DUTCH COMMODITIES ACT REGULATION on
PACKAGING AND CONSUMER ARTICLES
unauthorised translation of the text valid from November 27th, 2025

Dutch Ministry of Health, Welfare and Sport

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Regulation of the Minister for Public Health, Welfare and Sport of 14 March 2014, laying down the Commodities Act Regulation on Packaging and Consumer Articles coming into contact with foodstuffs (Commodities Act Regulation Packaging and Consumer Articles) [Warenwetregeling verpakkingen en gebruiksartikelen])

The Minister for Public Health, Welfare and Sport

Having regard to Article 3(1)(a), Article 4(1), and Article 6a(2) of the Commodities Act (Packaging and Consumer Articles) Decree [Warenwetbesluit verpakkingen en gebruiksartikelen];

Hereby decrees as follows:

Article 1

In the present Regulation, the Decree shall be understood to mean: the Commodities Act (Packaging and Consumer Articles) Decree.

Article 2

The following shall be designated as materials within the meaning of Article 3(1)(a) of the Decree:

a. plastics;
b. paper and cardboard;
c. rubber products;
d. metals;
e. glass and glass ceramics;
f. ceramic materials and enamels;
g. textile products;
h. foil made of regenerated cellulose;
i. wood and cork;
j. coatings;
k. colourants and pigments;
l. epoxy polymers.

Article 3

A material as referred to in Article 2 shall be manufactured from the substances listed for such material in the annex to this Regulation, which substances shall comply with the requirements set forth therein for such substances.

Article 4

When manufacturing packaging and consumer articles, any base materials and auxiliary materials for which the annex to this Regulation contains rules for their use, must not be used otherwise than specified in that annex.

Article 5

Packaging and consumer articles manufactured from materials as referred to in Article 2 must not release greater quantities of certain substances into foods and beverages than specified for such substances in the Annex to this Regulation.

Article 5a

Our Minister sets up a committee for the assessment of the safety of food contact materials. **Article 6**

Packaging and consumer articles consisting of materials as referred to in Article 2 shall be subject to the examination methods as contained in the annex to this Regulation.

Article 7

The Packaging and Consumer Articles Regulation (Commodities Act) [Regeling verpakkingen- en gebruiksartikelen (Warenwet)] is hereby repealed.

Article 8

The present Regulation shall enter into force with effect from 1 April 2014.

Article 9

The present Regulation shall be cited as the: Commodities Act Regulation Packaging and Consumer Articles [Warenwetregeling verpakkingen en gebruiksartikelen].

The present regulation shall be published in the Official Gazette [Staatscourant] together with its explanatory memorandum.

The Minister for Public Health, Welfare and Sport,

Dr E.I. Schippers

Explanatory memorandum

General remarks

The Annexes to the Commodities Act Regulation Packaging and Consumer Articles have been amended many times over the years. In addition, Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ (EU) 2011, L 12), below: Regulation (EU) 10/2011, was published on 15 January 2011. Regulation (EU) 10/2011 provides among others for the repeal of Directive 2002/72/EC[1]. That Directive had been implemented in Chapter I of Annex A to the Commodities Act Regulation Packaging and Consumer Articles. Regulation (EU) 10/2011 causes a large part of Chapter I to be superfluous.

In view of the large number of changes made, and the far-reaching nature of the changes with respect to plastics, it has been decided that the Regulation with its Annexes should be re-enacted.

In several places, the annex to the Regulation already mentions the TTC princiope described in part B, chapter III of the annex. However, this chapter is yet to be completed and is therefore not inserted in the annex.

The guidelines for adding new substances to Annex A to the present Regulation may be found on the web site of the National Institute for Public Health and the Environment [Rijksinstituut voor Volksgezondheid en Milieu, below: RIVM]. Requests for additions of substances to Annex A to the present Regulation may be submitted to:

RIVM
Secretariaat Commissie CBVV
Postbus 1, postbak 101
3720 BA Bilthoven

Notification

The draft of the present Regulation has been notified to the European Commission in fulfilment of Article 8(1) of Directive No 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services (OJ (EC) 1998, L 204), below: Directive 98/34/EC. Notification to the European Commission is required since Articles 3, 4 and 5 of this Regulation contain technical regulations as defined in Directive 98/34/EC.
In response to this the European Commission delivered a detailed opinion within the meaning of article 9(2) of Directive 98/34/EC. Below the elements of this detailed opinion and the way these have been taken into account are discussed.
The definition of 'consumer article' in chapter 0 of part A of the Annex would mean that the Draft Regulation would not be applicable to all materials and articles in contact with or intended to come into contact with food. This would mean Directive 2007/42/EC and Directive 84/500/EEC were not properly implemented. The original definition of "consumer article" in chapter 0 of part A was incomplete and superfluous and is therefore skipped. Artikel 1(b) of the Commodities Act (Packaging and Consumer Articles) Decree already contains a definition of "consumer article", which shows that all materials intended to come into contact woth food are included.
The European Commission urged a statement of mutual recognition was included. This request has been granded; the statement is included in artikel 1(2).
As a last remark, the European Commission pointed out that Directive 2007/42/EG had not been properly implemented, as regard the Declaration of Compliance. Chapter VIII of part A of the Annex was changed in orde to correct this mistake.

Administrative costs

The present regulation has no effect on the administrative costs to citizens or businesses, nor is it expected to have any effects on businesses.

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[1] Commission Regulation (EU) No 10/72 of 6 January 2002 on plastic materials and articles intended to come into contact with food (OJ (EU) 2002, L 220).

Regular Commodities Act Consultation Group [Regulier Overleg Warenwet]

The draft of the present regulation was presented to the members of the Regular Commodities Act Consultation Group (ROW)[2]. The ROW members have agreed to the draft, except for some comments that have meanwhile been incorporated.

The Minister for Public Health,Welfare and Sport,

E.I. Schippers

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[2] The ROW is attended by representatives of businesses (industry and trade), consumers, ministries (particularly Public Health, Welfare and Sports, and Economic Affairs), of the Netherlands Food and Consumer Product Safety Authority, and of commodity boards and trade organisations.

ANNEX TO THE COMMODITIES ACT REGULATION PACKAGING AND CONSUMER ARTICLES

Annex Part A

Chapter 0 - Rules applicable to all packaging and consumer articles

0.1 Introduction

Regulation (EC) No 1935/2004[3] lays down certain general requirements that must be fulfilled by all packaging materials and consumer articles that are or come into contact with food.
Regulation (EC) No 2023/2006[4] is a regulation applicable to all packaging materials and consumer articles, which defines requirements for the manufacture of such products.
Regulation (EU) No 10/2011[5] lays down the requirements for plastic packaging. This Regulation contains a list of permitted substances for making the packaging. However, the list of substances for polymerisation auxiliaries is incomplete. Chapter I of Annex A to the present regulation therefore contains an additional list of substances that are permitted at the national level, resulting in a complete list of permitted substances for the manufacture of plastic materials and article.
In addition to this, the Commission has enacted various regulations relating to a specific product, such as:

- Regulation (EC) No 1895/2005[6], on certain epoxy derivatives
- Regulation (EU) No 2022/1616[7], on the recycling of plastics
- Regulation (EC) No 450/2009[8], on certain active and intelligent materials

Materials and articles must comply with the regulations applicable to the specific material or article. In addition to the regulations, a number of Directives have been published by the Council or the Commission. This Directives have been implemented in the relevant chapters of Annex A.

Annex A contains rules and requirements for the following materials:

Chapter	**Type of material**
I	Plastics
II	Paper and cardboard
III	Rubber products
IV	Metals
V	Glass and glass ceramics
VI	Ceramic materials and enamels
VII	Textile products
VIII	Regenerated cellulose film
IX	Wood and cork
X	Coatings
XI	Colourants and pigments
XII	Epoxy polymers

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[3] Regulation (EC) No 1935/2004 of the European Parliament and the Council of 27 October 2004 on materials and articles intended to come into contact with food, and repealing Directives 80/590/EEC and 89/109/EEC (OJ (EC) 2004, L 338).

[4] Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ (EC) 2006, L 384).

[5] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ (EU) 2011, L 12).

[6] Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (OJ (EC) 2005, L 302).

[7] Commission Regulation (EU) No 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with food, and repealing Regulation (EC) no. 282/2008.

[8] Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food (OJ (EC) 2009, L 135).

0.2 Scope of the Commodities Act (Packaging and Consumer Articles) Decree

a) The following chapters of Annex A contain specific rules for the manufacture, processing and use of materials.The Commodities Act (Packaging and Consumer Articles) Decree is applicable to all materials as referred to in Section 0.1 that are intended to come into contact with food in one form or other.

b) The chapters of Annex A contain substances (base materials, base materials and auxiliary materials) that are permitted for the manufacture of a given material. Only the listed substances may be used for the manufacture of the respective material, taking account of the restrictions specified for the substance.

c) Colourants and pigments may be used in the manufacture of a final product, provided that the colourants and pigments as well as the final product meet the requirements set forth in Chapter XI.

d) For multilayer materials and articles, and for mixtures of materials, the composition of each layer or material must fulfil the composition requirements for the relevant material, if the latter falls within the scope of the Commodities Act (Packaging and Consumer Articles) Decree.

e) Annex B contains the methods that may or must be employed to demonstrate compliance of the packaging material, consumer item or substance with the requirements.

f) General requirements have been included in this chapter.
Specific requirements or exceptions to the general requirements have been included in the relevant chapter for a specific material.

g) Proof of compliance with the requirements of the Commodities Act (Packaging and Consumer Articles) Decree shall be subject to the rules for plastics as laid down in Article 18 of Regulation (EU) No 10/2011.
Deviations or exceptions to these have been included below, in the relevant chapter, or in Annex B.

0.3 Substances not included

Notwithstanding Section 0.2 (b), the following substances may be used or be present provided that the final product complies with Article 3 of Regulation (EC) No 1935/2004 and the total or specific migration limit is not exceeded.

a) solvents
Excluded are solvents for regenerated cellulose film.

b) aluminium, ammonium, barium, calcium, iron, potassium, cobalt, copper, lithium, magnesium, manganese, sodium and zinc salts (including double salts and acid salts) of the permitted acids, phenols and alcohols.
Migration of certain cations must comply with the limits set forth in Regulation (EU) No 10/2011, Annex II.
For cations not included here, for which Chapters I-XII contain a specific migration limit, the sum of the migration of the relevant cation, irrespective of the permitted salt, must not exceed the limit specified for the individual substance.

c) if used as an additive: natural or synthetic polymers with a molecular mass of at least 1 000 Da, with the exception of macromolecules obtained through microbial fermentation that meets the requirements of Regulation (EU) No 10/2011, if they can function as the main structural component of finished materials or articles;

d) if used as a monomer or other base substance: prepolymers and natural or synthetic macromolecular substances as well as mixtures thereof, with the exception of macromolecules obtained through microbial fermentation, if the monomers or base substances that are necessary for the synthesis of these compounds, are listed in Annex I, Table 1 of Regulation (EU) No 10/2011.

e) substances not falling within the scope of Sections (a) to (d) may be used provided that they meet the following requirements:

- Migration of the aforementioned substances into food or food simulants must not with statistical certainty in accordance with Article 34 (1), (2), (4) to (6), and Article 35, (1) and (2), of Regulation 2017/625[9], be demonstrable with an analytical method that has a detection limit of 0.01 mg/kg. This limit is always expressed as a concentration (mg/kg) in foodstuffs or food simulants, or if the ratio of surface area to volume is unknown, an area:volume ratio of 6 dm²/kg of food is assumed;
- The limit (0.01 mg/kg) applies to the sum of a group of compounds if they are structurally and toxicologically related, notably isomers or compounds with the same relevant functional group;
- The limit (0.01 mg/kg) also applies to substances that migrate into the food contact side through transfer, and then migrate into the food during contact with the food (set-off).

Substances as referred to in this subsection must not belong to any of the following categories:

- substances classified as "mutagenic", "carcinogenic" or "toxic for reproduction" in accordance with the criteria of Points 3.5, 3.6 and 3.7 of Annex I to Regulation (EC) No 1272/2008[10];
- substances in nano form.

f) substances that have not been deliberately added may be present, such as:

- contaminants in the substances used;
- intermediate products produced during manufacture;
- reaction or decomposition products.

0.4 Requirements for substances

0.4.1 General requirements

Substances used in the manufacture of materials and articles must be of appropriate technical quality and purity and must not be used in greater quantities than strictly necessary to manufacture the final product, in light of the intended and expected uses of the materials and articles. The manufacturer must know the composition of the substance and disclose it to the competent authorities upon request.

0.4.2 Specific requirements for substances

Substances used in the manufacture of materials and articles are subject to the following restrictions and specifications:

a) the specific migration limit as contained in the lists of substances in the relevant chapters;

b) the total migration limit;

c) the restrictions and specifications as contained in the lists of substances in the relevant chapters;

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

[10] Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ (EC) 2008, L 353).

d) substances subject to a restriction in food, for which specifications have been defined in Regulation (EU) No 231/2012[11], must comply with the purity requirements related to health risks For substances that do not meet the relevant purity requirements, the migration of the impurities must comply with Articles 3a and 3c of Regulation (EC) No 1935/2004;

e) Permitted substances consisting (partly) of nano particles may be used provided that the final product still complies with Article 3 of Regulation (EC) No 1935/2004.

0.5 Requirements for packaging and consumer articles

Migration requirements relate to the respective final product. If the final product is composed of several materials, including plastics, then the final product must comply with each of the specifications and restrictions laid down in the relevant chapters for the individual materials.

0.5.1 Specific migration requirements

a) The migration of ingredients of materials and articles into food must not be higher than the specific migration limits (SMLs) included in the lists for the relevant materials. The SMLs are expressed as mg of substance per kg of foodstuff (mg/kg).

b) If no specific migration limit or other restriction has been included in the lists for a given substance, then a default specific migration limit of 60 mg/kg applies.

c) Notwithstanding Sections (a) and (b), the migration of substances that are also permitted as food additives in Regulation (EC) No 1333/2008[12] or as flavourings pursuant to Regulation (EC) No 1334/2008[13], must not be such that the substance has a technical effect in the final foodstuff, and the migration:

- in foodstuffs where the use of the relevant substance as a food additive or flavouring is permitted pursuant to Regulation (EC) No 1333/2008 or Regulation (EC) No 1334/2008, must not be higher than the limits as contained in the aforementioned regulations or the lists of substances in Annex A,
- in foodstuffs where the use of the substance as a food additive or flavouring is not permitted, must not be higher than the limits contained in the lists in Annex A,

d) Notwithstanding Sections (a) and (b), the specific migration of ingredients of materials and articles expressed as mg/dm² after multiplication with an applicable factor as referred to in Annex B, Section 4.1.1.2, Table 4.1, must not be higher than the specific migration limit (SML) as included in the lists for the relevant materials.
1. For materials and articles consisting only of plastics, the factor is always 6.
2. For substances with a "non-detectable" (ND) migration limit, the factor is always 6.

e) The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo coupling shall comply with the requirements set out in Annex II, Section 2, to Regulation (EU) No 10/2011.

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[11] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ (EU) 2012, L 83).

[12] Regulation (EC) No 1333/2008 of the European Parliament and the Council of 16 December 2008 on food additives (OJ (EC) 2008, L 354).

[13] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulation (EC) No 2232/96, Regulation (EC) No 110/2008 and Directive 2000/13/EC (OJ (EC) 2008, L 354).

0.5.2 Total migration requirements[15]

a) The total migration of ingredients of materials and articles, including materials and articles composed of different materials, into food simulants, must not be higher than 10 mg per dm² of the area coming into contact with foodstuffs (mg/dm²), unless stated otherwise in the chapter for the relevant material.

b) Notwithstanding Subsection (a), the total migration of ingredients of materials and articles intended to come into contact with foodstuffs for infants and toddlers, as described in Regulation (EU) 609/2013, into food simulants, must not be higher than 60 mg per kg of food simulant.

c) Notwithstanding Subsection (a), the total migration into food simulants of the ingredients of materials and articles intended to come into contact with foodstuffs must not be higher than 60 mg per kg of food simulant if an applicable factor as referred to in Annex B, Section 4.1.1.2, Table 4.1, has been used.

d) Notwithstanding Subsection (a) the total migration limit does not apply to materials made of regenerated cellulose.

0.5.3 Requirements for residual content

a) The residual content (QM) of ingredients of materials and articles must not be higher than the values included in the lists for the relevant materials. The QM is expressed as mg of substance per kg of final product (mg/kg).

0.5.4 Requirements for residual content per surface area

a) The residual content (QMA) of ingredients of materials and articles must not be higher than the values included in the lists for the relevant materials. The QMA is expressed as mg of substance per 6 dm² of the final product that is or comes into contact with the foodstuff (mg/6 dm²), unless stated otherwise for the relevant substance.

0.6 Expression of the results of migration tests

a) To assess compliance, the specific migration values are expressed as mg/kg using the actual area-volume ratio during actual or expected use.

b) Notwithstanding Subsection (a) the migration is expressed as mg/dm² using an area/volume ratio of 6 dm² per kg of food for:

- receptacles and other articles containing less than 500 ml or g or more than 10 l but less than 25 l, or that are intended for such quantities,
- foil and film shaped into receptacles containing less than 500 ml or g,
- materials and articles for which, because of their shape, it is impracticable to estimate the ratio between the area of such materials or articles and the quantity of foodstuffs that will come into contact with them,
- foil and film that have not yet come into contact with foodstuffs.

c) For materials and articles that are not yet in contact with foodstuffs, and for which the ratio between area and foodstuff cannot be determined (yet), the migration is expressed as mg/dm² after applying a relevant factor as referred to in Annex B, Section 4.1.1.2, Table 4.1, for purposes of assessment of compliance with the migration requirements. Sections b) and c) do not apply to materials and articles that are intended to come into contact, or that are already in contact, with foodstuffs for infants and toddlers as described in Regulation (EU) 609/2013.

d) Notwithstanding Subsection (a), the specific migration for caps, covers, gaskets, plugs and similar materials and articles used for closing purposes, is expressed as:

- mg/kg using the actual volume of the receptacle for which the closing device is intended, or,

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[15] The total migration requirement is the sum of all non-volatile substances that are released into food simulants.

- as mg/dm^2 using the total contact surface between the closing article and the receptacle being closed, if the intended use of the article is known, subject to Subsection (b);
- mg/article if the intended use of the article is unknown.

e) For caps, covers, gaskets, plugs and similar materials and articles used for closing purposes, the total migration is expressed as:

- as mg/dm^2 using the total contact surface between the closing article and the receptacle being closed, if the intended use of the article is known;
- mg/article if the intended use of the article is unknown.

For demonstrations of compliance with the relevant migration requirements for the articles referred to in d) and e), the sum of the migration of the closing device and the receptacle must not exceed the specified requirements.

0.7 Rules for assessing compliance with the migration limits

1. For materials and articles that are already in contact with foodstuffs, compliance with the specific migration limits is determined pursuant to Annex B, Chapter I, Section 4.

2. For materials and articles that are not yet in contact with foodstuffs, compliance with the specific and total migration limits is determined pursuant to Annex B, Chapter I, Section 4.

3. For materials and articles that are not yet in contact with foodstuffs, compliance with the specific migration limit may be determined using the screening method pursuant to Annex B, Chapter I, Section 4. If the screening shows that a material or article does not comply with the migration limits, the lack of compliance should be confirmed in accordance with Subsection 2.
4. Test results for specific migration into foodstuffs take precedence over test results obtained with food simulants. Test results for specific migration into food simulants take precedence over results obtained through screening methods.

5. Where applicable, the correction factors specified in Annex B, Chapter I, Section 4.1.1.2, should be applied, in the manner indicated there, before comparing the test results for specific and total migration to the migration limits.

0.8 Assessment of substances not included in the EU list

For the substances referred to in Section 0.3, Sections a), e) and f), that are not included in the lists of substances in Annex A, Chapters I to XII, compliance with Article 3(1) (a) of Regulation (EC) No 1935/2004 is assessed on the basis of internationally recognised scientific risk assessment principles.

Assessment based on the TTC principle as described in Annex B, Chapter III is an accepted method.

0.9 Declaration of compliance

1. In all stages of the commercial cycle, except for retail trading, a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 must be available for all materials and articles, intermediate products and semifinished products thereof, as well as substances intended for the manufacture of such materials and articles.

2. The written declaration referred to in the previous subsection shall be issued by the operator and shall contain the information specified in Annex 1 to this chapter.

3. The written declaration must enable easy identification of the materials, articles, intermediate products, semifinished products or substances for which it was issued. In case of radical changes to the composition or manufacturing process that give rise to changes in migration rates from the materials or articles, or if new scientific data

become available, a new declaration must be issued.

4. The requirement of a declaration of compliance applies only if it has been specified in the chapter for the relevant material.

0.10 Definitions

Definitions in connection with plastics are contained in Regulation (EU) No 10/2011. Definitions included in the Plastics Regulation may also apply to non-plastic materials. This section contains definitions of general application for non-plastic materials. Specific definitions are contained in the chapters for the various materials in Annex A.

1. Prepolymer used as monomer: a polymer with often a relatively low molecular weight, and often an intermediate product between the monomer and the final polymer. A prepolymer used as monomer must consist of at least two monomer units of each of the monomers used. A prepolymer should be fully incorporated into the polymer chain, and will be deemed not to be present in the final product.

2. Threshold of Toxicological Concern (TTC): a concept used to derive human-exposure thresholds for groups of chemicals, below which no observable health risks are expected to occur. The TTC principle may be used to assess the safety of chemicals that may exhibit limited migration from packaging materials and consumer articles in compliance with Article 3(1)(a) of Regulation (EC) No 1935/2004.

0.11 Abbreviations used

Da = Dalton
DT = detection threshold of the analytical method
FP = final product
FCM no. = food contact material sequential number. The number refers to a substance listed in Annex I to Regulation (EU) No 10/2011
FRF = Fat Reduction Factor as referred to in paragraph 4.1 of chapter 4 of annexe V to Regulation (EU) No. 10/2011
MW = molecular weight
NCO = isocyanate group
ND = not detectable
In the present Regulation, ND (non-detectable) means that the presence of the substance cannot be demonstrated with an analytical method validated for the specified detection threshold.
If such a method is not yet available, then a method with an appropriate performance characteristic for the specified detection threshold may be used pending the development of a validated method.
NIAS = non-intentionally added substance
QM = maximum permitted residual quantity of the substance in the material or article. For purposes of these provisions, the quantity of the substance in the material or article is determined using a validated analytical method. If such a method is not yet available, then an analytical method with an appropriate performance characteristic for the specified threshold may be used pending the development of a validated method.
QMA = maximum permitted residual quantity of the substance in the final material or article, expressed as mg per 6 dm² of the area coming into contact with the foodstuff. For purposes of these provisions, the quantity of the substance in the area of the material or article must be determined using a validated analytical method. If such a method is not yet available, then an analytical method with an appropriate performance characteristic for the specified threshold may be used pending the development of a validated method.
QMA(T) = maximum permitted residual quantity of the substance in the material or article, as the total of the listed substance(s) or a part thereof, expressed as mg per 6 dm² of the area coming into contact with the foodstuff. For purposes of these provisions, the quantity of the substance in the area of the material or article must be determined using a validated analytical method. If such a method is not yet available, then an analytical method with an appropriate performance characteristic for the specified threshold may be used pending the development of a validated method.
QM(T) = maximum permitted residual quantity of the substance in the material or article, expressed as the total of the listed substance(s) or part thereof. For purposes of these provisions, the quantity of the substance in the material or article must be determined using a validated analytical method. If such a method is not yet available, then an analytical method with an appropriate performance characteristic for the specified threshold may be used pending the development of a validated method.
Ref No = reference number assigned by the European Commission. The number produces an alphabetical ordering for monomers and additives.
SENS = migration of the substance may negatively affect the sensory properties of foodstuffs coming into contact with the final product containing the substance. If that is the case, then the final product does not complies with the provisions of Article 3(1)(c) of Regulation (EC) No 1935/2004.
SML = specific migration limit in mg/kg in foodstuffs or in simulants, unless otherwise indicated. For purposes of this directive, the specific migration of the substance must be determined using a validated analytical method. If such a method is not yet available, then an analytical method with an appropriate performance characteristic for the specified threshold may be used pending the development of a validated method.
SML(T) = specific migration limit in mg/kg in foodstuffs or simulants, expressed as the total of the listed substance(s) or part thereof. For purposes of this Regulation, the specific migration of the substance must be determined using a validated analytical method. If such a method is not yet available, then an analytical method with an appropriate performance characteristic for the specified threshold may be used pending the development of a validated method.
TTC = threshold of toxicological concern.

ANNEX 1

Declaration of compliance

The written declaration referred to in Section 0.9 shall contain the following information:

1. the identity and address of the operator issuing the declaration of compliance;
2. the identity and address of the operator manufacturing or importing the materials or articles, intermediate products or semifinished products thereof, or substances intended for the manufacture of such materials or articles;
3. the identity of the materials or articles, intermediate products or semifinished products thereof, or substances intended for the manufacture of such materials or articles;
4. the date of the declaration;
5. a statement to the effect that the materials or articles, intermediate products or semifinished products thereof, or substances comply with the relevant requirements of this regulation and of Regulation (EC) No 1935/2004;
6. adequate information about the used substances or metabolites thereof, for which Chapters I–XII of Annex A contain restrictions or specifications, so that downstream operators can ensure compliance with those restrictions or specifications;
7. the use of substances as permitted in foodstuffs
   i) adequate information[16] about the substances for which a restriction applies in foodstuffs, obtained based on experimental data or theoretical calculations, about the specific migration of such substances
   ii) adequate information about purity requirements in accordance with Regulation (EU) No 231/2012[17], for substances that could present a risk to public health (e.g. mutagenic substances) or,
   iii) adequate information on the migration of impurities in accordance with Section 0.4.2 (d),

   enabling the user of such materials and articles to comply with the relevant EU provisions or, if those are absent, with the national provisions for foodstuffs;
8. the specifications for the use of the material or the article, such as:
   i) the type(s) of foodstuffs with which it is permitted to come into contact;
   ii) maximum duration and temperature during treatment and storage of the foodstuffs;
   iii) the ratio between the area coming into contact with foodstuffs and the volume, based on which it was found that the material or article meets the requirements;
9. if a substance as referred to in Section 0.3 (e) has been used, there must be a mention of the fact that the principle of "no migration" is used in respect of conformity with Article 3 of Regulation (EC) No 1935/2004.

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[16] If the migration of a dual-use additive from a packaging CANNOT constitute a significant contribution, it is not necessary to mention the presence of the additive to the next party down the chain. A significant contribution is defined here as a migratable volume of additive constituting no more than 5% of limit for the relevant food types.

[17] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ (EU) 2012, L 83).

Chapter I - Plastics

1. Introduction

Plastics in contact with or intended to come into contact with foodstuffs are subject to the requirements as laid down in Regulation (EU) No 10/2011. Certain groups of substances have not yet been included in the lists of permitted substances in Regulation (EU) No 10/2011. This is true particularly for substances necessary to make polymer resins. Without giving an exhaustive listing here, such substances might include:

- initiators, catalytic converters, catalyst carriers, chain-shortening and chain-lengthening substances, chain stoppers, chain-interlinking substances, polymerisation inhibitors, reducing reagents.

The aforementioned substances are necessary to produce the polymer resin and to give it its desired physical, chemical and technical characteristics. Substances are also needed to create the right medium and conditions in which polymerisation can take place. These substances include e.g. the following:

- anti-foaming agents, buffer solutions, build-up-suppressants, dispersants and emulsifiers, flow-control substances, pH regulators, solvents, surfactants, emulsion stabilisers, thickening agents and substances for the treatment of process water.

These groups of substances are together referred to as "polymerisation auxiliaries". Some substances in the aforementioned groups have been included in Regulation (EU) No 10/2011, but the list of substances is (still) incomplete. Authorisation for additional substances is the responsibility of the national government.
Substances included as additives in the list of authorised substances in Regulation (EU) No 10/2011 may also be used as polymerisation auxiliaries, provided that the applicable restrictions are observed.

2. List of additional substances

a) Residues and decomposition products of polymerisation auxiliaries can and may be present in the final product. However, to avoid classification as a monomer or additive pursuant to Regulation (EU) No 10/2011, the substance must not exhibit any physical or chemical effect in the final product.

b) Supplementing the list of substances in Annex I to Regulation (EU) No 10/2011, Table I-1 lists substances that may be used in or during the polymerisation process. Substances as referred to in Section 1, that are not listed in Annex I to Regulation (EU) No 10/2011, nor in Table I-1, may be used provided that the final product still complies with Article 3 of Regulation (EC) No 1935/2004 and with the provisions of Section 0.3 (f) of Annex A.

c) Table I-1 lists the substances that form the decomposition products of the used substance. Because the used substance has then been fully decomposed, a restriction has been included for the decomposition product. It is not permitted, however, to use the decomposition product as a base substance.

d) Supplementing Table I-1, polymerisation auxiliaries that fully decompose into substances that are all listed in Annex I to Regulation (EU) No 10/2011 or in Table I-1 of this chapter, may also be used.

3. Requirements for the final product

a) The final product must comply with the composition requirements applicable in accordance with Regulation (EU) No 10/2011 and Table I-1 of this chapter.

b) The final product must comply with the specific migration limit(s) as contained in Regulation (EU) No 10/2011 and in Table I-1 of this chapter.

c) Regulation (EU) No 10/2011 defines the requirements that plastic materials intended to come into contact with foodstuffs must fulfil.

d) The rules in Regulation (EU) No 10/2011 are also applicable to the list of substances included in Table I-1.

e) Substances belonging to the categories listed in Section 1, but not listed in Table I-1, may be used if they comply with the requirements in Section 0.3 (e) of Annex A.

f) The requirement of having a declaration of compliance and supporting documents included in Regulation (EU) No 10/2011 applies also to the substances referred to in Table I-1 and to substances used in accordance with Section 0.3 (f) of Annex A.

g) Where requirements and rules in Chapter 0 of Annex A contradict the requirements and rules of Regulation (EU) No 10/2011, then Regulation (EU) No 10/2011 prevails.

Table I-1 Polymerisation auxiliaries and their decomposition products that are still permitted for use at the national level.

Ref No	Cas No	Name	SMLmg/kg	Restriction or specification
-	37187-22-7	acetyl acetone peroxide	ND	(1)
-	3179-56-4	acetyl cyclohexane sulfonyl peroxide	ND	(1)
-	-	adipic acid, esters with alcohols, monovalent, aliphatic, non-branching, primary, saturated, C6-C12	-	
-	-	adipic acid, esters with alcohols, monovalent, aliphatic, branched, primary, saturated, C6-C12	18	
-	-	alkanes and cycloalkanes, boiling point up to 100 °C	-	
-	-	alkyl(C8-C14) mercaptane	-	
-	-	alkyl(C8-C18) poly(ethane or propene or butene oxide)-oxymethane carboxylic acid	-	
-	-	3-aminocrotonic acid, esters with aliphatic alcohols, C16-C18	-	
-	-	3-aminocrotonic acid, esters with 1,4-butanediol	-	
-	19341-54-9	aminoethane amidinehydrochloride (= ethylene guanidinehydrochloride)	ND	
-	10192-30-0	ammonium bisulfite	10	
-	7727-54-0	ammonium peroxodisulfate	ND	(1)
-	75-85-4	tert-amyl alcohol		(4)
-	13653-62-8	2,2-di-(tert-amylperoxy) butane	NA	(1)
-	686-31-7	tert-amylperoxy-2-ethyl hexanoate	ND	(1)
-	-	antimony oxides	0.04	as antimony
-	-	azelaic acid, esters with alcohols, monovalent, aliphatic, non-branching, primary, saturated, C6-C12	-	
-	-	azelaic acid, esters with alcohols, monovalent, aliphatic, branched, primary, saturated, C6-C12	18	
-	25551-14-8	azobis(cyclohexane carbonitril)	-	
-	78-67-1	2,2'-azobis(isobutyronitril)	-	
37520	2634-33-5	1,2-benzisothiazoline-3-one	0.5	
-	106-51-4	benzochinone	0.05	
-	56-93-9	benzyltrimethyl ammonium chloride	ND	
-	3088-74-2	2,2-bis [4,4-bis(tert-butyl peroxy) cyclohexyl]propane	ND	(1)
-	6410-72-6	bis(2-butoxyethyl) peroxydicarbonate	ND	(1)
-	15520-11-3	bis(4-tert-butyl cyclohexyl) peroxydicarbonate	ND	(1)
-	2212-81-9	1,3-bis(tert-butyl peroxy isopropyl) benzene	ND	(1)
-	25155-25-3	1.4-bis(tert-butyl peroxy isopropyl) benzene	ND	(1)
-	-	biscarbamidolactams	-	
-	94-17-7	bis(chlorobenzoyl) peroxide	ND	(1)
-	14245-74-0	bis(4-chlorobutyl) peroxydicarbonate	ND	(1)
-	133-14-2	bis(2,4-dichlorobenzoyl) peroxide	ND	(1)
-	16111-62-9	bis(2-ethylhexyl) peroxydicarbonate	ND	(1)
-	721-26-6	1,3-bis(alfa-hydroperoxyisopropyl)benzene	ND	(1)
-	3159-98-6	1.4-bis(alfa-hydroperoxyisopropyl)benzene	ND	(1)
-	-	bis(4-isocyanatophenyl) methane and its addition product with phenol	0.01	(2) (as NCO)
-	141-07-1	N,N'-bis(methoxymethyl) urea	-	
-	3034-79-5	bis(2-methyl benzoyl) peroxide	ND	(1)
-	3851-87-4	bis(3,5,5-trimethyl hexanoyl) peroxide	ND	(1)
-	7637-07-2	boron trifluoride	1	as boron
-	109-63-7	boron trifluoride-diethyl etherate	1	as boron
-	78-92-2	butanol-2	-	
-	627-27-0	3-butene-1-ol	-	
-	3457-61-2	tert-butylcumyl peroxide	ND	(1)
	58775-05-6	2,7-di-tert-butyl fluorene	0.01	as decomposition product
-	75-91-2	tert-butyl hydroperoxide	ND	(1)
-	109-72-8	n-butyl lithium		SML$_{Li}$ See Annex II, Regulation (EC) No 10/2011

Ref No	Cas No	Name	SMLmg/kg	Restriction or specification
-	598-30-1	sec-butyl lithium		SML$_{Li}$ See Annex II, Regulation (EC) No 10/2011
-	1232839-86-9	5-tert-butyl-3-methyl-1,2-phenylene dibenzo-ate	0.05	SML includes decomposition products
-	107-71-1	tert-butyl peroxyacetate	ND	(1)
-	614-45-9	tert-butyl peroxy benzoate	ND	(1)
-	-	tert-butyl peroxy butyrate	ND	(1)
-	2550-33-6	tert-butyl peroxy diethyl acetate	ND	(1)
-	-	tert-butyl peroxy-2,2-dimethyl octanoate	ND	(1)
-	-	tert-butyl peroxy esters of aliphatic carboxylic acids, C6-C14	ND	(1)
-	3006-82-4	tert-butyl peroxy-2-ethyl hexanoate	ND	(1)
-	109-13-7	tert-butyl peroxy isobutyrate	ND	(1)
-	2372-21-6	tert-butyl peroxy isopropyl carbonate	ND	(1)
-	26748-41-4	tert-butyl peroxy neodecanoate	ND	(1)
-	3006-82-4	tert-butyl peroxy octanoate	ND	(1)
-	927-07-1	tert-butyl peroxy pivalate	ND	(1)
-	14206-05-4	tert-butyl peroxy propionate	ND	(1)
-	13122-18-4	tert-butyl peroxy-3,5,5-trimethyl hexanoate	ND	(1)
-	7789-75-5	calcium fluoride	-	
-	-	cerium octanoate	1	as cerium
-	11118-57-3 or 1308-38-9	chromium oxide	0.1	as chromium
-	7738-94-5 or 13530-68-2	chromic acid	0.1	as chromium
-	-	citric acid, esters with alcohols, monovalent, aliphatic, non-branching, primary, saturated, C6-C12	-	
-	-	citric acid, esters with alcohols, monovalent, aliphatic, branched, primary, saturated, C6-C12	18	
-	-	rosin, calcium and zinc salts, according to chapter IV, point 2.2 (f)	-	SML (zinc): see annexe II, Regulation (EU) No. 10/2011
-	-	rosin (gum resin, wood resin, talc resin), whether or not modified through catalytic disproportioning, and wholly, partially or not saponified into potassium or sodium soaps		The product after catalytic disproportioning contains no more than 0.25% of substituted phenantrene (as retene)
-	80-15-9	cumyl hydroperoxide	ND	(1)
-	12262-38-7	cyclohexanone peroxide	ND	(1)
-	54693-46-8	di-acetone alcohol peroxide	ND	(1)
-	110-22-5	diacetyl peroxide	ND	(1)
-	1129-30-2	2,6-diacetyl pyridine	ND	(1) (4)
-		diacyl(C8-C14) peroxides	ND	(1)
-	-	dialkyl(C16-C18) methyl amine	0.7	
-	123-23-9	disuccinic acid peroxide	ND	(1)
-	94-36-0	dibenzoyl peroxide	ND	(1)
-	2568-90-3	dibutoxymethane (= butylal)	-	
-	111-92-2	di-n-butylamine	ND	
-	1869105-01-0	3-(3,6-di-tert-butyl-9H-carbazol-9-yl)-5'-fluoro-5-(2,4,4-trimethylpentane-2-yl)-[1,1'-biphenyl]-2,2'-diol	0.05	(4) (6); FRF applies
-	2036346-35-5	(((3'-(3,6-di-tert-butyl-9H-carbazol-9-yl)-5-fluoro-2'-hydroxy-5'-(2,4,4-trimethylpentane-2-yl)-[1,1'-biphenyl]-2-yl)oxy)methyl)diisopropylsilanol	0.05	(4) (6); FRF applies
-	2036346-36-6	3-(3,6-di-tert-butyl-1-ethyl-9H-carbazol-9-yl)-5`-fluoro-5-(2,4,4-trimethylpentan-2-yl)-[1,1’-biphenyl]-2,2'-diol	0.05	(4) (6); FRF applies

Ref No	Cas No	Name	SMLmg/kg	Restriction or specification
-	1616555-80-6	3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-2‵-(3-((3′-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5-fluoro-2‵-hydroxy-5′-(2,4,4-tri-methylpentane-2-yl)-[1,1'-biphenyl]-2-yl)oxy)propoxy)-5‵-fluoro-3′-methyl-5-(2,4,4-trimethylpentane-2-yl)-[1,1'-biphenyl]-2-ol	0.05	(4) (6); FRF applies
-	1821136-42-8	3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5'-fluoro-5-(2,4,4-trimethylpentane-2-yl)-[1,1'-biphenyl]-2,2'-diol	0.05	(4) (6); FRF applies
-	1821136-41-7	3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5'-fluoro-3'-methyl-5-(2,4,4-trimethylpentan-2-yl)-[1,1'-biphenyl]-2,2'-diol	-	(4) (6); FRF applies
-	2010152-49-3	3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5'-(dimethyl(octyl)silyl)-3‵-methyl-5-(2,4,4-trimethylpentan-2-yl)-[1,1′-biphenyl]-2,2'-diol	-	(4) (8); FRF applies
-	16580-06-6	di-tert-butyl diperoxyazelate	ND	(1)
-	961-24-7	N,N'-di-tert-butyl ethylene diamine	ND	
-	1808206-88-3	3",5,5"-tri-tert-butyl-5'-methyl-[1,1':3',1"-terphenyl]-2,2'-diol	0.05	(4) (7); FRF applies
-	2088749-18-0	3",5,5"-tri-tert-butyl-5'-octyl-[1,1':3',1"—terphenyl]-2,2'-diol	0.05	(4) (7); FRF applies
-	110-05-4	di-tert-butyl peroxide	ND	(1)
-	2167-23-9	2,2-di-tert-butyl peroxybutane	ND	(1)
-	995-33-5	4,4-di-tert-butyl peroxy-n-butyl valerate	ND	(1)
-	3006-86-8	1,1-di-tert-butyl peroxycyclohexane	ND	(1)
-	19910-65-7	di-sec-butyl peroxydicarbonate	ND	(1)
-	2167-23-9	2,2-di-tert-butyl peroxyhexane	ND	(1)
-	6731-36-8	1,1-di-tert-butyl peroxy-3,3,5-trimethyl cyclohexane	ND	(1)
-	95-50-1	1,2-dichlorobenzene	18	
-	80-43-3	dicumyl peroxide	ND	(1)
-	911296-54-3	2,2"'-(((1R,2R)—cyclohexane-1,2-diyl)bis-methylene))bis(oxy)-bis(3-(9H-carbazol-9-yl)-5-methyl-[1,1'-biphenyl]—2-ol)	0.05	(4); FRF applies
-	84-61-7	dicyclohexyl phthalate	15	
-	1561-49-5	dicyclohexyl peroxydicarbonate	ND	(1)
-	109-89-7	diethyl amine	ND	
-	91-66-7	N,N-diethyl aniline	ND	
-	100-37-8	diethyl hydroxyethyl amine	ND	
-	3710-84-7	N,N-diethyl hydroxyl amine		QMA = 0.01 mg/6 dm^2 Maximum quantity of N-nitrosodiethylamine = 0.5 mg per kg of N,N-diethyl hydroxyl amine; Maximum quantity of diethyl amine = 1 g per kg of N,N-diethyl hydroxyl amine
-	14666-78-5	diethyl peroxydicarbonate	ND	(1)
-	122-39-4	diphenyl amine	-	
-	98-29-3	1,2-di-hydroxy-4-tert-butyl benzene	-	
-	98-29-3	1.4-di-hydroxy-2-tert-butyl benzene	-	
	84-69-5	diisobutyl phthalate	0.6	(9)
-	3437-84-1	di-isobutyryl peroxide		Only to be used up to a maximum of 0.2% during suspension polymerisation of PVC
-	-	di-isocyanate of dimerised oleic acid	0.01	(2) (as NCO)
-	-	2,5-di-isocyanato-P-xylene	0.01	(2) (as NCO)
-	-	2.6-di-isocyanato-P-xylene	0.01	(2) (as NCO)

Ref No	Cas No	Name	SMLmg/kg	Restriction or specification
-	110-97-4	di-isopropanolamine	5	the SML does not apply to applications to which simulant D2 applies; in these cases, a QMA of 5 mg/6 dm^2 EP shall apply
-	26762-93-6	diisopropylbenzene hydroperoxide	ND	(1)
-	105-64-6	di-isopropyl peroxydicarbonate	ND	(1)
-	109-87-5	dimethoxymethane (methylal)	-	
-	8001-54-5	dimethyl alkyl(C8-C18) benzyl ammonium chloride	ND	(3)
-	-	dimethyl alkyl(C8-C18) benzyl ammonium phthalate	ND	(3)
-	-	dimethyl alkyl(C8-C18) benzyl ammonium saccharinate	ND	(3)
-	121-69-7	N,N-dimethyl aniline	ND	(3)
	118612-00-3	N,N-dimethyl anilinium tetrakis (pentafluorophenyl) borate	0.0025	SML applies to the total migration of fluorine
-	927-62-8	N,N-dimethyl-n-butylamine	ND	(3)
-	-	dimethyl dialkyl(C16 or C18) ammonium acetate	ND	(3)
-	78-63-7	2,5-dimethyl-2,5-di(tert-butyl peroxy) hexane	ND	(1)
-	1068-27-5	2,5-dimethyl-2,5-di(tert-butyl peroxy) hexyn-3	ND	(1)
-	112-18-5	N,N-dimethyl dodecyl amine	-	
-	131-11-3	dimethyl phthalate	20	
-	53220-22-7	dimyristyl peroxydicarbonate	ND	(1)
-	13372-18-4	dipalmityl phthalate	15	alone or with distearyl phthalate
-	26322-14-5	dipalmityl peroxydicarbonate	ND	(1)
-	13248-28-0	dipropionyl peroxide	ND	(1)
75760	14117-96-5	distearyl phthalate	15	alone or with dipalmityl phthalate
-	90894-12-5	ethanol, 2,2',2'' -nitrilotris-, titanium acetate complex	-	$SML_{\text{triethanol amine}}$: see Annex I to Regulation (EU) No 10/2011
-	622-08-2	ethylene glycol monobenzyl ether	-	
-	111-76-2	ethylene glycol monobutyl ether	-	
-	122-99-6	ethylene glycol monophenyl ether	-	
-	-	ethylene glycol monocresyl ether	-	
-	75-04-7	ethyl amine	-	
-	149-57-5	2-ethyl hexanoic acid	30	alone or with 2-ethyl hexanoic acid, nickel or tin salt (as 2-ethyl hexanoic acid)
-	4454-16-4	2-ethylhexanoic acid, nickel salt	30	alone or with 2-ethylhexanoic acid or 2-ethylhexanoic acid, tin salt (as 2-ethylhexanoic acid); SML (nickel): see annexe II, Regulation (EU) No. 10/2011
-	301-10-0	2-ethylhexanoic acid, tin (II) salt	30	alone or with 2-ethylhexanoic acid or 2-ethylhexanoic acid, nickel salt (as 2-ethylhexanoic acid)
-	-	phosphor oxides	-	
-	1310-53-8	germanium dioxide	0.1	as germanium
-	-	glycerol monobenzyl ether	-	
-	-	glycerol monobutyl ether	-	
-	-	glycerol monophenyl ether	-	
-	-	glycerol monocresyl ether	-	
	12055-23-1/ 37230-85-6	hafnium oxide	0.05	as hafnium
-	531-18-0	hexa (hydroxymethyl) melamine	-	
-	98-49-7	P-(alpha-hydroperoxyisopropyl)cumene	ND	(1)

