

**DECLARATION OF CONFORMITY OF MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD PRODUCTS****(in accordance with Art.16 Reg.1935/04/EC)****PBT - TRANSPARENT OR WHITE RECYCLABLE FILM**

1. The company PACKSTYLE SRL, with its registered office at Romano d'Ezzelino (VI) 36060, Via Fiorolle 10/A, as the processor of materials or articles intended to come into contact with foodstuffs,

**HEREBY DECLARES :**

2. That, in its production plant, located in Romano d'Ezzelino (VI) 36060, Via Fiorolle 10/A, manufactures plastic film, personalized with customer's graphic, produced in pouches or reels, with the following components

**3. MATERIALS**

- PLASTIC (PP CAST 15my) FOOD CONTACT SIDE;
- WHITE MASTERBATCH (in the white film);
- PLASTIC (PP BARRIER 20my)
- INK;
- PLASTIC (BOPP+EVA 20 + 34my);
- ACCESSORIES (zip, valve or spout in PP).

**4. VALIDITY**

5. This declaration is valid from the above date and will be substituted if substantial changes occur in the production of the material, which may change some essential requirements for the purpose of compliance, or when the legislative references cited in this declaration are modified and updated in a way that requires a new verification for the purpose of compliance.

**6. COMPLIANCE**

The products have been manufactured in compliance with the following EU regulations:

- Regulation (EC) No. 1935/2004 and subsequent amendments .
- Regulation (EC) No. 2023/2006 and subsequent amendments .
- Regulation (EU) No. 10/2011 and subsequent amendments .

and to the following Italian legislation:

- Ministerial Decree n°21/03/1973 and subsequent amendments .
- Presidential Decree n°777/1982 and subsequent amendments .
- Legislative Decree no. 29/2017 and subsequent amendments .

**7. PRESENCE OF SUBSTANCES SUBJECT TO SPECIFIC MIGRATION (SML)**

The following substances subject to SML (specific migration limit) are present in the product:

SOSTANZA	NR.CAS	N.RIF.	SML (mg/kg)
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	0002082-79-3	68320	6
bis(2,4-di-tert-butylphenyl) pentaerythritol diphosphite	0026741-53-7	38820	0,6
N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine hydrochlorides		39120	1,2
9,9-bis(methoxymethyl)fluorene	0182121-12-6	39815	0,05
N,N-bis(2-hydroxyethyl)alkyl (C8-C18)amine		39090	1,2
3,3-bis(methoxymethyl)-2,5-dimethylhexane	0129228-21-3	39925	0,05
cis-1,2-cyclohexanedicarboxylic acid, salts		45704	5
glycerides, castor-oil mono-, hydrogenated, acetates	0736150-63-3	55910	60
stearic acid	0000057-11-4	89040	60
1,1,1-trimethylolpropane	0000077-99-6	94960	6
phthalic acid, dibutyl ester	0000084-74-2	74880	0,3
maleic anhydride	0000108-31-6	19960	(3)
phthalic acid, bis(2-ethylhexyl) ester	0000117-81-7	74640	1,5
2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene	0007128-64-5	38560	0,6
1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione	0027676-62-6	95360	5
Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorous trichloride and biphenyl	0119345-01-6	83595	18

The above LMS are respected in the finished product. The statement is based on information received from our suppliers and checked also through our internal control analytical plan.

**8. PRIMARY AROMATIC AMINES AND METALS**

With reference to the article in question, compliance with the Specific Migrations of the substances present in Annex II of Regulation (EU) No. 10/2011 and subsequent amendments (Primary aromatic amines and metals) is declared. Test conditions: 10 days at 60°C in contact with 3% acetic acid.

**9. DUAL USE ADDITIVES**

The following substances authorised as additives (dual use substances) are present in the product regulated by Regulation 1333/08/EC and 1334/08/EC and subsequent amendments:

N° E	DENOMINAZIONE SOSTANZA DUAL USE	SML (mg/kg)
E 551	Silicon dioxide	60
E 330	Citric acid	60
E 470a	Sodium, potassium and calcium salts of fatty acids	60
E 470b	Magnesium salts of fatty acids	60
E 471	Mono- and diglycerides of fatty acids	60
E 475	Polyglycerol esters of fatty acids	60

E 304(i)	L-ascorbyl palmitate	60
E 307	Alpha-tocopherol	60
E 526	Calcium hydroxide	60
E 570	Fatty acids	60
E 1520	Propane-1, 2-diol (propylene glycol)	60
E 262	Sodium acetates	60
E 338	Phosphoric acid	60
E 422	Glycerol	60
E 435	Polyoxyethylene sorbitan monostearate (polysorbate 60)	60
E 900	Dimethyl polysiloxane	60

The possible migration limits set for these additives, listed above, are observed in the finish product.

