Introduction
DEONET Production B.V.
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Netherlands

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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
V-001010 Zero waste lunch box large M863 (Hereinafter referred to as "Product").

Product type: final product

Product description: V-001010 Zero waste lunch box large
Compliance work based on: 95,8 % PP+ PPR PPC BLEND POST INDUSTRIAL RECYCLED PP with maximum 3% mb and 1,2% liquid masterbatch

4. Issue date
2022-10-19

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. Specifications of use 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. Specifications of use 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. Specifications of use 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. Specifications of use 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). Specifications of use 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 Specifications of use 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 Specifications of use 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. Specifications of use n/a
	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. Specifications of use 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	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 Specifications of use 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. Specifications of use 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. Specifications of use 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) - 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 °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 - Article 19: NIAS PLASTICS *

Lead (Pb) *	CAS number: - Reference number: -	Fat-reduction factor:
Maximum concentration: 2,011 ppm	**Maximum Use Level:** n/a	
Restrictions and specifications		
Screening method: Migration testing	**Migration results:** < 0,010 mg/kg	

Europe - Article 19: NIAS PLASTICS *

Mercury (Hg) *	CAS number: - Reference number: -	Fat-reduction factor:
Maximum concentration: 0,008 ppm	**Maximum Use Level:** n/a	
Restrictions and specifications		
Screening method: Migration result (calculated from members)	**Migration results:** < 0,005 mg/kg	

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:** 5,000 mg/kg	

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

Antimony *	CAS number: 0007440-36-0 Reference number: -	Fat-reduction factor:
Maximum concentration: 0,067 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:** 0,037 mg/kg	

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

Arsenic *	CAS number: 0007440-38-2 Reference number: -	Fat-reduction factor:
Maximum concentration: 1,641 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 result (calculated from members)

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: 0,053 %

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: 0,037 mg/kg

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

Cadmium *

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

Fat-reduction factor:

Maximum concentration: 0,018 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 result (calculated from members)

Migration results: 0,002 mg/kg

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

Carbon black *

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:
Purity criteria: Carbon black should comply with any national (and European) requirement for food grade material. Furthermore, the tolueneextractable fraction of carbon black should not in any case exceed 0.15% in accordance with the method described in section III, paragraph 5.

Screening method: Other

Migration results: 905,250 mg/kg

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

Chromium *

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

Fat-reduction factor:

Maximum concentration: 29,464 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: 2,011 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: 0,008 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 0.005%.

Screening method: Migration result (calculated from members)

Migration results: < 0,005 mg/kg

France COLOURANTS & PIGMENTS *

Arsenic *

CAS number: 0007440-38-2
Reference number: -

Fat-reduction factor:

Maximum concentration: 1,641 ppm

Maximum Use Level:
n/a

Restrictions and specifications

No

Other Specifications:
Les pigments et colorants doivent presenter un degre de purete eleve. Notamment, leur teneur en elements mineraux ne doit pas depasser 0,005%.

Screening method: Migration result (calculated from members)

Migration results: < 0,010 mg/kg

France COLOURANTS & PIGMENTS *

Baryum *

CAS number: 0007440-39-3
Reference number: -

Fat-reduction factor:

Maximum concentration: 0,053 %

Maximum Use Level:
n/a

Restrictions and specifications

No

Other Specifications:
Les pigments et colorants doivent presenter un degre de purete eleve. Notamment, leur teneur en elements mineraux ne doit pas depasser 0,01% soluble dans ClH/N /10.

Screening method: 100% migration calculation

Migration results: 0,037 mg/kg

France COLOURANTS & PIGMENTS *

Cadmium *

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

Fat-reduction factor:

Maximum concentration: 0,018 ppm

Maximum Use Level:
n/a

Restrictions and specifications

No

Other Specifications:
Les pigments et colorants doivent presenter un degre de purete eleve. Notamment, leur teneur en elements mineraux ne doit pas depasser 0,1% soluble dans ClH/N /10.

