

COMPLIANCE TO FDA & EU REGULATIONS

This is to certify that our OPP product: CP7FILMS (Transparent and Metallised films) manufactured from Polypropylene are complied with food contact regulatory requirements as per FDA & EU Regulations.

PRODUCT : HS,HLC,HMZ,NI/NO,NB,NAT,NTG,NLH,HMD,LMD,HMB,LMB,UMD,UMB,NMT

DATE OF DECLARATION: JUNE 15, 2012

FDA REGULATIONS

FDA Regulation and Norms for Food Contact Substance (FCS) Migration = As per the document 7 Guidance for Industry – Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances : Chemistry Recommendations.

Food Additive regulated for its intended use as per 21 CFR 173 – 178 – exempted from regulation under Threshold of Regulation Process as per 21 CFR 170.39. Identification of Types of foods expected to be used in contact with FCS and maximum temperature and time condition of food contact as per 21 CFR 176.170.

Olefin Polymers as Indirect Food Additive as per 21 CFR 177.1520.

EU REGULATION

The monomers and additives used to manufacture the above product are listed in EU Regulation 10/2011 of 14th January 2011 and in the legislation which it replaces; Commission Directive 2002/72/EC (06/08/2002) relating to plastic materials and articles intended to come into contact with foodstuffs and its amendments 2004/1/EC (06/01/2004), 2004/19/EC (01/03/2004), 2005/79/EC (18/11/2005), 2007/19/EC (30/03/2007), 2008/39/EC (06/03/2008) and Regulation (EC) No. 975/2009 (19/10/2009)), within the framework defined by the regulation 1935/2004/EC (27/10/2004) on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

OVERALL MIGRATION LIMIT

The above product has been tested for overall migration with the simulants and test conditions listed below as defined in EC Directive 97/48/EC and EU Regulation 10/2011. The product was exposed to each stimulant and test condition to comply as defined in Commission Directive 2002/72/EC and EU Regulation 10/2011.

Food Simulants	Test Conditions	
	Duration	Temp (°C)
10 % ethanol (Simulant A)	10 days	40
3 % Acetic Acid (Simulant B)	10 days	40
20 % ethanol (Simulant C)	10 days	40
50 % ethanol (Simulant D1)	10 days	40
Rectified Olive Oil (Simulant D2)	10 days	40
n-Hexane	2 hrs	50
Xylene	2 hrs	25

The overall migration results were found to be below the limits defined in EC Directive 2002/72/E and EU Regulation 10/2011, which is presently defined as 10 mg/dm² of the surface area of the article. Constituent monomers and additives used to manufacture this product have the following specific migration requirements:

- 5 mg per kg of foodstuff

All polymers and additives in the composition of above mentioned film appear in the positive list of products accepted for the fabrication of packaging materials intended for food contact, as published by the Food and Drug Administration (USA) FDA 21 CFR 177.1520(c)1.1a (Polyolefins)

SPECIFIC MIGRATION LIMITS

We inform that for some of the additives that are used during OPP film production has Specific Migration Limits. We confirm that, according to our analysis, we do not exceed the specific migration limits.

Chemical Name	CAS / PM Ref Number	SML
Slip Agent	68400	5 mg/kg
Antioxidant	38820 – 38840 7 68320	0,6 – 5 – 6 mg/kg
Antistatic/Ethoxylated Amine	39090	1,2 mg/kg
Vinyl fluoride	26140	5 mg/kg

DUAL USE ADDITIVES :

We confirm that our films may contain following food additives

Chemical Name	CAS / PM Ref Number	E Number
Mono/diglycerides of fatty acids	PM/Ref: 56486	E471
Synthetic silica	CAS no 763178679	E551
Titanium dioxide (only in white films)	PM/Ref: 93440	E171

HEAVY METALS :

We declare that the raw materials used in the production of said OPP films, namely: PP homopolymers, PP copolymers, PP terpolymers, and masterbatches based on the above mentioned resins do not contain heavy metals such as, and not limited to: cadmium, hexavalent chromium, lead, antimony, nickel, tin, arsenic, PBB, PBDE and mercury, as declared by the suppliers of the above mentioned raw materials.

We also declare that neither the said heavy metals nor their compounds are intentionally added during the production of the said OPP films, nor they are used, directly or indirectly, in the production process itself.

