 205 shall not exceed a total of $7.5 \mathrm{mg} / \mathrm{kg}$ |
| 205 | 24940 | 000100-20-9 | Terephthalic acid dichloride | The specific migration of this substance along or together with item 204 shall not exceed $7.5 \mathrm{mg} /$ kg (expressed as terephthalic acid) |
| 206 | 24970 | 000120-61-6 | Terephthalic acid, dimethyl ester |  |
| 206A | 25080 | 001120-36-1 | 1-Tetradecene | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 207 | 25090 | 000112-60-7 | Tetraethylene glycol |  |
| 208 | 25120 | 000116-14-3 | Tetrafluoroethylene | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 209 | 25150 | 000109-99-9 | Tetrahydrofuran | The specific migration of this substance shall not exceed 0.6 $\mathrm{mg} / \mathrm{kg}$ |
| 210 | 25180 | 000102-60-3 | N,N,N'N'- <br> Tetrakis (2-hydroxypropyl)ethylenediamine |  |
| 211 | 25210 | 000584-84-9 | 2,4-Toluene diisocyanate | $\mathrm{QM}(\mathrm{~T})=1 \mathrm{mg} / \mathrm{kg}$ <br> (expressed as NCO) (25) |
| 212 | 25240 | 000091-08-7 | 2,6-Toluene diisocyanate | $\mathrm{QM}(\mathrm{~T})=1 \mathrm{mg} / \mathrm{kg}$ <br> (expressed as $\mathrm{NCO})(25)$ |

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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 213 | 25270 | 026747-90-0 | 2,4-Toluene diisocyanate dimer | $\begin{aligned} & \mathrm{QM}(\mathrm{~T})=1 \mathrm{mg} / \\ & \mathrm{kg} \text { (expressed as } \\ & \mathrm{NCO})(25) \end{aligned}$ |
| 214 | 25360 |  | Trialkyl ( $\mathrm{C}_{5}-\mathrm{C}_{15}$ <br> ) acetic acid, 2,3epoxypropyl ester | The quantity of this substance in the finished plastic material or article shall not exceed 1 mg / kg (expressed as epoxy group, molecular weight =43) |
| 214A | 25380 |  | Trialkyl acetic acid (C7-C17), vinyl esters (= vinyl versatate) | $\begin{aligned} & \mathrm{QMA}=0.05 \mathrm{mg} / \\ & \mathrm{g} \mathrm{dm}^{2} \end{aligned}$ |
| 214B | 25385 | 000102-70-5 | Triallylamine | In compliance with the specifications laid down in Schedule 4 |
| 215 | 25420 | 000108-78-1 | 2,4,6- <br> Triamino-1,3,5triazine | The specific migration of this substance shall not exceed 30 $\mathrm{mg} / \mathrm{kg}$ |
| 215A | 25450 | 26896-48-0 | Tricyclodecanedim thanol | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 216 | 25510 | 000112-27-6 | Triethylene glycol |  |
| 217 | 25600 | 000077-99-6 | $1,1,1-$ <br> Trimethylolpropan | The specific emigration of this substance shall not exceed 6 mg / kg |
| 217A | 25840 | 03290-92-4 | 1,1,1- <br> trimethylolpropane trimethacrylate | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 217B | 25900 | 00110-88-3 | Trioxane | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 218 | 25910 | 024800-44-0 | Tripropylene glycol |  |

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|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 218A | 25927 | 027955-94-8 | 1,1,1-Tris (4hydroxyphenyl) ethane | The quantity of this substance in the finished plastic material or article shall not exceed 0.5 mg / kg. For use only in polycarbonates |
| 219 | 25960 | 000057-13-6 | Urea |  |
| 220 | 26050 | 000075-01-4 | Vinyl chloride | The restrictions are those in regulation 6 <br> (1) of the 2005 Regulations when analysed by the method referred to in regulation 7 of those Regulations |
| 221 | 26110 | 000075-35-4 | Vinylidene chloride | The quantity of this substance in the finished plastic material or article shall not exceed $5 \mathrm{mg} /$ kg or the specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.05 $\mathrm{mg} / \mathrm{kg}$ ) |
| 222 | 26140 | 000075-38-7 | Vinylidene fluoride | The specific migration of this substance shall not exceed 5 mg / kg |
| 223 | 26155 | 001072-63-5 | 1-Vinylimidazole | The quantity of this substance in the finished plastic material or article shall not exceed $5 \mathrm{mg} / \mathrm{kg}$ |


|  | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No | CAS No | Name | Restrictions and specifications |
| 224 | 26170 | 003195-78-6 | N -Vinyl-Nmethylacetamide | The quantity of this substance in the finished plastic material or article shall not exceed $2 \mathrm{mg} / \mathrm{kg}$ |
| 225 | 26320 | 002768-02-7 | Vinyltrimethoxys | aTibe quantity of this substance in the finished plastic material or article shall not exceed $5 \mathrm{mg} / \mathrm{kg}$ |
| 226 | 26360 | 007732-18-5 | Water | In compliance with Directive 98/83/EC on the quality of water intended for human consumption |

## PART 2

## Supplementary

1. In regulation 4 and Part 1 of this Schedule-
(a) the PM/REF number. of any substance is its EEC packaging material reference number;
(b) the CAS number of any substance is its CAS (Chemical Abstracts Service) Registry Number;
(c) the name of any substance is its chemical name, and to the extent that there is any inconsistency between the CAS number and the name, the name shall take precedence over the CAS number; and
(d) references to specific migration are to be taken to mean specific migration as measured in accordance with Schedules 5 and 6.

## Commencement Information

I26 Sch. 1 para. 1 in operation at 30.6 .2006 , see reg. 1
2. If a substance appearing in Part 1 of this Schedule as an individual compound also falls within a generic term which appears therein, any restriction applying to that substance shall be that indicated for the individual compound and the entry applying to the generic term shall be treated as varied to such extent as is necessary.

## Commencement Information

I27 Sch. 1 para. 2 in operation at 30.6 .2006 , see reg. 1
3.-(1) The items identified in Part 1 of this Schedule shall be taken to include-
(a) substances undergoing polymerisation (including polycondensation, polyaddition or any other similar process) to manufacture macromolecules;
(b) natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers required to synthesise them are not so identified; and
(c) substances used to modify existing natural or synthetic macromolecular substances.
(2) If a substance identified in Part 1 of this Schedule is an acid, a phenol or an alcohol and has salts (including double salts) of one or more of the following names (that is to say salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc) then any such salts shall be treated as included in the specification of that substance.
(3) If, as indicated in paragraph 2 of Annex II to the Directive, a substance is identified in Part 1 of this Schedule as an "... acid, salt" and has salts of one or more of the following names (that is to say salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc), then the free acid corresponding to that substance is not treated as included in the specification of that substance.

## Commencement Information

I28 Sch. 1 para. 3 in operation at 30.6.2006, see reg. 1
4. Where an entry in column 4 of Part 1 of this Schedule (restrictions and specifications) includes a bracketed number, that entry shall be subject to a note relating to that number as follows, the following bracketed numbers corresponding with those appearing in that Part -
(1) Warning: there is a risk that the specific migration limit could be exceeded in fatty food simulants.
(2) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.
(3) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.
(4) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.
(5) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.
(14) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600.
(21) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 17260, 18670, 54880 and 59280].
(22) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13620, 36840, 40320 and 87040.
(23) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13720 and 40580.
(24) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 16650 and 51570.
(25) $\mathrm{QM}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the substances having PM/REF/Nos. 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.
(27) $\mathrm{QMA}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.
(28) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680
(29) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.
(32) Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant $D$ (unstable).
(33) $\mathrm{QMA}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.

## Commencement Information

I29 Sch. 1 para. 4 in operation at 30.6.2006, see reg. 1

## PART 1

Incomplete List of Additives Used in the Manufacture of Plastic Materials and Articles (not being Additives to which Paragraph 5 of Part 3 of this Schedule Applies)

| Commencement Information |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: |
| I30 Sch. 2 Pt. 1 in operation at 30.6.2006, see reg. 1 |  |  |  |  |
| Item | 1 | 2 | 3 | 4 |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 1 | 30000 | 000064-19-7 | Acetic acid |  |
| 2 | 30045 | 000123-86-4 | Acetic acid, butyl ester |  |
| 2A | 30080 | 004180-12-5 | Acetic acid, copper salt | $\operatorname{SML}(T)=30 \mathrm{mg} /$ kg (7) (expressed as copper) |
| 3 | 30140 | 000141-78-6 | Acetic acid, ethyl ester |  |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 4 | 30280 | 000108-24-7 | Acetic anhydride |  |
| 5 | 30295 | 000067-64-1 | Acetone |  |
| 6 | 30370 | - | Acetylacetic acid, salts |  |
| 7 | 30400 | - | Acetylated glycerides |  |
| 7A | 30610 | - | Acids $\mathrm{C}_{2}-\mathrm{C}_{24}$ aliphatic, linear monocarboxylic, from natural oils and fats and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included) |  |
| 7B | 30612 | - | Acids $\mathrm{C}_{2}-\mathrm{C}_{24}$ aliphatic linear, monocarboxylic, synthetic and their mono-, diand triglycerol esters |  |
| 8 | 30960 | - | Acids, aliphatic, monocarboxylic ( $\mathrm{C}_{6}-\mathrm{C}_{22}$ ), esters with polyglycerol |  |
| 9 | 31328 | - | Acids, fatty, from animal or vegetable foods fats and oils |  |
| 9A | 31530 | 123968-25-2 | Acrylic acid, 2,4-di-tert-pentyl-6[1(3,5-di-tert-pentyl-2hydroxphenyl) ethyl] phenyl ester | The specific migration of this substance shall not exceed 5 mg / kg |
| 10 | 31730 | 000124-04-9 | Adipic acid |  |
| 11 | 33120 | - | Alcohol's, aliphatic, monohydric, |  |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|  |  |  | saturated, linear, primary ( $\mathrm{C}_{4}-\mathrm{C}_{24}$ ) |  |
| 12 | 33350 | 009005-32-7 | Algnic acid |  |
| 12A | 33801 | - | $\begin{aligned} & \text { n-Alkyl } \\ & \left(\mathrm{C}_{10}-\mathrm{C}_{13}\right) \end{aligned}$ <br> benzenesulphonic acid | The specific migration of this substance shall not exceed 30 $\mathrm{mg} / \mathrm{kg}$ |
| 13 | 34281 | - | Alkyl ( $\mathrm{C}_{8}-\mathrm{C}_{22}$ ) sulphuric acids, linear, primary, with an even number of carbon atoms |  |
| 14 | 34475 | - | Aluminium calcium hydroxide phosphite, hydrate |  |
| 15 | 34480 | - | Aluminium <br> fibres, flakes and powders |  |
| 16 | 34560 | 021645-51-2 | Aluminium hydroxide |  |
| 17 | 34690 | 010978-59-9 | Aluminium magnesium carbonate hydroxide |  |
| 18 | 34720 | 001344-28-1 | Aluminium oxide |  |
| 18A | 34850 | 143925-92-2 | Amines, bis (hydrogenated tallow alkyl) oxidised | $\mathrm{QM}=$ For use only: <br> (a) in polyolefines at $0.1 \%$ (w/w) not in LDPE when it is in contact with foods for which Directive 85/572/EEC establishes a reduction |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|  |  |  |  | factor less than 3; <br> (b) in PET at $0.25 \%$ (w/w) in contact with foods other than those for which the simulant D is laid down in Directive 85/572/EEC $\mathrm{SML}=0.05$ $\mathrm{mg} / \mathrm{kg}$ |
| 18B | 34895 | 000088-68-6 | 2- <br> Aminobenzamide | To be used only for PET for water and beverages |
| 19 | 35120 | 013560-49-1 | 3-Aminocronic acid, diester with thiobis (2hydroxyethyl) ether |  |
| 19A | 35160 | 006642-31-5 | 6-Amino-1,3dimethyluracil | SML $=5 \mathrm{mg} / \mathrm{kg}$ |
| 19B | 35170 | 000141-53-5 | 2-Aminoethanol | $\mathrm{SML}=0.05$ $\mathrm{mg} / \mathrm{kg}$. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer |
| 19C | 35284 | 000111-41-1 | N -(2-aminoethyl) ethanolamine | $\mathrm{SML}=0.05$ $\mathrm{mg} / \mathrm{kg}$. Not for use in polymers contacting foods for which simulant D is laid down in |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|  |  |  |  | Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer |
| 20 | 35320 | 007664-41-7 | Ammonia |  |
| 21 | 35440 | 012124-97-9 | Ammonium bromide |  |
| 22 | 35600 | 001336-21-6 | Ammonium hydroxide |  |
| 23 | 35840 | 000506-30-9 | Arachidic acid |  |
| 24 | 35845 | 007771-44-0 | Arachidonic acid |  |
| 25 | 36000 | 000050-81-7 | Ascorbic acid |  |
| 26 | 36080 | 000137-66-6 | Ascorbyl palmitate |  |
| 27 | 36160 | 010605-09-1 | Ascorbyl stearate |  |
| 27B | 36840 | 12007-55-5 | Barium tetraborate | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=1 \mathrm{mg} / \\ & \mathrm{kg} \text { expressed } \\ & \text { as barium }(11) \\ & \text { and } \mathrm{SML}(\mathrm{~T})= \\ & 6 \mathrm{mg} / \mathrm{kg}(22) \\ & \text { (expressed as } \\ & \text { boron) without } \\ & \text { prejudice to } \\ & \text { the provisions } \\ & \text { of Directive } \\ & 98 / 83 / \mathrm{EC} \text { on } \\ & \text { water for human } \\ & \text { consumption } \end{aligned}$ |
| 28 | 36880 | 008012-89-3 | Beeswax |  |
| 29 | 36960 | 003061-75-4 | Behenamide |  |
| 30 | 37040 | 000112-85-6 | Behenic acid |  |
| 31 | 37280 | 001302-78-9 | Bentonite |  |
| 31A | 37360 | 000100-52-7 | Benzaldehyde | (10) |
| 32 | 37600 | 000065-85-0 | Benzoic acid |  |
| 33 | 37680 | 000136-60-7 | Benzoic acid, butyl ester |  |
| 34 | 37840 | 000093-89-0 | Benzoic acid, ethyl ester |  |

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| Item | PM/REF No. | CAS No. | 3 | Name |
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| Item | PM/REF No. | CAS No. | 3 | Name |
| :--- | :--- | :--- | :--- | :--- |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 40A | 40580 | 000110-63-4 | 1,4,-Butanediol | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.05 \\ & \mathrm{mg} / \mathrm{kg}(23) \end{aligned}$ |
| 41 | 41040 | 005743-36-2 | Calcium butyrate |  |
| 41A | 41120 | 010043-52-4 | Calcium chloride |  |
| 42 | 41280 | 001305-62-0 | Calcium hydroxide |  |
| 43 | 41520 | 001305-78-8 | Calcium oxide |  |
| 44 | 41600 | 012004-14-7 | Calcium sulphoaluminate |  |
|  |  | 037293-22-4 | "، ، "، ، "، ، ، " |  |
| 44A | 41680 | 000076-22-2 | Camphor | (10) |
| 45 | 41760 | 0008006-44-8 | Candelilla wax |  |
| 45A | 41840 | 00105-60-2 | Caprolactam | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=15 \mathrm{mg} / \\ & \operatorname{kg}(5) \end{aligned}$ |
| 46 | 41960 | 000124-07-2 | Caprylic acid |  |
| 47 | 42160 | 000124-38-9 | Carbon dioxide |  |
| 47A | 42320 | 007492-68-4 | Carbonic acid, copper salt | $\operatorname{SMT}(\mathrm{L})=30 \mathrm{mg} /$ kg (7) (expressed as copper) |
| 48 | 42500 | - | Carbonic acid, salts |  |
| 49 | 42640 | 009000-11-7 | Carboxymethylce | ulose |
| 50 | 42720 | 008015-86-9 | Carnauba wax |  |
| 51 | 42800 | 009000-71-9 | Casein |  |
| 51A | 42880 | 008001-79-4 | Castor oil |  |
| 52 | 42960 | 064147-40-6 | Castor oil, dehydrated |  |
| 53 | 43200 | - | Castor oil, monoand diglycerides |  |
| 54 | 43280 | 009004-34-6 | Cellulose |  |
| 55 | 43300 | 009004-36-8 | Cellulose acetate butyrate |  |
| 56 | 43360 | 068442-85-3 | Cellulose, regenerated |  |
| 57 | 43440 | 008001-75-0 | Ceresin |  |

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| Item | l | 2 | 3 | 4 |
| :--- | :--- | :--- | :--- | :--- |
|  | PM/REF No. | CAS No. | Name | Restrictions and <br> specifications |
| 57A | 43515 | - | Chlorides of <br> choline esters of <br> coconut oil fatty <br> acids | The quantity of <br> this substance <br> in the finished <br> plastic material or <br> article shall not <br> exceed $0.9 \mathrm{mg} / 6$ <br> dm |
|  |  |  |  |  |

