

Declaration of Conformity

For PET-films intended to come into contact with foodstuffs

1. General

We confirm that following Sarafil Polyester film types and applicable for all thickness:

SN	Type	Description
1.	TF/TFC/TICI, TICO, TFL, TFY/TFS, TFR100, TBB, UCF10D	Plain / Corona treated PET film
2.	TF110, TF111	Plain / Corona treated PET film
3.	S56, S56C, S52, S60, S60C, S156	Chemical Treated PET film
4.	CF120/100/101/102/104/105/108/111/121/122, CFL100	Clear polyester film (Chemically Treated)
5.	S42I/O, S42C, SL42, S44, S46, S46C, S48, S48C	Chemical Treated PET film
6.	SF150, 151, 152, 155, 161,162, 122, R0, R1, SF10R, SF1R1, SF144, SF126	Chemical Treated PET film
7.	SFU100, UF100/101, UFA100, PE191/0	Chemical Treated PET film
8.	DL101/110, DL104/ 140, DL120/102, DL104P/140P, DL100P/100, DH100 & DH300	Printable Matte Film, Chemical treated
9.	D2300/DM300, D1200	Matte PET film
10.	HS140, 104, 100, 100C, 101,200, HSA101, UP100 HSS100, HSS10A, HS200, HS102, HS10R, HSQ100 PES100, PEA100, PE100A, HSE, HSER, HHS100	Heat sealable/Coextruded film
11.	MB300, MW100/200, HZ100/200	Oven-able PET film
12.	HF120/121/112, 102, MF805/120/802	High Friction film - Chemical coated
13.	TFM140/150/105/1R0/1RR/MTFM140	Straight Tear PET, Chemically coated Inside
14.	TWL100/102/104/105/ 155/122/10A TWB122/155, TW100/102/104/105/155/152/122 TW155, TW141, TW110, TW111	White Opaque PET, with Uncoated/Chemical/Corona treated surfaces
15.	GW181, WGW181, WGW140, WGW184, WGW141	Green wrap PET film (Twist grades)
16.	WGW301	Green wrap METPET film (Twist grades)
17.	FD100, FD104/FD140	Transparent foldable PET Film
18.	FH100/FH1B0/FH105	Transparent Thermoformable PET film
19.	TH101, SH100/101/110/104	Transparent corona/coated thermoformable/shrinkable
20.	MHS100, MHS110, MHS140, MHS150, MHS101	Metallized PET film, Heat sealable one side
21.	MMTPP / HLTTPP/ HMTTPP (TPM, TMM, THM) MBC110	Metallized -Untreated PET film
22.	MMTPC / MMTPC /HLTPC / HLTCP/ HMTCP/ HMTPC (TPMC / TPCM/ TMMC/ TMCM/ THMC/ THCM)	Metallized-Corona treated PET film
23.	MMT56C / MMT56P / HLT56P/ HLT56C/ HMT56P / HMT56C (TPWMC/TPWM/ TMWM/ TMWMC/ THWM/ THWMC), HMT52P, HMT52C, MMT52P/C, MMTP560	Metallized-Chemical coated PET film
24.	MMT60C / MMT60P / HLT60P / HLT60C / HMT60P/ HMT60C (TPRMC /TPRM/TMRM/TMRMC/ THRM/THRMC), MMTPRI, MMTRCI, HLT62CI and HLT52CI	Metallized -Chemical coated PET film

Polyplex Corporation Limited

B-37, Sector 1, Noida - 201301, Distt. Gautam Budh Nagar (U.P.) India

Board: +91.120.2443716-19, Fax: +91.120.2443723 & 24

Registered office: Lohia Head Road, Khatima - 262308, Distt. Udham Singh Nagar, Uttarakhand, India

