

Product Data Sheet

| 1.0 Name of the product | Soffban Synthetic | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|-------------|-----------------|-------------|--------------|--------------|----|-------|----------|---------------|----|------|----------|---------------|---|------|----------|----------------|----|-------|----------|---------------|----|-------|----------|
| 2.0 Product description | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.1 Description | Soffban [®] Synthetic is a non-woven bandage for orthopedic or general padding. | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.2 Intended purpose | Soffban [®] Synthetic is intended for padding in fracture management and compression therapy environment. Application fields include casting & splinting procedures, compression therapy and cushioning in prosthetics. | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | Not applicable | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.5 Contraindications | None known | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.6 Transport Precautions | Not applicable | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.7 Duration of application | The padding can remain on the intact skin (and on surgical dressings) until end of cast treatment or change of compression bandages. Wear time typically ranges from 3 days to 12 weeks. | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.8 Information on reusable/ washable products | Do not re-use | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.9 Composition | 100% Polyester | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.10 Product range | <table border="1"> <thead> <tr> <th>Size/ Color</th> <th>Per folding box</th> <th>Per shipper</th> <th>Product code</th> </tr> </thead> <tbody> <tr> <td>5 cm x 2.7 m</td> <td>12</td> <td>24x12</td> <td>71464-01</td> </tr> <tr> <td>15 cm x 2.7 m</td> <td>12</td> <td>8x12</td> <td>71465-01</td> </tr> <tr> <td>20 cm x 2.7 m</td> <td>6</td> <td>12x6</td> <td>71466-01</td> </tr> <tr> <td>7.5 cm x 2.7 m</td> <td>12</td> <td>16x12</td> <td>71467-01</td> </tr> <tr> <td>10 cm x 2.7 m</td> <td>12</td> <td>12x12</td> <td>71486-05</td> </tr> </tbody> </table> | Size/ Color | Per folding box | Per shipper | Product code | 5 cm x 2.7 m | 12 | 24x12 | 71464-01 | 15 cm x 2.7 m | 12 | 8x12 | 71465-01 | 20 cm x 2.7 m | 6 | 12x6 | 71466-01 | 7.5 cm x 2.7 m | 12 | 16x12 | 71467-01 | 10 cm x 2.7 m | 12 | 12x12 | 71486-05 |
| Size/ Color | Per folding box | Per shipper | Product code | | | | | | | | | | | | | | | | | | | | | | |
| 5 cm x 2.7 m | 12 | 24x12 | 71464-01 | | | | | | | | | | | | | | | | | | | | | | |
| 15 cm x 2.7 m | 12 | 8x12 | 71465-01 | | | | | | | | | | | | | | | | | | | | | | |
| 20 cm x 2.7 m | 6 | 12x6 | 71466-01 | | | | | | | | | | | | | | | | | | | | | | |
| 7.5 cm x 2.7 m | 12 | 16x12 | 71467-01 | | | | | | | | | | | | | | | | | | | | | | |
| 10 cm x 2.7 m | 12 | 12x12 | 71486-05 | | | | | | | | | | | | | | | | | | | | | | |
| 2.11 Sizing Chart | Not applicable | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.12 Storage conditions | Dry, clean, and without exposure to direct sunlight | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.13 Shelf life/ Storage time | 5 years | | | | | | | | | | | | | | | | | | | | | | | | |
| 2.14 Sterilization | When autoclaved at 134°C - 138°C for 3 minutes in its paper sleeve, the bandage must continue to have a soft texture with minimal fiber shed and a low unrolling tension. | | | | | | | | | | | | | | | | | | | | | | | | |

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 |
| 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 | No |
| 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 Inc. cannot provide proof of absence.

History

| Version / Date | Page / Item | Description of Change |
|------------------------|-------------|-----------------------|
| 01 / 18.February .2021 | All | Set up new document |