



Introduction

DEONET Production B.V.
Dillenburgstraat 29, (De Hurk 7895)
5652 AM Eindhoven
Netherlands

Customer article code: N/A
Version: 3
Print date: 2022-12-08
Remarks on update:

COMMISSION REGULATION (EU) 2020/1245

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.

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 advices 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



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

P-100124 Morning and noon bowl M884A (Hereinafter referred to as "Product").

Product type: final product

Product description: P-100124 Morning and noon bowl grey

Compliance work based on: 48,5% PP homopolymer + 48,5% TALC filled pp + maximum 3% masterbatch 6 dm²/kg

4. Issue date

2022-10-11

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) 2020/1245 of 2 September 2020., (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
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>Specifications of use</u> n/a
GENERAL	Europe - Dual Use Additives: flavourings EC 1334/2008 (incl 2021/1917)	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 up to and including Commission Regulation (EU) 2021/1917. <u>Specifications of use</u> n/a
	Europe - Dual Use Additives: Food additives EC 1333/2008 (incl 2021/1175)	REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives up to and including Commission Regulation (EU) 2021/1175. <u>Specifications of use</u> n/a

	Europe - Framework Regulation (EC) No 1935/2004 (amended by 2019/1381)	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. (Amended by REGULATION (EC) No 2019/1381). Stating compliance with the Framework Regulation not only covers the safety aspects set out in Article 3(1)(a), but also covers: GMP (Article 3), labelling requirements (Article 15) and Traceability (Article 17). <u>Specifications of use</u> n/a
	Europe - GMP Regulation (EC) No 2023/2006	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 <u>Specifications of use</u> n/a
PLASTICS	Europe - 10/2011	COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Amended by: Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 Commission Regulation (EU) No 1282/2011 of 28 November 2011 Commission Regulation (EU) No 1183/2012 of 30 November 2012 Commission Regulation (EU) No 202/2014 of 3 March 2014 Commission Regulation (EU) No 2015/174 of 5 February 2015 Commission Regulation (EU) No 2016/1416 of 24 August 2016 Commission Regulation (EU) No 2017/752 of 28 April 2017 Commission Regulation (EU) No 2018/79 of 18 January 2018 Commission Regulation (EU) No 2018/213 of 12 February 2018 Commission Regulation (EU) No 2018/831 of 5 June 2018 Commission Regulation (EU) No 2019/37 of 10 January 2019 Commission Regulation (EU) No 2019/1338 of 8 August 2019 <u>Specifications of use</u> n/a
	Europe - 10/2011 up to 2020/1245	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) 2020/1245 Of 2 September 2020. <u>Specifications 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 and legislation for countries outside the EU: NOT SPECIFIED

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

- A - Ethanol 10% (v/v)
- B - Acetic acid 3% (w/v)
- D2 (assigned fatty food simulant) - 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 OM 2 covers also food contact conditions described for OM0, 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 - Article 19: NIAS PLASTICS *			
2-[bis(2-hydroxyethyl)amino]ethyl oleate *	CAS number: 10277-04-0 Reference number: -	Fat-reduction factor: unknown	
Maximum concentration: 0,022 %	Maximum Use Level: n/a		
Restrictions and specifications			
SML: 5 mg/kg			
Screening method: Migration testing		Migration results: 0,600 mg/kg	
France COLOURANTS & PIGMENTS *			
Noir de Carbone *	CAS number: 0001333-86-4 Reference number: -	Fat-reduction factor:	
Maximum concentration: 0,750 %	Maximum Use Level: n/a		
Restrictions and specifications			
No			
Other Specifications: Le noir de carbone ne doit pas donner un extrait benzeniquesuperieur a 0,1 % et doit etre exempt de benzo 3-4 pyrene.			
Screening method: Other		Migration results: 825,000 mg/kg	
Spain COLOURANTS & PIGMENTS *			
Carbon black (or smoke black) *	CAS number: 0001333-86-4 Reference number: -	Fat-reduction factor:	
Maximum concentration: 0,750 %	Maximum Use Level: 1,000 333.3		
Restrictions and specifications			

QM: 2,5 %

QM(T) Remark:

Maximum level of use of carbon black in the polymer: 2.5% w/w.

Other Specifications:

Toluene extractables: maximum 0,1%, determined according to ISO 6209 method. UV absorption of cyclohexane extract at 386 nm: <0.02 AU for a cell of 1 cm or <0.1 AU for a cell of 5 cm, determined according to a method of analysis with general recognition. Benzo (a) pyrene content: maximum of 0.25 mg / kg carbon black.

