

Product Data Sheet

1.0 Name of the product	Gypsona® S		
2.0 Product description			
2.1 Description	Gypsona® S is a plaster bandage which consists of 100% cotton fabric coated with a plaster mixture. The bandage is wound around a plastic core. The splints made of 4 layers folded together.		
2.2 Intended purpose	<p>Plaster of Paris bandages and pre-cut splints are for external rigid immobilization through casting and/or splinting procedures in all clinical situations judged suitable by qualified healthcare professionals. Application fields include:</p> <ul style="list-style-type: none">• immobilization of bone fractures• treatment of soft tissue and joint injuries• immobilization within treatments for correction or prevention of anatomical deformities (e.g. club foot, scoliosis)• total contact casting used for off-loading purposes in the treatment of diabetic foot ulcers <p>The device is non-sterile. Intended Users are Health Care Professionals.</p>		
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 Period of use	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 Information on reusable/ washable products	Single use		
2.9 Composition	Designation	Description	% of final product
	Fabric	cotton gauze bleached by hydrogen peroxide	5%
	Plaster mixture	Plaster of Paris and additives	95% (with 97% of natural plaster And 3% of additives)

2.10 Product range	Size	Per folding box	Per shipper	Product code
	5cm x 3m	2 bandage/ heat sealed packet	40	71993-36
	5cm x 2m	4 bandage/ heat sealed packet	60	71993-49
	10cm x 2m	2 bandage/ heat sealed packet	30	71993-50
	15cm x 2m		20	71993-51
	20cm x 2m		20	71993-52
	8cm x 3m		60	71993-55
	10cm x 3m		40	71993-56
	12cm x 3m			71993-57
	15cm x 3m			71993-58
	20cm x 3m		20	71993-59
	10cm x 4m		40	71993-62
	15cm x 4m			71993-63
	20cm x 4m		20	71993-64
	10cm x 25m	1 splint /Box	1	71998-00
	12cm x 25m			71998-01
	15cm x 25m			71998-02
	20cm x 25m			71998-03

2.11 Sizing Chart	Not applicable
2.12 Storage conditions	Cool, dry place, avoid direct sunlight
2.13 Shelf life/ Storage time	36 months / 3 years
2.14 Sterilization	Non-sterile

2.15 Key quality parameters	Bandage:		
	Characteristic	Method	Target
	Initial setting time on arm cast	Internal test method	140 s
	Maximum temperature		≤ 48°C
	Weight		480 g/m ²
	Splint:		
	Characteristic	Method	Target
	Initial setting time	Internal test method	155 s
	Maximum temperature		≤ 48°C
	Weight		480 g/m ²

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	Klucel G and Klucel M: Silicium dioxide (Synthetic Amorphous Silica) included in All the POP formulation.
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	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 / 27.04.2021	All	Set up of new document