Ref No	Cas No	Name	SMLmg/kg	Restriction or specification
	2226-96-2	4-hydroxy-2,2,6,6-tetramethyl piperidinoxyl		QMA = 0.05 mg/6dm^2
-	9004-65-3	hydroxypropyl methyl cellulose	-	
-	7705-08-0	iron(III)chloride		SML_{Fe} See Annex II, Regulation (EC) No 10/2011
-	1338-14-3	iron naphthenate		SML_{Fe} See Annex II, Regulation (EC) No 10/2011
-	3130-28-7	iron octanoate		SML_{Fe} See Annex II, Regulation (EC) No 10/2011
-	-	iron silicate		SML_{Fe} See Annex II, Regulation (EC) No 10/2011
90000	646-13-9	isobutyl stearate	-	
-	7727-21-1	potassium peroxodisulfate	ND	(1)
-	5931-89-5	cobalt acetate		SML_{Co} See Annex II, Regulation (EC) No 10/2011
-	1333-88-6	cobalt aluminate		SML_{Co} See Annex II, Regulation (EC) No 10/2011
-	61789-51-3	cobalt naphthenate		SML_{Co} See Annex II, Regulation (EC) No 10/2011
-	-	cobalt octanoate		SML_{Co} See Annex II, Regulation (EC) No 10/2011
-	-	hydrocarbons, C10-C14, aromate content ≤ 1%	-	
-	1338-02-9	copper naphthenate		SML_{Cu} See Annex II, Regulation (EC) No 10/2011
-	20543-04-8	copper octanoate		SML_{Cu} See Annex II, Regulation (EC) No 10/2011
	1310-65-2	lithium hydroxide		SML_{Li} See Annex II, Regulation (EC) No 10/2011
-	12057-24-8	lithium oxide		SML_{Li} See Annex II, Regulation (EC) No 10/2011
-	1336-93-2	manganese naphthenate		SML_{Mn} See Annex II, Regulation (EC) No 10/2011
-	-	manganese octanoate		SML_{Mn} See Annex II, Regulation (EC) No 10/2011
-	26762-92-5	p-menthane hydroperoxide	ND	(1)
-	60-24-2	2-mercaptoethanol	0.05	
21550	67-56-1	methanol	-	(5)
-	4088-22-6	N-methyl dioctadecyl amine	ND	
-	1338-23-4	methylethyl ketone peroxide	ND	(1)
-	97-30-3	alpha-methyl-d-glucoside	-	
-	-	1-methyl-2-hydroxy-4-tert-butyl benzene	-	
-	202667-45-6	6-methyl indacene	0.05	(4)
-	28056-59-9	methyl isobutyl ketone peroxide	ND	(1)
-	814-78-8	methyl isopropenyl ketone	-	
-	7439-98-7	molybdenum, powder	0.05	as molybdenum
-	108-90-7	monochlorobenzene	0.2	
-	110-27-0	myristic acid, isopropyl ester	0.05	for the reaction by-product 3-hexadecanol; (FRF applies)
-	-	naphthalene sulfonic acid-formaldehyde condensation products, ammonium, potassium and sodium salts	-	
-	577-11-7	sodium dioctyl sulfosuccinate	-	
-	7775-14-6	sodium dithionite	-	

Ref No	Cas No	Name	SMLmg/kg	Restriction or specification
-	7681-49-4	sodium fluoride	-	
-	10124-56-8	sodium hexametaphosphate	-	
-	149-44-0	sodium hydroxymethane sulfinate	-	
-	7775-27-1	sodium peroxodisulfate	ND	(1)
-	-	oxyisopropyl vanadate	0.05	as vanadium
-	19807-27-3 3375-31-3	palladium diacetate	0.05	as palladium
-	7575-23-7	pentaerythritol tetrakis (3-mercaptopropionate)	0.01	
-	-	polyethene oxide (4-14) ethers of alcohols, C5-C18	5	
-	-	polyethene oxide (4-14) ethers of alkyl(C5-C15) phenol	5	
-	-	polyethene oxide (4-14) ethers of nonyl phenol	5	
-	-	polyethene oxide (20-60) ethers of nonyl phenol	5	
-	-	polyethene oxide (4-14) ethers of nonyl phenol, esters with sulfosuccinic acid	5	
-	-	polyethene oxide (20-60) ethers of nonyl phenol, esters with sulfosuccinic acid	5	
-	-	polyethene oxide (4-14) ethers of octyl phenol	5	
-	-	polyethene oxide (20-60) ethers of octyl phenol	5	
-	-	polyethene oxide (4-14) ethers of octyl phenol, esters with sulfosuccinic acid	5	
-	-	polyethene oxide (20-60) ethers of octyl phenol, esters with sulfosuccinic acid	5	

-	-	polyether poly tert-butyl peroxy carbonate (diluted with ethyl benzene)		active oxygen: QM = 6.4 mg O_2/kg polymer;
				propoxylated pentaerithrytol: SML = 0.05 mg/kg;
				t-Butanol: SML = 10 mg/kg;
				ethyl benzene: SML = 0.6 mg/kg;

-	-	polypropene oxide, esters with lauric acid	-	
-	-	polypropene oxide, esters with oleic acid	-	
-	-	polypropene oxide, esters with ricinic acid	-	
-	-	polypropene oxide, esters with stearic acid	-	
-	25213-24-5	polyvinyl acetate, partially hydrolysed	-	
-	9002-89-5	polyvinyl alcohol (viscosity of the 4% solution in water at 20 °C ≥ 20 cP)	-	
-	25498-06-0	poly(vinylcyclohexane)	-	
-	-	poly-N-vinyl-N-methyl formamide, Mw= 40 000	-	
-	1613255-29-0	2‵,2"′-(propane-1,3-diylbis(oxy))bis(3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5'-fluoro-3'-methyl-5-(2,4,4-trimethylpentane-2-yl)-[1,1'-biphenyl]-2-ol)	0.05	(4) (6); FRF applies
-	2010152-48-2	2‵,2"′-(propane-1,3-diylbis(oxy))bis(3-(2,7-di-tert-butyl-9H-carbazol-9-yl)-5'-(dimethyl(octyl)silyl)-3'-methyl-5-(2,4,4-trimethylpentane-2-yl)-[1,1'-biphenyl]-2-ol	0.05	(4) (8); FRF applies
-	1042662-40-7	6",6""'-(propane-1,3-diylbis(oxy))bis(3,3",5-tri-tert-butyl-5'-methyl-[1,1':3',1"-terphenyl]-2'-ol)	0.05	(4) (7); FRF applies
-	2088749-17-9	6",6""'-((((diisopropyl-germaandiyl)bis-(methylene))bis(oxy))-bis(3,3‶,5-tri-tert-butyl-5'-octyl-[1,1':3',1”-terphenyl]-2'ol)	0.05	(4) (7); FRF applies
-	2010152-47-1	6',6"-(((diisopropyl-silaandiyl)bis-(methylene))bis(oxy)-bis(3-(3,6-di-tert-butyl-9H-carbazol-9-yl)-3‵-fluoro-5-(2,4,4-trimethylpentane-2-yl)-[1,1’-biphenyl]-2-ol)	0.05	(4) (6); FRF applies
-	-	resols	-	
-	19088-74-5	rubidium bicarbonate	1	as rubidium
-	584-09-8	rubidium carbonate	1	as rubidium
-	-	sebacic acid, esters with alcohols, monovalent, aliphatic, non-branching, primary, saturated, C6-C12	-	
-	-	sebacic acid, esters with alcohols, monovalent, aliphatic, branched, primary, saturated, C6-C12	18	
-	546-68-9	tetraisopropyl titanate	-	

Ref No	Cas No	Name	SMLmg/kg	Restriction or specification
-	22288-43-3	1,1,3,3-tetramethyl butyl peroxy-2-ethyl hexanoate	ND	(1)
-	1118-71-4 and 55252-75-0	2,2,6,6-tetramethyl-3,5-heptadione, tautomer mixture with 5-hydroxy-2,2,6,6-tetramethylhept-4-one-3-on	0.05	(4)
-	7550-45-0; 7705-07-9; 10049-06-6	titanium chloride	-	
-	88-20-0	o-toluene sulfonic acid	-	
-	104-15-4	p-toluene sulfonic acid	-	
-	78-40-0	triethyl phosphate (triethanol phosphate)	-	
-	121-44-8	triethyl amine	ND	
-	24748-23-0	3,6,9-triethyl-3,6,9-trimethyl-1,2,4,5,7,8-hexoxonane	ND	(1)
-	88-05-1	2,4,6-trimethyl anilin	ND	
-	-	2,4,4-trimethyl pentyl-2-hydroperoxide	ND	(1)
-	-	2,4,4-trimethyl pentyl-2-hydroxyperoxypentane	ND	(1)
-	-	2,4,4-trimethyl pentyl-2-peroxyphenoxyacetate	ND	(1)
-	-	2,4,4-trimethyl pentyl-2-peroxyneodecanoate	ND	(1) only in non-softened PVC
-	1613243-54-1	3,6,9-trimethyl-3,6,9-tris(ethyl and/or propyl)-1,2,4,5,7,8-hexoxane	0.05	(1)
-	1017-56-7	2,4,6-tris(hydroxymethyl) melamine	-	
	11099-11-9 1314-34-7 1314-62-1	vanadium oxide	0.05	as vanadium
-	-	fatty acids, C8-C22, esters with sorbitan	-	
-	-	fatty acids, C8-C22, esters with sorbitol	-	
-	7722-84-1	hydrogen peroxide	ND	(1)
-	-	xylene sulfonic acids	-	
-	12001-85-3	zinc naphthenate		SML_{Zn} See Annex II, Regulation (EC) No 10/2011
-	23519-77-9	zirconium (IV) n-propoxide	2	as zirconium
-	72854-21-8	zirconium naphthenate	2	as zirconium
-	-	zirconium octanoate	2	as zirconium
-	12036-01-0; 1314-23-4; 53801-45-9	zirconium oxide	2	as zirconium

ND Not detectable by methods with a detection threshold of 0.05 mg/kg.

(1) The sum of migration of all substances marked with (1) must not be detectable by a method with a detection threshold of 0.05 mg/kg.

(2) Demonstrate compliance with the restriction by determining the quantity per area. Quantity is expressed as mg/6 dm^2 of final product (as NCO). QMA (T) mg/kg is the sum of all substances marked with (2) and the isocyanates included in Regulation (EU) No 10/2011, Annex I, Table 2, Group 17.

(3) The sum of migration of all substances marked with (3) must not be detectable by a method with a detection threshold of 0.05 mg/kg. The sum of the migration of complete infant formulas and follow-on formulas and processed foodstuffs based on cereals and baby foods for infants and toddlers as defined in Regulation (EU) 609/2013 must not be higher than 0.01 mg/kg food as consumed.

(4) This is a decomposition product, not a permitted base substance.

(5) Methanol is also included as monomer. Migration must comply with any current or future restriction imposed at the European level.

(6) The sum of migration of all substances marked with (6) must not be detectable by a method with a detection limit of 0.05 mg/kg.

(7) The sum of migration of all substances marked with (7) must not be detectable by a method with a detection limit of 0.05 mg/kg.

(8) The sum of migration of all substances marked with (8) must not be detectable by a method with a detection limit of 0.05 mg/kg.

(9) The limit applies to the sum of dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and bis(2-ethylhexyl) phthalate (DEHP) expressed as DEHP equivalents using the following equation: DBP*5 + DIBP*4 + BBP*0,1 + DEHP*1.

Chapter II – Paper and cardboard

1. Paper and cardboard for general use[18]

1.1. *Description*

Under this regulation, paper and cardboard shall refer to all cellulose-based fibre materials formed from a suspension into a cohesive sheet or track, whether or not with the addition of filling and/or auxiliary substances, and packaging and consumer articles made thereof.

1.2. *Requirements for manufacture*

1.2.1. Only the following may be used as a raw material for the manufacture of paper and cardboard for general use:

- fresh cellulose-based fibre materials, bleached or not;
- old paper and cardboard;
- fibres of plastics, according to Chapter I, whether or not provided with a coating in accordance with Chapter X. section 3;
- fibres of regenerated cellulose pursuant to Chapter VIII;
- fibres of textile products pursuant to Chapter VII.

1.2.2. For the manufacture, processing or refinement of paper and cardboard, only the auxiliary materials and refining agents referred to below may be used. They must be of high technical quality and must not be used in larger quantities than strictly necessary for the manufacture of the final product. Unless specified otherwise, substances listed in a particular category may also be used for different technological purposes. Except for the base materials listed above, the final product must not contain any other substances than those listed below, including their decomposition products if any.
Where this chapter specifies an occurrence limit, and unless provided otherwise, this limit is expressed as a weight percentage of the substance or category of substances, based on the dry weight of the final product.

a. *basic auxiliaries:*

- sodium carbonate;
- sodium hydroxide;
- sulfates of aluminium, iron, potassium, magnesium, sodium and zinc.

b. *precipitation, fixation, retention and drainage agents:*

- acrylamide acrylic acid polymers obtained through partial hydrolyse of polyacrylamide or through copolymerisation of acrylamide and acrylic acid, containing no more than 0.2% of free acrylamide;
- acrylamide-2-ethyl acrylate diethyl methyl ammonium chloride-copolymer, in which no more than 10% of cationic monomer has been incorporated, for no more than 0.2%;
- acrylamide-2-ethyl acrylate diethyl methyl ammonium methylsulfate-copolymer, in which no more than 10% of cationic monomer has been incorporated, for no more than 0.2%;
- acrylamide-2-ethyl acrylate trimethyl ammonium chloride-copolymer,, in which no more than 10% of cationic monomer has been incorporated, for no more than 0.2%;
- acrylamide-2-ethyl acrylate trimethyl ammonium methylsulfate-copolymer, in which no more than 10% of cationic monomer has been incorporated, for no more than 0.2%;
- acrylamide-2-ethyl methacrylate trimethyl ammonium chloride-copolymer, in which no more than 10% of cationic monomer has been incorporated, for no more than 0.2%;
- acrylamide-2-ethyl methacrylate trimethyl ammonium methylsulfate-copolymer, in which no more than 10% of cationic monomer has been incorporated, for no more than 0.2%;

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[18] See Section 3 for paper and cardboard intended for use as cooking packaging and for contact with beverages at temperatures higher than 80 °C.

- aluminates of calcium and sodium;
- aluminium acetate;
- aluminium formiate;
- copolymers of dimethyl amine, epichlorohydrin and ethylene diamine, containing no. more than 0.3% of 1,3-dichloropropanol-2;
- copolymers of bis(2-aminoethyl) amine, dimethyl amine and epichlorohydrin, containing no more than 0.3% of 1,3-dichloropropanol-2;
- iron chlorides;
- naphthalene sulfonic acid-formaldehyde condensation product and their sodium salts, in fibre slurries only;
- polyacrylamide or copolymers of acrylamide with dimethyl aminoethyl-methacrylate, containing no more than 0.2% of free monomer, exclusively in cardboard intended for contact with dry foodstuffs, no more than 0.1%. For the manufacture of the polymer or the copolymers, only the following auxiliary materials may be used:
    - ammonium peroxodisulfate
    - tert-butyl hydroperoxide
    - ethylene diamine tetraacetic acid, sodium salt
    - potassium metabisulfite
    - potassium peroxodisulfate;

- poly(aluminium hydroxychloride sulfate);
- polyamide-epichlorohydrin resins obtained from the reaction of the condensation product of adipic acid and diethylene, modified with formic acid and formaldehyde triamine, with epichlorohydrin or with a mixture of epichlorohydrin and ammonia, no more than 0.2%;
- polyamide-polyamine-epichlorohydrin resins obtained from the reaction of adipic acid, caprolactam, diethylene triamine, epichlorohydrin and polyethylene glycol, no more than 4.0%;
- polyamide-polyamine-ethylene imine resins, obtained by interlinking the product of the reaction of the condensation product of adipic acid and diethylene triamine, modified with formic acid, with ethylene imine, with a polyadduct of polyethylene glycol and epichlorohydrin, no more than 0.2%;
- polyamide-polyamine-ethylene imine resins, obtained by interlinking the product of the reaction of the condensation product, modified with formic acid, of adipic acid, N-(2-aminoethyl)-1,3-diaminopropane and N,N'-bis(3-aminopropyl)-1,2-diamino-ethane with ethylene imine, with a polyadduct of polyethylene glycol and epichlorohydrin, no more than 0.2%;
- polyamine-dichloroethane resins, obtained from the reaction of aminoethyl piperazine, dichloroethane, diethylene triamine, triethylene tetramine, tetraethylene pentamine and pentaethylene hexamine, no more than 0.2%;
- nitric acid;
- tannin;
- sulphuric acid.

c. *desliming agents, for use in industrial water only:*[19]

- n-alkenyl(C_{12}-C_{18}) dimethyl ethyl ammonium bromide;
- n-alkyl(C_{12}-C_{18}) dimethyl benzyl ammonium bromide and chloride;
- 1,2-benzisothiazoline-3-one;
- bis(2-hydroxy-5-chlorophenyl) methane;
- 5-chlorine-2-methyl-4-isothiazoline-3-one;
- glutar dialdehyde;
- di-n-alkyl(C_{12}-C_{18}) methyl benzyl ammonium bromide;
- dimethyl dithiocarbamate;
- 3,5-dimethyl tetrahydro-2H-1,3,5-thiadiazine-2-thione;
- 2-mercaptobenzthiazol and the sodium salt, no more than 0.05%;
- 2-methoxycarbonyl benzimidazol and zinc dimethyl dithiocarbamate, in a ratio of 1:9;
- 3-methyl-4-chlorophenol and its sodium salt;
- N-methyl dithiocarbamate and its potassium and sodium salts;
- N,N'-methylene bis(dithiocarbamate) and its potassium and sodium salts;
- 2-methyl-4-isothiazoline-3-one;

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[19] These substances may be used only if a desliming agent containing one or several of these substances has been approved under the Pesticides and Biocides Act [Wet gewasbeschermingsmiddelen en biociden].

- tetramethyl thiuramdisulfide;
- trichlorophenol and its potassium and sodium salts.

Note: In paper and cardboard that does not come into contact with only dry foodstuffs, the total (di) thiocarbamates and thiuramdisulfide present must be no more than 1 mg/kg.

d. *bleaching agents:*

- chlorine dioxide;
- sodium chlorite;
- sodium hypochlorite;
- sodium perborate;
- sodium peroxide;
- sodium sulfite;
- sodium hydrogen sulfite;
- hydrogen peroxide;
- sulfur dioxide.

e. dispersants, flotation agents and anti-foaming agents:

- alcohols, monovalent, primary, non-branching, saturated, C_4-C_{22}, as well as oleyl alcohol;
- alkyl(C_8-C_{18}) benzene sulfonates, sodium salts;
- alkyl(C_8-C_{18}) sulfates, sodium salts;
- alkyl(C_8-C_{18}) sulfonates, sodium salts;
- ammonia;
- ammonium chloride;
- block copolymer of ethene oxide and propene oxide, molecular weight greater than 6800, esterified with stearic acid, only for coatings, no more than 0.05%;
- citric acid monoglyceryl ester;
- cumene sulfonic acid and its ammonium, potassium and sodium salts;
- dialkyl(C_4-C_{16}) sulfosuccinates, sodium salts;
- diethylene triaminepentaacetic acid, sodium salts;
- N,N′-distearoyl diaminoethane;
- ethylene diaminetetraacetic acid, sodium salts;
- phosphates of sodium;
- phosphoric acid;
- refined rapeseed oil;
- hydroabietyl alcohol;
- hydrocarbons, mainly aliphatic,
    - either C_{10}-C_{14}, primarily C_{12}-C_{14}, with a boiling interval of 180-260 °C, aromate content (benzene, toluene, xylene) no more than 1%
    - either with a boiling interval of 230-330 °C, aromate content no more than 25% and a proportion of polycyclic aromates no more than 0.5%
    - either with a boiling interval of 320-480 °C, aromate content no more than 25% and a proportion of polycyclic aromates no more than 0.5%;
- lignin sulfonates, calcium and sodium salts;
- organo polysiloxanes, containing two methyl groups on each silicon atom (silicones);
- paraffin, liquid (refined mineral oil) meeting the following specification:
    - colour weaker than Standard Saybolt 30
    - odour nearly absent
    - and whose absorption of UV light meets the requirements defined in Annex B (Assessment Methods);
- polyethene oxide (4-14) ethers of alcohols, monovalent, primary, non-branching, saturated, C_{12}-C_{18};
- polyethene oxide (4-14) ether of n-alkyl(C_8-C_{12})phenol;
- polyethene oxide (8-14) esterified with fatty acids as described below, or ricinic acid;
- polyethene oxide (20) sorbitan tristearate;
- polypropene oxide, esterified with lauric, oleic, ricinic or stearic acid;
- polyvinyl pyrrolidone (viscosity of the 5% solution in water at 20 °C at least 34 cP);
- pine oil;

- castor oil (according to the Dutch Pharmacopoeia), whether or not sulfonated, as well as sulfated or sulfonated ricinic acid;
- o- and p-toluene sulfonamide-formaldehyde condensation product, exclusively in paper and cardboard intended for contact with dry foodstuffs;
- toluene sulfonic acids and their ammonium, potassium or sodium salts;
- tributyl and triisobutyl phosphate, only for coatings, no more than 0.5%;
- fatty acids, non-branching, saturated and unsaturated, with an even number of carbon atoms, C_8-C_{22}, with a non-saponifiable ingredients content of no more than 2.5%;
- fatty acids as described above and their derived di- and trimers;
- fatty acids as described above, amides thereof;
- fatty acids as described above, esterified with alcohols, monovalent, aliphatic, non-branching, saturated, C_4-C_{18}, as well as oleyl alcohol;
- fatty acids as described above, esterified with glycerol to form mono-, di- and
- triglycerides;
- fatty acids as described above, esterified with polyols, C_3-C_6;
- fatty acids as described above, esterified with sorbitol or sorbitan;
- fatty acids as described above, as salts with aluminium, ammonium, calcium, potassium, magnesium and sodium;
- fatty acids as described above, as compounds with bis(2-hydroxy-ethyl) amine;
- fatty acids as described above, as compounds with tris(2-hydroxy-ethyl) amine;
- xylene sulfonic acids and their ammonium, potassium or sodium salts.

f. *fillers and their excipients:*

- 1-amino-2-propanol, containing up to 10 % 2-amino-1-propanol, only for use as a dispersant for fillers in paper and cardboard;
- carbonates of calcium and magnesium, whether or not containing the sodium salt of polyacrylate;
- oxides and hydroxides of aluminium, magnesium, silicon, titanium and zinc;
- silicates of aluminium, calcium, potassium, magnesium and sodium, including bentonite, diatomaceous earth, infusorial earth, kaolin, clay, mica and talc;
- sulfates of aluminium, barium and calcium, including satin white;
- zinc sulfide, including lithopone.

g. *colourants and pigments:*

- according to Chapter XI.

h. *glues and fibre binding agents:*

- alkyl ketene dimers produced from halogenated fatty acids originating from animal or vegetable oils and fats, no more than 0.4%;
- aluminium hydroxychloride, $Al_2(OH)_5Cl$;
- cellulose derivatives:
  - carboxy methyl cellulose
  - ethyl hydroxyl ethyl cellulose
  - hydroxyl ethyl cellulose
  - hydroxyl propyl cellulose
  - hydroxyl propyl methyl cellulose
  - methyl cellulose;

- copolymers of styrene with acrylic acid or maleic acid, according to Chapter I, as well as their ammonium and sodium salts;
- dextwash;
- dispersions in water of the macromolecular compounds referred to in 1.2.2 n;
- dispersions in water of the paraffins and waxes referred to in 1.2.2 i.;
- proteins: potato protein, animal glue, casein, gelatin, dermal adhesive, soy protein, wheat protein, fish glue and zein;
- rosin (wood resin, gum resin, tall resin, dark wood resin and dark tall resin), extracted from pine trees of the Pinus genus, Pinaceae family, whether or not modified through hydrogenation, dimerisation or dismutation (disproportioning);

- rosin as described above and its ammonium, calcium, potassium and sodium salts, whether or not modified through reaction with any of the following substances:
    - citric acid
    - formaldehyde
    - fumaric acid
    - maleic acid or
    - maleic anhydride
    - salicyl alcohol;

- rosin as described above and terpene resins as described in 1.2.2 n., whether or not modified through reaction with any of the following substances:
    - 2,2-bis(4-hydroxyphenyl) propane-formaldehyde condensation product
    - citric acid
    - phthalic anhydride
    - fumaric acid
    - maleic acid and maleic anhydride
    - fatty acids as described in 1.2.2(e)
    - hydrogen

  and - whether or not esterified with any of the following alcohols:
    - diols, C_2-C_6
    - glycerol
    - methanol
    - pentaerythritol
    - polyethene oxide, molecular weight greater than 200;

- polyanionic galactomannane phosphate esters, which comply with the following specification:
    - guar galactomannane content: min. 45%
    - phosphate content: max. 16% (as PO_4)
    - acetate content: max. 25%
    - moisture content: max. 10%;

- polyurethanes, water-soluble, anionic, produced from dimethyl propionic acid, glycerine monostearate, N-methyl diethanolamine, 2,4-and 2,6-toluene disocyanate using dibutyl tin diacetate, no more than 0.15% on dry substrate;
- polyurethanes, water-soluble, cationic, produced from glycerine monostearate, N-methyl diethanolamine, 2,4-and 2,6-toluene di-ïsocyanate using dibutyl tin diacetate, no more than 0.15% on dry substrate;
- thickening agents, according to Regulation (EC) No 1333/2008;
- starches, whether or not modified by any of the following operations (the percentages express the maximum permissible weight quantities of the agent in terms of starch, unless indicated otherwise):
    1) broken down with amylases, ammonium, potassium or sodium peroxodisulfate (0.6%), sodium chlorite (0.5%), sodium hydroxide (1%), sodium hypochlorite (7.5%, as chlorine), hydrogen peroxide (0.45%, as active oxygen), hydrochloric acid (7%) and sulphuric acid (2%)
    2) interlinked with boric acid or tetraborates of ammonium, potassium or sodium (2%, as B2O3), epichlorohydrin (0.3%), phosphoroxychloride (0.04%, incorporated in the starch as P), glyoxal (1%), sodium trimetaphosphate (0.04%, incorporated in the starch as P)
    3) esterified with acetic anhydride (8%), phosphoric acid or its potassium and sodium salts (6%), sodium polyphosphate (0.04%, incorporated in the starch as P), octenyl succinic anhydride (3%), urea (20%), vinyl acetate (7.5%)
    4) etherified with acrylnitril (5%), chlorohydroxypropyl trimethyl ammonium chloride (8%), diethyl aminoethyl chloride hydrochloride (8%), 2,3-epoxy-propyl trimethyl ammonium chloride (7%), ethene oxide (3%), monochloro-acetic acid (7.5%), propene oxide (10%).

i. *paraffins and waxes:*

- montane wax, consisting of:
    1) montanic acid C_{26}-C_{32}
    2) esters thereof with ethanediol or 1,3-butanediol
    3) or the calcium salt of these acids, and provided that the product complies with the purity requirements of Annex B (Assessment Methods);

- paraffin, microcrystalline, whose absorption of ultraviolet light complies with the values specified in Annex B (Assessment Methods);
- paraffin, solid, including synthetic, whose absorption of ultraviolet light complies with the values specified in Annex B (Assessment Methods);
- paraffin, liquid (refined mineral oil), which complies with the following specification:
    - colour weaker than Standard Saybolt 30
    - odour nearly absent
    - and whose absorption of ultraviolet light meets the requirements defined in Annex B (Assessment Methods);

- polyethene, molecular weight greater than 200;
- waxes: beeswax, candelilla, carnauba, copal, esparto, rotamo, shellack, spermaceti and flax wax.

j. *moisture-regulating agents:*

- chlorides of calcium, magnesium and sodium;
- dicyan diamide;
- glucose and massé;
- glycerol;
- 1,6-hexanediol;
- lecithin;
- sodium nitrate-urea complex, consisting of one part sodium nitrate and two parts urea, exclusively in paper and cardboard intended for contact with dry foodstuffs, no more than 15%;
- polyethene oxide, molecular weight greater than 200;
- polypropene oxide, molecular weight greater than 400;
- 1,2-propanediol;
- saccharose;
- sorbitan;
- sorbitol;
- urea.

k. *preservatives, only for the preservation of coatings:*

- 1,2-benzisothiazoline-3-one;
- benzoic acid, lactic acid, formic acid, propionic acid, sorbic acid and their calcium, potassium and sodium salts;
- boric acids and their sodium salts;
- 2-bromine-4-hydroxyacetophenone, no more than 0.006% of the coating;
- 3,5-dimethyl tetrahydro-2H- 1,3,5-thiadiazine-2-thione;
- o-phenyl phenol and its sodium salt;
- formaldehyde;
- hexamethylene tetramine;
- p-hydroxybenzoic esters of ethanol, methanol and propanols (as monovalent alcohols).

l. *preservatives to protect the packaged product:*

- biphenyl, only in packaging paper for citrus fruits.

m. *agents for improving the wet strength:*

- melamine-formaldehyde condensation products (hydroxymethyl melamines), whether or not chemically modified with 6-aminohexane carboxylic acid or sodium hydrogen sulfite, containing no auxiliary materials other than those permitted according to Chapter I;
- N-methyl diallyl aminehydrochloride-epichlorohydrin polymer, which complies with the following specification:

◦ proportion of 1,3-dichloropropanol-2	< 5.5%
◦ proportion of dichloropropanol-1	< 0.15%
◦ proportion of 3-chloropropanediol-1,2	< 1.0%
◦ maximum application	1.5%;

- polyamide-epichlorohydrin resins obtained from the reaction of the condensation product of adipic acid and bis(2-aminoethyl)amine with epichlorohydrin or with a mixture of epichlorohydrin and ammonia, no more than 1.5%;
- urea-formaldehyde condensation products, whether or not chemically modified with any of the following substances:
    - 6-aminohexane lactam
    - bis(2-aminoethyl) amine
    - diaminoethane
    - dicyan diamide
    - sodium hydrogen sulphite
    - triethylene tetramine
    - tris(2-hydroxyethyl) amine

  and containing no auxiliary materials other than those permitted according to Chapter I.

n. *macromolecular compounds:*

- cellulose microfibres produced with calcium carbonate, kaolin and/or other permitted mineral fillers;
- cellulose nitrate, proportion of nitrogen 10.8-12.4%;
- cumaron-indene resins, exclusively for paper and cardboard intended for contact with dry foodstuffs;
- cyclohexanon resins, exclusively for paper and cardboard intended for contact with dry foodstuffs;
- diphosphoric acid, polymers with ethoxylated, reduced methyl esters of reduced, polymerised and oxidated tetrafluoroethylene. CAS: 200013-65-6.
- ethene-vinyl acetate copolymers, containing no auxiliary materials other than those permitted in Chapter I;
- ethyl cellulose;
- alpha-methyl styrene-vinyl toluene copolymers, assuming that the two monomers have a molar ratio of 1:3, containing no auxiliary materials other than those permitted in Chapter I, melting point at least 75 °C;
- petroleum hydrocarbon resins, alicyclic, which comply with the following description and specification:
    - hybrid polymers prepared by polymerisation of dienes and olefins, unsaturated, non-branching and branched ring-shaped C_4-C_7 monomers, originating from the low-boiling point fractions (boiling endpoint lower than 200 °C) obtained by cracking petroleum, whether or not hydrogenated.
      These polymers are incompletely saturated, non- aromatic hydrocarbon resins containing methyl groups and non-aromatic methylated 5- and 6-carbon ring structures incorporated in the chain.

  The resins must comply with the following specification:

    - viscosity at 140 °C at least 3 000 cP
    - softening point at least 97 °C (ASTM E 28- 58T)
    - aniline point at least 90 °C (ASTM D 611- 64)
    - monomer content no more than 0.1%
    - aromate content no more than 0.5%
    - ash content no more than 0.1% (ASTM D 482)

  - a 50% solution in toluene must allow through at least as much light as a solution of 40 mg iodine in 100 ml potassium iodide solution (DIN53403);

- hydrogenated polycyclopentadiene resin, produced by polymerisation of a mixture consisting primarily of cyclopentadiene and the dimer thereof, originating from the boiling fraction between 80 °C and 180 °C distilled from the product obtained by cracking petroleum while adding steam. The polymerisation process is followed by hydrogenation of the polymer.
  The resins must comply with the following specification:
  - viscosity at 140 °C at least 2 000 cP
  - softening point at least 95 °C (ASTM E 28- 58T)
  - bromium number no more than 2 (ASTM D 1159)
  - ash content no more than 0.1% (ASTM D 482)
  - colour of a 10% solution in toluene weaker than Standard Saybolt 22 (ASTM D 156);

- polycondensate of potato protein, casein, gelatin or soy protein with no more than 6% glyoxal, determined based on the weight of the protein, exclusively for paper and cardboard that cannot come into contact with alcoholic foods and beverages;
- polyesters obtained from a reaction between one or several of the following polybasic acids and polyvalent alcohols, where the reaction can be terminated with one of the following monobasic acids or monovalent alcohols:
  1) *polybasic acids:*
     - adipic acid
     - 1,2,4-benzene tricarboxylic acid and anhydride
     - phthalic acids and -anhydrides
     - fumaric acid
     - itaconic acid
     - maleic acid and anhydride
     - sebacic acid
     - terpene-maleic acid adduct, acid number of the esterified product 35- 50
     - fatty acids as described in 1.2.2 e., dimerised
  2) *monobasic acids:*
     - benzoic acid
     - 4,4-bis(4-hydroxyphenyl)hexanoic acid
     - tert-butyl benzoic acid
     - rosin as described in 1.2.2 h.
     - ricinenic acid
     - trialkyl(C_4-C_{11}) methane-carboxylic acids
     - fatty acids as described in 1.2.2 e. as well as tall oil fatty acids
  3) *polyvalent alcohols:*
     - bis(2-hydroxyethyl) ether
     - 1,3-butanediol
     - 1,4-butanediol
     - ethanediol
     - glycerol
     - mannitol
     - methyl-alpha-D-glucoside
     - pentaerythritol
     - 1,2-propanediol
     - sorbitol
     - 1,1,1-tris(hydroxymethyl) ethane
     - 1,1,1-tris(hydroxymethyl) propane
  4) *monovalent alcohols:*
     - alcohols, monovalent, aliphatic, non-branching, saturated, C_4-C_{18}, as well as oleyl alcohol;

- polymers and polycondensation products, according to Chapter I;

- polyolefins, chlorinated, meeting the following specification:
    - chlorine content no more than 56%
    - molecular weight at least 100 000
    - solubility in n-hexane at 50 °C no more than 7%;

- polyvinyl acetate and copolymers of vinyl acetate with:
    - acrylamide
    - acrylnitril
    - acrylic acid and its esters with n-butanol and 2-ethylhexyl alcohol
    - methacryl amide
    - methacrylic acid and its esters with n-butanol, n-hexanol and 2-ethylhexyl alcohol
    - maleic anhydride
    - triallyl pentaerythritol, no more than 1% vinyl sulfonic acid and the sodium salt
    - containing no auxiliary materials other than those permitted in Chapter I;

- polyvinyl alcohol (viscosity of the 4% solution in water at 20 °C at least 5 mPas);
- polyvinyl propionate, containing no auxiliary materials other than those permitted in Chapter I;
- rubber, natural and synthetic, according to Chapter III, categories I and II, solid or in latex form;
- rubber, as described above, chlorinated, meeting the following specification: chlorine content no more than 67%
- viscosity of the 20% solution in toluene at 20 °C at least 4 cP;
- rubber as described above, cyclicised, provided that the proportion of free phenol is no more than 0.04% and exclusively for paper and cardboard intended for contact with dry foodstuffs;
- terpene resins, produced from alpha-pinene, beta-pinene or dipentene, whether or not modified with phenol, meeting the following specification:
    - acid number less than 5
    - saponification number less than 5
    - the colour of a 50% solution in white spirit must be less than four Gardner;

- fatty acids as described in 1.2.2 e., vinyl esters thereof.

o. *softeners:*

- acetyl tributyl citrate;
- acetyl triethyl citrate;
- adipic esters of alcohols, monovalent, aliphatic, saturated, C_6-C_{12};
- azelaic esters of alcohols, monovalent, aliphatic, saturated, C_6-C_{12};
- benzylbutyl phthalate containing no more than 1% dibenzyl phthalate;
- butyl stearate;
- citric acid esters of alcohols, monovalent, aliphatic, saturated, C_6-C_{12};
- dialkyl(C_7-C_9) phthalate;
- dibutyl phthalate;
- dibutyl sebacate;
- dicyclohexyl phthalate;
- di(2-ethylhexyl) phthalate;
- di-isobutyl adipate;
- di-isobutyl phthalate
- dimethyl sebacate;
- di-n-octyl phthalate;
- epoxidated soy oil with an oxirane content between 6.4% and 8%;
- isopropyl acetate;
- mono-, di- and tristearyl citrate;
- monoisopropyl citrate;
- n-octadecyl amineacetate;
- pentaerythritol tetrastearate;
- saccharose diacetate hexaisobutyrate;
- stearyl acetate;
- triethyl citrate;

- triethylene glycol.

p. *optic whiteners:*

- 4,4′-bis[[4-[bis(2-hydroxyethyl)amino]-6-(m-sulfoanilino)-s-triazine-2-yl]amino]-2,2′-stilbene disulfonic acid;
- 4,4′-bis[[4-[bis(2-hydroxyethyl)amino]-6-(o-sulfoanilino)-s-triazine-2-yl]amino]-2,2′-stilbene disulfonic acid;
- 4,4′-bis[[4-[bis(2-hydroxyethyl)amino]-6-(p-sulfoanilino)-s-triazine-2-yl]amino]-2,2′-stilbene disulfonic acid;
- 4,4′-bis[[4-diethylamino-6-(2,5-disulfoanilino)-s-triazine-2-yl]amino]-2,2-stilbene disulfonic acid;
- 4,4′-bis[[4-methoxy-6-anilino-s-triazine-2-yl]-amino]-2,2′-stilbene disulfonic acid;
- 4,4′-bis[[4-[mono en bis(2-hydroxyethyl)amino]-6-anilino-s-triazine-2-yl]- amino]-2,2′-stilbene disulfonic acid;
- 4,4′-bis[[4-morfolino-6-(2,5-disulfoanilino)-s-triazine-2-yl]amino]-2,2′-stilbene disulfonic acid;
- 4,4′-bis[[4-morfolino-6-(p-sulfoanilino)-s-triazine-2-yl]amino]-2,2′-stilbene disulfonic acid and the ammonium, potassium, sodium, calcium or magnesium salts of the aforementioned acids;
- 1-(4,6-dimethoxy-s-triazine-2-yl)pyrene.

q. *adhesives, solvents and inks:*

- adhesives	to the extent that the final product still complies with the provisions of Article 3(1) of Regulation (EC) No 1935/2004
- solvents	
- inks:	the requirements imposed in Chapter XI apply accordingly.

r. *other auxiliaries:*

- bis(2-hydroxyethyl)ether;
- bis(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- 2- and 3-tert-butyl hydroxyanisol (BHA), as a mixture, containing more than 0.05% monomethyl hydrochinonether;
- calcium formiate;
- chromium(III)myristo and chromium(III)stearatocomplex, exclusively on paper and cardboard to which a wax or coating is applied as a top layer;
- dialkyl(C_{16}-C_{18}) carbamoyl chloride, meeting the following specification:
    - alkyl isocyanate, no more than 1%
    - alkyl chloride, no more than 1%
    - di-, tri- and tetra-alkyl urea no more than 1%
    - phosgene, no more than 0.005%
    - mono-, di- and trialkyl aminehydrochloride, no more than 5%
    - toluene no more than 1%
    - other residues of amines (mainly hydrocarbons and alkyl nitrils), no more than 3%

  In the dispersion of the substance for practical use there must be no imines present;

- dibenzoyl peroxide;
- 2,6-di-tert-butyl-4-methyl phenol (BHT);
- dicyan diamide;
- dilauryl thiodipropionate;
- dimyristyl thiodipropionate;
- distearyl thiodipropionate;
- dodecyl mercaptane;
- glyoxal for water-proofing of starches in coatings, no more than 1%, determined based on the starch content of the coating and exclusively for paper and cardboard not intended for contact with alcoholic foods and beverages;
- 12-hydroxy stearic acid and the ester with glycerol;
- lanolin;
- 2-mercaptobenzthiazol and the sodium salt, exclusively as a preservative for adhesives;

- mono-, bis- and tris(2-hydroxyethyl) amine;
- naphthalene sulfonic acid-formaldehyde condensation product and the sodium salts, exclusively as emulsifier in wax emulsions;
- sodium chloride;
- sodium dithionite, only as antioxidant for waxes;
- sodium hydrocarbonate;
- n-octadecyl-beta-(4-hydroxy-3,5-di-tert-butylphenyl) propionate;
- soot (furnace black and channel black) and other carbon products such as graphite and coke powder, with a purity meeting the requirements laid down in Chapter XI;
- tetrakis[methylene-3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate]methane;
- thio-dipropionic acid;
- alpha-tocopherol;
- 1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene;
- 1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- tris(mono- and dinonyl phenyl) phosphite, containing no more than 1% tris(2-hydroxypropyl) amine;
- zinc bis(2-ethyl hexanoate);
- sulfur.

1.3 *Requirements for the final product:*

1.3.1 The total migration from the final product to which a coating has been applied, in reasonably expected conditions of use, and after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not exceed the value 60.

1.3.2 The total migration from the final product to which no coating has been applied, in reasonably expected conditions of use, and after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than 60; if it is more than 60, then both the methylene chloride-soluble fraction and the methylene chloride-insoluble fraction of the migrate must be more than 60.

