


Product Data Sheet

1.0 Name of the product	Hypafix													
2.0 Product description														
2.1 Description	Hypafix® consists of white, width-wise elastic polyester non-woven backing which is coated on one side with UV-cured acrylic adhesive. The adhesive area is covered completely with backside printed, one-side siliconized release paper with lateral split liners.													
2.2 Intended purpose	Hypafix® is intended for wide-area fixation of wound dressings, particularly on joints as well as on frequently moved and contoured parts of the body. The product can also be used to secure fixation of tubes, catheters, measuring devices and instruments.													
2.3 Instructions for use	Instructions for use not necessary for class I/Is/IIa products.													
2.4 Warnings and precautions for use	No warnings and precautions applicable for this product.													
2.5 Contraindications	There are no known contraindications.													
2.6 Transport Precautions	Dry, clean and without exposure to direct sunlight													
2.7 Duration of application Period of use	The product can be used for one day to several days depending on the status of the wound and on the skin condition.													
2.8 Composition	 <table border="1"> <thead> <tr> <th>Designation (incl. no. in drawing)</th> <th>Description</th> <th>% of final product</th> </tr> </thead> <tbody> <tr> <td>Backing (1)</td> <td>Polyester non-woven</td> <td>26,8</td> </tr> <tr> <td>Adhesive (2)</td> <td>Polyacrylate</td> <td>19,5</td> </tr> <tr> <td>Release Liner (3)</td> <td>Siliconized paper</td> <td>53,7</td> </tr> </tbody> </table>		Designation (incl. no. in drawing)	Description	% of final product	Backing (1)	Polyester non-woven	26,8	Adhesive (2)	Polyacrylate	19,5	Release Liner (3)	Siliconized paper	53,7
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2.9 Product range

Product name	Size	Color	Per folding box	Per shipper	Product code
Leukoplast® Hypafix®	15cm x 2m	White	1	12	71213-00
Hypafix® Sticker Tips	2.5cm x 5m			24	71442-00
	5cm x 5m				71442-01
	10cm x 5m			12	71442-02
	5cm x 5m			24	71442-03
Hypafix®	10cm x 5m			12	71442-04
	15cm x 5m				71442-05
	20cm x 5m				71442-06
	2.5cm x 10m				24
	5cm x 10m			71443-01	
	10cm x 10m			71443-02	
	15cm x 10m			71443-03	
	20cm x 10m			71443-04	
	30cm x 10m			71443-05	
	2.5cm x 10m			71444-00	
	5cm x 10m			71444-01	
	10cm x 10m			71444-02	
	15cm x 10m			71444-03	
	20cm x 10m			71444-04	
	5cm x 1m			71445-26	
	10cm x 2m			12	71939-00
	10cm x 2m				71939-19
	15cm x 2m				71939-20
	5cm x 2m				36
	Hypafix® Sticker Tips			10cm x 2m	12
Leukoplast® Hypafix®	5cm x 10m			24	79949-01
	5cm x 10m				79949-02
	5cm x 10m				79949-03
	10cm x 10m				79949-04
	10cm x 10m				79949-05
	10cm x 2m	12	79949-07		
	10cm x 2m		79949-08		

2.10 Sizing Chart

See 2.9

2.11 Storage conditions

Cool, dry place, avoid direct sunlight

2.12 Shelf life/ Storage time

60 months/ 5 years

2.13 Sterilization

N.a. as product 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
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	Partly in shipper case

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
03 / 19.05.2021	All	Set up new version of document