Screening method: Other

Migration results: 825,000 mg/kg

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
418 *	34720	0001344-28-1	aluminium oxide	98,400 ppm	n/a	10,824 mg/kg (12)
416 *	87680	0001338-43-8	sorbitan monooleate	-	n/a	- (4)
483 *	68860	0004724-48-5	n-octylphosphonic acid	0,012 %	n/a	< 0,050 mg/kg (4)
53 *	56585	—	glycerol, esters with stearic acid	-	-	-
610 *	93440	0013463-67-7	titanium dioxide	-	-	-
504 *	86240	0007631-86-9	silicon dioxide	-	-	-
106 *	24550, 89040	0000057-11-4	stearic acid	-	-	-
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)	-	-	-
21 *	42500	—	carbonic acid, salts	-	-	-
95 *	95883	—	white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	-	-	-
615 *	92080	0014807-96-6	talc	-	-	-
411 *	42080	0001333-86-4	carbon black	-	-	-

499 *	19965, 65020	0006915-15-7	malic acid	-	-	-
779 *	39815	0182121-12-6	9,9-bis(methoxymethyl)fluorene	-	-	-
157 *	74880	0000084-74-2	phthalic acid, dibutyl ester	-	-	-
283 *	74640	0000117-81-7	phthalic acid, bis(2-ethylhexyl) ester	-	-	-
292 *	94560	0000122-20-3	triisopropanolamine	-	-	-
923 *	39150	0000120-40-1	N,N-bis(2-hydroxyethyl)dodecane amide	-	-	-
715 *	46880	0065140-91-2	3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	-	-	-
141 *	13380, 25600, 94960	0000077-99-6	1,1,1-trimethylolpropane	-	-	-
433 *	68320	0002082-79-3	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	-	-	-

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
418 *		No		
416 *		No		
483 *		SML: 0,05 mg/kg		
53 *		No		
610 *		No		
504 *		No	Other Specifications: 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.	
106 *		No		
9 *		No		
21 *		No		

95 *		No	<p>Other Specifications: Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt ($8,5 \times 10^{-6}$ m²/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).</p>	
615 *		No		
411 *		QM: 2,5 %	<p>QM(T) Remark: Maximum use level of carbon black in the polymer: 2,5 % w/w.</p> <p>Other Specifications: 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.</p>	
499 *		<p>QM: (1) no (2) 1 %</p>	<p>QM(T) Remark: (1) In case of use as a additive and polymer production aid (PPA) (2) In case of use as a monomer only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis</p> <p>Other Specifications: In case of use as a monomer only to be used as a co-monomer in aliphatic polyesters up to maximum level of 1 % on a molar basis</p>	
779 *		SML: 0,05 mg/kg	<p>Notes: Note number (2): There is a risk that the SML or OML could be exceeded in fatty food simulants.</p>	(2)

157 *		<p>SML: (1) 0,3 mg/kg (2) 60 mg/kg</p> <p>QM: (1) no (2) 0,05 %</p>	<p>SML(T) Remark: Group 32: 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)</p> <p>QM(T) Remark: (1) Only to be used as: (a) plasticiser in repeated use materials and articles contacting non-fatty foods. (2) Only to be used as: (b) technical support agent in polyolefins in concentrations up to 0,05 % in the final product.</p> <p>Notes: Note number (7): If testing in food is performed, Annex V 1.4 shall be taken into account.</p> <p>Other Specifications: As a plasticiser in repeated use materials and articles contacting non-fatty foods; As a technical support agent in polyolefins in concentrations up to 0,05 % in the final product.</p>	(7)
-------	--	-------------------------------------------------------------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----

283 *		<p>SML: (1) 1,5 mg/kg (2) 60 mg/kg</p> <p>QM: (1) no (2) 0,1 %</p>	<p>SML(T) Remark: Group 32: 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)</p> <p>QM(T) Remark: (1) Only to be used as: (a)plasticiser in repeated use materials and articles contacting non-fatty foods (2) Only to be used as: (b)technical support agent in concentrations up to 0,1 % in the final product.</p> <p>Notes: Note number (7): If testing in food is performed, Annex V 1.4 shall be taken into account.</p> <p>Other Specifications: As plasticiser in repeated use materials and articles contacting non-fatty foods. As technical support agent in concentrations up to 0,1 % in the final product.</p>	(7)
292 *		SML: 5 mg/kg		
923 *		<p>SML: (1) 5 mg/kg (2) 0,3 mg/kg</p>	<p>SML(T) Remark: The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, shall not result in a migration of diethanolamine higher than 0,3 mg/kg food.</p> <p>Notes: Note number (18): There is a risk that the SML could be exceeded from low-density polyethylene (LDPE)</p> <p>Other Specifications: The residual amount of diethanolamine in plastics, as an impurity and decomposition product of the substance, shall not result in a migration of diethanolamine higher than 0,3 mg/kg food.</p>	(18)
715 *		SML: 6 mg/kg		
141 *		SML: 6 mg/kg		
433 *		SML: 6 mg/kg		

ii. Group restrictions; Annex I – table 2

Number	Restriction(s)	Other substances in this group
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

