



SOULPACK S.r.I

Sede legale: Via Cavour,28/A-29121 Piacenza Sede operativa: Via 2 Giugno, 139-21050 Gorla Maggiore VA CF/P.IVA 01561150333 N° Reg Impr PC 01561150333 REA 172958

tel. +39 0331 1813177 tel. +39 0331 827764 fax. +39 0331 1582089

Nome prodotto:		Doypack con Zipper	
Descrizione prodotto :		KRAFT CARTA40µm+Adhes.+ AL9µm+PE80µm	
Misure (mm):	110x180+2x35 / 130x225+2x40 / 160x270+2x45 / 180x290+2x45mm ( tolleranza: ± 2mm)		

CARATTERISTICHE TECNICHE						
PROPRIETA'	METODO	UNITA' DI MISURA	VALORE	TOLLERANZA		
Spessore	Interno	μm	129-134	± 10%		
Grammatura	Interno	g/m2	144-149	± 10%		
Forza di saldatura -laterale - Fondo	ASTM F-88-85	Kg/15 mm	9.45 - 9.80	+/- 10%		
Temper. di saldat.	Interno	°C	170			
OTR	ASTM F 1927-98	cm3/m2/24h	0,1			
WVTR	ASTM E 96	g/m2/24h	0,01			

Con la presente dichiariamo che i nostri prodotti sono conformi:

-Regolamento (CE) n. 1935/2004 del Parlamento europeo e del Consiglio, del 27 ottobre 2004; su materiali e oggetti destinati a venire a contatto con prodotti alimentari e che abroga le direttive 80/590 / CEE e 89/109 / CEE.

-La Direttiva CE 2002/72 del 6 agosto 2002; comitato che fa riferimento alle materie plastiche e agli articoli destinati a venire a contatto con prodotti alimentari.

-Regolamento (UE) n. 10/2011 della Commissione, del 14 gennaio 2011; su materie plastiche e articoli destinati a venire a contatto con alimenti; sostituendo efficacemente la direttiva 2002/72 / CE della Commissione del 6 agosto 2002 e successive modifiche.

-Questo materiale è stato fabbricato in conformità ai requisiti del regolamento della Commissione CE n. 2023/2006 sulle buone pratiche di fabbricazione per materiali e oggetti destinati a venire a contatto con i prodotti alimentari



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03.01.2020

## DECLARATION OF COMPLIANCE With Food Contact Regulations

## FOOD CONTACT REGULATION

This declaration is issued to comply with regulation (EU) No 1935/2004 EEC on materials and objects meant to come into contact with food products and regulation (EU) No 2019/1338 plastic materials and articles intended to come into contact with food.

This statement, relating to plastic materials and articles intended to use for the manufacture of food packaging, applies to flexible packaging consisting of the following films.

Kraft/PET/PE, Kraft/PET/PE(evoh)PE, Kraft/PET/CPP, Kraft/ALU/PE, Kraft/OPP, Kraft/metPET/PE, Kraft/ALU/CPP, Kraft/metPET/CPP, PE/PE, PE/PE(evoh)PE, PET/PE, PET/PE(evoh)PE, PET/ALU/PE, PET/metPET/PE, PET/CPP, metPET/CPP, PET/metPET/CPP, OPP/CPP, matPET/PE, matPET/PE(evoh)PE, matOPP/PE, matOPP/PE(evoh)PE, matOPP/PET/PE(evoh)PE, matOPP/ALU/PE, OPA/PE, Kraft/PET/PE(evoh)PE (>65% bio-based) "I'm green"

- Commission Regulation (EC) No 1935/2004
- Commission Regulation (EU) No 2019/1338 of 8 August 2019 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.
- Regulation (EC) No 2023/2006 of 22<sup>nd</sup> December 2006 amended on good manufacturing practices for materials and articles intended to come into contact with food.
- CFR-Code of Federal Regulations Title 21 (175.105, 175.300, 177.1520, 177.1630)
- Commission Regulation (EC) No 1895/2005
- Regulation (EU No 1169/2011 Annex II

## **OVERALL MIGRATION (OM)**

The migration tests for materials and articles intended to come into contact with food-stuffs should be carried out in accordance with the European Directives 82/711/EEC the basic rules neccessary for testing migration and 85/572/ EEC the list of simulants to be used for testing migration of plastic materials,

Regulation laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.