Screening method: Migration result (calculated from members)

Migration results: 0,002 mg/kg

France COLOURANTS & PIGMENTS *

Mercure *

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

Fat-reduction factor:

Maximum concentration: 0,008 ppm

Maximum Use Level:
n/a

Restrictions and specifications

No

Other Specifications:
Les pigments et colorants doivent presenter un degre de purete eleve. Notamment, leur teneur en elements mineraux ne doit pas depasser 0,005% soluble dans ClH/N /10.

Screening method: Migration result (calculated from members)

Migration results: < 0,005 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 dormer un extrait benzeniquesuperieur a 0,1 % et doit etre exempt de benzo 3-4 pyrene.

Screening method: Other

Migration results: 905,250 mg/kg

France COLOURANTS & PIGMENTS *

Plomb *

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

Fat-reduction factor:

Maximum concentration: 2,011 ppm

Maximum Use Level:
n/a

Restrictions and specifications

No

Other Specifications:
Les pigments et colorants doivent presenter un degre de purete eleve. Notamment, leur teneur en elements mineraux ne doit pas depasser 0,01%.

Screening method: Migration testing

Migration results: < 0,010 mg/kg

France COLOURANTS & PIGMENTS *

Zinc *

CAS number: 0007440-66-6
Reference number: -

Fat-reduction factor:

Maximum concentration: -

Maximum Use Level:
n/a

Restrictions and specifications

No

Other Specifications:
Les pigments et colorants doivent presenter un degre de purete eleve. Notamment, leur teneur en elements mineraux ne doit pas depasser 0,20% soluble dans ClH/N /10.

Screening method: Migration testing

Migration results: 0,010 mg/kg

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

Arsenic *

CAS number: 0007440-38-2
Reference number: -

Fat-reduction factor:

Maximum concentration: 1,641 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 result (calculated from members)

Migration results: < 0,010 mg/kg

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

Cadmium *

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

Fat-reduction factor:

Maximum concentration: 0,018 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 result (calculated from members)

Migration results: 0,002 mg/kg

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

Lead *

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

Fat-reduction factor:

Maximum concentration: 2,011 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
Reference number: -

Fat-reduction 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 0.005% (based on the colorant)

Screening method: Migration result (calculated from members)

Migration results: < 0,005 mg/kg

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

Chromium *

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

Fat-reduction factor:

Maximum concentration: -

Maximum Use Level:
-

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 results: -

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

Barium *

CAS number: 0007440-39-3
Reference number: -

Fat-reduction factor:

Maximum concentration: -

Maximum Use Level:
-

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 results: -

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

Antimony *

CAS number: 0007440-36-0
Reference number: -

Fat-reduction factor:

Maximum concentration: -

Maximum Use Level:
-

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: -

Migration results: -

Italy COLOURANTS & PIGMENTS *

Antimony *

CAS number: 0007440-36-0
Reference number: -

Fat-reduction factor:

Maximum concentration: 0,067 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: 0,037 mg/kg

Italy COLOURANTS & PIGMENTS *

Arsenic *

CAS number: 0007440-38-2
Reference number: -

Fat-reduction factor:

Maximum concentration: 1,641 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 result (calculated from members)

Migration results: < 0,010 mg/kg

Italy COLOURANTS & PIGMENTS *

Barium *

CAS number: 0007440-39-3
Reference number: -

Fat-reduction factor:

Maximum concentration: 0,053 %

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 HC1 N /10.

Screening method: 100% migration calculation

Migration results: 0,037 mg/kg

Italy COLOURANTS & PIGMENTS *

Cadmium *

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

Fat-reduction factor:

Maximum concentration: 0,018 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 HC1/10.

Screening method: Migration result (calculated from members)

Migration results: 0,002 mg/kg

Italy COLOURANTS & PIGMENTS *

Chromium *

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

Fat-reduction factor:

Maximum concentration: 29,464 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 COLOURANTS & PIGMENTS *

Mercury *

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

Fat-reduction factor:

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 0.005% soluble in N HC1/10.