25.	MMICP / MMIPC / MMIPP (TPMCI / TPCMI / TPMI)	Metallized - Isotropic PET film
26.	MMI60P, MMI56P	Metallized - Isotropic Chemical PET film
27.	MT5000, MT6000, MT6001, MT5002, MTH5000, MT5001	Metallized – Chemical coated PET film
28.	GW301/310, GW302	Metallized – Green wrap PET film
29.	MMTP42 / MMTC42 / MMCC42/HLTP42 / HLTC42 / HMTP42 / HMTC42/MMVP42//MMVP46/HMT56A1/HMT56AO/BMTC60B/MMCP42/HMTC56 (TPMA / TPCMA / TPCMA / TMMA / TMCMA /THMA/THCMA/BPMA/BPMF/TPMF/TPRMCM/MTH3013)	Metallized - Chemical coated PET film
30.	LSP019, LSP024, LSP025, LSP025, LSP030, LSTCP	Metallized – Susceptor PET Film
31.	MTWL102, 155, 142,152 MTW141/114 TWH100/104, MTW102	Metallized – White opaque Chemical coated PET film
32.	HB 1000, HB1001	Metallized - Chemical coated PET film
33.	MM1040, MM1010, MDS1142, MD1202 MM2002, HM2002, MM/HM/2000, MM200A	Metalized Mate PET film
34.	BioPET, PlantPET101/102, PlantMPET101	Transparent and metalized PET film for Sustainability

Are suitable for the production of packaging material which has come into contact with foodstuffs

They are in accordance with good manufacturing practice for materials and articles intended to come into contact with food EC- 2023/2006 and comply with the EC-Regulation 1935/ 2004 (including Articles 3, 11(5), 15 and 17).. The manufacturing of Polyester film is in compliance with PIM regulation 10/2011 including amendments 321/2011,1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/1338, 2020/1245 and the German “Lebensmittel-Bedarfsgegenstände- und Futtermittelgesetzbuch“ (LFBG, formerly LMBG), the Bedarfsgegenständeverordnung (BGV) as well as the FDA-Regulation 21 CFR § 177.1630 in the current valid version/s, BFR XVII. Poly (terephthalic acid diol esters), DM 21/3/73 material in contact with food for human consumption.

Only monomers and additives are used which are indicated in mentioned EU regulation PIM 10/2011 including its amendments. For further details to the implementation of PIM 10/2011 please note §2 of this Declaration of Conformity.

2. Migration

Migration testing compliance according to (EU) No.10/2011 regulation based on migration testing using food Simulant and test conditions established in the PIM.

Migration values conformity was expressed in mg/kg applying a surface to volume ratio of 6 dm² per kg of food.

2.1 Overall migration limit :

Overall migration testing according to regulation (EU) No. 10/2011 (inclusive of all amendments and supplements) is made. The area limiting value of 10 mg/dm² is maintained under the following test conditions:

Food Simulant	Test Conditions (Time / Temperature)
Simulant A : 10 % Ethanol	OM6 : 4 h at 100 °C
Simulant B : 3 % Acetic Acid	OM6 : 4 h at 100 °C
Simulant D2: Vegetable Oil (Olive Oil)	OM7 : 2 h at 175 °C

OML (Overall Migration limit) has been tested for all type of foods in worse condition as per regulation (EU) no. 10/2011 including all amendments. (The overall migration limit of 10 mg per 1 dm² results for a cubic packaging containing 1kg of food to a migration of 60 mg per kg food).

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Packed food storage conditions: Mentioned films passes OM6 as well as OM7 which covers food contact conditions described for OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants in contact with non-polyolefins.

2.2 Specific migration limit (SML) and maximum permitted quantity of “residual” substance (QM) or (QMA)

The required SML- and/or QM or QMA- limits according to EU Regulation PIM 10/2011(inclusive of all amendments and supplements) are met.

Simulant / Test Method	Test conditions (Time/ Temperature)
Simulant B (acetic acid 3% (w/v))	10 days at 60°C + 8 h at 100°C
EN13130-2/HPLC	Extraction / Residual Content
EN13130-7/GC/MS	Extraction / Residual Content
HPLC-UV	Extraction / Residual Content

Migration values conformity was checked in mg/kg applying a surface to volume ratio of 6 dm² per kg of food.

