

MSDS for Adhesive Plaster

1. Product description

1.1 The aseptic wound adhesive plaster/tape and aseptic adhesive plaster of the Company are produced with fabric or nonwoven fabric, PE, or PVC punched film as the base material, painted with adhesive cement mainly of natural rubber and zinc oxide, or the low allergic, nontoxic and nonirritating adhesive to form the back lining, then cut into certain width of patches, and combined with water absorbing material and protective film. The products are packed in sealed single sheet, and EO sterilized.

2.2 The product, when used on human body, shall not cause adverse effect on skin or mucous membrane, allergic reaction or other damage, nor separate out hazardous substances during use.

3. Contemplated application

It is mainly used for liquid absorption, homeostasis and control of the microorganism environment of the wound.

4. Contraindication

4.1 Ethylene oxide sterilization is adopted for the product, so it must be used within the shelf life. Do not use the product with the small package damaged.

5. Purpose of product risk analysis

The adhesive plasters are mainly used for applying on the surface wound fixing the recognized matured products, with simple formula and structure. In several years of our production and sales, there are no adverse effects and customer's complaint on hazard, yet there may existing some inevitable risks during production that may impact the clinic usage. To identify the suitability of the anticipated usage of the adhesive plaster, we conduct the validation again on its safety, including acceptability of the risks, so as to reduce the risks to the users to an acceptable level.

6. Reference of risk analysis

The risk analysis is conducted based on ISO14971 Medical devices - Application of risk management to medical devices >.

7. Analyze Report reference STP-CE002/B-01 《Adhesive Plaster Risk Analyze Report》.

Conclusion

According to the anticipated usage and the analysis on the risks, occurrence rate of the risks of the product is extremely low, and all the possible hazards can be prevented with some preventive measures, therefore, the risk in application of Aseptic Wound Adhesive Plaster is within the acceptable level. Beneficial greater than Risk.

8. Product profile:

Adhesive plaster :the fabric or non-woven fabrics, PE and PVC perforating film as the backing material, and applies adhesive cement such as native rubber and zinc oxide or the adhesive, which features low allergy, innocently and non-irritation, as the back lining, and then combines with the absorbent pad, PE protective layer or release paper to form the wound plaster. Product was sealed by Cold seal paper, Sterilize by EO, The term of validity is two years.

9 Main materials:

Rubber、 Zinc oxide、 Lanolin、 Yellow Vaseline、 Acrylic Adhesive、 Absorbent pad 、 PE film、 Non-woven fabrics、 Power fabric、 Printing & dying fabric、 silk fabrics.

Rubber cement

rubber molding → rubber coating → rubber rolling → parting cut → composite impact-cut → packing → outer packing → analysis → test → warehousing

10. Environmental requirement

From parting cut to composite impact-cut inward packing, the plant environment shall follow the 100,000-grade purification standard. The details thereof are listed as below:

Brilliancy	Max. dust particles quantity /m ³		Max. microorganism quantity	
	≥0.5μm	≥5μm	airborne microbe / m ³	settling microbe/ shallow container
100,000 grade	3,500,000	20,000	500	10
Temperature	18 □ ~ 26 □			
RH	45 % ~ 65 %			

Related examination and experimental introduction

1. Zinc Oxide Adhesive Plaster

Item Tested		Technical Requirement	Based on standard serial number
Physics Function	Appearance	Smooth, clean, soft, non-color spots, non-cement permeating; backing material color shall be evenly distributed. The size shall meet the requirement as specified.	YY0148-93
	Peel strength:	$\geq 1.0\text{N/cm}$	
	Adhesiveness	$\leq 2.5\text{mm}$	
	Glue content:	$\geq 115\text{g/m}^2$	
	residue level	After 30 minutes under 37°C the condition should not residual material	
Chemical Function	Zinc Oxide content	$\geq 10.0\%$	
Biological Function	Cytotoxicity test	cutaneous reaction shall be no more than level 1.	ENISO10993-5
	Allergic test	cutaneous reaction shall be no more than level 1	ENISO10993-10
	Skin stimulus test	dermoanergy, PII shall be 0 ~ 0.4	ENISO10993-10

2 Medical Ventilation Adhesive Plaster

Item Tested		Technical Requirement	Based on standard serial number
Physi cs Func tion	Appearance	Smooth, clean, soft, non-color spots, non-cement permeating; backing material color shall be evenly distributed. The size shall meet the requirement as specified.	YY0148-2006
	Peel strength:	$\geq 1.0\text{N/cm}$	
	Adhesiveness	$\leq 2.5\text{mm}$	
	Glue content:	$\geq 20\text{g} / \text{m}^2$	
	Steam transmissibility	$\geq 500\text{g} / \text{m}^2 \cdot 24\text{h}$	
Biolo gical Func tion	Cytotoxicity test	cutaneous reaction shall be no more than level 1.	ISO10993-5
	Allergic test	cutaneous reaction shall be no more than level 1	ISO10993-10
	Skin stimulus test	dermoanergy, PII shall be 0 ~ 0.4	ISO10993-10