

SUMILON POLYESTER LIMITED



HEAD OFFICE: PLOT NO 21, SUMILON COMPOUND, BEHIND JAISAGAR COMPLEX, KHATODADRA, RING ROAD, SURAT-395002, TEL. No: +91-261- 2441122 / 6797979, FAX NO: +91-261-2442952

COMPLIANCE DECLARATION FOR THE REGULATIONS OF EU, FDA & REACH

Sumilon Polyester Limited hereby confirm that basic raw material for following types is polyethylene terephthalate (PET) polymers as identified with Code list of Annexure 1 of Directive 97/129/EC in accordance with the procedure laid down in Article 1 of Directive 94/62/EC.

- **All types of Bare, Pretreated & Metallized films manufactured in various thicknesses.**

The Above mentioned grades are manufactured with monomers/starting substances all listed in commission regulation (EU) 10/2011 amended till (EC) 1282/2011 Annex I, relating to plastic materials and articles intended to come in contact with foodstuffs. All additives either listed in the plastic directive (EU) 10/2011 amended till (EC) 1282/2011 Annex I. These additives also comply with the BFR (German federal Institute for Risk Assessment, previously known as BgW & BGA) Recommendation XVII, Polyterephthalic acid diolesters. The film does not contain post-consumer recycle nor "active or intelligent" components, so regulations (EC) 282/2008 and 450/2009 are not applicable.

- Sumilon polyester films comply with the requirements of Directive 2004/1935/EC as amended till Commission Regulation (EC) No 450/2009.
- For traceability requirement, set out in article 17 of regulation (EC) 1935/2004, the sumilon polyester films comply with **traceability regulation**. Customer has to provide the "MFG. SR NO." printed on each roll slip to trace back any rolls.
- EC Directive 2004/l prohibit the use of **azodicarbonamide** as blowing agent from 2 August 2005. Sumilon Polyester films comply with this directive as azodicarbonamide is not used in their manufacture during any stage of production.
- Sumilon Polyester films comply with the Directive 1895/2005/EC amended to directives 2002/16/EC followed by 2004/13/CE. Ours film contains no substances that are derived from "**bisphenol A**" (2,2-Bis(4-hydroxyphenyl) propane), such as polycarbonate, "BADGE" (bisphenol A diglycidyl ether) or related compounds ("BFDGE" and "NOGE"), azodicarbonamide, vinyl chloride or 2,4,4'-trichloro-2'-hydroxydiphenyl ether (triclosan).
- Our films are in compliance to the Directive 2005/84/EC amending Directive 76/769/EEC regarding use of **Phthalates** as given below mentioned Phthalates is not added at any stage of production by us or in additives by suppliers. (bis (2- ethylhexyl) phthalate (DEHP), dibutyl phthalate (BDP), benzyl butyl phthalate (BBP), di-isononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP).
- A new reduction Factor should be introduced in migration testing (FRF) for **Lipophilic** substances. The Sumilon polyester films do not contain any substances falling under list of lipophilic substances.
- For the manufacturing of coating/primer component is covered by the plastics regulation (EU) 10/2011. Also, the coating complies with BfR Recommendation XIV and Council of Europe Resolution ResAP (2004)1.

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Migration limits and testing

The BOPET films are subject to migration as the plastic materials are not fully inert. There are substances that can transfer or migrate from the plastic packaging into the food and vice versa. This migration of substances is regulated by

Directive (EU) 10/2011 and its amendment (EC) 1282/2011 of 28 November with two different migration limits: Over All Migration & Specific Migration Limit. The Sumilon Polyester films meet both the limit accordingly.

A) Overall Migration Limit (OML)

Directive (EU) 10/2011, 2006/141/EC & 2006/125/EC limits the permissible overall migration limit i.e. the area limiting value of 10mg/dm² under the test conditions set out in Annex III in accordance with the rules set out in chapter 3, section 3.1 of Annex V. Sumilon Polyester Films meets the Over All Migration Limit.

