

**Änderungsnummer / Change Master: C1339**

**Objektverknüpfungen / Object Links:**

JBX 40023947 000 02 Fixomull/Hypafix gentle touch

JBX 40023947 000 03 Fixomull/Hypafix gentle touch

**Dokumentenstückliste / Document Structure:**

Status	Responsible	Date
IE in Erstellung	ZIMMERMANN	10.02.2017
AF Freigabeanford.	KRUEGAN	02.03.2017
FR freigegeben	ZIMMERMANN	03.03.2017

## Product Safety Data Sheet

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<b>1.0 Name of the product</b>	<b>Fixomull® gentle touch / Hypafix® gentle touch</b>
<b>2.0 Product description</b>	
<b>2.1 Description</b>	<p>Fixomull® gentle touch /Hypafix® gentle touch is a self-adherent, silicone coated non-woven/fleece roll (non-sterile) for gentle, yet reliable wide area fixation. Suitable for highly sensitive, delicate, cracked, fragile, elderly, neonatal, cortisone/medication-damaged, diabetic skin. For use on all body parts, including frequently moved or highly contoured parts of the body.</p>
<b>2.2 Characteristics</b>	<ul style="list-style-type: none"> <li>- Gentle fixation</li> <li>- High wearing comfort</li> <li>- Secure fixation of wound dressings and devices</li> <li>- Skin-friendly, atraumatic removal / change</li> <li>- Maintains skin integrity</li> <li>- Breathable, no skin macerations</li> <li>- Well tolerated by sensitive skin</li> <li>- Residue free removal</li> <li>- Minimal pain at dressing change</li> <li>- Reduces unnecessary dressing changes</li> <li>- Radio transparent</li> <li>- Water repellent for quick showers</li> <li>- Re-adjustable</li> <li>- Up to 7 days weartime</li> <li>- Wide-area fixation of wound dressing all-round guards against contamination</li> <li>- Easy handling</li> <li>- 5 years shelf life</li> <li>- Low sensitization or allergy potential</li> </ul>
<b>2.3 Intended use</b>	<p>Fixomull® gentle touch/Hypafix® gentle touch is intended for fixation of primary wound dressings and additional securement of devices, such as catheters, tubes, probes or drainages.</p>
<b>2.4 Instructions for use</b>	<p>Instructions for use not necessary for class 1 products. Product is self-explanatory, additional pictograms on folding box.</p>
<b>2.5 CE-class GMDN - code</b>	<p>Class 1 Rule 1, non-sterile GMND Code: 16866</p>

<b>2.6 Duration of application / Period of use</b>	One day to several days depending on the status of the wound and on the skin condition.
<b>2.7 Composition</b>	<p>Fixomull® gentle touch /Hypafix® gentle touch consists of non-woven fabric made of polyester which is coated on one side with a silicone adhesive. The product is covered with a release film.</p> <p><u>Components of the product:</u></p> <p>Substrate: Polyester, white, non woven          Area weight: 37 -54 g/m<sup>2</sup></p> <p>Adhesive mass: Silicone adhesive          Quantity: 105 - 135 g/m<sup>2</sup></p> <p>Release paper: Embossed PE liner          Area weight: 73,5.- 95,5 g/m<sup>2</sup></p>
<b>2.8 Latex in product and</b>	Product composition: No latex content Packaging material: No latex content
<b>2.9 Phthalate in product and packaging</b>	No content of phthalate in product No content of phthalate in packaging
<b>2.10 Controls</b>	<p><b>Raw materials</b></p> <p>Backing support: Weight g/m<sup>2</sup>          Thickness          Microbiological control          Maximum tensile strength (N/cm)          Extension at maximum strength (%)</p> <p>Adhesive mass: Viscosity</p> <p>Release paper: Weight g/m<sup>2</sup>          Thickness          Weight of silicone          Microbiological control</p> <p><b>Finished product</b> Adhesive strength          Water vapour permeability          Quantity of adhesive mass g/m<sup>2</sup></p>

### 2.11 Product range

Assortment	Product	Packaging	Per shipper	Product code
5 cm x 5 m	Fixomull® gentle touch	1 roll per box	24 boxes	79965-01
10 cm x 5 m		1 roll per box	12 boxes	79965-02
15 cm x 5 m		1 roll per box	12 boxes	79965-03
10 cm x 2 m		1 roll per box	12 boxes	79965-04
5 cm x 5 m	Hypafix® gentle touch	1 roll per box	24 boxes	79966-01
10 cm x 5 m		1 roll per box	12 boxes	79966-02
15 cm x 5 m		1 roll per box	12 boxes	79966-03
10 cm x 2 m		1 roll per box	12 boxes	79966-04
<b>2.12 Storage conditions</b>		Store under dry conditions. Keep away from light and heat.		
<b>2.13 Shelf life/Storage time</b>		Expiry date is printed on the packaging. Shelf life: 5 years		

<b>3.0 Safety information of Fixomull® gentle touch / Hypafix® gentle touch</b>	
<b>3.1 Recommendations / precautions for use</b>	No warnings and precautions applicable for this product.
<b>3.2 Physical &amp; Chemical Properties</b>	Combustible solid.
<b>3.3 Health Hazards</b>	No health hazard is anticipated during normal handling of this product.
<b>3.4 Contra Indications</b>	No contraindications known for this product.
<b>3.5 Fire Hazard and Emergency Action</b>	In case of fire any standard fire extinguisher may be used.
<b>3.6 Transport Precautions</b>	Not applicable.
<b>3.7 Handling/ Use/ Protecting Clothing</b>	Not applicable.
<b>3.8 First Aid</b>	a) Inhalation: Not applicable b) Contact with skin: Not applicable c) Contact with eyes: Not applicable d) Ingestion: Not applicable
<b>3.9 Disposal</b>	Controlled incineration/ landfill according to local environmental health guidelines.
<b>3.10 Additional Information</b>	Not applicable
<b>4.0 General information</b>	
<b>4.1 Name, address and telephone number of supplier</b>	BSN medical GmbH Quickbornstraße 24 D-20253 Hamburg  GERMANY  Tel. ++ 49 40 4909-909 Fax ++ 49 40 4909-6666
<b>4.2 Certificate</b>	Certificate acc. ISO 13485 (notified body: Dekra) available

### History

Version/Date	Page /Item	Description of Change
01/18.01.2017	All pages	Create new document