



Date of Issue: 31-01-2019. Rev:10

Max Specialty Films Limited
Compliance to EEC Directives & FDA Regulations of Thermal BOPP
Films

This is to certify that BOPP Thermal Films of following types are manufactured and supply by Max Specialty Films is comply with food contact regulatory requirements as per EEC directives and FDA regulations.

Table 1: List of BOPP Films

Segment	Film Description
Thermal Gloss	Extrusion coated Thermal Gloss BOPP Film
Thermal Matt	Extrusion coated Thermal Matt BOPP Film
Thermal Silk Matt	Extrusion coated Thermal Silk Matt BOPP Film
Thermal Super Silk	Extrusion coated Thermal Super Silk Matt BOPP Film
Super Silk Wet	One side coated Super Silk BOPP Film
Digital Thermal Gloss	Extrusion coated Digital Thermal Gloss BOPP Film
Digital Thermal Matt	Extrusion coated Digital Thermal Matt BOPP Film
Thermal Metalized	Extrusion coated Thermal Metalized BOPP Film
Thermal Scuff Free Matt	Extrusion coated Thermal Scuff free Matt BOPP Film
Scuff Free Matt for Wet	Scuff free Matt film

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1. European Economic Commission (EEC) Directive

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 **Commission Regulation (EU) No 10/2011 of 14 January 2011 and its further amendments up to EU 2019/37** on plastic materials and articles intended to come into contact with food.

The above mentioned products comply with the relevant requirement of Regulation 10/2011, applicable to intermediate materials (e.g. Plastic granules, additive master batches). This conformation is according to 2002/72/EC and its successive amendments 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC, 2009/975/EC, 10/EC/2011 up to EC1282/2011 and 1183/2012. These products contain only substances included in the Union list of authorized substances set out in Annex I of 10/2011/EC.

According to the provisions of the Regulation 1935/2004 and 10/2011/EC, the overall migration limit (OML), for which a maximum value of 10 mg/dm² is fixed, has to be controlled on the finished articles intended to come into contact with foodstuffs.

In order to be in full compliance with legislations on the migration of substances to foodstuffs, Thermal BOPP films are submitted at regular intervals to migration tests carried out at the conditions listed below

Table 1.1: Overall Migration

S. No.	Simulant Used Evaluation	Test Condition	Results (mg/dm ²)	Limits as per EEC (mg/dm ²)	Compliance
1	10% Ethanol (w/v) aq aqueous solution	10 days at 40°C	<5	10	yes
2	20% Ethanol (w/v) aqueous solution	10 days at 40°C	<5	10	yes
3	3% Acetic Acid Ethanol (w/v) aqueous solution	10 days at 40°C	<5	10	yes
4	50% Ethanol (w/v) aqueous solution	10 days at 40°C	<5	10	yes
5	Rectified Olive Oil	10 days at 40°C	<5	10	yes

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2. US Food and Drug Administration (FDA)

All the products mentioned in Table 1 meet the FDA requirements contained in the Code of Federal Regulations in Title 21 – volume 3 CFR 177.1520, revised as of April, 2014. FDA 21 CFR 177.1520(c)1.1.a. permitted by FDA for use in food-contact applications for food types identified in categories I through IX of table 1 under conditions of use A through H of table 2 in Title 21 CFR part 176.170 (c).-178.3130-178.3860-184

In order to be in full compliance with legislations on the migration of substances to foodstuffs, BOPP Thermal films are submitted at regular intervals to migration tests carried out at the conditions listed below:

Table 2.1: Amount of Extractives as indirect food additives

S. No.	Extractants Used	Test Condition	Results (%)	Limits as per US-FDA (%)	Compliance
1	n-Hexane	50°C/2 hours	<0.5	2.6	yes
2	Xylene	25°C/2 hours	<0.5	30	yes

It is the responsibility of the converter or food packager that markets the final material or article to guarantee its compliance under actual and foreseeable conditions of use, and to check it on a regular basis. The finished material or article should be technically suitable for the intended use.

Ref.: Code of federal regulations 21 parts 170 to 199.

3. Heavy Metals in Packaging and Packaging Waste: European Union (EU) Directive 94/62/EC

EU Packaging Directive 94/62/EC as amended by 2004/12/EC, is related to packaging waste and with permissible levels of heavy metals in packaging. Article 11 incorporates the limits of the American CONEG regulation (Coalition of North-eastern Governors).

The sum of the concentrations of Lead, mercury, cadmium & chromium ^(VI) must not exceed 100 ppm (total concentration in the colored or printed final product).

We declare that during manufacturing of the above mentioned products, we do not use or intentionally incorporate into it any of the heavy metals substances.