Testing	Simulant Used	Test condition	Results (mg/dm ²)	Max. Permissible Limit (mg/dm ²)
Overall Migration Test (OML)	10% Ethanol	40°C for 10Days	Not Detected	10
	20% Ethanol			10
	50% Ethanol			10
	3% Acetic acid			10
	Olive Oil			10
	2,6-Diphenyl-p-Phenylene oxide	04hrs. at 100°C		10
	10% Ethanol			10
	20% Ethanol			10
	50% Ethanol			10
	3% Acetic acid			10
Olive Oil	02hrs. at 175°C	10		

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B) Specific Migration Limit (SML)

Directive (EU) 10/2011 amended till EC/1282/2011 also stipulates specific migration limits (in mg/kg food) for certain substance. The Sumilon Polyester Films meet the specific migration limits accordingly under the test conditions set out in Annex III in accordance with the rules set out in chapter 2, section 2.1 of Annex V. The specific migration values given in mg/kg food are converted to mg/dm² film surface by multiplying with the standard conversion factor 6, since by definition 1 kg food is enclosed by 6dm² of film. Sumilon Polyester films meets the specific migration limit meets the above requirement.

Testing & Simulant Used	Test condition	Results (mg/kg)	Max. Permissible Limit (mg/kg)
Specific I Migration Test (SML) of Terephthalic in 95% Ethanol	40°C for 10Days	Not Detected	7.5
Specific I Migration Test (SML) of Isophthalic Acid 95% Ethanol			5.0
Ethylene Glycol & Diethylene Glycol in 95% Ethanol			30
Antimony in 3% Acetic Acid			0.04

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Compliance for Food contacts: Determination of amount of Overall & net chloroform soluble extractives

The Sumilon Polyester films comply with FDA regulations 21 CFR 177.1630 (a) (films made of Polyethylene terephthalate polymers) and specifications therein (e), (f) & (g) with regard to the results for net chloroform soluble fractions obtained from these films under the below mentioned conditions:

A): (US FDA 21 CFR 177.1630)

Simulant Used	Test condition	Results (mg/Inch ²)	Max. Permissible Limit (mg/Inch ²)
Distilled Water	250°F for 02hrs	<0.1	0.5
n-heptane	150°F for 02hrs	<0.1	0.5
50% Ethanol	120°F for 24hrs	<0.1	0.5
95% Ethanol	120°F for 24hrs	<0.1	0.5

Also our films comply with the US FDA 21CFR 175:300 under the below mentioned conditions:

B) US FDA 21 CFR 175.300

Simulant Used	Test condition	Results (mg/Inch ²)	Max. Permissible Limit (mg/Inch ²)
Distilled Water	120°F for 24hrs	<0.1	0.5
Distilled Water	70°F for 48hrs	<0.1	0.5
Distilled Water	212°F for 30Min.	<0.1	0.5
n-heptane	120°F for 30Min.	<0.1	0.5
8% Alcohol	120°F for 24hrs	<0.1	0.5
8% Alcohol	70°F for 48hrs	<0.1	0.5

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The Sumilon Polyester Films are suitable for food grade applications provided it is subject to limitations found in 21 CFR 177.1630 (e) & (g) where the non-coated side to be kept in direct contact with food and the films are used in accordance with the Good Manufacturing Practice –GMP regulations (defined in 21 CFR 174.5). Substances /Additives either as a base sheet or as constituents of coating used are as per FDA regulation 21 compliance requirements.

- Effective from July 14, 2004, The Food and Drug Administration (FDA) has issued regulation 21CFR Parts 189 and 700 to prohibit the use of certain cattle material, to address the potential risk of bovine spongiform encephalopathy (BSE) & Transmittable spongiform (TSE), in human food, including dietary supplements, and cosmetics. This action is consistent with the recent interim final rule issued by the U.S. Department of Agriculture (USDA) declaring specified risk materials and the carcasses and parts of nonambulatory disabled cattle to be inedible, unfit for human food, and prohibiting their use as human food and requiring that the entire small intestine be removed and disposed of as inedible.
- Further, Sumilon Polyester confirms that none of animal ingredients or its byproducts are being used in the manufacturing process. Thus the Sumilon Polyester films comply with the Food and Drug Administration (FDA) has issued regulation 21 CFR Parts 189 and 700 to prohibit the use of certain cattle material effective from July 14, 2004.

Dual Additives

Based on our current manufacturing practice and information provided by our raw material suppliers, the sumilon polyester films do not contain the dual additives (also called multiple function additives), which are covered by articles 5a of 2002/72/EC as amended by 2004/19/EC and 2005/79/EC.

