

TECHNICAL FILE

ALBAN IPEK

Surgical Zincoxide Silk Tape

DESCRIPTION OF THE PRODUCT

Alban pek is a surgical adhesive tape made from white, acetate fabric. The carrier is very light and can be carried clean, comfortably on the skin. Zincoxide adhesive provides strong fixation and is water, sweat, humidty-resistant. Permeable to air and water vapour. It can be removed painlessley and without leavig residues. Is easily tearible length and widthwise. Radiotransparent.

Main Uses

The fixation and securing of dressings, catheters, tubes, etc.

ALBAN PEK is for patients with sensitive skin.

PHYSICAL CHARACTERISTICS OF RAW MATERIALS

Carrier : Acetate rayon fabric

Adhesive : Zincoxide based adhesive

Laboratory tests found it skin-friendly and non-sensitising.

QUALITY SYSTEM

A ao lu has been manufacturing its products with the quality systems as given below;

DLIQ: EN-ISO 9001:2000

SZUTEST: EN-ISO 13485:2003

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MANUFACTURING OF THE PRODUCT

Alban pek is manufactured under following conditions;

Temperature : $15 - 25^{\circ}$ C

Relative Humidity : % 30 - % 70

These conditions are regularly verified by suitable instruments (thermo-hygrometer). If the storage and transport conditions are followed, it can be used till the exp. date.

PHYSICAL CHARACTERISTICS OF THE PRODUCT

Test Method	<u>Unit</u>	Standart	Method
Weight of Adhesive	g/m^2	min. 85	TS 3957
Weight of Carrier	g/m^2	min. 90	TS 3957
Adhesive Strength	gf/cm	min. 200	TS 3957
Amount of ZnO	%	min. 10	TS 3957
Tensile Strength	kgf/cm	min. 5	TS 3957
Stability of Adhesive		Should not stick to the outer surface	TS 3957
Straight Tearing		Must be straight	TS 3957

PACKING DETAILS

Code	<u>Size</u>	Quantity per Box	Qauntity per Carton
12501	5m x 1,25cm	1	200
12502	5m x 2,5cm	1	120
12505	5m x 5cm	1	100
12510	5m x 10cm	1	100

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IDENTIFICATION OF RISKS

Injurious effects on health : Not determinable

Injurious effects on the environment : Does not represent risks for the

environment provided that the national laws

for the refuses are respected.

Ways of fire extinguishing : Foam, powder, CO₂.Next to fire suitable

ways of fire extinguishing have to be

used.

INSTRUCTIONS FOR USE

Should be applied to clean and dry skin.

Pull plaster as long as needed and cut (plaster should be at least 2,5 cm longer than the wound dressing).

In order to avoid any skin trauma. It must be applied onto the skin without stretching.

To ensure well adhesion on the edges. It must be slightly rubbed over the center towards the edges.

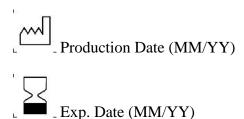
It must be removed in the direction of hair roots, parallel to the skin, by grasping the product in one end and tightening the skin with your other hand.

SHELFLIFE: 5 Years

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LABELLING







CE Shows the conformity to the european standarts for the self declerated Class I products.

STORAGE CONDITIONS

Store in a cool and dry place far from heat sources at a temperature exceeding 35°C / 91°F. Do not damage the packaging in order to ensure its hygenic security.

SAFETY INFORMATION

- Do not use if the package is damaged.
- Do not use the product after expiration date.
- The product does not cause allergies.

Deniz ACAR

R&D and Quality Control Representative

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