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

Number	Note
(2)	There is a risk that the SML or OML could be exceeded in fatty food simulants.
(7)	If testing in food is performed, Annex V 1.4 shall be taken into account.
(18)	There is a risk that the SML could be exceeded from low-density polyethylene (LDPE)

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 *	SML: 1 mg/kg	-	-	-
Iron *	SML: 48 mg/kg	-	-	-
Copper *	SML: 5 mg/kg	-	-	-
Zinc *	SML: 5 mg/kg	-	-	-

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	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 494	Sorbitan monooleate	-
E 171	Titanium dioxide	-
E 172	Iron oxides and hydroxides	-
E 471	Mono-and diglycerides of fatty acids	-
E 551	Silicon dioxide	-
E 173	Aluminium	-
E 180	Litholrubine BK	-
E 211	Sodium benzoate [14]	-
E 170	Calcium carbonate	-
E 296	Malic acid	-
E 905	Microcrystalline wax	-
E 470a	Sodium, potassium and calcium salts of fatty acids (example: Calcium Stearate)	-
E 553b	Talc	-
FL 8.015	Octadecanoic acid	-
FL 8.017	L-Malic acid	-

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 types of food: aqueous acidic and alcoholic foods (up to 10% alcohol) and foods that containing fats and oils.

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 °C ≤ T ≤ 100 °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:

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.



Introduction

DEONET Production B.V.
Dillenburgstraat 29, (De Hurk 7895)
5652 AM Eindhoven
Netherlands

Customer article code: N/A
Version: 3
Print date: 2022-12-08
Remarks on update:

COMMISSION REGULATION (EU) 2020/1245

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.

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 advices 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



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

Identical to the details listed under point 1 within this document.

3. Identity of the product

P-100109 Lid morning and noon or super bowl 200 ml M881C (Hereinafter referred to as "Product").

Product type: plastic intermediate

Product description: P-100109 Lid morning and noon or super bowl 200 ml grey

Compliance work based on: Tritan trp with TPE

4. Issue date

2022-11-10

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) 2020/1245 of 2 September 2020., (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
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>Specifications of use</u> n/a
GENERAL	Europe - Directive 94/62/EC Packaging and packaging waste.	Directive 94/62/EC sets out the EU's rules on managing packaging and packaging waste. <u>Specifications of use</u> n/a
	Europe - Dual Use Additives: flavourings EC 1334/2008 (incl 2021/1917)	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 up to and including Commission Regulation (EU) 2021/1917. <u>Specifications of use</u> n/a
	Europe - Dual Use Additives: Food additives EC 1333/2008 (incl 2022/141)	REGULATION (EC) No 1333/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on food additives up to and including Commission Regulation (EU) 2022/141. <u>Specifications of use</u> n/a

	Europe - Framework Regulation (EC) No 1935/2004 (amended by 2019/1381)	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. (Amended by REGULATION (EC) No 2019/1381). Stating compliance with the Framework Regulation not only covers the safety aspects set out in Article 3(1)(a), but also covers: GMP (Article 3), labelling requirements (Article 15) and Traceability (Article 17). <u>Specifications of use</u> n/a
	Europe - GMP Regulation (EC) No 2023/2006	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 <u>Specifications of use</u> n/a
PLASTICS	Europe - 10/2011	COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. Amended by: Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 Commission Regulation (EU) No 1282/2011 of 28 November 2011 Commission Regulation (EU) No 1183/2012 of 30 November 2012 Commission Regulation (EU) No 202/2014 of 3 March 2014 Commission Regulation (EU) No 2015/174 of 5 February 2015 Commission Regulation (EU) No 2016/1416 of 24 August 2016 Commission Regulation (EU) No 2017/752 of 28 April 2017 Commission Regulation (EU) No 2018/79 of 18 January 2018 Commission Regulation (EU) No 2018/213 of 12 February 2018 Commission Regulation (EU) No 2018/831 of 5 June 2018 Commission Regulation (EU) No 2019/37 of 10 January 2019 Commission Regulation (EU) No 2019/1338 of 8 August 2019 <u>Specifications of use</u> n/a
	Europe - 10/2011 up to 2020/1245	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) 2020/1245 Of 2 September 2020. <u>Specifications 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
COLOURANTS & PIGMENTS	Belgium - Requirements for colorants	Koninklijk Besluit dated 11.5.1992; Warenwetgeving (1), aanvulling nr. 18 - September 1992, purity requirements for colorants. <u>Specifications of use</u> n/a

