



Introduction

Depesche Vertrieb GmbH & Co. KG

Vierlander Str.14

21502 Geesthacht

Germany

Customer article code: N/A

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COMMISSION REGULATION (EU) 2019/1338

With this document I would like to explain you the procedures followed by DBP Plastics, before plastic food packaging can be sold and the declaration of compliance according to annex IV of regulation 10-2011.

Good manufacturing practices (GMP)

Food contact materials need to be produced according to good manufacturing practices, as laid down in European regulation 2023/2006. In this regulation the production circumstances to meet and control the quality- and hygiene criteria are clear. For example operators wear protective clothing to protect the packaging. Of course this is done at DBP Plastics as well, we are BRC Packaging certified with an AA+ grade. (Unannounced audits)

General

Food is being packed to store it and protect it for deterioration.

Substances can move from the packaging to the food, we call this migration. That is why all substances are prohibited as plastic food contact material unless can be demonstrated the substance is safe to use. To demonstrate this, we have to take into account different European legislations. According to article 3 of European Framework regulation 1935/2004 all food contact materials must be safe and endanger no human health. For plastic food contact materials additional European regulation 10/2011 is applicable.

Monomers

Monomers are the blocks plastic raw material is made of. Allowed monomers to use are recorded on the positive list European regulation 10/2011. Before these monomers are added on the list detailed toxicological investigation is done by an independent institute EFSA, the European Food Safety Authority. They check if the monomer is suitable to use in plastic food contact materials and advises the European Commission. Based on this advice the European Commission decided

to add the monomer on the positive list.

Additives

Additives are added to improve the plastic properties to achieve the requirements. These used additives are present on this same positive list as well and the same approval procedure is followed, like monomers.

Other used substances

Other used substances are on the European positive list, in regulations or legislations in other European member states or are investigated according to international allowed principles, and based on that considered as safe.

Phthalates

Tests with simulants according to European regulation 10/2011 demonstrated no phthalates could be detected. The detection limit was 0,02 ppm.

The polypropylene plastics we supply at DBP Plastics do not need these plasticizers to make them soft and flexible.

Bisphenol A and PVC

Based on statements from our raw material suppliers we are able to declare no Bisphenol A or PVC is present in our products. It is not intentionally added and not formed during our injection molding process.

For your information: Bisphenol A is formed during the production of polycarbonate.

At DBP Plastics we do not have polycarbonate or PVC products in our assortment.

Migration

Not only the raw materials must be tested to demonstrate they are food approved. Also on the finished products migration tests must be done. This is done at an independent accredited laboratory as written in article 1(32) of EU 10/2011. The total allowed amount of migrate-able substances is written in the European regulation and based on toxicological investigations.

At DBP Plastics we have the opinion plastic packaging can only be sold after detailed tests have been done to demonstrate the correct substances have been used and the movement of substances from the plastics to the food is in compliance.

DPB Plastics only sell products who comply to all food safety regulations.

Remark

This Declaration of Compliance is made in FOCOS, a software program supporting compliance work.

According to the European technical guidelines for migration testing, family approach is used. Compliance work on substances with a specific migration limit (sml) is done on the highest concentration in generic raw materials in worst case scenarios (6 dm²/kg) based on overall migration results, 100% migration calculations, maximum thickness calculations, compliance declarations from our suppliers, additional specific migration tests (10ppb scans) or modelling with AKTS and MIGRATEST software (using the plastic properties, solubility, concentration of substance, molecular weight, time and temperature).

The specific migration test results are calculated based on the maximum concentration which I received under secrecy agreement from our suppliers. As these actual concentrations in the plastics are usually lower, the migration results in practice will be lower as well as written in this declaration. As modelling, based on literature details, are always overestimated, these migration results will be lower as well in practice. The overall migration results are published as measured. No correction is made because of the measuring accuracy from 2 mg/dm² (12 mg/kg) for the aqueous simulants acetic acid and ethanol and the 3 mg/dm² (18 mg/kg) for the vegetable oil simulant.

According to this family approach the DoC is valid for a product family and independent from the colours and in mould labels used (where appropriate) on the finished products.

According to paragraph 32 of regulation EU 10-2011, test results should be regarded as valid as long as formulations and processing conditions remain constant as part of a quality assurance system.

On every raw material overall migration tests are done. According to paragraph 16 article 1 of regulation EU 10-2011, migration tests shall be made available by the business operator to the national competent authorities on request. They do not need to be sent to customers.

All products have to be stored under clean, dry and odorless conditions.

If you have questions about this Declaration of Compliance, please contact the Quality Manager at DBP Plastics n.v.

Kind regards,

Alfred Olthof

A handwritten signature in black ink, appearing to read 'Alfred Olthof', is written over a horizontal line. The signature is stylized and cursive.

DBP Plastics NV

Terbekehofdreef 25-29

2610

Antwerpen-Wilrijk

Belgium

1. Issued by

DBP Plastics NV (Hereinafter referred to as "We", "Us", or "Our").

Terbekehofdreef 25-29

2610

Antwerpen-Wilrijk

Belgium

2. Manufactured/imported by

DBP Plastics nv

Terbekehofdreef 25-29

2610

Wilrijk

Belgium

3. Identity of the product

V-000948 Snack box M829 (Hereinafter referred to as "Product").

