

Declaration of Compliance

With the regulation (EU) 10/2011 concerning Articles in contact with Foodstuffs.

Revision Date 31-July-2017

Article:

Product:	Biaxially Oriented Polypropylene – BOPP, Film and Bag, Plain and Printed.
Codes:	BOPP-SC; BOPP-ST; BOPP-SAT; BOPP-SC-AF (antifog coating) BOPP LTS.
Product:	Cast Polypropylene – CPP, Film and Bag, Plain and Printed.
Codes:	CPP; CPP-AF(Anti fog coating) BOPP LTS

We declare that the above mentioned products are in conformity with European legislation:
Regulations (EU) 1935/2004, Regulations (EU) 10/2011 with amendments.

1. We state that the conditions under which the food contact suitability and guaranteed:

	Yes	No	Period
For use with every type dry, aqueous, acidic foodstuff	x		
For use with Alcoholic (up to 50%)	x		
For use with every type of foodstuff including fatty food	x		
For use below -40°C		x	No limitation
For use up to +40°C	x		
For use up to +140°C		x	
For use in freezer			No limitation
BOPP -18°C to 0°C	x		
CPP -18°C to 0°C		x	
CPP Deep Freeze Grade -18°C to 0°C	x		
For use in refrigerator			No limitation
less than 5°C	x		
For use at room temperature (20°C)			No limitation
5°C to 40°C	x		
Warm			No limitation
40°C to 70°C	x		
Hot fill			Max. 60 min.
70°C to 100°C	x		
For use in a microwave without contact with food			Max. 10 min.
125°C	x		
For use in a microwave with contact with food			Max. 10 min.
125°C	x		
For use in a conventional oven			x
max. 175°C		x	
For use in a grill			x
max. 175°C		x	
Minimum contact temperature, °C			
BOPP			-18°C
CPP			0°C
CPP Deep Freeze Grade			-18°C
Maximum contact temperature, °C			125°C

2. Risk Management

2.1 Good Manufacturing practice (GMP) Regulation (EU) 2023/2006.

We have ISO 9001:2008 Quality Assurance System.

2.2 Traceability of used components is according to Commission Regulation (EU) 178/2002.

Purity criteria of substances are in accordance with Directives 95/31/EC, 96/77/EC.

We declare that in production no other raw materials or additives are used other than those permitted according to Regulation 10/2011. It is no hazardous to health as define by EU dangerous Substances / Preparations Directives.

Articles and its composition are not formulated to contain ingredients that have exposure limits established by US-FDA.

Material	CAS No	Melting Temperature
Polypropylene	9003-07-0 9010-79-10	135°C - 145°C

This Statement of Compliance has been drawn up on the basis of

Declaration of suppliers of raw materials	x
Analysis of migration	x
Analysis of substances that are subject to limitation	x
Presence of dual-use additives	x

Dual use substances: no dual use substances present at a level 5% or more. Material contains less than 500 ppm of calcium stearate. This does, however, meet the requirements of EU directive 76/768/EEC.

3. Overall and Specific migration

Overall and Specific migration of products are below limits in Regulation 10/2011 according to Test Reports and do not exceed the indicated limits.

Overall migration from film – Test Results

Simulants	Simulation for food	Extractives [mg/dm ²]	Limit [mg/dm ²]
3% w/w Acetic acid	Aqueous and acidic (10 days@ 40 °c)	<1	10
Tenax TA	Dry Food (10 days@ 40 °c)	<2	10
Vegetable oil	Fatty (10 days@ 40 °c)	<3.4	10
20% Ethanol	Alcoholic (10 days@ 40 °c)	<1	10

Material	CAS No	SML, mg/kg	Calculated migration mg/kg
3,9Bis(2,4 di tert butyl phenoxy)	26741-53-7	0.6	<0.6
Octadecyl-3-(3,5 di-tert-butyl-4-hydroxyphenyl) propionate	2082-79-3	6	<6
Stabilizer	27676-62-6	5	<5
Stabilizer	38613-77-3	18	<18
Antistatic Agent	97925-95-6	1.2	<1.2
Tetrakis (2,4-di-tert-butyl-phenyl) 4,4'-biphenylene-diphosphonite	119345-01-6	18	<18
2,5-Bis(5-tert-butyl-2-benzoxazolyl thiophene)	7128-64-5	0.6	<0.6

Specific migration of residual monomers by calculation

Remark: Detection limit = 1 ppm; ppm = part per million = mg/kg (1000 ppm = 1000 mg/kg = 0.1%)
ND – Not Detected; SML – Specific Migration Limit.

Specific migration of dual use substances by calculations

Material	CAS No
Monoglycerides of fatty acids	111-03-05
Di Methyl Polysiloxane	
Polyglycerol esters of fatty acids	
Calcium Stearate	

- List of monomers/additives **having a restriction** (in current Directives as amended by date):

Production Aids:

Name of Monomer/Additive	EU REF N°	CAS N°	SML
Alkoxylated Amine	39090	71786-60-2	1.2 mg/kg

Impurities in the "technical support agent" and catalyst system:

Name of Monomer/Additive	EU REF N°	CAS N°	SML
Di-butyl-phthalate (DBP)*	74880	84-74-2	0.3 mg/kg
Di(2-ethylhexyl) phthalate (DEHP)*	74640	117-81-7	1.5 mg/kg

* It is well known that phthalates are used as minor component of the catalyst system Of most polypropylene resins. Carmel Olefins also uses catalyst containing some Phthalates for that purpose. Analytical testing of several phthalates in our resins resulted in undetectable content (<1 ppm).

"Worst case" migration (100%) of residual monomers and dual-use substances is below specific migration limit.

Calculation is based on maximum amount of these components in raw materials according to "Declaration of Compliance" from suppliers.

The overall migration limit, together with the specific restrictions to which monomers and/or additives can be subject, are met in the abovementioned conditions of use. This statement is supported by analytic tests carried out in accordance with Regulation EU 10/2011 or on the basis of calculations made considering the content of the substances subjected to migration limits, Commission Regulation (EU) **2016/1416** of 08/24/16 and (EU) **2017/752** amending and correcting Regulation (EU) **No 10/2011** on plastic materials and articles intended to come into contact with food. Therefore, it will be the sole responsibility of the downstream user(s) to determine that the usage of product(s) complies with the information given in this document and is safe, lawful and technically suitable so that no change in flavors, taste or organoleptic properties occurs. In case the product(s) will be used in a different manner than tested, the information in this declaration of compliance will not apply and the downstream users shall be responsible for the compliance with the specific legislation and regulation(s).

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