	Germany - BfR IX Colorants (As of 01.06.2019)	BfR Recommendation IX Colorants for Plastics and other Polymers Used in Commodities. (As of 01.06.2019) <u>Specifications of use</u> n/a
	Italy - MD 21 March 1973	Ministerial Decree of 21 March 1973 as amended up to Decree No. 195 of 06 August 2015, purity requirements for colorants. <u>Specifications of use</u> n/a
	Netherlands - Hoofdstuk XI - Kleurstoffen en pigmenten	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), geamendeerd tot aan Regeling 1028394-156011-VGP van de Minister van Volksgezondheid, Welzijn en Sport van 26 oktober 2016. Hoofdstuk XI - Kleurstoffen en pigmenten <u>Specifications of use</u> n/a
	Spain - RD 847/2011	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. ANEXO II: Condiciones de identidad y pureza que deben cumplir las materias colorantes para su uso en los materiales poliméricos en contacto con los alimentos <u>Specifications of use</u> n/a

Legislation for countries outside the EU		
Material group	Country	Legislation
COLOURANTS & PIGMENTS	Turkey - Turkish Food Codex - Annex 6 dyes/colorants in plastics	Rules and requirements for food contact dyes/colorants in plastics. <u>Specifications of use</u> n/a
GENERAL	United States - CONEG Model Toxics Legislation	CONEG Model Toxics Legislation calls for the reduction of lead, mercury, cadmium and hexavalent chromium in packaging or packaging materials used or sold within the state. <u>Specifications of use</u> n/a

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
- A - Ethanol 10% (v/v) : 6,0 mg/kg - B - Acetic acid 3% (w/v) : 6,0 mg/kg - D2 (assigned fatty food simulant) - Vegetable oil. This may be any vegetable oil with a fatty acid distribution as described in EC 10/2011. : 30,0 mg/kg

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 °C ≤ T ≤ 100 °C for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.	Test OM 2 covers also food contact conditions described for OM0, 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 - CoE AP(89)1 COLOURANTS & PIGMENTS *			
Antimony *	CAS number: 0007440-36-0 Reference number: -	Fat-reduction factor:	
Maximum concentration: 0,027 ppm	Maximum Use Level: n/a		
Restrictions and specifications No	Other Specifications: Purity criteria: the content of metals and metalloids soluble in 0.1M hydrochloric acid, determined as a percentage in relation to the colourant, should not exceed 0.05%.		
Screening method: 100% migration calculation	Migration results: 0,004 mg/kg		
Europe - CoE AP(89)1 COLOURANTS & PIGMENTS *			
Arsenic *	CAS number: 0007440-38-2 Reference number: -	Fat-reduction factor:	
Maximum concentration: 0,657 ppm	Maximum Use Level: n/a		
Restrictions and specifications No	Other Specifications: Purity criteria: the content of metals and metalloids soluble in 0.1M hydrochloric acid, determined as a percentage in relation to the colourant, should not exceed 0.01%.		
Screening method: Migration testing	Migration results: < 0,010 mg/kg		
Europe - CoE AP(89)1 COLOURANTS & PIGMENTS *			
Barium *	CAS number: 0007440-39-3 Reference number: -	Fat-reduction factor:	
Maximum concentration: 0,022 %	Maximum Use Level: n/a		
Restrictions and specifications			

No

Other Specifications:

Purity criteria: the content of metals and metalloids soluble in 0.1M hydrochloric acid, determined as a percentage in relation to the colourant, should not exceed 0.01%.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Europe - CoE AP(89)1 COLOURANTS & PIGMENTS *

Cadmium *

CAS number: 0007440-43-9
Reference number: -

Fat-reduction
factor:

Maximum concentration: 0,008 ppm

Maximum Use Level:
n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: the content of metals and metalloids soluble in 0.1M hydrochloric acid, determined as a percentage in relation to the colourant, should not exceed 0.01%.

Screening method: 100% migration calculation

Migration results: 0,001 mg/kg

Europe - CoE AP(89)1 COLOURANTS & PIGMENTS *

Chromium *

CAS number: 0007440-47-3
Reference number: -

Fat-reduction
factor:

Maximum concentration: 11,786 ppm

Maximum Use Level:
n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: the content of metals and metalloids soluble in 0.1M hydrochloric acid, determined as a percentage in relation to the colourant, should not exceed 0.1%.The use of chromium VI pigments may pose a risk to human health and should be discouraged.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Europe - CoE AP(89)1 COLOURANTS & PIGMENTS *

Lead *

CAS number: 0007439-92-1
Reference number: -

Fat-reduction
factor:

Maximum concentration: 0,805 ppm

Maximum Use Level:
n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: the content of metals and metalloids soluble in 0.1M hydrochloric acid, determined as a percentage in relation to the colourant, should not exceed 0.01%.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Europe - CoE AP(89)1 COLOURANTS & PIGMENTS *

Mercury *

CAS number: 0007439-97-6
Reference number: -

Fat-reduction
factor:

Maximum concentration: 0,003 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: the content of metals and metalloids soluble in 0.1M hydrochloric acid, determined as a percentage in relation to the colourant, should not exceed 0.005%.