- Ref to Article 19 of Regulation 10/2011 regarding NIAS (Impurities and degradation products) we like to mention that the film has been tested and evaluated using 10 PPB screening with 95% ethanol (v/v) 10 days at 60 Deg. With GC-MS as well as other related methods and we confirm that no such substances identified which are subject to limitations.
- The film has been evaluated for Annex II substances from ingredient and all other possible sources and risk assessment has been carried out for presence of NIAS and they are found absent or they are not exceeding specified migration limits for the substances present in the film. We confirm absence of any substances with Genotoxicity

2.3 Coating

The employed coatings comply with the Council of Europe-Resolution AP (2004) 1 and/ or the FDA- Regulations (FDA 21 CFR) § 178 indirect food additives adjuvants, production aids and sanitizers and 21CFR§177 indirect food additives

2.4 Others

Please note that it is the responsibility of both the manufacturer of the finished food contact articles as well as the industrial food packer to ensure that the finished articles are in actual compliance with the specific and global migration limits. Our tests on the film cannot replace migration tests on the finished articles.

3. Hygiene

The supplier has got hygiene, cleaning/Housekeeping, and pest control-plan, which may be audited at any time as agreed. The production of the packing materials takes place under conditions of good hygiene practice, in particular for the determining of potential dangers, the assessment of the involved risks and a system to control detected dangers (chemical, physical and micro-biological risks in the e of HACCP) for the use with food stuffs.

Hygiene certification according to BRC/IOP/ISO22000

4. Heavy Metals

We confirm that heavy metals as cadmium, mercury, lead and chromium⁶⁺ as such and their compounds are not used in the manufacturing. The sum of these heavy metals from possible contaminations is below 100 ppm and complies with EU Directive 2011/65/EU amending directive 2002/95/EC, 2004/12/EC and 2015/863/EU.

They complies directive 94/62/EC and its amendment 2005/20/EC (on Packaging and packaging waste), with the CONEG Legislation in the USA as well as EN71.

We confirm that the film does not contain any substances listed under Restriction of Hazardous Substances (RoHS 2) 2011/65/EU Annex II

5. Other Substances

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For the production no dangerous substances and no any plasticizers or post consumer recycled contents are used and conforms regulation (EC) No 282/2008. The polyester film also in conformance to EC 450/2009 no any active or intelligent materials present in the film. In particular we certify that for the manufacturing of our film none of the substances listed in Appendix 1 are employed and that the manufacturing process complies with the regulations listed in Appendix II.

We confirm that no any manufacturing sites of mentioned films are from sites considered as radioactive.

6. Dual use Substances

With regard to dual-use substances which are authorized as direct food additives or as food flavourings we state that Sarafil Polyester Film complies with the purity criteria on food additives concerning colours, sweeteners and others as laid down in Regulation (EC) No 1333/2008 or as flavourings by Regulation (EC) No 1334/2008.

Following dual use additives are present in the film in respective type specified:

Silicon Dioxide (SiO₂), CAS no- 7631-86-9-In all types

Titanium Dioxide (TiO₂): CAS 13463-67-7-Only in opaque white type of films

Aluminium, (Al): CAS 7429-90-5-In metalized PET film

7. Use for food packaging in United States (FDA conformance)

Sarafil Polyester film, (Including Metalised and Coated films) complies with both the Food, Drug and Cosmetic Act of 1958 and all applicable indirect food additive regulations found in 21 CFR § 177.1630 [section (h) (1), (2) for oven baking or oven cooking at temperatures above 250°F (121°C)] and in accordance with good manufacturing practices (defined in 21 CFR § 174.5).

8. Recoverability

The film complies with the recoverability requirements set forth in Directive 94/62/EC. The film is not subject to labelling as a hazardous chemical or mixtures according to 1272/2008 (CLP regulation) and its amendments. There is no requirement for classification as hazardous to water according to German regulations (no "WGK"). The formulation of the film does not contain forbidden or restricted substances (perfluorooctane sulphonates) as mentioned in Directive 2006/122/EC amendment council directive 76/769/EC and 2003/11/EC. As waste, it does not form materials that require monitoring according to Directives 91/689/EEC and 91/156/EEC.