Product type: Final material or article

Product description: V-000948 Snack box Princess Mimi

Compliance work based on: SCHAR RANDOM PASTA IML 6 dm²/kg

4. Issue date

2019-11-25

5. Applicable legislation and purity confirmation

European Commission Regulation definition:

- REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC,

(hereinafter referred to as "Regulation (EC) No 1935/2004").

- 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, amended up to COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008, (hereinafter referred to as "Regulation (EC) No 2023/2006").

- COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended up to Commission Regulation (EU) 2019/1338 of 29 August 2019., (hereinafter referred to as "Regulation (EU) No 10/2011").

- COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006, amended up to COMMISSION REGULATION (EU) 2015/1906 of 22 October 2015, (hereinafter referred to as "Regulation (EC) No 282/2008").

A. Europe

i. Compliance with the requirements of the Framework Regulation

- Regulation (EC) No 2023/2006; Good Manufacturing Practice (GMP): YES
- Article 3 of Regulation (EC) No 1935/2004; General safety aspects: YES
- Article 17 of Regulation (EC) No 1935/2004; Traceability: YES

ii. Compliance with the requirements of the Plastics Regulation

- Regulation (EU) No 10/2011: YES

Plastics used to produce this Product and not separated from the food by a functional barrier are manufactured from only monomers, other starting substances and additives authorized under Regulation (EU) No 10/2011.

iii. Compliance with the requirements of the Recycled Plastics Regulation

- Regulation (EC) 282/2008: NOT APPLICABLE

iv. Other EU legislation

Material group	Country	Legislation
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PLASTICS	Europe - 10/2011	<p>COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.</p> <p>Amended by:</p> <p>Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011</p> <p>Commission Regulation (EU) No 1282/2011 of 28 November 2011</p> <p>Commission Regulation (EU) No 1183/2012 of 30 November 2012</p> <p>Commission Regulation (EU) No 202/2014 of 3 March 2014</p> <p>Commission Regulation (EU) No 2015/174 of 5 February 2015</p> <p>Commission Regulation (EU) No 2016/1416 of 24 August 2016</p> <p>Commission Regulation (EU) No 2017/752 of 28 April 2017</p> <p>Commission Regulation (EU) No 2018/79 of 18 January 2018</p> <p>Commission Regulation (EU) No 2018/213 of 12 February 2018</p> <p>Commission Regulation (EU) No 2018/831 of 5 June 2018</p> <p>Commission Regulation (EU) No 2019/37 of 10 January 2019</p> <p>Commission Regulation (EU) No 2019/1338 of 8 August 2019</p> <p><u>Specification of use</u></p> <p>n/a</p>
	Europe - 1895/2005	<p>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</p> <p><u>Specification of use</u></p> <p>n/a</p>
PRINTING INKS	Europe - 1935/2004; non- listed intentionally added substances	<p>Compliance with Article 3 of Regulation (EC) No 1935/2004 of non-listed intentionally added substances is assessed in accordance with internationally recognised scientific principles on risk assessment.</p> <p><u>Specification of use</u></p> <p>n/a</p>

PLASTICS	Europe - Article 19: NIAS	Article 19: Assessment of non intentionally added substances (NIAS) not included in the Union list Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment. <u>Specification of use</u> n/a
COLOURANTS & PIGMENTS	Europe - CoE AP(89)1	Council of Europe Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food. <u>Specification of use</u> n/a

B. Member State legislation and non-European legislation

Intentionally added substances not subject to listing in Annex I according to Article 6 of Regulation (EU) No 10/2011, and other components made from non-plastic materials, are either risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004 or comply with the requirements of the legislation listed below.

National legislation in EU Member States		
Material group	Country	Legislation
PLASTICS	Austria	Kunststoffverordnung Nr. 476/2003 as amended up to 45/2011. <u>Specification of use</u> n/a
	Belgium	Koninklijk besluit van 3 juli 2005 betreffende materialen en voorwerpen van kunststof bestemd om met voedingsmiddelen in aanraking te komen, as amended up to KB 10/2/2011. <u>Specification of use</u> n/a
	Czech Republic	Vyhláška Ministerstva zdravotnictví ? 38/2001 Sb., o hygienických požadavcích na výrobky určené pro styk s potravinami a pokrmý, as amended up to 111/2011 Sb <u>Specification of use</u> n/a
	Denmark	BEK nr 822 af 26/06/2013 Bekendtgørelse om fødevarekontaktmaterialer. <u>Specification of use</u> n/a