Screening method: 100% migration calculation

Migration results: 0,001 mg/kg

Germany - BfR IX Colorants (As of 01.06.2019) COLOURANTS & PIGMENTS *

Antimony *

CAS number: 0007440-36-0

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,027 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: Concentrations soluble in 0.07 N hydrochloric acid, determined according to DIN 537706, must not exceed 0.05% (based on the colorant)

Screening method: 100% migration calculation

Migration results: 0,004 mg/kg

Germany - BfR IX Colorants (As of 01.06.2019) COLOURANTS & PIGMENTS *

Arsenic *

CAS number: 0007440-38-2

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,657 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: Concentrations soluble in 0.07 N hydrochloric acid, determined according to DIN 537706, must not exceed 0.01% (based on the colorant)

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Germany - BfR IX Colorants (As of 01.06.2019) COLOURANTS & PIGMENTS *

Barium *

CAS number: 0007440-39-3

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,022 %

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: Concentrations soluble in 0.07 N hydrochloric acid, determined according to DIN 537706, must not exceed 0.01% (based on the colorant)

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Germany - BfR IX Colorants (As of 01.06.2019) COLOURANTS & PIGMENTS *

Cadmium *

CAS number: 0007440-43-9

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,008 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: Concentrations soluble in 0.07 N hydrochloric acid, determined according to DIN 537706, must not exceed 0.01% (based on the colorant)

Screening method: 100% migration calculation

Migration results: 0,001 mg/kg

Germany - BfR IX Colorants (As of 01.06.2019) COLOURANTS & PIGMENTS *

Chromium *

CAS number: 0007440-47-3

Fat-reduction

Reference number: -

factor:

Maximum concentration: 11,786 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: Concentrations soluble in 0.07 N hydrochloric acid, determined according to DIN 537706, must not exceed 0.1% (based on the colorant)

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Germany - BfR IX Colorants (As of 01.06.2019) COLOURANTS & PIGMENTS *

Lead *

CAS number: 0007439-92-1

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,805 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: Concentrations soluble in 0.07 N hydrochloric acid, determined according to DIN 537706, must not exceed 0.01% (based on the colorant)

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Germany - BfR IX Colorants (As of 01.06.2019) COLOURANTS & PIGMENTS *

Mercury *

CAS number: 0007439-97-6

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,003 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: Concentrations soluble in 0.07 N hydrochloric acid, determined according to DIN 537706, must not exceed 0.005% (based on the colorant)

Screening method: 100% migration calculation

Migration results: 0,001 mg/kg

Italy - MD 21 March 1973 COLOURANTS & PIGMENTS *

Antimony *

CAS number: 0007440-36-0

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,027 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: for coloring objects of plastics you can use all the dyes provided they are not released into the food and do not contain metals in amounts greater than 0.05% soluble in N / 10 HCl.

Screening method: 100% migration calculation

Migration results: 0,004 mg/kg

Italy - MD 21 March 1973 COLOURANTS & PIGMENTS *

Arsenic *

CAS number: 0007440-38-2

Fat-reduction factor:

Reference number: -

Maximum concentration: 0,657 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: for coloring objects of plastics you can use all the dyes provided they are not released into the food and do not contain metals in amounts greater than 0.005% soluble in N / 10 HCl.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Italy - MD 21 March 1973 COLOURANTS & PIGMENTS *

Barium *

CAS number: 0007440-39-3

Fat-reduction factor:

Reference number: -

Maximum concentration: 0,022 %

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: for coloring objects of plastics you can use all the dyes provided they are not released into the food and do not contain metals in amounts greater than 0.01% soluble in HCl N / 10.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Italy - MD 21 March 1973 COLOURANTS & PIGMENTS *

Cadmium *

CAS number: 0007440-43-9

Fat-reduction factor:

Reference number: -

Maximum concentration: 0,008 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Purity criteria: for coloring objects of plastics you can use all the dyes provided they are not released into the food and do not contain metals in amounts greater than 0.01% soluble in N HCl/10.