1.3.3 The specific migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not exceed the value given below for the specific ingredient.

substance/group of substances	**SML (mg/kg)**
acrolein:	ND[20]
sec-aliphatic amines:	ND
tert-aliphatic amines:	ND
allyl compounds:	ND
1-amino-2-propanol	QMA = 5 mg/6 dm² EP, alone or together with its isomer 2-amino-1-propanol; this mixture may contain up to 10 % 2-amino-1-propanol
2-amino-1-propanol	QMA = 5 mg/6 dm² EP, together with its isomer 1-amino-2-propanol; this mixture may contain up to 10 % 2-amino-1-propanol
diazonium compounds:	ND
1,3-dichloropropanol-2:	ND
diethyl aminoethyl chloridehydrochloride:	ND
epichlorohydrin:	QM = 1 mg/kg FP
isocyanate groups:	ND
mercaptanes:	ND
2-mercaptobenzthiazol and the sodium salt:	ND
peroxides:	ND
desliming agents as referred to in Subsection 1.2.2 c., unless listed individually below:	ND

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[20] The term 'ND' (not detectable) is equated for practical purposes with a value of no more than 0.05.

tetrahydrofurane:	ND
toluene sulfochloride:	ND
triallyl pentaerythritol:	ND
triethyl amine:	ND
urethane (only in case of contact with alcoholic beverages or their simulant):	ND
acrylamide and methacryl amide, total:	0.1
acrylnitril and methacryl nitril, total:	0.01
alkene imines, total:	0.01
prim. aliphatic amines, total:	3
alkyl(C8-C18) benzene sulfonates) alkyl(C8-C18) sulfates total: alkyl(C8-C18) sulfonates	30
aluminium	1
arsenic compounds, total:	0.01 (as arsenic)
barium compounds, total:	1 (as barium)
1.2 benzisothiazoline-3-one:	30
bis(2-methyl-4-hydroxy-5-tert-butylphenyl)butane (CAS 85-60-9):	0.3
bis(2-hydroxyethyl) ether bis(2-hydroxypropyl) ether total: ethanediol	30
2,2-bis(4-hydroxyphenyl)propane (bisphenol A, CAS 80-05-7):	0.05
bis [tri(ethene oxy)]hydroxymethyl phosphonate:	6
boron compounds, total:	1 (as boron)
cadmium compounds, total:	0.01 (as cadmium)
chlorophenols, total:	0.1
chlorohydroxypropyl trimethyl ammonium chloride:	0.05
5-chlorine-2-methyl-4-isothiazoline-3-one mixture with 2-methyl-4-isothiazoline-3-one (1:3):	QMA: 0.025 mg/dm^2
chromium compounds, total:	0.1 (as chromium)
dialkyl(C16-C18) carbamoyl chloride, total:	6
dialkyl(C7-C9) phthalate, total:	15
dibutyl phthalate benzylbutyl phtalate	0.6^2
dibutyl tin diacetate:	0.01 (as dibutyl tin)
dicyclohexyl phthalate:	30
di(2-ethylhexyl) phthalate:	0.6^2
di-isobutyl phthalate:	0.6^2
diphosphoric acid, polymers with ethoxylated, reduced methyl esters of reduced, polymerised and oxidated tetrafluoroethylene:	0.05
dimethyl aminoethyl methacrylate:	0.01
3,5-dimethyl tetrahydro-2H- 1,3,5-thiadiazine-2-thione:	0.3
di-n-octyl phthalate:	6
substances containing epoxy groups, other than epoxidated linseed and soy oil:	QM (T) = 5 mg/kg in FP (as epoxy group, Mw = 43)
phenolic compounds, total:	15 (as phenol)
o-phenyl phenol:	0.1
fluorine compounds, total:	1 (as fluorine)
formaldehyde and glyoxal and hexamethylene tetramine, total:	15
glutar dialdehyde:	3
mercury compounds, total:	0,005 (as mercury)
melamine:	2.5
2-methyl-4-isothiazoline-3-one:	0.5, alone or with 5-chlorine-2- methyl-4-isothiazoline-3-one
3 monochloro-1,2-propanediol	0.01
optic whiteners of the stilbene disulfonic acid type, referred to in Subsection 1.2.2 p., total:	6
organotin compounds, other than those mentioned in Chapter I, total:	0.05 (as tin)
polycyclic aromates, total:	0.01 (as benzo(a)-pyrene)
polyethene oxide (4-14) ethers of alcohols, monovalent, primary, non-branching, saturated, C12-C18, total:	5
polyethene oxide (4-14) ethers of n-alkyl(C8-C12) phenol, total:	5
polyhalogen bi- and terphenyls, total:	0.03

quaternary ammonium compounds, total:	0.5
salicyl alcohol:	30
tris(2-hydroxyethyl) amine:	0.01
1,1,1-tris(hydroxymethyl) ethane:	3
1,1,1-tris(hydroxymethyl) propane:	30
1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane:	3
fatty-acid compounds with bis(2-hydroxyethyl) amine:	30
zinc	5
zinc bis(2-ethyl hexanoate):	10

[1] The term 'ND' (not demonstrable) means – for practical application – a value of no more than 0.05.

[2] The limit applies to the sum of dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and bis(2-ethylhexyl) phthalate (DEHP) expressed as DEHP equivalents using the following equation: DBP*5 + DIBP*4 + BBP*0,1 + DEHP*1.

1.3.4 The release of monomers / base substances based on which condensation products, resins and polymerisation products are composed, as well as the additives used, must comply with the general and specific requirements laid down for these substances in this decree.

1.3.5 The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo coupling shall comply with the requirements set out in Annex II, Section 2, to Regulation (EU) No 10/2011.

1.3.6 If, in the manufacture, processing or refinement of paper or cardboard, materials described in other chapters are used, then the limits for specific migration of components relating to those materials must also be observed.

2. Paper and cardboard for hot use (use such as cooking packaging and for filtering drinks at temperatures above 80 °C)

2.1. *Description*

This part describes the requirements applicable to paper and cardboard intended for contact with food or drink products at temperatures from 80 °C to boiling temperature.

2.2. *Requirements for manufacture*

2.2.1. Only the following may be used as raw materials of paper and cardboard for hot use:

- fresh cellulose-based fibre materials, bleached or not;
- fibres of plastics as described in Chapter I, to the extent that such plastics do not contain any plasticisers, whether or not coated according to Chapter X, parts 1 and 2.

2.2.2. In the manufacture of the final product, only the auxiliaries and refining agents mentioned below may be used. They must be of high technical quality and must not be used in larger quantities than strictly necessary for the manufacture of the final product. Except for the base materials listed above, the final product must not contain any other substances than those listed below, including their decomposition products if any.

a. *parchmentising and neutralisation agents:*

- ammonia;
- sodium carbonate;
- sulfates of aluminium, potassium, magnesium and sodium;
- sulphuric acid.

b. *agents for improving the wet strength:*

- melamine-formaldehyde condensation products, containing no auxiliary materials other than those permitted in Chapter I;
- polyamide-epichlorohydrin resins, obtained by reaction of the condensation product of adipic acid and diethylene triamine with epichlorohydrin or with a mixture of epichlorohydrin and ammonia, no more than 1.5%.

2.3 *Requirements for the final product*

2.3.1. The total migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than 60.

2.3.2. The specific migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not exceed the value given below for the specific ingredient.

substance/group of substances	**SML(mg/kg)**
sec-aliphatic amines	ND
primary aromatic amines	ND[1]
diazonium compounds	ND
1,3-dichloropropanol	0.01
epichlorohydrin	QM = 1 mg/kg FP
mercaptanes	ND
peroxides	ND
desliming agents	ND
acrylamide and methacryl amide	0.1
acrylnitril and methacryl nitril	0.01
alkene imines	0.01
aluminium	1
substances containing epoxy groups, other than epoxidated soy oil, total	QM (T) = 5 mg/kg in FP (as epoxy group, Mw = 43)
formaldehyde:	15
mercury compounds (as mercury)	0.005
melamine	2.5
3 monochloro-1,2-dipropanediol	0.01
polycyclic aromates (as benzo (a) pyrene)	0.01
polyhalogen bi- and terphenyls, total	0.03
zinc	5

[1] Expressed as aniline. The detection limit is 0.002 mg/kg food or foodsimulant

2.3.3 The release of monomers/base substances from which condensation products, resins and polymerisation products are composed, as well as the additives used, must comply with the general and specific requirements for such substances in this Decree.

2.3.4 The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo coupling shall comply with the requirements set out in Annex II, Section 2, to Regulation (EU) No 10/2011.

2.3.5. If plastics are used in the manufacture, processing or refinement of paper or cardboard as referred to in this section, should then the limits for specific migration of components applicable to those plastics must also be observed.

Chapter III - Rubber products

1. Description

1.1. For purposes of these provisions, rubber products are understood to mean products based on elastomers to which any of the auxiliaries mentioned below have been added. The rubber products have been obtained from the mixtures of elastomers and auxiliaries through network formation at the molecular scale, customarily at higher temperatures and possibly under pressure.

1.2. For purposes of these provisions, elastomers are understood to be macromolecular natural and synthetic materials which at temperatures between 18 °C and 29 °C restore their shape quickly and vigorously after having been subjected to a strong deforming power, as soon as the operation of the force ceases.

2. Specification of elastomers

2.1. The molecules of elastomers are composed of at least 500 structural units originating from the monomers mentioned in this chapter. They may be chlorinated or brominated.

2.2. Elastomers can be vulcanised into a state in which they are nearly insoluble in boiling benzene, methylethyl ketone or an azeotropic mixture of ethanol and toluene; however, expansion of the elastomer may occur under the effect of these liquids.

2.3. Elastomers in their vulcanised state, containing no substances other than are necessary for vulcanising, will not break if they are extended to three times their original dimension at a temperature between 18 °C and 29 °C, and will contract within one minute to less than one and a half times their original length after having been extended to twice their original length and kept in that state for one minute.

3. Classification of rubber products into categories

3.1. Rubber products are used mainly as consumer articles. The contact with foods or beverages is typically very brief, and the contact surface very small. In those cases, any migration of components into the foodstuff or beverage in quantities that are harmful to public health will be negligible, and migration tests need not be carried out.

3.2. However, the criterion used to assess whether the migration is indeed negligible, is the product of four factors R_1 through R_4, relating to the relative contact surface, the contact temperature, the contact time and the number of times that the consumer article is reused, respectively. These rules do not apply to articles falling within Category I.

3.3. Category I includes rubber products that require particular care in light of their use, particularly infant pacifiers and articles intended to be taken into the mouth of infants or toddlers, as well as articles intended to come into contact with baby foods; the latter, however, only if they would not fall within Category III based on the calculation.
Category II includes rubber products for which the product of the factors R_1, R_2, R_3 and R_4 is greater than 0.001, so that migration tests according to Annex B (Assessment Methods) must be undertaken.
Category III includes rubber products for which the product of the aforementioned factors is less than 0.001, so that any migration of components is negligible.

3.4. The factors R_1, R_2, R_3 and R_4 are defined and determined as follows:

R_1 relates to the relative contact area (RA) between the rubber article and the foodstuff or beverage, expressed as cm^2 of rubber area per kg of foodstuff or beverage. For a relative area less than or equal to 100 cm^2/kg,the value of R_1 is determined by the formula:

$$R_1 = \frac{RA}{100}$$

For a relative area larger than 100 cm^2/kg, R_1 always has the value 1.00

R_2 relates to the temperature at which the contact between the rubber product and the foodstuff or beverage takes place. For a temperature lower than or equal to 130 °C, the value of R_2 is determined by the formula:

$$R_2 = 0.05\ e^{0.023T}$$

In this formula, the constant "e" is the base of the natural, or Napierian, logarithm, and T is the contact temperature expressed in °C. For a temperature higher than 130 °C R_2 always has the value 1.00.

R_3 relates to the time t during which a rubber product is in contact with the foodstuff or beverage, expressed in hours. For a contact time shorter than or equal to 10 hours, the value of R_3 is determined by the formula:

$$R_3 = \frac{t}{10}$$

For a contact time longer than 10 hours R_3 always has the value 1.00.

R_4 relates to the number of consecutive times N that a particular rubber article is brought into contact with the foodstuffs or beverages.

For a number of times greater than 1 000, R_4 is calculated according to the formula:

$$^{10}\log R_4 = 6 - 2\,^{10}\log N$$

For a number of times smaller or equal to 1 000, R_4 always has the value 1.00.

4. Requirements for the manufacture of the final product

4.1. In the manufacture of rubber products, only those base materials of each category may be used that are marked "+" in the appropriate column. The base materials must be of high technical quality; any auxiliaries must not be used in larger quantities than strictly necessary for the manufacture of the final product. Of the base materials mentioned below, no other materials may be present in the final product than are permitted for the relevant category, including any decomposition products of those base materials.

4.2. Substances that may be used in the manufacture of rubber products

		product category referred to in paragraph 3.3			*SML (mg/kg)*	
		I	*II*	*III*	*I*	*II*
4.2.1	*monomers and other starting substances:*					
	acrylic nitrile		+	+		ND (1)
	butadiene	+	+	+	ND (1)	ND (1)
	butyl acrylate			+		
	chlorobutadienes		+	+		0.05
	chlorethylvinyl ether			+		
	dicyclopentadiene		+	+		0.05
	divinyl benzene		+	+		ND (1)
	epichlorohydrin		+	+		ND (1)
	2,3-epoxypropyl acrylate			+		
	ethanediol dimethacrylate		+	+		0.05

		product category referred to in paragraph 3.3			*SML (mg/kg)*	
		I	*II*	*III*	*I*	*II*
	ethylene		+	+		
	ethyl acrylate			+		
	5-ethylidene bicyclo-[2.2.1]-hept-2-one		+	+		0.05
	hexafluoropropene with vinylidene fluoride only; molecular weight of the elastomer at least 70,000		+	+		0.05
	1,4-hexadiene		+	+		
	isobutene	+	+	+		
	isoprene (2-methyl-1,3-butadiene, CAS 78-79-5)	+	+	+	ND (1)	ND (1)
	methacrylic acid		+	+		3
	5-methylene bicyclo-[2.2.1]-hept-2-ene		+	+		0.05
	monochloroacetic ester of 5-hydroxymethyl bicyclo-[2.2.1]-hept-2-ene			+		
	monochlorotrifluorethene, with vinylidene fluoride only		+	+		0.05
	propene		+	+		
	rubber, natural	+	+	+		
	silanols with at least one hydroxyl group and one or more methyl groups on each silicon atom		+	+		
	siloxanes, with a hydrogen atom and a methyl group to each silicon atom	+	+	+		
	siloxanes, with two methyl groups on each silicon atom and one vinyl group on the terminal silicon atoms	+	+	+		
	styrene	+	+	+		
	tetrafluorethene, combined only with vinylidene fluoride and hexafluoropropene; molecular weight of the elastomer at least 100,000		+	+		0.05
	vinyl acetate		+	+		12
	5-vinyl bicyclo-[2.2.1]-hept-2-ene		+	+		0.05
	vinylidene fluoride		+	+		1
	hydrogen	+	+	+		
4.2.2	*auxiliary substances:*					
	a. *mesh formers*:					
	6-aminohexylcarbamic acid, only in elastomers, containing vinylidene fluoride as a building block, not more than 1.5%			+		
	4,4'-bis(aminocyclohexyl) methane-carbamate, only in elastomers containing vinylidene fluoride as a building block, not more than 2.5%			+		
	4,4-bis(tert-butyl peroxy) butane-carboxylic acid n-butyl			+		
	1,3-bis(tert-butyl peroxy isopropyl) benzene			+		
	tert-butylcumyl peroxide		+	+		ND (1)
	tert-butyl peroxy benzoate		+	+		ND (1)
	1,1-di-tert-butyl peroxy cyclohexane;		+	+		ND (1)
	1,1-di-tert-butylperoxy-3,3,5-trimethylcyclohexane		+	+		ND (1)
	2,4-dichlorodibenzoyl peroxide		+	+		ND (1)
	dibenzoyl peroxide		+	+		ND (1)
	di-tert-butyl peroxide		+	+		ND (1)
	dicumyl peroxide	+	+	+	ND (1.2)	ND (1)
	2,4,6-tris(allyloxy)-s-triazine		+	+		
	sulphur	+	+	+		
	b. accelerators, no more than 3 % in total:					
	2-aminoethylcarbamic acid, only in elastomers, containing vinylidene fluoride as a building block			+		
	2-benzothiazolyl-N,N-diethyl thiocarbamyl-sulfide			+		
	1,3-bis(2-benzothiazolyl mercapto-methyl)-urea			+		

		product category referred to in paragraph 3.3			*SML (mg/kg)*	
		I	*II*	*III*	*I*	*II*
	N-tert-butyl-2-benzothiazolylsulfeenamide			+		
	N-cyclohexyl-2-benzothiazolyl sulphene amide		+	+		0.05
	cyclohexyl ethyl amine			+		
	dibutylxanthanedisulfide			+		
	sym. diethyl thioureum			+		
	1,3-difenylguanidine		+	+		0.05
	1,3-diphenyl-2-thiourea			+		
	N,N-dimethyl cyclohexyl ammonium salt of dibutyl dithiocarbamic acid			+		
	sym. dimethyl diphenyl thiuramdisulfide	+	+	+	0.1 (2,3)	1 (3)
	2,6-dimethylmorpholine-2-thiobenz-thiazole			+		
	di-N-pentamethylene thiuram-tetrasulfide	+	+	+	0.1 (2,3)	1 (3)
	dithiobis(2-benzthiazol)		+	+		3
	glycol dimercaptoacetate		+	+		
	hexamethylene tetramine			+		
	potassium pentamethylenedithiocarbamate			+		
	copper dimethyl dithiocarbamate			+		
	2-mercaptobenzthiazol, not more than 0.05%		+	+		3
	2-mercaptoimidazoline		+	+		0.05
	2-mercaptothiazoline			+		
	morfolinothio-2-benzthiazol		+	+		3
	sodium dibutyldithiocarbamate			+		
	sodium dimethyl dithiocarbamate			+		
	piperidinium pentamethylene dithiocarbamate			+		
	tetrabutylthiurammonosulfide			+		
	tetraethyl thiuramdisulfide	+	+	+	0.1 (2.4)	1 (4)
	tetramethyl thiuramdisulfide	+	+	+	0.1 (2.4)	1 (4)
	tetramethylthiurammonosulfide	+	+	+	0.1 (2.4)	1 (4)
	tin(II)oleate, only in silicone rubber			+		
	O-tolylbiguanidine		+	+		0.05
	zinc butylxanthogenate			+		
	zinc dibutyl dithiocarbamate	+	+	+	0.1 (2.5,6)	1 (5,6)
	zinc diethyl dithiocarbamate	+	+	+	0.1 (2.5,6)	1 (5,6)
	zinc dimethyldithiocarbamate	+	+	+	0.1 (2.5,6)	1 (5,6)
	zinc ethylphenyl dithiocarbamate	+	+	+	0.1(2.5,6)	1 (5,6)
	zinc isopropyl xanthogenate			+		
	zinc-2-mercaptobenzthiazole	+	+	+	0.3 (2.6)	3 (6)
	zinc pentamethylene dithiocarbamate	+	+	+	0.1 (2.5,6)	1 (5,6)
	c. *retardants:*					
	benzoic acid	+	+	+		
	phthalic anhydride	+	+	+		
	salicylic acid			+		
	d. *activators*:					
	dibutylamine			+		
	dibutyl amine salt of oleic acid			+		
	diethyl amine			+		
	glycerol			+		
	magnesium carbonate			+		
	magnesium oxide		+	+		
	tin (II) chloride		+	+		
	linear, saturated and unsaturated fatty acids, with an equal number of carbon atoms, C_8-C_{22}, with a content not exceeding 2% of unsaponifiables	+	+	+		

		product category referred to in paragraph 3.3			*SML (mg/kg)*	
		I	*II*	*III*	*I*	*II*
	fatty acids as described above, amides thereof;	+	+	+		
	fatty acids as described above, as salts with zinc	+	+	+	(6)	(6)
	zinc oxide	+	+	+	(6)	(6)
	e. *protectants:*					
	N-alkyl(C_{14}-C_{18})-N,N',N'-triacetoyl-1,3-diaminopropane			+		
	2,2-bis(3-tert-butyl-4-hydroxyphenyl) propane esterified with p-nonyl phenyl phosphite			+		
	bis(2-hydroxy-3-cyclohexyl-5-methyl-phenyl)methane		+	+		0.05
	bis [2-hydroxy-3-(2-methyl cyclohexyl)-5-methyl phenyl]methane	+	+	+	0,6 (2)	6
	bis(2-hydroxy-3-nonyl-5-methyl phenyl)-methane			+		
	bis(2-hydroxy-3-tert-octyl-5-methylphenyl)-methane			+		
	bis(4-methoxyphenyl) amine			+		
	2,4-bis-n-octyl thio-6-(4'-hydroxy-3',5'-di-tert-butyl anilino)-1,3,5-triazine	+	+	+	3	30
	2,4-bis(octylthiomethyl)-6-methylphenol		+	+		6
	2,4-diaminotoluene			+		
	2,6-di-tert-butyl-4-phenyl phenol			+		
	2,6-di-tert-butyl-4-methoxymethylphenol			+		
	2,6-di-tert-butyl-4-methyl phenol	+	+	+		
	N-phenyl-N'-isohexyl-p-phenylene diamine, no more than 1.5 %			+		
	p-cresol dicyclopentadiene-isobutylene, copolymer, not more than 1.4 %		+	+		5
	2,2'-methylenebis(4-methyl-6-tert-butyl-phenol)	+	+	+	0.15 (2)	1.5
	n-octadecyl-beta-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate		+	+		6
	reaction product of styrene and diphenyl amine, not for contact with fatty foods and beverages		+	+		0.05
	reaction products of styrene or alpha-methylstyrene or alkenes, C_3-C_{12}, with phenol or methylphenol		+	+		0.05
	styrene (2 mol) condensed with 1 mol of a mixture of phenol and o-, m- and p-cresols if the final product has a Brookfield viscosity between 1,400 and 1,700 cP at 25 °C			+		
	tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyphenyl) propionate]methane	+	+	+		
	thiobis(2-methyl-4-hydroxy-5-tert-butyl-benzene)		+	+		0.3
	alpha-tocopherol	+	+	+		
	1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene		+	+		
	tris(2,4-di-tert-butylphenyl)phosphite	+	+	+		
	tris(mono- and dinonyl phenyl) phosphite containing no more than 1% tris(2-hydroxypropyl) amine			+		
	f. *plasticisers*:					
	acetyltributyl citrate			+		
	bis [2-(2-butoxyethoxy) ethyl]adipate			+		
	butyl acetyl ricinoleate			+		
	butyl laurate		+	+		
	butyl oleate		+	+		
	butyl stearate		+	+		
	calcium stearate	+	+	+		
	rosin, according to Chapter II		+	+		

		product category referred to in paragraph 3.3			SML (mg/kg)	
		I	II	III	I	II
	cumaron-indene resins			+		
	dibenzyl adipate			+		
	dibutyl phthalate		+	+		0.6[9]
	dibutylsebacate		+	+		
	di-n-decyl adipate			+		
	di-n-hexyl azelate			+		
	diisodecyl adipate			+		
	di-iso-octyl adipate		+	+		
	di(2-ethylhexyl) phthalate		+	+		0.6[9]
	di-isooctylsebacate			+		
	di-n-octyl phthalate		+	+		1.5
	di-n-octyl sebacate		+	+		
	esters of triethylene glycol, phthalic acid and benzoic acid			+		
	phenol-formaldehyde condensation products, containing no auxiliary substances other than those permitted in Chapter I		+	+		
	linseed oil			+		
	montan wax, consisting of: 1) montanic acids C_{26}-C_{32} 2) esters with ethanediol or 1,3-butanediol 3) or the calcium salt of these acids, if the product complies with the purity requirements set in part B (Research Methods);		+	+		
	N-octyl-n-decyladipate			+		
	paraffin, microcrystalline, whose ultraviolet light absorption complies with the values set in part B (Research Methods)	+	+	+		
	paraffin, solid, including synthetic, whose ultraviolet light absorption complies with the values set in part B (Test Methods)		+	+		
	paraffin, liquid (refined mineral oil) meeting the following specification: - colour weaker than the Standard Saybolt 30 - smell almost absent - the absorption of ultraviolet light complies with the values set in part B (Test Methods)	+	+	+		
	petrolatum (vaseline), according to Chapter X, paragraph 7, subsection f		+	+		
	polybutene		+	+		
	polycyclopentadiene resin, produced by polymerisation of a mixture primarily consisting of cyclopentadiene and the dimer thereof, originating from the boiling fraction between 80 °C and 180 °C distilled from the product obtained by cracking petroleum while adding steam. The polymerisation process is followed by hydrogenation of the polymer. The resins must comply with the following specification: - viscosity at 140 °C of at least 2000 cP - softening point at least 95 °C (ASTM E 28) - bromine value no more than 2 (ASTM D 1159) - ash content no more than 0.1% (ASTM D 482) - a 10 % solution in toluene must have a colour value of at least 22 on the Saybolt colour scale (ASTM D 156)		+	+		
	polyethene, according to Chapter I, molecular weight > 200	+	+	+		
	polypropene, according to Chapter I	+	+	+		
	polypropene adipate		+	+		
	polystyrene, according to Chapter I		+	+		
	1,2-propanediol			+		

		product category referred to in paragraph 3.3			*SML (mg/kg)*	
		I	*II*	*III*	*I*	*II*
	rapeseed oil		+	+		
	castor oil (according to the European Pharmacopoeia)		+	+		
	soybean oil, whether or not modified with or without sulphur (factice)		+	+		0.05
	soybean oil, epoxidised, with an oxirane content between 6.4 and 8%		+	+		
	triethylene glycoldicaproate			+		
	triethylene glycoldicaprylate			+		
	fatty acids as described in 4.2.2 d., esterified with pentaerythritol			+		
	g. *fillers*:					
	barium sulphate		+	+		1 (as Ba)
	carbonates of calcium, magnesium and zinc	+	+	+	(6)	(6)
	cotton (loose fibres or fabric)			+		
	cork			+		
	oxides of aluminium, calcium, magnesium, silicon and titanium	+	+	+		
	soot (furnace black and channel black) and other carbon products, such as graphite and coke powder, the purity of which meets the following requirements: - Primary particles of 10-300 nm, aggregated to 100-1 200 nm, that may form agglomerates with dimensions between 300 nm and several mm. - With toluene extractable substances: not more than 0.1 % determined in accordance with the ISO 6209 method. - UV absorption of a cyclohexane extract at 386 nm: extinction < 0.02 for a 1 cm or < 0,1 cuvet for a cuvet of 5 cm, determined by a generally recognised analytical method. - Benzo[a]pyrene content: not more than 0.25 mg/kg soot.		+	+		
	silicates of aluminium, calcium, potassium, magnesium and sodium, including diatomaceous earth, glass fibre, infusorial earth, kaolin, clay, mica and talc		+	+		
	fibres of plastics, according to Chapter I; of regenerated cellulose, according to Chapter VIII and of pure cellulose			+		
	zinc sulphide		+	+		(6)
	h. *emulsifiers and emulsion stabilisers*:					
	alkyl(C_8-C_{18})benzenesulfonates, sodium salts		+	+		30 (7)
	alkyl(C_8-C_{18})sulphates, sodium salts		+	+		30 (7)
	alkyl(C_8-C_{18})sulfonates, sodium salts		+	+		30 (7)
	dismutated colophonium as defined in Chapter II, as ammonium, potassium and sodium salts			+		
	hydroxyethylcellulose			+		
	lecithin, peroxide value maximum 10	+	+	+		
	methyl cellulose			+		
	naphthalenesulfonic acid-formaldehyde condensation product, sodium salt			+		
	polyethene oxide (4-14) ethers of octyl or nonyl phenol		+	+		5
	polyethylene oxide(4-14) ethers of monocarboxylic, primary, linear, saturated, alcohols, C_{12}-C_{18}	+	+	+	0.5 (2)	5
	fatty acids described in 4.2.2 d. esterified with glycerol to mono-, di- and triglycerides	+	+	+		

		product category referred to in paragraph 3.3			*SML (mg/kg)*	
		I	*II*	*III*	*I*	*II*
	fatty acids as described in 4.2.2 d., as salts with ammonium, potassium, sodium or zinc	+	+	+	(6)	(6)
	i. *dyes and pigments*:					
	according to Chapter XI.					
	j. *other auxiliary substances:*					
	azodicarbonamide			+		
	benzene sulfonhydrazide, not more than 3%			+		
	bis(2-hydroxyethyl) ether		+	+		30 (8)
	ethanediol		+	+		30 (8)
	tert-butyl peroxyacetate			+		
	4-tert-butyl-o-thiocresol			+		
	dialkyl(C_8-C_{18})dimethylammonium chloride			+		
	diethyl xanthogen disulfide			+		
	divinyltetramethyldisilazane	+	+	+		
	dodecyl mercaptane			+		
	ethylene diaminetetraacetic acid, sodium salts	+	+	+		
	ethynylcyclohexanol	+	+	+	1.8 (2)	
	glycine, sodium salt			+		
	hexachloroplatinic acid	+	+	+		
	hexamethyldisilazane	+	+	+		
	potassium peroxodisulphate			+		
	glue of animal origin			+		
	p-menthane hydroperoxide			+		
	2-methyl butyn-3-ol-2	+	+	+	3 (2)	
	sodium formaldehyde sulphoxylate			+		
	sodium nitrite			+		
	sodium polysulfide			+		
	sodium sulphide			+		
	organopolysiloxanes (silicone), containing two methyl groups on each silicon atom, molecular weight 13500 -30000	+	+	+	1.5 (2)	
	polyethene oxide, molecular weight > 200	+	+	+		
	polyethylene oxide(8-14), esterified with laurine, oil, ricinol or stearic acid		+	+		
	polypropene oxide, molecular weight > 400		+	+		
	regenerates of elastomers, to the extent that their composition is in accordance with this chapter and contains no other auxiliary substance than permitted for the corresponding category		+	+		
	sorbic acid	+	+	+		
	thioxylenols		+			
	tri-n-decyl mercaptane			+		
	tris-2-hydroxyethylamine, only in mould release agents	+	+	+	ND (1)	ND (1)
	tris(2-hydroxyethyl) amine phosphate, only in mould release agents	+	+	+	ND (1)	ND (1)
	urea		+	+		
	xylene formalaldehyde resins, not more than 3 %		+	+		
	zinc-4-tert-butyl thiophenolate, not more than 0.3%			+		
	zinc pentachlorothiophenolate, not more than 0.3%			+		
	k. *solvents:*					
	to the extent that the final product still complies with the provisions of article 3, first paragraph, of Regulation (EC) No. 1935/2004.	+	+	+		

(1) The term ND (not detectable) refers to a value not exceeding 0.01.

(2) For practical purposes, it is assumed that five disposable teats per day are used for a child. The specific migration limit per teat is therefore one-fifth part of the value given in the table. Reusable teats and pacifiers are subject to the provi-sions in part B, chapter I, subsection 4.2.1 (5), and subsection 4.2.2 (1), for the examination of articles intended to come into repeated contact with foodstuffs.

(3) SML for the sum of sym. dimethyldiphenylthiuram disulfide and di-N-pentamethylenethiuram tetrasulfide.
(4) SML for the sum of tetraethylthiuram disulfide, tetramethylthiuram disulfide and tetramethylthiuram monosulfide.
(5) SML for the sum of zinc dibutyl dithiocarbamate, zinc diethyl dithiocarbamate, zinc dimethyldithiocarbamate, zinc ethylphenyldithiocarbamate and zinc pen-tamethylenedithiocarbamate.
(6) SML(T) for zinc = 5.
(7) SML for the sum of sodium salts of alkyl(C8-C18)benzenesulfonates, alkyl(C8-C18)sulphates and alkyl(C8-C18)sulfonates.
(8) SML for the sum of bis(2-hydroxyethyl)ether and ethanediol.
(9) The limit applies to the sum of dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and bis(2-ethylhexyl) phthalate (DEHP) expressed as DEHP equivalents using the following equation: DBP*5 + DIBP*4 + BBP*0,1 + DEHP*1.

5. Requirements for the final product

5.1. The total migration of ingredients of rubber products in foodstuffs, under reasonably expected conditions of use, after multiplication by the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than the following values:

• for rubber products of Category I:	20[b]
• for rubber products of Category II	
- determined in 3% acetic acid:	100
- determined in water, 15% ethanol or olive oil:	60

5.2. The specific migration of ingredients of rubber products in foodstuffs, under reasonably expected conditions of use, after multiplication by the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than the values listed in the table for the respective substances.

5.3. The migration must be expressed in mg/kg of foodstuff or beverage, after examining:
- articles that can be filled, but whose contact area cannot be easily determined;
- overs, caps, gaskets and other articles and materials used for closing or sealing, not including rubber teats.

5.4. The migration of ingredients of rubber teats and of the rubber parts of pacifiers submits must be determined in mg per teat or pacifier [b].

5.5. Notwithstanding the provision in 5.4, the migration of N-nitrosamines and nitrosable compounds must be determined in mg per kg of teats or pacifiers [b].[21].
The migration must not exceed:
- N-nitrosamines, total: 0.01 mg/kg
- nitrosable compounds, total, determined as N-nitrosamines: 0.1 mg/kg

5.6. The migration of ingredients of materials and articles not covered by 5.3 and 5.4 must be determined in mg/dm^2. The factors listed in Annex B, Chapter I, Table 4.1 apply accordingly.

5.7. In addition to the specific migration limits listed in Subsection 4.2.1, materials and articles of the Categories I and II are subject to the following limits, applied accordingly:

category	*I*	*II*
6-aminohexane lactam	1.5[1]	15
aluminum	1	1
benzthiazol	0.05[1]	0.5
dibenzyl amine	0.05[1]	0.5
mercaptanes	ND[1,3]	ND[3]
primary aromatic amines	ND[1,2]	ND[2]
zinc	5	5

(1) For practical purposes, it is assumed that five disposable teats per day are used for a child. The specific migration limit per teat is therefore one-fifth part of the value given in the table. Reusable teats and pacifiers are subject to the provi-sions in part B, chapter I, subsection 4.2.1 (5), and subsection 4.2.2 (1), for the examination of articles intended to come into repeated contact with foodstuffs.
(2) The content is expressed as aniline. The detection limit is 0.002 mg/kg of food or food simulant.
(3) ND (not detectable). The detection limit is 0.002 mg/kg of food or food simulant.

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[21] Annex B, Chapter I, Subsection 5.3.7 gives the basic rule for determining the release of N-nitrosamines and N-nitrosable compounds.

5.8 The release of monomers/base substances from which condensation products, resins and polymerisation products are composed, as well as the additives used, must comply with the general and specific requirements for such substances in this Decree.

5.9 The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo coupling shall comply with the requirements set out in Annex II, Section 2, to Regulation (EU) No 10/2011.

5.10 If materials described in other chapters are used in the manufacture or processing of rubber products, then the specific migration limits for those materials must also be observed.

5.11 The packaging of rubber teats and pacifiers shall carry a text with the following content:

- clean the teat (pacifier) thoroughly before first use;
- then submerge the teat (pacifier) in boiling water for about 10 minutes;
- check the teat (pacifier) prior to each use. If the rubber teat (pacifier) is stretched, damaged or bitten through, then discard it and use a fresh one

Chapter IV – Metals

1. 1. Description

1.1 *In this regulation, the following definitions apply:*

alloy: a macroscopically homogeneous metal consisting of two or more chemical elements bonded together in such a way that they cannot be easily separated by mechanical means;

metals: substances characterized by the following physico-chemical properties in solid form:

a. reflectivity responsible for the characteristic metallic luster;
b. electrical conductivity;
c. thermal conductivity;
d. mechanical properties such as strength and ductility.

1.2 This Chapter applies to packaging and consumer articles made wholly or partly of metals or alloys and whether or not provided with a coating.

2. Packaging materials

2.1. In the manufacture and processing, only the base substances mentioned below may be used:

a. *base materials:*

- aluminium, whether or not alloyed with chromium, iron, copper, magnesium, manganese, silicon, titanium and no more than 0.25% of other elements;
- copper;
- steel, whether or not alloyed.

b. *solders:*

- alloys consisting primarily of copper, lead, tin, silver and zinc, compliant with the following specification:
    - proportion of antimony: no more than 3%
    - proportion of arsenic: no more than 0.05%
    - proportion of bismuth: no more than 0.1%
    - proportion of cadmium: no more than 0.5%.

Lead-containing solders may only be used on the exterior of the packaging material, unless the soldered joint is covered with a metallic coating according to c., with a paint layer according to 2.2 g. or taped over with adhesive tape as described under 2.2 e.

c. *metallic coatings:*

only coatings made of the following metals may be applied to the base materials referred to in a. and on the solders referred to in b.:

- aluminium, whether or not alloyed and whether or not anodically oxidated or eloxated;
- chromium, whether or not alloyed;
- copper, whether or not alloyed;
- nickel, whether or not alloyed;
- tin, to the extent that it complies with the following specification:
    - proportion of tin: at least 99.75%
    - proportion of arsenic: no more than 0.03%
    - proportion of cadmium: no more than 0.05%
    - proportion of lead: no more than 0.01%.

The aforementioned raw materials and metallic coatings may be passivated by means of a chemical or electrochemical post-treatment with chromium, manganese, titanium, tin and/or zirconium and/or their oxides and/or inorganic salts, and a polymer in compliance with subsection 2.2(g) and/or Chapters I and/or X.

For zirconium passivated metal, the following additional provision shall apply. If the properties of acetic acid predominate in the foods with which the metal comes into contact, zirconium passivated metal must be coated with organic polymers. This provision shall not apply to zirconium passivated metal in contact with non-acid foods or in contact with foodstuffs in which the properties of acids other than acetic acid predominate.

2.2. Requirements for the manufacture of the final product

For the manufacture and processing of the final product, only the aforementioned base substances and the auxiliaries mentioned below may be used. All materials and auxiliaries must be of high technical quality. Any auxiliaries must not be used in larger quantities than strictly necessary for the manufacture of the final product. The final product must not contain any substances other than the aforementioned base materials and solders and the auxiliaries mentioned below, the from this condensation products obtained from them, and the decomposition products of the auxiliaries, if any.

a. *greasing agents:*

- dioctyl azelate;
- dioctyl sebacate;
- glycerol monooleate;
- cottonseed oil;
- palm oil;
- paraffin, liquid (refined mineral oil) meeting the following specification:
  - colour weaker than Standard Saybolt 30
  - odour nearly absent
  - and whose ultraviolet light absorption meets the requirements as defined in Annex B (Assessment Methods).

b. *rolling oils:*

- alcohols, monovalent, aliphatic, saturated, C_{12}-C_{18};
- butyl stearate;
- hydrocarbons, mainly aliphatic, C_{10}-C_{14}, primarily C_{12}-C_{13}, with a boiling interval of 180 °C-260 °C, aromate content (benzene, toluene, xylenes) no more than 1%;
- palmseed fat.

c. *lubricants for pounding and pulling:*

- butyl stearate;
- dibutyl sebacate;
- dioctyl sebacate;
- epoxidated soy oil with an oxirane content between 6.4 and 8%;
- hydrocarbons, mainly aliphatic, C_{10}-C_{14}, primarily C_{12}-C_{13}, with a boiling interval of 180 °C-260 °C, aromate content (benzene, toluene, xylenes) no more than 1%;
- organopolysiloxanes, with one or two methyl groups and one or two hydrogen atoms per silicon atom (silicones), as an emulsion or as a solution in water;
- paraffin, solid, including synthetic, whose ultraviolet light absorption meets the requirements of Annex B (Assessment Methods);
- paraffin, liquid (refined mineral oil) meeting the following specification:
  - colour weaker than Standard Saybolt 30
  - odour nearly absent
  - and whose absorption of ultraviolet light meets the requirements defined in Annex B (Assessment Methods);

- rapeseed oil;
- castor oil, according to the European Pharmacopoeia;
- fatty acids, non-branching, saturated and unsaturated, with an even number of carbon atoms, C_8-C_{18}, with a non-saponifiable ingredient content of no more than 2%;
- fatty acids as described above, amides thereof;
- fatty acids as described above, salts with aluminium, calcium, potassium, magnesium, sodium and zinc;
- zinc powder.

d. *non-metallic joint sealants:*

Apart from the materials described under g., only the following auxiliaries may be used:

- polyamides obtained from the following acids and amines:
  - 12-aminododecanoic acid
  - 11- aminoundecanoic acid
  - diaminoethane
  - diethylene triamine
  - sebacic acid
  - tetraethylene pentamine
  - fatty acids, as described above, whether or not dimerised or trimerised.

e. *adhesive tape for covering the lengthwise joint:*

- carrier material:
  - aluminium as described in 2.1 a.;
  - polypropene, according to Chapter I;
  - terephthalic polyesters, according to Chapter I.
- adhesives:
  - only the materials described under g. may be used.

f. *sealants for lid and bottom seams:*

Except for the materials listed in d. and g., only the following auxiliaries may be used:

- alkyl(C_8-C_{18}) benzene sulfonates, sodium salts;
- alkyl(C_8-C_{18}) diphenyl etherdisulfonic acid, sodium salts;
- ammonium alginate;
- Arabic gum;
- ascorbic acid, sodium salt;
- 1,2-benzisothiazoline-3-one;
- benzoic acid, potassium and sodium salts;
- butadiene-styrene-fumaric acid copolymers, containing no auxiliary materials other than those permitted in Chapter I;
- calcium and zinc salts of rosin (wood resin, gum resin, tall resin, dark wood resin and dark tall resin) extracted from pine trees of the Pinus genus, Pinaceae family, whether or not modified by hydrogenation, dimerisation or dismutation (disproportioning);
- carboxymethyl cellulose, sodium salt;
- 2,2'-dibenzamidophenyl disulfide, no more than 0.7%;
- N,N'-di-2-naphthyl-p-phenylene diamine, containing no more than 10 mg/kg 2-naphthyl amine, no more than 0.6%;
- proteins: animal glue, casein, gelatin, dermal adhesive, fish glue and zein;
- ethylene diaminetraacetic acid, sodium salt;
- o-phenyl phenol, sodium salt;
- formaldehyde;
- glycerol;
- guttapercha;
- 1,6-hexanediol;
- hexamethylene tetramine;
- 4-hydroxy benzoezuur, methyl ester;
- karaya gum;
- sodium sulfite;
- paraffin, solid, including synthetic, whose absorption of ultraviolet light complies with the values specified in Annex B (Assessment Methods);
- paraffin, liquid (refined mineral oil), which complies with the following specification:
  - colour weaker than Standard Saybolt 30
  - odour nearly absent
  - and whose absorption of ultraviolet light meets the requirements defined in Annex B (Assessment Methods);

- polyethene oxide, molecular weight greater than 200;

- poly(ethene or propene or butene oxide) ethers of nucleus-sulfonated mono-, di- and trialkyl(C_4-C_{18}) phenols;
- polystyrene hybrid polymers and copolymers, according to Chapter I;
- rubber products, according to Chapter III, Category I and II;
- sorbic acid and its potassium and sodium salts;
- sulfosuccinic acid, esterified with poly(ethene or propene or butene oxide) ethers of alcohols, C_4-C_{18};
- 2,4,7,9-tetramethyl-5-decyn-4,7-diol, ethylene oxide adduct;
- triethylene glycol;
- tris(mono- and dinonyl phenyl) phosphite, containing no more than 1% tris(2-hydroxypropyl) amine.

g. *organic coatings:*

1°. *polymers:*

- cellulose acetate, according to Chapter I;
- cellulose acetate-butyrate, containing no auxiliary materials other than those permitted in Chapter I;
- cellulose acetate-propionate, containing no auxiliary materials other than those permitted in Chapter I;
- cellulose nitrate, containing 10.8-12.4% nitrogen;
- epoxy resins produced from polyethers formed by the reaction of epichlorohydrin with both phenolic hydroxyl groups of 2,2-bis(4-hydroxyphenyl)butane (CAS 77-40-7) or 2,2-bis(4-hydroxyphenyl)propane, whether or not after having reacted with one or several of the following hardening agents:

  di-isocyanates:

  - 4,4′-di-isocyanatodiphenyl methane
  - 1,6-di-isocyanatohexane
  - 2,4-di-isocyanatotoluene
  - 2,6-di-isocyanatotoluene
  - 3,3′-dimethyl-4,4′-di-isocyanatodiphenyl

  formaldehyde condensation products:

  - phenol-formaldehyde resins, as described below
  - melamine-formaldehyde resins, as described below
  - urea-formaldehyde resins, as described below

  amino compounds:

  - diaminoethane
  - diethylene triamine
  - polyamides, condensation products of dimerised linoleic, linolenic or dehydrated ricinic acid with 1,6-diaminohexane
  - polyaminoamides, condensation products of dimerised linoleic, linolenic or dehydrated ricinic acid with diaminoethane, diethylene triamine, tetraethylene pentamine and triethylene tetramine
  - tetraethylene pentamine
  - triethylene tetramine;

- ethyl cellulose;
- ethyl hydroxyethyl cellulose;
- phenol-formaldehyde condensation products, according to Chapter I, whether or not modified with drying oils, epichlorohydrin or fatty acids, saturated and unsaturated, with an even number of carbon atoms, C_8-C_{22}, with a non-saponifiable ingredient content of no more than 2%;
- hydroxyethyl cellulose;
- hydroxypropyl cellulose;
- hydroxypropyl methyl cellulose;
- rosin, according to Chapter II, whether or not after having reacted with one or several of the following reagents:
  - acrylic acid
  - bis(2-hydroxyethyl) ether

    - ethanediol
    - phenol-formaldehyde condensation products, as described above
    - glycerol
    - maleic anhydride
    - methanol
    - pentaerythritol;

- melamine-formaldehyde condensation products, according to Chapter I, whether or not modified with monovalent, aliphatic, saturated alcohols, C_1-C_{18}, diols, C_2-C_6, and polyols, C_3-C_6;
- methyl cellulose;
- natural resins: damar, copal;
- petroleum hydrocarbon resins, according to Chapter II;
- polyacrylate, according to Chapter I;
- polyamides, according to Chapter I;
- polycarbonate, according to Chapter I;
- polyethene, according to Chapter I;
- polyesters, unsaturated, according to Chapter I;
- polyesters obtained from a reaction between one or several of the following polybasic acids and one or several of the following polyvalent alcohols, where the reaction can be terminated with one of the following monobasic acids or monovalent alcohols:
    - polybasic acids:
        - adipic acid
        - azelaic acid
        - succinic acid
        - p-tert-butyl benzoic acid
        - 1,2,4-benzene tricarboxylic acid
        - cyclohexane-1,2-dicarboxylic acid
        - decane dicarboxylic acid
        - phthalic acids
        - maleic acid
        - sebacic acid
    - polyvalent alcohols:
        - 1,4-bis(hydroxymethyl) cyclohexane
        - 1,3-butanediol
        - 1,4-butanediol
        - diethylene glycolmonoethyl ether
        - 2,2-dimethyl propanediol
        - di-, tri- and polypropanediol-1,2
        - ethanediol
        - glycerol
        - 1,6-hexanediol
        - Mannitol
        - 1,2-propanediol
        - triethylene glycol monoethyl ether
        - 1,1,1-tris(hydroxymethyl) ethane
        - 1,1,1-tris(hydroxymethyl) propane
    - monobasic acids:
        - benzoic acid
        - 4,4-bis(4’-hydroxyphenyl)hexanoic acid
        - fatty acids as in Subsection 2.2 c
    - monovalent alcohols:
        - monovalent, aliphatic alcohols C_8-C_{18};

- polyesters, obtained from the methyl ester of rosin, phthalic anhydride, maleinezuuranhydride and ethanediol, acid number 4-11, colour K or lighter, Drop Softening point 70 °C90 °C;

- polypropene, according to Chapter I;
- polyurethane, according to Chapter I;
- polyvinyl acetate, according to Chapter I;
- polyvinyl acetals, produced from polyvinyl alcohol and aliphatic, saturated aldehydes, C_1-C_6, molecular weight greater than 10 000, containing no auxiliary materials other than those permitted in Chapter I;
- polyvinyl alcohol (viscosity of the 4% solution in water at 20 °C at least 5 mPas);
- polyvinyl chloride, according to Chapter I;
- polyvinylidene chloride, according to Chapter I;
- castor oil, whether or not hydrogenated or dehydrated and whether or not condensed or polymerised metadipic acid, citric acid, phthalic acids, maleic acid and sebacic acid;
- rubber products, synthetic, chlorinated or cyclicised, according to Chapter III;
- terpene resins, produced from alpha-pinene, beta-pinene or dipentene, whether or not modified with phenol, meeting the following specification:
    - acid number less than 5
    - saponification number less than 5
    - the colour of a 50% solution in white spirit must be less than four Gardner;
- urea-formaldehyde condensation products, according to Chapter I, whether or not modified with monovalent, aliphatic, saturated alcohols, C_1-C_{18}, diols, C_2-C_6, and polyols, C_3-C_6.