In order to be in full compliance with legislations on the Heavy Metals in packaging and packaging waste, BOPP films are submitted for Heavy Metal tests. Analysis of Lead (Pb), Cadmium (Cd) and Mercury (Hg) were performed by inductively coupled Argon Plasma Spectrometry. Analysis of Chromium (Cr⁶⁺) was performed by ICP-MS spectroscopy. The results showed that the heavy metals were not being able to detect in above mentioned products.

Table 3.1: Detection of Heavy Metals

Heavy Metals	Results (mg/kg)	Detection Limit (mg/kg)	Permissible Limit (mg/kg)
Lead (Pb)	Not Detected	5	--
Cadmium (Cd)	Not Detected	5	--
Mercury (Hg)	Not Detected	5	--
Hexa valent Chromium (Cr ⁶⁺)	Not Detected	2	--
Total (Pb+Cd+Hg+ Cr ⁶⁺)	<17	-	100

4. Commission Regulation (EC) No. 2023/2006: Good Manufacturing Practices

EC 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. This regulation lays down the rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food. These are some of the articles which have been mentioned in EC 2023/2006:

Article 2

Scope:

This regulation shall apply to all sectors and to all stages of manufacturer, processing and distribution of materials and articles, up to but excluding the production of starting substances.

Article 5

Quality assurance system:

1. The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system.
2. Starting materials shall be selected and comply with pre-established specifications that shall ensure compliance of the material or article with the rules applicable to it.
3. The different operations shall be carried out in accordance with pre-established instructions and procedures.

Article 6

Quality control system

1. The business operator shall establish and maintain an effective quality control system.
2. The quality control system shall include monitoring of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.

Article 7

Documentation

1. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article.
2. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to records covering the various manufacturing operations

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Performed which are relevant to compliance and safety of the finished material or article and with respect to the results of the quality control system.

3. The documentation shall be made available by the business operator to the competent authorities at their request.

The above mentioned products are not “materials or articles” but BOPP films which may be used for different end-applications, including food contact applications.

All products made by Max Specialty Films pass to the Quality Control.

Max Specialty Films has a certified Quality Assurance System according to ISO 9001:2008.

5. EC No. 999/2001: Ingredient derived from animal sources- Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)

We hereby declare that no material of any animal origin is intentionally used within the production of the above mentioned products.

Based on the absence of animal materials or materials derived from fatty acids of animal origin in the substances used in our products, to the best of our knowledge the risk of transmission of Bovine / Animal Spongiform Encephalopathy (BSE) is not relevant.

Since the presence of these substances under normal conditions cannot be expected, Max Specialty Films does not check their absence.

Ref.:

Note for guidance on minimizing the risk of transmitting spongiform encephalopathy agents via human and veterinary medicinal products (EMEA/410/01 Rev. 2 - October 2003) adopted by the Committee for Proprietary Medicinal Products (CPMP) and by the Committee for Veterinary Products (CVMP)-(2004/C 24/03)

Commission Regulation (EC) No 1326/2001 of 29 June 2001 laying down transitional measures to permit the changeover to the Regulation of the European Parliament and of the Council (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, and amending Annexes VII and XI to that Regulation

Article 2

Decisions 94/381/EC, 94/474/EC and 2000/418/EC are repealed.

Twenty Fourth commission directive 2000/6/EC of 29 February 2000 adapting to technical progress Annexes II, III, VI and VII to Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products

6. Coalition of Northeastern Governors (CONEG)

Cadmium (Cd), Chromium (Cr⁶⁺), Lead (Pb) and Mercury (Hg) are not used in the manufacture of or the formulation of above mentioned products. In addition, these products meet the CONEG requirements of less than 100 ppm for total incidental Cd, Cr⁶⁺, Pb and Hg.

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We have tested our films according to EU Packaging Directive 94/62/EC. Article 11 incorporates the limits of the American CONEG regulation (Coalition of North-eastern Governors). Please refer table 5 for the Heavy Metal test results.

7. Dioxin

Dioxin is not used in the manufacture of or the formulation of these products. However, these products have not been tested for this chemical substance. Dioxin is not known to be formed during processing of these products.

8. Polychlorinated Biphenyls (PCBs), Polychlorinated Terphenyls (PCTs), Polychlorinated Naphthalenes (PCNs), Polybrominated Biphenyls (PBBs), Polybrominated Diphenyl ethers (PBDEs) and Polybrominated terphenyls (PBTs)

Polychlorinated Biphenyls (PCBs), Polychlorinated Terphenyls (PCTs), Polychlorinated Naphthalenes (PCNs), Polybrominated Biphenyls (PBBs), Polybrominated Diphenyl ethers (PBDEs) and Polybrominated terphenyls (PBTs) are not used in the manufacture of or formulation of these products. However, these products have not been tested for these chemical substances.

