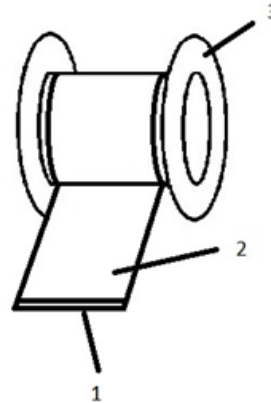


## Product Data Sheet

|  |   |
|--|---|
| <b>1.0 Name of the product</b>                       | Leukopor®   |
| <b>2.0 Product description</b>                       |   |
| <b>2.1 Description</b>                               | Leukopor® is a medical adhesive tape that consists of a micro-porous nonwoven fleece (polyester viscose) coated indirectly with a polyacrylate adhesive mass, then cured with UV light. The device is available in different sizes.   |
| <b>2.2 Intended purpose</b>                          | Leukopor® is intended for short time use on intact skin for fixation of dressings of all types and sizes, securing electrodes or other measuring devices, fixation and securing of probes, tubes and catheters.<br>The device is non-sterile and for single application use.<br>Intended users are health care professionals and patients. Use of the device is not restricted to specific populations. |
| <b>2.3 Instructions for use</b>                      | 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 (folding box).  |
| <b>2.4 Warnings and precautions for use</b>          | No warnings and precautions for this device.  |
| <b>2.5 Contraindications</b>                         | No contraindications are known for this device.   |
| <b>2.6 Transport Precautions</b>                     | not applicable  |
| <b>2.7 Duration of application<br/>Period of use</b> | The medical tape can stay on intact skin for one day to several days depending on the status of the fixated wound dressing and on the skin condition.   |

**2.8 Composition**



| Designation<br>(incl. no. in drawing)                          | Description                 | % of final product |
|--|-----------------------------|--------------------|
| Backing (1)  | Polyester viscose non-woven | 43                 |
| Adhesive (2)   | Polyacrylate                | 57                 |
| Antimicrobial spool with or without antimicrobial snapping (3) | PS & color                  | n.a.               |
| Polycore   | PS                          | n.a.               |

**2.9 Product range**

| Size                  | Color | Per folding box | Per shipper | Product code |
|-----------------------|-------|-----------------|-------------|--------------|
| 1.25 cm x 9.2 m       | White | 24              | 240         | 02453-00     |
| 2.25 cm x 9.2 m       |       | 12              | 120         | 02454-00     |
| 5 cm x 9.2 m          |       | 6               | 60          | 02455-00     |
| 7.5 cm x 9.2 m        |       | 4               | 48          | 02456-00     |
| 1.25 cm x 5 m         |       | 24              | 240         | 02471-00     |
| 1.25 cm x 5 m         |       | 12              | 120         | 02471-04     |
| 1.25 cm x 5 m (Label) |       | 24              | 240         | 02471-05     |
| 2.5 cm x 5 m          |       | 12              | 120         | 02472-00     |
| 2.5 cm x 5 m          |       | 12              | 120         | 02472-03     |
| 2.5 cm x 5 m (Label)  |       | 12              | 120         | 02472-04     |
| 5 cm x 5 m            |       | 6               | 60          | 02474-00     |
| 5 cm x 5 m (Label)    |       | 6               | 60          | 02474-01     |
| 1.25 cm x 5 m         |       | 24              | 240         | 02481-00     |
| 2.5 cm x 5 m          |       | 12              | 120         | 02482-00     |
| 5 cm x 5 m            |       | 6               | 60          | 02484-00     |
| 1.25 cm x 5 m         |       | 20              | 120         | 47451-00     |
| 2.5 cm x 5 m          |       | 10              | 60          | 47452-00     |
| 5 cm x 5 m            |       | 10              | 60          | 47454-00     |
| 10 cm x 10 m          |       | 0               | 21          | 47456-00     |
| 1.25 cm x 9.2 m       |       | 24              | 240         | 76446-00     |
| 1.25 cm x 9.2 m       |       | 24              | 240         | 76446-01     |
| 2.5 cm x 9.2 m        |       | 12              | 120         | 76447-00     |
| 2.5 cm x 9.2 m        |       | 12              | 120         | 76447-01     |
| 2.5 cm x 9.2 m (LPPR) | 12    | 120             | 76447-02    |              |

