

Declaration of compliance according 10/2011

Summary

EC premium- Standaard PPC IML

Version: 4 12/09/2018

On this page you will find a brief summary with the relevant information regarding your food certification of the product mentioned. No rights may be derived from the information in the summary below. Detailed information regarding the regulations and the migration test results can be found on the next pages of this document.

Issued by

HK Plastics BV

Overall migration test conditions

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: Vegetable oil. This may be any vegetable oil with a fatty acid distribution as described in EC 10/2011.

Test conditions

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

Specific migration test conditions

Test conditions

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

Specifications of use

All type of foods

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.

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

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

A surface/volume ratio expressed in dm² FCM/kg food of: 11 dm² FCM/ kg food
Worst case surface/volume ratio: dm² FCM/ kg food

Introduction

Dijkstra Plastics B.V.
Industriestraat 30/34
7482 EZ HAAKSBERGEN
Nederland (NL)

Customer article code: Bucket EC Premium with IML

Version: 4
Print date: 10/05/2019

Remarks on update: NOT SPECIFIED

1. Issued by

HK Plastics BV (Hereinafter referred to as "We", "Us", or "Our").
Bedrijvenpark Twente 96
7602 KD
Almelo
Netherlands

2. Manufactured/imported by

HK-Plastics BV
Bedrijvenpark Twente 96
7602 KD Almelo
Netherlands

Or

Dijkstra Plastics BV
Industriestraat 30-32
7482 EZ, Haaksbergen
Netherlands

3. Identity of the product

EC premium- Standaard PPC IML (Hereinafter referred to as "Product").

Product type: Final material or article
Product description: NOT SPECIFIED
Compliance work based on: STANDAARD PPC IML

4. Issue date

12/09/2018

5. Applicable legislation and purity confirmation

European Commission Regulation definition:

- REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, (hereinafter referred to as "Regulation (EC) No 1935/2004").
- COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, amended up to COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008, (hereinafter referred to as "Regulation (EC) No 2023/2006").
- COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended up to Commission Regulation (EU) 2019/37 of 10 January 2019., (hereinafter referred to as "Regulation (EU) No 10/2011").
- COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006, amended up to COMMISSION REGULATION (EU) 2015/1906 of 22 October 2015, (hereinafter referred to as "Regulation (EC) No 282/2008").

A. Europe

i. Compliance with the requirements of the Framework Regulation

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

ii. Compliance with the requirements of the Plastics Regulation

- Regulation (EU) No 10/2011: YES

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

iii. Compliance with the requirements of the Recycled Plastics Regulation

- Regulation (EC) 282/2008: NOT APPLICABLE

iv. Other EU legislation

Material group	Legislation
COLOURANTS & PIGMENTS Country: Europe - 1935/2004; non-listed intentionally added substances Status: Compliant	Compliance with Article 3 of Regulation (EC) No 1935/2004 of non-listed intentionally added substances is assessed in accordance with internationally recognised scientific principles on risk assessment.

<p>PLASTICS Country: Europe - Article 19: NIAS Status: Compliant</p>	<p>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.</p>
<p>COLOURANTS & PIGMENTS Country: Europe - CoE AP(89)1 Status: Compliant</p>	<p>Council of Europe Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food.</p>

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	Legislation
<p>COLOURANTS & PIGMENTS Country: Germany Status: Compliant</p>	<p>Recommendation IX Colorants for Plastics and other Polymers Used in Commodities, of the Federal Institute for Risk Assessment (BfR) dated 1994.06.01, as of 01.02.2015.</p>
<p>Country: Netherlands Status: Compliant</p>	<p>Regeling van de Minister van Volksgezondheid, Welzijn van 14 maart 2014, kenmerk 328583-117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen). Hoofdstuk XI –Kleurstoffen en pigmenten</p>

Legislation for countries outside the EU

Material group	Legislation
<p>PRINTING INKS Country: Switzerland - Printing inks - Annex 6 Status: Compliant</p>	<p>Annex 6 of the Ordinance of the FDHA on articles and materials of 23 November 2005 (RS 817.023.21): Lists of permitted substances for the manufacture of packaging inks, subject to the requirements set out therein</p>

