

Regulatory Compliance Certificate

BOPA Films

BOPALAIN BA 1011 & BOPALAIN BA 1031

EU Food Contact

We confirm that the production of our films that Süper Film supplies to the customer is made only from the materials sanctioned by EC Regulations for food contact packaging.

All components are in conformance with **COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011** including its amendments (EU) No. 1282/2011 of November 28,2011, (EU) No. 1183/2012 of November 30,2012, (EU) No. 202/2014 of 3 March 2014, (EU) No.2015/174 of 5 February 2015, (EU) No. 2016/1416 of 24 August 2016, (EU) No. 2017/752 of 28 April 2017, (EU) No. 2018/79 of 18 January 2018, (EU) No. 2018/213 of 12 February 2018, (EU) No. 2018/831 of 05 June 2018, (EU) No. 2019/37 of 10 January 2019, (EU) No. 2019/1338 of 8 August 2019, **(EU) 2020/1245 of 2 September 2020** on plastic materials and articles intended to come into contact with food or national legislations as listed.

We also remind that all products except metallized films are suitable for direct food contact applications while metallized films are for indirect food contact applications.

**All properties which has been tested and proven are included in Technical Data Sheet.*

Turkey: Turkish Legislation - 2019/43-44 (Gıda, Tarım ve Hayvancılık Bakanlığından: Türk Gıda Kodeksi Gıda İle Temas Eden Plastik Madde Ve Malzemeler Tebliği)

The United States: The US Food, Drug and Cosmetic Act of 1958 and applicable indirect food additive regulations of the United States of America as set out in the Code of Federal Regulations of the US Food and Drug Administration (FDA), under title 21 with sections as; 21 CFR 177.1520 (a)(1),(b) and (c)1.1 - 174.5 - 176.170(c), table1 - 178.3130 - 178.3860 - 178.2010 - 182.1711 - 184.1033 - 184.1324. - The USA CONEG Regulation.

This product may be used in contact with all food types as described in table 1 of CFR 21 §176.170(c), under conditions of use A through H as described in table 2 of CFR 21 §176.170(c) (including articles used for packing or holding food during cooking). It is the responsibility of the converter or food packer to control that the final packaging complies with the requirements of the intended and foreseeable conditions of use.

Italy: Decreto Ministeriale 21/03/1973 and subsequent amendments including D.M. of 23/4/09, N° 144

Spain: Official State Bulletin published the Royal Decree 1025/2015 of 13 November (amending a previous one) on the conditions to be met by recycled raw materials based on polymeric materials for their use in packaging and other articles in contact with food.

Mercosur:

- o GMC/RES N° 56/92 General provisions for plastic containers and equipment in contact with food;
- o GMC/RES No. 20/21 Modification of GMC Resolution No. 56/92 - General provisions for plastic packaging and equipment in contact with food;
- o GMC/RES No. 32/07 Mercosur technical regulation on “positive list of additives for plastic materials intended for the preparation of containers and equipment in contact with food” (repeal of GMC RES. No. 95/94 and 50/01);
- o GMC/RES No. 39/19 Mercosur technical regulation on the positive list of additives for the production of plastic materials and polymeric coatings intended to come into contact with food (repeal of GMC Resolution No. 32/07);



SÜPER FİLM AMBALAJ SANAYİ VE TİCARET A.Ş.

2.Organize Sanayi Bölgesi Hacı Sani Konukoğlu Bulvarı No:1 Şehitkamil/GAZİANTEP

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o GMC/RES No. 02/12 Mercosur technical regulation on the positive list of monomers, other starting substances and polymers authorized for the production of plastic containers and equipment in contact with food (repeal of GMC RES. No. 47/93, 86/ 93, 13/97, 14/97 and 04/24);

o GMC/RES No. 19/21 Modification of GMC Resolution No. 02/12 "Mercosur technical regulation on the positive list of monomers, other starting substances and polymers authorized for the production of plastic containers and equipment in contact with food.

