

Material Safety Datasheet

CURETAPE (Kinesiology tape)

(Class I Medical Device)

1. Product Specification

Section 1: Product

- **Product Name:** Kinesiology tape
- **Description:** elastic adhesive tapes used for taping muscles, joints and ligaments in physiotherapy, sport traumatology, pain therapy and other treatments where no complete immobilization of the taped area is aimed for.

The special cotton structure leads to high stretching properties. The Kinesiology Tape with its breathable acrylate adhesive is latex-free, can be worn at any time and is very comfortable to wear. It is a breathable, air-permeable and waterproof tape for sport, therapy and leisure applied on intact skin.

- **Material Composition:** 95% Cotton + 5% Spandex (Elastane) + Acrylic adhesive
- **Intended use:** to support muscles, joints and soft tissues without restricting movement.
- **Colour Options:** Multiple colours (see product guide attached)
- **Basic UDI:** 871762416elastic-tapeWX
- **Dimensions:** Main size 5 cm x 5 m, but several sizes available (see product guide attached)
- **Sterilization Method:** Not sterilized (non-invasive device, intended for external use)
- **Storage Conditions:** Store in a cool, dry place at a temperature between 5°C and 35°C, with relative humidity less than 60%. Basically room temperature.
- **Transport Conditions:** Avoid exposure to direct sunlight and extreme temperatures during transport.
- **Expiry Date:** 3 years from the manufacturing date when stored under proper conditions.

Material Characteristics Kinesiology Tape (5m x 5cm)

Product component:	Material composition
Elastic tape material:	95% Cotton and 5% Spandex (Elastane)
Adhesive coating:	pressure sensitive acrylic adhesive, breathable
Release paper:	coated paper



Section 2: Ingredients and characteristics

Product Characteristics Kinesiology Tape (5m x 5cm)

Property	Characteristics
Construction and dimensions:	5m x 5cm (LxW) per spool;
Elongation:	180±30 %
Adhesive coating:	transparent
Coat weight:	45-55 g/m ²
Peel adhesion	3-12 N/25mm
Storage/Transport conditions:	no storage permanently above 30°C
Shelf life:	3 years

(Technical modification subject to change)

<u>Ingredient(s)</u>	<u>CAS No.</u>
1. Support Material Cotton, Polyurethane	Non Hazardous Material
2. Adhesive Acrylic Co Polymer	Non Hazardous Material
3. Release Paper High Quality Substrate	Non Hazardous Material

Hazardous Ingredient(s)

1. Paints, preservations, and solvents:	None
2. Alloys and metallic coatings:	None
3. Hazardous mixtures of other liquids, or gases	None

Section 3: Physical Data

Boiling Point (degrees F)	N/A
Vapor Pressure	N/A
Vapor Density (air=1)	N/A
Solubility in Water	Insoluble in water
Specific gravity	N/A
% volatile by volume	NONE
Evaporation rate	N/A
Odor Threshold	N/A
Appearance	See brochure for colours

Section 4: Fire and Explosion Hazard Data

Flash point:	N/A
Flammable limits:	N/A
Extinguishing media:	Class B, C
Special fire fighting procedures:	N/A
Unusual fire and explosion hazard:	N/A



Section 5: Health Hazard Data

Threshold value:	N/A
Effects of overexposure:	None
Emergency and first aid procedures:	None

Section 6: Reactivity Data

Stability:	Stable
Conditions to avoid:	N/A
Incompatibility:	N/A
Hazardous decomposition products:	None
Hazardous polymerization:	Will not occur

Section 7: Spill or Leak Procedures

Steps to be taken in case material is released or spilled:	N/A
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Section 8: Special Protection Information

Respiratory protection:	None
Ventilation:	Adequate
Protective gloves:	No
Eye Protection:	Do not get into eyes
Other protection equipment:	None needed

2. Certificates

- **CE Certificate:** Class I non-sterile medical device, find attached
- **ISO 13485-2016 Certification:** IGC (MSCB-105) No. 21-B-0411 Rev.0
- **Other Certificates:** ISO 14001-2015 and ISO 9001-2015

3. Declaration of Conformity

- **Manufacturer:** ECOWORKS KOREA THYSOL HITECH CO.,LTD, 17-40, Hwaseong-ro 1424beon-gil, Manyang-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea.
SRN-number: KR-MF-000008975
- **GMDN Code:** 58884 (Kinesiology tape)
- **Risk Class:** Class I (non-sterile, non-measuring)
- **Conformity Standard:** Compliant with EU Medical Device Regulation (MDR) 2017/745.

4. Label Template

- **Importer:** same as CE REP, see below
- **Authorized Representative:** FysioTape BV, Josink Kolkweg 18, 7545 PR, Enschede, The Netherlands.
- SRN-number: NL-AR-000002061

5. Instructions for Use (see also insert)

- **Application:** Clean the skin before application. Apply directly to the skin to support joints or muscles.
- **Restrictions:** Do not apply on open wounds or irritated skin. Do not use if allergic to adhesive materials.

- **Flammability:** Product is non-flammable under normal conditions but should be kept away from open flames.
- **Cleaning/Washing Instructions:** The tape is for single-use and should not be washed or reused.

Warnings/Precautions (see also insert)

- Pregnant women should visit a doctor for advice before taping.
- Do not expose the tape to direct sunlight or high temperatures.
- Keep the product out of reach of children.
- Should applying the tape cause prolonged skin irritation in the form of itching, redness or rash for over 30 minutes, the tape should be removed immediately in accordance with the instructions. Contact a doctor if necessary.
- Do not tape over fresh injuries or thromboses; and do not apply in cases of skin allergies or skin irregularities.
- Do not use the tape in connection or reciprocally with other treatment methods (massage therapies, electrical stimulation treatment).
- Before applying, the skin must be clean and free of grease.
- If you are not sure how to apply the tape correctly, you can contact a therapist for an initial professional therapeutic treatment.
- It is advisable not to wear the tape for longer than 7-10 days, and then to remove it in order to protect the skin. Application can be repeated after 3-5 days for several times. Any remaining adhesive residue must be removed.
- In the event of acute injuries or complex symptoms you should consult a doctor or physiotherapist regarding taping.
- Careful use in patients with a history of allergy of glue and sensitivity to adhesive allergy. If in doubt, ask your doctor.

6. Storage and Transport Conditions

- **Storage Temperature:** Between 10°C and 35°C (room temperature), keep in cool/dry place. Keep out of reach of children.
- **Humidity Range:** Less than 60% relative humidity
- **Transport:** Protect from direct sunlight and avoid exposure to extreme temperatures during transit.



7. Various

Single Use Device

The tape is for single use only.

Product Disposal

To minimize the risk of potential infection hazards, or environmental pollution, disposable components of the product should follow disposal procedures according to applicable and local laws, rules, regulations and infection prevention standards.

Packaging Materials

All packing materials and packing components are conform to the relevant essential requirements (specific to manufacturing and composition, reusable nature and recoverable nature of packing) of the Packaging and Packaging Waste Directive 94/62/EC and amended directive 2004/12/EC respectively.

Incident Reporting

For a patient/user/third party in the European Union and in countries with identical regulatory regime (Regulation 2017/745/EU on Medical Devices); if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to the manufacturer and/or its authorised representative and to your national authority.

Additional Information:

- Documents along with the TDS; CE documentation, insert(s), packaging files, product brochures.

Prepared by: : FysioTape BV, Josink Kolkweg 18, 7545 PR, Enschede, The Netherlands.

Latest Date of Revision: 05-09-2024