


Product Data Sheet

1.0 Name of the product	Gypsona®
2.0 Product description	
2.1 Description	Gypsona® is a plaster bandage which consists of woven backing material made of 100% cotton Leno fabric and coated with a plaster mixture. The bandage is wrapped around a polypropylene plastic core.
2.2 Intended purpose	Plaster of Paris bandages are for external rigid immobilization through splinting procedures in all clinical situations judged suitable by qualified healthcare professionals. Plaster of Paris is intended for all kind of plaster cast for orthopaedic and traumatology. The device is non-sterile and for single use (bandage). Intended Users are Health Care Professionals. Use of product is not restricted to specific populations.
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	Professional Health Care Use only.
2.5 Contraindications	There are no contraindications known.
2.6 Transport Precautions	Not applicable.
2.7 Duration of application	Depending on the purpose of the immobilization treatment duration is between a couple of days and several weeks, physicians applying casts or splints decide on treatment duration according to the individual clinical situation.

2.8 Composition			
	Designation (incl. no. in drawing)	Description	% of final product
	Fabric (1)	Leno cotton gauze bleached	6%
	Plaster mixture (2)	Plaster of Paris and additives (98% of plaster and 2% of additives)	94%

2.9 Product range	Size/ Color	Per folding box	Per shipper	Product code
	10cm x 2.7m	1 bandage/ heat sealed packet	48	71985-00
	12.5cm x 2.7m	1 bandage/ heat sealed packet	24	71985-01
	15cm x 2.7m	1 bandage/ heat sealed packet	24	71985-02
	20cm x 2.7m	1 bandage/ heat sealed packet	24	71985-03
	5cm x 2.7m	1 bandage/ heat sealed packet	48	71985-04
	7.5cm x 2.7m	1 bandage/ heat sealed packet	48	71985-05
	10cm x 2m	1 bandage/ heat sealed packet	40	71985-06
	12.5cm x 2m	1 bandage/ heat sealed packet	20	71985-07
	15cm x 2m	1 bandage/ heat sealed packet	20	71985-08
	20cm x 2m	1 bandage/ heat sealed packet	20	71985-12
	5cm x 2m	1 bandage/ heat sealed packet	40	71985-13
7.5cm x 2m	1 bandage/ heat sealed packet	40	71985-14	
2.10 Sizing Chart	Not applicable.			
2.11 Storage conditions	Keep away from sunlight. Keep dry.			
2.12 Shelf life/ Storage time	3 years.			
2.13 Sterilization	Non-sterile.			
2.14 Key quality parameters	Characteristic		Method	Target
	Initial setting time on arm cast		Essity internal	113s

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)	Not intended
Nanoparticles	Hydroxypropylcellulose (comply 21CFR part 110); Silicon dioxide (Synthetic Amorphous Silica) included	

Fragrance/parfum	No
Antibiotics	No
Triclosan	Not intended
Chlorhexidine	Not intended
Polyhexanide	Not intended

Raw materials used in the packaging:

Substance	Included in formulation
Polyvinylchloride (PVC)	No
Natural rubber latex	No
Recycled material	Cardboard = Yes Plastic = 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 S.A.S. cannot provide proof of absence.

History

Version / Date	Page / Item	Description of Change
01 / 14.10.2021	All	Document created