ROHS & CONEG Legislation

We confirm that heavy metals such as Lead (Pb), Hexavalent Chromium (CrVI), Cadmium (Cd), and Mercury (Hg) as such and their compounds are neither used in the manufacturing of Polyester film nor they detected in the analysis with reference to IEC 62321-111/54/CDV by acid digestion and determined by AAS/ICP-OES (for Cd, Pb, Hg) and for Cr(VI) with reference to IEC 62321-111/54/CDV by alkaline digestion and determined by UV-VIS spectrophotometer . Further, the various brominated flame retardants like Monobromobiphenyl (PBBs) and Polybrominated Diphenyls Ethers (PBDEs) are not added in the manufacturing process nor they detected in the analysis with the reference to IEC 62321-111/95/CDV, by solvent extraction and determined by GC/MS and further HPLC confirmation.

Hence Sumilon Polyester films comply EU directive 2002/95/EC and 2004/12/EC amending directive 94/62/EEC (Packaging and Packaging Waste), ELV directive 2005/53/EC as well as with the CONEG Legislation USA, & EN71.

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European Standards for Packaging and Packaging Waste (EN 13427)

Sumilon Polyester films have following properties with respect to European Standard EN 13427 requiring prevention and recovery.

- From EN13428-30: The maximum used of Sumilon Polyester films are in lamination & printing. It can be recycled (Before going to converting process).
- EN13431-32: Sumilon Polyester Films cannot be used as fuel & in composting purpose.
- CR13695-1: Sumilon Polyester Films have been tested and the results are complying with as per the Heavy metal testing EU norms.
- CR 13965-2: Sumilon Polyester films comply for 151 SVHC Screening tests which is included in candidate list promulgated by European Chemical Agency (ECHA) before and after on December 16, 2013 defined in article 57 of REACH (EC 1907/2006).

REACH Requirement

- As per article 33(1) of REACH regulation (EC 1907/2006), recipient of product must be provided with information of safe use if any of the tested substances (SVHC) exceeded 0.1% (W/W). A product meets the requirement of article 33(1) by default when no SVHC exceeds 0.1% (W/W).
- Sumilon Polyester films comply with the above said regulation as all the SVHC listed in candidate list before and on December 16, 2013 were found <0.02%.

Coatings

The coating used in the manufacturing of Sumilon polyester films, the monomers/starting substances are all listed in commission regulation 10/2011 (EU) of 14th January 2011 amended till (EC) 1282/2011 Annex 1, or in one or more Member states legislation, pending full harmonization under directive 10/2011 (EU).

GMO's

Based on the supplier's information and knowledge of our production process, the sumilon Polyester films do not contain GMO's thus our films is in accordance with the Directive 2001/18/EC and repealing council directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms (GMO).

Estrogen Mimickers and Nano Particles

To the best of our knowledge, we confirm that above mentioned two substances neither used as a raw material nor added to the manufacturing process at any stage. We have no reason to expect the presence of above substances in our product.

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Other Compliance

- Sumilon Polyester films are free from Ozone Depletion Substances as defined in Directive 2000/2037/EC.
- Directive 2003/18/EC amending directive 83/477/EEC of European Parliament on protection of workers from the risk related to exposure to Asbestos at work. We do not test our products for these asbestos substances; based on our knowledge of the raw materials, chemical reactions and process to make these products, we would not expect it be present.
- The Sumilon Polyester films comply with the requirements of LMBG Act Section 30 for the levels of Polvaromatic Hydrocarbons (PAH).
- We confirms that our products do not contain any source of tin {Dibutyltin (DBT), Tributyltin (TBT), Monobutyltin (MBT), Alkyl tin or other organotin compounds } and not intentionally added during any stage of production.
- Directive 2002/61/EC of the European Parliament amending directive 76/769/EEC relating to restrictions on the use of certain dangerous substances and preparations (Azocolourants: Which may release one or more of the Aromatic Amines).Based on results obtained from specific migration test and declaration from suppliers, we hereby confirm the non-presence of Aromatic amines in our Sumilon polyester films grades.
- Sumilon Polyester films comply with the recoverability requirements set forth in directives 75/442/EEC (as amended by 91/156/EEC, 91/692/EEC & 96/350/EC), 94/62/EC, 1999/177/EC & 2001/524/EC. The recent amendments of 94/62/EC, 2004/12/EC, have no direct effect on the status Sumilon Polyester films grade in this regard.
- Halogen substances {Fluorinated substances (PFOS, PFOA), Chlorinated substances (Hydrocarbons, Paraffin, PVC, and Vinylchoride), Brominated substances, Iodinated & Astatinated substances} are not intentionally used in raw material or any stage of manufacturing of above mentioned products.
- The Sumilon Polyester film is not subject to labeling as a hazardous chemical or mixture according to 67/548/EEC, 1999/45/EC and 1272/2008 (GHS Regulation). It is not classified as hazardous to water according to German regulations (no "WGK"). The formulation contains no substances forbidden or restricted by 76/769/EC and Annex XVII of REACH or subject to authorization by Annex XIV of REACH. As waste, it does not form materials that require monitoring according to Directives 91/689/EEC and 91/156/EEC, i.e. it is not hazardous waste.
- Council Directive 78/142/EEC along with 80/766/EEC & 81/432/EEC lays down limits for the quantity of vinyl chloride monomer & its derived polymer (PVC) present in the plastic materials & articles intended to come into contact with foodstuffs. Our films comply with this regulation as vinyl chloride monomers & its derived polymer (PVC) are not added either as main constituent or as additives during any stage of film manufacturing.
- Directive 2003/118/EC amending directives 86/362/EEC, 86/363/EEC & 76/895/EEC, limits the maximum level of Pesticides like (Acephate, 2,4-D and Parathion methyl) in the material intended to come into contact with food stuff. Based on our knowledge of the material and process, none of these substances are present or intensely added during any stage of production, hence would not expect it to be present.
- Directive 90/220/EEC puts regulations over the deliberate release of genetically modified organisms into the environment. Sumilon polyester Films comply with this directive as no such organisms are used in their manufacture at any stage of production.
- During production of the above mentioned films no allergenic substances (Wheat, Crustaceans, Egg, Fish, Peanuts, soybeans, Milk, Tree Nuts, Mustard, Sesame, Lupin and their products thereof), for which a special food labeling is required by directive 2003/13/EC till amendment 2007/68/EC are being used.

