

Product Data Sheet

1.0 Name of the product	Leukoplast®
2.0 Product description	
2.1 Description	Leukoplast® is a medical adhesive tape that consists of a viscose fabric coated directly with a rubber-based caoutchouc adhesive mass containing Dry Natural Rubber (DNR) and perforated by air. The device is available in different sizes.
2.2 Intended purpose	<p>Leukoplast® is intended for short time use on intact skin for fixation of dressings of all types and sizes, for traction bandages or other devices.</p> <p>The device is non-sterile and for single application use. Intended users are health care professionals and patients. Use of the device is not restricted to specific populations.</p> <p>Note: Complete device description with contraindications and warnings and precautions will be available in the product family description (JBX).</p>
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	Tape contains dry natural rubber latex and colophony.
2.5 Contraindications	No contraindications known for this product.
2.6 Transport Precautions	Not applicable
2.7 Duration of application Period of use	One day to several days depending on the skin condition.

2.8 Composition



Designation (incl. no. in drawing)	Description	% of final product
Substrate (1)	Viscose fabric	48
Adhesive (2)	Natural rubber-based adhesive	52
Core (3)	Cardboard core, Antimicrobial spool with snapping, Antimicrobial spool without snapping	n.a.

2.9 Product range

Size	Color of Substrate	Spool	Snap Ring	Cardboard Core	Anti-microbial	Per folding box	Per shrink	Per shipper	Product code								
1.25cm x 5m	Tan	Yes	Yes	No	Yes	24	10	240	01521-00								
1.25cm x 5m Labeled									01521-05								
2.5cm x 5m						12		120	01522-00								
2.5cm x 5m Labeled									01522-05								
5cm x 5m						6		60	01524-00								
5cm x 5m Labeled									01524-03								
1.25cm x 5m						Yes		24	240	01531-00							
2.5cm x 5m						No		12	120	01532-00							
5cm x 5m						Yes		6	60	01534-00							
1.25cm x 9.2m								24	240	01536-00							
2.5cm x 9.2m		12	120	01537-00													
5cm x 9.2m		No	No	No	Yes	No	6	24	60	01539-00							
18cm x 5m							1		24	24	01546-00						
1.25cm x 9.2m							24		No	No	No	No	10	240	01691-00		
2.5cm x 9.2m															12	120	01692-00
9.2m x 5m															6	60	01693-00
9.2m x 10m							4							40	01696-00		
7.5cm x 5m															47535-00		
10cm x 5m							6							60	47536-00		
5cm x 5m															47714-00		
10cm x 5m	47715-00																
7.5cm x 5m	4	40	47725-00														
10cm x 5m			47726-00														
10cm x 10m			1	4	24	47826-00											
1.25cm x 4.6m	Yes	No	No	Yes	No	24	10	240	72668-00								
2.5cm x 4.6m									12	120	72668-01						
5cm x 4.6m						6		60	72668-02								

2.10 Storage conditions	Dry, clean and without exposure to direct sunlight.
2.11 Shelf life/ Storage time	5 years

<p>2.12 Sterilization</p>	<p>Non-sterile</p>																																								
<p>2.13 Key quality parameters</p>	<table border="1"> <thead> <tr> <th data-bbox="520 371 842 421">Characteristic</th> <th data-bbox="842 371 1150 421">Method</th> <th data-bbox="1150 371 1473 421">Target</th> </tr> </thead> <tbody> <tr> <td data-bbox="520 421 842 492">Adhesion to steel (final product)</td> <td data-bbox="842 421 1150 492">Essity internal</td> <td data-bbox="1150 421 1473 492">3.25 N/cm</td> </tr> </tbody> </table>			Characteristic	Method	Target	Adhesion to steel (final product)	Essity internal	3.25 N/cm																																
Characteristic	Method	Target																																							
Adhesion to steel (final product)	Essity internal	3.25 N/cm																																							
<p>3.0 Chemical substances of special concern to Essity</p> <p>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</p> <p>Deviations are covered in 3.1 Components.</p>																																									
<p>3.1 Components</p>	<p>Raw materials used in product formulation</p> <table border="1"> <thead> <tr> <th data-bbox="520 797 995 835">Substance</th> <th data-bbox="995 797 1473 835">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>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> <p>Raw materials used in the packaging</p> <table border="1"> <thead> <tr> <th data-bbox="520 1447 995 1485">Substance</th> <th data-bbox="995 1447 1473 1485">Included in formulation</th> </tr> </thead> <tbody> <tr><td>Polyvinylchloride (PVC)</td><td>No</td></tr> <tr><td>Natural rubber latex</td><td>No</td></tr> <tr><td>Recycled material</td><td>No</td></tr> </tbody> </table> <p>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 S.A.S. cannot provide proof of absence.</p>			Substance	Included in formulation	Natural rubber latex	Yes	Lanolin and its derivatives	Yes	Colophony	Yes	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	Polyvinylchloride (PVC)	No	Natural rubber latex	No	Recycled material	No
Substance	Included in formulation																																								
Natural rubber latex	Yes																																								
Lanolin and its derivatives	Yes																																								
Colophony	Yes																																								
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																																								
Polyvinylchloride (PVC)	No																																								
Natural rubber latex	No																																								
Recycled material	No																																								

History

Version / Date	Page / Item	Description of Change
01/21.05.05	Set up new document	
02/01.08.05	Item 7	General revision
03/05.06.12	All pages Page 5 / item 2.11	General revision. Additional NARTs
04/09.05.2017	All pages	General revision. Updating acc. latest version of PDF. Including data concerning antimicrobial spools
05/22.11.2017	Page 2, item 2.2 Page 3, item 2.10 Page 3 – 4, item 2.11	NARTS added
06/17.07.2019	Page 4-5, item 2.11	revision
07/09.04.2020	All pages pages 2/3-5 / item 2.2 / 2.11	General revision regarding MDR change C2365. Detailing on antimicrobial finish
08/21.05.05	All pages	General revision