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

Switzerland - Printing inks - Annex 6 PRINTING INKS		
Di-tert-butyl peroxide	CAS number: 0000110-05-4 Reference number: -	Fat-reduction factor: Unknown
Maximum concentration: -	Maximum Use Level: N/A	
Restrictions and specifications	SML(T) Remark:	
SML: (1) 0,01 mg/kg	(1) B-list: List of additives (without the additives used in the preparation of pigments)	
Screening method: Other	Migration results: < -	
Switzerland - Printing inks - Annex 6 PRINTING INKS		
Persulphuric acid, ammonium salt	CAS number: 0007727-54-0 Reference number: -	Fat-reduction factor: Unknown
Maximum concentration: -	Maximum Use Level: N/A	
Restrictions and specifications	SML(T) Remark:	
SML: (1) 0,01 mg/kg	(1) B-list: List of additives (without the additives used in the preparation of pigments)	
Screening method: Other	Migration results: < -	
Switzerland - Printing inks - Annex 6 PRINTING INKS		
Acrylic acid, triester with polyethylene glycol triether with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol	CAS number: 0028961-43-5 Reference number: -	Fat-reduction factor: Unknown
Maximum concentration: -	Maximum Use Level: N/A	

Restrictions and specifications

SML:

(1) 0,01 mg/kg

SML(T) Remark:

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

Screening method: Other

Migration results: < -

Switzerland - Printing inks - Annex 6 PRINTING INKS

alpha-Methylstyrene

CAS number: 0000098-83-9

Fat-reduction

Reference number: -

factor:

Maximum concentration: -

Maximum Use Level:

N/A

Restrictions and specifications

SML:

(1) 0,05 mg/kg

SML(T) Remark:

(1) SML= 0,05;

Notes:

A-list: List of binders (monomers)

Screening method: Other

Migration results: < -

Switzerland - Printing inks - Annex 6 PRINTING INKS

2,6-Di-tert-butyl-p-cresol (=BHT)

CAS number: 0000128-37-0

Fat-reduction

Reference number: -

factor:

Maximum concentration: -

Maximum Use Level:

N/A

Restrictions and specifications

SML:

(1) 3 mg/kg

SML(T) Remark:

(1) SML= 3;

Notes:

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

Screening method: Other

Migration results: < -

Switzerland - Printing inks - Annex 6 PRINTING INKS

2-Ethyl-1-hexanol

CAS number: 0000104-76-7

Fat-reduction

Reference number: -

factor:

Maximum concentration: -

Maximum Use Level:

N/A

Restrictions and specifications

SML:

(1) 30 mg/kg

SML(T) Remark:

(1) SML= 30;

Notes:

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

Screening method: Other

Migration results: < -

Switzerland - Printing inks - Annex 6 PRINTING INKS		
Acrylic acid	CAS number: 0000079-10-7 Reference number: -	Fat-reduction factor:
Maximum concentration: -	Maximum Use Level: N/A	
Restrictions and specifications	SML(T) Remark: (1) SML= 6 (T); s. annex 1, list III.17	
SML: (1) 6 mg/kg	Notes: A-list: List of binders (monomers);List of additives (without the additives used in the preparation of pigments)	
Screening method: Other	Migration results: < -	
Switzerland - Printing inks - Annex 6 PRINTING INKS		
Methacrylic acid	CAS number: 0000079-41-4 Reference number: -	Fat-reduction factor:
Maximum concentration: -	Maximum Use Level: N/A	
Restrictions and specifications	SML(T) Remark: (1) SML= 6 (T); s. annex 1, list III.18	
SML: (1) 6 mg/kg	Notes: A-list: List of binders (monomers)	
Screening method: Other	Migration results: < -	
Switzerland - Printing inks - Annex 6 PRINTING INKS		
Acrylic acid, n-butyl ester	CAS number: 0000141-32-2 Reference number: -	Fat-reduction factor:
Maximum concentration: -	Maximum Use Level: N/A	
Restrictions and specifications	SML(T) Remark: (1) SML= 6 (T); s. annex 1, list III.17	
SML: (1) 6 mg/kg	Notes: A-list: List of binders (monomers)	
Screening method: Other	Migration results: < -	

B. Substances with limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

Substance identification	Restrictions and specifications	Maximum concentration	Migration results

