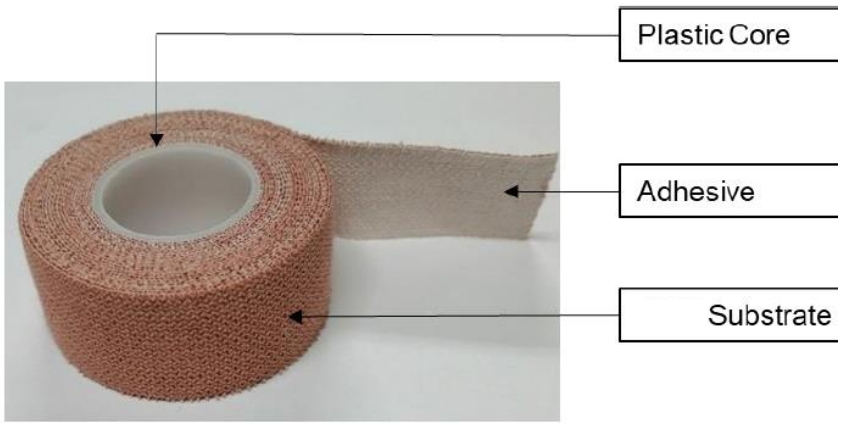
Product Data Sheet

1.0 Name of the product	Tensoplast® EAP
2.0 Product description	
2.1 Description	Tensoplast ® Elastic Adhesive Plasters consist of a flesh coloured plain woven 55% cotton and 45% viscose fabric, extensible in warp direction and spread evenly with adhesive.
2.2 Intended purpose	• Soft tissue injuries (e.g. strains, sprains) • Injury prevention (e.g. stabilization of joints) • Late-phase stabilization in fracture management (e.g. after cast removal) • Posture improvement • Elasto-compressive treatment in phlebology
2.3 Instructions for use	No IFU is required for this kind of product due to the low risk to user. All necessary information for safe use is available on labelling
2.4 Warnings and precautions for use	Product contains natural rubber latex and colophony
2.5 Contraindications	Do not use Tensoplast EAP on patients with known intolerance to latex or colophony
2.6 Transport Precautions	Not applicable
2.7 Duration of application Period of use	The device is non-sterile and for single application only. Intended duration of usage for not more than 30 days.
2.8 Information on reusable/ washable products	Not applicable

2.9 Composition



Designation (incl. no. in drawing)	Description	% of final product
Plastic Core	Polypropylene core	9
Adhesive	A smooth, off white, opaque, viscous homogenous mass. Rubber-based adhesive.	24
Substrate	Plain woven 55% cotton and 45% viscose fabric, extensible in the warp direction.	67

2.10 Product range

Product Code	Rolls per Folding Box	Folding Boxes per Tray/ Shrink Unit	Trays/Shrink Units per Shipper Case	Folding Boxes per Shipper Case	Rolls per Shipper Case
72050-58	12	N/A	N/A	12	144
72067-00	1	12	16	192	192

2.11 Sizing Chart

Width of Roll :25mm
Length of Roll: 4.5m fully stretched length

2.12 Storage conditions

Store in a cool, dry place, avoid direct sunlight.

2.13 Shelf life/ Storage time

36 Months (3 years)

2.14 Sterilization

Non-sterile

2.15 Key quality parameters

Characteristic	Method	Target
Adhesion to steel (final product)	Essity internal	> 150 mN/mm

3.0 Chemical substances of special concern to Essity

Essity has defined chemical substances that are of special concern and are subject to specific restrictions. A reference to the list of substances can be found in Annex A2 via the following link www.essity.com/gss

Deviations are covered in 3.1 Components.

3.1 Components

Raw materials used in product formulation

Substance	Included in formulation
Natural rubber latex	Yes
Lanolin and its derivatives	Yes
Colophony	Yes
Colophony derivatives	no
Bisphenol A (BPA)	No
Polyvinylchloride (PVC)	No
Methylmethacrylate	No
Butylacrylate	No
Microplastics (<5 mm)	No
Nanoparticles	No
Fragrance/parfum	No
Antibiotics	No
Triclosan	No
Chlorhexidine	No
Polyhexanide	No

Raw materials used in the packaging

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	Yes
Recycled material	No

Raw materials used in the product formulation and in the packaging may contain small amounts of the substances listed above and not marked as included in formulation as well as amounts of other substances not listed above. As trace level analysis is not performed for each batch BSN medical (Pty)Ltd. RSA cannot provide proof of absence.

3.2 Certificates

Not applicable

History

Document	Version / Date	Page / Item	Description of Change
JBM 40049388	01 / 17.05.2021		Set up new document