

	BSN documentation system JBM 40054943 000 01 PDS LP Wet Wipe	Released: Seite 1 von 4
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Product Data Sheet

1.0 Name of the product	Leukoplast® wet wipe
2.0 Product description	
2.1 Description	Leukoplast® wet wipes consist of a non-woven swab impregnated with isopropyl alcohol BP 70 % v/v. They are kept in sachets/pouches made of aluminium foil laminated paper. Two pouches are cohering and can be separated by perforation.
2.2 Intended purpose	The device is intended to reduce dirt in an injection area in order to prevent contamination and prepare for disinfection. It is non-sterile and for topical, single use on intact skin. The device is for transient use. Use of the device is not restricted to specific populations. Intended users are health care professionals.
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	The following symbols are used on every packaging level: • Do not use if package is damaged • Do not re-use • Do not cut • Non sterile    
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	For transient use.

2.8 Composition						
	Designation	Description				% of final product
	Wet wipe	Viscose 70% Polyester 30%				15
	Alcohol solution	Isopropyl Alcohol (2-Propanol), 70% v/v				85
Water, highly purified, 30% v/v						

2.9 Product range

Product code	Size	Ply	Wipes per Pouch	Pouches per Folding Box (= UoM)	Folding Boxes per Shipper Case	Wipes per Shipper Case
71291-00	3 x 3 cm/ 2 x 2 in	2	1	100	100	10000

2.10 Sizing Chart

See 2.9

2.11 Storage conditions

Dry, clean and without exposure to direct sunlight



2.12 Shelf life/ Storage time

4 years

2.13 Sterilization

Not applicable

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 and folding Box

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.

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History

Version / Date	Page / Item	Description of Change
01 / 01.2023	All	Set up new document
02 / 03.2023	2.9 Product range	The table has been redesigned