2°. *catalysts and other polymerisation regulators:*

- aluminium alcoholates, of monovalent, aliphatic alcohols, C_3-C_8;
- p-tert-butyl peroxy benzoate;
- dicarboxylic acids, unsaturated, aliphatic, C_4-C_8;
- dodecyl benzene sulfonic acid;
- phenol;
- phosphoric acid and its esters with monovalent, aliphatic alcohols, C_2-C_4;
- phthalic anhydride;
- fumaric acid;
- tetrabutyl titanate;
- tin(II)oleate;
- titanic acid, esterified with monovalent, aliphatic alcohols, C_3-C_8;
- toluene sulfonchloride;
- toluene sulfonic acids.

3°. *drying agents:*

- naphthenates, octanoates and oxides of calcium, cerium, iron, cobalt, lithium, manganese, zinc and zirconium;
- tin(II)stearate;
- fatty acids, monovalent, saturated, C_9-C_{11}, as salts of calcium, cerium, iron, cobalt, lithium, manganese, zinc and zirconium.

4°. *softeners:*

- acetyl tributyl citrate;
- acetyl tris(2-ethylhexyl) citrate:
- benzylbutyl phthalate containing no more than 1% dibenzyl phthalate;
- dibutyl phthalate;
- dibutyl sebacate;
- dicyclohexyl phthalate;
- di(2-ethylhexyl) phthalate;
- dihexyl azelate;
- phthalic acid, diesters with primary saturated C_9-C_{11}-alcohols with more than 90% C_{10} (CAS-No 0068515-49-1 and 0026761-40-0);
- epoxidated linseed oil;
- epoxidated soy oil with an oxirane content between 6.4 and 8%;
- tri-iso-octyl trimellitate.

5°. *lubricants:*

- N,N′-distearoyl- or N,N′-dipalmitoyl diaminoethane;
- lanolin;
- montane wax, consisting of:
  1) montanic acids C_{26}-C_{32}
  2) esters thereof with ethanediol or 1,3-butanediol
  3) or the calcium salt of these acids, and provided that the product complies with the purity requirements of Annex B (Assessment Methods);
- paraffin, solid, including synthetic, whose ultraviolet light absorption meets the requirements of Annex B (Assessment Methods);
- paraffin, liquid (refined mineral oil) meeting the following specification:
  - colour weaker than Standard Saybolt 30
  - odour nearly absent
  - and whose absorption of ultraviolet light meets the requirements defined in Annex B (Assessment Methods);
- polyethene, molecular weight greater than 200;
- fatty acids as described in c.;
- fatty acids, as described in c., esterified with glycerol to form mono-, di- and triglycerides;
- waxes: carnauba, spermaceti.

6°. *other auxiliaries:*

- phosphoric esters of epoxidised polybutadiene with terminal hydroxyl groups, CAS 1429907-37-8, to be used only in coatings on metal;
- organo polysiloxanes, containing two methyl groups on each silicon atom (silicones);
- oxides of aluminium, calcium, iron, silicon, titanium and zinc;
- silicates of aluminium, calcium, potassium, magnesium and sodium, including diatomaceous earth, fibreglass, infusorial earth, kaolin, clay, mica and talc;
- fatty acids as described in c., vinyl esters thereof;
- fatty acids as described in c., esterified with polyols, C_3-C_6;
- zinc carbonate.

7°. *colourants and pigments:*

- according to Chapter XI.

8°. *solvents and inks:*

solvents:

- to the extent that the final product still complies with the provisions of Article 3(1) of Regulation (EC) No 1935/2004;

inks:

- the requirements of Chapter XI apply accordingly.

3. Consumer articles

Consumer articles may only be manufactured from the materials mentioned below:

a. *base material:*

- aluminium, whether or not alloyed and whether or not anodically oxidated or eloxated;
- cast iron, whether or not alloyed;
- gold, platinum and silver, whether or not mixed or whether or not alloyed with copper, nickel, tin or zinc and containing no more than 0.5% cadmium;
- copper, whether or not alloyed, containing no more than 2% lead. Notwithstanding the above, copper alloys in applications requiring self-lubricating properties must contain no more than 5% lead;

- magnesium, whether or not alloyed;
- nickel, whether or not alloyed;
- steel, whether or not alloyed;
- tin, whether or not alloyed, containing no more than 0.5% lead;
- titanium, whether or not alloyed;
- zinc, whether or not alloyed.

b. *solders:*

- alloys consisting primarily of copper, lead, tin, silver or zinc, compliant with the following specification:
  - proportion of antimony: no more than 3%
  - proportion of arsenic: no more than 0.05%
  - proportion of bismuth: no more than 0.1%
  - proportion of cadmium: no more than 0.5%.

  Notwithstanding the above however, solders with no more than 20% cadmium may be used if the soldered points are covered entirely with a metallic coating.

c. welding materials:

- of such composition that the welded joint complies with Article 3(1) of Regulation (EC) No 1935/2004.

d. *metallic coatings:*

only coatings made of the metals mentioned below may be applied to the base materials referred to in a.:

- aluminium, copper, nickel and zinc as described in a.: base material;
- chromium, whether or not alloyed;
- gold, platinum and silver, whether or not mixed or whether or not alloyed with copper, nickel, tin or zinc and containing no more than 0.5% cadmium;
- tin, as described in Section 2(2.1c).

The aforementioned raw materials and metallic coatings may be passivated by means of a chemical or electrochemical post-treatment with chromium, manganese, titanium, tin and/or zirconium and/or their oxides and/or inorganic salts, and a polymer that meets Chapter 0, subsection 0.3(e) and/or Chapters I and/or X.

e. organic coatings:

- of a composition as defined in Section 2 (2.2 g).

4. Requirements for the final product

4.1. After manufacturing, a protective layer may be applied to the final products, but only such that this layer can be easily removed before the final product comes into contact with foods or beverages.

4.2. The total migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than 60.

4.3. The specific migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not exceed the value given below for the specific ingredient.

substance/group of substances	SML (mg/kg)
sec. aliphatic amines	ND[1]
aluminium	5
arsenic	0.002
cyanate groups or isocyanate groups	ND
epichlorohydrin	QM = 1 mg/kg FP
peroxides	ND
toluene sulfonchloride	ND
primary aliphatic amines, total	3
primary aromatic amines	ND[4]

substance/group of substances	SML (mg/kg)
alkyl(C_8-C_{18}) benzene sulfonates, total	30
antimony	0.04
bezylbutyl phthalate	0.6[2]
1,2-benzisothiazoline-3-one	30
bis(2-hydroxyethyl) ether and ethanediol, total	30
2,2-bis(4-hydroxyphenyl)propane	0.05
bismuth	1
p-tert-butyl benzoic acid	0.1
cadmium	0.005
chromium	0.25
dibutyl phthalate	0.6[2]
dicyclohexyl phthalate	30
diethylene glycolmonoethyl ether and triethylene- glycol monoethyl ether, total	30
di(2-ethylhexyl) phthalate	0.6[2]
phthalic acid, diesters with prim. sat. C_9-C_{11}-alcohols with > 90% C_{10}	1.8
substances containing epoxy groups, other than epoxidated linseed and soy oil, total	5 mg/kg in FP (as epoxy group, MW = 43)
phenolic compounds, total	15 (as phenol)
o-phenyl phenol, sodium salt	0.1
formaldehyde and hexamethylene tetramine, total	15
phosphoric esters of epoxidised polybutadiene with terminal hydroxyl groups	0.05
cobalt	0.02
copper	4
lithium compounds, total	0.48 (as lithium)
lead	0.1[2]
manganese	1.8
melamine	2.5
nickel	0.14
2,4,7,9-tetramethyl-5-decyn-4,7-diol, ethylene oxide adduct	0.05
vanadium	0.01
zinc	5
zirconium compounds, total	2[3]
barium	1.2
berylium	0.01
iron	40
mercury	0.003
molybdenum	0.12
thallium	0.0001
tin	100, or Reg 2023/915 [22]
silver	0.08

1. The term ‘ND’ (not detectable) is equated for practical purposes with a value of no more than 0.05.
2. The limit applies to the sum of dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and bis(2-ethylhexyl) phthalate (DEHP) expressed as DEHP equivalents using the following equation: DBP*5 + DIBP*4 + BBP*0,1 + DEHP*1.
3. Not applicable to tinned steel sheet used for food packaging.
4. The content is expressed as aniline. The detection limit is 0.002 mg/kg food or food simulant.
5. For passivated metals that come into contact (or may come into contact) with acidic foods, compliance with the SML for zirconium must be demonstrated in the food itself, or alternatively in 1.5% citric acid.

4.4. If materials described in other chapters have been used in the manufacture or processing of the materials described in this chapter, then the specific migration limits for the ingredients of those materials must also be observed.

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[22] Commission Regulation (EC) No 2023/915 Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels For certain contaminants in foodstuffs and repealing Regulation (EC) No 1881/2006

4.5. For packaging and consumer articles as described in this chapter that are intended to come into contact only with a particular foodstuff or beverage, the specific migration of the metals referred to in 4.3 into that foodstuff or beverage must be determined under the test circumstances as referred to in Annex B, Chapter I, Subsection 4.1.1.2. If they are intended for contact with non-specified foods or beverages, then the migration tests must be carried out with 3% acetic acid, notwithstanding the provisions of Annex B, Chapter I, Subsection 4.1.1.2(1)[23].

4.6. The migration of metals from the packaging and consumer articles as described in this chapter that are already in contact with foodstuffs or beverages, must be determined inside such foodstuff or beverage.

4.7. The migration requirements as described in 4.2 and 4.3 do not apply to sealants for lid and bottom seams pursuant to Subsection 2.2 f.

4.8. The release of monomers/base substances from which condensation products, resins and polymerisation products are composed, as well as the additives used, must comply with the general and specific requirements for such substances in this Decree.

4.9 The conformity of the materials and articles shall be demonstrated by the operator by means of a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 and Section 0.9 of Chapter 0, Annex Part A.

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[23] The release of metals into foodstuffs follows a complex process that depends on the composition of the foodstuff, the presence of oxygen, and any temperature treatments. Simulation of the release of metals in e.g. 3% acetic acid in containers that are hermetically sealed in practical conditions is not feasible in a laboratory setting. Amendments to assess hermetically sealed packaging for compliance with the requirements are being drafted and will be announced soon.

Chapter V – Glass and glass ceramics

1. Description

1.1. *Glass and crystal:* For purposes of these provisions, glass and crystal are understood to mean the inorganic products obtained by cooling a smelt of primarily quartz sand with alkali and alkaline-earth metal compounds, to which oxides of other elements may or may not have been added.

1.2. *Glass ceramics:* For purposes of these provisions, glass ceramics are understood to mean the products described in 1.1, where crystallisation of the mass is induced during cooling.

2. Types

2.1. *Industrial glass:* intended for the preparation, transport or storage of foods and beverages.

2.2. *Packaging glass:* intended to be used once or repeatedly as a packaging material for foods and beverages.

2.3. *Table glassware:* also referred to as kitchen glassware or household glassware: consumer articles intended for repeated use.

2.4. *Crystal:* consumer articles intended for repeated use. For the designations of the different categories of crystal, and the requirements for its composition (including the lead(II)oxide content), see Directive 69/493/EEC of the Council of 15 December 1969 on the approximation of the laws of the Member States relating to crystal glass (OJ (EC) 1969, L 326).

2.5. *Fireproof glass:* consumer articles intended to come into contact with foods and beverages at higher temperatures, and intended for repeated use.

2.6. *Glass ceramics:* consumer articles intended for repeated use.

3. Requirements for manufacture

3.1. The base materials and auxiliary materials used in the manufacture of glass and glass ceramics must be of high technical quality. The auxiliaries must not be used in larger quantities than strictly necessary for the manufacture of the final product.

3.2. Mercury compounds must not be used in the manufacture.

4. Requirements for the final product

4.1. The total migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than 60.

4.2. The specific migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not exceed the value given below for the specific ingredient.

substance/group of substances	SML (mg/kg)
antimony	0.04
arsenic	0.01
barium	1
boron	1
cadmium	0.01
cerium	1
chromium	0.1
fluorine	1
cobalt	0.05
lithium	0.6
lead	0.1
manganese	0.6
nickel	0.02
rubidium	1
zirconium	2

4.3. The total migration of ingredients must always be determined within the specified food simulants (see Annex B, Chapter I, Subsection 4.1.1.2).

4.4. For packaging and consumer articles as described in this chapter that are intended to come into contact only with a particular foodstuff or beverage, the specific migration of the elements referred to in 4.2 into that foodstuff or beverage must be determined under the test circumstances as referred to in Annex B, Chapter I, Subsection 4.1.1.2. If they are intended for contact with non-specified foods or beverages, then the migration tests must be carried out with 3% acetic acid, notwithstanding the provisions of Annex B, Chapter I, Subsection 4.1.1.2.

4.5. The migration of the elements referred to in 4.2 from the packaging and consumer articles as described in this chapter that are already in contact with a foodstuff or beverage, must be determined inside such foodstuff or beverage.

Chapter VI - Ceramic materials and enamels

1. Ceramic materials

1.1 Ceramic articles as referred to in Article 1(3) of Council Directive 84/500/EEC of 15 October 1984[24], that are intended to come into contact with foodstuffs as final products, or that come in contact with them in accordance with their intended use, must comply with the requirements of Article 2(1), (2), (3), (4) and (5), and must be traded in accordance with Article 2a of the aforementioned Directive.

1.2 The migration of lead and cadmium from ceramic articles as referred to in Subsection 1.1 shall be determined in accordance with Article 2(2) of Directive 84/500/EEC.

1.3 The determination of the migration of other ingredients from ceramic articles is subject to Subsections 2.3.1, 2.3.2, 2.3.3 and 2.3.4, applied accordingly.

1.4 Any amendment to Directive 84/500/EEC shall take effect, with respect to the application of Articles 2 and 2a and Annexes I, II and III of that Directive to Subsections 1.1 and 1.2, from the deadline for implementation of the relevant amendment directive, unless another date is laid down by Ministerial Decree published in the Official Gazette [Staatscourant].

2. Enamels

2.1 *Description*

For purposes of these provisions, enamels are understood to mean the vitreous masses of an inorganic, primarily oxidic compound, obtained by smelting or fritting, that are applied to metal articles in one or several layers and then fixed by heating.

2.2 *Requirements for manufacture*

The base materials and auxiliary materials used in the manufacture of enamels must be of high technical quality. The auxiliaries must not be used in larger quantities than strictly necessary for the manufacture of the final product.

2.3 *Requirements for the final product*

2.3.1 Notwithstanding the provisions of Annex B, Chapter I, Subsection 4.1.1.2(1), the migration of ingredients from the final product must be determined only with 3% acetic acid and under the test circumstances as referred to in Subsection 4.1.1.2(3), of the same chapter. The measurements expressed in mg/dm^2 must be divided by 10 and then assessed against the limits mentioned in Subsection 2.3.3.

2.3.2 Taking account of the remarks in Subsection 2.3.1, the total migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than 60.

2.3.3 Taking account of the remarks in Subsection 2.3.1, the total migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than the value given below for each respective element.

substance/group of substances	SML (mg/kg)
arsenic	0.01
barium	1
boron	1
cadmium	0.01
chromium	0.1
cobalt	0.05
mercury	0.005
lithium	0.6
lead	0.1
rubidium	1
selenium	0.01
strontium	1

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[24] Council Directive 84/500/EEC of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs (OJ (EC) 1984, L 277).

2.3.4 Notwithstanding the provisions of Subsection 2.3.3, for foods or beverages packaged in or otherwise in contact with enamelled final products, the quantity of each of the elements listed in Subsection 2.3.3, expressed in mg/kg, must not exceed the value given in Subsection 2.3.3 for each respective element.

Chapter VII - Textile products

1. Description

This chapter covers natural and synthetic textile fibres that are combined by some form of processing.

2. Requirements for manufacture

2.1 For the manufacture and processing fo textile fibres and textile products, only the base materials and auxiliaries referred to below may be used. All must be of high technical quality. The auxiliaries must not be used in larger quantities than strictly necessary for the manufacture of the final product. The final product must not contain any substances other than the base materials and auxiliaries mentioned below, and the decomposition products of the auxiliaries, if any.

a. *base materials:*

- regenerated cellulose pursuant to Chapter VIII;
- plant fibres;
- polypropene, according to Chapter I;
- terephthalic polyesters, according to Chapter I.

b. *preservatives:*

- boric acid and its sodium salts;
- formaldehyde;
- 2-mercaptobenzthiazol, sodium salt;
- sodium fluoride.

c. *refining agents:*

- plastics pursuant to Chapter I;
- organo polysiloxanes, containing two methyl groups on each silicon atom (silicones);
- paraffin, solid, including synthetic, whose ultraviolet light absorption meets the requirements of Annex B (Assessment Methods);
- polyvinyl alcohol (viscosity of the 4% solution in water at 20 °C at least 5 mPas).

d. *solvents:*

- to the extent that the final product still complies with the provisions of Chapter 0, Subsection 0.3.

e. *colourants and pigments:*

- according to Chapter XI.

f. *other auxiliaries:*

- alcohols, monovalent, primary, non-branching, saturated, C_4-C_{22}, as well as oleyl alcohol;
- alkyl(C_8-C_{18}) sulfates, sodium salts;
- dialkyl(C_4-C_{16}) sulfosuccinates, sodium salts;
- di-tert-butyl hydroquinone;
- ethylene diaminetetraacetic acid, sodium salt;
- sodium hydrogen sulfite;
- paraffin, liquid (refined mineral oil) meeting the following specification:
    - colour weaker than Standard Saybolt 30
    - odour nearly absent
    - and whose absorption of ultraviolet light meets the requirements defined in Annex B (Assessment Methods);

- polyethene oxide (8-14), esterified with lauric, oleic, ricinic or stearic acid;
- tris(2-hydroxyethyl)amine;

- fatty acids, non-branching, saturated and unsaturated, with an even number of carbon atoms, C_8-C_{22}, with a content in non-saponifiable ingredients of no more than 2%;
- fatty acids as described above, amides thereof;
- fatty acids as described above, esterified with glycerol to form mono-, di- and triglycerides;
- fatty acids as described above, esterified with polyols, C_3-C_6;
- fatty acids as described above, esterified with alcohols, monovalent, primary, non-branching, saturated, C_4-C_{18}, as well as oleyl alcohol;
- fatty acids as described above, as salts with aluminium, ammonium, calcium, potassium, lithium, magnesium, manganese and sodium;
- zinc hydrogen sulfite.

3 Requirements for the final product

3.1 The total migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than 60.

3.2 The specific migration into reasonably expected conditions, after multiplication by the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not exceed the value given below for the specific ingredient.

substance/group of substances	SML
mercaptanes	ND[25]
2-mercaptobenzthiazol, sodium salt	ND
alkyl(C_8-C_{18}) sulphates, total	30
aluminium	1
boron compounds, total	1 (as boron)
fluorine compounds, total	1 (as fluorine)
formaldehyde	15
hydroquinone and derivatives, total	0.01
lithium compounds, total	0.6 (as lithium)
manganese compounds, total	3 (as manganese)
tris(2-hydroxyethyl)amine	0.01
zinc	5

3.3 If materials described in other chapters have been used in the manufacture or processing of the materials described in this chapter, then the specific migration limits for the componens of those materials must also be observed.

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[25] The term 'ND' (not detectable) is equated for practical purposes with a value of no more than 0.05.

Chapter VIII - Regenerated cellulose film

1. This chapter is applicable to regenerated cellulose film as referred to in Annex I to Directive 2007/42/EC[26], which is intended to come into contact with foodstuffs or which, by virtue of its purpose, does come into such contact, and which either constitutes a finished product in itself or which forms part of a finished product containing other materials and which belongs to one of the following types:
   a. uncoated regenerated cellulose film;
   b. coated regenerated cellulose film with coating derived from cellulose; or
   c. coated regenerated cellulose film with coating consisting of plastics.

2. Regenerated cellulose film as referred to in Subsection 2 shall comply with the requirements imposed in Articles 3 to 6 of Directive 2007/42/EC.

3. This chapter shall not apply to synthetic casings of regenerated cellulose.

4. Any amendment to Directive 2007/42/EC shall take effect, with respect to the application of Articles 3 to 6 and Annex II of that Directive to Subsection 2, from the deadline for implementation of the relevant amendment directive, unless another date is laid down by Ministerial Decree published in the Official Gazette [Staatscourant].

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[26] Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (OJ (EC) 2007, L 172).

Chapter IX – Wood and cork

1. Description

These provisions cover packaging and consumer articles made of wood or cork or produced on the basis of wood or cork.

2. Requirements for manufacture

2.1. For the manufacture and processing of wood and cork, only the base materials and auxiliaries referred to below may be used. All must be of high technical quality. The auxiliaries must not be used in larger quantities than strictly necessary for the manufacture of the final product. The final product must not contain any substances other than the base materials and auxiliaries mentioned below, and their decomposition products if any.

a. *base materials:*

- wood and mechanically ground wood;
- cork, washed and made dust-free, cut or ground.

b. *preserving agents:*
The use of the agents mentioned below is only permitted in the country of origin of the base materials used, to the extent that their use is necessary:

- bis(tributyl tin)oxide;
- copper naphthenate;
- zinc naphthenate.

During the processing of the base materials into final products, the following substances may still be used, provided that they are used only if the pesticides containing such substances are permitted under the Plant Protection Products and Biocides Act:

- alkyl(C_8-C_{18})trimethyl ammonium chloride;
- azaconazol, with or without deltamethrin;
- carbendazim;
- 2-ethyl hexanoic acid;
- 2-phenyl phenol, potassium and sodium salts;
- mixtures of arsenic or chromium or copper salts;
- 2-(thio-cyanomethyl thio)benzthiazol.

c. *adhesives and thickening agents*:

- carboxymethyl cellulose;
- dextwash;
- epoxy polymers, in accordance with Chapter I or XII;
- proteins: casein, animal glue, gelatin, dermal adhesive, fish glue and zein;
- ethyl cellulose;
- ethyl hydroxyethyl cellulose;
- phenol, melamine and urea-formaldehyde condensation products, containing no auxiliary materials other than those permitted in Chapter I;
- guttapercha;
- hydroxyethyl cellulose;
- hydroxypropyl cellulose;
- hydroxypropyl methyl cellulose;
- rosin, in accordance with Chapter II;
- methyl cellulose;
- natural resins: damar, copal;
- neoprene rubber, in accordance with Chapter III;
- polyesters, obtained from the methyl ester of rosin, phthalic anhydride, maleic anhydride and ethanediol, acid number 4- 11, colour K or lighter, Drop Softening point 70 °-90 °C;
- polyurethane, in accordance with Chapter I;
- polyvinyl acetate, in accordance with Chapter I;
- resorcine-formaldehyde condensation products, containing no auxiliary materials other than those permitted in Chapter I, as well as 1,2-benzenediol.

d. *finishes and impregnating agents:*

- plastics, in accordance with Chapter I and X, as well as solutions and dispersions thereof.

e. *softeners:*

- no others than those permitted in Chapter I.

f. *solvents:*

- to the extent that the final product still complies with the provisions of Article 3(1) of Regulation (EC) No 1935/2004.

g. *colourants and pigments,*

- according to Chapter XI.

h. *other auxiliaries:*

- benzoic acid and the potassium and sodium salts;
- boric acid and the sodium salts;
- coconut shell flour, maize flour, rye flour and soymeal;
- formaldehyde;
- glycerol;
- 1,6-hexanediol;
- hexamethylene tetramine;
- paraffin, solid, including synthetic, whose ultraviolet light absorption meets the requirements of Annex B (Assessment Methods);
- paraffin, liquid (refined mineral oil) meeting the following specification:
    - colour weaker than Standard Saybolt 30
    - odour nearly absent
    - and whose absorption of ultraviolet light meets the requirements defined in Annex B (Assessment Methods);

- polyethene oxide, molecular weight greater than 200;
- polyvinyl alcohol (viscosity of the 4% solution in water at 20 °C at least 5 mPas);
- sorbic acid and its potassium and sodium salts;
- triethylene glycol;
- waxes: carnauba, Japan wax.

3. Requirements for the final product

3.1. The total migration, under reasonably expected conditions of use, multiplied by the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than 60.

3.2. The specific migration may, under reasonably expected conditions of use, multiplied by the applicable factor as referred to in Annex B, Chapter I, Table 4.1, not exceed the value given below for each respective component:

substance/group of substances	SML (mg/kg)
sec-aliphatic amines	ND[1]
primary aromatic amines	ND[3]
azaconazol	ND
carbendazim;	ND
deltamethrin	ND
epichlorohydrin	ND
prim. aliphatic amines, total	3
alkyl(C_8-C_{18})trimethyl ammonium chloride;	0.5
arsenic compounds, total	0.01 (as arsenic)
benzyl alcohol	30
bis(2-hydroxyethyl) ether and ethanediol, total	30

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[27] The term 'ND' (not detectable) is equated for practical purposes with a value of no more than 0.05.

substance/group of substances	SML (mg/kg)
bis(tributyl tin)oxide	0.01
boron compounds, total	1 (as boron)
butylphthalyl butylglycolate	15
chromium compounds, total	0.1 (as chromium)
dialkyl(C_7-C_9)phthalate, total	15
dibutyl phthalate	0.6[2]
dicyclohexyl phthalate	30
di(2-ethylhexyl)phthalate	0.6[2]
dimethyl phthalate	40
di-n-octyl phthalate	6
substances containing epoxy groups, other than epoxidated linseed and soy oil	5 mg/kg in FP (as epoxy group, Mw = 43)
phenolic compounds, total	15 (as phenol)
2-phenyl phenol, potassium and sodium salts	0.1
formaldehyde and hexamethylene tetramine, total	15
copper compounds, total	5 (as copper)
melamine	2.5
2-(thio-cyanatomethyl thio)benzthiazol	2

1. The term 'ND' (not detectable) is equated for practical purposes with a value of no more than 0.05.
2. The limit applies to the sum of dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and bis(2-ethylhexyl) phthalate (DEHP) expressed as DEHP equivalents using the following equation: DBP*5 + DIBP*4 + BBP*0,1 + DEHP*1.
3. The content is expressed as aniline. The detection limit is 0.002 mg/kg food or food simulant.

3.3 The discharge in monomers/base substances from which condensation products, resins and polymerisation products are made, as well as the additives used, must comply with the general and specific requirements for such substances in this Decree.

3.4 The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo coupling shall comply with the requirements set out in Annex II, Section 2, to Regulation (EU) No 10/2011.

3.5. Where materials described in other chapters have been used in the manufacture or processing of the materials described in this chapter, then the specific migration limits for the components of those materials must also be observed.

Chapter X -Coatings

1. Description

For purposes of these provisions a coating is understood to mean a layer applied to an existing substrate, with the exception of regenerated cellulose film:

- either by means of a dispersion as referred to under 3, 4 and 5;
- or by means of a solution as referred to under 6 and 7;
- or directly as solvent-free material as referred to under 8 and 9;
- or directly as metallic layer as referred to under 10;
- or as polytetrafluorethene for cooking and baking appliances as referred to under 11.

2. Requirements for manufacture

For the manufacture of coatings only the following may be used:

a. *base materials and auxiliary materials:*

- as referred to in the following relevant sections. The substances must be of high technical quality and must not be used in larger quantities than strictly necessary for the manufacture of the final product.

b. *colourants and pigments:*

- according to Chapter XI.

c. *inks:*

- the requirements imposed in Chapter XI apply accordingly.

d. *solvents:*

- to the extent that the final product still complies with the provisions of Article 3(1) of Regulation (EC) No 1935/2004.

No other substances than the aforementioned, the materials produced from them, as well as any decomposition products thereof, may be present in the final product.

3. Dispersions of macromolecular substances in water

These are understood here to mean dispersions of macromolecular substances in water for the manufacture of which, only the substances mentioned below may be used:

a. *monomers*:

- monomers, in accordance with Chapter I;
- 2-acrylamido-2-methyl propane sulfonic acid and the ammonium, potassium and sodium salts;
- adipic acid dihydrazide, CAS 1071-93-8; not to be used in coatings in direct contact with acidic food;
- aliphatic, saturated and unsaturated, one and polyvalent carboxylic acids, C_3-C_{12} and the ammonium, potassium and sodium salts;
- aliphatic, saturated and unsaturated, mono- and polyvalent carboxylic acids, C_3-C_{12}, esters with:
    - aliphatic, monovalent alcohols, C_1-C_{18}
    - alkoxyalcohols, C_2-C_{20}
    - alkyl(C_8-C_{18})aryl-poly(ethene or propene or butene oxide)(aryl = benzene or naphthalene)
    - alkyl(C_8-C_{18})poly(ethene or propene or butene oxide)
    - cyclohexanol
    - ethanediol, propanediol and butanediol (monoesters)
    - poly(ethene or propene or butene oxide);

- allyl-, crotonyl-, methallyl- and vinyl esters of saturated and unsaturated, mono- and polyvalent, aliphatic and cyclic carboxylic acids;
- allyl- and methallyl ethers of monovalent alcohols, C_1-C_{18}, and polyvalent alcohols, C_2-C_{12};
- amides of mono- and polyvalent, unsaturated, aliphatic carboxylic acids, C_3-C_{18}:
    - N-alkyl(C_1-C_6)amides
    - N-omega-hydroxyalkyl(C_1-C_6)amides
    - N-hydroxymethyl-n-alkyl(C_1-C_6)amides
    - N-methoxyalkyl(C_1-C_6)amides
    - N-methoxyalkyl(C_1-C_6)-n-alkyl(C_1-C_6)amides;
- N-aminoalkyl(C_2-C_8)-N',N'-dialkyl(C_1-C_4)acryl and methacryl amide 2-aminoethyl methacrylate;
- BADGE (=bisphenol A, diglycidyl ether = bis(4-hydroxyphenyl)propane, bis(2,3-epoxypropyl)ether);
- bisphenol A, diglycidyl ether (= BADGE = 2,2-bis(4-hydroxyphenyl)propane, bis(2,3-epoxypropyl)ether;
- 2,2-bis(4-hydroxyphenyl)propane, bis(2,3-epoxypropyl)ether (= BADGE = bisphenol A, diglycidyl ether);
- 1,2-bis(triethoxysilyl)ethane, only for use under hydrophobic coatings;
- 2-butyl-2-ethyl-1,3propanediol;
- cyclo (C_5-C_8)alkadienes and dicyclo (C_{10}-C_{16})alkadienes;
- N,N-dialkyl(C_1-C_4)aminoalkyl(C_2-C_8)acrylate and -methacrylate and the quaternary ammonium salts with acetic acid, benzene sulfonic acid, hydrobromic acid, chlorosulfonic acid and hydrochloric acid;
- N,N-dimethyl-2-aminoethyl methacrylate;
- N-(1,1-dimethyl-3-oxobutyl)acrylamide, CAS 2873-97-4, to be used only as co-monomer in acrylic copolymers, to induce keto-side groups crosslinked with adipic acid dihydrazide, in coatings on plastics and not in direct contact with food;
- bis(4-hydroxy-phenyl)methane;
- 2,2-bis(4-hydroxyphenyl)propane;
- 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, blocked with methyl ketone oxime, CAS 103170-26-9. A QMA of 0,05 mg/6 dm^2 is valid for the blocked trimer. Only to be used in thermosetting coatings of light weight metal packaging;
- 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, partially blocked with caprolactam (CAS No 1262431-48-0). The substance may be used as a monomer or starting material in polyester-based coatings for metal packaging for all types of foodstuffs, with the exception of infant formula;
- methacryl amidopropyl trimethyl ammonium chloride;
- methacrylic acid, 2-hydroxypropyl ester (CAS No 27813-02-1). This substance may be used in coatings of acrylic resins, up to a maximum of 20% in food packaging which have hardened at a temperature of at least 200 °C;
- monoallyl sulfosuccinate, potassium and sodium salts;
- 5-norbornene-2,3-dicarboxylic anhydride, (CAS No 826-62-0). This substance may be used as a comonomer in polyester-based coatings for metal packaging for all types of foodstuffs, with the exception of beverages, under the following conditions: cold fill packaging, hot fill packaging, and sterilisation for 1 hour at a temperature no higher than 131 °C and subsequent storage at room temperature;
- reaction products of mono- and polyvalent, unsaturated carboxylic acids, C_3-C_{18}, with:

    1) epoxy compounds, obtained by epoxidation of:

        - cyclohexene derivates
        - polybutadiene
        - polycyclopentene;

    2) esters, obtained by reaction of 2,3-epoxypropanol, epichlorohydrin or 2-(chloromethyl)-2-methyloxirane with:

        - aliphatic carboxylic acids, mono- and polyvalent, saturated and unsaturated, C1-C18
        - aliphatic carboxylic acids, unsaturated, di- and trimers
        - phthalic acids and hydrated phthalic acids
        - reaction products of unsaturated, polyvalent, aliphatic carboxylic acids, C4-C18;

3) ethers, obtained by reaction of epichlorohydrin or 2-(chloromethyl)-2-methyloxirane with:
    - alcohols, one- and polyvalent, C1-C18
    - alkoxyalcohols, C2-C18
    - bis(4-hydroxycyclohexyl)methane
    - 2,2-bis(4-hydroxycyclohexyl)propane
    - 2,2-bis(4-hydroxy-5-ethoxyphenyl)propane
    - 3,3-bis(4-hydroxyphenyl)butyric acid
    - bis(4-hydroxyphenyl)methane
    - 2,2-bis(4-hydroxyphenyl)propane
    - 1,4-di-hydroxy cyclododecane
    - 1,4-di-hydroxy-2-methyl cyclohexane
    - hydroquinone
    - 4-hydroxy benzophenone
    - 1,1,2,2-tetrakis (4-hydroxyphenyl)ethane;

- reaction products of propyleneimine with 1,6-diisocyanato-hexane homopolymer, blocked with butylglycidylether and monomethoxy polyethyleneglycol, CAS 2416007-57-1;
- styrene sulfonic acid and the ammonium, potassium and sodium salts;
- omega-sulfoalkyl(C_2-C_6)diesters of bivalent, unsaturated, aliphatic carboxylic acids, C_4-C_{12};
- omega-sulfoalkyl(C_2-C_6)esters of monovalent, unsaturated, aliphatic carbon- acids, C_3-C_{18};
- omega-sulfoalkyl(C_2-C_6)esters of monoalkyl(C_1-C_{18})esters of bivalent, unsaturated, aliphatic carboxylic acids, C_4-C_{12};
- 2- sulfoethyl methacrylate, potassium and sodium salts;
- N,N,N′,N′-tetrakis(2-hydroxypropyl)adipamide and 6-[bis(2-hydroxypropyl)amino]-6-oxohexanoic acid);
- triallyl- and trimethallyl cyanurate;
- triallyl- and trimethallyl isocyanurate;
- vinylidene fluoride;
- vinyl sulfonic acid and the ammonium, potassium and sodium salts;
- bis(4-hydroxyphenyl)methane;
- tetramethyl-bis(4-hydroxyphenyl)methane, reaction product with epichlorohydrin (TMBPF-DGE), CAS 113693-69-9.

b. *initiators and catalysts*:

- acetyl cyclohexane sulfonyl peroxide;
- aluminium trichloride;
- ammonium peroxodisulfate;
- azobis(cyclohexane carbonitril);
- 2,2′-azobis(isobutyronitril);
- bis(2-ethylhexyl)peroxydicarbonate;
- bis(2-methyl benzoyl)peroxide;
- bis(4-tert-butyl cyclohexyl)peroxydicarbonate;
- 1,3-bis(tert-butyl peroxy isopropyl)benzene;
- 1,3-bis(alpha-hydroperoxyisopropyl)benzene;
- 1,4-bis(alpha-hydroperoxyisopropyl)benzene;
- bis(3.5,5-trimethyl hexanoyl)peroxide;
- borium trifluoride;
- tert-butylcumyl peroxide;
- tert-butyl hydroperoxide;
- tert-butyl peroxyacetate;
- tert-butyl peroxy benzoate;
- tert-butyl peroxy butyrate;
- tert-butyl peroxy diethyl acetate;
- tert-butyl peroxy-2-ethyl hexanoate;
- tert-butyl peroxy isobutyrate;
- tert-butyl peroxy isopropyl carbonate;
- tert-butyl peroxy pivalate;
- tert-butyl peroxy propionate;
- tert-butyl peroxy-3,5,5-trimethyl hexanoate;
- cumyl hydroperoxide;
- cyclohexanone peroxide;
- diacetyl peroxide;

- diacyl(C_8-C_{14})peroxides;
- di-tert-butyl peroxide;
- 2,2-di-tert-butyl peroxy butane;
- 4,4-di-tert-butyl peroxy-n-butyl valerate;
- 1,1-di-tert-butyl peroxy cyclohexane;
- dibutyl peroxydicarbonate;
- di-sec-butyl peroxy dicarbonate;
- dicetyl peroxydicarbonate;
- dicumyl peroxide;
- dicyclohexyl peroxydicarbonate;
- diisopropylbenzene hydroperoxide;
- di-isopropyl peroxydicarbonate;
- dipropionyl peroxide;
- dipropyl peroxydicarbonate;
- p-(alpha-hydroperoxyisopropyl)cumene;
- potassium peroxodisulfate;
- p-menthane hydroperoxide;
- sodium metabisulfite;
- sodium peroxodisulfate;
- 2,4,4-trimethyl pentyl-2-hydroperoxide;
- hydrogen peroxide.

c. *reduction agents:*

- ascorbic acid and the ammonium, potassium and sodium salts thereof;
- bisulfates of ammonium, potassium and sodium;
- 1-butene-3-ol;
- dimethyl amine;
- dithionites of ammonium, potassium and sodium;
- hydroxymethane sulfinic acid, sodium salt;
- iron(II)chloride;
- iron(II)diammonium bisulfate;
- iron(II)sulfate;
- p-methoxyphenol;
- sodium thiosulfate;
- saccharose;
- sulphites of ammonium, potassium and sodium;
- tartaric acid and the ammonium, potassium and sodium salts thereof.

d. *polymerisation regulators:*

- alkyl(C_8-C_{18})aryl-monomer and polymer captanes, aryl = benzene and naphthalene;
- alkyl(C_8-C_{18})monomer and polymer captanes;
- benzene;
- dialkyl(C_1-C_4)dithiocarbamidezuren, sodium salts;
- dialkyl(C_4-C_{18})hydroquinone;
- dibutyl xanthogen disulfide;
- dichloroethane;
- di-isopropyl xanthogen disulfide;
- o-iso-octyl thioglycolate;
- tetrabromocarbon;
- tetrachlorocarbon;
- tribromomethane;
- trichloromethane.

e. *protective colloids and thickening agents:*

- agar-agar;
- alginic acid and the ammonium, calcium, potassium and sodium salts thereof;
- carragene, carragenanes, carragenates and carragenines;

- cellulose derivatives:
    - carboxymethyl cellulose and the sodium salt thereof;
    - ethyl carboxymethyl cellulose
    - hydroxyethyl cellulose and the methyl, ethyl and propyl ethers thereof
    - hydroxymethyl cellulose and the methyl, ethyl and propyl ethers thereof
    - hydroxypropyl cellulose and the methyl, ethyl and propyl ethers thereof
    - methyl carboxymethyl cellulose
    - methyl cellulose
    - methylethyl cellulose;

- dextwash;
- proteins: potato protein, animal glue, casein, gelatin, dermal adhesive, soy protein, wheat protein and zein;
- proteins, whether or not hydrolysed with alkali or enzymes and the potassium or sodium salts thereof;
- gums and ethers thereof:
    - arabic gum
    - guar gum
    - guar flour
    - carob powder
    - karaya gum
    - tamarind flour
    - tragacanth
    - xanthane gum;

- microcrystalline cellulose;
- pectins;
- polyacrylamide;
- polyethene oxide, molecular weight greater than 200;

- polyvinyl alcohol (viscosity of the 4% solution in water at 20 °C at least 5 mPas);
- polyvinyl pyrrolidone (viscosity of the 5% solution in water at 20 °C at least 34 cP);
- 1,2-propylene glycolalginate;
- starches, whether or not modified by means of one or several of the following operations (the percentages give the maximum permissible quantities of the agent by weight, determined based on starch, unless specified otherwise):

    1) broken down with amylases, ammonium, potassium or sodium peroxodisulfate (0.6%), potassium hydroxide (1.4%), potassium permanganate (0.2%), sodium chlorite (0.5%), sodium hydroxide (1%), sodium hypochlorite (7.5% as chlorine), sodium perborate (1%), hydrogen peroxide (0.45% as active oxygen), hydrochloric acid (7%) and sulphuric acid (2%)

    2) interlinked with adipic acid anhydride, boric acid or tetraborates of ammonium, potassium or sodium (2% calculated as B2O3), epichlorohydrin (0.3%), phosphoroxychloride (0.04% P, incorporated into the starch), glyoxal (1%), sodium trimetaphosphate (0.04% P, incorporated into the starch)

    3) esterified with adipic acid (0.12%), acetic anhydride (8%), cyanamide (6%), phosphoric acid or the potassium and sodium salts thereof (6%), maleic anhydride (3%), sodium tripolyphosphate (0.4% P, incorporated into the starch), octenyl succinic anhydride (3%), urea (20%), vinyl acetate (7.5%)

    4) etherified with acrylnitril (5%), chlorohydroxypropyl trimethyl ammonium chloride (8%), diethyl aminoethyl chloridehydrochloride (8%),2,3-epoxypropyl trimethyl ammonium chloride (7%), ethene oxide (3%), monochloroacetic acid (7.5%), propene oxide (10%).

f. *emulsifiers:*

- alkyl(C_8-C_{18})benzene sulfonates, ammonium, potassium and sodium salts;
- alkyl(C_8-C_{18}) diphenyl etherdisulfonic acid, sodium salts;
- alkyl(C_8-C_{18})-omega-hydroxyalkyl(C_2-C_6)amide;
- alkyl(C_8-C_{18})imidazolinium acetate, bromide and chloride;
- alkyl(C_8-C_{18})morfolinium acetate, bromide and chloride;
- alkyl(C_8-C_{18})naphthalene sulfonates, ammonium, potassium and sodium salts;
- alkyl(C_8-C_{18})poly(ethene or propene or butene oxide)oxymethane carboxylic acid;
- alkyl(C_8-C_{18})pyridinium acetate, bromide and chloride;
- alkyl(C_8-C_{18})sulfates, ammonium, potassium, sodium and tris(2-hydroxy-ethyl)amine salts;
- N-alkyl(C_8-C_{18})sulfosuccinic acid mono- and dicarbonamides, ammonium, potassium and sodium salts;
- alkyl(C_8-C_{18})sulfonates, ammonium, potassium and sodium salts;
- alkyl(C_8-C_{18})thioethers of poly(ethene or propene or butene oxide) and the mentioned below poly(ethene or propene or butene oxide)derivatives;
- dialkyl(C_8-C_{18})dipoly(ethene oxide)(4- 14)ammonium chloride;
- N-1,2-dicarboxyethyl-N'-octadecyl sulfosuccinic acid dicarbonamide, ammonium, potassium and sodium salts;
- alpha,omega-dimethyl poly(o-butyl poly(oxypropene)poly(oxyethene)poly- (dimethyl siloxane));
- phosphoric, sulfosuccinic and sulphuric esters of poly(ethene or propene or butene oxide), the poly(ethene or propene or butene oxide)derivatives, and of alcohols, C_8-C_{18}, as well as the ammonium, potassium and sodium salts thereof, as mentioned below;
- lecithin;
- methyl siloxane-ethanediol polycondensate;
- mono-, di- and trialkyl(C_8-C_{18})phenol ethers of poly(ethene or propene or butene oxide)methane-carboxylic acid;
- mono- and dialkyl(C_8-C_{18})amine, acetic and hydrochloric salts;