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| Item | 1 | 2 | 3 4 |
| :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name Restrictions and specifications |
| 67 | 46375 | 061790-53-2 | Diatomaceous earth |
| 68 | 46380 | 068855-54-9 | Diatomaceous earth. Soda ash flux-calcined |
| 69 | 46480 | 032647-67-9 | Dibenzylidene sorbitol |
| 69A | 46700 | - |  |
| 69B | 46720 | 004130-42-1 | 2,6-Di-tert- $\mathrm{QMA}=4.8 \mathrm{mg} / 6$ <br> butyl-4- <br> ethylphenol $\mathrm{dm}^{2}$ |
| 70 | 46790 | 004221-80-1 | 3,5-Di-tert-butyl-4hydroxybenzoic acid, 2,4-di-tertbutylphenyl ester |
| 71 | 46800 | 067845-93-6 | 3,5-Di-tert- <br> butyl-4- <br> hydroxybenzoic acid, hexadecyl ester |
| 72 | 46870 | 003135-18-0 | $\begin{aligned} & \text { 3,5-Di-tert- } \\ & \text { butyl-4- } \\ & \text { hydroxybenzylphosphonic } \end{aligned}$ |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|  |  |  | acid, dioctadecyl ester |  |
| 72A | 46880 | 065140-91-2 | $\begin{aligned} & \text { 3,5-Di-tert- } \\ & \text { butyl-4- } \\ & \text { hydroxybenzyl } \\ & \text { phosphonic acid, } \\ & \text { moneothyl ester, } \\ & \text { calcium salt } \end{aligned}$ | The specific migration of this substance shall not exceed 6 mg / kg |
| 72B | 47210 | 26427-07-6 | DibutylthiostannoicIn compliance acid polymer [ $=\quad$ with this thiobis(butyl- specifications tin sulphide), laid down in polymer] $\quad$ Schedule 4 |  |
| 73 | 47440 | 000461-58-5 | Dicyanodiamide |  |
| 73 A | 47540 | 027458-90-8 | Di-tert-dodecyl disulfide | $\begin{aligned} & \mathrm{SML}-0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 73B | 47680 | 000111-46-6 | Diethyleneglycol | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=30 \mathrm{mg} / \\ & \operatorname{kg}(3) \end{aligned}$ |
| 73C | 48460 | 000075-37-6 | $1,1-$ <br> Difluoroethane] |  |
| 73D | 48620 | 000123-31-9 | 1,4- <br> Dihydroxybenzene | $\mathrm{SML}=0.6 \mathrm{mg} / \mathrm{kg}$ |
| 73E | 48720 | 000611-99-4 | 4,4'Dihydroxybenzofillelan(in)e= 6 mg / kg (14) |  |
| 73F | 49485 | 134701-20-5 | 2,4- <br> Dimethyl-6-(1methylpentadecyl) phenol | The specific migration of this substance shall not exceed 1 mg / kg |
| 74 | 49540 | 000067-68-5 | Dimethyl sulphoxide |  |
| 75 | 51200 | 000126-58-9 | Dipentaerythritol |  |
| 75A | 51700 | 147315-50-2 | $2-(4,6-$ <br> Diphenyl-1,3,5-triazin-2-yl)-5(hexyloxy) phenol | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 76 | 51760 | 025265-71-8 | Dipropyleneglycol |  |
|  |  | 000110-98-5 | "، "، "، ، " |  |
| 77 | 52640 | 016389-88-1 | Dolomite |  |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 77A | 52645 | 010436-08-5 | Cis-11eicosenamide |  |
| 78 | 52720 | 000112-84-5 | Erucamide |  |
| 79 | 52730 | 000112-86-7 | Erucic acid |  |
| 80 | 52800 | 000064-17-5 | Ethanol |  |
| 81 | 53270 | 037205-99-5 | Ethylcarboxymethylcellulose |  |
| 82 | 53280 | 009004-57-3 | Ethylcellulose |  |
| 83 | 53360 | 000110-31-6 | N,N'- <br> Ethylenebisoleamid |  |
| 84 | 53440 | 005518-18-3 | N,N'- <br> Ethylenebispalmita | mide |
| 85 | 53520 | 000110-30-5 | N,N'- <br> Ethylenebisstearam |  |
| 86 | 53600 | 000060-00-4 | Ethylenediaminetet acid | traacetic |
| 86A | 53610 | 054453-03-1 | Ethylenediaminetet acid, copper salt | tusidetrid) $=30 \mathrm{mg} /$ kg (7) (expressed as copper) (3) |
| 86B | 53650 | 000107-21-1 | Ethyleneglycol | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=30 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 87 | 54005 | 005136-44-7 | $\begin{aligned} & \text { Ethylene-N- } \\ & \text { palmitamide-N'- } \\ & \text { stearamide } \end{aligned}$ |  |
| 88 | 54260 | 009004-58-4 | Ethylhydroxyethylcellulose |  |
| 89 | 54270 | - | Ethylhydroxymethylcellulose |  |
| 90 | 54280 | - | Ethylhydroxypropylcellulose |  |
| 90A | 54300 | 118337-09-0 | 2,2'-Ethylidenebis <br> (4,6-di-tert- <br> butylphenyl) <br> fluorophosphonite | The specific migration of this substance shall not exceed 6 mg / kg |
| 91 | 54450 | - | Fats and oils, from animal or vegetable food sources |  |
| 92 | 54480 | - | Fats and oils, hydrogenated, from animal or |  |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|  |  |  | vegetable food sources | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$ |
| 92A | 54930 | 025359-91-5 | Formaldehyde-1naphthol, copolymer [ = Poly (1-hydroxynaphthylmethane)] |  |
| 93 | 55040 | 000064-18-6 | Formic acid |  |
| 94 | 55120 | 000110-17-8 | Fumaric acid |  |
| 95 | 55190 | 029204-02-2 | Gadoleic acid |  |
| 96 | 55440 | 009000-70-8 | Gelatine |  |
| 97 | 55520 | - | Glass fibres |  |
| 98 | 55600 | - | Glass microballs |  |
| 99 | 55680 | 000110-94-1 | Glutaric acid |  |
| 100 | 55920 | 000056-81-5 | Glycerol |  |
| 101 | 56020 | 099880-64-5 | Glycerol dibehenate |  |
| 102 | 56360 | - | Glycerol, esters with acetic acid |  |
| 103 | 56486 | - | Glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms $\mathrm{C}_{14}-$ $\mathrm{C}_{18}$ ) and with acids, aliphatic, unsaturated, linear, with even number of carbon atoms $\left(\mathrm{C}_{16}-\mathrm{C}_{18}\right)$ |  |
| 104 | 56487 | - | Glycerol, esters with butyric acid |  |
| 105 | 56490 | - | Glycerol, esters with erucic acid |  |
| 106 | 56495 | - | Glycerol, esters with 12hydroxystearic acid |  |

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$\left.\begin{array}{llll}\hline \text { Item } & 1 & 2 & 3 \\ & \text { PM/REF No. } & \text { CAS No. } & \text { Name }\end{array} \begin{array}{l}\text { Restrictions and } \\ \text { specifications }\end{array}\right]$

| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 123 | 52780 | - | Glycerol monopalmitate, ester with citric acid |  |
| 124 | 57600 | - | Glycerol monostearate, ester with ascorbic acid |  |
| 125 | 57680 | - | Glycerol monostearate, ester with citric acid |  |
| 125A | 57800 | 018641-57-1 | Glycerol tribehenate |  |
| 126 | 57920 | 000620-67-7 | Glycerol triheptanoate |  |
| 127 | 58300 | - | Glycine, salts |  |
| 128 | 58320 | 007782-42-5 | Graphite |  |
| 129 | 58400 | 009000-30-0 | Guar gum |  |
| 130 | 58480 | 009000-01-5 | Gum arabic |  |
| 131 | 58720 | 000111-14-8 | Heptanoic acid |  |
| 131A | 59280 | 000100-97-0 | Hexamethylenetetr | asinihe $(T)=15$ <br> $\mathrm{mg} / \mathrm{kg}(21)$ <br> (expressed as Formaldehyde) |
| 132 | 59360 | 000142-62-1 | Hexanoic acid |  |
| 133 | 59760 | 019569-21-2 | Huntite |  |
| 134 | 59990 | 007647-01-0 | Hydrochloric acid |  |
| 135 | 60030 | 012072-90-1 | Hydromagnesite |  |
| 136 | 60080 | 012304-65-3 | Hydrotalcite |  |
| 137 | 60160 | 000120-47-8 | 4Hydroxybenzoic acid, ethyl ester |  |
| 138 | 60180 | 004191-73-5 | 4Hydroxybenzoic acid, isopropyl ester |  |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 139 | 60200 | 000099-76-3 | 4Hydroxybenzoic acid, methyl ester |  |
| 140 | 60240 | 000094-13-3 | 4- <br> Hydroxybenzoic acid, propyl ester |  |
| 140A | 60480 | 003864-99-1 | 2-(2- <br> Hydroxy-3,5,-di-tert-butylphenyl)-5chlorobenzotriazole | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=30 \mathrm{mg} / \\ & \mathrm{kg}(18) \end{aligned}$ |
| 141 | 60560 | 009004-62-0 | Hydroxyethylcellul |  |
| 142 | 60880 | 009032-42-2 | Hydroxyethylmethy | ylcellulose |
| 143 | 61120 | 009005-27-0 | Hydroxyethyl starch |  |
| 144 | 61390 | 037353-59-6 | Hydroxymethylcell | lulose |
| 145 | 61680 | 009004-64-2 | Hydroxypropylce | lose |
| 146 | 61800 | 009049-76-7 | Hydroxypropyl starch |  |
| 146 | 61840 | 000106-14-9 | 12- <br> Hydroxystearic acid |  |
| 148 | 62140 | 006303-21-5 | Hypophosphorous acid |  |
| 149 | 62240 | 001332-37-2 | Iron oxide |  |
| 150 | 62450 | 000078-78-4 | Isopentane |  |
| 151 | 62640 | 008001-39-6 | Japan wax |  |
| 152 | 62720 | 001332-58-7 | Kaolin |  |
| 153 | 62800 | - | Kaolin, calcined |  |
| 154 | 62960 | 000050-21-5 | Lactic acid |  |
| 155 | 63040 | 000138-22-7 | Lactic acid, butyl ester |  |
| 156 | 63280 | 000143-07-7 | Lauric acid |  |
| 157 | 63760 | 008002-43-5 | Lecithin |  |
| 158 | 63840 | 000123-76-2 | Levulinic acid |  |
| 159 | 63920 | 000557-59-5 | Lignoceric acid |  |
| 160 | 64015 | 000060-33-3 | Linoleic acid |  |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 161 | 64150 | 028290-79-1 | Linolenic acid |  |
| 162 | 64500 | - | Lysine, salts |  |
| 163 | 64640 | 001309-42-8 | Magnesium hydroxide |  |
| 164 | 64720 | 001309-48-4 | Magnesium oxide |  |
| 164A | 64800 | 00110-16-7 | Maleic acid | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=30 \mathrm{mg} / \\ & \operatorname{kg}(4) \end{aligned}$ |
| 165 | 65020 | 006915-15-7 | Malic acid |  |
| 166 | 65040 | 000141-82-2 | Malonic acid |  |
| 167 | 65520 | 000087-78-5 | Mannitol |  |
| 167A | 65920 | 066822-60-4 | N methacryloyloxyeth N,N-dimethyl-N-carboxymethylammonium chloride, sodium salt-octadecyl methacrylateethyl methacrylate -cyclohexyl methacrylate-N-vinyl-2pyrrolidone, copolymers | yl- |
| 168 | 66200 | 037206-01-2 | Methylcarboxymeth | hylcellulose |
| 169 | 66240 | 009004-67-5 | Methylcellulose |  |
| 169A | 66560 | 004066-02-8 | 2,2'-Methylenebis <br> (4-methyl-6cyclohexylphenol) | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=3 \mathrm{mg} / \\ & \mathrm{kg}(6) \end{aligned}$ |
| 169B | 66580 | 000077-62-3 | 2,2'-Methylenebis <br> (4-methyl-6-(1-methylcyclohexyl) phenol) | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=3 \mathrm{mg} / \\ & \operatorname{kg}(6) \end{aligned}$ |
| 170 | 66640 | 009004-59-5 | Methylethylcellulos |  |
| 171 | 66695 | - | Methylhydroxymeth | hylcellulose |
| 172 | 66700 | 009004-65-3 | Methylhydroxyprop | pylcellulose |
| 172A | 66755 | 002682-20-4 | 2-Methyl-4-isothiazolin-3-one | The specific migration of this substance shall |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|  |  |  |  | be not detectable (when measured by a method with a limit of detection of 0.02 $\mathrm{mg} / \mathrm{kg}$, analytical tolerance included |
| 173 | 67120 | 012001-26-2 | Mica |  |
| 173B | 67180 | - | Mixture of (50\% w/w) phthalic acid n-decyl noctyl ester, (25\% w/w) phthalic acid di-n-decyl ester, and ( $25 \%$ w/w) phthalic acid di-n-octyl ester | The specific migration of this substance shall not exceed 5 mg / kg (1) |
| 174 | 67200 | 001317-33-5 | Molybdenum disulphide |  |
| 175 | 67840 | - | Montanic acids and/or their esters with ethyleneglycol and/or with 1,3butanediol and/or with glycerol |  |
| 176 | 67850 | 008002-53-7 | Montan wax |  |
| 177 | 67891 | 000544-63-8 | Myristic acid |  |
| 178 | 68040 | 003333-62-8 | $\begin{aligned} & \text { 7-(2H-Naphtho- } \\ & \text { (1,2-D) } \\ & \text { triazol-2-yl)-3- } \\ & \text { phenylcoumarin } \end{aligned}$ |  |
| 178A | 68078 | 027253-31-2 | Neodecanoic acid, cobalt salt | $\operatorname{SML}(T)=0.05$ <br> $\mathrm{mg} / \mathrm{kg}$ (expressed as Neodecanoic acid) and SML(T) $=0.05 \mathrm{mg} / \mathrm{kg}\left({ }^{13}\right.$ ) (expressed as Cobalt). Not for use in polymers contacting foods for which |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|  |  |  |  | simulant D is laid down in Directive 85/572/EEC |
| 179 | 68125 | 037244-96-5 | Nepheline syenite |  |
| 179A | 68145 | 080410-33-9 | 2,2',2'-Nitrilo (triethyl tris (3,3',5,5'- tetra-tert-butyl-1-1'-bi-phenyl-2-2-diyl) phosphite) | The specific migration of this substance shall not exceed 5 $\mathrm{mg} / \mathrm{kg}$ (sum of phosphite and phosphate) |
| 180 | 68960 | 000301-02-0 | Oleamide |  |
| 181 | 69040 | 000112-80-1 | Oleic acid |  |
| 182 | 69760 | 000143-28-2 | Oleyl alcohol |  |
| 182A | 69920 | 000144-62-7 | Oxalic acid | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=6 \mathrm{mg} / \\ & \mathrm{kg}(29) \end{aligned}$ |
| 183 | 70000 | 070331-94-1 | 2,2'- <br> Oxamidobis(ethyl-3- <br> (3,5-di-tert- <br> butyl-4- <br> hydroxyphenyl) <br> propionate) |  |
| 184 | 70240 | 012198-93-5 | Ozokerite |  |
| 185 | 70400 | 000057-10-3 | Palmitic acid |  |
| 186 | 71020 | 000373-49-9 | Palmitoleic acid |  |
| 187 | 71440 | 009000-69-5 | Pectin |  |
| 188 | 71600 | 000115-77-5 | Pentaerythritol |  |
| 188A | 71635 | 025151-96-6 | Pentaerythritol dioleate | The specific migration of this substance shall not exceed 0.05 $\mathrm{mg} / \mathrm{kg}$. Not for use with foods for which simulant D is laid down in Directive 85/572/ EEC |
| 188B | 71670 | 178671-58-4 | Pentaerythritol <br> tetrakis (2- <br> cyano-3,3- <br> diphenylacrylate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.05 \\ & \mathrm{mg} / \mathrm{kg} \end{aligned}$ |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 189 | 71680 | 006683-19-8 | Pentaerythritol tetrakis [-3-(3,5-di-tert-butyl-4hydroxyphenyl) propionate] |  |
| 190 | 71720 | 000109-66-0 | Pentane |  |
| 191 | 72640 | 007664-38-2 | Phosphoric acid |  |
| 191A | 73160 |  | Phosphoric acid, mono- and di-nalkyl (C16 and C18) esters | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.05 \\ & \mathrm{mg} / \mathrm{kg} \end{aligned}$ |
| 191B | 73720 | 000115-96-8 | Phosphoric acid, trichloroethyl | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 $\mathrm{mg} / \mathrm{kg}$, analytical tolerance included |
| 191C | 74010 | 145650-60-8 | Phosphorous acid, bis (2,4-di-tert-butyl-6methylphenyl) ethyl ester | The specific migration of this substance shall not exceed 5 mg / kg (covering the sum of phosphite and phosphate) |
| 192 | 74240 | 031570-04-4 | Phosphorous acid, tris (2,4-di-tertbutylphenyl) ester |  |
| 193 | 74480 | 000088-99-3 | $o$-Phthalic acid |  |
| 194 | 76320 | 000085-44-9 | Phthalic anhydride |  |
| 195A | 76721 | $\begin{aligned} & 009016-00-6 \\ & 063148-62-9 \end{aligned}$ | Polydimethylsiloxa $(\mathrm{Mw}>6800)$ | ana compliance with the specifications laid down in Schedule 4 |
| 195B | 76730 |  | Polydimethylsiloxa gammahydroxypropylated | $\operatorname{abd} y \mathrm{~L}=6 \mathrm{mg} / \mathrm{kg}$ |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 195D | 76865 | - | Polyesters of 1, | SML $=30 \mathrm{mg} / \mathrm{kg}$ |
|  |  |  | 2-propanediol and/or 1,3and/or 1,4butanediol and/or polypropyleneglyco with adipic acid, which may be end-capped with acetic or fatty acids $\mathrm{C}_{12}-\mathrm{C}_{18}$ or n-octanol and/or n-decanol |  |
| 196 | 76960 | 025322-68-3 | Polyethyleneglycol |  |
| 197 | 77600 | 061788-85-0 | Polyethyleneglycol ester of hydrogenated caster oil |  |
| 198 | 77702 | - | Polyethyleneglycol esters of aliphatic monocarboxylic acids ( $\mathrm{C}_{6}-\mathrm{C}_{22}$ ), and their ammonium and sodium sulphates |  |
| 198A | 77895 | 068439-49-6 | Polyethyleneglycol $(\mathrm{EO}=2-6)$ <br> monoalkyl ( $\mathrm{C}_{16}{ }^{-}$ <br> $\mathrm{C}_{18}$ ) ether | $\mathrm{SML}=0.05$ <br> $\mathrm{mg} / \mathrm{kg}$ and in compliance with the specifications laid down in Schedule 4 |
| 199 | 79040 | 009005-64-5 | Polyethyleneglycol sorbitan monolaurate |  |
| 200 | 79120 | 009005-65-6 | Polyethyleneglycol sorbitan monooleate |  |
| 201 | 79200 | 009005-66-7 | Polyethyleneglycol sorbitan monopalmitate |  |
| 202 | 79280 | 009005-67-8 | Polyethyleneglycol sorbitan monostearate |  |