9. Responsibilities

By following the above mentioned regulations we have fulfilled our duty of care regarding the conformance of the film we supply with legislation governing food contact applications. It is the responsibility of the user to test the suitability of our products for the intended application. We accept no liability for losses arising from inadequate suitability of our products for the food medium being used by end users.

For **POLYPLEX**



Mintop Hazarika

Manufacturing sites:

1. India: Site I

Polyplex Corporation Limited
Lohia Head Road,

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Registered office: Lohia Head Road, Khatima - 262308, Distt. Udham Singh Nagar, Uttarakhand, India

Khatima-262308, Distt: Udham Singh Nagar, Uttrakhand, India
Tel # 05943 250165

2. India: Site II

Polyplex Corporation Ltd
Plot no. 227MI-228MI, Vikrampur, Bannakhera Road
Bazpur-262401, Distt: Udham Singh Nagar, Uttrakhand

3. Thailand:

Polyplex (Thailand) Public Company Ltd.
Siam Eastern Industrial Park, 60/24 Moo 3, Tambol Marbyangporn
Amphoe Pluakdaeng, Rayong-21140
Tel: + 663 889 1352-4

4. Turkey:

POLYPLEX EUROPA, Polyester Film San.ve Tic. A.S.
Avrupa Serbest Bolgesi 132. Ada 7.Parsel
Veli Mese Mevkii CORLU/TEKIRDAG
Tel: +90-282 691 10 51, Fax: +90 282 691 10 52,

5. USA:

Polyplex USA LLC
3001 Mallard Fox Dr NW, Decatur, AL 35601
(256) 686-2950, Fax: (256) 686-2951,

6. Indonesia:

PT. Polyplex Films Indonesia
Jl. Modern Industri XVIII Blok AN No. 7, Kawasan Industri Modern, Desa Nambo Udik
Kecamatan Cikande, Kabupaten Serang - 42186 (Banten), INDONESIA

Appendix I

Hereby we declare that the following substances are not employed for the manufacturing of our films and also not present in them:

SN	Substance	CAS No
1.	Phthalates (Diethylexyl-Phthalate; Diisobutyl-Phthalate; Dibutyl-Phthalate)	117-81-7, 84-69-5, 84-74-2
2.	PCB Polychlorinated biphenyl	1336-36-3
3.	BHA Butylated hydroxyanisole	25013-16-5
4.	Bisphenol A (BPA)	80-05-7
5.	Alkyl phenols, long chain alkylphenols" (LCAPs)	-
6.	Glycol ethers in the series E and Beta isomers of glycol ethers from series P	-
7.	Recycled PET from consumer sorting	-
8.	BHT (Butylated hydroxytoluene)	128-37-0
9.	Pentamethylheptane	13475-82-6
10.	Benzophenone	119-69-9
11.	Methylbenzophenone	134-84-9
12.	Isopropyl thioxanthone	83846-86-0
13.	Benzene, Styrene	71-43-2,100-42-5
14.	Halogens, Halogen containing polymer additives, Brominated Flame Retardants, Polybrominated biphenyls (PBB), Polybrominated diphenyl ethers (PBDE), Ozone depleting chemicals, Perflourinated alkyl compounds (PFA)	-