Germany: Bedarfsgegenständeverordnung 23/12/1997 und Änderungen vom 21/12/2000, 07/04/2003, 13/07/2005, 30/11/2006, 20/12/2006, 08/08/2007, 11/02/2008, 30/04/2008, 16/06/2008, 23/09/2009 sowie BfR Empfehlungen A - VII, Polypropylene Stand vom 01.06.2019(for PP products), XVII. Polyterephthalsäurediolester Stand vom 01.07.2016 (for PET products).

Switzerland: Swiss Ordinance 817.023.21 on materials and articles intended to come into contact with food (updated on 1 December 2019)

China: Food Safety Law – April 25, 2015 (implemented on October 1, 2015), National rules on food safety – standard GB including its amendments; GB 4806.1 – 2016, GB 31603 – 2015, GB 9685 – 2016, GB 4806.6 – 2016, GB 4806.7 – 2016, GB 31604.1 – 2015, GB 4806.9-2016 - GB 4806.10-2016

Japan: Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA), Japan Hygienic PVC Association (JHPA). The positive list (26.04.2022) of the Japanese Food Sanitation Act as amended by Notification No. 196 of 2020.

France: Decree 2007-766 of 10th May 2007 for the application of the French Consumer Code regarding materials and articles intended to come into contact with food (repealing decree 92-631 of 8th July 1992).

Decree 2008-1469 of 30th December 2008 amending decree 2007-766 of 10th May 2007.

Décret n°2007-1467 du 12 octobre 2007 and Code de l'environnement, section 5-Emballages, sub-section 1, Articles R 543-42 to R 543-52

Canada: Domestic Substances List (DSL)

Our products are in compliance with COMMISSION REGULATION (EU) No 10/2011.

Country-based statements have been added to Regulatory Compliance Certificate for specific customer request and it is valid within the time of declaration release date. However, with respect to our product compliance policy, we are regularly following up the EU regulations. So that it is customer responsibility to check any updates with respect to country specific regulations and inform Super Film Regulatory Affairs if there is any specific request.

Whereas Super Film Amb. San. and Tic. A.Ş. supplies to its customers the adequate information to allow them to fulfil their own responsibilities, the converters do have to check and confirm that the final article meets both the technical and regulatory requirements of the application.

Migration Test - EC

We confirm that the films complies with the migration testing of the regulation EU 10/2011 and its amendments.

In accordance with Commission Regulation (EU) 2016/1416, the overall migration shall not exceed 10 mg/dm² from plastic materials and articles, with the exception for plastic materials and articles intended to contact infant or child food (60mg/kg).

Our films are tested under the conditions 4 hours at 100°C (OM6) and 2 hours at 175°C (OM7) in the three standard food simulants; olive oil (simulant D2), acetic acid solution (simulant B) and ethyl alcohol solution (simulant A), show that the overall migration limit of 60 mg/kg or 10 mg/dm² food is not exceeded in accordance with European Standards ENV- 1186:2002.



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Compliance with the overall and specific migration limits as described above must be measured from the final packaging intended to come into contact with foodstuff by using real food or appropriate food simulants at the intended and foreseeable conditions of use as specified in Annex III of Commission Regulation (EU) 2016/1416. It is the responsibility of the converter or food packer to verify that the final packaging complies with the overall and specific migration limits as set out by the applicable legislation.

Specific Migration & Dual use substances (Food additives)

We would like to confirm that our films contain some SML substances according to EU commission 10/2011 and some dual use additives according to EU 1333/2008 (and its amendments).

We confirm that we got all SML information of our raw materials from our suppliers and according to our worst case calculation for our formulations, we do not exceed specific migration limits. Maximum usage quantity is given by raw material suppliers and the films are formulated accordingly to not to exceed specific migration limits.

Total packaging structure are beyond the control of SUPER FILM and are a part of the responsibility of the user of our product.

The thickness of the product is assumed min 10 / max 80 micron and the ratio of the area that comes into contact with foodstuffs to the volume, based on which the conformity of the material has been established is: 6 dm² of film per 1 kg of foodstuff.