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$\left.\begin{array}{llll}\hline \text { Item } & 1 & 2 & 3 \\ & \text { PM/REF No. } & \text { CAS No. } & \text { Name }\end{array} \quad \begin{array}{l}\text { Restrictions and } \\ \text { specifications }\end{array}\right]$

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 209 | 81520 | 007758-02-3 | Potassium bromide |  |
| 210 | 81660 | 001310-58-3 | Potassium hydroxide |  |
| 210A | 81760 | - | Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron | $\operatorname{SML}(\mathrm{T})=30 \mathrm{mg} /$ kg (7) (expressed as copper); the specific migration of this substance shall not exceed 48 $\mathrm{mg} / \mathrm{kg}$ (expressed as iron) |
| 211 | 81840 | 000057-55-6 | 1,2-Propanediol |  |
| 212 | 81882 | 000067-63-0 | 2-Propanol |  |
| 213 | 82000 | 000079-09-4 | Propionic acid |  |
| 214 | 82080 | 009005-37-2 | 1,2- <br> Propyleneglycol alginate |  |
| 215 | 82240 | 022788-19-8 | 1,2- <br> Propyleneglycol dilaurate |  |
| 216 | 82400 | 000105-62-4 | 1,2- <br> Propyleneglycol dioleate |  |
| 217 | 82560 | 033587-20-1 | 1,2- <br> Propyleneglycol dipalmitate |  |
| 218 | 82720 | 006182-11-2 | 1,2- <br> Propyleneglycol distearate |  |
| 219 | 82800 | 027194-74-7 | 1,2Propyleneglycol monolaurate |  |
| 220 | 82960 | 001330-80-9 | 1,2- <br> Propyleneglycol monooleate |  |
| 221 | 83120 | 029013-28-3 | 1,2Propyleneglycol monopalmitate |  |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 222 | 83300 | 001323-39-3 | 1,2- <br> Propyleneglycol monostearate |  |
| 223 | 83320 | - | Propylhydroxyethylcellulose |  |
| 224 | 83325 | - | Propylhydroxymethylcellulose |  |
| 225 | 83330 | - | Propylhydroxypropylcellulose |  |
| 226 | 83440 | 002466-09-3 | Pyrophosphoric acid |  |
| 227 | 83455 | 013445-56-2 | Pyrophosphorous acid |  |
| 228 | 83460 | 012269-78-2 | Pyrophyllite |  |
| 229 | 83470 | 014808-60-7 | Quartz |  |
| 229A | 83599 | 068442-12-6 | Reaction products of oleic acid, 2mercaptoethyl ester, with dichlorodimethyltin sodium sulphide and trichloromethyltin | $\operatorname{SML}(T)=0.18$ <br> $\mathrm{mg} / \mathrm{kg}$ (15) <br> (expressed as tin) |
| 230 | 83610 | 073138-82-6 | Resin acids and rosin acids |  |
| 231 | 83840 | 008050-09-6 | Rosin |  |
| 232 | 84000 | 008050-31-5 | Rosin, ester with glycerol |  |
| 233 | 84080 | 008050-26-8 | Rosin, ester with pentaerythritol |  |
| 234 | 84210 | 065997-06-0 | Rosin, hydrogenated |  |
| 235 | 84240 | 065997-13-9 | Rosin, hydrogenated, ester with glycerol |  |
| 236 | 84320 | 008050-15-5 | Rosin, hydrogenated, ester with methanol |  |
| 237 | 84400 | 064365-17-9 | Rosin, hydrogenated, |  |


| Item | l | 2 | 3 | 4 |
| :--- | :--- | :--- | :--- | :--- |
|  | PM/REF No. | CAS No. | Name | Restrictions and <br> specifications |
|  |  |  | ester with <br> pentaerythritol |  |
| 238 | 84560 | $009006-04-6$ | Rubber, natural |  |
| 249 | 84640 | - | $000069-72-7$ | Salicylic acid |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 249 | 87520 | 062568-11-0 | Sorbitan monobehenate |  |
| 250 | 87600 | 001338-39-2 | Sorbitan monolaurate |  |
| 251 | 87680 | 001338-43-8 | Sorbitan monooleate |  |
| 252 | 87760 | 026266-57-9 | Sorbitan monopalmitate |  |
| 253 | 87840 | 001338-41-6 | Sorbitan monostearate |  |
| 254 | 87920 | 061752-68-9 | Sorbitan tetrastearate |  |
| 255 | 88080 | 026266-58-0 | Sorbitan trioleate |  |
| 256 | 88160 | 054141-20-4 | Sorbitan tripalmitate |  |
| 257 | 88240 | 026658-19-5 | Sorbitan tristearate |  |
| 258 | 88320 | 000050-70-4 | Sorbitol |  |
| 259 | 88600 | 026836-47-5 | Sorbitol monstearate |  |
| 259A | 88640 | 008013-07-8 | Soybean oil, epoxidized | In compliance with the specifications laid down in Schedule 4 |
| 260 | 88800 | 009005-25-8 | Starch, edible |  |
| 261 | 88880 | 068412-29-3 | Starch, hydrolysed |  |
| 262 | 88960 | 000125-26-5 | Stearamide |  |
| 263 | 89040 | 000057-11-4 | Stearic acid |  |
| 263A | 89200 | 007617-31-4 | Stearic acid, copper salt | $\operatorname{SML}(\mathrm{T})=30 \mathrm{mg} /$ <br> kg (7) (expressed as copper) |
| 263B | 89440 | - | Stearic acid, esters with ethyleneglycol | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=30 \mathrm{mg} / \\ & \operatorname{kg}(3) \end{aligned}$ |
| 264 | 90720 | 058446-52-9 | Stearoylbenzoylm | thane |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
| 265 | 90800 | 005793-94-2 | Stearoyl-2lactylic acid, calcium salt |  |
| 266 | 90960 | 000110-15-6 | Succinic acid |  |
| 267 | 91200 | 000126-13-6 | Sucrose acetate isobutyrate |  |
| 268 | 91360 | 000126-14-7 | Sucrose octaacetate |  |
| 269 | 91840 | 007704-34-9 | Sulphur |  |
| 270 | 91920 | 007664-93-9 | Sulphuric acid |  |
| 270A | 92030 | 010124-44-4 | Sulphuric acid, copper salt | $\operatorname{SML}(\mathrm{T})=30 \mathrm{mg} /$ kg (7) (expressed as copper) |
| 271 | 92080 | 014807-96-6 | Talc |  |
| 271A | 92150 | 001401-55-4 | Tannic acids | According to the JECFA specifications |
| 272 | 92160 | 000087-69-4 | Tartaric acid |  |
| 273 | 92195 | - | Taurine, salts |  |
| 274 | 92205 | 057569-40-1 | Terephthalic acid, diester with 2,2'methylenebis (4-methyl-6-tertbutylphenol) |  |
| 275 | 92350 | 000112-60-7 | Tetraethyleneglycol |  |
| 276 | 92640 | 000102-60-3 | N,N,N', N'- <br> Tetrakis (2hydroxypropyl) ethylenediamine |  |
| 276A | 92700 | 078301-43-6 | 2,2,4,4- <br> Tetramethyl-20-(2,3-epoxypropyl)-7-оха-3,20-diazadispiro-[5.1.11.2]-heneicosan-21one, polymer | The specific migration of this substance shall not exceed 5 mg / kg |
| 276B | 92930 | 120218-34-0 | Thiodiethanolbis (5-methoxycarbonyl-2 | The specific migration of this ,̧tbstance shall |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|  |  |  | dimethyl-1,4-dihydropridine-3carboxylate) | not exceed $6 \mathrm{mg} /$ kg |
| 277 | 93440 | 013463-67-7 | Titanium dioxide |  |
| 278 | 93520 | 000059-02-9 | alpha-Tocopherol |  |
|  |  | 010191-41-0 | ، "، ، ، ، ، " |  |
| 279 | 93680 | 009000-65-1 | Tragacanth gum |  |
| 279A | 93720 | 000108-78-1 | $2,4,6-$ <br> Triamino-1,3,5triazine | $\mathrm{SML}=30 \mathrm{mg} / \mathrm{kg}$ |
| 280 | 94320 | 000112-27-6 | Triethyleneglycol |  |
| 280A | 94960 | 000077-99-6 | $1,1,1-$ <br> Trimethylolpropan | The specific emigration of this substance shall not exceed 6 mg / kg |
| 280B | 95000 | 028931-67-1 | Trimethylolpropane trimethacrylatemethyl methacrylate copolymer] |  |
| 281 | 95200 | 001709-70-2 | 1,3,5- <br> Trimethyl-2,4,6tris (3,5-di-tert-butyl-4hydroxybenzyl) benzene |  |
| 281A | 95270 | 161717-32-4 | 2,4,6-Tris(tertbutyl) phenyl 2-butyl-2-ethyl-1,3propanediol phosphite | $\begin{aligned} & \mathrm{SML}=2 \mathrm{mg} / \\ & \mathrm{kg}(\text { as sum } \\ & \text { of phosphite, } \\ & \text { phosphate and } \\ & \text { the hydrolysis } \\ & \text { product = TTBP) } \end{aligned}$ |
| 281B | 95725 | 110638-71-6 | Vermiculite, reaction product with citric acid, lithium salt | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (8) (expressed as lithium) |
| 281C | 95855 | 007732-18-5 | Water | In compliance with Directive 98/83/EC |
| 281D | 95859 | - | Waxes, refined, derived from petroleum based | In compliance with the specifications |


| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REF No. | CAS No. | Name | Restrictions and specifications |
|  |  |  | or synthetic hydrocarbon feedstocks | laid down in Schedule 4 |
| 281E | 95883 | - | White mineral oils, paraffinic, derived from petroleum based hydrocarbon deedstocks | In compliance with the specifications laid down in Schedule 4 |
| 282 | 95905 | 013983-17-0 | Wollastonite |  |
| 283 | 95920 | - | Wood flour and fibres, untreated |  |
| 284 | 95935 | 011138-66-2 | Xanthan gum |  |
| 285 | 91690 | 020427-58-1 | Zinc hydroxide |  |
| 286 | 96240 | 001314-13-2 | Zinc oxide |  |
| 287 | 96320 | 001314-98-3 | Zinc sulphide |  |

## PART 2

Incomplete List of Additives Used in the Manufacture of Plastic Materials and Articles (Being Additives to which Paragraphs 5 of Part 3 of this Schedule Applies)

## Commencement Information

I31 Sch. 2 Pt. 2 in operation at 30.6.2006, see reg. 1
\(\left.$$
\begin{array}{lllll}\hline \text { Item } & \text { PM/REFNo. } & \text { CAS No } & \text { Name } & \begin{array}{l}\text { Restrictions and } \\
\text { specifications }\end{array} \\
\hline 1 & 30180 & 002180-18-9 & \begin{array}{l}\text { Acetic acid, } \\
\text { manganese salt }\end{array} & \begin{array}{l}\text { SML(T) }= \\
0.6 \mathrm{mg} / \mathrm{kg}(9) \\
\text { (expressed as }\end{array} \\
2 & 31520 & 061167-58-6 & \begin{array}{l}\text { Acrylic acid, } \\
\text { manganese) }\end{array}
$$ \& SML=6 \mathrm{mg} / \mathrm{kg} <br>

2-tert-butyl-6-\end{array}\right]\)| (3-tert- butyl- |
| :--- |
| 2-hydroxy-5- |
| methylbenzyl)-4- |
| methylphenyl |
| ester |

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| :---: | :---: | :---: | :---: | :---: |
|  | PM/REFNo. | CAS No | Name | Restrictions and specifications |
| 3 | 31920 | 000103-23-1 | Adipic acid, bis (2-ethylhexyl) ester | $\mathrm{SML}=18 \mathrm{mg} / \mathrm{kg}$ <br> (1) |
| 4 | 34230 |  | Alkyl ( $\mathrm{C}_{8}-\mathrm{C}_{22}$ ) sulphonic acids | $\mathrm{SML}=6 \mathrm{mg} / \mathrm{kg}$ |
| 4A | 34650 | 151841-65-5 | Aluminium hydroxybis [2,2'methylenebis (4,6-di-tertbutylphenyl) phospate | $\mathrm{SML}=5 \mathrm{mg} / \mathrm{kg}$ |
| 5 | 35760 | 001309-64-4 | Antimony trioxide | $\begin{aligned} & \mathrm{SML}=0.02 \mathrm{mg} / \\ & \mathrm{kg} \text { (expressed } \\ & \text { as anti-monium } \\ & \text { and analytical } \\ & \text { tolerance } \\ & \text { included) } \end{aligned}$ |
| 6 | 36720 | 017194-00-2 | Barium hydroxide | $\operatorname{SML}(T)=1$ <br> $\mathrm{mg} / \mathrm{kg}$ (11) <br> (expressed as barium) |
| 7 | 36800 | 010022-31-8 | Barium nitrate | $\operatorname{SML}(T)=1$ <br> $\mathrm{mg} / \mathrm{kg}$ (11) (expressed as barium) |
| 7A | 38000 | 000553-54-8 | Benzoic acid, lithium salt | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (8) (expressed as lithium) |
| 8 | 38240 | 000119-61-9 | Benzophenone | $\mathrm{SML}=0.6 \mathrm{mg} / \mathrm{kg}$ |
| 9 | 38560 | 007128-64-5 | 2,5-Bis (5-tert-butyl-2benzoxazolyl) thio-phene | $\mathrm{SML}=0.6 \mathrm{mg} / \mathrm{kg}$ |
| 10 | 38700 | 063397-60-4 | Bis (2carbobutoxyethyl) tin- bis (isooctylmercaptoacetate) | $\mathrm{SML}=18 \mathrm{mg} / \mathrm{kg}$ |
| 11 | 38800 | 032687-78-8 | N,N'-Bis (3-(3,5- <br> di-tert-butyl-4hydroxyphenyl) | $\mathrm{SML}=15 \mathrm{mg} / \mathrm{kg}$ |