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	compounds), perfluorinated compound (PFC) and PFAS (per- and polyfluoroalkyl substances)	
15.	Penta-BDE Octa-BDE, DEKA-BDE and DEHA (Di-2-Ethylhexyladipat) DINP (Diisononyl Phthalate)	
16.	Photo-initiators like for example ITX (Isopropylthioxanthone)	
17.	Azodicarbonamide	123-77-3
18.	Semicarbazid	57-56-7
19.	Epoxidised oil of Soya, GMO substances	-
20.	Mineral oils: <ul style="list-style-type: none"> • MOSH – Mineral Oil Saturated Hydrocarbons • MOAH – Mineral Oil Aromatic Hydrocarbons • PAH – Polycyclic Aromatic Hydrocarbons • POSH – Polyolefin oligomeric Saturated Hydrocarbons • POMH and Arvin-substance 	-
21.	Animal origin products, BSE/TSE	-
22.	Natural rubber and/or any dry rubber latex, Azo Pigments	-
23.	Radioactive substances	-
24.	GBL Butyro-1,4-lacton	96-48-0
25.	Acetylaceton	123-54-6
26.	Titanium acetylacetonate	97281-09-9
27.	2-EHA (2-ethylhexyl acrylate)	102-11-7
28.	Dimethyl fumarate	624-49-7
29.	Decabromodiphenyl ether	1163-19-5
30.	Bisphenol A diglycidyl ether	1675-54-3
31.	Bisphenol S (BPS)	-
32.	2-Ethyl Hexanoic Acid	149-57-5
33.	Perfluorooctanoic acid	335-67-1
34.	Organic fluorine	-
35.	Titanium-Acetyl Acetonate (TAA)	17927-72-9
36.	Tin organic compounds/ Organostrannic components	-
37.	Primary aromatic Amine	-
38.	4-Hydroxybenzophenone	1137-42-4
39.	2,2-Dimethoxy-2-phenylacetophenone	24650-42-8
40.	Formaldehyde	50-00-0
41.	Beryllium oxide	1304-56-9
42.	Coabaldichloride	7646-79-9
43.	2-(2'-Hydroxy-3',5'-di-tert-butylphenyl) benzotriazole	3846-71-7
44.	Tetrabromobispheno-A (TBBP-A)	79-94-7
45.	Triphenyl Phosphate (TPP)	115-86-6
46.	Bromine	7726-95-6
47.	(2-ethylhexyl)maleat DEHM	142-16-5
48.	Diocetyl sodium sulfosuccinate DSS	577-11-7
49.	PCP (Pentachlorophenol)	87-86-5

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50.	N-Ethyl ortho-Toluene Sulfonamide	1077-66-1
51.	N-Ethyl para-Toluene Sulfonamide	80-39-7
52.	Nano Particles <100nm with significant different characteristics	-
53.	Nickel	7440-02-0
54.	Asbestos	-
55.	Ethyl acrylate	140-88-5
56.	Pyridine	110-86-1
57.	Myrcene (7-methyl-3-methylene-1,6-octadiene)	123-35-3
58.	Eugenyl methyl ether (4-allylveratrole or methyl eugenol)	93-15-2
59.	Pulegone (p-menth-4(8)-en-3-one)	89-82-7
60.	PVC and PVDC	-
61.	Perfluorooctanesulfonic acid (PFOS) , Perfluorooctanoic acid (PFOA)	-

Hereby we declare that the mentioned film does comply with the following regulations:

SN	Regulation	Topic
1.	1895/2005/EC	Epoxy derivatives 1895/2005/EC
2.	Reg (EU) No. 1169/2011 (repealing Directive 2000/13/EC and its amendments)	Allergens
3.	2003/53/EC, 76/769/EEC and 2005/84/EC	Council directive related to restrictions of nonylphenol, nonylphenol ethoxylate, phathales and cement
4.	96/5/CE	Directive related to processed cereal-based foods and baby foods for infants and young children
5.	CoE AP (89)1	Use of colourants (including dyes and pigments) in plastics material coming in to contact with food
6.	CoE AP (92)2	Control of Aids to polymerization
7.	76/768/EEC	Cosmetic legislation
8.	2002/16 EC	"BADGE" (Bisphenol A diglycidyl ether) or related compounds ("BFDGE" and "NOGE")
9.	94/62/EC	Packaging and packaging waste
10.	1223/2009/EC	Cosmetic Regulation Annexes II and III
11.	1999/13/EC	Directive on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations
12.	Arrêté du 27 août 1987	We certify that the Aluminium wire used for the production of metallized film complies with the French regulation "Arrêté du 27 août 1987"
13.	Regulation (EC) No 1272/2008 And amendment 944/2013	On classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
14.	REACH 1907/2006	Annex XV11
15.	Regulation / EC) No 453/2010	(EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
16.	(EC) No 282/2008	On Recycled plastic materials and articles intended to come into contact with foods
17.	(EC) No 450/2009	On active and intelligent materials and articles intended to come into contact with food
18.	(EC) No 1895/2005	On the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food
19.	SR 817.023.21	Swiss Regulation SR 817.023.21 (2019)

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