	Finland	KTM Asetukset 953/2002 as amended up to 106/2011 <u>Specification of use</u> n/a
	France	Arrêté du 2 janvier 2003 relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact des denrées, produits et boissons alimentaires J.O. du 9/01/2003, p.1771 as amended up to Arrêté du 1er avril 2011 <u>Specification of use</u> n/a
	Germany - Food and Feed law	Legislation is made under powers of the Lebensmittel- und Futtermittelgesetzbuch [Food and Feed law]. Bedarfsgegenständeverordnung v. 23.12.1997, including LFGB § 30, 31 and 33 as amended up to Verordnung vom 15 Februar 2016 (BGBl. I S. 198). <u>Specification of use</u> n/a
	Greece	Υπουργική Απόφαση υπ' αριθ. 458/2003 as amended up to ΑΧΣ decision no 6/2011 <u>Specification of use</u> n/a
	Ireland	European Communities (Plastics and other materials)(Contact with food) Regulations, 2007 (S.I. No. 587 of 2007) as amended up to amendment No. 2 Regulations 2010 (S.I. No. 301 of 2010) <u>Specification of use</u> n/a
	Italy	Ministerial Decree of 21 March 1973 as amended up to Decreto 16 febbraio 2011 <u>Specification of use</u> n/a
	Luxembourg	Mémorial A n° 194 du 07.12.2005 as amended up to Mémorial A n° 27 du 14.02.2011 <u>Specification of use</u> n/a
	Netherlands - Hoofdstuk I – Kunststoffen	Regeling van de Minister van Volksgezondheid, Welzijn van 14 maart 2014, kenmerk 328583-117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen). Hoofdstuk I – Kunststoffen <u>Specification of use</u> n/a

	Norway	Regulations 21 December 1993 No 1381 on materials and articles intended to come into contact with foodstuffs Chapter I General regulations as amended up to 2013-05-03-461. <u>Specification of use</u> n/a
	Portugal	Decreto Lei N. 29/2009 of 2/2/2009 <u>Specification of use</u> n/a
	Spain	Real Decreto 847/2011, de 17 de junio, por el que se establece la lista positiva de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos. <u>Specification of use</u> n/a
	Sweden	Statens livsmedelsverks kungörelse LIVSFS 2003:2 as amended up to LIVSFS 2011:2 <u>Specification of use</u> n/a
	United Kingdom	Plastic Materials and Articles in Contact with Food (England) Regulations 2009, as amended up to REGULATIONS 2011 No. 231 <u>Specification of use</u> n/a

Legislation for countries outside the EU		
Material group	Country	Legislation
PLASTICS	Switzerland	817.023.21 Ordonnance du DFI du 23 novembre 2005 sur les objets et matériaux as amended up to législatif 4 avril 2011 RO 2011 1411 <u>Specification of use</u> n/a
PRINTING INKS	Switzerland - Printing inks - Annex 10	Annex 10 of the DFI Ordinance on Materials and Objects to come into contact with foodstuffs. List of substances permitted for the manufacture of packaging inks and requirements relating thereto (Edition: 1.1 - Entry into force: May 1, 2017). <u>Specification of use</u> n/a
	Switzerland - Printing inks - Annex 6	Annex 6 of the Ordinance of the FDHA on articles and materials of 23 November 2005 (RS 817.023.21): Lists of permitted substances for the manufacture of packaging inks, subject to the requirements set out therein <u>Specification of use</u> n/a

PLASTICS	United States - § 177.1520	TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION (CONTINUED) PART 177 INDIRECT FOOD ADDITIVES: POLYMERS B--Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces § 177.1520 - Olefin polymers. <u>Specification of use</u> n/a
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C. Non-intentionally added substances

Non-intentionally added substances in plastics, according to Article 6(4a) of Regulation (EU) No 10/2011, and in non-plastic materials, are risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004. Adequate information on non-intentionally added substances can be found in section 6A of this document.

D. Overall migration limit

This product complies with the overall migration limit tested under the following conditions:

Simulants
<ul style="list-style-type: none"> - B: Acetic acid 3% (w/v) - D1: Ethanol 50% (v/v) - D2: Vegetable oil. This may be any vegetable oil with a fatty acid distribution as described in EC 10/2011.

Test conditions			
Test Number	Test conditions	Intended food contact conditions	Covers also food contact conditions described for
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.	Test OM2 covers also food contact conditions described for OM1 and OM3.

E. Organoleptic properties

We have not determined whether a material or final article that is produced with this Product will induce an unacceptable change in the composition of the food or will cause deterioration of the organoleptic properties of the food. It is the responsibility of the downstream user to perform these tests.

6. Limits, restrictions and compositional specifications

A. Limits and restrictions of non-listed substances

Europe - 1935/2004; non-listed intentionally added substances PRINTING INKS		
Benzoylbenzoate, esters with branched polyols	CAS number: n.a. Reference number: -	Fat-reduction factor: unknown
Maximum concentration: -	Maximum Use Level: n/a	
Restrictions and specifications	SML(T) Remark: (1) SML= 0,05; under re-evaluation	
SML: (1) 0,05 mg/kg	Notes: A-list: List of photoinitiators	
Screening method: Other	Migration results: -	

Europe - CoE AP(89)1 COLOURANTS & PIGMENTS		
Copper Phthalocyanine	CAS number: - Reference number: -	Fat-reduction factor: unknown
Maximum concentration: 0,233 %	Maximum Use Level: n/a	
Restrictions and specifications		
No		
Screening method: Other	Migration results: -	

Switzerland - Printing inks - Annex 10 PRINTING INKS		
Pigment Orange 64 (C.I. 12760)	CAS number: 0072102-84-2 Reference number: SO nr: 4010	Fat-reduction factor:
Maximum concentration: -	Maximum Use Level: n/a	
Restrictions and specifications		

No

SML(T) Remark:

(1) A-list

Screening method: Overall migration test

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Siloxanes and silicones, di-Me, Me hydrogen

CAS number: 0068037-59-2

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -

Maximum Use Level: n/a

Restrictions and specifications

SML:

(1) 0,01 mg/kg

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Benzoylbenzoate, esters with branched polyols

CAS number: n.a.

