

MATERIAL SPECIFICATION & REGULATORY DATA SHEET

Customer: **WOOSON CHEM CO. LTD., Republic of Korea**

Manufacturer: **Constantia Patz Ges.m.b.H.**

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A-2620 Loipersbach

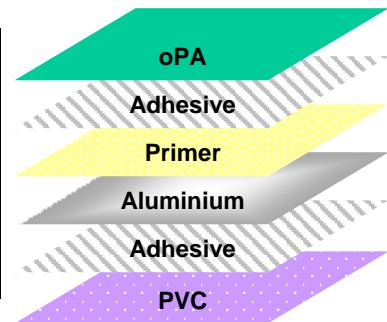
Material: **PATZ 497/25-45-60 coldform - unprinted**
Cold-formable aluminium bottom foil for "Alu-Alu" Blister

1. APPLICATION:

Packaging material for solid pharmaceutical products

2. MATERIAL (FROM OUTSIDE TO INSIDE):

LAYER	BASE	THICKNESS / GRAMMAGE
oPA	Polyamide	25 µm = 28.8 g/m ² ± 10%
Adhesive	Polyurethane	2.7 - 4.3 g/m ² = 2σ
Primer	Epoxy resin	1.0 - 1.4 g/m ² = 2σ
Aluminium soft dull / bright	Alloy 8079 CP	47 µm = 126.9 g/m ² ± 8%
Adhesive	Polyurethane	3.2 - 4.8 g/m ² = 2σ
PVC	Polyvinyl chloride	60 µm = 78.6 g/m ² ± 10%
Total weight:		243.0 g/m² (4.1 m²/kg) ± 10%



3. DRUG MASTER FILE:

The material is listed in the US drug master file **4889**.

4. WARRANTY AND STORAGE:

The warranty for

- Sealing & Forming: max. 18 months from delivery date
- Function: max. 5 years after processing on the packaging line

only maintains if the recommended storage conditions are observed:

- No direct sunlight
- Storage climate: 15 to 35 °C, relative humidity 30 - 70%

5. QUALITY GUIDELINES:

Constantia Patz Ges.m.b.H. works in accordance with quality and hygiene requirements and is certified for ISO 9001, ISO 14001, ISO 15378, BRC.

6. CONFORMITY BY LAW :

This certificate confirms that the afore mentioned packaging material was produced in accordance with the legal regulations under state of the art conditions of production following the good manufacturing practice requirements for materials and articles intended to come into contact with food (EU regulation 2023/2006).

The material conforms to the legal requirements of regulation 1935/2004/EC for "materials in contact with food".

The following guidelines, directives, regulations & standards (including effective amendments) are also adhered to:

- EU 10/2011 "Plastic materials in contact with foodstuffs"
- 94/62/EC "Heavy metal content"
- 1895/2005/EC "Epoxy derivatives"
- 78/142/EEC "Limit of vinyl chloride monomer in PVC"
- EN 602:2004-07 "Aluminium & aluminium alloys in food contact"

The material fulfils the following national legal regulations and guidelines:

Austria:

- Österreichisches Lebensmittel- und Verbraucherschutzgesetz (LMSVG) BGBl I, 13/2006 as amended

Germany:

- Lebensmittel- Bedarfsgegenstände- und Futtermittelgesetzbuch (LFGB) §§ 30, 31 and 32
- Bedarfsgegenständeverordnung
- Recommendation of the Bundesinstitut für Risikobewertung (BfR): PVC II, adhesive XXVIII

USA:

- US FDA 21 CFR §§ 175.105 (adhesive), 177.1500 (oPA)
- The residual content of vinyl chloride monomer (VCM) is according to the recommendations of the FDA less than 10 ppb.

The laminated PVC-layer is tin stabilized and in accordance with the European Pharmacopoeia chapter 3.1.11 and the USP 661 "Physicochemical tests – Plastics" in the current issue.

The product complies with the "Note for Guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" (EMA/410/01 Rev. 3).

In most circumstances the most environmentally efficient recovery route for the packaging foil (according to 94/62/EC) is incineration with energy recovery (EN 13431:2004).

Disclaimer:

This information is correct to the best of our knowledge. However, Constantia Patz makes no warranties, express or implied, and assumes no liability in connection with any use of this knowledge.

This certificate pertains only to the composition of the above mentioned material build-up. The packer is responsible for ensuring that the finished package complies with applicable migration limits under actual conditions of use. Possible interactions of the film and its components with the packaged products are to be checked prior to final use.

Checked and approved on mailing date.

Constantia Patz Ges.m.b.H.

Regulatory Affairs: i.A. Stefan Stix

Application Engineer: i.A. technician in charge

This document has been created electronically and is valid without signature.