Specific migration analysis is not performed for products that comply with the overall migration limits except for special cases. (Article 11(2) - (EU) No 10/2011)

According to COMMISSION REGULATION (EU) No 10/2011; recommended conditions for specific migration analysis: A, B, D2 Simulants for 10days at 60° C.

SML information is given for special for film code as confidential document. Please contact with sales department.

Compound	PM/Pref	Cas No	SML
Caprolactam		105-60-2	15 mg/kg
Primary Aromatic Amine	-	-	0,01 mg/kg

We confirm that the films meet above mentioned legislations requirements of not containing more than 100 ppm of heavy metals.

Phthalates

We confirm that our products do not contain any of the below-mentioned substances above the specified limits. Concentrations less than 0,1 % are considered negligible for migration, according to Regulation (EU) No 10/2011. The information is provided to the best of our knowledge and is based on supplier certifications.

- Ortho-phthalates
- Diisohexyl phthalate
- DCHP (Dicyclohexyl phthalate)
- DIBP (Di-isobutyl phthalate)
- DEHP (Bis(2-ethylhexyl) phthalate)

- DBP (Di-butyl phthalate)
- BBP (Butyl-benzyl phthalate)
- DIDP (Di-isodecyl phthalate)
- DINP (Di-isononyl phthalate)
- DIPP (Di-isopropyl phthalate)
- DNPP (Di-n-pentyl phthalate)
- DMEP (Di-methoxyethyl phthalate, n-pentyl-isopentyl phthalate)
- DNOP (Di-n-octyl phthalate) etc. Diarsenic trioxide (HBCDD)

REACH / SVHC

Süper Film is committed to fully respect REACH legislation and will only use fully REACH compliant raw materials.

We are aware of the new European Community Regulation (EC 1907/2006) titled REACH (Registration, Evaluation, Authorization and Restriction of Chemical substances) which entered into force on 1st June 2007.

According to the definition given in Article 3 number 3 of Regulation (EC) No 1907/2006 (REACH) and the Technical Guidance Document on requirements for substances in articles, packaging films are regarded as articles, since their form or surface determines their function to a greater degree than does their chemical composition. Articles don't require registration under REACH.

We also declare that our films contain no substances of very high concern (SVHC) list published at ECHA website updated 10.06.2022 are present in products which are produced by SÜPER FİLM AMBALAJ SANAYİ VE TİCARET A.Ş.

Notwithstanding the fact that the substances referred to in this declaration have not been intentionally added during the production process of the Süper Film products, the absence of such substances has not been verified by analysis or tests and is therefore declared to the best of our knowledge and based on the information available to us from our raw material suppliers. It can therefore not be excluded that trace levels of these substances may be unintentionally present (amongst others because they may be ubiquitous in the environment) or may result from the specific characteristics of the raw materials or the manufacturing process and are therefore not picked up by our quality control.

This declaration does not warrant any specific properties and does not relieve processor from carrying out its own in-house tests and inspections amongst others to determine their suitability for a particular purpose.

Our guarantee is not cover any subsequent modification of the composition of the products, whatever that modification may be, any usage which might produce a denaturalized material, inappropriate use of material or objects.

Absence of substances and chemicals

In the films which are produced by SÜPER FİLM AMB. SAN. VE TİC. A.Ş. that we supply you, we can say that they are not formulated with below mentioned substances, which means that we do not intentionally use it as a raw material. And this is also declared and certified by our raw material suppliers. Therefore we do not expect they are presence. However, products have not been tested for these chemical materials.