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -

Maximum Use Level: n/a

Restrictions and specifications

SML:

(1) 0,05 mg/kg

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Ammoniumperoxodisulfat

CAS number: 0007727-54-0

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -

Maximum Use Level: n/a

Restrictions and specifications

SML:

(1) 0,01 mg/kg

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Di-tert-butylperoxid

CAS number: 0000110-05-4

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -

Maximum Use Level: n/a

Restrictions and specifications**SML:**

(1) 0,01 mg/kg

Screening method: Other**Migration results:** -

Switzerland - Printing inks - Annex 6 PRINTING INKS

butanone oxime

CAS number: 0000096-29-7

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -**Maximum Use Level:**

n/a

Restrictions and specifications**SML:**

(1) 0,01 mg/kg

Screening method: Other**Migration results:** -

Switzerland - Printing inks - Annex 6 PRINTING INKS

phenothiazine

CAS number: 0000092-84-2

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -**Maximum Use Level:**

n/a

Restrictions and specifications**SML:**

(1) 0,01 mg/kg

Screening method: Other**Migration results:** -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Hexane, 1,6-diisocyanato-, homopolymer

CAS number: 0028182-81-2

Reference number: -

Fat-reduction factor: Unknown

Maximum concentration: -**Maximum Use Level:**

n/a

Restrictions and specifications**SML:**

(1) 0,01 mg/kg

Screening method: Other**SML(T) Remark:**

(1) B-list: List of binders (monomers)

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Acrylic acid, triester with polyethylene glycol triether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol

CAS number: 0028961-43-5

Reference number: -

Fat-reduction factor: Unknown

Maximum concentration: -

Maximum Use Level:

n/a

Restrictions and specifications

SML:

(1) 0,01 mg/kg

SML(T) Remark:

(1) B-list: List of solvents (including the energy curing monomers);List of additives (without the additives used in the preparation of pigments)

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Polypropyleneglycol glycerol ether triacrylate

CAS number: 0052408-84-1

Fat-reduction factor:

Reference number: -

Unknown

Maximum concentration: -

Maximum Use Level:

n/a

Restrictions and specifications

SML:

(1) 0,01 mg/kg

SML(T) Remark:

(1) B-list: List of solvents (including the energy curing monomers);List of additives (without the additives used in the preparation of pigments)

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Alcohols (C12-C14) ethoxylated

CAS number: 0068439-50-9

Fat-reduction factor:

Reference number: -

Unknown

Maximum concentration: -

Maximum Use Level:

n/a

Restrictions and specifications

SML:

(1) 0,01 mg/kg

SML(T) Remark:

(1) B-list: List of solvents (including the energy curing monomers)

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Glycerin, propoxylated, esterified with acrylic acid

CAS number: 52408-84-1

Fat-reduction factor:

Reference number: -

unknown

Maximum concentration: -

Maximum Use Level:

n/a

Restrictions and specifications

SML:

(1) 0,01 mg/kg

SML(T) Remark:

(1) B-list

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Dipropylenglycol monomethyl ether

CAS number: 0034590-94-8

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -

Maximum Use Level: n/a

Restrictions and specifications

SML:

(1) 0,05 mg/kg

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Benzoic acid, 2-benzoyl-, methyl ester

CAS number: 0000606-28-0

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -

Maximum Use Level: n/a

Restrictions and specifications

SML:

(1) 0,05 mg/kg

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Benzoic acid, 4-(dimethylamino)-, ethyl ester

CAS number: 0010287-53-3

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -

Maximum Use Level: n/a

Restrictions and specifications

SML:

(1) 0,05 mg/kg

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Polypropyleneglycol glycerol ether triacrylate

CAS number: 0052408-84-1

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: -

Maximum Use Level: n/a

Restrictions and specifications

SML:

(1) 0,05 mg/kg

Screening method: Other**Migration results:** -

Switzerland - Printing inks - Annex 6 PRINTING INKS

2-ethylhexanoic acid (Co and Mn salts of)

CAS number: 0000149-57-5

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: 63,000 ppm**Maximum Use Level:** n/a**Restrictions and specifications****SML:**

(1) 0,05 mg/kg

Screening method: Other**Migration results:** -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Benzoic acid, 2-benzoyl-, methyl ester

CAS number: 0000606-28-0

Reference number: -

Fat-reduction factor:

Maximum concentration: -**Maximum Use Level:** n/a**Restrictions and specifications****SML:**

(1) 0,05 mg/kg

SML(T) Remark:

(1) SML= 0,05;

Notes:

A-list: List of binders (monomers);List of photoinitiators

Screening method: Other**Migration results:** -

Switzerland - Printing inks - Annex 6 PRINTING INKS

Trimethylolpropane triacrylate

CAS number: 0015625-89-5

Reference number: -

Fat-reduction factor:

Maximum concentration: -**Maximum Use Level:** n/a**Restrictions and specifications****SML:**

(1) 0,05 mg/kg

SML(T) Remark:

(1) SML= 0,05;

Notes:

A-list: List of solvents (including the energy curing monomers)

Screening method: Other**Migration results:** -

Switzerland - Printing inks - Annex 6 PRINTING INKS

1-Butanone, 2-(dimethylamino)-2-[(4-methylphenyl)methyl]-1-[4-(4-morpholinyl)phenyl]-

