

# Technical Data Sheet

SVAM Packaging Industries Pvt. Ltd.

Product number: ALB 002

## 1. Product

### **Alublis®45**

laminate for cold forming for blister pack bottom foil

## 2. Material Composition (from outer side to inner side)

Components	No.	Chemical Base	Thickness (μ)	limit	Weight (g/m <sup>2</sup> )	limit
BOPA film		polyamide	25.0	± 1.25	28.8	± 1.25
Adhesive		polyurethane	-	-	4.0	± 0.5
Al foil soft (dull side ↑)		EN AW-8021 B DIN EN 573-3	45.0	± 3.6	121.95	± 9.8
Adhesive		polyurethane	-	-	4.0	± 0.5
PVC film (hard)		Content of free VCl ≤ 10 ppb	60.0	± 3.0	82.8	± 4.14
<b>Total</b>			<b>139.0</b>	<b>± 6.95</b>	<b>241.6</b>	<b>± 12.1</b>

## 3. Material Properties

- Sealing strength > 7 N/15 mm versus TOP FOIL LID at 170 degree C; dwell time 0.5 second; angle of opening 180 degree
- WVTR: ≤ 0.01 g/m<sup>2</sup> x day (less than detection limit) at 38 degree C, 90 % RH
- OTR: ≤ 0.005 cm<sup>3</sup> / m<sup>2</sup> x day (less than detection limit) at 23 degree C, 50 % RH

## 4. Clearance Certificate for Foodstuff

If stored and used properly the above mentioned material complies with the regulation for food contact.

### 4.1. Outer Side

Adhesive: USFDA 21 CFR § 175.105

### 4.2. Aluminum

Al foil: USFDA 21 CFR § 178.3910

### 4.3. Inner Side

PVC film: European Pharmacopeia edition 6 (2008); EC directive 2002/72/EC and amendments



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#### 4.4. Other Information

- residual solvents: ICH topic Q3C, solvent class 3
- other components: free of phthalates, latex and gluten
- BSE/TSE: With this statement we confirm that the lubricants in the PVC film could contain animal fats. These fats are produced as requested by the 24<sup>th</sup> EC Directive 2000/6 appendix II, February 29, 2000.  
It is applicable for manufacturer of non-food products, cosmetics or packaging material. Moreover the film is in accordance with EMEA 410/01, revision 2004/C24/03 "Note for guidance on minimizing the risk of TSE".
- laminate:
  - GMP regulation EC 2023/2006
  - CONEG and EC directive 94/62/EC Art. 11 →  
level of heavy metals like Pb, Cd, Hg and hexavalent Cr is less than 100 ppm
  - Framework regulation EC 1935/2004

Product is listed at DMF of M/s Svam number 22097

#### 5. Recommended Storage Conditions

Please see DS 0001

#### 6. Liability Exclusion

The competent producer or packer (or an assigned authority) has to judge the specific suitability of the above mentioned material for the intended use.