- mono- and dialkyl(C_5-C_{18})esters of sulfosuccinic acid, as well as the ammonium, potassium and sodium salts thereof;
- mono- and diphosphates of polyethene oxide ethers of monoalkyl(C_4-C_{18})phenol;
- polyethene oxide (20-60)ether of octyl phenol;
- poly(ethene or propene or butene oxide);
- poly(ethene or propene or butene oxide)ethers of alcohols, C_4-C_{18};
- poly(ethene or propene or butene oxide)ethers of mono-, di- and trialkyl(C_4-C_{18})phenol sulfonated in the nucleus, and the ammonium, potassium and sodium salts thereof;
- poly(ethene or propene or butene oxide)ethers of mono-, di- and trialkyl(C_4-C_{18})phenol;
- poly(ethene or propene or butene oxide)ethers of castor oil;
- poly(ethene or propene or butene oxide)reaction products with diaminoethane;
- poly(ethene or propene or butene oxide)reaction products with mono- and dialkyl(C_8-C_{18})amines;
- quaternary ammonium compounds (Q1, Q2, Q3, Q4-ammonium chloride or-bromide), where Q1 = alkyl(C_8-C_{18}) and Q2, Q3 and Q4 = hydrogen, alkyl(C_1-C_4) or benzyl;
- fatty acids, non-branching, saturated and unsaturated, with an even number of carbon atoms, C_8-C_{22}, with a non-saponifiable ingredients content not exceeding 2%;
- fatty acids as described above, as compounds with 2- amino-2-ethyl-1,3-propanediol, bis- and tris(2-hydroxyethyl)amine and triethyl amine;
- fatty acids as described above, as salts with ammonium, potassium and sodium;
- fatty acids as described above, esterified with sorbitol and sorbitan and the poly(ethene or propene or butene oxide) derivatives of these esters.

g. *preservatives:*

- acetylacetic acid, sodium salt;
- ascorbic acid;
- 1,2-benzisothiazoline-3-one;
- benzoic acid, calcium, potassium and sodium salts;
- benzyl formal;

- 2-bromine-4-hydroxy acetophenone, no more than 0.006%, determined based on the coating;
- 2-bromine-2-nitropropanediol-1,3;
- chloroacetamide;
- p-chlorine-m-cresol, sodium salt;
- 5-chlorine-2-methyl-4-isothiazolin-3-one;
- 3,5-dimethyl tetrahydro-2H-1,3,5-thiadiazine-2-thione;
- o-phenyl phenol, sodium salt;
- formaldehyde;
- hexamethylene tetramine;
- p-hydroxy benzoic acid, esters with benzyl alcohol, ethanol, methanol and monovalent propanols;
- 2-methyl-4-isothiazolin-3-one;
- pimaricin;
- sorbic acid, calcium, potassium and sodium salts;
- tetraethyl thiuramdisulfide;
- tetramethyl thiuramdisulfide;
- zinc dimethyl dithiocarbamate.

h. *anti-foaming agents:*

- aliphatic hydrocarbons with a boiling point up to 250 °C (benzene must not be present);
- alcohols, aliphatic, C_3-C_{22};
- organopolysiloxanes, containing one or two methyl groups on each silicon atom (silicone);
- polyethene oxide (2-4) ethers of monovalent, primary, non-branching, saturated alcohols, C_3-C_{18};
- fatty acids, non-branching, saturated and unsaturated with an even number of carbon atoms, C_8-C_{22}, with a non-saponifiable ingredients content not exceeding 2%;
- fatty acids as described above, esterified with polyols, C_3-C_6.

i. *filming auxiliaries:*

- aliphatic hydrocarbons with a boiling point up to 160 °C;
- aromatic hydrocarbons with a boiling point up to 180 °C (not including benzene);
- acetic acid;
- butanol;
- ethanediol diacetate;
- p-mentha-1,8-diene (dipentene);
- 2-methyl-2,4-pentanediol and the mono- and di-isobutyric esters thereof;
- N-methyl pyrrolidon;
- monoalkyl(C_1-C_4)ethers of bis(2-hydroxyethyl)ether and ethanediol, esterified with acetic acid;
- mono- and dialkyl(C_1-C_4)ethers of bis(2-hydroxyethyl)ether, ethanediol and 1,3-propanediol;
- N-vinyl pyrrolidon.

j. *antioxidants:*

- N-alkyl(C_{12}-C_{20})alkylene (C_2-C_6)diamine triacetic acid, ammonium, potassium and sodium salts;
- 2,2-bis(3,5-di-n-octyl-4-hydroxyphenyl)propane;
- bis(2-hydroxy-3-cyclohexyl-5-methyl phenyl)methane;
- bis(2-hydroxy-3-2-methyl cyclohexyl)-5-methyl phenyl methane;
- bis(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- 2- and 3-tert-butyl hydroxyanisol (BHA), as a mixture, containing more than 0.05% monomethyl hydrochinonether;
- citric acid;
- 2,5-di-tert-amyl hydroquinone;
- 2,6-di-tert-butyl-4-methyl phenol (BHT);
- 4,4’-di-hydroxy diphenyl;
- dilauryl thiodipropionate;
- dimyristyl thiodipropionate;
- distearyl thiodipropionate;

- butylated, styrenised cresols, produced by reacting equimolecular quantities of isobutene, styrene and a mixture of m- and p-cresol. The cresol mixture must have a 3 °C boiling interval that contains 202 °C.
  Composition of the final product:
  20-24% butylated cresols, 23.5-28.5% styrenised cresols and 42-48% butylated and styrenised cresols. Acidity no more than 0.003%, refraction index at 25 °C between 1.5500 and 1.5600 (ASTM D1218-61);
- mixture of 2-(3-tert-butyl-4-hydroxyphenyl)-2-(4-hydroxyphenyl)propane and 2,2-bis(3-tert-butyl-4-hydroxyphenyl)propane;
- n-octadecyl-beta-(4-hydroxy-3,5-di-tert-butylphenyl) propionate;
- soot (furnace black and channel black) and other carbon products such as graphite and coke powder, whose purity meets the requirements imposed in Annex B (Assessment Methods);
- tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyphenyl) propionate]methane;
- thiobis(2-methyl-4-hydroxy-5-tert-butyl benzene);
- trialkyl(C_8-C_{12})phosphite;
- thio-dipropionic acid;
- 1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene;
- 1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-s-triazine-2,4,6-trione;
- 1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- tris(mono- and dinonyl phenyl)phosphite, containing no more than 1% tris(2-hydroxypropyl)- amine;
- sulfur.

k. *softeners*:

- acetyl tributyl citrate;
- bis(alkoxyalkyl(C_3-C_{18}))phthalates;
- benzylbutyl phthalate containing no more than 1% dibenzyl phthalate;
- butylphthalyl butylglycolate;
- citric acid esters of alcohols, aliphatic, primary, saturated, C_6-C_{12};
- dialkyl(C_1-C_8)esters of aliphatic dicarboxylic acids, C_4-C_{10};
- dialkyl(C_7-C_9) phthalate;
- dibutyl phthalate;
- dicyclohexyl phthalate;
- di(2-ethylhexyl)phthalate;
- di-isobutyl phthalate;
- polyesters with an average molecular weight greater than 1 000, obtained from a reaction of adipic acid, azelaic acid, succinic acid, decane dicarboxylic acid, phthalic acid and sebacic acid with 1,3-butanediol, 2,2-dimethyl-1,3-propanediol, ethanediol, glycerol, 1,6-hexanediol and 1,2-propanediol, where the reaction may optionally be terminated by means of fatty acids as described above, or alcohols as described above;
- tetra-alkyl(C_1-C_8)pyromellitates;
- trialkyl(C_4-C_{16})phosphates, up to a maximum of 0.5%;
- trialkyl(C_1-C_8)trimellitates, up to a maximum of 0.5%;
- tris(alkoxyalkyl(C_3-C_8))phosphates.

l. UV absorbers:

- 2-(2′-hydroxy-5′-methyl phenyl)benztriazol.

m. *other substances:*

- aliphatic alcohols, C_1-C_{18};
- aliphatic carboxylic acids, C_1-C_{20}, esterified with alcohols, C_1-C_{18};
- aluminium, ammonium, calcium, potassium and sodium salts of acetic acid, boric acid, citric acid, phosphoric acid, carbon dioxide, polyphosphoric acid, nitric acid, sorbic acid, tartaric acid, hydrochloric acid and sulphuric acid;
- 1-amino-2-propanol, containing up to 10 % 2-amino-1-propanol, only for use as a dispersant for titanium dioxide in coatings on paper and cardboard
- calcium stearate;
- dibutyl titanate;
- diethylene triaminepentaacetic acid, sodium salts;
- diethyl hydroxyethyl amine;

- dimethyl hydroxyethyl amine;
- ethylene diaminetetraacetic acid, sodium salts;
- 2-ethyl hexanoic acid, cerium, cobalt, manganese and zinc salts;
- hydroxides of ammonium, potassium and sodium;
- N-hydroxyethyl ethylene diaminetriacetic acid, sodium salts;
- rosin, whether or not modified, in accordance with Chapter II, Section 1.2.2 h.;
- lithium polysilicate;
- montane wax, consisting of:

  1) montanic acids C_{26}-C_{32}
  2) esters thereof with ethanediol or 1,3-butanediol
  3) or the calcium salt of these acids

  and provided that the product complies with the purity requirements imposed in Annex B (Assessment Methods);

- natural latex;
- organopolysiloxanes, containing one or two methyl groups on each silicon atom (silicone);
- oxides of aluminium, magnesium, silicon and titanium;
- paraffin, microcrystalline, whose absorption of ultraviolet light complies with the values specified in Annex B (Assessment Methods);
- paraffin, solid, including synthetic, whose ultraviolet light absorption meets the requirements of Annex B (Assessment Methods);
- paraffin, liquid (refined mineral oil) which complies with the following specification:
  - colour weaker than Standard Saybolt 30
  - odour nearly absent
  - and whose absorption of ultraviolet light meets the requirements defined in Annex B (Assessment Methods);

- polyesters of fatty acids, C18-unsaturated, dimers, hydrogenated, with 1,4-cyclohexane dimethanol, ethylene glycol, 1,4-cyclohexane dicarboxylic acid and 2,2-dimethyl-1,3-propanediol, which are copolymerised with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane homopolymer partially blocked with caprolactam, for use as a polymer additive in PVC coatings for cans for all types of foodstuffs with the exception of infant formula and alcoholic beverages with a high alcohol content(>15 % alcohol), 95 % of the polymer additive must have a molecular weight of >1000 Da;
- polyethene, molecular weight greater than 200;
- polypropene, molecular weight greater than 400;
- polyvinyl butyral;
- polyvinyl formal;
- silicates of aluminium, calcium, potassium, magnesium and sodium, including diatomaceous earth, fibreglass, infusorial earth, kaolin, mica and talc;
- terpene resins, produced from alpha-pinene, beta-pinene or dipentene, whether or not modified with phenol, meeting the following specification:
  - acid number< 5
  - saponification number< 5
  - the colour of a 50% solution in white spirit is less than four Gardner;

- o- and p-toluene sulfonic acid;
- triethyl amine;
- tris(2-hydroxyethyl)amine;
- waxes: beeswax, candelilla, carnauba, copal, esparto, rotamo, shellack, spermaceti and flax wax;
- zinc stearate;
- zirkonyl ammonium carbonate.

4. Dispersions of paraffins and waxes in water

These are understood herein to mean dispersions in water of paraffins and waxes referred to in Chapter II, Section 1.2.2 i. for the manufacture of which only the substances mentioned below may be used:

a. *paraffins and waxes:*

- in accordance with Chapter II, Section 1.2.2 i.;
- damar gum;

b. *macromolecular compounds:*

- in accordance with Chapter II, Section 1.2.2 n.;
- oxidated polyethene, which complies with the following specification:
  - molecular weight: 5 000;
  - oxygen content: 1.2%;
  - epoxy groups: not detectable;
  - up to a maximum of 0.5% on the final product;

c. *dispersants, flotation agents and anti-foaming agents:*

- in accordance with Chapter II, Section 1.2.2 e.

d. *antioxidants:*

- bis(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- 2- and 3-tert-butyl hydroxyanisol (BHA), as a mixture, containing more than 0.05% monomethyl hydrochinonether;
- 2,6-di-tert-butyl-4-methyl phenol (BHT);
- dilauryl thiodipropionate;
- dimyristyl thiodipropionate;
- distearyl thiodipropionate;
- n-octadecyl-beta-(4-hydroxy-3,5-di-tert-butylphenyl) propionate;
- soot (furnace black and channel black) and other carbon products such as graphite and coke powder, whose purity meets the requirements imposed in Annex B (Assessment Methods);
- tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyphenyl) propionate]methane;
- thio-dipropionic acid;
- 1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxy-benzyl)benzene;
- 1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- tris(mono- and dinonyl phenyl) phosphite, containing no more than 1% tris(2-hydroxypropyl) amine;
- sulfur.

5. Dispersions of macromolecular substances in organic liquids

These are understood herein to mean dispersions of macromolecular substances in an organic liquid or a mixture of organic liquids, for the manufacture of which only the substances mentioned below may be used:

- polyvinyl chloride, in accordance with Chapter I;
- substances in accordance with Chapter IV, Section 2.2 g.

6. Solutions in water

These are understood herein to mean solutions in water of macromolecular substances for the manufacture of which only the substances mentioned below may be used:

a. *monomers:*

- acrylamide;
- acrylnitril;
- acrylic acid, ammonium, potassium and sodium salts thereof;
- acrylic acid and its esters with alcohols, monovalent, aliphatic, saturated, C_1-C_{18};
- di-isobutene;
- dimethyl propionic acid;

- ethene;
- glycerol monostearate;
- maleic acid or maleic anhydride and its esters with alcohols, monovalent, aliphatic, saturated, C_1-C_{18};
- methacryl amide;
- methacrylic acid, ammonium, potassium and sodium salts thereof;
- methacrylic acid and its esters with alcohols, monovalent, aliphatic, saturated, C_1-C_{18};
- styrene;
- toluene di-isocyanate;
- vinyl acetate;
- vinyl esters of saturated and unsaturated, mono- and polyvalent, aliphatic and cyclic carboxylic acids, C_2-C_{20};
- vinyl ethers of alcohols, monovalent, aliphatic, saturated, C_1-C_{18};
- N-vinyl pyrrolidon.

b. *initiators and catalysts:*

- in accordance with Section 3 b. of this Chapter.

c. *reduction agents:*

- in accordance with Section 3 c. of this Chapter.

d. *polymerisation regulators:*

- in accordance with Section 3 d. of this Chapter.

e. *protective colloids and thickening agents:*

- in accordance with Section 3 e. of this Chapter.

f. *anti-foaming agents:*

- alcohols, aliphatic, C_3-C_{22};
- methyl isobutyl ketone;
- organopolysiloxanes, containing one or two methyl groups on each silicon atom (silicone);
- pine oil;
- tributyl citrate;
- tributyl phosphate;
- fatty acids, non-branching, saturated and unsaturated, with an even number of carbon atoms, C_8-C_{22}, with a non-saponifiable ingredient content not exceeding 2.5%;
- fatty acids as described above, esterified with mono- or polyvalent alcohols.

g. *preservatives:*

- ascorbic acid;
- barium tetraborate;
- benzimidazol carbamic methyl ester;
- 1,2-benzisothiazoline-3-one;
- benzoic acid and the calcium, potassium and sodium salts thereof;
- 2-bromine-4-hydroxy acetophenone, no more than 0.006%, determined based on the coating;
- 2-bromine-2-nitropropanediol-1,3;
- chloroacetamide;
- p-chlorine-m-cresol;
- 3,5-dimethyl tetrahydro-2H-1,3,5-thiadiazine-2-thione;
- o-phenyl phenol;
- p-hydroxybenzoic esters of benzyl alcohol, ethanol, methanol and monovalent propanols;
- sodium tetraborate;
- sorbic acid and the calcium, potassium and sodium salts thereof.

h. *softeners:*

- ethanediol;
- glycerol;
- invert sugar;
- mono (2-hydroxyethyl)amine;
- montane wax, consisting of:

  1) montanic acids C_{26}-C_{32}
  2) esters thereof with ethanediol or 1,3-butanediol
  3) or the calcium salt of these acids

  and provided that the product complies with the purity requirements imposed in Annex B (Assessment Methods);

- nitrates of ammonium and sodium;
- paraffin, solid, including synthetic, whose ultraviolet light absorption meets the requirements of Annex B (Assessment Methods);
- polyethene oxide, molecular weight greater than 200;
- sorbitol;
- stearates of aluminium, ammonium, calcium and sodium;
- waxes:
  - candelilla
  - carnauba.

i. *liquefying agents:*

- ammonium thiocyanate;
- dicyan diamide;
- alpha-naphthalene sulfonic acid, sodium salt;
- polyethene oxide (8-14), esterified with stearic acid;
- polyvinyl pyrrolidone (viscosity of the 5% solution in water at 20 °C at least 34 cP);
- urea.

j. *fillers:*

- carbonates of calcium and magnesium;
- oxides and hydroxides of aluminium, magnesium, silicon, titanium and zinc;
- silicates of aluminium, calcium, magnesium, potassium and sodium, including bentonite, clay, diatomaceous earth, infusorial earth, kaolin, mica and talc;
- sulfates of aluminium, barium and calcium, including satin white;
- zinc powder;
- zinc sulfide, including lithopone.

k. *emulsifiers and dispersants:*

- alkyl(C_8-C_{18})benzene sulfonates, sodium salts;
- alkyl(C_8-C_{18})naphthalene sulfonates, sodium salts;
- alkyl(C_8-C_{18})sulfonates, sodium salts;
- ammonium polyacrylate;
- sodium citrate;
- sodium hexametaphosphate;
- sodium metasilicate;
- sodium polyacrylate;
- sodium sesquisilicate;
- sodium tetraphosphate;
- pentasodium tripolyphosphate;
- tetrasodium pyrophosphate.

l. *water-proofing agents:*

- acetone-formaldehyde resins;
- alkyl ketene dimers;
- aluminium acetate;
- aluminium formate;
- aluminium hydroxychloride;
- aluminium sulfate;

- ammonium zincate;
- chrome alum;
- formaldehyde;
- glutar dialdehyde;
- glyoxal;
- hexamethylene tetramine;
- melamine-formaldehyde condensation products, in accordance with Chapter I;
- urea-formaldehyde condensation products, in accordance with Chapter I.

m. *optical whiteners:*

- in accordance with Chapter II, Section 1.2.2 p.

mi. *other substances:*

- ammonium chloride;
- ethylene diamine tetraacetic acid, sodium salt;
- hydroxides of ammonium, calcium and sodium;
- potassium pyroantimonate;
- sodium acetate;
- sodium aluminate;
- sodium bicarbonate;
- sodium bisulfite;
- sodium carbonate;
- sodium phosphate;
- sodium sulfate;
- sodium sulfite;
- polyamide-epichlorohydrin resins;
- polyamine-epichlorohydrin resins;
- zinc sulfate;
- zirkonyl ammonium carbonate;
- hydrochloric acid.

7. Solutions in organic solvents

These are understood herein to mean solutions in an organic solvent, or a mixture of organic solvents, of macromolecular substances for the manufacture of which only the substances mentioned below may be used;

a. *monomers:*

- monomers, in accordance with Chapter I;
- 2,2-bis(4-hydroxyphenyl)butane;
- diaminoethane;
- diethylene triamine;
- 1,4-di(hydroxymethyl)cyclohexane;
- drying oils;
- tetraethylene pentamine;
- 2,2,4,4-tetramethylcyclobutane-1,3-diol, CAS 3010-96-6;
- triethylene tetramine.

b. *initiators and catalysts:*

- in accordance with Section 3 b. of this Chapter;
- in accordance with Chapter IV, Section 2.2 g.2.;
- dibutyl tin dilaurate;
- dibutyl tin oxide;
- dodecyl sulfonic acid;
- oxalic acid;
- tin(II)chloride;
- tin(II)oxalate;
- tin(II)stearate;
- tin(II)sulfate.

c. *macromolecular compounds*:

- condensation and polymerisation products, in accordance with Chapter IV, Section 2.2 g.1.;
- cellulose derivatives, in accordance with Section 3 e. of this Chapter;
- cellulose acetate-butyrate;
- cellulose acetate-propionate;
- proteins: animal glue, casein, gelatin, dermal adhesive, fish glue and zein;
- regenerated cellulose pursuant to Chapter VIII;
- guttapercha;
- plastics pursuant to Chapter I;
- macromolecular compounds, in accordance with Chapter II, Section 1.2.2 n.;
- montane wax, consisting of:

  1) montanic acids C_{26}-C_{32}
  2) esters thereof with ethanediol or 1,3-butanediol
  3) and/or the calcium salt of these acids

  and provided that the product complies with the purity requirements imposed in Annex B (Assessment Methods);

- natural resins: copal, damar, shellack;
- paraffin, solid, including synthetic, whose ultraviolet light absorption meets the requirements of Annex B (Assessment Methods);
- paraffin, liquid (refined mineral oil) meeting the following specification:

  - colour weaker than Standard Saybolt 30
  - odour nearly absent
  - and whose absorption of ultraviolet light meets the requirements defined in Annex B (Assessment Methods);

- petroleum hydrocarbon resins, aliphatic-aromatic, produced from a cracked petroleum fraction (boiling endpoint no more than 220 °C), which contain vinyl toluene, indenes, dicyclopentadiene and alpha-methyl styrene as the main resin formers, whether or not copolymerised with mono- or polyunsaturated aliphatic hydrocarbons, C_3-C_6. The resins must comply with the following specification:

  - viscosity at 120 °C:

    - for copolymerised resins at least 3 000 cP
    - for non-copolymerised resins at least 8 000 cP

  - softening point at least 80 °C (ASTM E 28-58 T)
  - bromium number no more than 40 (ASTM D 1159)
  - aniline point at least 5 °C (ASTM D 611-64)
  - monomer content no more than 0.02%
  - ash content no more than 0.02% (ASTM D 482)
  - colour of a 50% solution in toluene no more than 11 Gardner;

- petroleum hydrocarbon resins, aliphatic-aromatic, as described above, hydrogenated;
- polyamide resins, obtained from dimerised and trimerised unsaturated fatty acids and polyamines with a molecular weight greater than 600;
- polyamides obtained from the following acids and amines:

  - 12-aminododecanoic acid
  - 11-aminoundecanoic acid
  - diaminoethane
  - diethylene triamine
  - sebacic acid
  - tetraethylene pentamine
  - fatty acids as described above, whether or not dimerised or trimerised;

- polyesters obtained from a reaction between any of the following polybasic acids and polyvalent alcohols, where the reaction can be terminated with one of the following monobasic acids or monovalent alcohols:

  1) polybasic acids:
     - 1,2,4-benzene tricarboxylic acid and anhydride
     - dicarboxylic acids, saturated, aliphatic, C_4-C_{12}
     - phthalic acids and -anhydrides, whether or not hydrogenated or chlorinated
     - fumaric acid, whether or not modified by reaction with cyclopentadiene
     - maleic acid and anhydride, whether or not modified by reaction with cyclopentadiene

  2) monobasic acids:
     - benzoic acid
     - tert-butyl benzoic acid
     - ricinic acid, whether or not hydrogenated or dehydrated
     - fatty acids, non-branching, saturated and unsaturated with an even number of carbon atoms, C_2-C_{24}, with a non-saponifiable ingredients content not exceeding 2%

  3) polyvalent alcohols:
     - bis- and tris-ethers of saturated aliphatic diols, C_2-C_3
     - 1,4-bis(hydroxymethyl) cyclohexane
     - diols, saturated, aliphatic, C_2-C_6
     - 2,3-epoxypropyl esters of trialkyl(C_4-C_{11})methane-carboxylic acids
     - glycerol
     - pentaerythritol
     - sorbitol
     - 1,1,1-tris(hydroxymethyl) ethane
     - 1,1,1-tris(hydroxymethyl) propane

  4) monovalent alcohols:
     - alcohols, monovalent, aliphatic, non-branching, saturated, C_1-C_4
     - caprolacton

  whether or not after having reacted with one or several of the following hardening agents:
     - condensation products of urea, melamine and 2,4-di-amino-6-phenyl-s-triazine (benzoguanamine) with formaldehyde or glyoxal, whether or not modified with monovalent, aliphatic, saturated alcohols, C_1-C_4, diols, C_2-C_4, or polyols, C_3-C_4
     - di- and polyisocyanates, in accordance with Chapter I
     - epoxy polymers, in accordance with Chapter XII, and Chapter IV, Section 2.2g.1;
- reaction products of propyleneimine with 1,6-diisocyanato-hexane homopolymer, blocked with butylglycidylether and monomethoxy polyethyleneglycol, CAS 2416007-57-1;
- rubber products, in accordance with Chapter III;
- silicon dioxide top layer obtained from the monomers hexamethyl disiloxane and hexamethyl disilazane by plasma-impulse-chemical vapour precipitation in argon or oxygen atmosphere. QMA (hexamethylene disiloxane) = 0.01 mg/6 dm^2
- waxes: carnauba, spermaceti.

d. *anti-foaming agents:*

- in accordance with Section 3 h. of this Chapter.

e. *drying agents:*

- decanoates, naphthenates, octanoates and oxides of calcium, cerium, iron, cobalt, lithium, manganese, zinc and zirconium;
- fatty acids, monovalent, branched, saturated, C_9-C_{11}, as salts with calcium, iron, cobalt, lithium, manganese, zinc and zirconium.

f. *lubricants:*

- in accordance with Chapter IV, Section 2.2 g.5.;
- polyethene in accordance with Chapter I;
- paraffin, microcrystalline, whose absorption of ultraviolet light complies with the values specified in Annex B (Assessment Methods);
- petrolatum (vaseline), whose ultraviolet light absorption as determined pursuant to Annex B (Assessment Methods) is indicated for solid paraffin and microcrystalline paraffin, meets the following specification per cm of optic path length of the iso-octane solution:
  - 280-289 nm 0.25 max.
  - 290-299 nm 0.20 max.
  - 300-359 nm 0.14 max.
  - 360-400 nm 0.04 max.;

g. *fillers*:

- carbonates of calcium, magnesium and zinc;
- oxides and hydroxides of aluminium, calcium, magnesium, silicon, titanium and zinc;
- silicates of aluminium, calcium, potassium, magnesium and sodium, including
- diatomaceous earth, kaolin, clay, mica and talc;
- sulfates of aluminium, barium and calcium;
- zinc sulfide, including lithopone.

h. *softeners*:

- in accordance with Chapter IV, Section 2.2 g.4.

i. *other substances*:

- alcohols, monovalent, primary, non-branching, saturated, C_1-C_{18};
- alkyl(C_8-C_{18})benzene sulfonates, sodium salts;
- benzoic acid and the potassium and sodium salts thereof;
- benzoquinone;
- benzoine;
- 1,4-butanediol diacrylate;
- gamma-butyrolacton;
- diethyl oxalate;
- dimethyl dialkyl(C_8-C_{18})ammonium chloride;
- ethylene diaminetetraacetic acid, sodium salt;
- hexanediol diacrylate;
- hexamethylene tetramine;
- hydroquinone;
- iron acetyl acetonate;
- salicylic acid;
- sorbic acid and the calcium, potassium and sodium salts thereof;
- triethylene diamine;
- triethylene glycol;
- trimethyl hexamethylene di-isocyanate;
- tris-2,4,6-dimethyl aminomethyl phenol;
- tris(mono- and dinonyl phenyl)phosphite, no more than 1% tris(2-hydroxypropyl)-amine containing;
- vanadyl-n-butylate;
- vanadyl isopropylate;
- fatty acids as described above, esterified with glycerol to form mono-, di- and triglycerides.

8. Solvent-free material consisting of waxes and waxy products

These are understood below to be materials based on waxes or macromolecular substances, for the manufacture of which only the substances listed below may be used. Some substances are permitted to make up only a certain maximum (weight) percentage of the coating.

The weight of the applied layer, in case of continuous contact between the foodstuff and the packaging material, must be no more than 50 g/m^2, but may be up to 100 g/m^2 in case of discontinuous contact. For packaging fatty foodstuffs, these materials are permitted only if the fat content is less than 40%, and also the contact between the packaging material and the packaged materials is mostly discontinuous.

a. *base materials:*

- carbonates of calcium and magnesium, no more than 50% of coating;
- cumaron-indene resins, only for paper and cardboard intended for contact with dry foodstuffs, no more than 50% of coating;
- cyclohexanon resins, only for paper and cardboard intended for contact with dry foodstuffs, no more than 50% of coating;
- ethene-vinyl acetate copolymers, containing no auxiliary materials other than those permitted in Chapter I, no more than 50% of coating;
- ethyl cellulose, no more than 50% of coating;
- rosin (wood resin, gum resin, tall resin, dark wood resin and dark tall resin), extracted from pine trees of the Pinus genus, Pinaceae family, whether or not modified by hydrogenation, dimerisation or dismutation (disproportioning), no more than 50% of coating;
- rosin as described above and terpene resins as described in Subsection 1.2.2 n. of Chapter II, whether or not modified by reaction with one or several of the following substances:
    - 2,2-bis(4-hydroxyphenyl)propane-formaldehyde condensation product
    - citric acid
    - phthalic anhydride
    - fumaric acid
    - maleic acid and maleic anhydride
    - fatty acids, as under 1.2.2 e. of Chapter II described
    - hydrogen

  and whether or not esterified with one or several of the following alcohols:

    - diols (C_2-C_6)
    - glycerol
    - methanol
    - pentaerythritol
    - polyethene oxide, molecular weight greater than 200.

  no more than 50% of coating;

  alpha-methyl styrene-styrene copolymers, containing at least 50 mol.percent alpha-methyl styrene, softening point at least 75 °C;
- alpha-methyl styrene-vinyl toluene copolymers, assuming the two monomers are in a molar ratio of 1:3, containing no auxiliary materials other than those permitted in Chapter I, softening point at least 75 °C, no more than 50% of coating;
- montane wax, consisting of:
    1) montanic acids C_{26}-C_{32}
    2) esters thereof with ethanediol or 1,3-butanediol
    3) or the calcium salt of these acids,
       and provided that the product complies with the purity requirements of Annex B (Assessment Methods);

- oxides and hydroxides of aluminium, magnesium, silicon, titanium and zinc, no more than 50% of coating;
- paraffin, microcrystalline, whose absorption of ultraviolet light complies with the values specified in Part B (Assessment Methods);
- paraffin, solid, including synthetic, whose ultraviolet light absorption meets the requirements of Annex B (Assessment Methods);

- paraffin, liquid (refined mineral oil) meeting the following specification:
    - colour weaker than Standard Saybolt 30
    - odour nearly absent
    - and whose absorption of ultraviolet light meets the requirements defined in Annex B (Assessment Methods);
- petroleum hydrocarbon resins, alicyclic, which comply with the following description:
    - hybrid polymers prepared by polymerisation of dienes and olefins, unsaturated, non-branching and branched ring-shaped C_4-C_7 monomers, originating from the low-boiling point fractions (boiling endpoint lower than 200 °C) obtained by cracking petroleum, whether or not hydrogenated. This polymers are incompletely saturated, non- aromatic hydrocarbon resins containing methyl groups and non-aromatic methylated 5- and 6-carbon ring structures incorporated in the chain.

  The resins must comply with the following specification:

    - viscosity at 140 °C at least 4 000 mpa.s
    - softening point at least 90 °C
    - (ASTM E 28-58 T)
    - aniline point at least 120 °C (ASTM D 611-64)
    - monomer content no more than 0.1%
    - aromate content no more than 0.5%
    - ash content no more than 0.1% (ASTM D 482)
    - a 50% solution in toluene must at least equally many light passages as a solution to 40 mg iodine in 100 ml potassium iodide solution (DIN 53403).

  No more than 50% of coating;

- petroleum hydrocarbon resins, aliphatic-aromatic, produced from a cracked petroleum fraction (boiling endpoint no more than 220 °C), which as main resin formers vinyl toluene, indenes, dicyclopentadiene and alpha-methyl styrene contain, whether or not copolymerised with mono- or polyunsaturated aliphatic hydrocarbons, C_3-C_6.

  The resins must comply with the following specification:

    - viscosity at 120 °C: for copolymerised resins at least 3 000 cP, for non-copolymerised resins at least 8 000 cP
    - softening point at least 80 °C (ASTM E 28-58 T)
    - bromium number no more than 40 (ASTM D 1159)
    - aniline point at least 5 °C (ASTM D 611-64)
    - monomer content no more than 0.02%
    - ash content no more than 0.02% (ASTM D 482)
    - colour of a 50% solution in toluene no more than 11 Gardner;
- polyamide resins obtained from dimerised and trimerised unsaturated fatty acids and polyamines with a molecular weight greater than 600;
- polycyclopentadiene resin, hydrogenated, produced by polymerisation of a mixture consisting primarily of cyclopentadiene and the dimer thereof, originating from the boiling fraction between 80 °C and 180 °C distilled from the product obtained by cracking petroleum while adding steam. The polymerisation process is followed by hydrogenation of the polymer.
  The resins must comply with the following specification:

    - viscosity at 140 °C at least 2 000 mpa.s
    - softening point at least 95 °C (ASTM E 28-58 T)
    - bromium number no more than 2 (ASTM D 1159)
    - ash content no more than 0.1% (ASTM D 482)
    - colour of a 10% solution in toluene weaker than Standard Saybolt 22 (ASTM D 156)

  No more than 50% of coating;

- polymers and polycondensation products, according to Chapter I;
- rubber, natural and synthetic, in accordance with Chapter III, Category I and II, in solid or latex form;

- rubber as described above, cyclicised, provided that the proportion of free phenol is no more than 0.04% and exclusively for paper and cardboard intended for contact with dry foodstuffs;
- silicates of aluminium, calcium, potassium, magnesium and sodium, including bentonite, diatomaceous earth, infusorial earth, kaolin, clay, mica and talc, no more than 50% of coating;
- sulfates of aluminium, barium, calcium, including satin white, no more than 50% of coating;
- terpene resins, produced from alpha-pinene, beta-pinene or dipentene, whether or not modified with phenol, meeting the following specification:

    - acid number less than 5
    - saponification number less than 5
    - the colour of a 50% solution in white spirit must be less than four Gardner.

  No more than 50% of coating;

- fatty acids, non-branching, saturated and unsaturated, with an even number of carbon atoms, C_8-C_{22}, with a non-saponifiable ingredients content not exceeding 2%;
- fatty acids as described above and their derived di- and trimers;
- waxes: beeswax, candelilla, carnauba;
- starches, whether or not modified by any of the following operations (the percentages express the maximum permissible weight quantities of the agent in terms of starch, unless indicated otherwise):

    1) broken down with amylases, ammonium, potassium or sodium peroxodisulfate (0.6%), sodium chlorite (0.5%), sodium hydroxide (1%), sodium hypochlorite (7.5%, as chlorine), hydrogen peroxide (0.45%, as active oxygen), hydrochloric acid (7%) and sulphuric acid (2%)
    2) interlinked with boric acid or tetraborates of ammonium, potassium or sodium (2% calculated as B2O3), epichlorohydrin (0.3%), phosphoroxychloride (0.04% P, incorporated into the starch), glyoxal (1%), sodium trimetaphosphate (0.04% P, incorporated into the starch)
    3) esterified with acetic anhydride (8%), phosphoric acid or potassium and sodium salts thereof (6%), sodium tripolyphosphate (0.4% P, incorporated into the starch), octenyl succinic anhydride (3%), urea (20%), vinyl acetate (7.5%).

  No more than 50% of coating.

b. *auxiliaries:*

- bis(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- 2-and 3-tert-butyl hydroxyanisol (BHA), as a mixture, containing more than 0.05% monomethyl hydrochinonether;
- 2,6-di-tert-butyl-4-methyl phenol (BHT);
- dilauryl thiodipropionate;
- dimyristyl thiodipropionate;
- dioctadecyl dimethyl ammonium chloride;
- distearyl thiodipropionate;
- n-octadecyl-beta-(4-hydroxy-3,5-di-tert-butylphenyl) propionate;
- polyethene oxide, molecular weight greater than 200, no more than 10% of coating;
- polypropene oxide, molecular weight greater than 400, no more than 10% of coating;
- castor oil (food quality);
- soot (furnace black and channel black) and other carbon products such as graphite and coke powder, whose purity meets the requirements imposed in Annex B (Assessment Methods);
- tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyphenyl) propionate]methane;
- thio-dipropionic acid;
- 1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene;
- 1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- tris(mono- and dinonyl phenyl) phosphite, containing no more than 1% tris(2-hydroxypropyl) amine;
- fatty acids as described above, amides thereof;
- fatty acids as described above, esterified with alcohols, monovalent, aliphatic, non-branching, saturated, C_4-C_{18}, as well as oleyl alcohol, no more than 2% of coating;

- fatty acids as described above, esterified with glycerol to form mono-, di- and triglycerides;
- zinc dibutyl dithiocarbamate, no more than 0.5% of coating;
- zinc diethyl dithiocarbamate, no more than 0.5% of coating;
- sulfur.

9. Other solvent-free materials

These are understood herein to mean the substances mentioned in a., to which substances listed under b. and c. may or may not have been added.

a. *macromolecular compounds:*

- chromium nitride (CAS no 24094-93-7 or 12053-27-0), in chromium nitride-based coatings obtained by 'Physical Vapor Deposition' (PVD);
- other substances: in accordance with Section 7 c. of this Chapter.

b. *antioxidants:*

- bis(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- 2- and 3-tert-butyl hydroxyanisol (BHA), as a mixture, containing more than 0.05% monomethyl hydrochinonether;
- 2,6-di-tert-butyl-4-methyl phenol (BHT);
- dilauryl thiodipropionate;
- dimyristyl thiodipropionate;
- distearyl thiodipropionate;
- n-octadecyl-beta-(4-hydroxy-3,5-di-tert-butylphenyl) propionate;
- soot (furnace black and channel black) and other carbon products such as graphite and coke powder, whose purity meets the requirements imposed in Annex B (Assessment Methods);
- tetrakis [methylene (3,5-di-tert-butyl-4-hydroxyphenyl) propionate]methane;
- thio-dipropionic acid;
- 1,3,5-trimethyl-2,4,6-tris(3,5-di-tert-butyl-4-hydroxybenzyl) benzene;
- 1,1,3-tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane;
- tris(mono- and dinonyl phenyl) phosphite, containing no more than 1% tris(2-hydroxypropyl) amine;
- sulfur.

c. *lubricants and solvents:*

- erucamide;
- montane wax, consisting of:
    1) montanic acids C_{26}-C_{32}
    2) esters thereof with ethanediol or 1,3-butanediol
    3) or the calcium salt of these acids, and provided that the product complies with the purity requirements of Annex B (Assessment Methods);
- paraffin, microcrystalline, whose absorption of ultraviolet light complies with the values specified in Annex B (Assessment Methods);
- petrolatum (vaseline), in accordance with Section 7 f.;
- polyethene, molecular weight greater than 200, whether or not oxidated.

d. *other auxiliaries:*

- di(2-ethylhexyl) phthalate;
- di-isooctyl phthalate;
- epoxidated soy oil with an oxirane content between 6.4 and 8%;
- titanium dioxide.

10. Metallic coatings

These are understood herein to mean layers applied through evaporation of metal to an existing substrate, as well as coatings in accordance with Chapter IV, Sections 2 and 3.

a. *base substances:*

- the metals in accordance with Chapter IV, Section 2.1 c. and Section 3 d.

11. Polytetrafluorethene intended to be used as a coating for cooking and baking equipment, to the extent that when properly used, it is heated up to a maximum of 140 ºC, or 230 ºC respectively.

11.1. *Description*

The product consisting of polytetrafluorethene as referred to under 11.2.1.1a., as well as the product consisting of a mixture of this polymer and one or several of the fluoropolymers as referred to under 11.2.1.1 b. and 11.2.1.1 c., which products may be mixed with any of the binding resins as referred to under 11.2.1.2.

11.2. *Requirements for manufacture*

11.2.1. For the manufacture of polytetrafluorethene, only the fluoropolymers and binding resins mentioned below may be used, such that the fluoropolymer referred to under 11.2.1.1 c. and the binding resins referred to under 11.2.1.2. e. and f. may only be used for coatings which are not heated to temperatures above 140 ºC.

11.2.1.1. fluoropolymers:

a. *polytetrafluorethene*

- in accordance with Chapter I, meeting the following specification:
    - melting point at least 320 °C
    - melting viscosity at 380 °C at least 50 Pa.s.;

b. *copolymers of tetrafluorethene and perfluoroalkyl(C_1-C_3) vinyl ether* and optionally hexafluoropropene, for the manufacture of which only the following auxiliaries may be used:

1. *catalysts:*
    - ammonium peroxodisulfate
    - disuccinic acid peroxide
    - potassium peroxodisulfate
    - sodium disulfite.
2. *emulsifiers:*
    - ammonium perfluoroctanoate
    - perfluoropropyl ether with perfluoropropanic acid, QMA (T) = 0.01 mg/6 dm^2, QMA (T) implies in this specific case that the restriction must not be exceeded by the sum of the residues of the following compounds:
        1) hydride of perfluoropropyl ether with perfluoropropanic acid (= perfluoropropoxy-1,2,2,2-tetrafluorethane) and
        2) hydride of poly-perfluoropropyl ether with perfluoropropane acidic (MW<1 000 Da), (= poly-perfluoropropoxy-1,2,2,2-tetrafluorethane (MW< 1 000 Da)
    - polyethene oxide (4-14) ethers of octyl or nonyl phenol
    - poly-perfluoropropyl ether with perfluoropropanic acid, hexafluoropropylene oxide<5 µg/kg
    - poly-perfluoropropyl ether with perfluoropropanic acid, QMA (T) = 0.01 mg/6 dm^2, QMA (T) implies in this specific case that the restriction must not be exceeded by the sum of the residues of the following compounds:
        1) hydride of poly-perfluoropropyl ether with perfluoropropanic acid (MW<1 000 Da), (=. poly-perfluoropropoxy-1,2,2,2-tetrafluoroethane (MW<1 000 Da) and
        2) hydride of perfluoropropyl ether with perfluoropropanic acid (= perfluoropropoxy-1,2,2,2-tetrafluorethane).
3. *other auxiliaries:*
    - ammonium carbonate
    - ammonium hydroxide
    - barium nitrate
    - methanol
    - molybdene sulfide

- sodium tetraborate
- paraffin, solid, including synthetic, whose ultraviolet light absorption meets the requirements of Annex B (Assessment Methods)
- powders of the following metals, or alloys respectively:
    - bronze
    - corrosion-resistant steel
    - molybdenum
    - nickel
    - silicates of aluminium, calcium, magnesium, potassium and sodium, including diatomaceous earth, fibreglass, infusorial earth, kaolin, mica and talc
    - silicon carbide

c. *copolymers of tetrafluorethene and hexafluoropropene*

- only for uses up to a maximum of 140 ºC, see 11.2.1., and compliant with the following specification:
    - melting point at least 305 ºC
    - melting viscosity at 372 ºC at least 103 Pa.s
    - the copolymer must not consist to more than 5% of structural units originating from perfluoroalkyl(C_1-C_3)vinyl ether or hexafluoropropene.