CAS number: 0119344-86-4

Fat-reduction factor:

Reference number: -

Maximum concentration: -

Maximum Use Level:
n/a

Restrictions and specifications

SML:

(1) 0,05 mg/kg

SML(T) Remark:

(1) SML= 0,05; under re-evaluation

Notes:

A-list: List of additives (without the additives used in the preparation of pigments); List of photoinitiators

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

1-[4-(4-Benzoylphenyl)sulfanyl]phenyl]-2-methyl-2-[(4-methylphenyl)sulfonyl]propan-1-one

CAS number: 0272460-97-6

Fat-reduction factor:

Reference number: -

Maximum concentration: -

Maximum Use Level:
n/a

Restrictions and specifications

SML:

(1) 0,05 mg/kg

SML(T) Remark:

(1) SML= 0,05; under re-evaluation

Notes:

A-list: List of photoinitiators

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

(Dimethylamino)benzoate, esters with branched polyols

CAS number: n.a.

Fat-reduction factor:

Reference number: -

Maximum concentration: -

Maximum Use Level:
n/a

Restrictions and specifications

SML:

(1) 0,05 mg/kg

SML(T) Remark:

(1) SML= 0,05; under re-evaluation

Notes:

A-list: List of photoinitiators

Screening method: Other

Migration results: -

Switzerland - Printing inks - Annex 6 PRINTING INKS

1-Butanone, 2-(dimethylamino)-1-[4-(4-morpholinyl)phenyl]-2-(phenylmethyl)-	CAS number: 0119313-12-1 Reference number: -	Fat-reduction factor:
Maximum concentration: -	Maximum Use Level: n/a	
Restrictions and specifications	SML(T) Remark: (1) SML= 0,15; under re-evaluation	
SML: (1) 0,15 mg/kg	Notes: A-list: List of binders (monomers);List of photoinitiators	
Screening method: Other	Migration results: -	

Switzerland - Printing inks - Annex 6 PRINTING INKS		
1,2-Benzisothiazolin-3-one	CAS number: 0002634-33-5 Reference number: -	Fat-reduction factor: unknown
Maximum concentration: -	Maximum Use Level: n/a	
Restrictions and specifications	Notes: compliance by the supplier based on 100% migration calculation	
SML: (1) 0,5 mg/kg	Migration results: -	
Screening method: Other		

Switzerland - Printing inks - Annex 6 PRINTING INKS		
tert-Butanol	CAS number: 0000075-65-0 Reference number: -	Fat-reduction factor: unknown
Maximum concentration: -	Maximum Use Level: n/a	
Restrictions and specifications		
SML: (1) 10 mg/kg	Migration results: -	
Screening method: Other		

Switzerland - Printing inks - Annex 6 PRINTING INKS		
Phenyl bis(2,4,6-trimethylbenzoyl) phosphine oxide	CAS number: 0162881-26-7 Reference number: -	Fat-reduction factor: unknown
Maximum concentration: -	Maximum Use Level: n/a	
Restrictions and specifications		

SML:

(1) 3,3 mg/kg

Screening method: Other**Migration results:** -

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mono-tert-butylhydroquinone

CAS number: 0001948-33-0

Reference number: -

Fat-reduction factor: unknown

Maximum concentration: 3,000 ppm**Maximum Use Level:** n/a**Restrictions and specifications****SML:**

(1) 42 mg/kg

Screening method: Other**Migration results:** -**B. Substances with limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I**

FCM num.	EEC reference number	CAS number	Substance name	Maximum concentration	Maximum use level	Migration results
878*	31335	—	acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with branched alcohols, aliphatic, monohydric, saturated, primary (C3-C22)	-	n/a	- (5)
187*	22210	0000098-83-9	a-methylstyrene	-	n/a	- (5)
879*	31336	—	acids, fatty (C8-C22) from animal or vegetable fats and oils, esters with alcohols, linear, aliphatic, monohydric, saturated, primary (C1-C22)	-	n/a	- (5)

500*	38560	0007128-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	-	n/a	- (5)
661*	95360	0027676-62-6	1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	-	n/a	- (5)
209*	17050	0000104-76-7	2-ethyl-1-hexanol	-	n/a	- (5)
451*	66755	0002682-20-4	2-methyl-4-isothiazolin-3-one	-	n/a	- (5)
356*	18820	0000592-41-6	1-hexene	-	n/a	- (5)
433*	68320	0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	-	n/a	- (5)
811*	80077	0068441-17-8	polyethylene waxes, oxidised	-	n/a	- (2)
282*	18430	0000116-15-4	hexafluoropropylene	-	n/a	- (5)
198*	16630	0000101-68-8	diphenylmethane-4,4'-diisocyanate	-	(unknown)	- (5)
652*	38820	0026741-53-7	bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphate	-	n/a	- (5)
880*	31348	—	acids, fatty (C8-C22), esters with pentaerythritol	-	n/a	- (2)
799*	77708	—	polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C8-C22) alcohols	-	n/a	- (5)
95*	95883	—	white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	-	n/a	- (5)
295*	15940; 18867; 48620	0000123-31-9	1,4-dihydroxybenzene	-	n/a	- (5)
98*	17260; 54880	0000050-00-0	formaldehyde	-	n/a	- (5)