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- Allergens
 - Acrylamide (acrylate/acrylamide copolymer (Cas n° 25085-02-3))
 - Active and intelligent materials and articles (Regulation 450/2009/EC of 29th May 2009
 - Any material included in the SIN (Substitute It Now) list
 - Acrylonitrile
 - Animal derived substances which may cause Transmissible Spongiform Encephalopathies (TSE) or Bovine Spongiform Encephalopathy (BSE)
 - Benzo [def]chrysene (Benzo[a]pyrene)
 - 1,7,7-trimethyl-3- (phenylmethylene)bicyclo[2.2.1]heptan-2- one(3-benzylidenecamphor)
 - 2-2'-dimethoxy-2-phenylacetophenon
 - (-)-1,7,7-trimethyl-3-[(4- methylphenyl)methylene]bicyclo[2.2.1]heptanes-2-one(4-methylbenzylidene camphor)
 - [3-(2,3-epoxypropoxy)propyl]trimethoxy silane
 - Isocyanates
 - Antraquinone
 - Aromatic amines
 - Asbestos
 - Azodicarbonamide or semi-carbazide compounds
 - Bamboo Flour & Corn Flour
 - Benzophenone, hydroxybenzophenone and 4-methyl benzophenone
 - Benzene
 - Benzonitrile
 - Biocides / Biocidal products
 - Brominated flame retardants
 - Carbon black
 - CMR compounds
 - Chlorophenols
 - Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)
 - Conflict minerals:
 - Columbite-tantalite (Coltan, Niobium, Tantalum)
 - Cassiterite (Tin)
 - Wolframite (Tungston)
 - Gold
 - Decabromodiphenylether (decaBDE)
 - 2-Ethylhexanoic Acid (2-EHA)
 - Di(ethylhexyl) adipate (DEHA) and di(ethylhexyl) maleate (DEHM)
 - Dimethyl Fumarate (DMF)
 - Dioxins and furans
 - Substances identified as endocrine disruptors at EU level - (Potential) Endocrine Disruptors identified in AGECE Article 13 by the French ANSES (04/2022)
 - Endocrine Disruptors listed in the Japanese authority list "Strategic Programs on Environmental Endocrine Disruptors '98 (SPEED '98) - Table-3: Chemicals Suspected of Having Endocrine Disrupting Effects
 - Epoxy derivatives:
 - BADGE [2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether],
 - BFDGE [bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether],
 - NOGE [novolac glycidyl ether]
- as defined in Directive 2002/16/EC amended by 2004/13/EC, repealed by the Regulation 1895/2005/EC
- Epoxidised Soya Bean Oil (ESBO)
 - Ethylenimine
 - Ethylbenzene
 - California Proposition 65 List of Chemicals
 - 1,7,7-trimethyl-3-(phenylmethylene)bicyclo[2.2.1]heptan-2-one
 - 2,2-bis(4'-hydroxyphenyl)-4-methylpentane
 - Benzo[k]fluoranthene
 - Fluoranthene
 - Phenanthrene
 - Pyrene

- Pentachlorophenol
- Hydraquinone
- Isopropyltioxanthone (ITX)
- Lactone
- Latexes
- Melamine and cyanuric acid
- Mercapto mix
- Microplastics
- N-ethyl-o,p-toluolsulfonamide (NETSA) (CAS nb 1077-66-1)
- N-ethyl-p-toluenesulphonamide (NE-PTSA) (CAS nb 80-39-7)
- Nanoparticles
- Nonylphenol and its derivatives
- Octamethylcyclotetrasiloxane
- Decamethylcyclopentasiloxane
- Dodecamethylcyclohexasiloxane
- Lead
- Disodium octaborate
- Benzo[ghi]perylene
- Terphenyl hydrogenated
- Ethylenediamine (EDA)
- Benzene-1,2,4-tricarboxylic acid 1,2 anhydride (trimellitic anhydride) (TMA)
- o-Phenylphenol and its salts (sodium, potassium and MEA o-Phenylphenate)
- Organotin compounds as tributyl-tin (TBT), dibutyl-tin (DBT), monobutyl-tin (MBT)
- Palm oil
- Polyacrylonitrile (PAN)
- Polystyrene (PS)
- Pentabromodiphenyl ether, octabromodiphenyl ether
- Pentachlorophenol
- Perchloric acid, perchlorate
- Pigment colorants based on antimony
- Poly(aromatic hydrocarbons) according to US Environmental Protection Agency Method 610 (EPA 610)
- Polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs), polybrominated terphenyls (PBTs)
- Polychlorinated biphenyls (PCBs), polychlorinated terphenyls (PCTs), polychlorinated naphthalenes (PCNs), per- and polyfluoroalkyl substances (PFAs)
- Polycyclic Aromatic Hydrocarbons (PAH)
- Polyethylene Glycol (PEG)
- Recycled products as defined by Regulation (EC) 282/2008
- Rhodamine based pigments
- Short chained chlorinated paraffins
- Silicone
- Styrene
- Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
- Thiuram mix
- Titanium Acetyl Acetone (TAA)
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) (CAS 3380-34-5)
- Vinyl chloride monomer (VCM) and its polymers or copolymers (PVC, PVDC, ...)
- Diarsenic pentaoxide
- Lead chromate
- Lead sulfochromate yellow (CI Pigment Yellow 34)
- Lead chromate molybdate sulphate red (CI Pigment Red 104)
- Tris(2-chloroethyl)phosphate (TCEP)
- 2,4-dinitrotoluene (2,4-DNT)
- MOSH (Mineral Oil Saturated Hydrocarbon)
- MOAH (Mineral Oil Aromatic Hydrocarbon)
- Nitrate
- Nitrosamine