Any incidental amount of heavy metals contained does not exceed 100 ppm (by weight). For these reasons, we hereby declare that the said OPP films comply with the following regulations:

- USA CONEG REGULATION
- CEN Standard EN 71/3 and its successive amendments.
- 1994/62/CE (Packaging Waste Management)
- ROHS Regulation (2002/95/EC)
- WEEE Regulation (2002/96/EC)
- 2003/11/EC

GMO – DIOXINE – ALLERGENS – RECYCLED RAW MATERIAL USAGE:

According to the information received from our suppliers the additives and PP homopolymers, terpolymers used for the production of said films do not contain any genetically modified organisms (GMO)

1895/2005 EC (related with dioxine and dioxine related PCB's in the food chain) is not applicable to our products.

Our films do not contain any allergic substances and we hereby confirm that our film complies with 2003/89 EC.

ABSENCE OF SUBSTANCES :

We declare that the raw materials used in the production of said OPP films do not contain the following substances, as also declared by the relevant raw materials suppliers:

Latex, Bisphenol A&F, BHT, BHA, Polychlorinated biphenyls, Bis(2-ethylhexyl)phthalate, di(2-ethylhexyl) phthalate, 2-Ethylhexyl Acrylate, Polychlorinated naphthalates, n-butyl benzyl phthalate, Chlorinated Paraffins, Polybrominated biphenyls, Polybrominated diphenylethers, Organic Tin Compounds (tributyl or triphenyl tin), Asbestos, Azo Compounds, Formaldehyde, Mirex (perchlorodecone), Alkyl Phenols – Octyl & Nonyl, Alkyl Phenol Ethoxylates, Octyl & Nonyl phthalates, Butyl Benzyl Phthalate, Dibutyl Phthalate, Diethyl Hexyl Phthalate, CFC, HCFC, Pentachlorophenol, Triclosan, PVC, PVDC, Acrylamide, Dioxin etc, BADGE, BFGDE, NOGE, Melamine, Ammeline, TXIB, PCDD (polychloride dibenzo-p-dioxin), PCDF (polychloride dibenzo-p-furan), PCB (Polychloride biphenyl), HAP (Polycyclic aromatic hydrocarbon), SCCP (Chlorinated paraffin short chain), HCH (Hexachlorocyclohexane), Hexabromocyclododecane (HBCD), PCP (Pentachlorophenol), Semicarbazide, Adipates, ESBO (Epoxidised Soybean Oil), Cyanuric acid, Dimethylfumarate, Isocyanates, Titanium Acetyl Acetate (TAA)

We also declare that neither the said substances are intentionally added during the production of the said OPP films, nor they are used, directly or indirectly, in the production process itself.

REACH :

Under the REACH regulation, all the products CP7FILMS are manufactured items obtained from polymers, and so exempted from REACH registration.

Chiripal Polyfilms have taken all the necessary steps to ensure that the chemical components from which CP7 FILMS products are obtained fulfill the obligation of the REACH registration, with specific requests of declarations from raw material suppliers.

Raw material suppliers to Chiripal Polyfilms are:

Producers of Polymers
Producers of Polymer Masterbatches (admixture of Polymers and other components)

Polymers are exempted from the provisions of registration of Title II of REACH (Article 2(9))
Polymer Masterbatches are considered, in regulatory terms, "preparations", and are exempted from the provisions of registration.

Nevertheless, the obligation of registration of the individual chemical substances used by the raw material suppliers (Producers of Polymers and Producers of Polymer Masterbatches) goes down in the supply chain to the obliged parties that supply the base chemicals and monomers (namely: propylene monomer) to the Producers of Polymers and Producers of Polymer Masterbatches that are the present suppliers.

SVHC :

We declare that our films do not contain substances of very high concern (SVHC) of the candidate list which is frequently renewed by EHCA. New list is updated regularly, if necessary.

DISCLAIMER

The foregoing information regarding CP-FILMS grades is provided in good faith and is based upon information in the possession of Chiripal Polyfilms as of the date of the response. However, the customer must make their own determination and analysis that use of our product is safe, lawful and technically suitable in their intended use. Since the conditions of use is beyond our control, Chiripal Poly Films Limited makes no warranties, express or imply and assume no liability with any use of this information.

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