Screening method: 100% migration calculation

Migration results: 0,001 mg/kg

Italy - MD 21 March 1973 COLOURANTS & PIGMENTS *

Chromium *	CAS number: 0007440-47-3 Reference number: -	Fat-reduction factor:
Maximum concentration: 11,786 ppm	Maximum Use Level: n/a	
Restrictions and specifications No	Other Specifications: Purity criteria: for coloring objects of plastics you can use all the dyes provided they are not released into the food and do not contain metals in amounts greater than 0.1% soluble in N HC1/10.	
Screening method: Migration testing	Migration results: < 0,010 mg/kg	

Italy - MD 21 March 1973 COLOURANTS & PIGMENTS *

Mercury *	CAS number: 0007439-97-6 Reference number: -	Fat-reduction factor:
Maximum concentration: 0,003 ppm	Maximum Use Level: n/a	
Restrictions and specifications No	Other Specifications: Purity criteria: for coloring objects of plastics you can use all the dyes provided they are not released into the food and do not contain metals in amounts greater than 0.005% soluble in N HC1/10.	
Screening method: 100% migration calculation	Migration results: 0,001 mg/kg	

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

mercury *	CAS number: 0007439-97-6 Reference number: -	Fat-reduction factor:
Maximum concentration: 0,003 ppm	Maximum Use Level: n/a	
Restrictions and specifications SML: 0,005 mg/kg	SML(T) Remark: 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 be exceeded	
Screening method: 100% migration calculation	Notes: 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: 0.005 %.	
	Migration results: 0,001 mg/kg	

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

arsenic *

CAS number: 0007440-38-2

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,657 ppm

Maximum Use Level:

n/a

Restrictions and specifications

SML: 0,01 mg/kg

SML(T) Remark:

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 be exceeded

Notes:

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: 0.01 %.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

cadmium *

CAS number: 0007440-43-9

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,008 ppm

Maximum Use Level:

n/a

Restrictions and specifications

SML: 0,01 mg/kg

SML(T) Remark:

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 be exceeded

Notes:

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: 0.1 %.

Screening method: 100% migration calculation

Migration results: 0,001 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

antimony *

CAS number: 0007440-36-0

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,027 ppm

Maximum Use Level:

n/a

Restrictions and specifications

SML: 0,04 mg/kg

SML(T) Remark:

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 be exceeded

Notes:

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: 0,2%

Screening method: 100% migration calculation

Migration results: 0,004 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

antimoon (antimony) *

CAS number: -

Fat-reduction

Reference number: -

factor: no

Maximum concentration: 0,027 ppm

Maximum Use Level:

n/a

Restrictions and specifications

SML: 0,04 mg/kg

Notes:

Bij extractie met 0,1 N zoutzuur volgens deel B van de bijlage, hoofdstuk II, onderdeel 5 mogen uit de kleurstof of het pigment de volgende elementen tot ten hoogste de aangegeven hoeveelheid, berekend op kleurstof of pigment, in oplossing gaan: 0.2 %.

Screening method: 100% migration calculation

Migration results: 0,004 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

cobalt *

CAS number: 0007440-48-4

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,576 ppm

Maximum Use Level:

n/a

Restrictions and specifications

SML: 0,05 mg/kg

SML(T) Remark:

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 be exceeded

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

chromium *

CAS number: 0007440-47-3

Fat-reduction

Reference number: -

factor:

Maximum concentration: 11,786 ppm

Maximum Use Level:

n/a

Restrictions and specifications**SML:** 0,1 mg/kg**SML(T) Remark:**

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 be exceeded

Notes:

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: 0.1 %.

Screening method: Migration testing**Migration results:** < 0,010 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

chrom (chromium) *

CAS number: -

Fat-reduction

Reference number: -

factor: unknown

Maximum concentration: 11,786 ppm**Maximum Use Level:**

n/a

Restrictions and specifications**SML:** 0,1 mg/kg**Notes:**

Bij extractie met 0,1 N zoutzuur volgens deel B van de bijlage, hoofdstuk II, onderdeel 5 mogen uit de kleurstof of het pigment de volgende elementen tot ten hoogste de aangegeven hoeveelheid, berekend op kleurstof of pigment, in oplossing gaan: 0.1 %.

Screening method: Migration testing**Migration results:** < 0,010 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

lead *

CAS number: 0007439-92-1

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,805 ppm**Maximum Use Level:**

n/a

Restrictions and specifications

SML: 0,1 mg/kg

SML(T) Remark:

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 be exceeded

Notes:

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: 0.01%

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

lithium *

CAS number: 0007439-93-2

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,030 ppm

Maximum Use Level:

n/a

Restrictions and specifications

SML: 0,6 mg/kg

SML(T) Remark:

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 be exceeded

Screening method: 100% migration calculation

Migration results: 0,004 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

manganese *

CAS number: 0007439-96-5

Fat-reduction

Reference number: -

factor:

Maximum concentration: 10,514 ppm

Maximum Use Level:

n/a

Restrictions and specifications

SML: 0,6 mg/kg

SML(T) Remark:

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 be exceeded

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

barium *

CAS number: 0007440-39-3

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,022 %

Maximum Use Level:

n/a

Restrictions and specifications

SML: 1 mg/kg

SML(T) Remark:

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 be exceeded

Notes:

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: 0.01%

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

nickel *

CAS number: 0007440-02-0

Fat-reduction

Reference number: -

factor:

Maximum concentration: 3,402 ppm

Maximum Use Level:

n/a

Restrictions and specifications

SML: 1 mg/kg

SML(T) Remark:

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 be exceeded

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

zinc *

CAS number: 0007440-66-6

Fat-reduction

Reference number: -

factor:

Maximum concentration: 26,400 ppm

Maximum Use Level:

n/a

Restrictions and specifications

SML: 25 mg/kg

SML(T) Remark:

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 be exceeded

Screening method: 100% migration calculation

Migration results: 3,374 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

iron *

CAS number: 0007439-89-6

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,534 %

Maximum Use Level:

n/a

Restrictions and specifications

SML: 48 mg/kg

SML(T) Remark:

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 be exceeded

Screening method: Migration testing

Migration results: 0,000 mg/kg

Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten COLOURANTS & PIGMENTS *

copper *

CAS number: 0007440-50-8

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,024 %

Maximum Use Level:

n/a

Restrictions and specifications

SML: 5 mg/kg

SML(T) Remark:

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 be exceeded

Screening method: Migration testing

Migration results: 0,000 mg/kg

Spain - RD 847/2011 COLOURANTS & PIGMENTS *

Antimony *

CAS number: 0007440-36-0

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,027 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Maximum level of soluble impurities in 0.1N hydrochloric acid, relative to the colorant: 500 mg/kg

Screening method: 100% migration calculation

Migration results: 0,004 mg/kg

Spain - RD 847/2011 COLOURANTS & PIGMENTS *

Arsenic *

CAS number: 0007440-38-2

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,657 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Maximum level of soluble impurities in 0.1N hydrochloric acid, relative to the colorant: 100 mg/kg.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Spain - RD 847/2011 COLOURANTS & PIGMENTS *

Barium *

CAS number: 0007440-39-3

Fat-reduction

Reference number: -

factor:

Maximum concentration: 0,022 %

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Maximum level of soluble impurities in 0.1N hydrochloric acid, relative to the colorant: 100 mg/kg.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Spain - RD 847/2011 COLOURANTS & PIGMENTS *

Cadmium *

CAS number: 0007440-43-9

Fat-reduction factor:

Reference number: -

Maximum concentration: 0,008 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Maximum level of soluble impurities in 0.1N hydrochloric acid, relative to the colorant: 100 mg/kg.

Screening method: 100% migration calculation

Migration results: 0,001 mg/kg

Spain - RD 847/2011 COLOURANTS & PIGMENTS *

Chromium *

CAS number: 0007440-47-3

Fat-reduction factor:

Reference number: -

Maximum concentration: 11,786 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Maximum level of soluble impurities in 0.1N hydrochloric acid, relative to the colorant: 1000 mg/kg.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Spain - RD 847/2011 COLOURANTS & PIGMENTS *

Lead *

CAS number: 0007439-92-1

Fat-reduction factor:

Reference number: -

Maximum concentration: 0,805 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Maximum level of soluble impurities in 0.1N hydrochloric acid, relative to the colorant: 100 mg/kg.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

Spain - RD 847/2011 COLOURANTS & PIGMENTS *

Mercury *

CAS number: 0007439-97-6

Fat-reduction factor:

Reference number: -

Maximum concentration: 0,003 ppm

Maximum Use Level:

n/a

Restrictions and specifications

No

Other Specifications:

Maximum level of soluble impurities in 0.1N hydrochloric acid, relative to the colorant: 50 mg/kg.

Screening method: 100% migration calculation **Migration results:** 0,001 mg/kg

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
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	< 60,000 mg/kg (4)
575 *	76721	0063148-62-9	polydimethylsiloxane (Mw > 6800 Da)	30,000 ppm	n/a	3,834 mg/kg (1)
288 *	24970	0000120-61-6	terephthalic acid, dimethyl ester	-	-	-
210 *	13390, 14880	0000105-08-8	1,4-bis(hydroxymethyl)cyclohexane	-	-	-
504 *	86240	0007631-86-9	silicon dioxide	-	-	-
615 *	92080	0014807-96-6	talc	-	-	-
246 *	25150	0000109-99-9	tetrahydrofuran	-	-	-
207 *	31920	0000103-23-1	adipic acid, bis(2-ethylhexyl) ester	-	-	-
716 *	60800	0065447-77-0	1-(2-hydroxyethyl)-4-hydroxy-2,2,6,6-tetramethyl piperidine-succinic acid, dimethyl ester, copolymer	-	-	-
254 *	13720, 40580	0000110-63-4	1,4-butanediol	-	-	-
881 *	25187	0003010-96-6	2,2,4,4-tetramethylcyclobutane-1,3-diol	-	-	-
811 *	80077	0068441-17-8	polyethylene waxes, oxidised	-	-	-