- Polycarbonate
- di- n-octyltin thiobenzoate 2-ethylhexyl mercaptoacetate
- benzoic acid, methyl ester
- benzoic acid, ethyl ester
- 4-hydroxybenzoic acid, propyl ester
- 4-hydroxybenzoic acid, methyl ester
- 4-hydroxybenzoic acid, ethyl ester
- benzoic acid, butyl ester
- benzoic acid, propyl ester
- 4-hydroxybenzoic acid, isopropyl ester
- 3,5-di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester
- 3,5-di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester
- diantimony trioxide (CAS 1309-64-4)
- Tris(nonylphenyl)phosphite (CAS 26523-78-4)
- 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts and its acyl halides covering any of their individual isomers and combinations thereof
- 2-methoxyethyl acetate
- 4-tert-butylphenol
- Tris(4-nonylphenyl, branched and linear) phosphite (TNPP) with $\geq 0.1\%$ w/w of 4-nonylphenol, branched and linear (4-NP)
- Substances listed in:
 - California Proposition 65 State regulation as amended
 - GADSL, "Global Automotive Declarable Substance List", as amended
 - IKEA Specification, IOS-MAT-0010, chapter 3 & 6, as amended
 - IKEA Specification, IOS-MAT-0054, as amended
- 2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one
- 2-benzyl-2-dimethylamino-4'-morpholinobutyrophenone
- 1,2,3 Benzotriazole (BTA)
- Polystyrene (PS/HIPS/EPS)
- Oxo-degradable products
- Disposable Plastic Cutlery
- Disposable Plastic Plates and Bowls
- Plastic Stems
- Plastic Straws
- Cotton buds with plastic stems
- Perfluorinated tenside (PFT), Perfluorooctanoic acid (PFOA), Perfluorooctane sulfonate (PFOS), Perfluorobutane sulfonic acid (PFBS) and its salts, Perfluorinated alkylsulfonic acids (PFASs), Perfluorinated alkylcarboxylic acids (PFCAs), Perfluoroalkoxy alkanes (PFA), perfluorononanoic acid (PFNA), perfluorohexane sulfonic acid (PFHxS)
- Bisphenol-A (BPA), Bisphenol-B (BPB), Bisphenol-S (BPS) and Bisphenol-F (BPF)
- Lanoline
- Cellophane
- Tris(nonylphenyl) phosphite (TNPP), 4-nitrophenyl phosphate (4NP), Pentamethylheptane
- Triacetin
- Tertiary Butylhydroquinone (TBHQ)
- Triethyl phosphate, Trimethyl phosphate
- Nitrocellulose
- Amin
- Melamine
- Tallow
- POPs List
 - Perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds
 - Tetrabromodiphenyl ether C₁₂H₆Br₄O
 - Pentabromodiphenyl ether C₁₂H₅Br₅O
 - Hexabromodiphenyl ether C₁₂H₄Br₆O
 - Heptabromodiphenyl ether C₁₂H₃Br₇O
 - Bis(pentabromophenyl)ether (decaBDE)
 - Perfluorooctane sulfonic acid and its derivatives (PFOS) C₈F₁₇SO₂X (X = OH, Metal salt (O-M⁺), halide, amide, and other derivatives including polymers)