Screening method: Migration result (calculated from members)

Migration results: < 0,005 mg/kg

Netherlands COLOURANTS & PIGMENTS *

antimoon (antimony) *

CAS number: -
Reference number: -

Fat-reduction factor: no

Maximum concentration: 0,067 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: 0,037 mg/kg

Netherlands COLOURANTS & PIGMENTS *

chroom (chromium) *

CAS number: -
Reference number: -

Fat-reduction factor: unknown

Maximum concentration: 29,464 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 COLOURANTS & PIGMENTS *

Soot (furnace black and channel black) and other carbon products, such as graphite and coke powder *

CAS number: 0001333-86-4
Reference number: -

Fat-reduction factor:

Maximum concentration: 0,750 %

Maximum Use Level:
n/a

Restrictions and specifications

No

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

Screening method: Other

Migration results: 905,250 mg/kg

Netherlands COLOURANTS & PIGMENTS *

mercury *

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

Fat-reduction factor:

Maximum concentration: 0,008 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

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 %.

Screening method: Migration result (calculated from members)

Migration results: < 0,005 mg/kg

Netherlands COLOURANTS & PIGMENTS *

arsenic *

CAS number: 0007440-38-2
Reference number: -

Fat-reduction factor:

Maximum concentration: 1,641 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 result (calculated from members)

Migration results: < 0,010 mg/kg

Netherlands COLOURANTS & PIGMENTS *

cadmium *

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

Fat-reduction factor:

Maximum concentration: 0,018 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: Migration result (calculated from members)

Migration results: 0,002 mg/kg

Netherlands COLOURANTS & PIGMENTS *

antimony *

CAS number: 0007440-36-0
Reference number: -

Fat-reduction factor:

Maximum concentration: 0,067 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: 0,037 mg/kg

Netherlands COLOURANTS & PIGMENTS *

cobalt *

CAS number: 0007440-48-4
Reference number: -

Fat-reduction factor:

Maximum concentration: 1,438 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 result (calculated from members)

Migration results: < 0,050 mg/kg

Netherlands COLOURANTS & PIGMENTS *

chromium *

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

Fat-reduction factor:

Maximum concentration: 29,464 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 COLOURANTS & PIGMENTS *

lead *

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

Fat-reduction factor:

Maximum concentration: 2,011 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 COLOURANTS & PIGMENTS *

lithium *

CAS number: 0007439-93-2
Reference number: -

Fat-reduction factor:

Maximum concentration: 0,074 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 result (calculated from members)

Migration results: 0,009 mg/kg

Netherlands COLOURANTS & PIGMENTS *

manganese *

CAS number: 0007439-96-5
Reference number: -

Fat-reduction factor:

Maximum concentration: 26,285 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 result (calculated from members)

Migration results: < 0,600 mg/kg

Netherlands COLOURANTS & PIGMENTS *

barium *

CAS number: 0007440-39-3
Reference number: -

Fat-reduction factor:

Maximum concentration: 0,053 %

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: 100% migration calculation

Migration results: 0,037 mg/kg

Netherlands COLOURANTS & PIGMENTS *

nickel *

CAS number: 0007440-02-0
Reference number: -

Fat-reduction factor:

Maximum concentration: -

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: < 0,020 mg/kg

Netherlands COLOURANTS & PIGMENTS *

zinc *

CAS number: 0007440-66-6
Reference number: -

Fat-reduction factor:

Maximum concentration: -

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: Migration testing

Migration results: 0,010 mg/kg

Netherlands COLOURANTS & PIGMENTS *

iron *

CAS number: 0007439-89-6
Reference number: -

Fat-reduction factor:

Maximum concentration: -

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: 6,000 mg/kg

Netherlands COLOURANTS & PIGMENTS *

copper *

CAS number: 0007440-50-8
Reference number: -

Fat-reduction factor:

Maximum concentration: -

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: 0,600 mg/kg

Spain COLOURANTS & PIGMENTS *

Antimony *

CAS number: 0007440-36-0
Reference number: -

Fat-reduction factor:

Maximum concentration: 0,067 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: 0,037 mg/kg

Spain COLOURANTS & PIGMENTS *

Arsenic *

CAS number: 0007440-38-2
Reference number: -

Fat-reduction factor:

Maximum concentration: 1,641 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 result (calculated from members)

Migration results: < 0,010 mg/kg

Spain COLOURANTS & PIGMENTS *

Barium *

CAS number: 0007440-39-3
Reference number: -

Fat-reduction factor:

Maximum concentration: 0,053 %

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: 0,037 mg/kg

Spain COLOURANTS & PIGMENTS *

Cadmium *

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

Fat-reduction factor:

Maximum concentration: 0,018 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 result (calculated from members)

Migration results: 0,002 mg/kg

Spain COLOURANTS & PIGMENTS *

Chromium *

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

Fat-reduction factor:

Maximum concentration: 29,464 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 COLOURANTS & PIGMENTS *

Lead *

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

Fat-reduction factor:

Maximum concentration: 2,011 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 COLOURANTS & PIGMENTS *

Mercury *

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

Fat-reduction factor:

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: 50 mg/kg.

Screening method: Migration result (calculated from members)

Migration results: < 0,005 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: 905,250 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	11,877 mg/kg (12)
575 *	76721	0063148-62-9	polydimethylsiloxane (Mw > 6800 Da)	75,000 ppm	n/a	9,053 mg/kg (12)
416 *	87680	0001338-43-8	sorbitan monooleate	-	n/a	-
483 *	68860	0004724-48-5	n-octylphosphonic acid	0,012 %	n/a	< 0,050 mg/kg (12)
116 *	13090, 37600	0000065-85-0	benzoic 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 occuring 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	-	-	-
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	-	-	-
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	-	-	-
500 *	38560	0007128-64-5	2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	-	-	-
207 *	31920	0000103-23-1	adipic acid, bis(2-ethylhexyl) ester	-	-	-
20 *	39120	—	N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochlorides	-	-	-
19 *	39090	—	N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine	-	-	-
283 *	74640	0000117-81-7	phthalic acid, bis(2-ethylhexyl) ester	-	-	-
292 *	94560	0000122-20-3	triisopropanolamine	-	-	-
808 *	38550	0882073-43-0	bis(4-propylbenzylidene)propylsorbitol	-	-	-
923 *	39150	0000120-40-1	N,N-bis(2-hydroxyethyl)dodecanamide	-	-	-
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	-	-	-
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

418 *		No		
575 *	no	No	**Other Specifications:** Viscosity at 25 °C not less than 100 cSt (100 × 10-6 m2/s)	
416 *		No		
483 *		**SML:** 0,05 mg/kg		
116 *		No		
9 *		No		
21 *		No		
95 *		No	**Other Specifications:** Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt (8,5 × 10-6 m2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).	
615 *		No		
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		
411 *		**QM:** 2,5 %	**QM(T) Remark:** Maximum use level of carbon black in the polymer: 2,5 % w/w. **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.	

499 *		**QM:** (1) no (2) 1 %	**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 **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	
779 *		**SML:** 0,05 mg/kg	**Notes:** Note number (2): There is a risk that the SML or OML could be exceeded in fatty food simulants.	(2)
157 *		**SML:** (1) 0,3 mg/kg (2) 60 mg/kg **QM:** (1) no (2) 0,05 %	**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) **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. **Notes:** Note number (7): If testing in food is performed, Annex V 1.4 shall be taken into account. **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.	(7)
500 *		**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)
20 *		**SML:** 1,2 mg/kg	**SML(T) Remark:** Group 7: expressed as tertiary amine (19, 20). SML(T) expressed excluding HCl. **Other Specifications:** SML(T) expressed excluding HCl	
19 *		**SML:** 1,2 mg/kg	**SML(T) Remark:** Group 7: expressed as tertiary amine (19, 20)	
283 *		**SML:** (1) 1,5 mg/kg (2) 60 mg/kg **QM:** (1) no (2) 0,1 %	**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) **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. **Notes:** Note number (7): If testing in food is performed, Annex V 1.4 shall be taken into account. **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.	(7)
292 *		**SML:** 5 mg/kg		