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|  | PM/REFNo. | CAS No | Name | Restrictions and specifications |
|  |  |  | pro-pionyl) hydrazide |  |
| 12 | 38820 | 026741-53-7 | Bis (2,4-di-tertbutylphenyl) pentaery-thritol diphosphite | $\mathrm{SML}=0.6 \mathrm{mg} / \mathrm{kg}$ |
| 13 | 39060 | 035958-30-6 | 1,1-Bis (2-hydroxy-3, 5-di-tert-butylphenyl) ethane | SML $=5 \mathrm{mg} / \mathrm{kg}$ |
| 14 | 39090 |  | N,N-bis (2hydroxyethyl) alkyl ( $\mathrm{C}_{8}-\mathrm{C}_{18}$ ) amine | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=1.2 \\ & \mathrm{mg} / \mathrm{kg}(12) \end{aligned}$ |
| 15 | 39120 |  | N,N-bis (2-hydroxyethyl)alkyl ( $\mathrm{C}_{8}$ $\mathrm{C}_{18}$ ) amine hydrochlorides | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=1.2 \\ & \mathrm{mg} / \mathrm{kg}(12) \\ & \text { expressed as } \\ & \text { tertiary amine } \\ & \text { (expressed } \\ & \text { excluding } \mathrm{HCI} \text { ) } \end{aligned}$ |
| 16 | 40000 | 00991-84-4 | $\begin{aligned} & \text { 2,4-Bis } \\ & \text { (octylmercapto) } \\ & \text { - 6-(4-hydroxy- } \\ & \text { 3,5,di-tert- } \\ & \text { butylanilino) - } \\ & \text { 1,3,5-triazine } \end{aligned}$ | $\mathrm{SML}=30 \mathrm{mg} / \mathrm{kg}$ |
| 17 | 40020 | 110553-27-0 | $\begin{aligned} & \text { 2,4-Bis } \\ & \text { (octylthiomethyl) } \\ & -6 \text {-methylphenol } \end{aligned}$ | $\mathrm{SML}=6 \mathrm{mg} / \mathrm{kg}$ |
| 18 | 40160 | 61269-61-2 | N,N'-bis (2,2,6,6-tetramethyl-4piperidyl) hexamethy-lenediamine- 1,2dibromoethane,cop | $\mathrm{SML}=2.4 \mathrm{mg} / \mathrm{kg}$ |
| 18A | 40720 | 025013-16-5 | Tert-butyl-4hydroxyanisole (= BHA) | $\mathrm{SML}=30 \mathrm{mg} / \mathrm{kg}$ |
| 19 | 40800 | 13003-12-8 | 4,4' - butylidenebis (6-tert-butyl-3-methylphenylditridecyl phosphite) | $\mathrm{SML}=6 \mathrm{mg} / \mathrm{kg}$ |

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|  | PM/REFNo. | CAS No | Name | Restrictions and specifications |
| 20 | 409080 | 19664-95-0 | Butyric acid, manganese salt | SML(T) = <br> $0.6 \mathrm{mg} / \mathrm{kg}(9)$ (expressed as manganese) |
| 21 | 42000 | 63438-80-2 | (2carbobutoxyethyl) tin-tris (isooctylmercaptoacetate) | $\mathrm{SML}=30 \mathrm{mg} / \mathrm{kg}$ |
| 22 | 42400 | 010377-37-4 | Carbonic acid, lithium salt | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (8) (expressed as lithium) |
| 23 | 42480 | 000584-09-8 | Carbonic acid, rubidium salt | $\mathrm{SML}=12 \mathrm{mg} / \mathrm{kg}$ |
| 24 | 43600 | 004080-31-3 | 1- (3- <br> Chloroallyl) - 3,5,7 - triaza-1- <br> azoniaadamantane chloride | $\mathrm{SML}=0.3 \mathrm{mg} / \mathrm{kg}$ |
| 25 | 43680 | 000075-45-6 | Chlorodifluorometh | $h S M E L=6 \mathrm{mg} /$ <br> kg and in compliance with the specifications laid down in Schedule 4 |
| 26 | 44960 | 011104-61-3 | Cobalt oxide | $\operatorname{SML}(T)=0.05$ <br> $\mathrm{mg} / \mathrm{kg}$ (13) (expressed as cobalt) |
| 27 | 45440 | - | Cresols, butylated, styrenated | $\mathrm{SML}=12 \mathrm{mg} / \mathrm{kg}$ |
| 27A | 45650 | 06197-30-4 | 2-Cyano-3,3diphenylacrylic acid, 2-ethylhexyl ester | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 27B | 46640 | 000128-37-0 | 2,6-di-tert-butyl-p-cresol (= BHT) | $\mathrm{SML}=3.0 \mathrm{mg} / \mathrm{kg}$ |
| 29 | 47600 | 084030-61-5 | Di-n-dodecyltin bis (isooctyl mercaptoacetate) | $\mathrm{SML}=12 \mathrm{mg} / \mathrm{kg}$ |

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|  | PM/REFNo. | CAS No | Name | Restrictions and specifications |
| 30 | 48640 | 000131-56-6 | $2,4-$ <br> Dihydroxybenzoph | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=6 \mathrm{mg} / \\ & \text { hdvg(184) } \end{aligned}$ |
| 31 | 48800 | 000097-23-4 | 2,2'- <br> Dihydroxy-5,5'dichlorodiphenylm | $\begin{aligned} & \mathrm{SML}=12 \mathrm{mg} / \mathrm{kg} \\ & \text { nethane } \end{aligned}$ |
| 32 | 48880 | 000131-53-3 | 2,2'Dihydroxy-4methoxybenzophe | $\begin{aligned} & \operatorname{SML}(T)=6 \mathrm{mg} / \\ & \text { nligge }(14) \end{aligned}$ |
| 33 | 49600 | 026636-01-1 | Dimethyltin bis (isooctyl mercaptoaecetate) | $\begin{aligned} & \mathrm{SMT}(\mathrm{~T}) 0.18 \\ & \mathrm{mg} / \mathrm{kg}(15) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 34 | 49840 | 002500-88-1 | Dioctadecyl disulphide | $\mathrm{SMT}=3 \mathrm{mg} / \mathrm{kg}$ |
| 35 | 50160 |  | Di-n-octyltin bis(n-alkyl ( $\mathrm{C}_{10}$ $-\mathrm{C}_{16}$ ) mercapto acetate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & (\text { expressed as tin }) \end{aligned}$ |
| 36 | 50240 | 010039-33-5 | Di-n-octyltin bis (2-ethylhexyl maleate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 37 | 50320 | 015571-58-1 | Di-n-octyltin bis (2-ethylhexyl mercaptoaectate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 38 | 50360 |  | Di-n-octyltin bis (ethyl maleate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 39 | 50400 | 033568-99-9 | Di-n-octyltin bis (isooctyl maleate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & (\text { expressed as tin) } \end{aligned}$ |
| 40 | 50480 | 026401-97-8 | Di-n-octyltin bis (isooctyl mercaptoacetate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 41 | 50560 |  | Di-n-octyltin 1,4butanediol bis (mercaptoacetate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 42 | 50640 | 003648-18-8 | Di-n-octyltin dilaurate | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 43 | 50720 | 015571-60-5 | Di-n-octyltin dimaleate | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & \text { (expressed as tin) } \end{aligned}$ |


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|  | PM/REFNo. | CAS No | Name | Restrictions and specifications |
| 44 | 50800 |  | Di-n-octyltin dimaleate, esterified | $\operatorname{SML}(T)=0.04$ <br> $\mathrm{mg} / \mathrm{kg}$ (16) <br> (expressed as tin) |
| 45 | 50880 |  | Di-n-octyltin dimaleate, polymers ( $\mathrm{n}=$ 2-4) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & (\text { expressed as tin) } \end{aligned}$ |
| 46 | 50960 | 69226-44-4 | Di-n0octyltin ethyleneglycol bis (mercaptoacetate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & (\text { expressed as tin) } \end{aligned}$ |
| 47 | 51040 | 15535-79-2 | Di-n-octyltin mercaptoacetate | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.04 \\ & \mathrm{mg} / \mathrm{kg}(16) \\ & (\text { expressed as tin) } \end{aligned}$ |
| 48 | 51120 |  | Di-n-octyltin thiobenzoate 2-ethyl-hexyl mercaptoacetate | $\operatorname{SML}(T)=0.04$ <br> $\mathrm{mg} / \mathrm{kg}$ (16) <br> (expressed as tin) |
| 49 | 51570 | 000127-63-9 | Diphenyl sulphone | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=3 \mathrm{mg} / \\ & \mathrm{kg}(24) \end{aligned}$ |
| 50 | 51680 | 000102-08-9 | $\mathrm{N}, \mathrm{N}^{\prime}-$ diphenylthiourea | SML $=3 \mathrm{mg} / \mathrm{kg}$ |
| 51 | 52000 | 027176-87-0 | Dodecylbenzenesu acid | LPAMWie $=30 \mathrm{mg} / \mathrm{kg}$ |
| 52 | 52320 | 052047-59-3 | 2-(4- <br> Dodecylphenyl) indole | $\begin{aligned} & \mathrm{SML}=0.06 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 53 | 52880 | 023676-09-7 | 4-Ethoxybenzoic acid, ethyl ester | $\mathrm{SML}=3.6 \mathrm{mg} / \mathrm{kg}$ |
| 54 | 53200 | 023949-66-8 | 2-Ethoxy-2'ethyloxanilide | $\mathrm{SML}=30 \mathrm{mg} / \mathrm{kg}$ |
| 54A | 54880 | 000050-00-0 | Formaldehyde | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=15 \mathrm{mg} / \\ & \operatorname{kg}\left({ }^{21}\right) \end{aligned}$ |
| 54B | 55200 | 001166-52-5 | Gallic acid, dodecyl ester | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=30 \mathrm{mg} / \\ & \operatorname{kg}\left({ }^{34}\right) \end{aligned}$ |
| 54C | 55280 | 001034-01-1 | Gallic acid, octyl ester | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=30 \mathrm{mg} / \\ & \operatorname{kg}\left({ }^{34}\right) \end{aligned}$ |
| 54D | 55360 | 000121-79-9 | Gallic acid, propyl ester | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=30 \mathrm{mg} / \\ & \operatorname{kg}\left({ }^{34}\right) \end{aligned}$ |
| 55 | 58960 | 000057-09-0 | Hexadecyltrimethy bromide | 18imithorifomg $/ \mathrm{kg}$ |

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| 56 | 59120 | 023128-74-7 | 1,6- <br> Hexamethylenebis (3- (3,5-di-tert-butyl-4hydroxyphenyl) propionamide) | $\mathrm{SML}=45 \mathrm{mg} / \mathrm{kg}$ |
| 57 | 59200 | 035074-77-2 | 1,6- <br> Hexamethylenebis (3- (3,5-di-tert-butyl-4hydroxyphenyl) propionate | SML $=6 \mathrm{mg} / \mathrm{kg}$ |
| 58 | 60320 | 070321-86-7 | $\begin{aligned} & \text { 2- (2- } \\ & \text { Hydroxy-3,5- } \\ & \text { bis }(1,1- \\ & \text { dimethylbenzyl) } \\ & \text { phenyl) } \\ & \text { benzotriazole } \end{aligned}$ | $\mathrm{SML}=1.5 \mathrm{mg} / \mathrm{kg}$ |
| 59 | 60400 | 003896-11-5 | ```2- (2'-Hydroxy-3'- tert-butyl- 5'- methylphenyl) -5- chlorobenzotriazole``` | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=30 \\ & \mathrm{mg} . / \mathrm{kg}(18) \end{aligned}$ |
| 60 | 60800 | 065447-77-0 | 1-(2- <br> Hydroxyethyl) - <br> 4-hydroxy- 2,2, <br> 6,6-tetramethyl, <br> pipe ridinesuccinic acid, dimethyl ester, copolymer | $\mathrm{SML}=30 \mathrm{mg} / \mathrm{kg}$ |
| 61 | 61280 | 003293-97-8 | 2-Hydroxy-4-nhexyloxybenzophe | $\begin{aligned} & \operatorname{SML}(\mathrm{T})=6 \mathrm{mg} / \\ & \text { nlog(14) } \end{aligned}$ |
| 62 | 61360 | 000131-57-7 | 2-Hydroxy-4methoxybenzophen | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=6 \mathrm{mg} / \\ & \text { ndrgeg (14) } \end{aligned}$ |
| 63 | 61440 | 002440-22-4 | $\begin{aligned} & \text { 2-(2-Hydroxy-5- } \\ & \text { methylphenyl) } \\ & \text { benzotriazole } \end{aligned}$ | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=30 \mathrm{mg} / \\ & \operatorname{kg}(18) \end{aligned}$ |
| 64 | 61600 | 001843-05-6 | 2-Hydroxy-4-noctyloxybenzophen | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=6 \mathrm{mg} / \\ & \text { ndrged }(14) \end{aligned}$ |
| 65 | 63200 | 051877-53-3 | Lactic acid, manganese salt | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}(9)$ (expressed as manganese) |

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| 66 | 64320 | 010377-51-2 | Lithium iodide | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=1 \\ & \mathrm{mg} / \mathrm{kg}(10) \\ & \text { (expressed as } \\ & \text { iodium) and } \\ & \mathrm{SML}(\mathrm{~T})= \end{aligned}$ |
|  |  |  |  | $0.6 \mathrm{mg} / \mathrm{kg}\left({ }^{8}\right)$ (expressed as lithium) |
| 67 | 65120 | 007773-01-5 | Manganese chloride | $\operatorname{SML}(\mathrm{T})=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (9) (expressed as manganese) |
| 68 | 65200 | 012626-88-9 | Manganese hydroxide | $\operatorname{SML}(\mathrm{T})=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (9) (expressed as manganese |
| 69 | 65280 | 010043-84-2 | Manganese hypophosphite | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (9) (expressed as manganese |
| 70 | 65360 | 011129-60-5 | Manganese oxide | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}(9)$ (expressed as manganese |
| 71 | 65440 |  | Manganese pyrophosphite | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (9) (expressed as manganese |
| 72 | 66360 | 085209-91-2 | 2-2'-Methylene bis (4,6-di-tertbutylphenyl) sodium phosphate | $\mathrm{SML}=5 \mathrm{mg} / \mathrm{kg}$ |
| 73 | 66400 | 000088-24-4 | 2-2'-Methylenbis (4-ethyl-6-tertbutylphenol) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=1.5 \\ & \mathrm{mg} / \mathrm{kg}(19) \end{aligned}$ |
| 74 | 66480 | 000119-47-1 | 2-2'- Methylenbis (4-methyl-6-tertbutylphenol) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=1.5 \\ & \mathrm{mg} / \mathrm{kg}(19) \end{aligned}$ |
| 75 | 67360 | 067649-65-4 | Mono-ndodecyltin tris (isooctyl mercaptoacetate) | $\mathrm{SML}=24 \mathrm{mg} / \mathrm{kg}$ |

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|  | PM/REFNo. | CAS No | Name | Restrictions and specifications |
| 76 | 67520 | 054849-38-6 | Monomethyltin tris (isooctyl mercaptoacetate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=0.18 \\ & \mathrm{mg} / \mathrm{kg}(15) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 77 | 67600 |  | Mono-n-octyltin tris (alkyl ( $\mathrm{C}_{10}-\mathrm{C}_{16}$ ) mercaptoacetate | $\operatorname{SML}(T)=1.2$ <br> $\mathrm{mg} / \mathrm{kg}$ (17) <br> (expressed as tin) |
| 78 | 67680 | 027107-89-7 | Mono-n-octyltin tris (2-ethylhexyl mercaptoacetate | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=1.2 \\ & \mathrm{mg} / \mathrm{kg}(17) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 79 | 67760 | 026401-86-5 | Mono-n-octyltin tris (isooctyl mercaptoacetate) | $\begin{aligned} & \mathrm{SML}(\mathrm{~T})=1.2 \\ & \mathrm{mg} / \mathrm{kg}(17) \\ & \text { (expressed as tin) } \end{aligned}$ |
| 79A | 67896 | 020336-96-3 | Myristic acid, lithium salt | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (8) (expressed as lithium) |
| 81 | 68320 | 002082-79-3 | Octadecyl 3- (3,5-di-tert-butyl-4hydroxylphenyl) propionate | $\mathrm{SML}=6 \mathrm{mg} / \mathrm{kg}$ |
| 82 | 68400 | 010094-45-8 | Octadecylerucamid | SML $=5 \mathrm{mg} / \mathrm{kg}$ |
| 82A | 68860 | 004724-48-5 | nOctylphosphonic acid | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg} \end{aligned}$ |
| 83 | 69840 | 016260-09-6 | Oleylpalmitamide | SML $=5 \mathrm{mg} / \mathrm{kg}$ |
| 83A | 71935 | 007601-89-0 | Perchloric acid, sodium salt monohydrate | $\begin{aligned} & \mathrm{SML}=0.05 \mathrm{mg} / \\ & \mathrm{kg}(31) \end{aligned}$ |
| 84 | 72160 | 000948-65-2 | 2-Phenylindole | SML $=15 \mathrm{mg} / \mathrm{kg}$ |
| 85 | 72800 | 001241-94-7 | Phosphoric acide, diphenyl 2ethylhexyl ester | $\mathrm{SML}=2.4 \mathrm{mg} / \mathrm{kg}$ |
| 86 | 73040 | 013763-32-1 | Phosphoric acid, lithium salts | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (8) (expressed as lithium) |
| 87 | 73120 | 010124-54-6 | Phosphoric acid, manganese sale | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (9) (expressed as manganese |