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- Directive 93/10/EEC relates to the materials & articles made up from regenerated cellulose film intended to come into contact with the foodstuffs. As per annexure I of this Directive, the regenerated cellulose film is obtained from refined cellulose derived from unrecycled wood or cotton is not classified as plastic. In the manufacture of above mentioned Sumilon polyester films such refined cellulose derivatives are not used at any stage of production.
- Above mentioned Sumilon polyester films are free from Latex content as it is not used as main constituents or as additive in their manufacture during any stage of manufacture.
- The California proposition 65. The Safe Drinking Water and Toxic Enforcement Act of 1986, was intended to protect California citizens and the State's drinking water sources from chemicals known to cause cancer, birth defects or other reproductive harm, and to inform citizens about exposures to such chemicals. We certify that the composition for the above mentioned Sumilon polyester film does not contain such chemicals and thus comply with the above regulation.
- The above mentioned films also comply with German „Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch, LFGB §§ 30 and 31" (book of legislations for food stuff, daily needs and animal feed) in the edition as of 01.09.2005 and „Bedarfsgegenstandsverordnung" (regulation for the use of daily needs) from 10.04.1992, modified on 21.12.2000 (Implementation of supplementary directive 99/91/EC).
- The above mentioned packaging films are being produced under the Good manufacturing practices and within a quality management system, certified as per ISO 9001:2008).
- Commission regulation (EC) 282/2008 of 27th March 2008 on recycled material and article intended to come into contact with food regulates the use of material produced from waste. As described in (Point no. 6 & 7 page-1 of 282/2008), Offcuts and scraps from the production of plastic food contact material, that has not been in contact with food or otherwise contaminated and is re-melted on the premises into new product or sold to a third party as part of a quality control system in compliance with rules for good manufacturing practice laid down in Regulation (EC) 2023/2006 would be considered as suitable for food contact application and should not fall under the scope of this regulation.
- We hereby declare that above mentioned films grade grades do not contain any recycled material produced by chemical de-polymerization, process, hence complies with this regulation.
- We do not test our film for the substances listed in Canadian Chemicals Management plan Challenge list batches (Batches 1 to 12). Based on our current knowledge of raw material and process, we have no reason to expect that any of these substances would be present. However we cannot exclude that the product may contain traces of substances as introduced from raw materials for which we are currently not aware of and that do not allow us to guarantee completeness of information.
- Section 1502 of the Dodd-Frank Act amends Section 13 of the Securities Exchange Act of 1934 and requires the Securities and Exchange Commission (SEC) to enact rules and regulations that impose disclosure and, in some instances, auditing requirements on publicly traded companies who use "conflict minerals" {defined as (a) gold, wolframite, cassiterite, columbite-tantalite (coltan) or their derivatives; or (b) "any other mineral or its derivatives determined by the Secretary of State to be financing conflict in the DRC (Democratic Republic of the Congo) or an-

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