This declaration is based on the information obtained from our suppliers and checked through our internal control analytic plan.

## 10. TERMS OF USE

The product is in conformity with the following specific conditions:

- Kind of food products which the product is appropriated to come in contact with: for single use, **suitable for every kind of food**.
- Duration and temperature of treatment or preservation of the food in contact with the product: for contact and extended preservation at room temperature or below, including hot filling and/or warming up to 70 °C for 2 hours or warming up to 100 °C for 15 minutes (as per regulation up to 70 °C  $\leq T \leq 100$  °C for  $t = 120/2^{(T-70)/10}$  minutes maximum).
- Surface/volume ratio used to check the compliance: 6 dm<sup>2</sup>/kg

## 11. FUNCTIONAL BARRIER

The plastic layer in contact with the food product has been validated as a functional barrier and it is confirmed that said material or object complies with the requirements of Article 13, paragraphs 2,3,4 or Article 14, paragraphs 2 and 3 of Regulation (EU) 10/2011.

## 12. ORGANOLEPTIC-SENSORY INERTIA AND SCREENING TESTS

With regard to the analysis of the risk of sensory damage to the food, no significant alterations in odor and flavor were detected; the analyses were carried out on the material in question under the following test conditions:

- (40±2) °C for 24h in the dark for direct contact with the following foods: thinly sliced melted cheese simulant H (taste test),
- (23±2) °C for 24h in the dark without food (olfactory test).

With regard to the toxicological risk analyses carried out on the material in question, it is declared that:

- SPME/GC-MS, HS/GC-MS and GC-MS screening with isooctane simulant
- the evaluation of the set-off verification performed through HS/GC-MS and GC-MS screening

they did not highlight dangerous compounds or quantities potentially dangerous for the consumer.

## 13. NIAS

NIAS substances have been controlled and managed and do not affect compliance with Article 3 of Reg. 1935/2004. Based on our supplier's declaration and to the best of our knowledge, the list of substances below is not used in production or in the formulation of these materials, in particular the following substances:

- BISPHENOL A (in accordance with the restrictions in Article 2 of Reg. 1818/213 and the requirements set out in Articles 3, 15 and 17 of Reg. 1935/2004/EC)
- MOSH and MOAH (Non-authorized Mineral Oils, are not used in the production processes as ingredients of the products as constituents or additives for the production of MOCA. In this context, it must be noted that these substances are ubiquitous pollutants, therefore potentially coming from other involuntary contaminations and not intentionally added)
- PFAS (in accordance with the restrictions in Reg. 1021/2019/UE, POPs, PFAS and PFASs are under control. It must be noted that these substances are ubiquitous pollutants, therefore potentially coming from other involuntary contaminations and not intentionally added).

## 14. ALLERGENS AND ADDITIVES

Based on the declarations of our raw material suppliers, none of the allergenic ingredients listed in Annex II of Regulation (EU) No. 1169/2011 (reproduced below) are present in the material in question, nor are any additives or substances derived from genetically modified organisms (GMOs) added or used.

The use in industrial or commercial purposes of the material indicated in this declaration doesn't exclude the verification of its compliance with current standards of competence as well as its technological suitability for the purpose for which it's intended.

We also specify that this declaration is valid exclusively for the object we supply and cannot be extended to any transformation of the same.

With regard to the storage and marketing stages of the object sold to your Company, we declare that we:

- have implemented a company quality assurance and quality control system in compliance with Regulation (EC) No. 2023/2006;
- comply with the requirements of Art. 15, of Regulation (EC) No. 1935/2004, regarding labeling;
- comply with the requirements of Art. 17, of Regulation (EC) No. 1935/2004, regarding traceability.

In support of the above, the company declares that it has available to the competent authorities the test reports carried out and the suppliers' declarations of conformity.

Nicoletta Garbo  
Legal representative