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| 88 | 74400 |  | Phosphorous acid, tris (nonyl- and/ or dinonylphenyl) ester | $\mathrm{SML}=30 \mathrm{mg} / \mathrm{kg}$ |
| 88A | 76680 | 068132-00-3 | Polycyclopentadien hydrogenated | $\mathrm{n} \&, \mathrm{ML}=5 \mathrm{mg} / \mathrm{kg}$ <br> (1) |
| 89 | 77440 |  | Polyethyleneglycol diricinoleate | $1 \mathrm{SML}=42 \mathrm{mg} / \mathrm{kg}$ |
| 90 | 77520 | 061791-12-6 | Polyethyleneglycol ester of caster oil | $1 \mathrm{SML}=42 \mathrm{mg} / \mathrm{kg}$ |
| 91 | 78320 | 009004-97-1 | Polyethyleneglycol monoricinoleate | $1 \mathrm{SML}-42 \mathrm{mg} / \mathrm{kg}$ |
| 92 | 81200 | 071878-19-8 | Poly [6- [1,1,3,3tetramethylbutyl) - amino]- 1,3,5-triazine-2,4-diyl]- [(2,2,6,6-tetramethyl- 4-piperidyl)-imino] hexamethylene-[2,2,6,6-tetramethyl-4piperidyl) imino] | $\mathrm{SML}=3 \mathrm{mg} / \mathrm{kg}$ |
| 93 | 81680 | 007681-11-0 | Potassium iodide | $\operatorname{SML}(T)=1$ <br> $\mathrm{mg} / \mathrm{kg}$ (10) (expressed as iodium) |
| 94 | 82020 | 019019-51-3 | Propionic acid, cobalt salt | $\operatorname{SML}(T)=0.05$ <br> $\mathrm{mg} / \mathrm{kg}$ (13) (expressed as cobalt) |
| 95 | 83595 | 119345-01-6 | Reaction product of di-tertbutylphosphonite with biphenyl, obtained by condensation of 2,4-di-tertbutylphenol with Friedel Craft reaction product of phosphorus trichloride and biphenyl | $\mathrm{SML}=18$ <br> $\mathrm{mg} / \mathrm{kg}$ and in compliance with the specifications in Schedule 4 |

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| Item | 1 | 2 | 3 | 4 |
| :---: | :---: | :---: | :---: | :---: |
|  | PM/REFNo. | CAS No | Name | Restrictions and specifications |
| 96 | 83700 | 000141-22-0 | Ricinoleic acid | $\mathrm{SML}=42 \mathrm{mg} / \mathrm{kg}$ |
| 97 | 84800 | 000087-18-3 | Salicylic acid, 4-tert-butylphenyl ester | $\mathrm{SML}=12 \mathrm{mg} / \mathrm{kg}$ |
| 98 | 84880 | 000119-36-8 | Salicylic acid, methyl ester | $\mathrm{SML}=30 \mathrm{mg} / \mathrm{kg}$ |
| 99 | 85760 | 012068-40-5 | Silicic acid, lithium aluminium salt (2:1:1) | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (8) (expressed as lithium) |
| 100 | 85920 | 012627-14-4 | Silicic acid, lithium salt | $\operatorname{SML}(T)=$ <br> $0.6 \mathrm{mg} / \mathrm{kg}$ (8) (expressed as lithium) |
| 100A | 86480 | 007631-90-5 | Sodium bisulphite | $\operatorname{SML}(T)=10$ <br> $\mathrm{mg} / \mathrm{kg}$ (30) (expressed as $\mathrm{SO}_{2}$ ) |
| 101 | 86800 | 007681-82-5 | Sodium iodide | $\operatorname{SML}(T)=1$ <br> $\mathrm{mg} / \mathrm{kg}$ (10) (expressed as iodium) |
| 102 | 86880 |  | Sodium monoalkyl dialkylphenoxyben sulphonate | $\mathrm{SML}=9 \mathrm{mg} / \mathrm{kg}$ <br> zenedi- |
| 102A | 86920 | 007632-00-0 | Sodium nitrite | $\mathrm{SML}=0.6 \mathrm{mg} / \mathrm{kg}$ |
| 102B | 86960 | 007757-83-7 | Sodium sulphite | $\operatorname{SML}(T)=10 \mathrm{mg} /$ $\mathrm{kg}(30)$ expressed as $\mathrm{SO}_{2}$ ) |
| 102C | 87120 | 07772-98-7 | Sodium thiosulphate | $\operatorname{SML}(\mathrm{T})=10 \mathrm{mg} /$ kg (30) expressed as $\mathrm{SO}_{2}$ ) |
| 103 | 89170 | 013586-84-0 | Stearic acid, cobalt salt | $\operatorname{SML}(T)=0.05$ <br> $\mathrm{mg} / \mathrm{kg}$ (13) expressed as cobalt) |
| 104 | 92000 | 007727-43-7 | Sulphuric acid, barium salt | $\operatorname{SML}(\mathrm{T})=1 \mathrm{mg} /$ kg (11) expressed as barium) |
| 105 | 92320 |  | Tetradecylpolyethyleneglycol | $\mathrm{SML}=15 \mathrm{mg} / \mathrm{kg}$ |

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| Item | 1 | 2 | 3 | 4 |
| :--- | :--- | :--- | :--- | :--- |
|  | PM/REFNo. | CAS No | Name | Restrictions and <br> specifications |
|  |  |  |  |  |


| Item | 1 | 2 | 3 | 4 |
| :--- | :--- | :--- | :--- | :--- |
|  | PM/REFNo. | CAS No | Name | Restrictions and <br> specifications |
|  |  | butylphenyl) <br> butane |  |  |

## PART 3

## Supplementary

1. In regulations 5 and 7 and Parts 1 and 2 of this Schedule-
(a) the PM/REF No of any additive is its EEC packaging material reference number,
(b) the CAS No. of any additive is its CAS (Chemical Abstracts Service) Registry Number; and
(c) the name of any additive is its chemical name, and to the extent that there is any inconsistency between the CAS No. and the name, the name shall take precedence over the CAS No.

## Commencement Information

I32 Sch. 2 para. 1 in operation at 30.6 .2006 , see reg. 1
2. If a substance identified in Parts 1 or 2 is an acid, a phenol or an alcohol and has salts (including double salts) of one or more of the following names (that is to say salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc), then any such salts shall be treated as included in the specification of that substance.

## Commencement Information

I33 Sch. 2 para. 2 in operation at 30.6.2006, see reg. 1
3. If, as indicated in paragraph 2 of Annex III to the Directive, a substance is identified in Parts 1 or 2 as an "... acid, salt" and has salts of one or more of the following names (that is to say, salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc), then the free acid corresponding to that substance is not treated as included in the specification of that substance.

## Commencement Information

I34 Sch. 2 para. 3 in operation at 30.6.2006, see reg. 1
4. Where an entry in column 4 of Part 1 or Part 2 includes a bracketed number, that entry shall be subject to a note relating to that number as follows, the following bracketed numbers corresponding with those appearing in those Parts -
(1) Warning: there is a risk that the SML could be exceeded in fatty food simulants.
(2) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.
(3) $\operatorname{SML}(T)$ in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.
(4) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.
(5) $\operatorname{SML}(T)$ in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.
(6) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 66560 and 66580.
(7) $\operatorname{SML}(T)$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.
(8) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 38000, 42400, 64320, [67896,] 73040, 85760, 85840,85920 and 95725.
(9) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30180, 40980, 63200, 65120, 65200, 65280, 65360,65440 and 73120.
(10) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels (expressed as iodine) of the substances having PM/REF Nos. 45200, 64320, 81680 and 86800 .
(11) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 36720, 36800, 36840 and 92000.
(12) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 39090 and 39120.
(13) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 44960, 68078, 82020 and 89170.
(14) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600 .
(15) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 49600, 67520 and 83599.
(16) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.
(17) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PR/REF Nos. 67600, 67680 and 67760.
(18) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 60400, 60480 and 61440.
(19) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 66400 and 66480.
(20) $\operatorname{SML}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 93120 and 93280.
(21) $\operatorname{SML}(\mathrm{T})$ in this cases means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 17260, 18670, 54880 and 59280.
(22) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13620, 36840, 40320 and 87040.
(23) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13720 and 40580.
(24) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 16650 and 51570.
(26) $\mathrm{QMA}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.
(27) $\mathrm{QMA}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.
(28) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680.
(29) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.
(30) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 86480, 86960 and 87120.
(31) Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.
(32) Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant $D$ (unstable).
(33) $\mathrm{QMA}(\mathrm{T})$ in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.
(34) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 55200, 55280 and 55360.

## Commencement Information

I35 Sch. 2 para. 4 in operation at 30.6.2006, see reg. 1
5. In this case of the substances listed in Part 2, the specific migration limits specified in column 4 of that Part (restrictions and specifications) shall have effect with effect from 1st July 2006 where the verification of compliance is carried out in simulant D or in test media of substitute tests as prescribed in Council Directive 82/711/EEC and Council Directive 85/572/EEC.

## Commencement Information

I36 Sch. 2 para. 5 in operation at $30.6 \cdot 2006$, see reg. 1

SCHEDULE 3
Regulation 8
Products Obtained by Bacterial Fermentation

## Commencement Information

137 Sch. 3 in operation at 30.6 .2006, see reg. 1

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| Item | 1 | 2 | 3 | 4 |
| :--- | :--- | :--- | :--- | :--- |
|  | PM/REF No | CAS No | Name | Restrictions and <br> specifications |
| 1 | 18888 | $080181-31-3$ | 3- <br> hydroxybutanoic <br> acid- | In compliance <br> with <br> specifications <br> included in |
|  |  | 3- <br> hydroxypentanoic <br> acid, copolymer |  |  |

SCHEDULE 4
Schedules $1,2 \& 3$

Specifications

Commencement Information
I38 Sch. 4 in operation at 30.6.2006, see reg. 1

(1) Quantity of substance used/quantity of formulation

(1) Quantity of substance used/quantity of formulation

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(1) Quantity of substance used/quantity of formulation

| Item | 1 | 2 |
| :---: | :---: | :---: |
|  | PM/REF No | Specifications |
| 4 | 23547 | - arsenic Not more than $1 \mathrm{mg} /$ <br> kg of plastic |
|  |  | - chromium $\quad$Not more than $1 \mathrm{mg} /$ <br> kg of plastic |
|  |  | Polydimethylsiloxane ( $\mathrm{Mw}>6800$ ) |
|  |  | Minimum viscosity $100 \times 10^{-6} \mathrm{~m}^{2} / \mathrm{s}(=100$ centistokes) at $25^{\circ} \mathrm{C}$ |
| 5 | 25385 | Triallylamine |
|  |  | $40 \mathrm{mg} / \mathrm{kg}$ hydrogel at a ratio of 1 kg food to a maximum of 1.5 grams of hydrogel. For use only in hydrogels intended for non-direct food contact use. |
| 6 | 38320 | 4-(2-Benzoxazolyl)-4'- (5-methyl-2benzoxazolyl) stilbene |
|  |  | Not more than $0.05 \%$ w/w (quantity of substance used / quantity of the formulation) |
| 7 | 43680 | Chlorodifluoromethane |
|  |  | Content of chlorofluoromethane less than 1 mg / kg of the substance |
| 8 | 47210 | Dibutylthiostannoic acid polymer <br> Molecular unit $=\left(\mathrm{C}_{8} \mathrm{H}_{18} \mathrm{~S}_{3} \mathrm{Sn}_{2}\right) \mathrm{n}(\mathrm{n}=1.5-2)$ |
|  |  |  |
| 9 | 76721 | Polydimethylsiloxane ( $\mathrm{Mw}>6800$ ) |
|  |  | Minimum viscosity $100 \times 10^{-6} \mathrm{~m}^{2} / \mathrm{s}(=100$ centistokes) at $25^{\circ} \mathrm{C}$ |
| 10 | 77895 | Polyethyleneglycol ( $\mathrm{EO}=2-6$ ) monoalkyl $\left(\mathrm{C}_{16}-\right.$ $\mathrm{C}_{18}$ ) ether |
|  |  | The composition of this mixture is as follows: -polyethyleneglycol ( $\mathrm{EO}=2-6$ ) monoalkyl ( $\mathrm{C}_{16}-\mathrm{C}_{18}$ ) ether approximately 28\%) |
|  |  | -fatty alcohols ( $\mathrm{C}_{16}-\mathrm{C}_{18}$ ) (approximately 48\%) |
|  |  | -ethyleneglycol monoalkyl ( $\mathrm{C}_{16}-\mathrm{C}_{18}$ ) ether (approximately 24\%) |
| 11 | 83595 | Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorus trichloride and biphenyl <br> Composition |
|  |  |  |

(1) Quantity of substance used/quantity of formulation

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| Item | 1 | 2 |
| :---: | :---: | :---: |
|  | PM/REF No | Specifications |
|  |  | -4,4'-Biphenylene-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 38613-77-3) (36-46\% w/w)( ${ }^{1}$ ) |
|  |  | -4,3'-Biphenylene-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 118421-00-4) (17-23\% w/w $)^{(1)}$ |
|  |  | -3-3'-Biphenylene-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] CAS No. 118421-01-5) (1-5\% W/w $)^{(1)}$ |
|  |  | -4-Biphenylene-0,0-bis [0,0-bis (2,4-di-tertbutylphenyl) phosphonite] (CAS No. 91362 -37-7 (11-19\% w/w) ${ }^{(1)}$ |
|  |  | -Tris (2,4-di-tert-butylphenyl) phosphite (CAS No. 31570-04-4) (9-18\% w/w $)^{(1)}$ |
|  |  | -4,4'-Biphenylene-0,0-bis (2,4-di-tertbutylphenyl) phosphonate-0,0-bis (2,4-di-tertbutylphenyl) phosphonite (CAS No. 112949-97-0) ( $<5 \% \mathrm{w} / \mathrm{w}^{(1)}$ ) |
|  |  | Other specifications |
|  |  | -Phosphor content of minimum 5.4\% to maximum 5.9\% |
|  |  | -Acid value of maximum 10 mg KOH per gram |
|  |  | -Melt range of $85-110^{\circ} \mathrm{C}$ |
| 12 | 88640 | Soybean oil, epoxidized |
|  |  | Oxirane less than $8 \%$, iodine number $<6$ |
| 13 | 95859 | Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks. The product should have the following specifications: |
|  |  | Phosphor content of minimum $5.4 \%$ to maximum 5.9\% |
|  |  | -Content of mineral hydrocarbons with carbon number less than 25 : not more than $5 \%(\mathrm{w} / \mathrm{w})$ |
|  |  | -Viscosity not less than $11 \times 10^{-6} \mathrm{~m}^{2} / \mathrm{s}(=11$ centistokes) at $100^{\circ} \mathrm{C}$ |
|  |  | -Average molecular weight not less than 500 |
| (1) Quantity of substance used/quantity of formulation |  |  |


| Item | 1 | 2 |
| :--- | :--- | :--- |
|  | PM/REF No | Specifications |
| 14 | 95883 | White mineral oils, paraffinic, derived from <br> petroleum based hydrocarbon feedstocks |
|  | The product shall have the following |  |
|  | specifications: |  |
|  | -Content of mineral hydrocarbons with carbon |  |
|  | number less than $25:$ not more than $5 \%(\mathrm{w} / \mathrm{w})$ |  |
|  |  | -Viscosity not less than $8.5 \times 10^{-6} \mathrm{~m}^{2} / \mathrm{s}(=8.5$ |
|  | centistokes) at $100^{\circ} \mathrm{C}$ |  |
|  |  | - Average molecular weight not less than 480 |
|  |  |  |

(1) Quantity of substance used/quantity of formulation

SCHEDULE 5
Provisions Applicable when Testing Compliance with the Migration Limits

## General Provisions

1. When the results of the migration tests specified in this Schedule and, where appropriate Schedule 6, are analytically determined, the specific gravity of any simulants used shall be assumed to be 1 , so that milligrams of any substance released per litre of simulant will correspond numerically to milligrams of that substance released per kilogram of that simulant.