- DDT (1,1,1-trichloro-2,2-bis(4-chlorophenyl)ethane)
- Chlordane
- Hexachlorocyclohexanes, including lindane
- Dieldrin
- Endrin
- Heptachlor
- Endosulfan
- Hexachlorobenzene
- Chlordane
- Aldrin
- Pentachlorobenzene
- Polychlorinated Biphenyls (PCB)
- Mirex
- Toxaphene
- Hexabromobiphenyl
- Hexabromocyclododecane
- Hexachlorobutadiene
- Pentachlorophenol and its salts and esters
-
- Alkanes C10-C13, chloro (short-chain chlorinated paraffins) (SCCPs)
- Polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/PCDF)
- Polycyclic aromatic hydrocarbons (PAHs)
- Phenol, alkylation products (mainly in para position) with C12-rich branched alkyl chains from oligomerisation, covering any individual isomers and/ or combinations thereof (PDDP)
- orthoboric acid, sodium salt
- Medium-chain chlorinated paraffins (MCCP)
- Glutaral
- 4,4'-(1-methylpropylidene)bisphenol
- 2-(4-tert-butylbenzyl)propionaldehyde and its individual stereoisomers
- 2,2-bis(bromomethyl)propane-1,3-diol (BMP); 2,2-dimethylpropan-1-ol, tribromo derivative/3-bromo-2,2-bis(bromomethyl)-1-propanol (TBNPA); 2,3-dibromo-1-propanol (2,3-DBPA)
- 1,4-dioxane
- Dioctyltin dilaurate, stannane, dioctyl-, bis(coco acyloxy) derivs., and any other stannane, dioctyl-, bis(fatty acyloxy) derivs. wherein C12 is the predominant carbon number of the fatty acyloxy moiety
- Bis(2-(2-methoxyethoxy)ethyl)ether
- Nitrocellulose
- Photoinitiators
- Formaldehydes
- Nano materials
- Genetically Modified Organisms

This certificate will be updated when appropriate. Therefore, it is recommended to contact with sales represents at least once a year for these subjects. It is the responsibility of the customer to check the suitability of the finished article for the intended application.

Recycling

Our films are produced only from virgin resins and do not contain post-consumer recycled components, and no obligation exists under the legislation.

We declare that our products do not contain any outsourced recycled material.

We only use in-house recycled material in our production. Scraps are recycled in a clean area and be used in regranulated form in our production taking care of the type of the film produced and at a limited percentage as an industrial fact and practice.



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Non-Intentionally Added Substances (NIAS)

Non intentionally added substances (NIAS) are all chemical substances which are not intentionally added and do not have an intended or specific function within the final food contact material.

Our products comply with the requirements of Commission Regulation (EU) No 10/2011, including Regulation (EC) No 1935/2004. A NIAS assessment has been considered in accordance to Article 19 of Commission Regulation (EU) No 10/2011, in compliance with Article 3 of Regulation (EC) No 1935/2004.

This letter confirms that all raw material suppliers of SÜPER FİLM AMBALAJ SANAYİ VE TİCARET A.Ş. carry out screening tests to determine the presence and levels of Non-Intentionally Added Substances (NIAS) in the products and it is confirmed that there is no NIAS issue related with the raw materials thus the Products of Super Film.

GMP / Food contact

The production and distribution processes of films have been submitted to a systematic review in regards to Good Manufacturing Practices as defined by the framework Regulation (EC) 1935/2004 and the “GMP” Regulation (EC) 2023/2006 as amended. As a result of this review, Süper Film Amb. San. Ve Tic. A.Ş. can state that the production and distribution processes of this product are compliant with the here-above mentioned Regulations.

