

PRODUCT

Pharmaceutical push through foil, unprinted

MATERIAL COMPOSITION

Primer for printing / Aluminium 25µm hard tempered / 20 g/Sqm lacquered PVDC

Stratigraphy composition	Code	Thickness (µm)		Weight (g/m²)		Chemical composition
		Value	Tol.	Value	Tol.	
Primer	CT311	-	-	0,8	± 0,2	Polyester
Aluminium hard tempered		25,0	± 2,0	67,5	± 5,4	DIN EN 573-3 EN AW 8079
Heat seal	CT299	-	-	20,0	± 2,0	PVDC dispersion
Overall		40,2 (*)	± 3,6 (*)	88,3	± 7,6	

(*) Obtained from grammage

MATERIAL PROPERTIES

Residual solvent (IO 13)	<= 10 mg/m²
Varnishes adhesion to the substrate (IO 06)	No detachment
Bonding to PVDC (IO 05)	>= 9 N/15mm (220°C - 267 N/cm² - 1 second - 180°)
FT-IR Spectra heat-seal lacquer compare (IO 34)	>= 98,5 %
Melting point of thermosealable varnish (IO 17)	100 °C ± 10
Primer for printing resistance to temperature (IO 11)	<= 290 °C
Water vapor permeability (DIN ISO 15106-3)	<= 0,001 g/m² (24h - 38°C / 90% r.h. and 25°C / 100% r.h. - detection limit)
Oxygen permeability (DIN 53 380-3)	<= 0,005 cc/m² (24h - 23°C / 50% r.h. and 25°C / 50% r.h. - detection limit)

CLEARANCE CERTIFICATE

Product	This laminate is registered at the Food and Drug Administration with the DMF number 11322. CE Regulation 1935/2004 - 1895/2005 - 2023/2006 (GMP). Directive 94/62/CE and CONEG. EMA/410/01. It doesn't contain phthalates.
Nitrosamines statement	The product is Nitrosamines-free. The product doesn't include within its composition nor Nitrosamines as such neither possible precursors of the same. The presence of such chemicals is excluded both by our raw material suppliers and specific analysis, performed periodically, in order to exclude the presence of such chemicals also as Not Intentionally Added Substances as well as impurities/contaminants. Anyhow Aluberg doesn't check each batch produced for Nitrosamines presence, and a.m. analysis are conducted on scheduled base.
Thermosealable lacquer	FDA 21 CFR § 175.300 - 175.320 - 178.3400 (Registered at FDA with DMF 8738) CE Regulation n. 10/2011 Resolution of the Council of Europe AP(2004)1 European Pharmacopoeia paragraphs 3.1.11 and 3.2.2

WARRANTY, STORAGE AND SHELF-LIFE

This warranty is only valid if the following conditions of storage are observed:

Condition of storage	Recommended storage conditions: - no direct sunlight - room temperature between 18°C - 30°C (optimum 18°C - 20°C) - relative humidity between 40% and 60% (optimum 40% - 50%)
Workability	Maximum 2 years from delivery date for sealing. Maximum 6 months from the date of availability for printability.
Function	Maximum 5 years after processing on the packaging line.

LIABILITY EXCLUSION

Data mentioned in the technical specification, obtained in our laboratory or in our raw material supplier's laboratories, are valid as a general indication for the use of the product.

So, even if valid, they don't bind our Company that can not check the conditions of their use.