FCM: 132* EEC ref: 26140 CAS: 0000075-38-7 vinylidene fluoride	SML: 5 mg/kg - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 147* EEC ref: 10690 CAS: 0000079-10-7 acrylic acid	Group: (22) Group (22)SML(T) 6 mg/kg; expressed as acrylic acid. - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 150* EEC ref: 20020 CAS: 0000079-41-4 methacrylic acid	Group: (23) Group (23)SML(T) 6 mg/kg; expressed as methacrylic acid. - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 156* EEC ref: 21130 CAS: 0000080-62-6 methacrylic acid, methyl ester	Group: (23) Group (23)SML(T) 6 mg/kg; expressed as methacrylic acid. - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 157* EEC ref: 74880 CAS: 0000084-74-2 phthalic acid, dibutyl ester	SML: 0,3 mg/kg Group: (32) QM: (see restriction) Group (32)SML(T) 60 mg/kg; expressed as the sum of the substances. Only to be used as: (a)plasticiser in repeated use materials and articles contacting non-fatty foods;(b)technical support agent in polyolefins in concentrations up to 0,05 % in the final product. FRF: no Compliance Notes: (7)	-	< - Method= (5)

FCM: 176* EEC ref: 11710 CAS: 0000096-33-3 <i>acrylic acid, methyl ester</i>	Group: (22) Group (22)SML(T) 6 mg/kg; expressed as acrylic acid. - FRF: no Compliance Notes:	0,135 ppm	< - Method= (1)
FCM: 185* EEC ref: 20440 CAS: 0000097-90-5 <i>methacrylic acid, diester with ethyleneglycol</i>	SML: 0,05 mg/kg - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 187* EEC ref: 22210 CAS: 0000098-83-9 <i>a-methylstyrene</i>	SML: 0,05 mg/kg - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 19* EEC ref: 39090 CAS: — <i>N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine</i>	Group: (7) Group (7)SML(T) 1,2 mg/kg; expressed as tertiary amine. - FRF: no Compliance Notes:	-	< 0,700 mg/kg Method= (5)
FCM: 20* EEC ref: 39120 CAS: — <i>N,N-bis(2-hydroxyethyl)alkyl(C8-C18)amine hydrochlorides</i>	Group: (7) Group (7)SML(T) 1,2 mg/kg; expressed as tertiary amine. SML(T) expressed excluding HCl FRF: no Compliance Notes:	1,530 ppm	< 0,700 mg/kg Method= (5)
FCM: 206* EEC ref: 11500 CAS: 0000103-11-7 <i>acrylic acid, 2-ethylhexyl ester</i>	SML: 0,05 mg/kg - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 209* EEC ref: 17050 CAS: 0000104-76-7 <i>2-ethyl-1-hexanol</i>	SML: 30 mg/kg - FRF: no Compliance Notes:	-	< - Method= (5)

FCM: 264* EEC ref: 22660 CAS: 0000111-66-0 1-octene	SML: 15 mg/kg - FRF: no Compliance Notes:	-	< - Method= (3)
FCM: 281* EEC ref: 25120 CAS: 0000116-14-3 tetrafluoroethylene	SML: 0,05 mg/kg - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 282* EEC ref: 18430 CAS: 0000116-15-4 hexafluoropropylene	SML = ND - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 283* EEC ref: 74640 CAS: 0000117-81-7 phthalic acid, bis(2-ethylhexyl) ester	SML: 1,5 mg/kg Group: (32) QM: (see restriction) Group (32)SML(T) 60 mg/kg; expressed as the sum of the substances. Only to be used as: (a)plasticiser in repeated use materials and articles contacting non-fatty foods;(b)technical support agent in concentrations up to 0,1 % in the final product. FRF: no Compliance Notes: (7)	-	< - Method= (5)
FCM: 292* EEC ref: 94560 CAS: 0000122-20-3 triisopropanolamine	SML: 5 mg/kg - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 315* EEC ref: 46640 CAS: 0000128-37-0 2,6-di-tert-butyl-p-cresol	SML: 3 mg/kg - FRF: no Compliance Notes:	0,011 %	< - Method= (5)

FCM: 325* EEC ref: 10780 CAS: 0000141-32-2 <i>acrylic acid, n-butyl ester</i>	Group: (22) Group (22)SML(T) 6 mg/kg; expressed as acrylic acid. - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 326* EEC ref: 12763; 35170 CAS: 0000141-43-5 <i>2-aminoethanol</i>	SML: 0,05 mg/kg Not to be used for articles in contact with fatty foods for which simulant D1 and/or D2 is laid down. For indirect food contact only, behind a PET layer. FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 356* EEC ref: 18820 CAS: 0000592-41-6 <i>1-hexene</i>	SML: 3 mg/kg - FRF: no Compliance Notes:	-	< - Method= (4)
FCM: 411* EEC ref: 42080 CAS: 0001333-86-4 <i>carbon black</i>	QM: 2,5 % Primary particles of 10 – 300 nm which are aggregated to a size of 100 – 1200 nm which may form agglomerates within the size distribution of 300 nm – mm. Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis. Benzo(a)pyrene content: max 0,25 mg/kg carbon black. Maximum use level of carbon black in the polymer: 2,5 % w/w. FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 433* EEC ref: 68320 CAS: 0002082-79-3 <i>octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate</i>	SML: 6 mg/kg - FRF: yes Compliance Notes:	9,900 ppm	< - Method= (1)