11.2.1.2. binding resins:

a. *polyamidimide:*

1. the copolymer obtained from the reaction of bis(4-isocyanatophenyl)methane with trimellitic anhydride and optionally ethylene glycolmonomethyl ether, with a nitrogen content between 7.8 and 8.2%;
2. the copolymer obtained from the reaction of bis(4-aminophenyl)methane with benzoyl chloride-3,4-dicarboxylic acid anhydride;
3. the copolymer obtained from the reaction of the reaction product of trimellitic anhydride and bis(4-aminophenyl)methane with bis(4-ethoxyallyl aminophenyl)methane and bis(4-isocyanatophenyl)methane.

b. *polyphenylene sulfide:*

- the polymer obtained by reaction of equimolar quantities of p-dichlorobenzene and sodium sulfide, with a sulfur content between 28.2 and 29.1%.

c. *polyether sulfone:*

- the polymer obtained either by polycondensation of the potassium salt of 4- chlorine-4'-hydroxydiphenyl sulfone with a sulfur content between 13 and 14%, or by polycondensation of equimolar quantities of the dipotassium salt of 4,4-di-hydroxy diphenyl sulfon and 4,4'-dichlorodiphenyl sulfone.

d. *silicone resin*

e. *epoxy polymers:*

- in accordance with Chapter XII, only for use up to a maximum of 140 ºC, see 11.2.1.

f. *polysulfone:*

- in accordance with Chapter I, only for uses up to a maximum of 140 °C, see 11.2.1.
  For the manufacture of the final product only the following auxiliaries may be used:
  1. *lubricants and mould release agents:*
     - organopolysiloxanes, containing two methyl groups on each silicon atom (silicone)
  2. *other auxiliaries:*
     - dimethyl sulfoxide, up to a maximum of 50 mg/kg in the final product
     - glass fibres
     - monochlorobenzene
     - sodium hydroxide.

11.2.2. In the manufacture of the final product, only the auxiliaries mentioned below may be used. They must be of high technical quality and must not be used in larger quantities than strictly necessary for the manufacture of the final product. Except for the base materials listed above, the final product must not contain any other substances than those listed below, including their decomposition products if any.

a. *adhesives for coatings without binding resin:*

- aluminium phosphate;
- chromic acid;
- phosphoric acid
- lithium hydroxide
- sodium chloride
- silica

b. *emulsifiers*:

- alkyl(C_{10}-C_{20})sulfates, sodium salts;
- ammonium perfluoroctanoate;
- copolymers of ethene oxide and propene oxide, which consist to more than 10% of structural units originating from ethene oxide;
- mono- and diesters of phosphoric acid with monovalent, primary, non-branching, saturated alcohols, C_{12} C_{18}, ammonium, potassium, sodium and bis-(2-hydroxyethyl)amine salts;
- mono-2-hydroxyethyl ammonium lauryl sulfate;
- naphthalene sulfonic acid-formaldehyde condensation products, ammonium, potassium and sodium salts;
- polyethene oxide (4-14)ethers of alkyl(C_5-C_{15})phenol;
- polyethene oxide (4-14)ethers of alcohols, C_5-C_{15};
- soy lecithin;
- 2,4,7,9-tetramethyl-5-decyn-4,7-diol, ethylene oxide adduct;
- tris(2-hydroxyethyl)ammonium oleate.

c. *fillers*:

- cobalt aluminate;
- mica;
- oxides of aluminium, iron, cobalt, manganese, silicon and titanium;
- soot;
- silicon carbide;
- sulfosilicates of aluminium with sodium.

d. *thickening agents*:

- ethyl cellulose;
- hydroxyethyl cellulose;
- methyl cellulose.

e. *colourants and pigments*:

- in accordance with Chapter XI

f. *solvents*:

- to the extent that the final product still complies with the provisions of 3(1) of Regulation (EC) No 1935/2004.

g. *other auxiliaries*:

- ammonium peroxodisulfate;
- cerium octanoate;
- diethyl hydroxyethyl amine;
- potassium citrate;
- polyacrylate, according to Chapter I;
- silicone oil;
- triethyl amine;
- triethanol phosphate.

12. Requirements for the final product

12.1. The total migration into reasonably expected conditions of use, after multiplication with the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not be more than 60.

12.2. Notwithstanding the provisions in 12.1, there are no migration requirements for coatings as referred to in Subsection 8.

12.3. The specific migration, under reasonably expected conditions of use, multiplied by the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not exceed the value given in Chapter I or listed below for the relevant substance:

substance/group of substances	SML (mg/kg)
sec-aliphatic amines	ND[1]
tert-aliphatic amines	ND
benzyl formal	ND
cyanate groups or isocyanate groups	ND
N-hydroxyethyl ethylene diaminetriacetic acid, sodium salts	ND
pimaricin	ND
adipic acid dihydrazide	5
alkyl(C_8-C_{18})aryl-monomer and polymer captanes, total	0.05
alkyl(C_8-C_{18})aryl-monomer and polymer captanes, total	0.05
allyl esters of saturated and unsaturated, a- and polyvalent, aliphatic and cyclic carboxylic acids, total	0.05
allyl ethers of monovalent alcohols, C_1-C_{18} and polyvalent alcohols, C_2-C_{12}, total	0.05
aluminium	1
amides, total	0.05
N-aminoalkyl(C_2-C_8)-N′,N′-dialkyl(C_1-C_4) acryl- and methacryl amide, total	1
2-aminoethyl methacrylate	1
1-amino-2-propanol	QMA: 5 mg/6 dm² EP, alone or together with 2-amino-1-propanol; this mixture may contain up to 10 % 2-amino-1-propanol
2-amino-1-propanol	QMA: 5 mg/6 dm² EP, together with 1-amino-2-propanol; this mixture may contain up to 10 % 2-amino-1-propanol
ammonium thiocyanate	0.05
barium tetraborate	1 (as barium)
benzene	0.05
benzimidazol carbamic methyl ester	1
1,2-benzisothiazoline-3-one	30
bis(alkoxyalkyl(C_3-C_{18}))phthalates, total	15
2,2-bis(4-hydroxyphenyl)propane, bis(2,3-epoxypropyl) ether (bisphenol A, diglycidyl ether = BADGE)	according to Regulation (EC) No. 1895/2005
6-[bis(2-hydroxypropyl)amino]-6-oxohexanoic acid (reaction product of N,N,N′,N′-tetrakis(2-hydroxypropyl)adipamide)	• 5; alone or together with N,N,N',N'-tetrakis(2-hydroxypropyl)adipa-

substance/group of substances	SML (mg/kg)
	mide, not for foodstuffs to which simulant D2 applies - QMA = 5 mg/6 dm^2; alone or together with N,N,N',N'-tetrakis(2-hydroxypropyl)adipamide, for foodstuffs to which simulant D2 applies
bis{1-[(2-hydroxypropyl)amino]propan-2-yl} adipate (reaction product of N,N,N′,N′-tetrakis(2-hydroxypropyl)adipamide)	0,1[2], alone or together with 1-[(2-hydroxypropyl)amino]-2-propanyl 6-[bis(2-hydroxypropyl)-amino]-6-oxohexanoate
1,2-bis(triethoxysilyl)ethane	0.05[3]
boron compounds, total	1 (as boron)
tert-butyl benzoic acid	0.1
benzylbutyl phthalate	0.6[5]
2-butyl-2-ethyl-1,3-propanediol	5
carbamates, total	1
chloroacetamide	0.6
chlorophenols, total	0.1
chlorohydroxypropyl trimethyl ammonium chloride	0.05
5-chloro-2-methyl-4-isothiazolin-3-one	0.01; alone or together with 2-methyl-4-isothiazolin- 3-one
crotonyl esters of saturated and unsaturated, mono- and polyvalent, aliphatic and cyclic carboxylic acids, total	0.05
chromium compounds, total	0.1 (as chromium)
N,N-dialkyl(C_1-C_4)aminoalkyl(C_2-C_8)acrylate and- methacrylate, total	1
dialkyl(C_1-C_4)dithiocarbamidezuren, sodium salts, total	0.05
diallyl phthalate	0.05
dibutyl phthalate	0.6[5] 0.6[5]
di(2-ethylhexyl phthalate	0.6[5]
dibutyl tin dilaurate and dibutyl tin oxide, total	0.01 (as dibutyl tin)
dibutyl xanthogen disulfide	0.05
di-isobutyl phthalate	0.6[5]
diisopropanolamine (reaction product of N,N,N′,N′-tetrakis(2-hydroxypropyl)adipamide	- 5; not for foodstuffs for which simulant D2 applies - QMA = 5 mg/6 dm^2, for foodstuffs for which simulant D2 applies
di-isopropyl xanthogen disulfide	0.05
N,N-dimethyl-2-aminoethyl methacrylate	1
N-(1,1-dimethyl-3-oxobutyl)acrylamide	0.05
3,5-dimethyl tetrahydro-2H- 1,3,5-thiadiazine-2-thione	0.3
dodecyl sulfonic acid	30
epichlorohydrin	1 mg/kg in FP
substances containing epoxy groups, other than epoxidated linseed and soy oil, total	5 mg/kg in FP (as epoxy group, Mw = 43)
o- phenyl phenol and the sodium salt, total	0.1
formaldehyde	total: 15 (as formaldehyde)
glyoxal	
hexamethylene tetramine	
glutar dialdehyde	3
hydroquinone and derivatives, total	0.01
1-[(2-hydroxypropyl)amino]-2-propanyl 6-[bis(2-hydroxypropyl)amino]-6-oxohexanoate (reaction product of N,N,N′,N′-tetrakis(2-hydroxypropyl)adipamide)	0,1[2], alone or together with bis{1-[(2-hydroxypropyl)amino]-2-propanyl} adipate
iron acetyl acetonate	0.05

substance/group of substances	SML (mg/kg)
1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, partially blocked with caprolactam	QMA: 0.01 mg/6 dm^2 (sum of all components with a free NCO group, as isocyanate)
cobalt compounds, total	1 (as cobalt)
copper compounds, total	10 (as copper)
lithium compounds, total	0.6 (as lithium)
methacryl amidopropyl trimethyl ammonium chloride	0.05
methallyl esters of saturated and unsaturated, mono- and polyvalent aliphatic and cyclic carboxylic acids, total	0.05
methallyl ethers of monovalent alcohols, C_1-C_{18} and polyvalent alcohols, C_2-C_{12}, total	0.05
2-methyl-4-isothiazolin-3-one	0.01; alone or together with 5-chloro-2-methyl-4-isothiazolin-3-one
monoalkyl(C1-C4)ethers of bis(2-hydroxyethyl)ether and ethanediol, esterified with acetic acid, total	30
mono- and dialkyl(C1-C4)ethers of diethylene glycol, ethanediol and 1,3-propanediol, total	30
monoalkyl sulfosuccinate, potassium and sodium salts, total	0.05
alpha-naphthalene sulfonic acid, sodium salt	30
5-norbornene-2,3-dicarboxylic anhydride	QMA: 0.05 mg/6 dm^2 EP (sum of the two isomers of 5-norbornene-2,3-dicarboxylic anhydride and their hydrolysis products)
polyesters based on 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane homopolymer, partially blocked with caprolactam	QMA: 0.01 mg/6 dm^2 EP (sum of all components with a free NCO group, as isocyanate)
polyvinyl formal	2 (as formaldehyde)
quaternary ammonium compounds, total	0.5
2 sulfoethyl methacrylate, potassium and sodium salts, total	1
tetrachlorocarbon	0.05
tetraethyl thiuramdisulfide and tetramethyl thiuramdisulfide, total	1
N,N,N',N'-tetrakis(2-hydroxypropyl)adipamide	• 5; alone or together with 6-[bis(2-hydroxy-propyl)amino]-6-oxohexanoic acid, not for foodstuffs to which simulant D2 applies • QMA = 5 mg/6 dm^2; alone or together with 6-[bis(2-hydroxy-propyl)amino]-6-oxohexanoic acid, for foodstuffs to which simulant D2 applies
tetramethyl-bis(4-hydroxyphenyl)methane, reaction product with epichloro-hydrin (TMBPF-DGE)	SML (T) = 0.2 mg/kg (sum of TMBPF, TMBPF-DGE, TMBPF-DGE.H2O and TMBPF-DGE.2H2O)^4 SML(T) = 0.05 mg/kg (sum of TMBPF-DGE.HCl, TMBPF-DGE.2HCl and TMBPF-DGE.HCl.H2O)^4
reaction products of propyleneimine with 1,6-diisocyanato-hexane homopolymer, blocked with butylglycidylether and monomethoxy polyethyleneglycol, CAS 2416007-57-1	0.05

substance/group of substances	SML (mg/kg)
2,2,4,4-tetramethylcyclobutane-1,3-diol	5
2,4,7,9-tetramethyl-5-decyn-4,7-diol, ethylene oxide adduct	0.05
triallyl- and trimethallyl cyanurate, total	0.05
triallyl- and trimethallyl isocyanurate, total	0.05
tribromomethane	0.05
tributyl phosphate	0.05
trichloromethane	0.05
tris(2,4,6-dimethyl aminomethyl phenol)	0.05
vinyl esters of saturated and unsaturated, a- and polyvalent, aliphatic and cyclic carboxylic acids (with the exception of vinyl acetate and vinyl propionate), total	0.05
zinc	5
zirconium	2[2]

[1] The term 'ND' (not detectable) is equated for practical purposes with a value of no more than 0.05.

[2] This SML is only relevant for foodstuffs to which simulant B applies and whose contact temperature is greater than or equal to 70 °C. Under other circumstances, these reaction products do not form.

[3] No analytical method for determining migration is available.

[4] TMBPF: tetramethyl bisphenol F; TMBPF-DGE: tetramethyl bisphenol F — diglycidyl ether, synonymous with tetramethyl bis(4 hydroxyphenyl) methane, reaction product with epichlorohydrin.

[5] The limit applies to the sum of dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and bis(2-ethylhexyl) phthalate (DEHP) expressed as DEHP equivalents using the following equation: DBP*5 + DIBP*4 + BBP*0,1 + DEHP*1.

12.4. If substances from the substrate migrate through the coating, then the substrate must comply with the requirements of the Commodities Act Regulation Packaging and Consumer Articles (

12.5 The discharge of monomers/base substances from which condensation products, resins and polymerisation products are made, as well as the additives used, must comply with the general and specific requirements for such substances in this Decree.

12.6 The release of primary aromatic amines from materials or articles manufactured using aromatic isocyanates or dyes prepared by diazo coupling shall comply with the requirements set out in Annex II, Section 2, to Regulation (EU) No 10/2011.

12.7 If materials described in other chapters have been used in the manufacture or processing of the materials described in this chapter, then the specific migration limits for the components of those materials must also be observed.

Explanatory memorandum

The present Chapter X Coatings is intended as a general regime for coatings except for coatings for foil made of regenerated cellulose, for which Chapter VIII contains specific rules.
To the extent that substances and materials for the manufacture of coatings are regulated in preceding chapter, their use will still be permitted.

Chapter XI - Colourants and pigments

1. Introduction

Colourants and pigments is a general term for all substances used to impart a colour to a packaging material or consumer article that is intended for contact with foodstuffs, including plastics. Colourants and pigments may be added to the material in various ways, e.g. by mixing them with the material or by using them in printing inks.
The colourants may be mixed with auxiliaries to facilitate or improve technical processing. The substances used as auxiliaries must comply with Article 3 of Regulation (EC) No 1935/2004. If colourants or pigments are mixed with base materials or permitted auxiliaries for which (European) regulations for food contact have been enacted, then the final product must meet the requirements laid down therein.

Colourants and pigments may be applied to the outside of the packaging, e.g. by using a printing ink. If a colourant may pass through transfer from the outside to the food contact side, then the rules and requirements below are also applicable to materials coloured on the outside.

2. Permitted substances

Colourants and pigments for colouring and printing on packaging materials and consumer articles are permitted, if they comply with the provisions of Subsection 3 of this chapter. The final product must comply with the requirements set forth below and with Article 3 of Regulation (EC) No 1935/2004 as well as the requirements imposed in Subsection 4 of this chapter.

3. Requirements for colourants and pigments

a. Upon extraction with 0.1 N hydrochloric acid in accordance with Annex B, Chapter II, Subsection 5, no more than the following quantities of the elements specified, as a proportion of the quantity of colourant or pigment, may dissolve from the colourant or pigment:

antimony:	0.2	%
arsenic:	0.01	%
barium:	0.01	%
cadmium:	0.1	%
chromium:	0.1	%
mercury:	0.005	%
lead:	0.01	%
selenium:	0.01	%

b. Upon extraction with 2 N ethanolic hydrochloric acid in accordance with Annex B, Chapter II, Subsection 6, no more than 0.05% in primary aromatic amines, as a proportion of the colourant or pigment, must dissolve from the colourant or pigment.

c. Soot (furnace black and channel black) and other carbon products, such as graphite and coke powder, must comply with the following requirements:

- Primary particles of 10-300 nm, aggregated to 100-1 200 nm, that may form agglomerates with dimensions between 300 nm and several mm.
- Toluene-extractable substances: no more than 0.1%, determined in accordance with the method of ISO norm 6209.
- UV absorption of a cyclohexane extract at 386 nm: extinction < 0.02 for a 1 cm cuvette or < 0.1 for a 5 cm cuvette, determined according to a generally accepted analytical method.
- Benzo [a] pyrene content: a maximum of 0.25 mg/kg of soot.

4. Requirements for the coloured final product

a. The specific migration of ingredients of colourants and pigments, under reasonably expected conditions of use, multiplied by the applicable factor as referred to in Annex B, Chapter I, Table 4.1, must not exceed the value given below for each respective component:

substance/group of substances	SML (mg/kg)
aluminium	1
antimony	0.04
arsenic	0.01
barium	1
cadmium	0.01
chromium	0.1
iron	48
cobalt	0.05
copper	5
mercury	0.005
lithium	0.6
lead	0.01
manganese	0.6
nickel	0.02
selenium	0.01
zinc	5

b. In the filtering paper test pursuant to Annex B, Chapter I, Subsection 5.3.6, coloured packaging and consumer articles must not exhibit any colour difference with respect to the blank.

c. Coloured packaging and consumer articles that are manufactured using aromatic isocyanates or colourants produced by azo coupling, must comply with the requirements imposed in Chapter 0.5.1(e).

Chapter XII - Epoxy Polymers

1. Description

The products obtained by a polyaddition reaction of epoxy groups containing compounds with substances that contain two or more active hydrogen atoms per molecule or that may form them during the reaction (hardening agents), or with condensation products of polyols and isocyanates. The polymer part of the final product must consist of epoxy polymer to at least 50%.

2. Requirements for manufacture

For the manufacture and processing of epoxy polymers, only the compounds described above, and the auxiliaries specfiied below, may be used. They must be of high technical quality and must not be used in larger quantities than strictly necessary for the manufacture of the final product.

No other substances than the compounds described above, the product obtained from them through polyaddition or polycondensation respectively, and the auxiliaries listed in Table XII-1, as well as any decomposition products thereof, must be present in the final product:

Table XII-1 Auxiliaries

List of auxiliaries for the manufacture of epoxy polymers for which only the substances mentioned below may be used.

FCM NO	Ref NO	CAS NO	Name	SML mg/kg	Restrictions and specifications
138	93760	77-90-7	acetyl tributyl citrate	-	(1)
			acetyl triethyl citrate	-	(1)
160	84800	87-18-3	p-tert-butylphenyl salicylate	12	(1)
			butylphthalyl butylglycolate	-	(1)
301	89120	123-95-5	butyl stearate	-	(1)
			calcium carbonate	-	
			dialkyl(C7-C9) phthalate	9	(1)
157	74880	84-74-2	dibutyl phthalate	0.6	(1)(2)
242	85360	109-43-3	dibutyl sebacate	-	(1)
283	74640	117-81-7	di(2-ethylhexyl) phthalate	0.6	(1)(2)
			di-isobutyl adipate	-	(1)
			di-isooctyl azelate	-	(1)
	75840	117-84-0	di-n-octyl phthalate	1.5	(1)
			ethyl phthalyl ethyl glycolate	-	(1)
532	88640	8-7-8013	epoxidated soy oil with an oxirane content between 6.4 and 8%	-	(1)
103	55920	56-81-5	glycerol	-	(1)
49	56540		glycerol monooleate	-	(1)
40	56360		glycerol triacetate	-	(1)
528	63760	8002-43-5	lecithin	-	
			mono-, di- and tristearyl citrate	-	(1)
			mono-isopropyl citrate	-	(1)
			montanic acids C26-C32	-	the product complies with the purity requirements imposed in Annex B, Chapter II, Subsection 3
			montanic acids C26-C32, esters of this with ethanediol or 1,3-butanediol or glycerol	-	the product complies with the purity requirements imposed in Annex B, Chapter II, Subsection 4
			organopolysiloxanes, containing two methyl groups on each silicon atom (silicone)	-	
			oxides of aluminium, iron, magnesium, silicon and titanium	-	
			paraffin, microcrystalline	-	the ultraviolet light absorption meets the requirements of Annex B, Chapter II, Subsection 1

FCM NO	Ref NO	CAS NO	Name	SML mg/kg	Restrictions and specifications
			paraffin, solid, including synthetic	-	the ultraviolet light absorption meets the requirements of Annex B, Chapter II, Subsection 1
			paraffin, liquid (refined mineral oil)	-	The paraffin must comply with the following requirements:– kleur zwakker dan Standaard Saybolt 30 – geur vrijwel afwezig – absorptie van ultraviolet licht voldoet aan de waarden gesteld in bijlage deel B, hoofdstuk II, onderdeel 2– colour weaker than Standard Saybolt 30 – odour nearly absent – ultraviolet light absorption meets the requirements of Annex B, Chapter II, Subsection 2
638	76960	25322-68-3	polyethene oxide, molecular weight = 200	-	
639	80800	25322-69-4	polypropene oxide, molecular weight = 400	-	(1)
			polyvinyl acetate	-	
			polyvinyl alcohol	-	viscosity of the 4% solution in water at 20 ºC at least 5 mPas
109	81840	57-55-7	1,2-propanediol	-	
			soot (furnace black and channel black) and other carbon products, such as graphite and coke powder	-	the purity must comply with the requirements imposed in Annex B, Chapter II, Subsection 4
			silicates of aluminium, calcium, potassium, magnesium and sodium, including diatomaceous earth, fibreglass, infusorial earth, kaolin, mica and talc	-	
			sulfates of barium and calcium	-	
140	44640	77-93-0	triethyl citrate	-	(1)
266	94320	112-27-6	triethylene glycol	-	(1)
			fatty acids, non-branching, saturated and unsaturated, with an even number of carbon atoms, C8-C22, with a non-saponifiable ingredient content not exceeding 2%	-	
			fatty acids, as described above, esterified with glycerol to form mono-, di- and triglycerides	-	
			fibres of plastics and of regenerated or unregenerated cellulose	-	these fibres should comply with the requirements for these materials.
			waxes: beeswax, carnauba	-	
			zinc stearate.	-	

(1) The sum of the migration of all substances marked with (1) must not be higher than 60 mg/kg.

(2) The limit applies to the sum of dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), benzyl butyl phthalate (BBP) and bis(2-ethylhexyl) phthalate (DEHP) expressed as DEHP equivalents using the following equation: DBP*5 + DIBP*4 + BBP*0,1 + DEHP*1.

3. Requirements for the final product

3.1 Finished new products should be thoroughly cleaned with hot water or steam before being brought into contact with foods and beverages.

3.2 The total migration, under reasonably expected conditions of use, multiplied by the applicable factor referred to in Annex B, Chapter I, Table 4.1, must not exceed a value of 60.

3.3 The specific migration under reasonably foreseeable conditions of use multiplied by the applicable factor set out in annexe part B, chapter I, table 4.1 shall not exceed:

substance/group of substances	SML (mg/kg)
substances listed in table XII-1	the value indicated there
substances containing epoxy groups, other than epoxidised soybean oil	QM (T) = 5 mg/kg in FP (as epoxy group, Mw = 43)
zinc	5

3.4 Where, in the manufacture or processing of the epoxy polymer as described in this subsection, other plastics have been used, then the limits relating to those plastics with respect to specific migration of substances must also be observed.

3.5 These provisions do not apply to the following epoxy derivatives:

- 2,2-bis(4-hydroxyphenyl) propane-bis(2,3-epoxypropyl) ether 'BADGE' i.e. Bisphenol-A-DiGlycidyl-Ether) and the derivatives listed in Annex 1 to Regulation (EU) No 10/2011 on restrictions on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs;
- bis(hydroxyphenyl) methane-bis(2,3-epoxypropyl) ethers ('BFDGE' i.e. Bisphenol-F-DiGlycidyl-Ether);
- Novolac-glycidyl ethers ('NOGE').

4. General requirements

4.1 Declaration of complianceMaterials manufactured from epoxy polymer, with or without a coating, and auxiliaries intended for the manufacture of epoxy-polymer packaging and consumer articles, shall be accompanied, when sold other than in retail, by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004 and Section 0.9 of Chapter 0, Annex A.

Annex Part B

Assessment Methods

CHAPTER I ASSESSMENT OF PACKAGING AND CONSUMER ARTICLES

1 OVERVIEW OF ASPECTS TO BE ASSESSED

A packaging, or consumer article respectively, to be referred to hereinafter as a 'material', must comply with the requirements imposed under or pursuant to the Commodities Act (Packaging and Consumer Articles) Decree.

The requirements relate specifically to the following:

a. the qualitative composition of the material;

b. the quantitative composition of the material;

c. the migration of ingredients from the material into foodstuffs or food simulants.

   A distinction is made between:
   - the total migration of the ingredients of the material: the total migration
   - the migration of individual ingredients of the material: the specific migration.

   The total migration and specific migration of ingredients of a material must not exceed the limits given in Part A.
   Migration of non-intentionally added substances (NIAS) must comply with the requirements imposed in Article 3, sub a, of Regulation (EC) No 1935/2004;

d. the sensory quality of the material;

e. the purity of the base materials and auxiliary materials permitted for the manufacture of a material.

For determining the specific migration, a method of assessment conducted in the foodstuff itself is preferred. If such an assessment is not possible for practical reasons, then a method conducted in simulants may be used. Such practical reasons may be analytical in nature; but the fact that a material will be used in contact with a wide range of foodstuffs can also be a valid reason to use simulants.

Due to the rapid developments in new analytical methods as to identification, selectivity and detection limit for specific substances, it is not useful to include the details of specific analytical methods in these provisions. Any analytical method may be used to demonstrate compliance with regulations, provided that the method has appropriate performance characteristics for the relevant criterion and substance (selectivity, detection threshold, accuracy, etc.). The analytical methods used should be appropriately validated so that the reliability of the relevant analytical method can be demonstrated via supporting documents.

Sections 5 and 6 of this Chapter, as well as Chapter II, include some rules that are still useful. Other requirements have been included since they relate to certain requirements in this regulation, or are a consequence of the implementation of EU Directives. These requirements should be viewed as guidelines, unless expressly stated otherwise for the relevant substance or provision.

2. DIRECTIVES FOR QUALITATIVE ASSESSMENTS OF SUBSTANCE COMPOSITION

2.1 Identification of the material and the substances used

A correct identification of the material to be assessed is important for further assessment. Analytical methods are available, such as infrared spectrometry, nuclear magnetic resonance (NMR), chromatographic techniques with specific detection methods, allowing the identity of a material to be determined. The method of investigation may need adjustments depending on the complexity of the material (e.g. multilayer material).

When investigating the composition, it is sometimes essential, or will at least simplify the investigation, to obtain information from the manufacturer of the material. The declaration of compliance and the supporting documents may provide useful information.

For identifying additives and reaction or decomposition products, it may be necessary to prepare an extract from the material. After concentrating the extract and then applying an appropriate separation and identification technique, the relevant substances can often be identified, after which an assessment can be made of whether the substances are on the positive list of the respective material, and whether any restrictions have been listed for the relevant substance.

Overviews of chemical and physical methods that could be used for the identification of many different types of materials can be found in the literature.

3 QUANTITATIVE EXAMINATION OF SUBSTANCE COMPOSITION

The determination of substances for which a maximum residue in the end material has been specified may be undertaken using any appropriate method, provided that such a method has appropriate performance characteristics for the relevant criterion and substance (selectivity, detection threshold, accuracy, etc.).

The Joint Research Centre (JRC)[28] in Ispra, Italy, has drafted documents for the validation of analytical methods. The JRC website also has links to methods developed and validated by CEN (European Committee for Standardisation), Technical Committee 194. The guidelines can be applied to checks for residues of substances in materials.

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[28] http://crl-fcm.jrc.it/

4. ASSESSING THE MIGRATION OF INGREDIENTS

4.1 Requirements for assessments of migration against the specified limits

4.1.1 General requirements

4.1.1.1 Assessment of plastic materials

For assessments of plastic materials, see the relevant Regulation of the European Commission (EU), No 10/2011. For substances not included in this European Regulation but included in Chapter I, the same rules apply to demonstrations of compliance with the present regulation as for substances that have been harmonised at the European level and for which the requirements have been included in Regulation (EU) No 10/2011. The rules and requirements laid down in Chapter 0 and Chapter I of Annex A must be observed.

4.1.1.2 Assessment of materials that do not or not solely consist of plastics

For the assessment of materials that do not or not solely consist of plastics, the same rules apply with respect to demonstrations of compliance as for plastic materials. The rules are given in Regulation (EU) No 10/2011 unless stated otherwise in the chapter for the respective material.

1. Choice of food stimulants

   For conducting migration tests in food simulants, the relevant rules are given in Regulation (EU) No 10/2011, Annex III.

2. Notwithstanding the specifications for simulant D2, vegetable oil, in Regulation (EU) No 10/2011, Annex III, all edible oils and fats may be used for the determination of global and specific migration into fat simulant. However, the fat simulant must be free of components that could distort the determination of the migration of a specific ingredient.
   For the determination of global migration, the proportion of non-saponifiable ingredients in the simulant must be as low as possible, but in any case not more than 1%. This is often achievable only after refining the oils and fats.

3. Selection of test conditions for the determination of the migration into simulants
   For conducting migration tests in food simulants, the relevant rules are given in Regulation (EU) No 10/2011, Annex V.

In addition, the following exceptions and additions with respect to Regulation (EU) No 10/2011 apply:

1. If migration tests with the fatty-food simulant (to be referred to hereinafter as the 'fat simulant' or 'Simulant D2') cannot be conducted due to chemical or physical reasons relating to the reactivity of a substance, the properties of the material, or the analytical method, then replacement tests shall be undertaken using the test media specified in Section 4.2 and observing the standard test circumstances given in Table 4.2.

2. If a stimulant as specified in Regulation (EU) No 10/2011 causes physical or chemical changes in or to the material that would not be caused during contact with the relevant foodstuff itself, then the simulant may be adjusted. The simulant may be adjusted to avoid chemical or physical changes, but then it should reasonably be demonstrated that the migration into the adjusted simulant is at least as high or higher than the migration into the foodstuff itself.[29].

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[29] The use of e.g. 3% acetic acid in contact with rubber or painted tins can produce extreme migration values related to the type of acid, while migration into acidic foodstuffs would be limited.

3. If a test condition (contact time and temperature) as specified in Regulation (EU) No 10/2011 causes physical or chemical changes in or to the material that would not be caused during contact with the relevant foodstuff itself, then the test condition may be adjusted. The test condition may be adjusted to prevent chemical or physical changes but most likely will be made that the migration under the tailored test condition at least is equal to or higher than the migration into the foodstuff[30].

4. At the end of the specified duration, the foodstuff or simulant is analysed to determine the total migration or the specific migration of substances.

5. Similarly to plastic materials, any adjustment factor for fat consumption (FRF) or for migration into simulant D2 (DRF) must not be used for substances in the tables in Annex A for which SML = ND has been specified, nor for substances that are not included in the tables in Annex A, which are not permitted to have any detectable migration.

6. If the migration has been determined in mg/dm^2, then the result must be converted to a value in mg/kg of foodstuff or simulant before being assessed against the relevant migration limit. For materials based on plastics in accordance with Chapter I, a multiplication factor of six must be used; for materials based on a material regulated in another chapter, the multiplication factor must be taken from Table 4.1, unless provided otherwise.

Table 4- 1 Multiplication factors for converting mg/dm^2 to mg/kg of foodstuff or stimulant

category	description	factor
A	for a material which wholly or largely envelops the foodstuff, or is intended to do so.	6
B	for a material of which a relatively small area is or will be in contact with foodstuffs, or where the contact time is very short for normal uses. Example: articles that may be classified under Category III according to the categorisation system described in Chapter III "Rubber Products" of Annex A	0.5
C	for containers, including tanks, with a volume ≥ 25 l and ≤ 10 000 l	2
D	storage or transport tanks with a volume ≥ 10 000 l	0.3
E	for materials not falling under a t/m d	3
F	for pipes and hoses normally used for the continuous transport of liquids.	0.1

4.2 Other ways to determine the migration into fatty foodstuffs

It has been found that simulant D2 often cannot be used in migration tests, due to physical or chemical reasons relating to the analytical method to be used or the stability of the substance. In those cases, the method for *replacement migration tests* as described in Section 4.2.1 may be used. The results obtained may be used to assess the material, provided that the conditions given in that section are met.
Alternative tests such as those described in Section 4.2.2 may be used to demonstrate compliance with the requirements.

4.2.1 Replacement migration tests

1. In migration tests, if simulant D2 cannot be used due to physical, chemical or analytical reasons, the migration into fatty foodstuffs must be determined by means of replacement tests. These are tests where a sample of the material to be assessed is brought into contact not with simulant D2 but with other test media. Those test media are iso-octane, ethanol (95% v/v) and MPPO, a modified phenylene oxidepolymer.

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[30] The use of e.g. accelerated tests at 60 ºC with 3% acetic acid in contact with painted tins can produce extreme migration values caused by a combination of the type of acid and the high temperature.

2. Table 4.2.1 lists the most commonly used standard test circumstances for migration tests with simulant D2 and the corresponding standard conditions for replacement tests. If necessary, e.g. in light of experience gained with the material to be assessed, the relationships given in Table 4.2.1 between test circumstances for simulant D2 and those for the test media may be used to derive other circumstances for conducting replacement tests.

3. In each replacement test, all three test media must be used under the specified test circumstances for each. A new test sample shall be taken for each of the tests with a given test medium.

4. Test conditions selected based on Table 4.2.1 may lead to physical or other changes in the test sample that would not take place in the material in real situations. If physical or other changes in the test sample take place that affect the migration characteristics, then the migration test must be done under the strictest circumstances where such changes do not occur.

5. If a test medium given in Table 4.2.1 is generally considered unsuitable for migration tests with a certain type of material, then the migration test done with such test medium shall be disregarded in the assessment of the material.

6. The highest result obtained with any of the test media, after applying the reduction factor given in Regulation (EU) No 10/2011 or in Table 4.1, must not be greater than the migration limit applicable to the relevant case. If this condition is met, then the material shall be considered to meet the requirements.

Table 4.2 Standard conditions for replacement migration tests

Test Circumstances			
with simulant D2	**with iso-octane**	**with 95% ethanol**	**with MPPO ***
10d - 5 °C	0.5d - 5 °C	10d - 5 °C	-
10d - 20°C	1d - 20 °C	10d - 20 °C	-
10d - 40 °C	2d - 20 °C	10d - 40° C	-
2h - 70 °C	0.5h - 40 °C	2h - 60 °C	-
0.5h - 100 °C	0.5h - 60 °C **	2.5h - 60 °C **	0.5h - 100 ºC
1h - 100 °C	1h - 60 °C **	3h - 60°C**	1h - 100ºC
2h - 100°C	1.5h - 60°C**	3.5h - 60°C**	2h - 100ºC
0.5h - 121°C	1.5h - 60°C**	3.5h - 60°C**	0.5h - 121ºC
1h - 121°C	2h - 60°C**	4h - 60°C**	1h - 121ºC
2h - 121°C	2.5h - 60°C**	4.5h - 60°C**	2h - 121ºC
0.5h - 130°C	2h - 60°C**	4h - 60°C**	0.5h - 130ºC
1h - 130°C	2.5h - 60°C**	4.5h - 60°C**	1h - 130ºC
2h - 150°C	3h - 60°C**	5h - 60°C**	2h - 150ºC
2h - 175°C	4h - 60°C**	6h - 60°C**	2h - 175ºC

* MPPO = modified poly(phenylene oxide) or poly(2,6-diphenyl-p-phenylene oxide) particle size 60-80 mesh, pore size 200 nm.

** The volatile test media are used at temperatures up to 60 °C. The replacement tests may only be undertaken if the material is resistant to the test circumstances that would otherwise be applied to simulant D2. To determine this, submerge a test sample in olive oil under the relevant circumstances. If the physical properties change (e.g. the test sample melts or is deformed), then the material is considered unsuitable for practical use at that temperature. If the test sample does not change, replacement migration tests may be done with new test samples.

4.2.2 Alternative tests

1. Alternative migration tests are tests where a test sample of the material being examined is brought into contact not with simulant D2 but with a volatile liquid with a strong extraction power, under appropriate circumstances. Such a liquid might be e.g. acetone, acetonitril, ethanol, diethyl ether, heptane, hexane, isopropanol or iso-octane.

2. Alternative tests may be used if comparative testing shows, or if it is generally acknowledged based on the outcomes of similar experiments, that the results of these alternative tests are equal to or higher than the results that were or would have been obtained in migration tests with simulant D2 for a duration and temperature adjusted to the most stringent expected circumstances of practical contact, pursuant to Regulation (EU) No 10/2011.

3. The result of the alternative test, after applying the reduction factor as referred to in Regulation (EU) No 10/2011, and the multiplication factor derived from Table 4.1 if specified for the relevant material in Annex A, must not be greater than the migration limit applicable to the relevant case. If this condition is not met, a migration test with simulant D2 must be conducted.

5 CONDUCTING OF MIGRATION TESTS

5.1 General remarks

General instructions for conducting migration tests have been laid down in the European standards EN 1186-1* and EN 13130-1*. Although the methods are intended for assessing plastics, they can also be applied to materials that do not consist only of plastics.

5.2 Total migration

The total migration is the sum of all non-volatile substances that are released by a packaging or consumer article into a simulant. The total migration into simulants is determined according to the methods described in EN 1186[31].If a migrated substance forms a reaction product with the stimulant, so that the resulting weight is higher or lower[32], then the migration residue may be corrected for the difference in weight between the migrated substance and the reaction product of the simulant.

5.2.1 Determination of the methylene chloride-soluble part of total migration into aqueous stimulants

Note: this is only determined when assessing paper or cardboard that does not have a coating based on a plastic or metal, and only to the extent that it will come into contact with moist foods or beverages.

a. *Reagents*

- distilled or demineralised water
- acetic acid, 3% (m/v) in water
- 10% (v/v) ethanol
- phosphoropentoxide
- methylene chloride p.a.

b *Determination of the methylene chloride-soluble part*

Conduct the migration test with the relevant aqueous simulants as described in EN 1186. Then filter the contents of the beaker through a glass filter G3, and wash the beaker and filter with 25 ml of simulant. Transfer the filtrate to a 500 ml separatory funnel and extract the filtrate five times, each time with 50 ml of methylene chloride. Evaporate the collected extracts to a dry state by means of a rotating vacuum evaporator, then determine the weight of the evaporation residue in the manner as described in EN 1186.

c. *Calculation of the methylene chloride-soluble part*

From the weight of the evaporation residue, subtract the weight of the evaporation residue of the reagent blank. Assume the corrected weight is *a* mg. From this, calculate the methylene chloride-soluble part of the total migration $M_{t(CH2Cl2)}$ using the formula:

$$M_{t(CH2Cl2)} = \frac{a}{b} \quad mg/dm^2$$

where *b* represent the area (dm²) of the test sample.

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[31] Can be obtained from NEN, Postbus 5059, 2600 GB Delft

[32] Particularly migration into 3% acetic acid can give rise to a weight difference between the migrated substance and the reaction product. E.g.: migration of aluminium will produce aluminium acetate, which has considerably higher molecular weight, which will increase the weight of the total migration by the acetate component. Determining the quantity of Al allows making a correction for the contribution of acetate. For salts (e.g. calcium carbonate), the weight difference between the migrated salt and the acetic salt should be taken into account.

5.3 Specific migration

The methods below can be used to assess both plastics and non-plastic materials.

5.3.1 Phenolic compounds

5.3.1.1 Migration into aqueous simulants

a. *Introduction*

The method described below may be used to determine the migration of simple phenols, such as phenol, cresols, xylenols, chlorophenols, bisphenols and naphthol.

b. *Principle*

A test sample is brought into contact with water.[33] At the end of the storage time, buffer, 4-aminoantipyrine and potassium cyanoferrate (III)are added to an appropriate quantity of the simulant. The orange-coloured compounds that form in the presence of phenols are extracted with chloroform and quantitatively determined using spectrophotometry.

c. *Equipment*

- laboratory glassware and laboratory equipmentmigration cell, see NEN EN 1186spectrophotometer.

d. *Reagents*

- acetic acid, 3% (m/v) in water
- 1 N sodium hydroxide
  buffer pH 10: dissolve 12.37 g boric acid and 14.91 g potassium chloride in water and make up to 1 l. Mix 250 ml of this solution with 44 ml of 1 N sodium hydroxide and make up with water to 1 l4-aminoantipyrine, 2% (m/v) in water, always freshly preparedpotassium cyanoferrate (III), 8% (m/v) in water, always freshly preparedchloroform p.a.
  standard solution of phenol: 0.001% (m/v) in water.

e. *Calibration line*

From the standard solution, place 2, 4, 6 and 8 ml respectively (20, 40, 60 and 80 µg phenol) in a 250 ml separatory funnel. Make up with water to 100 ml. Add 20 ml of buffer solution. Check the pH of the solution with suitable pH paper. The pH should be between 9.8 and 10.2. If necessary, add 3% acetic acid or 1 N sodium hydroxide. Add 1 ml 4-aminoantipyrine solution and mix. Then add 1 ml of potassium cyanoferrate (III)solution and mix again. Leave the mixture to stand for 5 min. Then shake the liquid out twice with 10 ml of chloroform. Filter the chloroform extracts through a funnel with a small cotton wad into a 25 ml measuring flask. Wash with a small amount of chloroform and fill the measuring flask up. Ensure that no water enters the measuring flask. Measure the extinction of the solution at 455 nm in a 1 cm cell with respect to the reagent blank. Plot the obtained values graphically against the amounts of phenol used.

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[33] It is assumed that the migration into 3% acetic acid or 10% ethanol is equal to that in water.

f. *Conducting the migration test*

Bring an amount of material corresponding to at least 1.5 dm^2 (assume *b* dm^2) into contact with water. For this, use one of the methods described in EN 13130.[34] If possible, add 200 ml (assume *c* ml) of preheated water per dm^2. Leave the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the simulant off.

g. *Determining the phenolic compounds*

Place an appropriate quantity of the simulant (*d* ml, containing no more than 100 µg 'fenol') in a 250 ml separatory funnel. Make up with water to 100 ml. Continue as described under e. Determine the quantity of phenolic compounds (as phenol) using the calibration graph.

h. *Calculation*

Assume this quantity to be *a* mg. From this, calculate the specific migration M_s of phenolic compounds using the formula:

$$M_s = \frac{a * c}{b * d} \; mg/dm^2$$

5.3.1.2 Migration into fat

a. *Principle*

A test sample is brought into contact with the fat simulant. At the end of the storage time, the fat simulant is separated from the test sample and diluted with n-pentane. The phenolic compound is isolated from the solution in pentane using water. A buffer solution, pH = 10, and 4-aminoantipyrine and potassium cyanoferrate (III)are added to the aqueous solution. The orange-coloured compounds produced in the presence of phenols are extracted with chloroform and quantitatively determined by means of spectrophotometry.

b. *Equipment*

- laboratory glassware and laboratory equipment;
- migration cell, see EN 13130;
- spectrophotometer.

c. *Reagents*

- fat simulant: a synthetic triglyceride mixture, e.g. Miglyol, or a natural oil or fat that contains little or no colour, e.g. refined coconut fat;
- acetic acid, 3% (m/v) in water;
- 1 N sodium hydroxide;
- n-pentane;
- buffer pH 10 (see Section 5.3.1.1 d);
- 4-aminoantipyrine, 2% (m/v) in water, always freshly prepared;
- potassium cyanoferrate (III), 8% (m/v) in water, always freshly prepared;
- chloroform p.a.;
- standard solution of phenol: 0.25% (m/v) in chloroform.

d. *Calibration line*

Place 20 g of fat simulant each into six 250 ml separatory funnels. Add 0, 0.1, 0.2, 0.3, 0.4 and 0.5 ml respectively of the standard solution; place 40 ml of pentane in each separatory funnel and mix. Then shake the solution out in pentane with 25 ml of water. Filter the water layers through a funnel with a small cotton wad into a second 250 ml separatory funnel. Add 20 ml of buffer and continue as described in Section 5.3.1.1 e.

