

**PRODUCT**

Pharmaceutical Cold-Form (Alu-Alu), unprinted

**MATERIAL COMPOSITION**

OPA 25µm / Aluminium 45µm soft tempered / PVC 60µm

Stratigraphy composition	Code	Thickness (µm)		Weight (g/m <sup>2</sup> )		Chemical composition
		Value	Tol.	Value	Tol.	
Oriented Polyamide Film		25,0	± 2,5	28,8	± 2,9	
Adhesive	CT414	-	-	4,0	± 0,3	Polyester polyurethane
Primer	CT409	-	-	2,0	± 0,2	Polyester
Aluminium soft tempered		45,0	± 3,6	121,5	± 9,7	DIN EN 573-3 EN AW 8021B
Adhesive	CT305	-	-	4,0	± 0,5	Polyester polyurethane
PVC Rigid Film		60,0	± 6,0	79,2	± 8,0	
<b>Overall</b>		<b>140,0 (*)</b>	<b>± 13,1 (*)</b>	<b>239,5</b>	<b>± 21,6</b>	

(\*) Obtained from grammage

**MATERIAL PROPERTIES**

Residual solvent (IO 13)	<= 10 mg/m <sup>2</sup>
FT-IR Spectra PVC compare (IO 34)	>= 98,5 %
Burst Pressure (IO 38)	>= 350 kPa
Convex height (IO 38)	>= 27 mm
Water vapor permeability (DIN ISO 15106-3)	<= 0,01 g/m <sup>2</sup> (24h - 38°C / 90% r.h. and 25°C / 100% r.h.)
Oxygen permeability (DIN 53 380-3)	<= 0,005 cc/m <sup>2</sup> (24h - 23°C / 50% r.h. and 25°C / 50% r.h.)
Aluminium finesses	>= 98 %
Stability test (7 days 40°C 75% RH) (IO 58)	In conformity
Control of the adhesion between ALU/OPA (IO 03)	>= 3,5 N/15mm
Control of the adhesion between ALU/PVC (IO 03)	>= 5 N/15mm
Ultimate tensile strength (IO 12)	>= 140 N/15mm
Elongaton to break (IO 12)	>= 45 %

**CLEARANCE CERTIFICATE**

<b>Bisphenol-A statement</b>	<p>The product is "BPA-free".</p> <p>Conformity of the product to the current norms is guaranteed by Aluberg according to the certifications issued by the suppliers of raw materials.</p> <p>The company assures not using Bisphenol-A or its derivatives during the production process.</p> <p>Any impurities of this substance, in the extend of ppm, could be present because deriving from the production process of the raw materials or as a random pollutant.</p>
<b>Product</b>	<p>This laminate is registered to the Food and Drug Administration with the DMF number 17383.</p> <p>We hereby certify that all raw materials used for this laminate are health harmless according to the existing scientific knowledge and according to our supplier's declarations.</p> <p>This laminate is manufactured in constant quality, with strict processing methods, based on the principle of Good Manufacturing Practices (GMP).</p> <p>Drug Master File of Food and Drug Administration is applicable to:</p> <ol style="list-style-type: none"> <li>Oriented Polyamide Film</li> </ol> <p>As stated by suppliers, it corresponds to the following recommendations and directives:</p> <ul style="list-style-type: none"> <li>-FDA 21 CFR paragraph 177.1500</li> <li>-CE Regulation n. 10/2011</li> <li>-94/62 EC, art. 11 - CONEG on heavy metals Pb, Hg, Cd, Cr(IV) &lt; 100 ppm</li> </ul> <ol style="list-style-type: none"> <li>Adhesive (internal and external side of the aluminium foil)</li> </ol> <p>As stated by suppliers, it corresponds to the following recommendations and directives:</p> <ul style="list-style-type: none"> <li>-FDA 21 CFR paragraph 175.105 - Adhesive</li> <li>-94/62 EC, art. 11 - CONEG on heavy metals Pb, Hg, Cd, Cr(IV) &lt; 100 ppm</li> </ul> <ol style="list-style-type: none"> <li>PVC Film</li> </ol> <p>As stated by suppliers, their formulations are filed on DMF number at U.S. F.D.A. and comply to the limit of 10 ppb for monomeric vinyl chloride. The following directives apply too:</p> <ul style="list-style-type: none"> <li>- CE Regulation n. 10/2011</li> <li>- European Pharmacopoeia chapter 3.1.11 and 3.2.2</li> <li>- US American Pharmacopoeia "USP 661.1" in its actual version</li> <li>-94/62 EC, art. 11 - CONEG on heavy metals Pb, Hg, Cd, Cr(IV) &lt; 100 ppm</li> </ul>
<b>Nitrosamines statement</b>	<p>The product is Nitrosamines-free.</p> <p>The product doesn't include within its composition nor Nitrosamines as such neither possible precursors of the same. The absence 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.</p> <p>Anyhow Aluberg doesn't check each batch produced for Nitrosamines presence, and a.m. analysis are conducted on scheduled base.</p>

**WARRANTY, STORAGE AND SHELF-LIFE**

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

<b>Condition of storage</b>	<p>Store in dry and clean area.</p> <p>Recommended storage conditions:</p> <ul style="list-style-type: none"> <li>- no direct sunlight</li> <li>- room temperature between 5°C - 30°C</li> <li>- maximum relative humidity 70%</li> </ul> <p>The laminate should be stored for 24 hours at room temperature before use.</p>
<b>Workability</b>	<p>Maximum 2 years from delivery date for formability and sealing.</p>
<b>Function</b>	<p>Maximum 5 years after processing on the packaging line.</p>

**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.