



Date: 26/07/2022

DECLARATION OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

Declarant: Zhangjiagang Free Trade Zone Kangde Film Industry Co., Ltd.

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Manufacturer: Zhangjiagang Free Trade Zone Kangde Film Industry Co., Ltd.

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Product Name: Classic/Premium gloss BOPP thermal film

Specifications: 16μm, 17μm, 18μm, 20μm, 22μm, 24μm, 25μm, 28μm, 30μm

The materials intended for the manufacturing of these products are:

- BOPP Gloss film (Bi-axially Oriented Polypropylene Gloss film)
- EVA(Ethylene Vinyl Acetate)

We declare that the above product, when leaving the factory, has a composition that meet the relevant requirements laid down in the following Commission Regulation and Directive:

- Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and its amendment 321/2011, 1282/2011, 1183/2012, 202/2014, 865/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, **2019/37, 2019/988, 2019/1338, 2020/1245**;
- Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and its amendment 596/2009 ;
- Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food and its amendment 282/2008;
- Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food;

- Regulation (EC) No 1333/2008 on food additives and its amendment 238/2010, 1129/2011, 1152/2013, 1130/2011, 1131/2011, 232/2012, 380/2012, 470/2012, 471/2012, 472/2012, 570/2012, 583/2012, 675/2012, 1049/2012, 1057/2012, 1147/2012, 1148/2012, 1149/2012, 1166/2012, 25/2013, 244/2013, 256/2013, 438/2013, 509/2013, 510/2013, 723/2013, 738/2013, 739/2013, 816/2013, 817/2013, 818/2013, 913/2013, 1068/2013, 1069/2013, 1274/2013, 59/2014, 264/2014, 298/2014, 497/2014, 505/2014, 506/2014, 601/2014, 685/2014, 923/2014, 957/2014, 969/2014, 1084/2014, 1092/2014, 1093/2014, 2015/537, 2015/538, 2015/639, 2015/647, 2015/649, 2015/1362, 2015/1378, 2015/1739, 2015/1832, 2016/56, 2016/263, 2016/324, 2016/441, 2016/479, 2016/683, 2016/691, 2016/1776, 2017/335, 2017/839, 2017/871, 2017/874, 2017/1270, 2017/1271, 2017/1399, 2018/74, 2018/97, 2018/627, 2018/677, 2018/682, **2018/1461, 2018/1481, 2018/1497, 2019/800, 2019/801, 2019/891, 2019/1676, 2020/268, 2020/279, 2020/351, 2020/355, 2020/356, 2020/771, 2020/1419, 2020/1819, 2021/1156, 2021/1175, 2022/63, 2022/141, 2022/1023, 2022/1037, 2022/1038** ;
 - Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and its amendment 872/2012, 545/2013, 985/2013, 246/2014, 1098/2014, 2015/648, 2015/1102, 2015/1760, 2016/54, 2016/55, 2016/178, 2016/637, 2016/692, 2016/1244, 2017/378, 2017/1250, 2018/678, **2018/1246, 2018/1482, 2018/1649, 2019/36, 2019/799, 2020/1681, 2021/1532, 2021/1916, 2021/1917**;
 - Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods and its amendment 2015/1906;
 - COUNCIL DIRECTIVE 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs and its amendment 2007/19/EC, 10/2011;
 - COUNCIL DIRECTIVE 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs and its amendment 93/8/EEC, 97/48/EC;
 - Directive 94/62/EC on packaging and packaging waste and its amendment 1882/2003, 2004/12/EC, 2005/20/EC, 219/2009, 2013/2/EU, 2015/720, **2018/852**;
- REGULATION (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and its amendment 1354/2007, 987/2008, 1272/2008, 134/2009, 552/2009, 276/2010, 453/2010, 143/2011, 207/2011, 252/2011, 253/2011, 366/2011, 494/2011, 109/2012, 125/2012, 412/2012, 835/2012, 836/2012, 847/2012, 848/2012, 126/2013, 348/2013, 517/2013, 1272/2013, 301/2014, 317/2014, 474/2014, 895/2014, 2015/282, 2015/326, 2015/628, 2015/830, 2015/1494, 2016/26, 2016/217, 2016/863, 2016/1005, 2016/1017, 2016/1688, 2016/2235, 2017/227, 2017/706, 2017/999, 2017/1000, 2017/1510, 2018/35, 2018/588, 2018/589, **2018/675, 2018/1513, 2018/1881, 2018/2005, 2019/957, 2019/1148, 2019/1691, 2020/171, 2020/507, 2020/878, 2020/1149, 2020/2081, 2020/2096, 2020/2160, 2021/57, 2021/979, 2021/1199, 2021/1297, 2021/2030, 2021/2045, 2021/2204, 2022/586**;
- Commission Regulation (EC) No 450/2009 active and intelligent materials and articles intended to come into contact with food

The above product can be in contact with the following type of foods:

- All aqueous foods
- All acidic foods

- All fatty foods
- All alcoholic foods

TEST Results for Regulation (EU) No 10/2011:

Test Requested	Conclusion
Overall migration	PASS
Specific migration of heavy metal	PASS

Overall migration

Test Requested: In accordance with Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments, to determine overall migration.