FCM: 451* EEC ref: 66755 CAS: 0002682-20-4 2-methyl-4-isothiazolin-3-one	SML: 0,5 mg/kg Only to be used in aqueous polymer dispersions and emulsions FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 500* EEC ref: 38560 CAS: 0007128-64-5 2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	SML: 0,6 mg/kg - FRF: yes Compliance Notes:	-	< - Method= (5)
FCM: 504* EEC ref: 86240 CAS: 0007631-86-9 silicon dioxide	No For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size. FRF: no Compliance Notes:	-	< - Method= (2)
FCM: 575* EEC ref: 76721 CAS: 0063148-62-9 polydimethylsiloxane (Mw > 6800 Da)	No Viscosity at 25 °C not less than 100 cSt (100 × 10 ⁻⁶ m ² /s) FRF: no Compliance Notes:	50,000 ppm	< - Method= (2)
FCM: 587* EEC ref: 68400 CAS: 0010094-45-8 octadecylceramide	SML: 5 mg/kg - FRF: yes Compliance Notes:	-	< - Method= (5)
FCM: 652* EEC ref: 38820 CAS: 0026741-53-7 bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	SML: 0,6 mg/kg - FRF: yes Compliance Notes:	-	< - Method= (5)

FCM: 661* EEC ref: 95360 CAS: 0027676-62-6 1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	SML: 5 mg/kg - FRF: yes Compliance Notes:	7,710 ppm	< - Method= (1)
FCM: 688* EEC ref: 92560 CAS: 0038613-77-3 tetrakis(2,4-di-tert-butyl-phenyl)-4,4'-biphenylene diphosphonite	SML: 18 mg/kg - FRF: yes Compliance Notes:	-	< - Method= (5)
FCM: 689* EEC ref: 95280 CAS: 0040601-76-1 1,3,5-tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	SML: 6 mg/kg - FRF: yes Compliance Notes:	-	< - Method= (5)
FCM: 715* EEC ref: 46880 CAS: 0065140-91-2 3,5-di-tert-butyl-4-hydroxybenzylphosphonic acid, monoethyl ester, calcium salt	SML: 6 mg/kg - FRF: no Compliance Notes:	10,500 ppm	< - Method= (1)
FCM: 749* EEC ref: 66360 CAS: 0085209-91-2 2,2'-methylene bis(4,6-di-tert-butylphenyl) sodium phosphate	SML: 5 mg/kg - FRF: yes Compliance Notes:	0,020 %	< - Method= (3)

FCM: 760* EEC ref: 83595 CAS: 0119345-01-6	SML: 18 mg/kg Composition: 4,4'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0038613-77-3) (36-46 % w/w (*)),4,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-00-4) (17-23 % w/w (*)),3,3'-biphenylene-bis[0,0-bis(2,4-di-tert-butylphenyl)phosphonite] (CAS No 0118421-01-5) (1-5 % w/w (*)),4-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0091362-37-7) (11-19 % w/w (*)),tris(2,4-di-tert-butylphenyl)phosphite (CAS No 0031570-04-4) (9-18 % w/w (*)),4,4'-biphenylene-0,0-bis(2,4-di-tert-butylphenyl)phosphonate-0,0-bis(2,4-di-tert-butylphenyl)phosphonite (CAS No 0112949-97-0) (< 5 % w/w (*))(*Quantity of substance used/quantity of formulationOther specifications: Phosphor content of min. 5,4 % to max. 5,9 %,Acid value of max. 10 mg KOH per gram,Melt range of 85-110 °C, FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 773* EEC ref: 38840 CAS: 0154862-43-8	SML: 5 mg/kg SML expressed as sum of the substance itself, its oxidised form bis(2,4-dicumylphenyl)pentaerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol) FRF: yes Compliance Notes:	-	< - Method= (2)
FCM: 779* EEC ref: 39815 CAS: 0182121-12-6	SML: 0,05 mg/kg - FRF: yes Compliance Notes: (2)	1,590 ppm	< - Method= (3)
9,9-bis(methoxymethyl)fluorene	FRF: yes Compliance Notes: (2)	-	Method= (3)