We confirm that for the production of our films, listed we use only monomers, starting substances and additives listed in the Union List of Authorized Substances of (EU) 2019/1338 and its successive amendments up to including (EU) No 2016/1416.

**Soulpack** have confirmed that the overall migration (simulants A, B, C, D2 and E for 10 days @ 40  $^{\circ}$ C + 4 hours @ 100 $^{\circ}$ C) shall be lower than 10 mg/dm<sup>2</sup>.

Simulant A , B, C, D2 are used for OML testing for all types of food types, therefore OML testing with tenax (Simulant E) for dry and powdered foods is not required at all.

The migration limits are in compliance under the following conditions (limit of 10 mg/dm<sup>2</sup>).

According to food type/ Food contact conditions	Simulant	Testing conditions	Unit
10 % Ethanol Solution (v/v)	A (Alcohol)	10 days @ 40 °C + 4 hours @ 100°C	mg/dm <sup>2</sup>
3% Acetic Acid Solution (v/v)	B (acid)	10 days @ 40 °C + 4 hours @ 100°C	mg/dm <sup>2</sup>
20 % Ethanol Solution	C (Alcohol)	10 days @ 40 °C + 4 hours @ 100°C	mg/dm <sup>2</sup>
Veg. Oil containing less than 1 % unsaponified matter	D2 (oil)	10 days @ 40 °C + 4 hours @ 100°C	mg/dm²
Poli 2,6- diphhenyleneoxide	E	10 days @ 40 °C + 4 hours @ 100°C	mg/dm <sup>2</sup>

According to directive 85/572/EC the above mentioned products are suitable for packaging, aqueous, alcoholic, fatty and dry food types taking into account the above mentioned food contact conditions. The overall migration tests are repeated annually.

Moreover, directive 85/572/EC the user of our food packaging should satisfy himself as of the suitability of our products for the intended application.

For conditions of use other than those already covered by our test results, users of the products in its finished state shall carry out the appropriate tests. Therefore, we disclaim any liability for damages arising from the non-suitability of our products for the intended specific application.

## SPECIFIC MIGRATION LIMITS

During the production of our films, we use following additives which are included in the Union List of Authorized Monomers and other starting substances in Annex I of EC Directive (EU) No 2018/831 and its successive amendments up to and including (EU) No 2016/1416.

## **HEAVY METALS**

We confirm that raw materials and films used in the production do not contain heavy metals including cadmium, hexavalent chromium, lead and mercury. The sum of concentrations of these heavy metals doest not exceed 100 ppm and complies with EU Directive 94/62/EC and its amendments.

Analysis of Manganese, Lithium, Cobalt, Iron, Copper, Barium, Zinc and Aluminium were analyzed according to Annex II of EC Directive (EU) No 2018/831.

## **DUAL USE ADDITIVES**

According to the Annexes in Directive 95/2/EC of food additives, we declare that we never buy directly the additives mentioned in the Annexes.

However ,the lack of information on this category of additives from our certain suppliers, which have the same difficulties as we do, do not allow as to guarantee the completeness of the information. Dual use additives are available upon request.

#### NANOFORM SUBSTANCES

In the manufacture of the films, we do not use any nanoform substances because EU Regulation 10/2011 prohibits the use of nanoform substances that are not specifically authorized in nanoform. Substances in nanoform shall only be used if explicitly authorized and mentioned in the specifications in Annex I of EU Regulation 10/2011 and its amendments.

## RECOVERABILITY

The film complies with the recoverability requirements set forth in Directive 94/62/EC. The film is not subjected to labeling as a hazardous chemical or according to 1999/45/EC.

## **RECYCLED MATERIALS**

**Soulpack** declares that our packaging products do not contain recycled raw materials.

## ABSENCE OF SUBSTANCES AND CHEMICALS

According to the information received from our suppliers;

None of the following substances are intentionally added or used as additives or raw materials in the manufacture of the films. However, since we do not systematically conduct specific analytical tests to verify the absence of these substances, we cannot guarantee that there is no trace amount of these substances, as impurity, residue or otherwise, in the films. The following materials are not expected to be present in the films:

- Allergens (as defined in Regulation (EU) 1169/2011 Annex II)
  - (If the packaging has cold seal application, we inform you that the structure contains latex. The food packaging industry recognizes that natural rubber latex is known to contain some naturally occurring proteins that have been shown to have the potential to cause sensitisation or allergic reactions to some people).
- Asbestos
- Azodicarbonamide or semi-carbazide compounds
- Biocides
- Bisphenol A. Regarding to our world brand's adhesive supplier's declaration, some of adhesive hardener which is for application of solvent based lamination contain polyol component, based on ethoxylated and propoxylated Bisphenol A. Actually, Bisphenol A (BPA, Cas No 80-05-7) itself is not a part of formulation. Also, Bisphenol A is not released during the curing process of two component systems. NCO component is always in excess in two component systems must have reacted during the curing process. According to this consideration, in no case Bisphenol A can be present in the fully cured adhesive.
- Bisphenol S
- Di(ethylhexyl) adipate (DEHA)
- Dioxins
- Epoxidized soybean oil (ESBO)
- Epoxy derivatives:
  - a. BADGE [2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether]
  - b. BFDGE [bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether]
  - c. NOGE [novolac glycidyl ether]
- 2-Ethylhexanoic acid (2-EHA)

- Formaldehyde (formol)
- Genetically modified organisms
- Isopropyltioxanthone (ITX)
- Melamine and cyanuric acid
- Organotin compounds as tributyl-tin (TBT), dibutyl-tin (DBT) and monobutyl-tin (MBT)
- Perfluorinated tenside (PFT), perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS)
- Phthalates. Based on the BOPP suppliers' information, no phthalates of whichever chemical form are intentionally added as modifiers, plasticizers, additives or processing aids to BOPP films. However, Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP) and Bis(2-ethylhexyl) phthalate (DEHP) are used to improve the efficiency of the catalyst and control the isotacticity of polymer during PP production. The potential residual traces of phthalates in PP have been known below the limits defined by REACH (0.1%, by weight) for decades. Thus, no commercial PP is subjected to any restriction or ban in that respect.
- Polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs) and polybrominated terphenyls (PBTs)
- Polychlorinated biphenyls (PCBs), polychlorinated terphenyls (PCTs) and polychlorinated naphthalenes (PCNs)
- Polycyclic aromatic hydrocarbons (PAH)
- Recycled products as defined by Regulation (EC) 282/2008
- Titanium acetyl acetone (TAA)
- "Mineral oil saturated hydrocarbons" (MOSH) as well as "Mineral oil aromatic hydrocarbons" (MOAH) are not intentionally added during the manufacturing process of our products. Based on the ink supplier's declaration, the presence of traces of these substances in the product coming from raw material impurities, from the process or as adventitious contaminant cannot be excluded. They declare that potential traces of these substances in our products are kept below 0.1%, in accordance with BfR Opinion No. 008/2010, 09 December 2009.

# **REACH:** Declaration of non-use of SVHC list (Substances of very high concern)

Declared by our suppliers we can state that our products do not contain;

- a) Substances for intended release as defined in REACH Regulation 1907/2006, Article 7.1
- b) Any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern above the 0.1% threshold as stated in REACH Regulation 1907/2006, Article 57.

According to the confirmation received from our raw material suppliers we can state that substances / monomers / chemicals contained in our products have been registered and do not contain any chemicals from SVHC list (Substance Very High Concern).

## RESPONSIBILITIES

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 finished articles cannot replace migration tests under the real conditions. For conditions of use other than those already covered by our test results, users of the material or article in its finished state shall carry out the appropriate tests for their specific conditions of use.

The information contained herein relates exclusively to our products when not used in conjunction with any third-party materials. No liability can be accepted in respect of the use of our products with other materials and/or cannot be extended to the end-products obtained by:

- any ulterior modification of the composition of our products, hereby guaranteed, by the addition of any substances not in conformity with the legislations, •
- any processing technique, condition or improper storage which could change the physical, chemical, barrier and optical properties of our products and lead to deteriorated and damaged materials and/or products,.
- improper use of our products.

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, and storage, processing and handling of our products. We disclaim any liability for inappropriate, unsafe, illegal use, and improper storage, processing and handling of our products for the customer's particular purpose, the intended specific application and the particular foodstuff being used.

This declaration has been prepared and issued on the basis of currently applicable laws and regulations, and our best knowledge and expertise currently available.

Quality Assurance Manager



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