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[34] EN 13130 can be obtained from NEN, Postbus 5059, 2600 GB Delft

e. *Conducting the migration test*

Bring an amount of material corresponding to at least 2 dm^2 (assume b dm^2) into contact with preheated oil. For this, use one of the methods described in EN 13130. If possible, add 50 ml (assume c ml) of preheated oil per dm^2. Place the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the fat simulant into a 250 ml separatory funnel.

f. *Determining phenolic compounds*

Add 40 ml of pentane to the simulant in the separatory funnel and mix. Then shake the pentane solution out four times with 25 ml of water. Filter the water layers through a funnel with a small cotton wad into a second 250 ml separatory funnel. Add 20 ml of buffer and continue as described in Section 5.3.1.1 e. Determine the quantity of phenolic compounds (as phenol) using the calibration graph.

g. *Calculation*

Assume this quantity to be *a* mg. From this, calculate the specific migration M_s of the phenolic compound(s) with the formula:

$$M_s = \frac{a}{b} \ mg/dm^2$$

5.3.2 *Diphenyl thioureum*

5.3.2.1 *Migration into aqueous simulants*

a. *Objective and scope of application*

The method serves to determine the migration of diphenyl thioureum into aqueous simulants. The lower limit for determining diphenyl thioureum is 20 mg/l. Provided that the area-volume ratio recommended under g is observed, that is enough to determine whether the examined material complies with the specified limit for the migration of diphenyl thioureum.

b. *Principle*

A test sample is brought into contact with 3% acetic acid[35]. At the end of the storage time, the quantity of diphenyl thioureum present in the simulant is quantitatively determined through high-pressure liquid chromatography (HPLC).

c. *Equipment*

- laboratory glassware and laboratory equipment;
- migration cell, see EN 13130;
- HPLC equipment.

d. *Reagents*

- acetonitril p.a.;
- acetic acid, 3% (m/v) in water;
- chloroform p.a.;
- methanol p.a.;
- diphenyl thioureum p.a.;
- standard solution of diphenyl thioureum: 0.04% (m/v) in methanol.

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[35] It is assumed that the migration into water or 10% ethanol is equal to that in 3% acetic acid.

e. *Calibration line*

Place 200 ml of 3% acetic acid each into six 500 ml separatory funnels. Add 0, 1, 2, 3, 4 and 5 ml respectively of standard solution and 6, 5, 4, 3, 2, and 1 ml respectively of methanol. Shake the liquid out twice with 25 ml of chloroform and collect the chloroform layers. Evaporate the solvent and collect the residue in 25 ml of methanol. From the obtained solutions, transfer 10 µl to the chromatography column. In the chromatograms, determine the areas of the diphenyl thioureum peak and plot it graphically against the quantities of diphenyl thioureum used.

f. *Liquid chromatography*

The determination may e.g. be done under the following conditions:
– high-pressure liquid chromatograph with UV detector, enabling measurement of the absorption of the liquid at 272 nm;
– column: length 25 cm, interior diameter 4.6 mm, filled with Lichrosorb RP-8, 10 µm;– mobile phase: water-acetonitril, 1:1;
– liquid rate: 1.5 ml/min.

g. *Conducting the migration test*

Bring an amount of material corresponding to at least 1.5 dm^2 (assume b dm^2) into contact with 3% acetic acid. For this, use one of the methods described in EN 13130[36]. Add per dm^2 no more than 200 ml preheated 3% acetic acid. Place the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the simulant into a 500 ml separatory funnel.

h. *Determining diphenyl thioureum*

Shake the simulant out twice with 25 ml of chloroform and collect the chloroform layers. Evaporate the solvent and collect the residue in 25 ml of methanol. From the obtained solution, transfer 10 µl to the chromatography column. In the chromatogram, determine the area of the diphenyl thioureum peak, and from the calibration graph derive the quantity of diphenyl thioureum in the simulant.

i. *Calculation*

Assume the quantity to be *a* mg. From this, calculate the specific migration M_s of diphenyl thioureum with the formula:

$$M_s = \frac{a}{b} \quad mg/dm^2$$

5.3.2.2 Migration into fat

a. *Objective and scope of application*

The method serves to determine the migration of diphenyl thioureum into fat simulant. The lower limit for the determination of diphenyl thioureum in fat simulant is 10 mg/kg. Provided that the area-volume ratio recommended under g is observed, that is adequate to determine whether the examined material complies with the specified limit for the migration of diphenyl thioureum.

b. *Principle*

A test sample is brought into contact with the fat simulant. At the end of the storage time, the fat simulant is separate from the test sample and diluted with chloroform. In the dilution, diphenyl thioureum is quantitatively determined through high-pressure liquid chromatography (HPLC).

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[36] EN 13130 can be obtained from NEN, Postbus 5059, 2600 GB Delft

c. *Equipment*

- laboratory glassware and laboratory equipment;
- migration cell, see EN 13130;
- HPLC equipment.

d. *Reagents*

- fat simulant: a synthetic triglyceride mixture, e.g. Miglyol, or a natural oil or fat with no substances present that could disturb the analysis disturb, e.g. refined coconut fat;
- acetonitril p.a.;
- chloroform p.a.;
- diphenyl thioureum p.a.;
- standard solution of diphenyl thioureum: 0.005% (m/v) in chloroform.

e. *Calibration line*

In 25 ml measuring flasks, place 0, 1, 2, 4, 6, 8 and 10 ml respectively of standard solution. Add 5 g fat simulant and make up with chloroform to 25 ml. Of the obtained solutions, transfer 10 µl onto the chromatography column. In the chromatograms, determine the areas of the diphenyl thioureum peak and plot these graphically against against the quantities of diphenyl thioureum used.

f. *Liquid chromatography*

This determination may be done e.g. under the following conditions:

- high-pressure liquid chromatograph with UV detector, with which the absorption of the liquid can be measured at 272 nm;
- column: length 25 cm, inw. diam. 4.6 mm, filled with Lichrosorb RP-8, 10 µm;
- mobile phase: water-acetonitril, 1:1;
- liquid rate: 1.5 ml/min.

g. *Conducting the migration test*

Bring an amount of material corresponding to at least 2 dm^2 (assume b dm^2) in contact with preheated oil. For this, use one of the methods described in EN 13130. If possible, add no more than 50 ml (assume c ml) of preheated oil per dm^2. Place the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the fat simulant off.

h. *Determining diphenyl thioureum*

Weigh about 5 g (assume *d* g) of the poured-off fat simulant into a 25 ml measuring flask, make up with chloroform and mix. Of the obtained solution, transfer 10 µl onto the chromatography column. In the chromatogram, determine the area of the diphenyl thioureum peak; then derive from the calibration graph the quantity of diphenyl thioureum in the quantity of fat simulant that was used.

i. *Calculation*

Assume the quantity to be *a* mg. From this, calculate the specific migration M_s of diphenyl thioureum with the formula:

$$M_s = \frac{a * c}{b * d} \quad mg/dm^2$$

5.3.3 Bis(2-hydroxyethyl)-2-hydroxy-3-dodecoxypropyl methyl ammonium chloride

5.3.3.1 Migration into aqueous simulants

a. *Principle*

A test sample brought into contact with water[37]. At the end of the storage time, the solution, made basic, is shaken with acetic anhydride-containing dichloroethane. This serves to mask any disrupting primary and secondary amines through acetylation. The disruptive tertiary amines pass into the dichloroethane layer. After separation of the dichloroethane layer, 2,4-dinitro-6-phenyl phenol is added to the watery phase. The complex formed with the cationoactive substance is then shaken out with 1,2-dichloroethane and quantitatively determined by means of spectrophotometry.

b. *Equipment*

- laboratory glassware and laboratory equipment;
- migration cell, see EN 13130;
- spectrophotometer.

c. *Reagents*

- 2 N sodium hydroxide;
- 1,2-dichloroethane;
- 0.01 M acetic anhydride in 1,2-dichloroethane;
- buffer solution pH = 10.5: dissolve 0.48 g of sodium hydroxide and 2.5 g of sodium tetraborate on in 250 ml of water;
- 2,4-dinitro-6-phenyl phenol solution: dissolve 250 mg of 2,4-dinitro-6-phenyl phenol on in 200 ml of buffer solution. Make up with water to 250 ml;
- sodium sulfate, water-free;
- standard solution of bis(2-hydroxyethyl)-2-hydroxy-3-dodecoxypropyl methyl ammonium chloride: dilute the commercial solution (10%) down to 0.005% with water.

d. *Calibration line*

Of the standard solution, place 4, 3, 2, 1 and 0.5 ml respectively into a 250 ml separatory funnel. Make up with water to 100 ml. Add 15 ml of 2,4-dinitro-6-phenyl phenol solution and 25 ml of 1,2-dichloroethane. Shake vigorously for at least five min. and leave to demix. Filter the dichloroethane layer through a layer of water-free sodium sulfate. Measure the extinction of the solution at 370 nm in a 3 cm cell in comparison to a reagent blank. Plot the obtained values graphically against the quantities of quaternary ammonium compounds used.

e. *Conducting the migration test*

Bring an amount of material corresponding to at least 1.5 dm^2 (assume b dm^2) into contact with water. For this, use one of the methods described in EN 13130[38]. If possible, add 200 ml (assume *c* ml) of preheated water per dm^2. Place the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the simulant off.

f. *Determining the quaternary ammonium compounds*

Place an appropriate quantity of the extract (assume *d* ml, containing 25-200 µg of quaternary ammonium compounds) into a 250 ml separatory funnel. Make up with water to 100 ml. Use 2 N sodium hydroxide to bring the pH of the solution to 10-11. Add 40 ml of 0.01 M acetic anhydride solution in 1,2-dichloroethane; then shake for 10 min. Leave to demix. Measure the dichloroethane layer quantitatively and treat the watery phase as described under d. Use the calibration line to determine the quantity of quaternary ammonium compounds.

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[37] It is assumed that the migration into 3% acetic acid or 10% ethanol is equal to that in water.

[38] EN 13130 can be obtained from NEN, Postbus 5059, 2600 GB Delft

g. *Calculation*

Assume the quantity to be *a* mg. From this, calculate the specific migration M_s with the formula:

$$M_s = \frac{a * c}{b * d} \ mg/dm^2$$

5.3.3.2 Migration into fat

a. *Principle*

A test sample is brought into contact with the fat simulant. At the end of the storage time, the fat simulant is separated from the test sample and diluted with pentane. The quaternary ammonium compound is then isolated from the pentane solution with water, and quantitatively determined as indicated in Section 5.3.3.1 a.

b. *Equipment*

- laboratory glassware and laboratory equipment;
- migration cell, see EN 13130;
- spectrophotometer.

c. *Reagents*

- fat simulant: a synthetic triglyceride mixture, e.g. Miglyol, or a natural oil or fat with no substances present that could disrupt the analysis, e.g. refined coconut fat;
- n-pentane, p.a.;
- 2 N sodium hydroxide;
- 1,2-dichloroethane;
- 0.01 M acetic anhydride in 1,2-dichloroethane;
- buffer solution pH = 10.5: dissolve 0.48 g sodium hydroxide and 2.5 g sodium tetraborate in 250 ml of water;
- 2,4-dinitro-6-phenyl phenol solution: dissolve 250 mg 2,4-dinitro-6-phenyl phenol in 200 ml of buffer solution. Make up with water to 250 ml;
- sodium sulfate, water-free;
- standard solution of bis(2-hydroxyethyl)-2-hydroxy-3-dodecoxypropyl methyl ammonium chloride: dilute 1 ml of the commercial solution (10%) to 0.1% with 90% (v/v) acetone.

d. *Calibration line*

Place 20 g of fat stimulant each into six 250 ml separatory funnels. Add 0, 0.25, 0.5, 1,0, 1.5 and 2.0 ml respectively of the standard solution, place 40 ml of pentane into each separatory funnel, and mix. Then shake the pentane solution out four times with 25 ml of water. Filter the water layers through a funnel with a small cotton wad into a second 250 ml separatory funnel. Add 15 ml of 2,4-dinitro-6-phenyl phenol solution and 25 ml of 1,2-dichloroethane. Shake vigorously for at least five min. and leave to demix. Filter the dichloroethane layer through a layer of water-free sodium sulfate. Measure the extinction of the solution at 370 nm in a 3 cm cell in comparison to a reagent blank. Plot the obtained values graphically against the quantities of quaternary ammonium compounds that were used.

e. *Conducting the migration test*

Bring an amount of material corresponding to at least 2 dm^2 (assume *b* dm^2) into contact with preheated oil. For this, use one of the methods described in EN 13130. If possible, add no more than 50 ml (assume *c* ml) of preheated oil per dm^2. Place the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the fat simulant into a 250 ml separatory funnel.

f. *Determining the quaternary ammonium compound*

To the fat simulant in the separatory funnel, add 40 ml of pentane, and continue as described under d. Use the calibration line to determine the quantity of quaternary ammonium compounds.

g. *Calculation*

Assume the quantity to be *a* mg. From this, calculate the specific migration M_s with the formula:

$$M_s = \frac{a * c}{b * d} \quad mg/dm^2$$

5.3.4 Anionic surfactants

5.3.4.1 Migration into aqueous simulants

a. *Introduction*

The method described below may be used to determine the migration of the following substances:

alkyl(C_8-C_{18})benzene sulfonates;
alkyl(C_8-C_{18})sulfates;
alkyl(C_8-C_{18})sulfonates;
dialkyl(C_4-C_{14})sulfosuccinates.

b. *Principle*

A test sample is brought into contact with water[39]. At the end of the storage time, a solution of Azure A is added to the solution. The complex formed with the anionoactive substance is shaken out with chloroform and quantitatively determined by means of spectrophotometry.

c. *Equipment*

- laboratory glassware and laboratory equipment; wash all glassware, first with diluted sulphuric acid, then with distilled or demineralised water, and finally with absolute ethanol;
- migration cell, see EN 13130;
- spectrophotometer.

d. *Reagents*

- 0.1 N sulphuric acid;
- chloroform p.a.;
- Azure A solution: dissolve 40 mg Azure A (7-dimethyl amino-3-imino-3-Hphenothiazinehydrochloride) in 5 ml of 0.1 N sulphuric acid and dilute with water to 100 ml;
- standard solutions of the substances referred to sub a: 0.001% (m/v) in water.

e. *Calibration lines*

Of the standard solution, place 5, 4, 3, 2 and 1 ml respectively into a 250 ml separatory funnel. Make up with water to 50 ml. Add 5 ml of 0.1 N sulphuric acid, 1 ml of Azure A solution, and 10 ml of chloroform. Shake for at least five min. and allow to demix thoroughly. Pour the chloroform layer off into a 50 ml conical flask. Measure the extinction of the solution at 455 nm in a 1 cm cell in comparison to the reagent blank. Plot the obtained values graphically against the amounts of anionoactive substance used.

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[39] It is assumed that the migration into 3% acetic acid or 10% ethanol is equal to that in water.

f. *Conducting the migration test*

Bring an amount of material corresponding to at least 1.5 dm^2 (assume *b* dm^2) into contact with water. For this, use one of the methods described in EN 13130[40]. If possible, add 200 ml of preheated water per dm^2. Place the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the simulant off.

g. *Determination of the anionoactive substances*

Place an appropriate quantity of the extract (assume *d* ml, containing 1-30 µg of anionoactive substance) into a 250 ml separatory funnel. Make up with water to 50 ml and continue as described under e. Use the calibration line to determine the quantity of anionoactive substance.

h. *Calculation*

Assume the quantity to be *a* mg. From this, calculate the specific migration M_s with the formula:

$$M_s = \frac{a * c}{b * d} \quad mg/dm^2$$

5.3.4.2 Migration into fat

a. *Introduction*

The method described below may be used to determine the migration of the following substances into fat simulant:

alkyl(C_8-C_{18})benzene sulfonates;
alkyl(C_8-C_{18})sulfates;
alkyl(C_8-C_{18})sulfonates;
dialkyl(C_4-C_{14})sulfosuccinates.

b. *Principle*

A test sample is brought into contact with the fat simulant. At the end of the storage time, the fat simulant is separate from the test sample and diluted with cyclohexane. The cyclohexane solution is shaken out with water. A solution of Azure A is added to the water layer. The complex formed with the anionoactive substance is shaken out with chloroform and quantitatively determined by means of spectrophotometry.

c. *Equipment*

- laboratory glassware and laboratory equipment; wash all glassware, first with diluted sulphuric acid, then with distilled or demineralised water, and finally with absolute ethanol;
- migration cell, see EN 13130;
- spectrophotometer.

d. *Reagents*

- fat simulant: a synthetic triglyceride mixture, e.g. Miglyol, or a natural oil or fat with no substances present that could disrupt the analysis, e.g. refined coconut fat;
- cyclohexane p.a.;
- 0.1 N sulphuric acid;
- chloroform p.a.;
- Azure A solution: dissolve 40 mg of Azure A (7-dimethyl amino-3-imino-3-Hphenothiazinehydrochloride) in 5 ml of 0.1 N sulphuric acid and dilute with water up to 100 ml;
- standard solutions of the above substances: 0.005% (m/v) in water.

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[40] EN 13130 can be obtained from NEN, Postbus 5059, 2600 GB Delft

e. *Calibration line*

Of the standard solutions, place 5, 3, 1 and 0 ml respectively into a 250 ml separatory funnel. Make up with water to 50 ml. Add 5 ml of 0.1 N sulphuric acid, 1 ml of Azure A solution, and 10 ml of chloroform. Shake for at least two min. and allow to demix thoroughly. Pour the chloroform layer off into a 100 ml conical flask. Measure the extinction of the solution at 623 nm in a 1 cm cell in comparison to the reagent blank. Plot the obtained values graphically against the amounts of anionoactive substance used.

f. *Conducting the migration test*

Bring an amount of material corresponding to at least 2 dm^2 (assume *b* dm^2) into contact with preheated oil. For this, use one of the methods described in EN 13130. If possible, add no more than 50 ml (assume *c* ml) of preheated oil per dm^2. Place the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the fat simulant off.

g. *Determining the anionoactive substances*

Place about 25 g (assume *d* g) of the fat simulant into a 250 ml separatory funnel. Add 250 ml of cyclohexane and 50 ml of water. Shake for 3 min. and leave to demix. Pour the watery phase off into a 100 ml conical flask. Pipette 2 ml of the watery phase into a 250 ml separatory funnel and continue as described under e. Use the calibration line to determine the quantity of anionoactive substance.

h. *Calculation*

Assume the quantity to be *a* mg. From this, calculate the specific migration M_s with the formula:

$$M_s = \frac{25\,a * c}{b * d} \; mg/dm^2$$

5.3.5 *N,N-bis(2-hydroxyethyl)alkyl(C_{12}-C_{18})amine*

5.3.5.1 *Migration into aqueous simulants*

a. *Introduction*

The method described below may be used to determine the migration of tertiary aliphatic amines (TAA) with at least one alkyl group and a chain length of C_{12} or higher, in water, 3% acetic acid and 10% ethanol.

b. *Principle*

A test sample is brought into contact with 3% acetic acid[41]. At the end of the storage time, a proportional part of the solution is shaken with a solution of acetic anhydride in 1,2-dichloroethane, in order to mask primary and secondary aliphatic amines through acetylation. Then, the pH of the watery layer is brought to 11.5, and the mixture is shaken again. Any present quaternary ammonium compounds will remain in in the watery layer, but the tertiary aliphatic amines will fully pass into the dichloroethane layer. This layer is separated from the watery layer and then shaken together with an acidic methyl orange solution. The TAA methyl orange complex that forms is quantitatively determined in the dichloroethane layer by means of spectrophotometry

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[41] It is assumed that the migration into water or 10% ethanol is equal to that in 3% acetic acid.

c. *Equipment*

- laboratory glassware and laboratory equipment;
- migration cell, see EN 13130;
- spectrophotometer.

d. *Reagents*

- 0.01 M acetic anhydride in 1,2-dichloroethane;
- 4.5 N sodium hydroxide;
- citrate-phosphate buffer pH = 4; dissolve 12.9 g of citric acid-1aq and 13.7 g of disodium hydrogen phosphate-2aq in 1 l of water;
- methyl orange solution: dissolve 0.5 g of methyl orange (sodium salt) in 400 ml of buffer solution and make up with water to 1 l;
- standard solution of N,N-bis(2-hydroxyethyl)alkyl(C_{12}-C_{18})amine: 0.005% (m/v) in water;
- diluted standard solution of N,N-bis(2-hydroxyethyl)alkyl(C_{12}-C_{18})amine: dilute 20 ml of the aforementioned standard solution with water to 100 ml.

e. *Calibration line*

Use a pipette to place 0, 1, 2, 4, 10 and 20 ml respectively of the diluted standard solution into six 250 ml separatory funnels. Make up with 3% acetic acid solution to 20 ml. Use a pipette to add 10 ml of 0.01M acetic anhydride solution in 1,2-dichloroethane and shake the mixture for 10 min. Then add 5 ml of 4.5 N sodium hydroxide solution added and again shake for 1 min. Leave to demix. Pour the dichloroethane layer off quantitatively into a 250 ml separatory funnel. Add 10 ml of methyl orange solution and shake for 1 min. Leave to demix. Measure the extinction of the dichloroethane layer at 425 nm in a 1 cm cell in comparison to a reagent blank, and plot the measured values graphically against the used quantities of tertiary amine.

f. *Conducting the migration test*

Bring an amount of material corresponding to at least 2 dm^2 (assume *b* dm^2) into contact with 3% acetic acid. For this, use one of the methods described in EN 13130. If possible, add a maximum of 60 ml (assume *c* ml) of preheated acetic acid solution per 2 dm^2, and seal the beaker. Place the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the simulant off.

g. *Determination of N,N-bis(2-hydroxyethyl)alkyl(C_{12}-C_{18})amine*

Pipette 20 ml of the stimulant into a 250 ml separatory funnel and continue as described under e. Use the calibration line to determine the quantity of tertiary aliphatic amines.

h. *Calculation*

Assume the quantity to be *a* mg. From this, calculate the specific migration M_s with the formula:

$$M_s = \frac{a * c}{20b} \ mg/dm^2$$

5.3.5.2 Migration into fat

a. *Introduction*

The method described below may be used to determine the migration of tertiary aliphatic amines (TAA) with at least one alkyl group and a chain length of C_{12} or higher, into fat simulant.

b. *Principle*

A test sample is brought into contact with the fat simulant. At the end of the storage time, the fat simulant is separated from the test sample and diluted with pentane. The pentane solution is shaken out with water. Part of the aqueous solution is shaken with a solution of acetic anhydride in 1,2-dichloroethane, in order to mask primary and secondary aliphatic amines through acetylation. Then, the pH of the watery layer is brought to 11.5, and the mixture is shaken again. Any present quaternary ammonium compounds will remain in in the watery layer, but the tertiary aliphatic amines will fully pass into the dichloroethane layer. This layer is separated from the aqueous layer and then shaken together with an acidic methyl orange solution. The TAA methyl orange complex that forms is quantitatively determined in the dichloroethane layer by means of spectrophotometry

c. *Equipment*

- laboratory glassware and laboratory equipment;
- migration cell, see EN 13130;
- spectrophotometer.

d. *Reagents*

- fat simulant: a synthetic triglyceride mixture, e.g. Miglyol, or a natural oil or fat with no substances present that could disrupt the analysis, e.g. refined coconut fat;
- n-pentane;
- 0.01 M acetic anhydride in 1,2-dichloroethane;
- 4.5 N sodium hydroxide;
- citrate-phosphate buffer pH = 4: dissolve 12.9 g of citric acid-1aq and 13.7 g of disodium hydrogen phosphate-2aq in 1 l of water;
- methyl orange solution: dissolve 0.5 g of methyl orange (sodium salt) in 400 ml of buffer solution and make up with water to 1 l;
- standard solution of N,N-bis(2-hydroxyethyl)alkyl(C_{12}-C_{18})amine: 0.2% (m/v) in acetone.

e. *Calibration line*

Place 20 g of fat stimulant and 0, 0.1, 0.2, 0.4, 0.6 and 0.8 ml respectively of the standard solution into six 250 ml separatory funnels. Dilute the fat simulant with 40 ml pentane. Shake the pentane solution out four times with 20 ml water. Filter the water layers through a funnel with a small cotton wad, into a 100 ml measuring flask. Make up with water and mix. Pipette 20 ml of the extract into a 250 ml separatory funnel. Use a pipette to add 10 ml of 0.01 M acetic anhydride solution in 1,2-dichloroethane, and shake the mixture for 10 min. Then add 5 ml of 4,5 N sodium hydroxide solution added and shake for another 1 min. Leave to demix. Pour the dichloroethane layer off quantitatively into a 250 ml separatory funnel. Add 10 ml of methyl orange solution and shake for 1 min. Leave to demix. Measure the extinction of the dichloroethane layer at 425 nm in a 1 cm cell in comparison to a reagent blank, and plot the measured values graphically against the used quantities of tertiary amine.

f. *Conducting the migration test*

Bring an amount of material corresponding to at least 2 dm^2 (assume *b* dm^2) into contact with preheated oil. For this, use one of the methods described in EN 13130. If possible, add 50 ml of preheated oil per dm^2. Place the sample with simulant in an area at the specified temperature for the specified duration (see Regulation (EU) No 10/2011). At the end of the storage time, pour the fat simulant into a 250 ml separatory funnel.

g. *Determination of N,N-bis(2-hydroxyethyl)alkyl(C_{12}-C_{18})amine*

Add 400 ml of pentane to the fat simulant in the separatory funnel and mix. Then shake the mixture out four times with 20 ml of water. Filter the water layers through a funnel with a small cotton wad into a 100 ml measuring flask. Make up with water and mix. Continue as described under e. Use the calibration graph to determine the quantity of N,N-bis(2-hydroxyethyl) alkyl(C_{12}-C_{18}) amine.

h. *Calculation*

Assume this quantity to be *a* mg. From this, calculate the specific migration M_s of N,N-bis(2-hydroxyethyl)alkyl(C_{12}-C_{18})amine using the formula:

$$M_s = \frac{5a}{b} \ mg/dm^2$$

5.3.6 *Colourants – filtering paper test*

5.3.6.1 *Specification*

Packaging or consumer articles coloured with colourants or pigments must not exhibit any colour difference in comparison to the blank in the filtering paper test.

5.3.6.2 *Conducting the determination with 3% acetic acid*

In an exsiccator, place an amount of 3% acetic acid sufficient to completely cover the bottom. Place the exsiccator in a room at a temperature of 40 ± 2 °C. Saturate a 5 x 2 cm strip of filter paper (for qualitative analysis, medium-speed) with 3% acetic acid and place the strip on a 9 x 6 cm flat piece of packaging material or consumer article. Cover the strip with a 9 x 6 cm glass plate and place a 0.1 kg weight on top. In a similar manner, for the blank, place a strip of filtering paper moistened with 3% acetic acid between two glass plates; then place both packs in the heated exsiccator for 5 hours. Then take both strips of filtering paper out of the exsiccator, and dry them at approximately 40 °C. There should be no discernible colour difference between the two strips. If a flat piece of packaging material or consumer article is not available, proceed as follows:

> Place a strip of filter paper of appropriate size (10 to 15 cm), that has been saturated with 3% acetic acid, into the surface of the packaging material or consumer article. Cover it with a piece of aluminium foil, such that this protrudes approximately 0.5 cm over the filtering paper on each side. Attach the aluminium foil with colourless adhesive tape, and proceed as described above.

5.3.6.3 *Conducting the determination with fat (simulant)*

Use clear arachide oil, coconut oil, sunflower oil, olive oil or Miglyol. Proceed in the same manner as described under 5.3.6.2, but with the filtering paper being saturated with fat (simulant), and no fat (simulant) needing to be placed in the exsiccator. Drying of the filtering paper strips at the end of the contact period is not necessary.

5.3.7 *Discharge of N-nitrosamines and N-nitrosable compounds by rubber teats and pacifiers of elastomer or rubber*

(basic rule)

a. *saliva stimulant*

The saliva simulant is obtained by dissolving 4.2 g of sodium bicarbonate ($NaHCO3$), 0.5 g of sodium chloride (salt), 0.2 g of potassium carbonate ($K2CO3$) and 30 mg of sodium nitrite ($NaNO3$) in 1 l of distilled water or water of equivalent quality. The solution must have pH equal to 9.

b. *test circumstances*

Test samples obtained from a sufficient number of rubber teats or pacifiers from the same lot, are submerged in the saliva simulant for 24 hours at a temperature of 40±2 °C.

c. *determination of N-nitrosamines*

The discharge of N-nitrosamines is determined in a proportional part of each solution as obtained under b. The N-nitrosamines are extracted from the solution using nitrosamine-free dichloromethane (DCM) and then quantitatively determined using gas chromatography.

d. *determination of N-nitrosable compounds*

The discharge of N-nitrosable compounds is determined in a second proportional part of each solution obtained under b. The nitrosable compounds are converted to N-nitrosamines by acidifying the solution with hydrochloric acid. The N-nitrosamines are extracted from the solution using nitrosamine-free dichloromethane (DCM) and then quantitatively determined using gas chromatography.

6 SENSORY ASSESSMENT

a. *Objective and scope of application*

This method serves to determine whether the use of a packaging material or consumer article, below 'material', causes unacceptable changes to the taste or odour of the products with which it is brought into contact.[42] [43] The method is essentially applicable to all possible combinations of materials and foodstuffs or beverages. However, the rule has been formulated in general terms. In specific cases, it may be necessary to include additional instructions in the provision.

b. *Principle*

A certain quantity of the foodstuff or beverage is brought into contact with the material for a specified time at a specified temperature. At the end of the storage time, a number of tasters compare the taste or odour of the product with the taste or odour of an amount of the product that has not been in contact with the material, but has otherwise been stored under the same circumstances. This comparison is undertaken by means of an extended triangle test. In this test, each taster is given three portions of the product simultaneously. Two of the three portions are identical, coming from either the analysis sample or the control sample. The tasters are first asked to indicate which two portions are most alike in terms of taste or odour, and then how large the difference in taste or odour is between them and the third portion. Finally, if they find an abnormality in either lot, they are asked to try and describe the nature of the abnormality. The data from the actual triangle test are processed statistically, after which it is determined, based on the outcome of this processing and on the comments about the size of the difference and the nature of the abnormality, whether there are any sensory objections to the use of the material in contact with foods and beverages.

c. *Description of terms*

The most important terms in connection with these assessments are defined as follows:

test material:	packaging material or consumer article to be assessed
sample:	the part of the test sample that is brought into contact with the foodstuff or beverage
test sample:	the part of the test material that is used for the sensory assessment*test food:* the foodstuff or beverage used in the sensory assessment of the test material
analysis sample:	the quantity of test food that has been in contact with the sample under the specified conditions
control sample:	an equal quantity of the test food that has not been in contact with the test material, but was stored under the same conditions.

d. *Test requirements*

tasters:	the panel conducting the triangle test should consist of at least nine and at most 18 persons. It is recommended to have equal numbers of men and women. Panel members should have experience in assessing taste or odour under the procedure described herein.
testing room:	a room that is free of odours that could affect the outcome of the sensory assessment
storage jars:	e.g. exsiccators or preserving jars of appropriate size
aluminium foil:	uncoated and grease-proof
petri dishes:	glass, 8 x 2 cm
cutlery:	stainless steel.

Note: The glassware, aluminium foil and cutlery should be odour-free.

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[42] 'in contact' does not mean only direct contact, but indirect contact as well, for example with the outer wrapping.

[43] See Article 3(1)(c) of Regulation (EC) No 1935/2004.

e. *Sampling*

Before taking a test sample from a stack or roll of test material, always discard at least the first five layers. If the test material is packaged in a box, the sample should preferably be taken fom the centre of the box; if it is taken from a continuous production line, allow at least the first 20 units to pass.

If the sensory assessment cannot be conducted immediately, the test samples should be kept in properly sealable glass jars (preserving jars) or fully wrapped in aluminium foil.

f. *Procedure*

1. *Preparation of analysis and control samples*

   Bring a suitable sample[44] into contact with an appropriate quantity of test food, in a manner reflecting actual practice, and place the unit so created in an exsiccator or preserving jar of appropriate size. Then place an equal quantity of test food into into a sealable glass jar or in aluminium foil, and place the pot/package into a second exsiccator or preserving jar. Leave the storage jars with their contents to stand in conditions reflecting actual practice as to time and temperature, in the dark where appropriate.

2. *Implementation of the triangle test*

   Conduct the triangle test in the testing room, under conditions that are as similar as possible for all tasters. Have 18 triangles assessed, two by each person in case of nine tasters, or one by each in case of 18 tasters. To avoid taster fatigue, a panel of 18 persons is preferred.

   - *placement of the triangles*

     Arrange three petri dishes next to each other for each tasting. Mark the dishes – starting with the leftmost dish of the first triangle, then the middle dish, finally the rightmost dish, then the leftmost dish of the second triangle, and so on. – with three-digit code taken from the randomised table in Annex 1 for numerical codes.

     Proceed as follows:

     - Choose a numerical code from the table and assign it to the first petri dish. Start from the cell of the first code, choose a direction within the table, and start taking codes for the other petri dishes from the table in the chosen direction.
     - When the codes in a table row have been used up, then continue taking codes from the next row rule in the same direction. When all dishes have been assigned a code, use a balanced scheme of 18 combinations, randomly chosen from Annex 2, to decide which dishes will contain an analysis sample (A) and which a control sample (B).
     - Record the codes of the dishes and the associated letters of analysis and control samples on a form in accordance with Annex 3.
     - Then use the arrangement so obtained to place appropriate quantities of analysis and control samples into the dishes

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[44] The non-specific descriptions used in these general rules, such as "suitable sample" "suitable quantity," and so on, should be replaced with specific descriptions in product-oriented requirements.

- *taster instruction*

  Ensure that the tasters always taste each sample set in the same order, e.g. starting with the sample in the leftmost dish. Retasting should be allowed, however.Ask the tasters to record the following on a form pursuant to Annex 4, using the relevant codes:

  - which two samples are most alike in terms of taste or odour
  - whether the difference in taste or odour between those two samples and the third sample is small, moderate or large
  - whether one of both lots is abnormal in taste or odour, and if so, which lot it is, and what is the nature of the abnormality.

3. *Processing the results*

On each of the completed forms pursuant to Annex 4, and then on the form pursuant to Annex 3, indicate whether the combination recorded by the taster was correct or incorrect. Then used the table below to determine whether the taste or odour of the analysis sample was different from that of the control sample for a 5% level of statistical significance.

TABLE Minimum number of panel members that should have answered the test(s) correctly to be able to conclude with a 5% significance level that there is a difference in taste or odour between the analysis sample and the control sample.

N	Nm
9	4
18	10

N: total number of tasters
Nm: minimum number of tasters that should have correctly completed the test (18-person panel) or both tests (9-person panel).

g. *Assessment of the material*

A material will be considered to cause unacceptable changes in the taste or odour of the foodstuff or beverage with which it comes into contact if it is found that:

- there is a difference in taste or odour between the analysis sample and the control sample at a 5% level of statistical significance.
- the difference is rated moderate or large by a majority of tasters who corrected identified the combinations(s) offered to them.
- the comments about the nature of the abnormality - again only for those tasters who correctly identified their combination(s) - that are relevant in connection with the assessment.

The packaging material or consumer article must then be considered to be unsuitable for its intended use. If any of the above criteria is not fulfilled, then the material can be considered not to cause unacceptable changes in the taste or odour of the foodstuff or beverage. In that case, there are no objections to the use of the packaging material or consumer article.

ANNEX 1

Sensory assessment of packaging material and consumer articles

Randomised table for numerical codes

887	308	883	009	140	014	439	315	799	024	021	185	400	945	654	619
288	033	978	120	040	740	624	173	577	570	300	731	384	559	626	206
822	050	609	711	600	437	136	451	155	395	883	597	913	175	446	722
348	570	056	357	216	024	821	374	691	353	518	505	177	250	711	872
093	645	240	293	912	980	088	963	726	393	985	305	931	682	677	568
150	476	172	402	739	319	140	069	257	923	909	633	150	470	986	545
391	064	301	134	567	413	311	700	232	409	239	476	121	464	129	385
033	920	563	671	895	294	613	577	762	544	712	594	991	604	941	883
590	059	365	746	078	282	616	545	697	085	757	475	479	496	679	308
205	510	393	657	980	932	186	465	026	690	727	254	334	794	646	833
892	085	663	526	269	169	641	454	670	856	517	762	243	117	586	078
908	650	736	955	382	711	126	754	376	788	825	467	882	021	765	100
559	536	677	309	583	087	681	077	693	277	648	844	488	230	437	021
305	685	986	143	025	950	176	070	136	032	926	468	554	192	584	090
613	746	999	331	630	929	271	970	091	410	699	484	755	131	595	720
456	527	209	133	266	379	932	929	850	054	376	394	927	201	645	387
354	115	662	811	922	733	839	739	958	130	073	043	659	332	626	343
083	801	786	358	189	277	468	387	529	571	240	050	346	553	656	653
200	928	817	933	281	942	024	033	055	275	142	770	873	365	716	396
452	329	968	059	832	969	640	530	080	719	711	007	718	553	127	913
064	843	309	880	068	429	586	365	060	927	687	170	377	145	731	969
880	268	713	048	480	584	025	233	270	589	576	161	403	841	957	989
328	872	957	680	054	705	880	092	382	765	225	401	174	258	189	239
423	148	749	096	000	917	388	690	963	867	402	464	071	012	921	502
704	841	327	970	010	449	913	576	999	438	164	514	090	560	469	975

ANNEX 2

Sensory assessment of packaging material and consumer articles

Combination schemes

1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
01 ABB	01 BAA	01 BAA	01 AAB	01 AAB	01 BAB	01 AAB	01 ABA
02 BAA	02 AAB	02 AAB	02 ABA	02 ABB	02 BBA	02 BAB	02 BBA
03 BAA	03 BBA	03 BAB	03 BAA	03 BAA	03 ABB	03 BBA	03 BAB
04 ABB	04 BAB	04 AAB	04 ABB	04 BAB	04 ABA	04 BBA	04 BBA
05 BBA	05 ABA	05 ABB	05 ABB	05 ABB	05 ABA	05 ABA	05 BAA
06 ABA	06 AAB	06 BBA	06 BAA	06 ABA	06 BAA	06 BAA	06 BAB
07 ABA	07 BAB	07 ABB	07 ABA	07 AAB	07 BAA	07 ABB	07 BAA
08 BAA	08 ABB	08 ABB	08 BAB	08 BAA	08 BAB	08 BAB	08 AAB
09 BAB	09 BAA	09 AAB	09 BAA	09 BAB	09 AAB	09 ABA	09 BAB
10 BAB	10 BBA	10 ABA	10 BBA	10 AAB	10 AAB	10 BBA	10 AAB
11 AAB	11 BAA	11 BAA	11 ABB	11 BAA	11 BBA	11 AAB	11 ABB
12 BBA	12 ABB	12 BAA	12 BBA	12 BBA	12 ABB	12 BAA	12 BBA
13 AAB	13 ABB	13 BBA	13 ABA	13 BBA	13 BBA	13 BAB	13 AAB
14 ABA	14 ABA	14 BAB	14 AAB	14 ABA	14 BAB	14 ABB	14 BAA
15 AAB	15 BBA	15 BBA	15 BAB	15 ABB	15 ABA	15 ABA	15 ABA
16 ABB	16 AAB	16 ABA	16 AAB	16 BBA	16 ABB	16 ABB	16 ABA
17 BAB	17 BAB	17 BAB	17 BBA	17 BAB	17 AAB	17 BAA	17 ABB
18 BBA	18 ABA	18 ABA	18 BAB	18 ABA	18 BAA	18 AAB	18 ABB

ANNEX 3

Sensory assessment of packaging material and consumer articles

Outcome of the triangle test

triangle test No: date: analysis No:

test material: scheme No:

test food: time-temperature:

triangle number	code	combination	abnormal sample	indication		difference		
				correct	incorrect	k	m	g
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
..	.../.../...	./././.	...	0	0	0	0	0
total								

CONCLUSION:

ANNEX 4

Sensory assessment of packaging material and consumer articles

Taster Form

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triangle no:	arrangement:.../.../...	taster:
test food:	date:	analysis no:

- of the three samples offered to you, two are from the same lot. Please indicate, using the codes, which two samples are most alike in taste or odour:

  ... and...

- indicate how large you rate the difference between these two samples and the third sample:

  small: 0 moderate: 0 large: 0

- If you feel that one of the sample, or the two others, are abnormal in odour or taste, please try to describe the nature of the abnormality:

  sample... smells or tastes of:

  or:

  samples.../... smell or tast of:

Not to be completed by the taster:

identification: correct: 0 incorrect: 0

CHAPTER II ASSESSMENT OF BASE MATERIALS AND AUXILIARY MATERIALS

1 Ultraviolet light absorption by solid paraffins and microcrystalline paraffins

a. *Introduction*

This method is intended to determine traces of polycyclic aromatic hydrocarbons in paraffins and microcrystalline paraffins that come into contact with foods and beverages. These paraffins are petroleum-derived mixtures of solid hydrocarbons (containing a small proportion of liquid hydrocarbons), intended to be used, among others, for packaging foods and beverages.

b. *Principle*

The procedure essentially comprises two phases: phase A and phase B.

- *phase A*

  A solution of the paraffin sample in iso-octane is subjected to triple extraction at 90 °C with a mixture of dimethyl sulfoxide and orthophosphoric acid (4:1, v/v) to isolate the polycyclic aromatic hydrocarbons. Each extract is washed three times with iso-octane at room temperature. The washed extracts are joined and centrifugated to remove any dispersed paraffin particles. Since dimethyl sulfoxide absorbs light in the wavelength band up to 300 nm, the extract is diluted with water and then extracted several times with iso-octane. The UV extinction of this iso-octane solution is then measured in certain specified conditions. If the UV extinction per cm of optic path length meets the following specification, the paraffin is approved.

wavelength (nm)	*extinction per cm of optic path length*
280-289 nm	no more than 0.15
290-299 nm	no more than 0.12
	no more than 0.08
360-400 nm	no more than 0.02

  If the extinctions so found are higher than the specified limits, the analysis should be continued with phase B.

- *phase B*

  The solution is concentrated once again and then purified with sodium tetrahydroborate to remove hetero compounds. After removing the excess sodium tetrahydroborate, the solution is percolated through a chromatography column with a special adsorbent. The polycyclic aromatic hydrocarbons are recovered from the column, and the UV absorption spectrum of this final extract is then measured. If the extinction per cm of optic path length still exceeds the limits specified in phase A, the paraffin is rejected.

c. *Equipment*

- *separatory funnels*
  - made of borosilicate glass, fitted with normal ground joints 19/26, plugs and PTFE taps. Volumes 500, 1 000 and 2 000 ml
  - made of borosilicate glass, fitted with normal ground joints 24/29, plugs and PTFE taps. Volume 250 ml
  - made of borosilicate glass, fitted with normal ground joints 19/26, plugs and PTFE taps. Volume 100 ml

- equipment for isolating polycyclic aromatic hydrocarbons, see Figure 1.1
  - chromatography column, length 180 mm, internal diam. 17.5 ± 0.1 mm, fitted with a porous, coarsely sintered glass plate, a PTFE tap with bevelled outlet tube, and a normal ground joint 29/32 with glass hooks at the top end
  - spherical reservoir made of borosilicate glass, volume 500 ml, fitted with normal ground joints 29/32, a core at the bottom and a mantle at the top end, both fitted with glass hooks
  - a normal ground joint 29/32 with glasses hooks to introduce a nitrogen flow into the reservoir

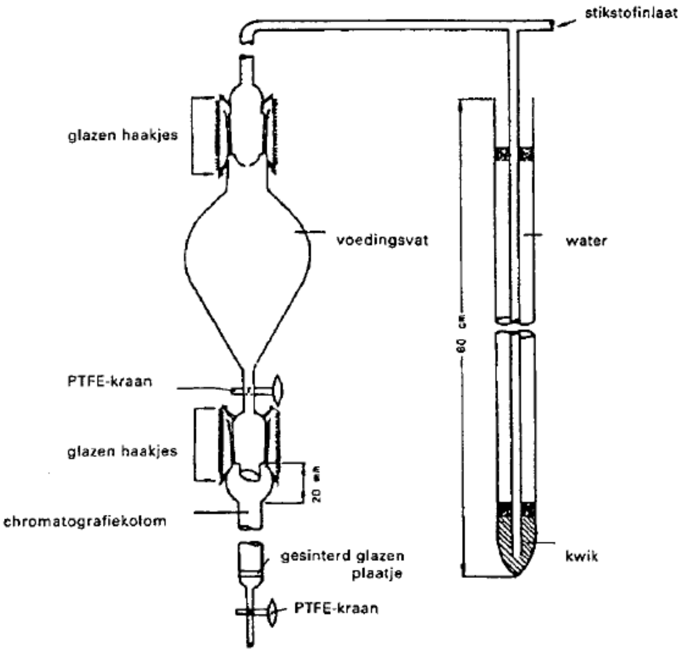

Figure 1.1 Equipment for the chromatographic isolation of polycyclic aromatic hydrocarbons.