| <b>2.10 Storage conditions</b>       | cool, dry place, avoid direct sunlight  |  |        |        |                   |                 |           |                  |                 |  |
|--------------------------------------|---|--|--------|--------|-------------------|-----------------|-----------|------------------|-----------------|--|
| <b>2.11 Shelf life/ Storage time</b> | 60 Months (5 years)   |  |        |        |                   |                 |           |                  |                 |  |
| <b>2.12 Key quality parameters</b>   | <table border="1"> <thead> <tr> <th data-bbox="528 488 847 533">Characteristic</th> <th data-bbox="847 488 1161 533">Method</th> <th data-bbox="1161 488 1469 533">Target</th> </tr> </thead> <tbody> <tr> <td data-bbox="528 533 847 566">Adhesion to steel</td> <td data-bbox="847 533 1161 566">Essity internal</td> <td data-bbox="1161 533 1469 566">1.90 N/cm</td> </tr> <tr> <td data-bbox="528 566 847 607">Air permeability</td> <td data-bbox="847 566 1161 607">Essity internal</td> <td data-bbox="1161 566 1469 607">&gt; 1 cm<sup>3</sup>/cm<sup>2</sup> s</td> </tr> </tbody> </table> | Characteristic                         | Method | Target | Adhesion to steel | Essity internal | 1.90 N/cm | Air permeability | Essity internal | > 1 cm <sup>3</sup> /cm <sup>2</sup> s |
| Characteristic                       | Method  | Target                                 |        |        |                   |                 |           |                  |                 |  |
| Adhesion to steel                    | Essity internal   | 1.90 N/cm                              |        |        |                   |                 |           |                  |                 |  |
| Air permeability                     | Essity internal   | > 1 cm <sup>3</sup> /cm <sup>2</sup> s |        |        |                   |                 |           |                  |                 |  |

**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](http://www.essity.com/gss)

Deviations are covered in 3.1 Components.

| <b>3.1 Components</b>  | <p>Raw materials used in product formulation</p> <table border="1"> <thead> <tr> <th data-bbox="528 913 1007 947">Substance</th> <th data-bbox="1007 913 1469 947">Included in formulation</th> </tr> </thead> <tbody> <tr><td>Bisphenol A</td><td>No</td></tr> <tr><td>Natural rubber latex</td><td>No</td></tr> <tr><td>Colophonium</td><td>No</td></tr> <tr><td>Phthalates</td><td>No</td></tr> <tr><td>SVHC acc. REACH</td><td>No</td></tr> <tr><td>Prop. 65</td><td>No</td></tr> <tr><td>Heavy metals</td><td>No</td></tr> <tr><td>Organo tin compounds</td><td>No</td></tr> <tr><td>Animal Derived Material</td><td>No</td></tr> <tr><td>Azo dyes</td><td>No</td></tr> </tbody> </table> | Substance               | Included in formulation | Bisphenol A | No                   | Natural rubber latex | No                | Colophonium | No | Phthalates | No | SVHC acc. REACH | No | Prop. 65 | No | Heavy metals | No | Organo tin compounds | No | Animal Derived Material | No | Azo dyes | No |
|--|--|-------------------------|-------------------------|-------------|----------------------|----------------------|-------------------|-------------|----|------------|----|-----------------|----|----------|----|--------------|----|----------------------|----|-------------------------|----|----------|----|
|  | Substance  | Included in formulation |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Bisphenol A  | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Natural rubber latex   | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Colophonium  | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Phthalates   | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| SVHC acc. REACH  | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Prop. 65   | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Heavy metals   | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Organo tin compounds   | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Animal Derived Material  | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Azo dyes   | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| <p>Raw materials used in the packaging</p> <table border="1"> <thead> <tr> <th data-bbox="528 1424 1007 1458">Substance</th> <th data-bbox="1007 1424 1469 1458">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 GmbH cannot provide proof of absence.</p> | Substance  | Included in formulation | Polyvinylchloride (PVC) | No          | Natural rubber latex | No                   | Recycled material | No          |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Substance  | Included in formulation  |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Polyvinylchloride (PVC)  | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Natural rubber latex   | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |
| Recycled material  | No   |                         |                         |             |                      |                      |                   |             |    |            |    |                 |    |          |    |              |    |                      |    |                         |    |          |    |

## History

| Version / Date | Page / Item | Description of Change |
|----------------|-------------|-----------------------|
| 01 / 02.2021   | All         | Set up new document   |