Test Method: With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of conditions and EN1186-1:2002 for selection of test methods;

EN1186-3:2002 aqueous food simulants by total immersion method;

EN1186-2:2002 olive oil by total immersion method;

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001 Overall migration</u>
10% ethanol	240.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²
3% Acetic acid (W/V) Aqueous solution	240.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²
Rectified olive oil	240.0hr(s)	40°C	10mg/dm ²	<3.0mg/dm ²

Notes:

(1) Analytical tolerance of aqueous simulants is 2 mg/dm² or 6mg/kg.

(2) Analytical tolerance of fatty food simulants is 3 mg/dm² or 20mg/kg.

Specific Migration of Heavy Metal

Test Requested: In accordance with Commission Regulation (EU) No 10/2011 of 14 January 2011 with amendments, to determine specific migration of heavy metal.

Test Method: With reference to EN13130-1:2004, analysis was performed by ICP-OES.

Simulant Used : 3% Acetic acid (W/V) aqueous solution

Test Condition: 40°C 240.0 hr (s)

<u>Test Item(s)</u>	<u>Max. Permissible Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>Test result</u>
Barium	1	mg/kg	0.25	ND
Cobalt	0.05	mg/kg	0.01	ND
Copper	5	mg/kg	0.25	ND
Iron	48	mg/kg	0.25	ND
Lithium	0.6	mg/kg	0.5	ND



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Manganese	0.6	mg/kg	0.25	ND
Zinc	5	mg/kg	0.5	ND
Aluminium	1	mg/kg	0.1	ND
Nickel	0.02	mg/kg	0.01	ND

Remark:

(1)MDL=Method Detection Limit

(2)ND=Not Detected (<MDL)

The BOPP gloss Thermal film can contain some other substances for which a specific migration limit(SML) is established. But the SML will not be exceeded even to a maximum film thickness of 350um (assuming that 1 kg of food is packaged with 6 dm² of film).

FCM substance No.	Ref. No.	CAS No.	SML(mg/kg)
106	89040	057-11-4	25
157	74880	084-74-2	0.3
234	19960	108-31-6	30(T)
283	74640	117-81-7	1.5
433	68320	2082-79-3	6
500	38560	7128-64-5	0.6
661	95360	27676-62-6	5
760	83595	119345-01-6	18

DUAL-USE ADDITIVES

The dual use additives as silicon dioxide and GMS restricted in (EU) No. 10/2011 and (EC) No 1333/2008 are present in BOPP Gloss Thermal Films.

FCM substance No	E-number	Ref. No	CAS No	Substance name	SML (T) [mg/kg]
41	E471	56486	-	GMS	-
504	E551	86240	0007631-86-9	Silicon dioxide	-

But, their migration levels comply with (EU) No. 10/2011.

OTHER SUBSTANCES

BOPP Gloss Thermal Films above are not intentionally added the substances as follows: Phthalates, Lead, Cadmium, Mercury, Hexavalent Chromium, Sum of PBBs, Sum of PBDEs, Halogen, Soluble Heavy Metal Contents, Substances in the Candidate List of SVHC.

USA

The above listed films are suitable for use in food contact applications in compliance with applicable U.S. FDA food packaging regulations. Specifically, the raw materials used in the composition are in compliance with the requirements of the Federal Food & Drug(FDA) and Cosmetic act under FDA 21 CFR 177.1520, 21 CFR 175.300, 21 CFR 175.320, 21 CFR 178.2010 and other applicable regulations in 21 CFR referenced therein..



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RECYCLABILITY:

BOPP Gloss Thermal Films above can be disposed of through incineration substantially. Full combustion of them for which the heat of 24 MJ/kg could be yielded would almost generate carbon dioxide and water. Except for these compliance above, we do not intentionally add some harmful materials restricted by relevant provisions in EU. And customer should use in accordance with the Technical Data Sheet.