FCM: 783* EEC ref: 55910 CAS: 0736150-63-3 <i>glycerides, castor-oil mono-, hydrogenated, acetates</i>	Group: (32) Group (32)SML(T) 60 mg/kg; expressed as the sum of the substances. - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 799* EEC ref: 77708 CAS: — <i>polyethyleneglycol (EO = 1-50) ethers of linear and branched primary (C8-C22) alcohols</i>	SML: 1,8 mg/kg In compliance with the maximum ethylene oxide content as laid down in the purity criteria for food additives in Commission Regulation (EU) No 231/2012. FRF: no Compliance Notes:	0,014 %	< - Method= (4)
FCM: 811* EEC ref: 80077 CAS: 0068441-17-8 <i>polyethylene waxes, oxidised</i>	SML: 60 mg/kg - FRF: no Compliance Notes:	-	< - Method= (5)
FCM: 813* EEC ref: 91530 CAS: — <i>sulphosuccinic acid alkyl (C4-C20) or cyclohexyl diesters, salts</i>	SML: 5 mg/kg - FRF: no Compliance Notes:	-	< - Method= (4)
FCM: 816* EEC ref: 45704 CAS: — <i>cis-1,2-cyclohexanedicarboxylic acid, salts</i>	SML: 5 mg/kg - FRF: no Compliance Notes:	0,017 %	< 0,614 mg/kg Method= (3)
FCM: 817* EEC ref: 38507 CAS: — <i>cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, salts</i>	SML: 5 mg/kg Not to be used with polyethylene in contact with acidic foods. Purity = 96 %. FRF: no Compliance Notes:	-	< - Method= (3)

FCM: 819* EEC ref: 68110 CAS: — <i>neodecanoic acid, salts</i>	SML: 0,05 mg/kg Not to be used in polymers contacting fatty foods. Not to be used for articles in contact with fatty foods for which simulant D1 and/or D2 is laid down. SML expressed as neodecanoic acid. FRF: no Compliance Notes:	-	< -	Method= (5)
FCM: 95* EEC ref: 95883 CAS: — <i>white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks</i>	No Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt (8,5 × 10 ⁻⁶ m ² /s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w). FRF: no Compliance Notes:	-	< -	Method= (2)

Legend screening methods: (1) 100% migration calculation, (2) Overall migration test, (3) Migration modelling, (4) Migration testing, (5) Other (like for instance suppliers information)

Notes on verification of compliance; Annex I – table 3

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

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

Name / Element	Restriction	Maximum concentration	Screening method	Migration results
Aluminium (Al)*	1 mg/kg food or food simulant	0,090 %	Migration testing	< -
Barium (Ba)*	1 mg/kg food or food simulant.	0,186 %	Migration testing	< -
Copper (Cu)*	5 mg/kg food or food simulant.	-	Migration testing	< -
Iron (Fe)*	48 mg/kg food or food simulant.	0,786 %	Migration testing	< -
Nickel (Ni)*	0,02 mg/kg food or food simulant	-	Migration testing	< -

Zinc (Zn)*	5 mg/kg food or food simulant (EU 10/2011, amended by EU 2016/1416; shall apply from September 14, 2018)	-	Migration testing	< -
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D. 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: YES

E. Compliance confirmation

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

Specific migration is tested under the following conditions:

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

7. Dual Use Additive(s)

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

Number (E or FL)	Name	Maximum concentration
E 475	Polyglycerol esters of fatty acids	-
E 553b	Talc	1,278 %
E 170	Calcium carbonate	-
E 319	Tertiary-butyl hydroquinone (TBHQ)	-
E 551	Silicon dioxide	-
E 530	Magnesium oxide	-
E 470b	Magnesium salts of fatty acids	-
E 470a	Sodium, potassium and calcium salts of fatty acids (example: Calcium Stearate)	-
E 570	Fatty acids	-
E 172	Iron oxides and hydroxides	0,990 %
E 527	Ammonium hydroxide	-
E 322	Lecithins	-
E 171	Titanium dioxide	-
E 330	Citric acid	-
E 321	Butylated hydroxytoluene (BHT)	0,011 %
E 503	Ammonium carbonates	-

E 900	Dimethyl polysiloxane	-
E 173	Aluminium	0,090 %
E 471	Mono-and diglycerides of fatty acids	-
E 211	Sodium benzoate [14]	-

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 type of foods

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 $\leq T \leq 100$ °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: NO

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

A surface/volume ratio expressed in dm² FCM/kg food of: 11 dm² FCM/ kg food

Worst case surface/volume ratio: dm² FCM/ kg food

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.

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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.