

Direzione Ricerca e Sviluppo: Via De Gasperi, 2 48010 Cotignola (RA) Tel. +39 054537411 - Fax +39 054542191

ALI\_PVC\_EN\_v1.4

Vulcaflex Packaging S.r.I. Società uni personale Sede Legale: Via De Gasperi, 2 48010 Cotignola (RA) Tel. +39 054537411 - Fax +39 054542191 e-mail packaging@vulcaflex.com

## FOOD PACKAGING COMPLIANCE DECLARATION

#### **TECNOVIL**

Pag.1/2

This declaration is valid starting from the below written date and it will be replaced in case of changes in production or in raw materials which are relevant to food contact legislation, or when legislation will be changed or updated in a way that requires new compliance verification.

#### Composition

Transparent or pigmented rigid PVC sheet (side that is directly in contact with food).

There is no use of recycled material and the traceability is granted, in compliance with Regulation 1935/2004/CE

# Compliance with legislation for items intended to come into contact with foodstuffs

This film is in compliance with

the following CE legislation:

Regulation 1935/2004/CE; Regulation 1895/2005/CE; Commission Regulation 10/2011/UE and subsequent amendments the following Italian legislation:

Decreto ministeriale dated 21/03/73 and subsequent amendments; DPR 777/82 and subsequent amendments and it's produced in compliance with:

Regulation CE 2023/2006 (GMP); BRC/IOP Global Standard issue 4 (packing category HHR)

#### Further compliances

The film is in compliance with Commission Directive 94/62/CE art. 9 dated 20.12.94: the heavy metals content (Lead, Mercury, Cadmium, hexavalent Chrome) is below 100 ppm.

Pigments, if present in formulation, comply with Resolution AP (89) 1 of the Council of Europe.

## Overall and specific migration

The film contains substances which are subjected to restrictions in the above mentioned legislation. Overall migration limits, as well as other specific restrictions (Annex I) for monomers and/or additives that are contained in our material, are met into the following simulants and conditions:

simulant B: acetic acid 3%, aqueous solution; time and temperature: 10 days at 40°C

simulant C: ethanol 10%, aqueous solution; time and temperature: 10 days at 40°C

simulant D: rectified olive oil; time and temperature: 10 days at 40°C

The film is suitable to contact with all types of foods; contact at room temperature (or less) for a not defined time.

In order to guarantee the respect of the above mentioned limits, we carried out migration tests in compliance with Commission Directives 82/711/CE, 85/572/CE and Italian DM 21/03/1973 or we evaluated that on calculations, by considering the amount of substances subjected to restrictions. We assumed that 1 kg of food comes into contact with 6 dm<sup>2</sup> of packaging material.

## Dual use additives

The user of material intended to come in contact with foodstuff has the responsibility to inform Vulcaflex Packaging about further restrictions due to composition (additives and flavouring substances) of the foodstuff, that can be present in the packaging material (dual use additives). Due to our knowledge, based on the information provided by raw material suppliers, adequate information about the substances can be provided upon request.

#### General reccomendations

Please note that, according to the above mentioned legislation, the final packaging suitability has to be verified and tested by the final customer for migration and food stability in real conditions of use.

We ask you to inform us in case the conditions of use of the product should be different from the above mentioned ones or in case the foodstuff in contact with the film shouldn't correspond to the conditions and simulants described above.

Date 13/11/18

VULCAFLEX s.p.a. Ricerca & Sviluppo Dr. Sergio Ballardini



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### ANNEX I

### Substances subjected to specific restrictions

Pag. 2/2

CAS	Ref. 10/2011	Substance	Restriction
75-01-4	26050	Vinyl chloride monomer	QM = 1 mg/Kg / SML = 0,01 mg/Kg
108-05-4	10120	Vinyl acetate	SML = 12 mg/kg
103-23-1	31920	Dioctyl adipate	SML = 18 mg/Kg
8013-07-8	88640	Soja bean oil, epoxidized	SML(T) = 60 mg/Kg
15571-58-1	50320	Di-n-octyltin bis(2-ethylhexyl mercaptoacetate)	SML(T) = 0,006 mg/kg (as Sn)
27107-89-7	67680	Mono-n-octyltin tris (2-ethylhexyl mercaptoacetate	SML(T) = 1,2 mg/kg (as Sn)
106-99-0	13630	Butadiene	QM = 1 mg/kg / LMS = NR (LR = 0,01 mg/Kg)
-	Group 23	Methacrylic acids and ist esters	SML(T) = 6 mg/Kg
-	Group 22	Acrylic acid and ist esters	SML(T) = 6 mg/Kg
123-31-9	48620	1,4-dihydroxybenzene	SML = 0,6 mg/Kg
-	89440	Stearic acid, esters with ethyleneglycol	SML(T) = 30 mg/Kg
1321-74-0	16690	Divinylbenzene	QMA = 0,01 mg/6dm2
123-28-4	93120	Dilauryl 3,3'-thiodipropionate	SML(T) = 5 mg/Kg
2082-79-3	68320	Octadecyl-3,5-di-tert-butyl-4 hydroxyhydrocinnamate	SML = 6 mg/Kg
134701-20-5	49485	Phenol, 2,4-dimethyl-6-(1-methylpentadecyl)	SML = 1 mg/Kg
36443-68-2	94400	Triethyleneglycol bis[3-(3-tert-butyl-4-hydroxy-5- methylphenyl) propionate]	SML = 9 mg/kg
128-37-0	46640	2,6-di-ter-butyl-p-cresol	SML = 3 mg/kg
166412-78-8	45705	1,2-cyclohexanedicarboxylic acid, diisononyl ester	SML(T) = 60 mg/Kg
123-31-9	48620	1,4-dihydroxybenzene	SML = 0,6 mg/Kg
25013-16-5	40720	Tert-butyl-4-hydroxyanisole	SML = 30 mg/Kg
25359-91-5	54930	Formaldehyde-1-naphthol, copolymer	SML = 0,05 mg/Kg
-	Annex II	Iron compounds	SML = 48 mg/Kg
-	Annex II	Zinc compounds	SML = 25 mg/Kg

Date 13/11/18

VULCAFLEX s.p.a. Ricerca & Sviluppo Dr. Sergio Ballardini