808 *		**SML:** 5 mg/kg	**SML(T) Remark:** Annex I. SML including the sum of its hydrolysis products. **Other Specifications:** SML including the sum of its hydrolysis products	
923 *		**SML:** (1) 5 mg/kg (2) 0,3 mg/kg	**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. **Notes:** Note number (18): There is a risk that the SML could be exceeded from low-density polyethylene (LDPE) **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.	(18)
715 *		**SML:** 6 mg/kg		
141 *		**SML:** 6 mg/kg		
433 *		**SML:** 6 mg/kg		
811 *		**SML:** 60 mg/kg		

ii. Group restrictions; Annex I – table 2

Number	Restriction(s)	Other substances in this group
Group 7	SML(T) 1.2 mg/kg; expressed as tertiary amine expressed excluding HCl..	19, 20). SML(T
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
Cadmium *	SML: 0,002 mg/kg	0,018 ppm	Migration result (calculated from members)	0,002 mg/kg
Arsenic *	SML: 0,01 mg/kg	1,641 ppm	Migration result (calculated from members)	< 0,010 mg/kg
Lead *	SML: 0,01 mg/kg	2,011 ppm	Migration testing	< 0,010 mg/kg
Mercury *	SML: 0,01 mg/kg	0,008 ppm	Migration result (calculated from members)	< 0,005 mg/kg
Nickel *	SML: 0,02 mg/kg	-	Migration testing	< 0,020 mg/kg
Cobalt *	SML: 0,05 mg/kg	1,438 ppm	Migration result (calculated from members)	< 0,050 mg/kg
Europium *	SML: 0,05 mg/kg	0,012 ppm	Migration result (calculated from members)	0,002 mg/kg
Gadolinium *	SML: 0,05 mg/kg	0,012 ppm	Migration result (calculated from members)	0,002 mg/kg
Lanthanum *	SML: 0,05 mg/kg	0,012 ppm	Migration result (calculated from members)	0,002 mg/kg
Terbium *	SML: 0,05 mg/kg	0,012 ppm	Migration result (calculated from members)	0,002 mg/kg
Lithium *	SML: 0,6 mg/kg	0,074 ppm	Migration result (calculated from members)	0,009 mg/kg
Manganese *	SML: 0,6 mg/kg	26,285 ppm	Migration result (calculated from members)	< 0,600 mg/kg
Chromium *	SML:(1) 0,01 mg/kg(2) 3,6 mg/kg	-	-	-
Antimony *	SML: 0,04 mg/kg	-	-	-
Aluminium *	SML: 1 mg/kg	-	-	-
Barium *	SML: 1 mg/kg	-	-	-
Iron *	SML: 48 mg/kg	-	-	-
Zinc *	SML: 5 mg/kg	-	-	-
Copper *	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

FCM number	EEC reference number	CAS number	Substance name
416 *	87680	0001338-43-8	sorbitan monooleate

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 900	Dimethyl polysiloxane	75,000 ppm
E 494	Sorbitan monooleate	-
E 570	Fatty acids	-
E 180	Litholrubine BK	-
E 210	Benzoic acid [14]	-
E 211	Sodium benzoate [14]	-
E 914	Oxidised polyethylene wax	-
E 170	Calcium carbonate	-
E 553b	Talc	-
E 172	Iron oxides and hydroxides	-
E 471	Mono-and diglycerides of fatty acids	-
E 551	Silicon dioxide	-
E 173	Aluminium	-
E 296	Malic acid	-
E 905	Microcrystalline wax	-
E 470a	Sodium, potassium and calcium salts of fatty acids (example: Calcium Stearate)	-
FL 8.021	Benzoic acid	-
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 contaning 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 dm² 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.
EXCP[1]: 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.
EXCP[2]: 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.