Product Data Sheet

1.0 Name of the product	Fixomull® skin sensitive/ Hypafix® skin sensitive
2.0 Product description	
2.1 Description	Fixomull®/Hypafix® skin sensitive 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.
2.2 Intended purpose	Fixomull®/Hypafix® skin sensitive is intended for fixation of primary wound dressings and additional securement of devices, such as catheters, tubes, probes or drainages.
2.3 Instructions for use	Instructions for use not necessary for class 1 products. Product is self-explanatory, additional pictograms on folding box.
2.4 Warnings and precautions for use	None known
2.5 Contraindications	None known
2.6 Transport Precautions	Not applicable
2.7 Duration of application Period of use	One day to several days depending on the status of the wound and on the skin condition.
2.8 Composition	Fixomull®/Hypafix® skin sensitive consists of non-woven made of polyester which is coated on one side first with polyacrylate adhesive and afterwards with a silicone adhesive. The product is covered with a release film. Components of the product:

Designation (incl. no. in drawing)	Description	% of final product
Backing	Polyester non-woven, printed with blue waves	16
Adhesive 1	Polyacrylate adhesive	11
Adhesive 2	Silicone adhesive	41
Release liner	HDPE-film	32

2.9 Product range

Product name	Size	Per folding box	Per shipper	Product code
Fixomull® skin sensitive	5cm x 5m	1	24	79965-01
	10cm x 5m		12	79965-02
	15cm x 5m			79965-03
	10cm x 2m			79965-04
Hypafix® skin sensitive	5cm x 5m		24	79966-01
	10cm x 5m		12	79966-02
	10cm x 2m			79966-04

2.10 Sizing Chart	See 2.9
2.11 Storage conditions	Cool, dry place, avoid direct sunlight
2.12 Shelf life/ Storage time	Expiry date is printed on the packaging. Shelf life: 5 years
2.13 Sterilization	Non-sterile
2.14 Reimbursement Information	Class 1 Rule 1, non-sterile GMND Code: 16866

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.

3.2 Certificates

Following certificates are available for this product:

- 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
02/ 11.05.2017	Page 2/ 2.2 Page 3/ 2.7 and 2.10 Page 4/ 2.11	Claims added Unnecessary data deleted New ref. added
03/ 23.08.17	Page 3/ 2.7	Composition corrected
04/ 16.04.2019	All pages	General revision because of change C2181, change of name, product range, etc. update acc. new PFD and product specification
05/ 19.12.2019	Page 2/ 2.2	2 claims deleted
06/ 01.09.2021	All 2.11	Create new version of previous document Remove temperature limitation < 50°C