

TECHNICAL FILE

ALBAN IPEK

Surgical Zincoxide Silk Tape

DESCRIPTION OF THE PRODUCT

Alban ipek 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, humidity-resistant. Permeable to air and water vapour. It can be removed painlessly and without leaving residues. Is easily tearable 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

MANUFACTURING OF THE PRODUCT

Alban ipek is manufactured under following conditions ;

Temperature : 15 – 25°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

<u>Test Method</u>	<u>Unit</u>	<u>Standart</u>	<u>Method</u>
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

<u>Code</u>	<u>Size</u>	<u>Quantity per Box</u>	<u>Qauntity per Carton</u>
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

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.

SHELF LIFE: 5 Years

LABELLING



Production Date (MM/YY)



Exp. Date (MM/YY)



Lot Number



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

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