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
9 *	no	No		

575 *	no	No	Other Specifications: Viscosity at 25 °C not less than 100 cSt (100 × 10 ⁻⁶ m ² /s)	
288 *		No		
210 *		No		
504 *		No	Other Specifications: 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.	
615 *		No		
246 *		SML: 0,6 mg/kg		
207 *		SML: (1) 18 mg/kg (2) 60 mg/kg	SML(T) Remark: Group 32: 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) Notes: Note number (2): There is a risk that the SML or OML could be exceeded in fatty food simulants.	(2)
716 *		SML: 30 mg/kg		
254 *		SML: 5 mg/kg	SML(T) Remark: Group 30: expressed as 1,4-butanediol (254, 344, 672)	
881 *		SML: 5 mg/kg	Other Specifications: (a) repeated use articles for long term storage at room temperature or below and hotfill;(b) single use materials and articles as a co-monomer at a maximum use level of 35 mole % of the diol component of polyesters, and if such materials and articles are for long term storage at room temperature or below of food types which have an alcohol content of up to 10 % and for which Table 2 of Annex III does not assign simulant D2. Hot fill conditions are allowed for such single use materials and articles.	
811 *		SML: 60 mg/kg		

ii. Group restrictions; Annex I – table 2

Number	Restriction(s)	Other substances in this group
Group 30	SML(T) 5 mg/kg; expressed as 1,4-butanediol.	254, 344, 672
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

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

Number	Note
(2)	There is a risk that the SML or OML could be exceeded in fatty food simulants.

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

Name / Element	Restriction	Maximum concentration	Screening method	Migration results
Cadmium *	SML: 0,002 mg/kg	0,008 ppm	100% migration calculation	0,001 mg/kg
Arsenic *	SML: 0,01 mg/kg	0,657 ppm	Migration testing	< 0,010 mg/kg
Lead *	SML: 0,01 mg/kg	0,805 ppm	Migration testing	< 0,010 mg/kg
Mercury *	SML: 0,01 mg/kg	0,003 ppm	100% migration calculation	0,001 mg/kg
Chromium *	SML:(1) 0,01 mg/kg(2) 3,6 mg/kg	11,786 ppm	Migration testing	< 0,010 mg/kg
Nickel *	SML: 0,02 mg/kg	3,402 ppm	Migration testing	< 0,010 mg/kg
Antimony *	SML: 0,04 mg/kg	0,027 ppm	100% migration calculation	0,004 mg/kg
Cobalt *	SML: 0,05 mg/kg	0,576 ppm	Migration testing	< 0,010 mg/kg
Europium *	SML: 0,05 mg/kg	0,005 ppm	100% migration calculation	0,001 mg/kg
Gadolinium *	SML: 0,05 mg/kg	0,005 ppm	100% migration calculation	0,001 mg/kg
Lanthanum *	SML: 0,05 mg/kg	0,005 ppm	100% migration calculation	0,001 mg/kg
Terbium *	SML: 0,05 mg/kg	0,005 ppm	100% migration calculation	0,001 mg/kg
Lithium *	SML: 0,6 mg/kg	0,030 ppm	100% migration calculation	0,004 mg/kg
Manganese *	SML: 0,6 mg/kg	10,514 ppm	Migration testing	< 0,010 mg/kg
Aluminium *	SML: 1 mg/kg	0,086 %	Migration testing	0,840 mg/kg
Barium *	SML: 1 mg/kg	0,022 %	Migration testing	< 0,010 mg/kg
Iron *	SML: 48 mg/kg	0,534 %	Migration testing	0,000 mg/kg
Copper *	SML: 5 mg/kg	0,024 %	Migration testing	0,000 mg/kg

Zinc *	SML: 5 mg/kg	26,400 ppm	100% migration calculation	3,374 mg/kg
--------	--------------	------------	----------------------------	-------------

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	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 173	Aluminium	0,086 %
E 900	Dimethyl polysiloxane	30,000 ppm
E 914	Oxidised polyethylene wax	-
E 551	Silicon dioxide	-
E 553b	Talc	-

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 types of food: aqueous acidic and alcoholic foods (up to 10% alcohol) and foods that containing fats and oils.

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: 6 dm ² FCM/ kg food

9. Functional barrier

This Product contains a functional barrier: YES

Substances behind this functional barrier that are not authorized by Regulation (EU) No 10/2011 will not migrate in quantities above the detection limit of 0.01mg/kg.

These non-authorized substances are not classified as "mutagenic", "carcinogenic" or "toxic to reproduction" in accordance with the criteria set out in sections 3.5, 3.6 and 3.7 of Annex I to CLP Regulation (EC) No 1272/2008 of the European Parliament and the Council.

These non-authorized substances are not in Nano form as defined by the Commission Recommendation on the 18 of October 2011 on the definition of nanomaterial (2011/696/EU).

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.