As for 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 repealing Directives 80/590/EEC and 89/109/EEC, and, in particular, its Articles 3, 11(5), 15 and 17, SÜPER FİLM certifies that all the references supplied as to date are in full compliance with the aforementioned Regulation.

* We would like to say that our products which are produced in Süper Film Ambalaj San. Ve Tic. A.Ş. comply with the requirements in *European Pharmacopoeia (3.1.6) Polypropylene Containers and Closures for Parenteral Preparations and Ophthalmic Preparations*.

Allergen Statement

The food ingredients listed in Annex II of Regulation (EU) No 1169/2011, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

All raw materials used in the manufacture of our films are free from below indicated substances and this is also declared and certificate by our raw material supplier.

1. Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof, except:
 - (a) Wheat-based glucose syrups including dextrose (1)
 - (b) Wheat-based maltodextrins (1)
 - (c) Glucose syrups based on barley
 - (d) Cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages
2. Crustaceans and products thereof
3. Eggs and products thereof
4. Fish and products thereof, except:
 - (a) Fish gelatine used as carrier for vitamin or carotenoid preparations
 - (b) Fish gelatin or isinglass used as fining agent in beer and wine
5. Peanuts and products thereof
6. Soybeans and products thereof, except:
 - (a) Fully refined soybean oil and fat (1)
 - (b) Natural mixed tocopherol (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources
 - (c) Vegetable oils derived phytosterols and phytosterol esters from soybean sources
 - (d) Plant stanol ester produces from vegetable oil sterols from soybean sources



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7. Milk and products thereof (including lactose), except:
(a) Whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages
8. Nuts, i.e. almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglas regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*) macadamia nuts and Queensland nuts (*Macadamia ternifolia*), and products thereof, except:
(a) Nuts used for making distillates or ethyl alcohol of agricultural origin for spirits drinks and other alcoholic beverages
9. Celery and products thereof
10. Mustard and products thereof
11. Sesame seeds and products thereof
12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO₂
13. Lupin and products thereof
14. Molluscs and products thereof

Statement of Animal Origin

- Genetically Modified Organisms (GMO)
- Transmissible Spongiform Encephalopathy (TSE) or Bovine Spongiform Encephalopathy (BSE)
- Animal components or derivatives from animal sources
- Animal testing either directly or via commissioned processes
- Lubricants/grease from animal sources (MOSH/MOAH)
- Pig, lard or dog
- Blood
- Carnivorous animals
- Birds with talons or feed by snatching tearing
- Reptiles & insects
- Marine animals except fish
- Animals that live on land & water
- Animals that have died by any means other than according to Islamic Law.
- Animals generally considered repulsive
- The bodies of animals permitted under Islamic Law but not slaughtered according to Islamic Law.
- Wine, ethyl alcohol or spirits which remain in their original chemical form
- Any product or by-product derived from one or more of the above.

Concerning the absence of above substances in all films, we can say that they are not formulated with these substances, which means that we do not intentionally use them as raw material. Therefore, we do not expect their presence. This concerns only the composition of films produced by us and does not guarantee the compliance of final articles made by using our films.

Statement of Islamic Law (HALAL)

- Pig, lard or dog
- Blood
- Carnivorous animals (excluding fish).
- Birds with talons or feed by snatching tearing
- Reptiles & insects
- Marine animals except fish
- Animals that live on land & water
- Animals that have died by any means other than according to Islamic Law.
- Animals generally considered repulsive
- The bodies of animals permitted under Islamic Law but not slaughtered according to Islamic Law.
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Food Fraud

We declare that the products that we supply are produced and packaged in accordance with the Food, Agriculture and livestock regulations, and that there are no fraud and adulteration during the production, packaging, shipment.

Disclaimer: This declaration has been prepared and issued on the basis of information provided by our raw material suppliers, of currently applicable laws and regulations and to the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication. SÜPER FİLM makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose. It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.

No liability can be accepted in respect of the use of SÜPER FİLM products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

Please feel free to contact us if you have any question.

SUPER FILM - Regulatory Affairs