283*	74640	0000117-81-7	phthalic acid, bis(2-ethylhexyl) ester	-	(unknown)	- (5)
409*	62240	0001332-37-2	iron oxide	0,815 %	n/a	- (2)
610*	93440	0013463-67-7	titanium dioxide	-	n/a	- (5)
615*	92080	0014807-96-6	talc	-	n/a	- (5)
688*	92560	0038613-77-3	tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite	-	n/a	- (5)
150*	20020	0000079-41-4	methacrylic acid	-	n/a	- (5)
411*	42080	0001333-86-4	carbon black	0,600 %	> 100	- (5)
689*	95280	0040601-76-1	1,3,5-tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	-	n/a	- (5)
20*	39120	—	N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides	-	n/a	- (5)
813*	91530	—	sulphosuccinic acid alkyl (C4-C20) or cyclohexyl diesters, salts	-	n/a	- (5)
783*	55910	0736150-63-3	glycerides, castor-oil mono-, hydrogenated, acetates	-	n/a	- (5)
36*	54450	—	fats and oils, from animal or vegetable food sources	-	n/a	- (2)
315*	46640	0000128-37-0	2,6-di-tert-butyl-p-cresol	-	n/a	- (5)
629*	34560	0021645-51-2	aluminium hydroxide	-	n/a	- (2)
185*	20440	0000097-90-5	methacrylic acid, diester with ethyleneglycol	-	n/a	- (5)
292*	94560	0000122-20-3	triisopropanolamine	-	n/a	- (5)

483*	68860	0004724-48-5	n-octylphosphonic acid	-	n/a	- (5)
167*	25240	0000091-08-7	2,6-toluene diisocyanate	-	(unknown)	- (5)
779*	39815	0182121-12-6	9,9-bis(methoxymethyl)fluorene	-	n/a	- (5)
808*	38550	0882073-43-0	bis(4-propylbenzylidene)propylsorbitol	0,233 %	n/a	1,440 mg/kg (4)
206*	11500	0000103-11-7	acrylic acid, 2-ethylhexyl ester	-	n/a	- (5)
139*	14680; 44160	0000077-92-9	citric acid	-	n/a	- (2)
9*	30610	—	acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	-	n/a	- (5)
575*	76721	0063148-62-9	polydimethylsiloxane (Mw > 6800 Da)	-	n/a	- (2)
372*	18640	0000822-06-0	hexamethylene diisocyanate	-	(unknown)	- (5)
157*	74880	0000084-74-2	phthalic acid, dibutyl ester	-	(unknown)	- (5)
325*	10780	0000141-32-2	acrylic acid, n-butyl ester	-	n/a	- (5)
587*	68400	0010094-45-8	octadecylceramide	-	n/a	- (5)
819*	68110	—	neodecanoic acid, salts	-	n/a	- (5)
141*	13380; 25600; 94960	0000077-99-6	1,1,1-trimethylolpropane	-	n/a	- (5)
741*	24070; 83610	0073138-82-6	resin acids and rosin acids	-	n/a	- (2)
106*	24550; 89040	0000057-11-4	stearic acid	-	n/a	- (5)
281*	25120	0000116-14-3	tetrafluoroethylene	-	n/a	- (5)

19*	39090	—	N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine	-	n/a	- (5)
504*	86240	0007631-86-9	silicon dioxide	-	n/a	- (5)
156*	21130	0000080-62-6	methacrylic acid, methyl ester	-	n/a	- (5)
760*	83595	0119345-01-6	reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	-	n/a	- (5)
510*	12789; 35320	0007664-41-7	ammonia	-	n/a	- (2)
207*	31920	0000103-23-1	adipic acid, bis(2-ethylhexyl) ester	0,350 %	n/a	- (4)
773*	38840	0154862-43-8	bis(2,4-dicumylphenyl)penterythritol-diphosphite	-	n/a	- (5)
147*	10690	0000079-10-7	acrylic acid	-	n/a	- (5)
354*	25210	0000584-84-9	2,4-toluene diisocyanate	-	(unknown)	- (5)
285*	66480	0000119-47-1	2,2'-methylene bis(4-methyl-6-tert-butylphenol)	-	n/a	- (5)
132*	26140	0000075-38-7	vinylidene fluoride	-	n/a	- (5)
549*	80000	0009002-88-4	polyethylene wax	-	n/a	- (2)

Legenda screening methods: (1) 100% migration calculation (2) Overall migration test (3) Migration modelling (4) Migration testing (5) Other

C. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

i. Restrictions; Annex I – table 1

FCM number	Fat-reduction factor	Restriction(s)	Restrictions and specifications	Notes
878*	no	No	-	
187*	no	SML: 0,05 mg/kg	-	
879*	no	No	-	
500*	yes	SML: 0,6 mg/kg	-	
661*	yes	SML: 5 mg/kg	-	
209*	no	SML: 30 mg/kg	-	
451*	no	SML: 0,5 mg/kg	Only to be used in aqueous polymer dispersions and emulsions	
356*	no	SML: 3 mg/kg	-	
433*	yes	SML: 6 mg/kg	-	
811*	no	SML: 60 mg/kg	-	
282*	no	SML = ND	-	
198*	no	Group: (17) QM: 1 ppm	1 mg/kg in final product expressed as isocyanate moiety	(10)
652*	yes	SML: 0,6 mg/kg	-	
880*	no	No	-	
799*	no	SML: 1,8 mg/kg	In compliance with the purity criteria for ethylene oxide as laid down in Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners (OJ L 253, 20,9.2008, p. 1)	
95*	no	No	Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt (8,5 × 10 ⁻⁶ m ² /s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).	
295*	no	SML: 0,6 mg/kg	-	
98*	no	Group: (15)	-	
283*	no	SML: 1,5 mg/kg Group: (32) QM: (see restriction)	Only to be used as: (a)plasticiser in repeated use materials and articles contacting non-fatty foods;(b)technical support agent in concentrations up to 0,1 % in the final product.	(7)
409*	no	No	-	
610*	no	No	-	
615*	no	No	-	
688*	yes	SML: 18 mg/kg	-	

150*	no	Group: (23)	-	
411*	no	QM: 2,5 %	Primary particles of 10 – 300 nm which are aggregated to a size of 100 – 1200 nm which may form agglomerates within the size distribution of 300 nm – mm. Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of carbon black in the polymer: 2,5 % w/w.	
689*	yes	SML: 6 mg/kg	-	
20*	no	Group: (7)	SML(T) expressed excluding HCl	
813*	no	SML: 5 mg/kg	-	
783*	no	Group: (32)	-	
36*	no	No	-	
315*	no	SML: 3 mg/kg	-	
629*	no	No	-	
185*	no	SML: 0,05 mg/kg	-	
292*	no	SML: 5 mg/kg	-	
483*	no	SML: 0,05 mg/kg	-	
167*	no	Group: (17) QM: 1 ppm	1 mg/kg in final product expressed as isocyanate moiety	(10)
779*	yes	SML: 0,05 mg/kg	-	(2)
808*	no	SML: 5 mg/kg	SML including the sum of its hydrolysis products	
206*	no	SML: 0,05 mg/kg	-	
139*	no	No	-	
9*	no	No	-	
575*	no	No	Viscosity at 25 °C not less than 100 cSt (100 × 10 ⁻⁶ m ² /s)	
372*	no	Group: (17) QM: 1 ppm	1 mg/kg in final product expressed as isocyanate moiety	(10)

157*	no	SML: 0,3 mg/kg Group: (32) QM: (see restriction)	Only to be used as: (a)plasticiser in repeated use materials and articles contacting non-fatty foods;(b)technical support agent in polyolefins in concentrations up to 0,05 % in the final product.	(7)
325*	no	Group: (22)	-	
587*	yes	SML: 5 mg/kg	-	
819*	no	SML: 0,05 mg/kg	Not to be used in polymers contacting fatty foods. Not to be used for articles in contact with fatty foods for which simulant D1 and/or D2 is laid down. SML expressed as neodecanoic acid.	
141*	no	SML: 6 mg/kg	-	
741*	no	No	-	
106*	no	No	-	
281*	no	SML: 0,05 mg/kg	-	
19*	no	Group: (7)	-	
504*	no	No	For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size.	
156*	no	Group: (23)	-	

760*	no	SML: 18 mg/kg	Composition: 4,4'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0038613-77-3) (36-46 % w/w (*)),4,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)),3,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)),4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)),tris(2,4-di-tert-butylphenyl)phosphite (CAS No 0031570-04-4) (9-18 % w/w (*)),4,4'-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0112949-97-0) (< 5 % w/w (*))(*Quantity of substance used/quantity of formulationOther specifications: Phosphor content of min. 5,4 % to max. 5,9 %,Acid value of max. 10 mg KOH per gram,Melt range of 85– 110 °C,	
510*	no	No	-	
207*	yes	SML: 18 mg/kg Group: (32)	-	(2)
773*	yes	SML: 5 mg/kg	SML expressed as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol)	
147*	no	Group: (22)	-	
354*	no	Group: (17) QM: 1 ppm	1 mg/kg in final product expressed as isocyanate moiety	(10)
285*	yes	Group: (13)	-	
132*	no	SML: 5 mg/kg	-	
549*	no	No	-	

ii. Group restrictions; Annex I – table 2

Number	Restriction(s)	Other substances in this group
Group (23)	SML(T) 6 mg/kg; expressed as methacrylic acid.	150, 156, 181, 183, 184, 355, 370, 374, 439, 440, 447, 457, 482
Group (22)	SML(T) 6 mg/kg; expressed as acrylic acid.	70, 147, 176, 218, 323, 325, 365, 371, 380, 425, 446, 448, 456, 636
Group (7)	SML(T) 1,2 mg/kg; expressed as tertiary amine.	19, 20
Group (17)	SML(T) ND mg/kg; expressed as isocyanate moiety.	4, 167, 169, 198, 274, 354, 372, 460, 461, 475, 476, 485, 490, 653
Group (13)	SML(T) 1,5 mg/kg; expressed as the sum of the substances.	163, 285
Group (32)	SML(T) 60 mg/kg; expressed as the sum of the substances.	8, 72, 73, 138, 140, 157, 159, 207, 242, 283, 532, 670, 728, 729, 775, 783, 797, 798, 810, 815
Group (15)	SML(T) 15 mg/kg; expressed as formaldehyde.	98, 196

iii. Notes on verification of compliance; Annex I – table 3

Number	Note
Note (10)	Verification of compliance by residual content per food contact surface area (QMA) in case of reaction with food or simulant.
Note (2)	There is a risk that the SML or OML could be exceeded in fatty food simulants.
Note (7)	If testing in food is performed, Annex V 1.4 shall be taken into account.

D. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex II, Metals

Name / Element	Restriction	Maximum concentration	Screening method	Migration results
Aluminium (Al)*	1 mg/kg food or food simulant	-	Other	-

Zinc (Zn)*	5 mg/kg food or food simulant (EU 10/2011, amended by EU 2016/1416; shall apply from September 14, 2018)	-	Other	-
Iron (Fe)*	48 mg/kg food or food simulant.	0,570 %	Migration testing	-
Copper (Cu)*	5 mg/kg food or food simulant.	0,026 %	Migration testing	-

E. Limits and restrictions as listed in Regulation (EC) No 10/2011, Annex II, Primary Aromatic Amines

This Product may contain Primary Aromatic Amines according to Annex II: NO

F. Compliance confirmation

This Product complies with the limits and restrictions in points 6A, 6C, 6D and 6E within this document, based on worst-case calculations, migration modeling or migration testing.

Specific migration is tested under the following conditions:

Test conditions			
Contact time:	Above 6 months at room temperature and below	Contact temperature:	10 days at 60 °C
Test time:	10 days at 60 °C	Test temperature:	60°C

The following substances with limitations in this Product have not yet been risk assessed by Us and therefore need to be evaluated by the downstream user based on the information listed below:

i. Non-listed substances

All substances comply with the applicable limitations.

ii. Substances listed in Regulation (EU) No 10/2011, Annex I

All substances comply with the applicable limitations.

iii. Substances listed in Regulation (EU) No 10/2011, Annex II, Metals

All metals comply with the applicable limitations.

iv. Substances listed in Regulation (EU) No 10/2011, Annex II, Primary Aromatic Amines

Primary Aromatic Amines will not migrate in detectable quantities above the detection limit of 0.01mg/kg.

G. Inks, coatings or adhesives

In case this Product is printed on, covered by a coating, or if different layers are held together by adhesives, We confirm that substances listed in Annex I, coming from inks, adhesives or coatings used in this Product, comply with the relevant restrictions.

This Product may contain substances with limitations listed in the tables under 6A or 6B within this document coming from inks, adhesives or coatings but may not be identified as such by Our suppliers.

7. Dual Use Additive(s)

A substance is defined as a "Dual Use Additive" if the chemical identity of the plastic additive matches that of an authorized food additive or flavoring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic. In the case of salts it is the salt that matters, not the authorized acid, phenol or alcohol.

Number (E or FL)	Name	Maximum concentration
E 475	Polyglycerol esters of fatty acids	-
E 170	Calcium carbonate	-

E 319	Tertiary-butyl hydroquinone (TBHQ)	-
E 551	Silicon dioxide	-
E 321	Butylated hydroxytoluene (BHT)	-
E 553b	Talc	-
E 527	Ammonium hydroxide	-
E 470a	Sodium, potassium and calcium salts of fatty acids (example: Calcium Stearate)	-
E 322	Lecithins	-
E 172	Iron oxides and hydroxides	0,815 %
E 470b	Magnesium salts of fatty acids	0,026 ppm
E 330	Citric acid	-
E 171	Titanium dioxide	-
E 503	Ammonium carbonates	-
E 900	Dimethyl polysiloxane	-
E 572	Calcium stearate	-
E 914	Oxidised polyethylene wax	0,175 %
E 558	Bentonite	-
E 471	Mono-and diglycerides of fatty acids	-

The purity of the Dual Use Additives used in this Product respect the purity criteria set out in Annex I of Regulation (EU) No 10/2011.

8. Specifications for use

Specifications of use as regards of type or types of food

All aqueous, acidic and alcoholic foods, foods which contain free fats at the surface and milk products

Specifications for use as regards of time and temperature of treatment and storage of food

Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum $t = 120/2^{((T-70)/10)}$ minutes.

Any other limitations of use

Compliant with the provisions within Regulation (EU) No 10/2011 for infants and young children: YES

Compliant with the provisions within Regulation (EU) No 10/2011 for repeated-use articles: YES

Surface/volume ratio used for compliance assessment: 6 dm ² FCM/ kg food Worst case surface/volume ratio: dm ² FCM/ kg food
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9. Functional barrier

This Product contains a functional barrier: NO

Legend

If the compliance assessment is based on a worst-case family strategy, the identity of the product on which the compliance assessment is based will be indicated here.

* Substances marked with a single asterisk in this document are reportable substances with variable concentrations due to variations in supply source.

** Substances marked with a double asterisk in this document are not present in this Product. However, they are included in this document due to compliance assessment of a worst-case product.

*** Substances marked with a triple asterisk in this document are substances to which both remarks * and ** apply.

For all substances with a single asterisk, *, you are advised to contact your supplier before carrying out any specific migration tests to verify the concentration of the substance within this Product.

EXCP¹: If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

EXCP²: If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

Disclaimer

The information included in this document is based on the present state of our knowledge and is valid from the stated issue date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in this Product, we cannot guarantee that the status of this document will remain unchanged. It will be renewed in all cases where the previous conformity is no longer ensured.