## Commencement Information

I39 Sch. 5 para. 1 in operation at 30.6 .2006 , see reg. 1
2. Where any migration test specified in this Schedule and, where appropriate, Schedule 6 is carried out on any sample taken from any plastic material or article and the quantities of food or simulant placed in contact with the sample differ from those employed in the actual conditions under which the plastic material or article is used or is to be used, the results obtained should be corrected by applying the formula $\mathrm{M}=\left(\left(\mathrm{m} \cdot \mathrm{a}_{2} / \mathrm{a}_{1} \cdot \mathrm{q}\right) \cdot 1000\right)$ where -
(a) M is the migration in $\mathrm{mg} / \mathrm{kg}$ :
(b) $m$ is the mass in the $m g$ of substance released by the sample as determined by the migration test;
(c) $\mathrm{a}_{1}$ is the surface area in square decimetres of the sample in contact with the food or simulant during the migration test;
(d) $\mathrm{a}_{2}$ is the surface area in square decimetres of the plastic material or article in actual conditions of use; and
(e) q is the quantity in grams of food in contact with the plastic material or article in actual conditions of use.

## Commencement Information

I40 Sch. 5 para. 2 in operation at 30.6.2006, see reg. 1
3.-(1) Subject to sub-paragraph (2), any testing of migration from any plastic material or article shall be carried out on that plastic material or article.
(2) In any case where determination in accordance with sub-paragraph (1) is impracticable, such testing shall be carried out, using either specimens taken from that plastic material or article, or where appropriate, specimens representative of that plastic material or article.
(3) Any sample used for such testing shall be placed in contact with the simulant or food, as the case may be, in a manner representing the contact conditions in actual use, and for this purpose the testing shall be carried out in such a way that only those parts of the sample intended to come into contact with food in actual use will be in contact with the simulant or food.

Any migration testing of caps, gaskets, stoppers or similar devices for sealing shall be carried out on these articles by applying them to the containers for which they are intended in a manner which corresponds to the conditions of closing in normal or foreseeable use.
Any sample of plastic material or article shall be placed in contact with the appropriate simulant or the food for a period and at a temperature which are chosen by reference to the contact conditions in actual use in accordance with the provisions of this Schedule and, where appropriate, Schedule 6.
(4) At the end of the period referred to in sub-paragraph (1), analytical determination of the total quantity of substances (overall migration), each specific quantity of a substance (specific migration) or, as the case may be, both that total and that specific quantity released by the sample shall be carried out on the simulant or food, as the case may be.
(5) Verification that migration into food complies with a migration limit specified in regulation 9, Schedule 1 or Schedule 2 shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use in accordance with the provisions of this Schedule.
(6) Verification that migration into food simulants complies with a migration limit specified in regulation 9, Schedule 1 or Schedule 2 shall be carried out in accordance with the provisions of this Schedule and using conventional migration tests, the basic rules for which are set out in Schedule 6.

## Commencement Information

I41 Sch. 5 para. 3 in operation at 30.6.2006, see reg. 1
4. Where a plastic material or article is intended to come into repeated contact with food, any migration test shall (subject to paragraph 7 below) be carried out three times on a single sample in accordance with the conditions laid down in this Schedule and, where appropriate, Schedule 6 using separate samples of the simulant or, as the case may be food, on each occasion, and the level of the migration found in the third test shall be treated as the level relevant to that test.

## Commencement Information

I42 Sch. 5 para. 4 in operation at 30.6.2006, see reg. 1

## Commencement Information

I39 Sch. 5 para. 1 in operation at 30.6 .2006 , see reg. 1

I40 Sch. 5 para. 2 in operation at 30.6.2006, see reg. 1
I41 Sch. 5 para. 3 in operation at 30.6.2006, see reg. 1
I42 Sch. 5 para. 4 in operation at 30.6.2006, see reg. 1

## Special provisions relating to overall migration

5.-(1) Subject to sub-paragraph (2), any method of analytical determination may be used to prove excess of an overall migration limit in relation to a plastic material or article.
(2) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with regulation 9 it shall be a defence for the person charged to prove that-
(a) if an aqueous simulant specified in Schedule 6 had been used, and the analytical determination of the total quantity of substances released by a sample of the plastic material or article tested had been carried out by evaporation of the simulant and weighing of the residue; or
(b) if rectified olive oil or any of its substitutes had been used as a simulant and-
(i) a sample of the plastic material or article had been weighed before and after contact with the simulant;
(ii) the simulant absorbed by the sample had been extracted and determined quantitatively;
(iii) the quantity of simulant so found had been subtracted from the weight of the sample measured after contact with the simulant; and
(iv) the difference between the initial and corrected final weights had been determined to represent the overall migration of the sample examined,
there would have been no such excess so determined.

## Commencement Information

I43 Sch. 5 para. 5 in operation at 30.6.2006, see reg. 1
6.-(1) Where a plastic material or article is intended to come into repeated contact with food and it is technically impossible to carry out the test described in paragraph 5 , the test shall be so modified as to enable the level of migration occurring during the third such test to be determined and, subject to sub-paragraph (2), such a determination may be used to prove excess of an overall migration limit in relation to a plastic material or article.
(2) In any proceedings for an offence under these Regulations where it is alleged, following determination under sub-paragraph (1), that a plastic material or article does not comply with regulation 9 it shall be a defence for the person charged to prove that, if-
(a) three identical samples of the plastic material or article had been procured;
(b) one of them had been subjected to the appropriate test according with paragraph 4 and the overall migration determined $\left(\mathrm{M}_{1}\right)$;
(c) the second and third samples had been subjected to the same conditions of temperature but the period of contact had been two and three times that specified and overall migration had been determined in each case ( $\mathrm{M}_{2}$ and $\mathrm{M}_{3}$ respectively); and
(d) the plastic material or article had been deemed to comply with the overall migration limit relevant to it provided that either $\mathrm{M}_{1}$ or $\mathrm{M}_{3}-\mathrm{M}_{2}$ did not exceed that overall migration limit, the plastic material or article would not have been deemed to exceed that limit.

## Commencement Information

I44 Sch. 5 para. 6 in operation at 30.6 .2006 , see reg. 1
7.-(1) Any plastic material or article which exceeds its overall migration limit by an amount not exceeding the analytical tolerance specified in sub-paragraph (2) shall be deemed for the purposes of these Regulations not to exceed its overall migration limit.
(2) The following analytical tolerances shall be applied for limits of overall migration-
(a) $20 \mathrm{mg} / \mathrm{kg}$ or, as the case may be, 3 milligrams per square decimetre in migration tests using as a simulant rectified olive oil or substitutes;
(b) $12 \mathrm{mg} / \mathrm{kg}$ or, as the case may be, 2 milligrams per square decimetre in migration tests using other simulants referred to in Schedule 6.

## Commencement Information

I45 Sch. 5 para. 7 in operation at 30.6 .2006, see reg. 1

## Commencement Information

I43 Sch. 5 para. 5 in operation at 30.6.2006, see reg. 1
I44 Sch. 5 para. 6 in operation at 30.6.2006, see reg. 1
$\mathbf{I 4 5}$ Sch. 5 para. 7 in operation at 30.6.2006, see reg. 1

## Overall and Specific Migration Testing Using Food Simulants

## PART 1

## Basic Rules

1. Subject to paragraphs 2,3 and 4 of this Part, migration tests for the determination of specific and overall migration shall be carried out using the food simulants specified in Parts 2, 3 and, where appropriate 4, and under conventional migration test conditions as specified in Part 5.

## Commencement Information

I46 Sch. 6 para. 1 in operation at 30.6.2006, see reg. 1
2. Subject to paragraphs 3 and 4 of this Part, substitute tests which use test media under the conventional substitute test conditions as specified in Part 6 shall be carried out if the migration test using the fatty food simulants specified in Part 3 is not feasible for technical reasons connected with the method of analysis.

## Commencement Information

I47 Sch. 6 para. 2 in operation at 30.6.2006, see reg. 1
3. Subject to paragraph 4 of this Part, alternative tests as specified in Part 7 may be used instead of the migration test with fatty food simulants specified in Part 3 but the results of such alternative tests may not be used to determine compliance with a migration limit unless the conditions specified in Part 7 are fulfilled.

## Commencement Information

I48 Sch. 6 para. 3 in operation at 30.6.2006, see reg. 1
4. In migration testing it is permissible to-
(a) reduce the number of tests to be carried out to that or those which, in the specific ase under examination, is or are generally recognised to be the most severe on the basis of scientific evidence;
(b) omit the migration, the substitute or the alternative tests where -
(i) there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article, or
(ii) the conditions for non-compulsory testing set out in Article 8.2 or 8.3 of the Directive are met.

## Commencement Information

I49 Sch. 6 para. 4 in operation at 30.6 .2006 , see reg. 1

## PART 2

## Food Simulants to be Used in Migration Testing

5. Subject to Parts 3, 4, 5 and 7, the simulants to be used in migration testing are specified in the Table to this paragraph (referred to in this Part as "the Table").

| 1 | 2 |
| :--- | :--- |
| Abbreviation | Food Simulant |
| Simulant A: | Distilled water or water of equivalent quality <br> $3 \%$ Acetic acid (w/v) in aqueous solution |
| Simulant B: | $10 \%$ Ethanol $(\mathrm{v} / \mathrm{v})$ in aqueous solution save that <br> the concentration of ethanol solution shall be <br> adjusted to the actual alcoholic strength of the <br> food if it exceeds $10 \%$ (v/v) |
| Simulant C: | Rectified olive oil having the characteristics <br> specified in paragraph 3 of this Part of this <br> Schedule or, subject to paragraph 5 of this Part <br> of this Schedule, any of the fatty food simulants |

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| 1 | 2 |
| :--- | :--- |
| Abbreviation | Food Simulant |
|  | specified in paragraph 4 of this Part of this <br> Schedule |

## Commencement Information

150 Sch. 6 para. 5 in operation at 30.6 .2006 , see reg. 1
6. For the purposes of this Schedule a reference to an abbreviation in column 1 of the Table shall mean a reference to the simulant in column 1 of that Table opposite that abbreviation.

## Commencement Information

I51 Sch. 6 para. 6 in operation at 30.6.2006, see reg. 1
7. The characteristics of rectified olive oil referred to in the Table are -
(a) Iodine value $(\mathrm{Wijs})=80$ to 88
(b) Refractive index at $25^{\circ} \mathrm{C}=1.4665$ to 1.4679
(c) Acidity (expressed as $\%$ of oleic acid) $=0.5 \%$ maximum
(d) Peroxide number (expressed as oxygen milli-equivalents per kg of oil) $=10$ maximum

## Commencement Information

152 Sch. 6 para. 7 in operation at 30.6.2006, see reg. 1
8. The fatty food simulants referred to in the Table are -
(a) corn oil with standardised specifications;
(b) sunflower oil, the characteristics of which are -
(i) Iodine value $(\mathrm{Wijs})=120$ to 145
(ii) Refractive index at $20^{\circ} \mathrm{C}=1.474$ to 1.476
(iii) Saponification number $=188$ to 193
(iv) Relative density at $20^{\circ} \mathrm{C}=0.918$ to 0.925
(v) Unsaponifiable matter $=0.5 \%$ to $1.5 \%$.
(c) a synthetic mixture of triglycerides the composition of which is as set out in the following tables:

## Fatty acid distribution

| No of Catoms in fatty acid residu | 6 | 8 | 10 | 12 | 14 | 16 | 18 | others |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| GLC area (\%) | $\sim 1$ | 6-9 | 8-11 | 45-52 | 12-15 | 8-10 | 8-12 | 1 |
| Purity |  |  |  |  |  |  |  |  |
| Content of monoglycerides (enzymatically) |  |  |  | $\leq 0.2 \%$ |  |  |  |  |
| Content of diglycerides (enzymatically) |  |  |  | $\leq 2.0 \%$ |  |  |  |  |
| Unsaponifiable matter |  |  |  | $\leq 0.2 \%$ |  |  |  |  |
| Iodine value |  |  |  | $\leq 0.1 \%$ |  |  |  |  |
| (Wijs) |  |  |  |  |  |  |  |  |
| Acid value |  |  |  | $\leq 0.1 \%$ |  |  |  |  |
| Water content (K Fischer) |  |  |  | $\leq 0.1 \%$ |  |  |  |  |
| Melting point |  |  |  | $28 \pm 2^{\circ} \mathrm{C}$ |  |  |  |  |

Typical absorption spectrum (thickness of
layer: $d=1 \mathrm{~cm}$; Reference: water at $35^{\circ} \mathrm{C}$ )

| Wavelengen <br> (nm) | 310 | 330 | 350 | 370 | 390 | 430 | 470 | 510 |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Transmittahnce <br> $(\%)$ | $\sim 15$ | $\sim 37$ | $\sim 64$ | $\sim 80$ | $\sim 88$ | $\sim 95$ | $\sim 97$ | $\sim 98$ |

At least $10 \%$ light transmittance at 310 nm

## Commencement Information

153 Sch. 6 para. 8 in operation at 30.6.2006, see reg. 1
9. Where fatty food simulant specified in paragraph 4 is used in migration testing and the result of that test shows that a plastic material or article does not comply with any migration limit specified in regulation 9 or Schedule 1, verification that the plastic material or article does not comply with the specified migration shall be carried out by testing that material or article using olive oil if such
testing is technically feasible, and if such testing is not technically feasible the plastic material or article shall be deemed not to comply with the specified migration limit.

## Commencement Information

154 Sch. 6 para. 9 in operation at 30.6.2006, see reg. 1

## PART 3

## Selection of Food Simulants

## Testing, reduction factors and definition of food types

10. The testing of plastic materials and articles shall be carried out under the test conditions specified in Part 5 using a simulant or simulants selected in accordance with this Part and taking a new test specimen of the plastic material or article for each simulant used.

## Commencement Information

155 Sch. 6 para. 10 in operation at 30.6 .2006, see reg. 1
11.-(1) Where a test is carried out on a plastic material or article intended to come into contact with more than one food or group of foods and a reduction factor is specified for one or more of those foods or groups of foods which is not equivalent to the reduction factor specified for one or more of the other foods or groups of foods with which the plastic material or article is intended to come into contact-
(a) the reduction factor specified for each food or group of foods, as appropriate, shall be applied to the test result; and
(b) the plastic material or article shall be treated as being capable of transferring its constituents to food with which it may come into contact in excess of a migration limit specified in regulation 9 or Schedule 1 if, following application of those specified reduction factors, one or more of the results show that the material or article does not comply with that specified migration limit.
(2) For the purpose of this paragraph -
(a) a reduction factor is the figure which follows an " X " and oblique stroke in the group of columns headed "Simulants to be used" in the Table to Part 4;
(b) a reduction factor is specified for a food or group of foods where, in the Table to Part 4 -
(i) the food or group of foods is described in the column headed "Description of food", and
(ii) " X " is placed in a column headed by a specified simulant opposite that food or group of foods followed by an oblique stroke and a reduction factor;
(c) a reduction factor shall be applied to a test result by dividing the result by that reduction factor.

## Commencement Information

I56 Sch. 6 para. 11 in operation at 30.6.2006, see reg. 1
12. Food types are defined in Table 1 below as follows -

Table 1: Food types

| Definition | Meaning |
| :--- | :--- |
| Aqueous foods having a $\mathrm{pH}>4.5$ | Foods in relation to which simulant A only is <br> specified in the Table to Part 4 |
| Acidic foods having a $\mathrm{pH} \leq 4.5$ | Foods in relation to which simulant B only is <br> specified in Table to Part 4 |
| Alcoholic foods | Foods in relation to which simulant C only is <br> specified in the Table to Part 4 |
| Fatty foods | Foods in relation to which simulant D only is <br> specified in the Table to Part 4 |
| Dry Foods | Foods in relation to which no simulant is <br> specified in the Table to Part 4 |

## Commencement Information

157 Sch. 6 para. 12 in operation at 30.6 .2006 , see reg. 1

## Commencement Information

I55 Sch. 6 para. 10 in operation at 30.6.2006, see reg. 1
I56 Sch. 6 para. 11 in operation at 30.6.2006, see reg. 1
157 Sch. 6 para. 12 in operation at 30.6.2006, see reg. 1

## Selection of simulants for testing materials and articles intended for contact with all food types

13. The simulants to be used in testing a plastic material or article which is intended for contact with all food types are simulant B , simulant C and simulant D which, at the test conditions specified in Part 5, are considered to be more severe.

## Commencement Information

158 Sch. 6 para. 13 in operation at 30.6.2006, see reg. 1

## Selection of simulants for testing materials and articles which are already in contact with a known food

14. The simulant or simulants to be used in testing a plastic material or article which is already in contact with a known food shall be -
(a) where -
(i) the known food is a specific food or is within a specific group of foods described in column 2 of the Table to Part 4 and,
(ii) for the purposes of that Part, a simulant is, or simulants are, specified in relation to that specific food or specific group of foods,
the simulant or simulants so specified;
(b) where -
(i) the known food is neither a specific food, nor
(ii) within a specific group of foods described in the Table to Part 4 of this Schedule,
the simulant or simulants in column 2 of Table 2 opposite the description of food in column 1 of that Table which corresponds most closely to the known food.