9. Vinyl Chloride (CAS No. 75-01-4) and Polyvinyl Chloride

Vinyl chloride and PVC resins are not used in the manufacture of or the formulation of these products. However, we do not test these products for these chemical substances.

10. Regulation (EC) 1895/2005

BADGE, NOGE and BFDGE are not used in the manufacture of or the formulation of these products according to requirement of regulation no. 1895/2005

11. Benzotriazole and 2-mercaptobenzothiazole (MBT)

2-(2H-1,2,3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol [also called 2-(2'-Hydroxy-3',5'-di-t-butylphenyl) benzotriazole] (CAS No. 3846-71-7) and 2-Mercaptobenzothiazole [also called 2(3H)-Benzothiazolethione or Benzothiazole-2-thiol or MBT] (CAS No. 149-30-4) are not used in the manufacture of or the formulation of these products. However, we do not test these products for these substances.

12. Styrene (CAS No. 100-42-5) and Polystyrene

Styrene (chemical name: ethenylbenzene) and polystyrene resins are not used in the manufacture of or the formulation of these products. However, we do not test these products for these substances.

13. Acrylamide (CAS No. 79-06-1)

Acrylamide is not used in the manufacture of or the formulation of these products. However, we do not test these products for acylamide.

14. Aromatic Amines

Aromatic amines are not used in the manufacture of or the formulation of these products. However, we do not test these products for these chemical substances.

15. Epichlorohydrin (CAS No. 106-89-8)

Epichlorohydrin is not used in the manufacture of or the formulation of these products. However, we do not test these products for these chemical substances.

16. Alkylphenol

Alkylphenol ethoxylates are not used in the manufacture of or the formulation of these products. However, we do not test these products for these chemical substances.

17. Organo-tin Compounds

Tributyl-tin (TBT), Dibutyl-tin (DBT), monobutyl-tin (MBT) or any other organo-tin compounds are not used in the manufacture of or the formulation of these products. However, we do not test these products for these chemical substances.

18. Fluorocarbons

Fluorotemers, Zonyl fluoroadditives, perfluorooctane sulfonate (PFOS), Perfluoro octane sulfonate (PFOS), Perfluorooctanoic acid (PFOA), perfluorochemicals (PFS) or other fluorocarbon substances are not used in the manufacture of or the formulation of these products. However, we do not test these products for these chemical substances.

19. Sulphur Dioxide (CAS No. 7446-09-5)

Suphur dioxide is not used in the manufacture of or the formulation of these products. However, we do not test these products for these chemical substances.

20. Polycyclic Aromatic Hydrocarbons (PAHs)

We do not intentionally use the Polycyclic Aromatic Hydrocarbons (PAHs) in the manufacture of or formulation of these products. However, we do not test these products for these chemical substances.

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21. Proposition 65 compliance

Chemicals listed in Proposition 65 are not used in the manufacture of or the formulation of these products. However, we do not test these products for these chemical substances.

22. Allergens (Directive 2000/13 EU) and 1169/2011 (joint II)

We do not intentionally use no content of allergens in the manufacture of or formulation of these products. However, we do not test these products for these chemical substances.

23. Phthalates and its derivatives

The phthalates for which opinions have been given by EFSA (European Food Safety Authority) and TDI's (Tolerable Daily Intake) established for use plastics in food applications, are not intentionally added in the manufacture of or the formulation of these products. The phthalates are di-iso-nonyl phthalate (DINP), di-(2-ethylhexyl) phthalate (DEHP), di-n-butyl phthalate (DBP), di-iso-decyl phthalate (DIDP), butyl benzyl phthalate (BBP).

The phthalates are "technical support agents" as defined by European Union Regulation 10/2011. None of the four phthalates has been determined to be human carcinogens or endocrine disrupters at the low levels as suggested by environmentalists. A SML (specific migration limit) equal to 0.3 mg/kg (300 ppb) has been established in European Union Regulation 10/2011 for DNBP.

24. EC 282/2008 on Recycled Plastic

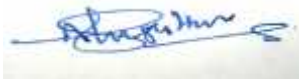
We hereby declare that our products are complined as per the above regulation.

25. EC 450/2009 on Active & Intelligent plastics

We hereby declare that our products are complined as per the above regulation.

Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications. This certificate shall continue in effect for 1 year from its effective date unless it is modified before.

Certified by:



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