

Product Data Sheet

1.0 Name of the product	Tensoplast ® EAB 1972
2.0 Product description	
2.1 Description	Tensoplast ® Elastic is a natural unbleached, undyed elastic cotton and rayon bandage, extensible in the warp direction and spread with adhesive. The bandages are porous and have an unspread margin on either side with a continuous yellow thread running lengthwise down the centre. The bandages are either spooled with the adhesive on the inside (normal spool) or with the adhesive on the outside (reverse spool).
2.2 Intended purpose	<ul style="list-style-type: none"> • Soft tissue injuries (e.g. strains, sprains) • Injury prevention (e.g. stabilization of joints) • Late-phase stabilization in fracture mana (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 EAB 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	
			Reverse Spool	Normal Spool
	Core	A high impact polystyrene white lipped core OR a low density polyethylene core.	8	
	Substrate	Fabric is unbleached and undyed and is comprised of 58% cotton and 42% viscose. Yellow thread is positioned and running continuously through the centre of the fabric roll.	67	
Adhesive	A smooth, off white, opaque, viscous homogenous mass. Natural-rubber adhesive:	25	24	
Release Paper	A translucent embossed white polyethylene film.	N/A	1	

2.10 Product range	Product code	Size (width x fully stretched length)	Bandages per Folding Box or Polybag	Folding Boxes per Shrink Unit	Shrink Units per Shipper Case	Folding Boxes or Polybags per Shipper Case	Bandages per Shipper Case
	71545-05	50mm x 2.7m	1	12	6	72	72
	71545-06	75mm x 2.7m	1	12	6	72	72
	71545-07	100mm x 2.7m	1	12	6	72	72
	71545-00	50mm x 4.5m	1	12	6	72	72
	71546-00	75mm x 4.5m	1	12	6	72	72
	71547-00	100mm x 4.5m	1	12	6	72	72
	72050-32	50mm x 4.5m	1	12	6	72	72
	72050-36	75mm x 4.5m	1	12	6	72	72
	72050-29	100mm x 4.5m	1	12	6	72	72
	72050-52	50mm x 4.5m	1	12	6	72	72
	72050-53	75mm x 4.5m	1	12	6	72	72
	72050-49	100mm x 4.5m	1	12	6	72	72
	72050-59	50mm x 4.5m	6	N/A	N/A	10	60
	72050-34	75mm x 4.5m	6	N/A	N/A	8	48
2.11 Storage conditions	Store in a cool, dry place, avoid direct sunlight.						
2.12 Shelf life/ Storage time	48 months (4 years)						
2.13 Sterilization	Non-sterile						
2.14 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																																
	<table border="1"> <thead> <tr> <th>Substance</th> <th>Included in formulation</th> </tr> </thead> <tbody> <tr><td>natural rubber Latex</td><td>Yes</td></tr> <tr><td>Lanolin and its derivatives</td><td>Yes</td></tr> <tr><td>Colophony</td><td>Yes</td></tr> <tr><td>Colophony derivatives</td><td>No</td></tr> <tr><td>Bisphenol A (BPA)</td><td>No</td></tr> <tr><td>Polyvinylchloride (PVC)</td><td>No</td></tr> <tr><td>Methylmethacrylate</td><td>No</td></tr> <tr><td>Butylacrylate</td><td>No</td></tr> <tr><td>Microplastics (<5 mm)</td><td>No</td></tr> <tr><td>Nanoparticles</td><td>No</td></tr> <tr><td>Fragrance/parfum</td><td>No</td></tr> <tr><td>Antibiotics</td><td>No</td></tr> <tr><td>Triclosan</td><td>No</td></tr> <tr><td>Chlorhexidine</td><td>No</td></tr> <tr><td>Polyhexanide</td><td>No</td></tr> </tbody> </table>	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
	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																																	
<table border="1"> <thead> <tr> <th>Substance</th> <th>Included in formulation</th> </tr> </thead> <tbody> <tr><td>Polyvinylchloride (PVC)</td><td>No</td></tr> <tr><td>Natural rubber latex</td><td>Yes</td></tr> <tr><td>Recycled material</td><td>No</td></tr> </tbody> </table>	Substance	Included in formulation	Polyvinylchloride (PVC)	No	Natural rubber latex	Yes	Recycled material	No																									
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	ISO 13485 :2016																																

History

Document	Version / Date	Page / Item	Description of Change
JBM 40049387	01 / 17.05.2021		Set up new document
JBM 40049387	02/ 14.11.2023		Updated document in scope of C2875.