## Commencement Information

159 Sch. 6 para. 14 in operation at 30.6.2006, see reg. 1

## Selection of simulants for testing materials and articles which are accompanied by a specific indication

15. The simulant or simulants to be used in testing a plastic material or article which, pursuant to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food(25) ("Regulation 1935/2004"), is accompanied by a specific indication stating any type or types of food described in Table 1 with which it may or may not be used shall be the simulant or simulants in column 2 of Table 2 opposite the contact food in column 1 of that Table which corresponds most closely to the type or types of food with which it may be used, as identified by the indication which accompanies the plastic material or article.

## Commencement Information

I60 Sch. 6 para. 15 in operation at 30.6.2006, see reg. 1
16. The simulant or simulants to be used in testing a plastic material or article which, pursuant to Regulation 1935/2004, is accompanied by a specific indication, expressed in accordance with paragraph 8 , stating any food or group of foods described in the Table to Part 4 with which it may or may not be used shall be-
(a) where the indication states that the plastic material or article may be used with a food or group of foods described in column 2 of the Table to Part 4, the food simulant or food simulants which, for the purposes of Part 4 , is or are specified in relation to that food or group of foods;
(b) where the indication states that the plastic material or article should not be used with any food or group of foods described in column 2 of Table to Part 4, a simulant other than the simulant or simulants which, for the purposes of Part 4, is or are specified in relation to that food or group of foods.

## Commencement Information

I61 Sch. 6 para. 16 in operation at 30.6.2006, see reg. 1
17. A specific indication referred to in paragraph 7 is expressed in accordance with this paragraph if it is expressed-
(a) at a marketing stage other than retail, by using the reference number in column 1 of the Table to Part 4 of these Regulations or the description of food in column 2 of that Table which, in either case, corresponds to the food;
(b) at the retail stage, by using an indication which refers to only a few foods or groups of foods described in the Table to Part 4.

Table 2: Simulants to be selected for testing food contact materials in special cases

| Contact foods | Simulant |
| :--- | :--- |
| Only aqueous foods | Simulant A |
| Only acidic foods | Simulant B |
| Only alcoholic foods | Simulant C |
| Only fatty foods | Simulant D |
| All aqueous and acidic foods | Simulant B |
| All alcoholic and aqueous foods | Simulant C |
| All alcoholic and acidic foods | Simulant C and B |
| All fatty and aqueous foods | Simulants D and A |
| All fatty and acidic foods | Simulants D and B |
| All fatty, alcoholic and aqueous foods | Simulants D and C |
| All fatty, alcoholic and acidic foods | Simulants D, C and B |

## Commencement Information

I62 Sch. 6 para. 17 in operation at 30.6 .2006, see reg. 1

## Commencement Information

I60 Sch. 6 para. 15 in operation at 30.6.2006, see reg. 1
I61 Sch. 6 para. 16 in operation at 30.6.2006, see reg. 1
I62 Sch. 6 para. 17 in operation at 30.6.2006, see reg. 1

## PART 4

## Selection of Food Simulants

18. For the purposes of this Schedule a simulant is specified in relation to a specific food or a specific group of foods where " X " is placed in the column headed by that simulant opposite that specific food or specific group of foods in the Table to this Part, and the Table shall be read in conjunction with the notes to it and with paragraphs 2 to 5 .

## Commencement Information

I63 Sch. 6 para. 18 in operation at 30.6 .2006, see reg. 1
19. For the purposes of this Part -
(a) a reduction factor is the figure which follows an " X " and oblique stroke in the group of columns headed "Simulants to be used" in the Table to this Part;
(b) a reduction factor is specified in relation to a specific food or group of foods where, in the Table -
(i) the food or group of foods is described in the column headed "Description of food"; and
(ii) " X " is placed in a column headed by a specified simulant opposite that food or group of foods allowed by an oblique stroke and a reduction factor.

## Commencement Information

I64 Sch. 6 para. 19 in operation at 30.6.2006, see reg. 1
20. Where a reduction factor is specified in the Table in relation to a specific food or a specific group of foods, that reduction factor shall be applied to the result of any migration test using the simulant specified in relation to that food or group of foods by dividing the result of the test by the reduction factor.

## Commencement Information

I65 Sch. 6 para. 20 in operation at 30.6 .2006, see reg. 1
21. Where the letter " $a$ " is shown in brackets after the " $X$ ", only one of the two simulants specified shall be used in the migration test, that is to say -
(a) if the pH value of the food is higher than 4.5 , simulant A shall be used;
(b) if the pH value of the foodstuff is 4.5 or less, simulant B shall be used.

## Commencement Information

I66 Sch. 6 para. 21 in operation at 30.6 .2006 , see reg. 1
22. Where a food is listed in the Table under both a specific and a general heading, the simulant relating to the specific heading is the simulant which falls to be used for the migration test.

| Reference Number | Description of food | Simulants to be used |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | A | B | C | D |
| 01 | Beverages |  |  |  |  |
| 01.01 | Non-alcoholic beverages or alcoholic beverages of | X(a) | X(a) |  |  |
| (1) Simulant B shall not be used where the pH is more than 4.5 . |  |  |  |  |  |
| (2) This test shall be carried out in the cas solutions of ethanol of a similar stre |  | ase of 1 gth. | ages of |  |  |
| (3) If it can with the | monstrated under regu material or article, s | ation 1 <br> mulant | means used. |  |  |

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| Reference Number | Description of food | Simulants to be used |  | C | D |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | A | B |  |  |
|  | an alcoholic strength lower than 5\% vol: |  |  |  |  |
|  | - Waters, ciders, fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other |  |  |  |  |
| 01.02 | Alcoholic beverages of an alcoholic strength equal to or exceeding 5\% vol. |  | $\mathrm{X}^{(1)}$ | $\mathrm{X}^{(2)}$ |  |
|  | — Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5\% vol. |  |  |  |  |
|  | - Wines, spirits and liqueurs |  |  |  |  |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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| Reference Number | Description of food | Simulants to be used |  |  |
| :---: | :---: | :---: | :---: | :---: |
|  |  | B | C | D |
| 01.03 | Miscellaneous: $X^{(1)}$ undenatured ethyl alcohol | $\mathrm{X}^{(1)}$ | $\mathrm{X}^{(1)}$ |  |
| 02 | Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares |  |  |  |
| 02.01 | Starches |  |  |  |
| 02.02 | Cereals, unprocessed, puffed, in flakes (including popcorn, cornflakes and the like) |  |  |  |
| 02.03 | Cereal flour and meal |  |  |  |
| 02.04 | Macaroni, spaghetti and similar products |  |  |  |
| 02.05 | Pastry, biscuits, cakes and other bakers' wares, dry: |  |  |  |
|  | A With fatty substances on the surface |  |  | X/5 |
|  | B Other |  |  |  |
| 02.06 | Pastry, biscuits, cakes and other |  |  |  |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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| Reference Number | Description of food | Simulants to be used |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | A | B | C | D |
|  | bakers' wares, fresh: |  |  |  |  |
|  | A With fatty substances on the surface |  |  |  | X/5 |
|  | B Other | X |  |  |  |
| 03 | Chocolate, sugar and products thereof Confectionery products |  |  |  |  |
| 03.01 | Chocolate, chocolatecoated products, substitutes and products coated with substitutes |  |  |  | X/5 |
| 03.02 | Confectionery products: |  |  |  |  |
|  | A in solid form: |  |  |  |  |
|  | - with fatty substances on the surface |  |  |  | X/5 |
|  | - Other |  |  |  |  |
|  | $B$ in paste form: |  |  |  |  |
|  | - with fatty substances on the surface |  |  |  | X/3 |
|  | - moist | X |  |  |  |
| 03.03 | Sugar and sugar products |  |  |  |  |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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| Reference Number | Description of food | Simulants to be used |  | C | D |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | A | B |  |  |
|  | A In solid form |  |  |  |  |
|  | B Honey and the like | X |  |  |  |
|  | $\quad$ C Molasses and syrups |  |  |  |  |
| 04 | Fruit, vegetable and products thereof |  |  |  |  |
| 04.01 | Whole fruit, fresh or chilled |  |  |  |  |
| 04.02 | Processed fruit: |  |  |  |  |
|  | A Dried or dehydrated fruit, whole or in the form of flour or powder |  |  |  |  |
|  | B Fruit in the form of chunks, puree or paste |  | X(a) |  |  |
|  | C Fruit preserves (jams and similar products whole frui or chunks or in the form of flour or powder, preserved in a liquid medium): |  |  |  |  |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant $D$ shall not be used.

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| Reference Number | Description of food | Simulants to be used |  | C | D |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | A | B |  |  |
| 06.01 | Fish: |  |  |  |  |
|  | A Fresh, chilled, salted, smoked | X |  |  | $\mathrm{X} / 3^{(3)}$ |
|  | B In the form of paste | X |  |  | $\mathrm{X} / 3^{(3)}$ |
| 06.02 | Crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells | X |  |  |  |
| 06.03 | Meat of all zoological species (including poultry and game): |  |  |  |  |
|  | A Fresh, chilled, salted, smoked | X |  |  | X/4 |
|  | B In the form of paste, creams | X |  |  | X/4 |
| 06.04 | Processed meat products (ham, salami, bacon and other) | X |  |  | X/4 |
| 06.05 | Preserved and part-preserved meat and fish: |  |  |  |  |
|  | A In an aqueous medium |  | $\mathrm{X}(\mathrm{a})$ |  |  |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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| Reference <br> Number | Description of food | Simulants to be used |  | C | D |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | A | B |  |  |
| 06.06 | B In an oily medium | X(a) | X(a) |  | X |
|  | Eggs not in shell: |  |  |  |  |
|  | A Powdered or dried |  |  |  |  |
| 06.07 | B Other | X |  |  |  |
|  | Egg yolks: |  |  |  |  |
|  | A Liquid | X |  |  |  |
|  | B Powdered or frozen |  |  |  |  |
| 06.08 | Dried white of egg |  |  |  |  |
| 07 | Milk products |  |  |  |  |
| 07.01 | Milk: |  |  |  |  |
|  | A Whole | X |  |  |  |
|  | B Partly dried |  |  |  |  |
|  | C Skimmed or partly skimmed |  |  |  |  |
|  | D Dried |  |  |  |  |
|  | Fermented milk such as yoghurt, buttermilk and such products in association with fruit and fruit products |  | X |  |  |
| 07.03 | Cream and sour cream | X(a) | X(a) |  |  |
| 07:04 | Cheeses: |  |  |  |  |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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| Reference Number | Description of food | Simulants to be used | C | D |
| :---: | :---: | :---: | :---: | :---: |
|  |  | B |  |  |
| 07:05 | A Whole, with rind |  |  |  |
|  | B Processed X(a) cheeses | X(a) |  |  |
|  | $\underset{\text { others }}{\text { C All }} \quad \mathrm{X}(\mathrm{a})$ | $\mathrm{X}(\mathrm{a})$ |  | $\mathrm{X} / 3^{(3)}$ |
|  | Rennet: |  |  |  |
|  | A In liquid X(a) or viscous form | $\mathrm{X}(\mathrm{a})$ |  |  |
|  | B Powdered or dried |  |  |  |
| 08 | Miscellaneous products |  |  |  |
| 08.01 | Vinegar | X |  |  |
| 08.02 | Fried or roasted foods: |  |  |  |
|  | A Fried potatoes, fritters and the like |  |  | X/5 |
|  | B Of animal origin |  |  | X/4 |
| 08.03 | Preparations for soups, broths in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes: |  |  |  |
|  | A Powdered or dried |  |  |  |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant $D$ shall not be used.

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| Reference Number | Description of food | Simulants to be used | C | D |
| :---: | :---: | :---: | :---: | :---: |
|  |  | B |  |  |
|  | -i) |  |  | X/5 |
|  | With fatty substances on the surface |  |  |  |
|  | $\begin{aligned} & -\mathrm{ii} \\ & \text { Other } \end{aligned}$ |  |  |  |
|  | B Liquid or paste: |  |  |  |
|  | —i) $\quad \mathrm{X}(\mathrm{a})$ With fatty substances on the surface | X(a) |  | X/3 |
|  | $\begin{aligned} & -\mathrm{ii}) \quad \mathrm{X}(\mathrm{a}) \\ & \text { Other } \end{aligned}$ | X(a) |  |  |
| 08.04 | Yeasts and raising agents: |  |  |  |
|  | A In paste $\mathrm{X}(\mathrm{a})$ form | X(a) |  |  |
|  | B Dried |  |  |  |
| 08.05 | Salt |  |  |  |
| 08.06 | Sauces: |  |  |  |
|  | A Without $\mathrm{X}(\mathrm{a})$ fatty substances on the surface | X(a) |  |  |
|  | B Mayonnais*,(a) sauces derived from mayonnaise, salad creams and other oil in water emulsions | X(a) |  | X/3 |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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| Reference Number | Description of food | Simulants to be used |  | C | D |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | A | B |  |  |
|  | C Sauce containing oil and water forming two distinct layers | X(a) | X(a) |  | X |
| 08.07 | Mustard <br> (except powdered mustard under heading 08.17) | X(a) | X(a) |  | $\mathrm{X} / 3^{(3)}$ |
| 08.08 | Sandwiches, toasted bread and the like containing any kind of foodstuff: |  |  |  |  |
|  | A With fatty substances on the surface |  |  |  | X/5 |
|  | B Other |  |  |  |  |
| 08.09 | Ice-creams | X |  |  |  |
| 08.10 | Dried foods: |  |  |  |  |
|  | A With fatty substances on the surface |  |  |  | X/5 |
|  | B Other |  |  |  |  |
| 08.11 | Frozen or deep-frozen foods |  |  |  |  |
| 08.12 | Concentrated extracts of an alcoholic strength equal to or exceeding 5\% vol |  | $\mathrm{X}^{(1)}$ | X |  |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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| Reference Number | Description of food | Simulants to be used |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  |  | A | B | C | D |
| 08.13 | Cocoa: |  |  |  |  |
|  | A Cocoa powder |  |  |  | $\mathrm{X} / 5^{(3)}$ |
|  | B Cocoa paste |  |  |  | $\mathrm{X} / 3^{(3)}$ |
| 08.14 | Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered |  |  |  |  |
| 08.15 | Liquid coffee extracts | X |  |  |  |
| 08.16 | Aromatic herbs and other herbs: |  |  |  |  |
|  | Camomile, mallow, mint, tea, lime blossom and others |  |  |  |  |
| 08.17 | Spices and seasonings in the natural state: |  |  |  |  |
|  | Cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and other |  |  |  |  |

(1) Simulant B shall not be used where the pH is more than 4.5 .
(2) This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding $10 \%$ vol with aqueous solutions of ethanol of a similar strength.
(3) If it can be demonstrated under regulation 12 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

## Commencement Information

I67 Sch. 6 para. 22 in operation at 30.6.2006, see reg. 1

## PART 5

## Migration Test Conditions (Times and Temperatures)

## General criteria

23. Subject to paragraphs 2, 4, 6 and 7 below and to paragraph 4.4 of Chapter II of the Annex to Directive $82 / 711$, when carrying out migration tests the time and temperature used shall be the time and temperature selected from column 2 of the Table to this Part which correspond to the worst foreseeable conditions of contact specified in column 1 of that Table for the plastic material or article being tested and to any labelling information on maximum temperature for use.

## Commencement Information

I68 Sch. 6 para. 23 in operation at 30.6.2006, see reg. 1
24. Where the plastic material or article being tested is intended for a food contact application covered by a combination of two or more times and temperatures specified in column 2 of the Table to this Part, the migration test shall be carried out by subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

## Commencement Information

I69 Sch. 6 para. 24 in operation at 30.6.2006, see reg. 1
25. For the purposes of this Part the worst foreseeable conditions of contact are those which are recognised to be the most severe on the basis of scientific evidence.

## Commencement Information

I70 Sch. 6 para. 25 in operation at 30.6.2006, see reg. 1

## Commencement Information

I68 Sch. 6 para. 23 in operation at 30.6.2006, see reg. 1
I69 Sch. 6 para. 24 in operation at 30.6.2006, see reg. 1
I70 Sch. 6 para. 25 in operation at 30.6.2006, see reg. 1

## Volatile migrants

26. When carrying out a test of the specific migration of volatile substances any test using a simulant shall be performed in a manner which recognises the loss of volatile migrants which may occur in the worst foreseeable conditions of use.

## Commencement Information

I71 Sch. 6 para. 26 in operation at 30.6.2006, see reg. 1

## Special cases

27. When carrying out a migration test of a plastic material or article which is intended for use in a microwave oven, if the appropriate time and temperature is selected from the table to this Part, either a conventional oven or a microwave oven may be used.

## Commencement Information

I72 Sch. 6 para. 27 in operation at 30.6.2006, see reg. 1
28. Where the carrying out of a migration test under contact conditions specified in the Table to this Part causes any physical or other change in the test specimen which does not occur under the worst foreseeable conditions of use of the plastic material or article being tested the migration test shall be carried out in the worst foreseeable conditions of use in which such physical or other change does not occur.

