

TECHNICAL DATA SHEET

ALUPHARM OLV 50

ALUPHARM OLV is made from Alu foil laminated with OPA film, then laminated with PVC film on Alu foil side. It possesses excellent barrier against moisture, gas and aroma. It also has excellent cold form property without heating, well be suitable to pack tablets, capsules or other solid dosages as cold form blister (CFF), which is extrremely sensitive to moisture.

Product

Type	OPA/ALU/PVC 25/50/60 OLV 50
Color	Silver S1
Surface	Bright/Dull
Form	Roll

Specification

Sr.	Item	Unit	Specification	
1	Appearance	NA	No odor, convex, wrinkle, oil, foreign matter, bubbles, adhesion, perforation and other defects	
2	ID	IR	NA	
3	Thickness	µm	specified ± 7%	
4	Width	mm	width ± 1mm	
5	WVTR	g/m ² .24h	≤ 0.5	
6	OTR	cm ³ /m ² .24h.	≤ 0.5	
7	Heat seal strength	N/15mm	≥ 6	
8	Peel off strenght	N/15mm	≥ 8 for OPA/ALU ≥ 7 for ALU/PVC	
9	VCM	PPM	≤ 1	
10	Residual of Solvent	mg/m ²	≤ 5, Benzene or Benzenes shall not be detected	
11	Residual of Oxide	ml	≤ 1.5	
12	Non volatile matters	water	mg/100ml	≤ 30
		65% ethanol	mg/100ml	≤ 30
		n-hexane	mg/100ml	≤ 30
13	Heavy mental	PPM	≤ 1	
14	Limited Microbe	Microbe	cfu/100cm ²	≤ 1000
		Mildew	cfu/100cm ²	≤ 100
		Coliform	NA	Non detected
15	Toxic	NA	Non toxic	

Regulatory

- Commission Regulation (EC) No. 2023/2006 - on good manufacturing practice for materials and articles intended to come into contact with food
 - Commission Regulation (EU) No. 1935/2004 - Materials and articles intended to come into contact with food
 - Commission Regulation (EU) No. 10/2011- Plastic materials and articles intended to come into contact with food
 - Commission Directive 94/62/EC- Packaging and packaging waste (providing limits for the heavy metal content)
 - Council Directive 78/142/EEC – Materials & articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs
 - EN 602:2004 - "Aluminium and aluminium alloys - Wrought products – Chemical composition of semi-finished product used for the fabrication of articles for use in contact with foodstuffs".
- In addition to above, products also complies with-
- USP Chapter Biological Reactivity Tests, In vivo – For non toxicity
 - 21 CFR Part 170 to 190 – Indirect food additives
 - China CDE/NMPA registration as well as YBB 00242002-2015

The PVC layer complies with the requirements of European Pharmacopoeia Monograph No. 3.1.11 for Materials based on non-plasticized polyvinylchloride for containers for dry dosage forms for oral administration.

This product as well as the ingredients used in this product is not derived from specified risk materials as defined in European Commission Decision EMEA / 410 / 01. Therefore this product is free from BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy)

Storage condition

- Material has to keep in original pack condition;
- Storage condition: 15-35 °C; 30-70% RH;
- Re test period: 18 months

Declaration

All the above data and information represent the current state of our knowledge. It is given in good faith but without any guarantee. It is responsibility of the user to ensure that the product complies with his requirement and with any legislation related to its use.