- equipment for purification of iso-octane, see Figure 1.2
  - chromatography column, length about 1 200 mm, internal diam. 50 mm, fitted with a PTFE tap and a side tube for overflow at the top end
  - a spherical vessel made of borosilicate glass, fitted with a PTFE tap at the bottom, connected, by a normal ground joint 29/32 with glasses hooks and and at the top end by a normal ground joint 29/32, to a right-angle pipe for pressure equalisation between the column and the reservoir

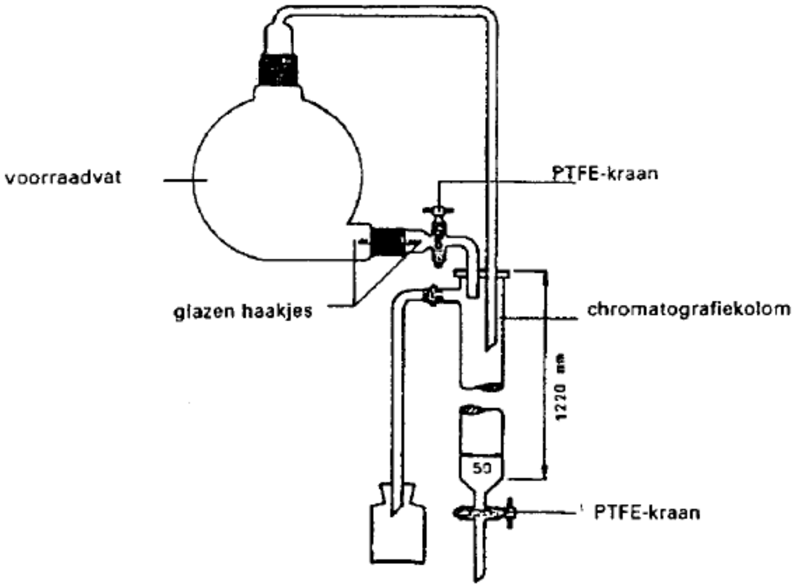

Figure 1.2 Equipment for purification of iso-octane.

- evaporation flasks, made of borosilicate glass, fitted with normal ground joints 29/32 and plugs. Volumes 250 and 500 ml
- equipment for measuring sodium tetrahydroborate, measuring glasses with small glass handles, volume corresponding to 0.3 g of sodium tetrahydroborate
- measuring flasks, volume 25 ml, fitted with plugs

- equipment for the reaction with sodium tetrahydroborate
  - straight cooler, length 500 mm, fitted with normal ground joints 29/32
  - drying tube for connection to the cooler, fitted with a normal ground joint 29/32
- distillation equipment for solvents
  - thermostatically controlled heating jacket for round-bottomed flasks with a volume of 2 000 ml
  - round-bottomed flasks made of borosilicate glass, volume 2 000 ml, with normal ground joint 29/32
  - fractionating column, vigreux type, length 800 mm, diam. 30 mm, fitted with a normal ground joint 29/32 at the bottom end and a ground joint at the top end, to attach a thermometer
  - thermometer with ground joint for use with the aforementioned column
  - helical cooler for use with the aforementioned column
- automatic distillation equipment for doubly distilled water
- heating jacket for melting paraffin, conical with lateral opening, for use with 500 ml separatory funnels
  - equipment for activating the adsorbents
  - sieves with mesh sizes of 60 and 180 mesh
  - mortar
  - glass plate for the drying process
  - oven, suitable for temperatures up to 200 °C
- suction filters
  - büchner suction filters made of porcelain, diam. 120 mm
  - büchner suction filters made of glass, with sintered glass plate, type Jena G/1 or 17D/1
  - büchner suction filter as above, with a normal ground joint 25/29 and a side pipe for vacuum on the same ground joint
  - small conical suction filters made of glass, with sintered glass plates, for fast filtering, type G/1 or equivalent
- rotating vacuum evaporator
- pressurised nitrogen in cylinders, oxygen content less than 100 ppm (v/v), cylinder with reducing valve
- spectrophotometer
  - wavelength band 220-400 nm, with a special slit width of 2 nm or less. The device must also fulfil the following requirements:
    - duplicability of the extinction: ± 0.01 for an extinction of 0.4
    - accuracy of the extinction: ± 0.05 for an extinction of 0.4
    - duplicability of the wavelength: ± 0.2 nm
    - accuracy of the wavelength: ± 1.0 nm
- quartz cuvettes with the following optical path lengths:
  - ± 1.000 cm ± 0.005 cm
  - ± 5.000 cm + 0.005 cm
- laboratory centrifuge, speed 2 000 rpm, fitted with glass centrifuge tubes of 250 ml volume.

d. *Reagents and purification of reagents and auxiliaries*

- iso-octane (2,2,4-trimethyl pentane), for spectrophotometry. Purify if necessary by percolating through a column of activated silicagel, until the extinction per cm of optic path length at 220 nm is less than 0.10
- benzene p.a., distil before use
- acetone p.a., purified if necessary by boiling with potassium permanganate, with backflow cooling, followed by distilling. The fraction between 5% and 95% is to be collected
- 10% benzene in iso-octane: add 50 ml benzene to 450 ml iso-octane and mix
- 20% benzene in iso-octane: add 50 ml benzene to 200 ml iso-octane and mix
- acetone-benzene-water mixture: add 20 ml water to 380 ml acetone and mix with 200 ml benzene
- n-hexadecane, 99%, free of alkenes, purify if necessary by percolating through a column of activated silicagel, followed by vacuum distillation. Collect the fractions with an extinction at 220 nm per cm of optic path length of less than 0.10
- methanol p.a., purify if necessary by distilling

- dimethyl sulfoxide (DMSO) for spectrophotometry, moisture content no more than 0.10%, determined according to Karl Fischer, or with an initial freezing point of at least 18.3 °C. The DMSO extinction is measured in a cuvette with an optic path length of 1 cm with respect to distilled water, after oxygen has been removed from the DMSO through purification by passing a small flow of nitrogen. The extinction must not exceed the following limits:

wavelength (nm)	*extinction per cm of optic path length*
261.5	1.00
264	0.64
270	0.19
275	0.07
280	0.03
300	0.010

  The extinction curve must not exhibit any irregularities in the 280-400 nm wavelength band. If necessary, the DMSO may be purified in accordance with the method described in Annex 1 to this section. The DMSO must be stored in a dark-coloured glas bottle. Due to the hygroscopic characteristics of DMSO, avoid unnecessary exposure to air. Contact with metals should also be avoided, since DMSO reacts with certain metals, e.g. copper, in the presence of air
- orthophosphoric acid, 85% purity
- sodium tetrahydroborate, 98% purity
- magnesium oxide, 60-180 mesh, Sea Sorb 43[45] or equivalent type, purified as follows: Wash the adsorbent with 300 ml benzene which is then separated through vacuum filtration. Dry the magnesium oxide in an oven at 100 °C. Then place 100 g of the oxide in a large beaker, together with 700 ml doubly distilled water to obtain a fine paste. Heat the paste for 30 min. over a water bath; stir occasionally to ensure that the adsorbent remains completely moistened. Filter under vacuum through a büchner filter of appropriate diameter and with Schleicher and Schuell No 597* filtering paper or equivalent paper type. Suction the magnesium oxide off until it is dry. Place the adsorbent on a glass plate. Break the coarse parts with a clean spatula and spread the material to obtain an even 1 to 2 cm layer. Dry for 24 hours in an oven at 160 °C. Grind the magnesium oxide to a powder in a mortar. Sieve the powdered adsorbent through two sieves with mesh sizes of 60 and 180 mesh. Use the magnesium oxide that remains on the 180 mesh sieve
- diatomaceous earth, Celite 545 (Johns Manville Co, USA)*
- mixture of magnesium oxide (60-180 mesh) and Celite 545, 2:1 (m/m). Transfer the mixture to a conical flask with a glass plug and shake vigorously for 10 min. to obtain a homogeneous mixture. Transfer the mixture to on a glass plate and spread it evenly into a 1 to 2 cm layer. Heat the mixture for 2 hours at 160 °C ± 1 °C, and then store it in a tightly sealed bottle
- sodium sulfate water-free, p.a.
- DMSO-orthophosphoric acid iso-octane mixtures:For each analysis, place 300 ml of DMSO into a 1 000 ml separatory funnel and add 75 ml of orthophosphoric acid. Mix the contents of the separatory funnel and leave it to stand for 10 min. The reaction that occurs is moderately exothermic. Add 150 ml of iso-octane and shake to bring the mixture to equilibrium. Separate the two layers and store them separately in sealed bottles
- activated silicagel, Davison grade 923*. Activate the gel by heating 500 g in an oven at 160 °C for 24 hours; then leave to cool in an exsiccator. Store the gel in a tightly sealed glass bottle - molecular sieve, Union Carbide*, type 4A (0.5-5 µm). Activate by heating for 24 hours at 350 ± 5 °C. Cool and store in an exsiccator or tin box
- doubly distilled water, obtained by treating distilled water with a potassium permanganate solution that has been acidulated with sulphuric acid, and then distilling it again
- pressurised nitrogen, oxygen content less than 100 ppm (v/v)
- fine quartz or glass wool
- aluminium foil.

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[45] Specific trademarks or trade names are mentioned not as an endorsement but merely for identification purposes.

e. *Inspecting solvents and reagents for purity*

- dimethyl sulfoxide

  Place 120 ml of dimethyl sulfoxide in a 500 ml separatory funnel that contains 240 ml of doubly distilled water. Mix and leave to cool for 5 to 10 min. Then add 40 ml of iso-octane and extract by shaking vigorously for 2 min. Siphon the aqueous phase off into a second 500 ml separatory funnel that contains 40 ml of iso-octane, and again extract for 2 min. while shaking vigorously. Pour the aqueous phase off. Wash both extracts of 40 ml iso-octane separately three times, each for 1 min. with 50 ml of doubly distilled water. Pour the aqueous phase off. Filter the first extract over water-free sodium sulfate (previously washed with iso-octane) into a 250 ml evaporation flask. Wash the first separatory funnel while swivelling with the second extract and transfer the solvent to the same evaporation flask through the same sodium sulfate. In this order, wash the second and first separatory funnels with 10 ml iso-octane, and then combine the washing liquids, after filtering it through sodium sulfate, with the two filtrated extracts. Add 1 ml n-hexadecane and evaporate the iso-octane over a water bath of 80 °C, using the rotating vacuum evaporator while passing a small flow of nitrogen, until a volume of 1 ml is obtained. Add 10 ml iso-octane and again evaporate under the described conditions until a volume of 1 ml is obtained. Once again add 10 ml iso-octane and evaporate the solvent. Dissolve the remaining volume in 5 ml iso-octane and transfer the solution quantitatively to a 25 ml measuring flask. Then wash the evaporation flask four times with 4 ml iso-octane; transfer these portions to the measuring flask as well and fill with iso-octane up to the mark. Determine the extinction of the solution with respect to iso-octane between 280 and 400 nm in civets with an optic path length of 4 or 5 cm. The extinction should not be greater than 0.02 per cm of optic path length

- iso-octane

  Place 180 ml of iso-octane in a 250 ml evaporation flask together with 1 ml n-hexadecane, and follow the procedure described above. The extinction of the solution must not be greater than 0.01 per cm of optic path length

- acetone

  Place 200 ml of acetone in a 250 ml evaporation flask together with 1 ml n-hexadecane and follow the procedure described above. In this case, the temperature of the water bath should be 50 °C. The extinction of the solution must not be greater than 0.01 per cm of optic path length

- benzene

  Place 150 ml benzene in a 250 ml evaporation flask together with 1 ml n-hexadecane and follow the procedure described above. In this case, the temperature of the water bath should be 70 °C, and the two successive additions of 10 ml iso-octane should be replaced with two additions of 10 ml methanol. The extinction of the solution must not be greater than 0.01 per cm of optic path length. If the extinction curve exhibits the typical benzene peaks in the 250-260 nm wavelength band, evaporate again, and repeat until benzene is no longer detectable

- methanol

  Place 10 ml of methanol in a 250 ml evaporation flask together with 1 ml n-hexadecane, and follow the procedure described above. In this case, the temperature of the water bath should be 50 °C. The extinction of the solution must not be greater than 0 per cm of optic path length

- n-hexadecane

  Dilute 1 ml of n-hexadecane to 25 ml with iso-octane. The extinction of the solution must with respect to to iso-octane must not be greater than 0 per cm of optic path length in the 280-400 nm wavelength band

- doubly distilled water

  If the purity test described above for DMSO produces a higher value than the indicated limit, check whether the doubly distilled water is of the required purity by conducting the same test in the absence of DMSO

- sodium sulphate

  Wash 25 g of water-free sulfate in a buchner filter with 15 ml of purified iso-octane each time. The sodium sulfate is suitable for use if the extinction of the last portion of iso-octane per cm of optic path length in the 280 to 400 nm wavelength band, measured with respect to iso-octane, is not more than 0. Three portions of iso-octane are typically sufficient.

f. *Cleaning the glassware*

In light of the sensitivity of the method, it is necessary to remove all contaminations. To that end, the glassware must be subjected to several treatments with potassium dichromate-sulphuric acid, followed by washing with copious quantities of distilled water. In addition, all glassware must be washed with purified iso-octane prior to use.When using cleaning agents, it should be kept in mind that even traces of these can have disruptive effects on the method since they absorb UV light.Fats must not be used for greasing taps and ground joints; all taps should be made of PTFE. It is advisable to all glassware under UV light for any remaining fluorescent contaminants. Since some polycyclic aromatic hydrocarbons are prone to photo-oxidation, the entire procedure should be carried out in dimmed light.

g. *Procedure*

- *reagent blank*

  Simultaneously with the analysis of a paraffin sample, carry out the entire procedure as a blank test with the reagents, at the same temperature (90 °C). The UV extinction obtained in the reagent blank test after the extraction phase (phase A) must not be greater than 0.06 per cm of optic path length in the 280 to 400 nm wavelength band. The extinction obtained in the blank test with reagents after the chromatography phase (phase B) must not be greater than 0.07 per cm of optic path length in the 280 to 299 nm wavelength band, and not greater than 0.045 between 300 and 400 nm. If the extinction curve exhibits the typical benzene peaks between 250 and 260 nm, then the evaporation should be followed by adding new methanol and evaporating again, and then repeating these steps until benzene is no longer detectable.

- *phase A*

  Place a representative paraffin sample of 1 kg or, if this amount is not available, the entire sample, in a beaker of sufficient volume to contain three times the sample amount, and heat the beaker over a water bath while stirring continuously, until all the paraffin is completely melted and homogeneous. Weigh four amounts of melted paraffin of 25 ± 0.2 g each into individual 100 ml beakers. Conduct these steps in duplicate and reserve two portions in case the analysis must be repeated. Pour one of the fully melted weighed amounts into a 500 ml separatory funnel (separatory funnel No 1) containing 100 ml of the DMSO-orthophosphoric acid mixture, previously brought to equilibrium, that has been heated to a temperature of about 90 °C in the thermostatically controlled heating jacket. Complete the transfer of the sample into the separatory funnel with amounts of iso-octane, previously brought to equilibrium, while heating the beaker, and using a total volume of iso-octane of exactly 50 ml. Extract the paraffin by shaking vigorously for a few minutes, taking the customary precautions. Keep the temperature of separatory funnel No 1 at 90 °C. Prepare a series of four 250 ml separatory funnels, one of which is empty (No 2), while the other three contain 30 ml each of iso-octane previously brought to equilibrium (separatory funnels No 3, 4 and 5). After fully separating the two phases in separatory funnel No 1, carefully pour off the lower phase into the empty separatory funnel No 2. Leave this extract to cool down to room temperature. Paraffin crystals may develop on the surface of the liquid. Then slowly filter the extract through a wad of fine quartz wool of about 2 cm thick, tightly packed into a funnel of 7 cm internal diameter, into separatory funnel No 3. Extract the filtrate with the iso-octane present in this separatory funnel by shaking vigorously for 1 min. and after separating the phases, transfer the lower phase directly to separatory funnel No 4.

After a similar extraction and separation, transfer the lower phase from separatory funnel No 4 to separatory funnel No 5, and extract this by shaking vigorously for 1 min. and leave to demix. Then place the lower phase in a 2 000 ml separatory funnel (separatory funnel No 6). If a solid paraffin layer has remained in separatory funnel No 2, seal it with a plug, heat the funnel over a steam bath until the paraffin has melted; then pour the melted paraffin back into separatory funnel No 1. Then extract the solution of the paraffin sample in separatory funnel No 1 twice more, in the manner described above, each with 100 ml of DMSO-phosphoric acid mixture, previously brought to equilibrium, following all the above steps, until the three extracts of DMSO-phosphoric acid (3 x 100 ml) have been combined in the aforementioned separatory funnel (separatory funnel No 6).

Divide the extract among two 250 ml centrifuge tubes, them add 10 ml iso-octane to each tube. Centrifuge for 15 min. at 2 000 rpm; then carefully transfer the contents of the two tubes to the separatory funnel used earlier (separatory funnel No 6).Remove the iso-octane layer. Add 480 ml of doubly distilled water, mix the contents together, and leave to cool for a few minutes. Add 80 ml of iso-octane and extract by shaking vigorously for 2 min. Then transfer the aqueous sublayer to a 2 000 ml separatory funnel (separatory funnel No 7), which also contains 80 ml iso-octane. Repeat the extraction in separatory funnel No 7; after phase separation, remove the aqueous phase.

Wash each of the two 80 ml iso-octane extracts in the two 2 000 ml separatory funnels (Nos 6 and 7) successively with three portions of doubly distilled water of 100 ml each. Pour the washing water off after demixing. The shaking time for these washings is 1 min. each, paying special attention to the separation of the phases after the washings, since some emulsification may occur in the separation plane. A longer waiting time is sufficient for the emulsion to be undone. Filter the first extract through a buchner filter containing 35 g of purified water-free sodium sulfate, and collect the filtrate in a 250 ml evaporation flask.

Wash separatory funnel No 6 with the second iso-octane extract and filter through the same büchner filter. In the order indicated, wash separatory funnels Nos 7 and 6 with a single 20 ml portion of iso-octane, and then filter through the same buchner filter into the evaporation flask.

To the filtrate so collected, ad 1 ml of n-hexadecane and evaporate using the rotating evaporator over a 80 °C water bath while applying a small flow of nitrogen and very little vacuum.

Stop the evaporation when a little more than 1 ml of liquid is left. Add two successive 10 ml portions of iso-octane, each time repeating the evaporation and dissolving the final 1 ml evaporation residue in 5 ml iso-octane. Transfer this quantitatively to a 25 ml measuring flask, wash the evaporation flask four times with 4 ml iso-octane each, and then fill the contents up to the mark with the same solvent.

In a cuvette with an optic path length of 5 cm, determine the extinction curve between 280 and 400 nm:

- of the reagent blank solution with respect to iso-octane
- of the solution obtained from the paraffin sample being examined with respect to the reagent blank solution.

As indicated above, the extinction of the reagent blank solution in the 280 to 400 nm wavelength band must not be more than 0.060 per cm of optic path length. The paraffin being examined may be considered suitable for use if the extinction per cm of optic path length does not exceed the following limits:

wavelength (nm)	*extinction per cm of optic path length*
280 – 289	0.15
290 - 299	0.12
300 - 359	0.08
360 - 400	0.02

If the extinction values do exceed these limits, the procedure is as follows:

- *phase B*

Transfer the iso-octane solution quantitatively to a 250 ml evaporation flask and evaporate the solution using the rotating evaporator in the manner described above until a 1 ml residue of n-hexadecane is obtained. To this, add 10 ml methanol and - using the measuring glass - about 0.3 g sodium tetrahydroborate, taking care that the exposure of this salt to the ambient air is kept as short as possible. This is facilitated by using the calibrated measuring glass. The reagent may be placed directly in the flask without sticking to the ground joint, so that the flask can be removed from the cooler without problem. Then quickly place the straight cooler onto the flask and attach a drying pipe, containing a molecular sieve A4, to the end. Leave the whole combination to stand at ambient temperature for 30 min., shaking from time to time. Then remove the cooler and carefully evaporate the methanol in the rotating evaporator, while adding a small nitrogen flow and a little vacuum, without submerging the flask in the water bath, until a 3 to 4 ml volume remains. Then add 10 ml iso-octane to the flask and evaporate to a 3 to 4 ml volume; again add 10 ml iso-octane and evaporate until the volume of the residue is about 5 ml.
Transfer the liquid quantitatively to a 100 ml separatory funnel and wash the flask with 5 ml iso-octane. Dissolve the sodium tetrahydroborate residue in the flask in 5 ml doubly distilled water, encouraging it to dissolve fully by heating carefully over the water bath; then transfer the solution to the same separatory funnel. Wash the flask with three more 5 ml portions of doubly distilled water, and finally with 5 ml iso-octane; then pour each portion of washing liquid off into the same separatory funnel.
Extract by shaking for 1 min. and pour the aqueous phase off into a second 100 ml separatory funnel. Add 5 ml iso-octane, shake for 1 min. and pour the aqueous phase off. Filter the first 15 ml iso-octane extract through a conical funnel fitted with a filter that contains 6 g of purified water-free sodium sulfate, and collect the filtrate in a 50 ml flask.
Wash the first separatory funnel with the second 5 ml iso-octane extract, and then filter the washing liquid through the same filter with sodium sulfate into the 50 ml flask. Carry out a final wash of the second and first separatory funnels, in the order given, with a single 5 ml portion of iso-octane; then filter the washing liquid as well through the same filter with sodium sulfate into the 50 ml flask.
Prepare the chromatography column as follows:
Weigh 14 g of the 2:1 magnesium oxide and Celite 545 mixture; then transfer the adsorbent to the chromatography column, taking care that it is filled evenly by using a glass rod that has been flattened at one end to a diameter slightly smaller than that of the column itself. If this procedure is followed, the filling level will be 10 to 11 cm. To prevent photo-oxidation of polycyclic aromatic hydrocarbons the column must be wrapped in aluminium foil.Place a 500 ml reservoir onto the chromatography column, and then connect the nitrogen supply to it. Percolate 100 ml iso-octane through the column. Adjust the nitrogen pressure to obtain an iso-octane outflow rate of 2 to 3 ml/min.Remove the pressure just before the last portion of iso-octane reaches the level of the adsorbent. The liquid level must not drop below the adsorbent level. Transfer the iso-octane extract in the 50 ml flask to the column, and then wash the flask with 10 ml iso-octane.

Successively place the extract and the washing liquid onto the column; before the liquid level reaches the adsorbent level, add 80 ml iso-octane to the reservoir. Percolate at the aforementioned rate, and add 100 ml of a solution of 10% benzene in iso-octane, just before the iso-octane level reaches the adsorbent level. Then continue the percolation at the same rate. Just before the level of this mixture reaches the adsorbent level, add 25 ml of a solution of 20% benzene in iso-octane and continue the percolation at the same rate until all liquid has passed through the column. Remove the percolated liquid collected up to this time. To the reservoir add 300 ml of the acetone benzene-water mixture and eluate at a rate of 2 to 3 ml/min. Collect the eluated product in a 500 ml flask until all liquid has fully run out of the column. Add 1 ml n-hexadecane to the eluate, and evaporate using the rotating evaporator over a 60 °C water bath to a volume of about 1 ml. Successively add two 10 ml portions of methanol for a better removal of the benzene, evaporating each to about 1 ml. Add 5 ml iso-octane to the last residue; then transfer the whole amount quantitatively into a 25 ml measuring flask, wash the evaporation flask with four successive 4 ml portions of iso-octane, and fill with the same solvent up to the mark.

In a cuvette with an optic path length of 5 cm, determine the extinction curve between 250 and 400 nm:

- of the reagent blank solution with respect to iso-octane
- of the solution of the paraffin sample being examined with respect to the reagent blank solution.

The extinction of the reagent blank solution must not be greater than 0.070 per cm of optic path length between 280 and 299 nm, and 0.045 between 300 and 400 nm. The extinction of the paraffin sample being examined must meet the requirements specified in Section 1(b).

If one or both spectra exhibits the typical benzene peaks in the 250 to 260 nm range, evaporate the liquid again, add 10 ml methanol, and then evaporate once more. Repeat these steps, collect the residue in iso-octane, transfer the whole amount quantitatively into a 25 ml measuring flask, and then fill the volume with iso-octane up to the mark. Then determine the extinction again.

ANNEX 1. Procedure for the determination of dimethyl sulfoxide for spectrophotometry from a less pure product

a. *Principle*

Dimethyl sulfoxide (DMSO) that does not meet the requirements is purified by percolating through a chromatography column containing a layer of silica gel and a layer of active carbon.

b. *Equipment and reagents*

- chromatography column, for percolation of DMSO. Length 150 cm, internal diam. 2.5 cm, fitted with ground joints. The bottom of the column tapers to an internal diameter of 0.6 cm. The column is fitted with a PTFE tap
- separatory funnel, 2 000 ml volume, fitted with a ground joint, PTFE tap and drying pipe, with molecular sieve, type 5A, activated at 350 °C for 24 hours
- cylindrical receptacle, 1 000 ml volume, with 50 ml graduation, fitted with a ground joint, PTFE tap and a drying pipe with molecular sieve, type 5A, activated at 350 °C for 24 hours
- activated silica gel, Davison grade 923[46]100-200 mesh, activated at 190 °C for 24 hours and cooled down in an exsiccator prior to use
- active carbon, 30-50 mesh, Norit N.*, or equivalent type, activated at 190 °C for 24 hours and cooled down in an exsiccator prior to use
- molecular sieve, Union Carbide*, type 5A, activated at 350 °C for 24 hours prior to use
- quartz cuvettes with an optic path length of 1 cm, with tightly-closing PTFE plug.

c. *Procedure*

The percolation equipment is set up as follows:

Insert a wad of glass wool into the lower end of the column, place 50 g of silica gel into the column and place 175 g active carbon on top. Place the separatory funnel onto the column and connect the cylindrical receptacle to the bottom of the column. Place 1 600 ml of the DMSO being purified in the separatory funnel, and percolate the DMSO at atmospheric pressure. The percolation rate is about 100 ml/hr. Discard the first 50 ml fraction. Then collect about 950 ml in three fractions of about 300 ml each.
Check the purity of each fraction by measuring the UV extinction in a quartz cuvette of 1 cm, after having removed all oxygen from the contents of the cuvette by passing nitrogen through for 15 min. Measure the extinction with respect to distilled water. Fractions meeting the specifications for DMSO given in Section 1(d) are suitable for UV spectroscopy. Repeat the percolation process with fresh adsorbents if the extraction agent fails to meet the specification. Combine the usable fractions and store the DMSO under nitrogen in dark-coloured glass bottles tightly sealed with glas plugs. The extraction agent is now ready for use.

Note: It is found in practice that despite careful purification, the DMSO from some suppliers still fails to meet the aforementioned specifications. When small discrepancies are found, this should be taken into account in the remaining steps.

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[46] Specific trademarks or trade names are mentioned not as an endorsement but merely for identification purposes.

2 Ultraviolet light absorption by liquid paraffins

a. *Introduction*

This method is intended for the determination of traces of polycyclic aromatic hydrocarbons in liquid paraffins that come into contact with foodstuffs. These products are petroleum-derived mixtures of saturated liquid hydrocarbons containing traces of monoaromates. This method cannot be applied to paraffins containing additives or substances that are soluble in dimethyl sulfoxide and that either exhibit or dampen fluorescence.

b. *Principle*

A sample of the paraffin, dissolved in n-hexane, is extracted once with dimethyl sulfoxide. The extract is washed once with n-hexane and then centrifuged to accelerate the phase separation. The clear extract is placed into a quartz cuvette, and pure nitrogen is passed through to remove any dissolved oxygen. The UV extinction of the extract is then measured in the 260-350 nm wavelength band with respect to a reagent blank. If the extinction of the extract does not exceed 0.10 at any wavelength in this range, the paraffin is approved.

c. *Equipment*

- separatory funnels, made of borosilicate glass, fitted with normal ground joints and plugs and PTFE taps. Volumes 50 ml and 100 ml
- 5 ml pipettes
- measuring cylinders, volume 25 ml, with graduation
- chromatography column, see Figure 1.2, length about 1 200 mm, internal diam. 50 mm, fitted with a PTFE tap and fitted with a side pipe at the top for overflow
- a spherical reservoir made of borosilicate glass, connected to a PTFE tap at the bottom by a normal ground joint 29/32, and to a right-angle pipe at the top, also by a normal ground joint 29/32, for pressure equalisation between the column and the reservoir
- spectrophotometer, 220-400 nm wavelength band, with a spectral slit width of 2 nm or less. The device must also meet the following requirements:

  - duplicability of the extinction: ± 0.01 for an extinction of 0.4
  - accuracy of the extinction: ± 0.05 for an extinction of 0.4
  - duplicability of the wavelength: ± 0.2 nm
  - accuracy of the wavelength: ± 1.0 nm

- quartz cuvettes with an optic path length of 1.000 ± 0.005 cm, fitted with a tight-fitting PTFE plug.
  Note: For cuvettes with a loose lid, entry of air into the cuvette cannot be prevented. The use of this type of cuvette is therefore strongly discouraged.
- laboratory centrifuge, speed 2 500 rpm, fitted with conical glass centrifuge tubes with a volume of 10 ml with tightly fitting PTFE plugs.

d. *Reagents and purification of reagents and auxiliaries*

- n-hexane, for spectrophotometry, with an UV extinction per cm of optic path length in the 260-350 nm wavelength band of no more than 0.02. If necessary, n-hexane for spectrophotometry may be prepared as follows from 'pure' n-hexane:
  Combine 10 volume parts n-hexane with one volume part 98% sulphuric acid and shake or stir vigorously for 10 min. Let it stand for 10 minimum, and then siphon off the sulphuric acid layer. Repeat this operation until the acid layer remains colourless. Wash the hexane layer with a 5% aqueous solution of potassium hydroxide until the washing water reacts basically. Then wash with distilled water until the washing water reacts neutrally. Dry the n-hexane layer over activated molecular sieve 4A granules and percolate through activated silicagel until the eluaat meets the aforementioned UV extinction requirement
- iso-octane (2,4,4-trimethyl pentane) for spectrophotometry, purified if necessary by percolating through activated silicagel until the extinction per cm of optic path length at 220 nm is less than 0.10

- dimethyl sulfoxide (DMSO) for spectrophotometry, moisture content no more than 0.10%, determined according to Karl Fischer, or with an freezing start point of at least 18.3 °C. The extinction of DMSO is measured in a cuvette with an optic path length of 1 cm with respect to distilled water, after the DMSO has been cleared of oxygen in the cuvette by passing a small flow of dry nitrogen through for 15 min. The extinction must not exceed the following limits:

wavelength, nm	*extinction per cm of optic path length*
261.5	1.00
264	0.64
270	0.19
275	0.07
280	0.03
300	0.01

The extinction curve must not exhibit any irregularities in the 260-350 nm wavelength band. If necessary, the DMSO may be purified, following the method described in Annex 1 of Section 1. The DMSO must be stored in a tightly sealed, dark-coloured glass bottle with a PTFE screwcap. In view of the strongly hygroscopic properties of DMSO, excessive exposure to the ambient air should be avoided. Contact with metals should also be avoided, since DMSO reacts with some metals, e.g. copper, in the presence of air

- naphthalene, National Bureau of Standards Material No 577 or material of equivalent purity
- standard reference solution containing 7.0 mg of naphthalene per l of iso-octane.This solution has an extinction at 275 nm of about 0.30 in a cuvette with an optic path length of 1 cm
- pressurised nitrogen, oxygen content less than 10 ppm (v/v).
- molecular sieve, Union Carbide, type 4 [47], granules of 1.6 mm. Activate by heating to 350±5 °C for at least 24 hours. Keep the granules in an exsiccator or in a closed tin box
- activated silicagel, Davison grade 12*. Activate by heating at 190 °C for 24 hours and then leave to cool in an exsiccator. Store in a tightly sealed glass bottle or tin.

e. *Treatment of the sample and cleaning of glassware*

In light of the sensitivity of the method, any possible contamination should be avoided. Therefore, avoid contact between the paraffin sample and any plastic packaging material or vessel - other than PTFE - which may contain extractable softeners, antioxidants, UV stabilisers, etc. Use only brown glass bottles with a glass or PTFE plug.
The laboratory glassware must be subjected to several treatments with potassium dichromate-sulphuric acid followed by washing with copious quantities of distilled water. In addition, all glassware must be washed with purified n-hexane prior to use.
When using cleaning agents, it should be kept in mind that even traces of these can have disruptive effects on the method since they absorb UV light.
Fats must not be used for greasing taps and ground joints; all taps should be made of PTFE. It is advisable to all glassware under UV light for any remaining fluorescent contaminants.
Since some polycyclic aromatic hydrocarbons are prone to photo-oxidation, the entire procedure should be carried out in dimmed light.

f. *Procedure*

Check the spectrophotometer by determining the extinction of the standard reference solution at 275 nm in a 1 cm cuvette with respect to iso-octane. This extinction should be about 0.30.
Measure 25 ml of the paraffin sample into a 25 ml measuring cylinder and transfer this quantity to a 100 ml separatory funnel. Then measure 25 ml n-hexane in the same measuring glass, transfer it to the funnel and mix.
Using a pipette, add 5.0 ml dimethyl sulfoxide and shake the mixture vigorously for 2 min. Remove the plug from the separatory funnel to allow the liquid film between the ground joint of the funnel and the plug to flow back into the funnel, and immediately place the plug

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[47] Specific trademarks or trade names are mentioned not as an endorsement but merely for identification purposes.

back on the funnel. Let it stand for 15 min.
Transfer the lower layer to a 50 ml separatory funnel, add 2 ml n-hexane and shake the mixture vigorously for 2 min. Let it stand for 2 min. Then carefully pour most of the lower layer off into a conical centrifuge tube with a volume of 10 ml until the separation plane is 1 to 2 mm higher than the opening of the tap on the separatory funnel.
Close the centrifuge tube immediately with a PTFE plug; then centrifuge for 10 min. at 2 500 rpm. Transfer the entirely clear lower layer, referred to as the "paraffin extract," to a cuvette with an optic path length of 1 cm, using a 5 ml pipette.
If the lower layer is not clear, the centrifuging should be repeated until it is clear. Prepare the reagent blank as follows:
Using a pipette, add 5.0 ml dimethyl sulfoxide to 25 ml n-hexane in a 50 ml separatory funnel. Shake the mixture vigorously for for 2 min. and let it stand for 2 min. Then carefully pour off the majority of the lower layer into a centrifuge tube with a volume of 10 ml, until the separation plane is 1 to 2 mm higher than the opening of the tap. Immediately close the centrifuge tube with a PTFE plug and centrifuge for 10 min. at 2500 rpm.
Use a pipette to transfer the entire clear lower layer, referred to as 'reagent blank', to a 1 cm cuvette. Remove the oxygen from the contents of both cuvettes by passing a small dry nitrogen flow (about 0.7 l/hr) for 15 min. through a feeder tube with an internal. diam. of about 5 mm, one end of which has been elongated to a capillary with an internal diam. of 0.5 mm. Ensure that the contents of the cuvettes do not foam over. Then immediately seal the cuvettes tightly with a PTFE plug.
Dissolved oxygen increases significantly increases the UV extinction of dimethyl sulfoxide. Serious errors can easily occur if either the extract or the reagent blank solution still contains small quantities of dissolved oxygen. Conversely, the presence of about 1% water, caused by exposure of the highly hygroscopic DMSO to the ambient air, will lead to a reduction in the UV extinction of DMSO.
Immediately after passing the nitrogen through, determine the extinction of the paraffin extract with respect to the reagent blank in the 260-350 nm wavelength band, to two decimals. The results of a duplicate test carried out by the same laboratory assistant must differ by no more than 0.02 in the 260-350 nm wavelength band.

g. *Reporting*

Give the extinction of the paraffin extract, measure with respect to the reagent blank, to two decimals for the wavelengths 260, 264, 270, 275, 280, 285, 290, 295, 300, 325 and 350 nm. If the extinction does not exceed 0.10 for any of the indicated wavelengths, the paraffin is approved.

3 Ultraviolet light absorption by montane waxes

a. *Introduction*

This method is intended to determine traces of polycyclic aromatic hydrocarbons with four or more condensed benzene rings in montane waxes intended for use on or in packaging materials or consumer articles coming into contact with foods or beverages.

b. *Principle*

The procedure is largely the same as described in Section 1 for the determination of the proportion of polycyclic aromatic hydrocarbons in paraffin. However, montane waxes contain more polar ingredients in addition to hydrocarbons, which must be separated from the aromatic compounds using adsorption chromatography over aluminium oxide, prior to the UV extinction measurement.

c. *Equipment*

The equipment is the same as described in Section 1 c. However, the adsorption chromatography uses a tub with a length of 1 200 mm, fitted with a porous, coarsely sintered glass plate, a PTFE tap, and a normal ground joint B 24/29 with glass hooks at the top end.

d. *Reagents and purification of reagents and auxiliaries*

For the specification and purification of the solvents and auxiliaries mentioned below, see Section 1 d.

- iso-octane
- benzene
- n-hexadecane
- dimethyl sulfoxide
- orthophosphoric acid
- dimethyl sulfoxide-orthophosphoric acid mixture
- sodium sulfate, water-free
- iso-octane, saturated with dimethyl sulfoxide-orthophosphoric acid
- silica gel
- molecular sieve, type 44
- nitrogen
- heating liquid (silicone oil)
- quartz or glass wool
- aluminium oxide, Woelm[48], neutral, activity I or equivalent material.

Deactivate this aluminium oxide as follows:

> Use a pipette to place 1 ml of distilled water into a glass bottle with plug. Divide the water as evenly as possible over the interior wall of the bottle; then place 200 ml aluminium oxide in the bottle. Shake until there are no more lumps or moisture stains visible, and let it stand for another 2 hours.

Check the purity of the reagents and auxiliaries in accordance with Section 1 and clean the glassware in accordance with Section 1 f. Conduct the reagent blank determination in accordance with Section 1 g.

e. *Procedure*

Conduct the determination of the polycyclic aromatic compounds proportion in montane wax as described in Section 1 g, phase A for solid paraffins, up to the step of processing the iso-octane-dissolved residue of the iso-octane extract. Then proceed as follows:Add 1 ml of purified n-hexadecane and evaporate the iso-octane at reduced pressure (water-jet pump) at a temperature not exceeding 100 °C (silicone oil bath), and then slowly percolate nitrogen through the liquid. Keep the flask in the oil bath for another 1 hour.

Fill the chromatography column as follows: Place 200 ml of deactivated aluminium oxide into the column, while softly tapping the tube wall with a piece of vacuum tube, starting from the lower end of the tube and proceeding slowly upwards, until the adsorbent level is stable.

Wrap the column in aluminium foil to prevent photo-oxidation of polycyclic compounds during chromatographic separation. Do not moisten the column. Dissolve the residue obtained from the iso-octane in 10 ml benzene and place the solution onto the column. Wash the flask twice more with 5 ml benzene. Allow the liquid level, applying slight nitrogen pressure, to drop to just above the adsorbent level. Connect the reservoir to the top end of the chromatography column, and fill it with benzene. Then percolate with a total of 700 ml benzene at a rate of 2 to 3 ml/min. Stop the percolation when the benzene level has reached the adsorbent level.

Place successive parts of the eluaat into a 250 ml distillation flask, and remove all benzene by evaporating under lowered pressure (water-jet pump), while passing a small flow of nitrogen through the liquid. The temperature of the bath must not be higher than 100 °C. Stop the evaporation when no more than 1 ml of residue (the previously added quantity of n-hexadecane) is left.

Add 10 ml of iso-octane, evaporate again, and repeat to remove all benzene.Transfer the residue with a little iso-octane quantitatively to a 25 ml measuring flask, wash the evaporation flask four times with 4 ml iso-octane, and fill the measuring flask with iso-octane up to the mark.

Then determine, in a 5 cm cuvette, the extinction curve between 250 and 400 nm:

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[48] Specific trademarks or trade names are mentioned not as an endorsement but merely for identification purposes.

- of the reagent blank solution with respect to iso-octane
- of the solution of the montane wax sample being examined, with respect to the reagent blank solution.

The extinction of the reagent blank must not be more than 0.070 per cm of optic path length between 280 and 299 nm. The extinction of the wax sample being examined must meet the following specification:

wavelength (nm)	*extinction per cm of optic path length*
280 - 289	no more than 0.15
290 – 299	no more than 0.12
300 - 359	no more than 0.08
360 - 400	no more than 0.02

Evaporate the liquid again if either spectrum exhibits the typical benzene peaks in the 250 to 260 nm range. Then add 10 ml of methanol and evaporate again. Repeat these steps, collect the residue in iso-octane, transfer the liquid quantitatively to a 25 ml measuring flask, and make up with iso-octane. Then determine the extinction again.

4 Purity of soot (furnace black and channel black) and other carbon products such as graphite and coke powder

4.1 Determination of the toluene-soluble part

a. *Specification*

The proportion of toluene-extractable components of soot and other carbon products, to be referred to hereinafter as 'soot', must not be higher than 0.15%.

b. *Principle*

The soot is extracted with toluene in a Soxhlet extractor. After the extraction period, the extraction agent is evaporated, and the residue is weighted.

c. *Equipment*

- Soxhlet extraction equipment
- extraction sleeves of paper fibre that can contain 10 g of soot
- laboratory glassware
- hearth that can be set to 140 ± 5 °C.

d. *Reagents*

- toluene.

e. *Conducting the determination*

Dry a sufficiently large sample of soot at 105 ± 2 °C for 1 hour. Place about 10 g of soot, weighed with a precision of 0.1 g, in a toluene-extracted extraction sleeve. Seal the sleeve with a wad of toluene-extracted cottonwool; then place the sleeve into the Soxhlet extractor. Extract the soot for 8 hours with about 150 ml of toluene. Adjust the heater setting so that the extraction agent in the extraction vessel is replaced about 10 times per hour.
Then allow to cool down, remove the flask from the extractor, and evaporate the extract to a small volume. Transfer the residue with a little toluene to a weighed glass dish (weight a g) and evaporate the toluene over a water bath. Then place the dish in a hearth at 140±5 °C for 2 hours. Allow to cool down in an exsiccator, then weigh the dish again (weight b g).

f. *Calculation*

From the weight difference, b minus a, calculate the toluene-extractable part E of the soot using the formula:

E = 10 (b - a)%

5 The proportion of soluble elements in colourants and pigments

a. *Specification*

When extracting with 0.1 N hydrochloric acid, the quantities of any of the elements listed in in Annex A, Chapter XI, dissolved from colourants or pigments (to be referred to hereinafter as 'colouring agents') used for colouring packaging materials or consumer articles, must not exceed the quantity specified in that section, calculated based on the weight of the colourant.

b. *Determation of solubility in 0.1 N hydrochloric acid*

In a conical flask or beaker, place 10 g of colouring agent, and moisten with some ethanol. Then add 150 ml of 0.1 N hydrochloric acid of about 23 °C. Stir the mixture for 15 min. such that all of the colouring agent is in suspension, keeping the temperature constant at 23 °C. Then filter or centrifuge the suspension. In the extract, determine the proportion of the elements listed in Annex A, Chapter XI, using customary methods, and express the results as a percentage of the weight of the colouring agent. Then assess the results against the specified limits.

6 Proportion of soluble aromatic amines in colourants and pigments

a. *Specification*

When extracting ethanolic hydrochloric acid, the quantity of aromatic amines dissolved from colourants or pigments (referred to hereinafter as 'colouring agents') must be no more than 0.05% in terms of the weight of the colouring agent.

b. *Conducting the determination*

Weigh about 2 g of colouring agent accurately into a 300 ml conical flask with a plug. Then add 100 ml of 2 N ethanolic hydrochloric acid and 20 ml of distilled water. Shake the closed conical flask vigorously at room temperature for 15 min., using a shaking device. Then transfer the contents of the flask to a beaker and dilute with a triple quantity of distilled water. Stir the mixture and filter through a glass filter. Transfer the filter cake to a second conical flask and repeat the steps. Collect the filtrates in a 1 l measuring flask and make up with distilled water.
Pipette 20 ml of the solution into a 100 ml conical flask and add 1.7 ml of a 8.8 N hydrobromic acid solution. Cool to a temperature between 0 and 5 °C; then add 0.4 ml of a 0.5 M sodium nitrite solution. Keep the temperature constant for 5 min. Decompose the excess sodium nitrite with 1 ml of a 1 M ammonium sulfamate solution. Swivel vigorously, and then let it stand for a few minutes. Then place 4 ml of a 0.75% solution of the disodium salt of 2-naphthol-3,6-disulfonic acid (R-salt) in 6M ammonia into a 50 ml measuring flask, and wash the diazoted solution in the conical flask with distilled water, passing it into the measuring flask. Let it stand at room temperature for about 10 min.; then shake vigorously. Fill the measuring flask up with distilled water.
In a 1 cm cuvette, measure the extinction of the solution at the maximum of the extinction curve. The maximum is located between 490 and 520 nm. Using a calibration line based on aniline, determine the concentration of aromatic amines in the solution, calculated as aniline, and express the result as a percentage of the weight of the colouring agent.

CHAPTER III Risk assessment of non-intentionally added substances (NIAS) based on the TTC principle