## Commencement Information

I73 Sch. 6 para. 28 in operation at 30.6.2006, see reg. 1
29. Where, in actual use, the plastic material or article being tested is intended to be used for periods of less than 15 minutes at any temperature of not less than $70^{\circ} \mathrm{C}$ and not more than $100^{\circ}$ C and such use is indicated by appropriate labelling or instructions no test other than for 2 hours at $70^{\circ} \mathrm{C}$ shall be carried out on the plastic material or article unless the plastic material or article is also intended to be used or storage at room temperature in which case no test other than for 10 days test at $40^{\circ} \mathrm{C}$ shall be carried out.

## Commencement Information

I74 Sch. 6 para. 29 in operation at 30.6.2006, see reg. 1
30. The Table to this Part shall be read with the notes to it.

| Conditions of contact in worse foreseeable <br> use | Test conditions |
| :--- | :--- |
| Contact time: | Test time: |
| less than or equal to 5 minutes | (1) |
| $>5$ minutes but less than or equal to 0.5 hours | 0.5 hours |
| $>0.5$ hours but less than or equal to 1 hour | 1 hour |
| $>1$ hour but less than or equal to 2 hours | 2 hours |
| (1) The period of time which represents the worst foreseeable conditions of contact. |  |
| (2) This temperature shall be used only for simulant D. For simulant A, B or C the test may be replaced by a test at $100^{\circ} \mathrm{C}$ or |  |
| at reflux temperature for a duration of four times the time selected in accordance with paragraph 1 of this Part. |  |


| Conditions of contact in worse foreseeable <br> use | Test conditions |
| :--- | :--- |
| $>2$ hours but less than or equal to 4 hours | 4 hours |
| $>4$ hours but less than or equal to 24 hours | 24 hours |
| $>24$ hours | 10 days |
| Contact temperature: | Test temperature: |
| less than or equal to $5^{\circ} \mathrm{C}$ | $5^{\circ} \mathrm{C}$ |
| $>5^{\circ} \mathrm{C}$ but less than or equal to $20^{\circ} \mathrm{C}$ | $20^{\circ} \mathrm{C}$ |
| $>20^{\circ} \mathrm{C}$ but less than or equal to $40^{\circ} \mathrm{C}$ | $40^{\circ} \mathrm{C}$ |
| $>40^{\circ} \mathrm{C}$ but less than or equal to $70^{\circ} \mathrm{C}$ | $70^{\circ} \mathrm{C}$ |
| $>70^{\circ} \mathrm{C}$ but less than or equal to $100^{\circ} \mathrm{C}$ | $100^{\circ} \mathrm{C}$ or reflux temperature |
| $>100^{\circ} \mathrm{C}$ but less than or equal to $121^{\circ} \mathrm{C}$ | $121^{\circ} \mathrm{C}$ (2) |
| $>121^{\circ} \mathrm{C}$ but less than or equal to $130^{\circ} \mathrm{C}$ | $130^{\circ} \mathrm{C}{ }^{(2)}$ |
| $>130^{\circ} \mathrm{C}$ but less than $150^{\circ} \mathrm{C}$ | $150^{\circ} \mathrm{C}$ (2) |
| $>150^{\circ} \mathrm{C}$ | $175^{\circ} \mathrm{C}$ (2) |

(1) The period of time which represents the worst foreseeable conditions of contact.
(2) This temperature shall be used only for simulant D. For simulant $\mathrm{A}, \mathrm{B}$ or C the test may be replaced by a test at $100^{\circ} \mathrm{C}$ or at reflux temperature for a duration of four times the time selected in accordance with paragraph 1 of this Part.

## Commencement Information

175 Sch. 6 para. 30 in operation at 30.6 .2006, see reg. 1

## Commencement Information

I72 Sch. 6 para. 27 in operation at 30.6.2006, see reg. 1
I73 Sch. 6 para. 28 in operation at 30.6.2006, see reg. 1
I74 Sch. 6 para. 29 in operation at 30.6.2006, see reg. 1
I75 Sch. 6 para. 30 in operation at 30.6.2006, see reg. 1

## PART 6

## Substitute Fat Test for Overall and Specific Migration

31. Subject to paragraphs 2,4 and 5 , all the test media specified in the Table to this Part shall be used in the substitute fat test for overall or specific migration under the test conditions corresponding to the test conditions for simulant D .

## Commencement Information

I76 Sch. 6 para. 31 in operation at 30.6 .2006, see reg. 1
32. Test conditions other than those specified in the Table to this Part may be used in the substitute fat test if the assumptions underlying the test conditions specified in that Table and, where the plastic material or article being tested is a polymer, the existing experience of that type of polymer are taken into account.

## Commencement Information

I77 Sch. 6 para. 32 in operation at 30.6 .2006, see reg. 1
33. For each test-
(a) a new test specimen shall be used;
(b) the rules prescribed for simulant D in Parts 3, 4 and 5 of this Schedule shall be applied for each test medium;
(c) subject to paragraph 4 , compliance with a migration limit shall be determined by selecting the highest value using all the test methods.

## Commencement Information

I78 Sch. 6 para. 33 in operation at 30.6.2006, see reg. 1
34. Where carrying out a migration test causes any physical or other change in the test specimen which does not occur under the worst foreseeable conditions of use of the plastic material or article the result of that test shall not be used to ascertain compliance with a migration limit.

## Commencement Information

I79 Sch. 6 para. 34 in operation at 30.6 .2006 , see reg. 1
35. Any test conditions in the Table to this Part which are generally recognised on the basis of scientific evidence as not being appropriate for the material or article to be tested shall not be used.

## Commencement Information

$\mathbf{I 8 0}$ Sch. 6 para. 35 in operation at 30.6.2006, see reg. 1
36. The Table to this Part shall be read with the notes to it.

CONVENTIONAL CONDITIONS FOR SUBSTITUTE TESTS

| Test conditions with <br> simulant $D$ | Test conditions with <br> isooctane | Test conditions with <br> ethanol $95 \%$ | Test conditions with <br> $M P P O^{(I)}$ |
| :--- | :--- | :--- | :--- |
| 10 days at $5^{\circ} \mathrm{C}$ | 0.5 days at $5^{\circ} \mathrm{C}$ | 10 days at $5^{\circ} \mathrm{C}$ |  |
| 10 days at $20^{\circ} \mathrm{C}$ | 1 day at $20^{\circ} \mathrm{C}$ | 10 days at $20^{\circ} \mathrm{C}$ |  |

(1) $\mathrm{MPPO}=$ Modified polyphenylene oxide
(2) The volatile test media are used up to a maximum temperature of $60^{\circ} \mathrm{C}$. A precondition of using these tests is that the material or article will withstand the test conditions that would otherwise be used with simulant D. Immerse a test specimen in olive oil under the appropriate conditions. If the physical properties are changed (eg melting, deformation) then the material is considered unsuitable for use at that temperature. If the physical properties are not changed then proceed with the substitute tests using new specimens.

| Test conditions with <br> simulant $D$ | Test conditions with <br> isooctane | Test conditions with <br> ethanol $95 \%$ | Test conditions with <br> MPPO |
| :--- | :--- | :--- | :--- |
| 10 days at $40^{\circ} \mathrm{C}$ | 2 days at $20^{\circ} \mathrm{C}$ | 10 days at $40^{\circ} \mathrm{C}$ |  |
| 2 hours at $70^{\circ} \mathrm{C}$ | 0.5 hours at $40^{\circ} \mathrm{C}$ | 2 hours at $60^{\circ} \mathrm{C}$ |  |
| 0.5 hours at $100^{\circ} \mathrm{C}$ | 0.5 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 2.5 hours at $60^{\circ} \mathrm{C}$ | 0.5 hours at $100^{\circ} \mathrm{C}$ |
| 1 hour at $100^{\circ} \mathrm{C}$ | 1 hour at $60^{\circ} \mathrm{C}^{(2)}$ | 3 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 1 hour at $100^{\circ} \mathrm{C}$ |
| 2 hours at $100^{\circ} \mathrm{C}$ | 1.5 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 3.5 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 2 hours at $100^{\circ} \mathrm{C}$ |
| 0.5 hours at $121^{\circ} \mathrm{C}$ | 1.5 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 3.5 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 0.5 hours at $121^{\circ} \mathrm{C}$ |
| 1 hour at $121^{\circ} \mathrm{C}$ | 2 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 4 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 1 hour at $121^{\circ} \mathrm{C}$ |
| 2 hours at $121^{\circ} \mathrm{C}$ | 2.5 hours at $60^{\circ} \mathrm{C}$ | 4.5 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 2 hours at $121^{\circ} \mathrm{C}$ |
| 0.5 hours at $130^{\circ} \mathrm{C}$ | 2 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 4 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 0.5 hours at $130^{\circ} \mathrm{C}$ |
| 1 hour at $130^{\circ} \mathrm{C}$ | 2.5 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 4.5 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 1 hour at $130^{\circ} \mathrm{C}$ |
| 2 hours at $150^{\circ} \mathrm{C}$ | 3 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 5 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 2 hours at $150^{\circ} \mathrm{C}$ |
| 2 hours at $175^{\circ} \mathrm{C}$ | 4 hours at $60^{\circ} \mathrm{C}^{(2)}$ | 6 hours at $60^{\circ} \mathrm{C}$ | 2 hours at $175^{\circ} \mathrm{C}$ |

(1) $\quad$ MPPO $=$ Modified polyphenylene oxide
(2) The volatile test media are used up to a maximum temperature of $60^{\circ} \mathrm{C}$. A precondition of using these tests is that the material or article will withstand the test conditions that would otherwise be used with simulant D. Immerse a test specimen in olive oil under the appropriate conditions. If the physical properties are changed (eg melting, deformation) then the material is considered unsuitable for use at that temperature. If the physical properties are not changed then proceed with the substitute tests using new specimens.

## Commencement Information

I81 Sch. 6 para. 36 in operation at 30.6.2006, see reg. 1

## PART 7

## Alternative Fat Tests for Overall and Specific Migration

37. Subject to paragraph 2 of this Part the conditions which must be fulfilled to allow the result of either test specified in paragraph 3 be used as an alternative to the result of a migration test carried out under Part 3 are that-
(a) the result obtained in a "comparison test" shows that the values are equal to or greater than those obtained in the test with simulant D ; and
(b) the migration occurring in either test specified in paragraph 3 does not, after application of the appropriate reduction factor, exceed the appropriate migration limit.

## Commencement Information

I82 Sch. 6 para. 37 in operation at 30.6.2006, see reg. 1
38. The condition in sub-paragraph (a) of paragraph 1 does not have to be fulfilled if it can be shown on the basis of the result of scientific experiment that the values obtained in either of the
tests specified in paragraph 3 are equal to or greater than those obtained in any of the migration tests specified in Part 3.

## Commencement Information

I83 Sch. 6 para. 38 in operation at 30.6 .2006, see reg. 1
39. The migration tests referred to in paragraphs 2 and 3 are -
(a) a test carried out using volatile media including isooctane, ethanol $95 \%$, other volatile solvents or a mixture of solvents at such contact conditions as would result in values equal to or greater than those obtained in a test using simulant D ;
(b) other tests using media having a very strong extraction power under very severe test conditions where, on the basis of scientific evidence, it is generally recognised that the results using these tests are equal to or higher than those obtained in a test using simulant D .

## Commencement Information

I84 Sch. 6 para. 39 in operation at 30.6.2006, see reg. 1

## EXPLANATORY NOTE

## (This note is not part of the Regulations)

1. These Regulations revoke the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998 as amended ("the 1998 Regulations") and re-enact or re-enact with changes certain provisions contained in those Regulations. The principal Directives that continue to be implemented by these Regulations are listed in paragraph 5 below. These Regulations also provide for the execution and enforcement of Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food ("Regulation 1895/2005").
2. The Regulations in Part 2 -
(a) prohibit specified activities in relation to any plastic material or article (as defined in regulation 2) which fails to meet the appropriate required standards set out in the Regulations (regulation 3);
(b) prohibit the use of monomers and additives in the manufacture of plastic materials and articles other than in accordance with specified conditions (regulation 4 and Schedule 1 in the case of monomers and regulation 5 and Schedule 2 in the case of additives);
(c) specify the required standards relating to the capability of a monomer or an additive to confer its constituents to food (regulation 6 for monomers and regulation 7 for additives);
(d) specify the required standard for products obtained by bacterial fermentation (regulation 8 and Schedule 3);
(e) specify the required standard relating to overall migration limits from plastic materials or articles to food (regulation 9);
(f) specify the required standards relating to the migration of primary aromatic amines from plastic materials or articles to food (regulation 10);
(g) specify the methods for determining the capability of a plastic material or article to transfer its constituents to food, and for detecting the presence of any such constituents in food (regulation 11 and Schedules 5 \& 6);
(h) provide that prior to the retail stage plastic materials and articles must be accompanied by certain specified written information, including a declaration of legislative compliance (regulation 12);
(i) provide for the enforcement of Regulation 1895/2005, which contains Community provisions relating to the epoxy derivatives known as BADGE, BFDGE and NOGE (regulation 13).
3. The Regulations in Part 3 -
(a) designate district councils as the enforcement authorities in their respective areas or districts (regulation 14);
(b) specify the offences that may be committed under these Regulations and set out the maximum penalties on conviction (regulation 15);
(c) provide for defences of a general nature, such as exercise of due diligence etc, to offences under regulation 15 (regulation 10);
(d) provide for transitional defences in relation to certain plastic materials or articles that have already been manufactured or put into circulation in advance of a change in the law that would otherwise have made their manufacture or circulation unlawful (regulation 17);
(e) specify the procedure to be followed when sending a sample for analysis (regulation 18);
(f) make provision for a reference sample to be analysed by the Laboratory for the Government Chemist (regulation 19);
4. Part 4 of the Regulations contains provisions relating to the procedure to be followed and the time limit to be observed where a person wishes apply to the European Food Safety Authority for the authorisation of a new additive (regulation 20).
5. The principal Directives implemented by the 1998 Regulations which these Regulations continue to implement are -
(a) Council Directive 82/711/EEC (OJ No. L297, 23,10,1982, p.26) laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs, as amended by Commission Directives 93//8/EEC (OJ No. L90, 14.4.1993, p.22) and 97/48/EC (OJ No. L222, 12.8.1997, p.10);
(b) Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (OJ No. L372, 31.12.1985, p.14);
(c) Commission Directive 2002/72/EC (OJ No. L220, 15.8.2002, p.18) relating to plastic materials and articles intended to come into contact with foodstuffs, as amended by Commission Directives 2004/1/EC (OJ No. L7, 13.1.2004, p.45) and 2004/19/EC (OJ No. L71, 10.3.2004, p.8).

## Changes to legislation:

There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2006. Any changes that have already been made by the team appear in the content and are referenced with annotations.
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## Changes and effects yet to be applied to :

Regulations revoked by S.R. 2006/420 reg. 25


[^0]:    Changes to legislation: There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 2006. Any changes that have already been made by the team appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

[^1]:    (1) Formerly the Department of Health and Social Services see S.I.1999/283 (N.I.1) Article 3(6)
    (2) S.I. 1991/762 (N.I.7) as amended by S.I. 1996/1663 (N.I.12), paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c. 28 and S.R. 2004 Nos. 482 and 505
    (3) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (OJ No. L245, 29.9.2003, p.4)

[^2]:    (4) OJ No. L297, 23.10.1982, p. 26
    (5) OJ No. L222, 12.8.1997, p. 10
    (6) OJ No. L372, 31.12.1985, p. 14
    (7) OJ No. L184, 15.7.1988, p. 61
    (8) OJ No. L40, 11.2.1989, p. 27
    (9) OJ No. L220, 15.8.2002, p. 18
    (10) OJ No. L71, 10.3.2004, p. 8

[^3]:    (11) S.R. 1998 No. 264, as amended by S.R. 2000 No. 402, S.R. 2002 No. 316, S.R. 2003 No. 2, S.R. 2004 No. 493 and S.R. 2005 No. 49
    (12) S.R. 2005 No. 210
    (13) OJ No. L178, 28.7.97, p.1, as last amended by Commission Directive 2004/46, OJ No. L114, 21.4.2004, p. 15
    (14) OJ No. L226, 22.9.95, p.1, as last amended by Commission Directive 2004/47, OJ No. L113, 20.4.2004, p. 24
    (15) OJ No. L339, 30.12.96, p.1, as last amended by Commission Directive 2003/95, OJ No. L283, 31.10 .2003 , p. 71
    (16) OJ No. L302, 19.11.2005, p. 28

[^4]:    (17) Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ No. L338, 13.11.2004, p.4)

[^5]:    (20) S.R. 2000 No. 402
    (21) S.R. 2002 No. 316
    (22) S.R. 2003 No. 2
    (23) S.R. 2004 No. 493
    (24) S.R. 2005 No. 49

