


Product Data Sheet

| 1.0 Name of the product | Gazofix® / Gazofix® color (latexfree) | | | | | | | | | |
|---|--|--|--|----------------|----------------|------------------------------|-------------------|---|-----------------------------|--|
| 2.0 Product description | | | | | | | | | | |
| 2.1 Description | Gazofix® / Gazofix® color (latexfree) is an elastic cohesive bandage made of polyamide and cotton coated with a latex free synthetic polymer. | | | | | | | | | |
| 2.2 Intended purpose | <p>Gazofix® / Gazofix® color (latexfree) is intended for fixation of wound dressings of all types and sizes as well as devices such as splints, tubes and paddings, for short term application of compression and to provide general support.</p> <p>Gazofix® / Gazofix® color (latexfree) is non-sterile, for single use on intact skin only. Intended users are healthcare professionals and patients.</p> <p>Use of the device is not restricted to specific populations.</p> | | | | | | | | | |
| 2.3 Instructions for use | Instructions for use not necessary for class I/Is/IIa products. Product is well-known and self-explanatory. Pictograms and symbols on folding box are guiding to a safe use. | | | | | | | | | |
| 2.4 Warnings and precautions for use | Do not re-use. Upper limit of temperature 30°C. | | | | | | | | | |
| 2.5 Contraindications | There are no known contraindications known for this product. | | | | | | | | | |
| 2.6 Transport Precautions | Not applicable | | | | | | | | | |
| 2.7 Duration of application Period of use | The bandages can be used from one day to several days depending on the treatment needs but cumulative use can be longer than 30 days. For single use on intact skin only. | | | | | | | | | |
| 2.8 Information on reusable/ washable products |  for single application use only. Do not re-use. | | | | | | | | | |
| 2.9 Composition | <table border="1"> <thead> <tr> <th>Material Composition Substrate only</th> <th>Material Composition Substrate & Cohesive Compound</th> </tr> </thead> <tbody> <tr> <td>ca. 40% cotton</td> <td>ca. 29% cotton</td> </tr> <tr> <td>ca. 60% polyamide (textured)</td> <td>ca. 44% polyamide</td> </tr> <tr> <td>-</td> <td>ca. 27% latex free compound</td> </tr> </tbody> </table> | Material Composition Substrate only | Material Composition Substrate & Cohesive Compound | ca. 40% cotton | ca. 29% cotton | ca. 60% polyamide (textured) | ca. 44% polyamide | - | ca. 27% latex free compound | |
| Material Composition Substrate only | Material Composition Substrate & Cohesive Compound | | | | | | | | | |
| ca. 40% cotton | ca. 29% cotton | | | | | | | | | |
| ca. 60% polyamide (textured) | ca. 44% polyamide | | | | | | | | | |
| - | ca. 27% latex free compound | | | | | | | | | |

| | Size | Color | Per folding box | Per shrink | Per shipper | Product code | |
|--------------------------|---------------------------|-----------------|-----------------|------------|-------------|--------------|----------|
| | 2.10 Product range | 4cm x 4m | Tan | | 10 | 280 | 02935-01 |
| 6cm x 4m | | 280 | | | | 02936-01 | |
| 8cm x 4m | | 140 | | | | 02937-01 | |
| 10cm x 4m | | 140 | | | | 02938-01 | |
| 12cm x 4m | | 140 | | | | 02939-01 | |
| 4cm x 4m | | Tan | | | | | 10 |
| 6cm x 4m | | | 46641-01 | | | | |
| 8cm x 4m | | | 46642-01 | | | | |
| 10cm x 4m | | | 46643-01 | | | | |
| 12cm x 4m | | | 46644-01 | | | | |
| 6cm x 20m | | | Blue | | - | | |
| 8cm x 20m | | 47329-01 | | | | | |
| 6cm x 20m | | Yellow | | - | | 47331-01 | |
| 8cm x 20m | | | | | | 47332-01 | |
| 6cm x 20m | | Green | | 1 | | 47334-01 | |
| 8cm x 20m | | | | | | 47335-01 | |
| 6cm x 20m | | Pink | | | 24 | 47337-01 | |
| 8cm x 20m | | | | | | 47338-01 | |
| 6cm x 20m | | Blue | | | | 76047-01 | |
| 8cm x 20m | | | | | | 76048-01 | |
| 6cm x 20m | | Yellow | | | | 76049-01 | |
| 8cm x 20m | | | | | | 76050-01 | |
| 6cm x 20m | | Pink | | | 6 | 76051-01 | |
| 8cm x 20m | | | | | | 76052-01 | |
| 6cm x 20m | | Green | | | | 79993-00 | |
| 8cm x 20m | | | | | | 79993-01 | |
| 2.11 Sizing Chart | | Please see 2.10 | | | | | |

| | |
|--------------------------------------|--|
| 2.12 Storage conditions | Dry, clean and without exposure to direct sunlight Max. storage condition: 30°C |
| 2.13 Shelf life/ Storage time | The product has a shelf life of 3 years, if stored appropriately |
| 2.14 Sterilization | Non-sterile |

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 | No |
| Lanolin and its derivatives | No |
| Colophony | No |
| Colophony derivatives | No |
| Polyvinylchloride (PVC) | No |
| Methylmethacrylate | No |
| Butylacrylate | No |
| Microplastics (<5 mm) | No |
| Nanoparticles | No |
| Fragrance/parfum | No |
| Chlorhexidine | No |

Raw materials used in the packaging

| Substance | Included in formulation |
|-------------------------|-------------------------|
| Polyvinylchloride (PVC) | No |
| Natural rubber latex | 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 GmbH cannot provide proof of absence.

History

| Version / Date | Page / Item | Description of Change |
|-----------------|-------------|--|
| 01 / 25.02.2005 | All | Set up new document under 40002469.000.01 |
| 02 / 01.08.2005 | Item 7 | See Change Control No.: 7_348 |
| 03 / 14 06 2018 | All pages | General revision due to change of product in latexfree. New form of PSDS, safety information included; see change no C1378 |
| 01 / 02.2021 | All | Set up new document according to new template. 40002959 000 03 will be replaced by 40047770.000.01 |