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Objektverknüpfungen / Object Links:

JBX 40010461 000 01 BPF Physiopack

Dokumentenstückliste / Document Structure:

JBR JBR05266 000 72075-XX Physiopack Leaflet

Status	Responsible	Date	
IE	in Erstellung	KRUEGAN	08.12.2009
AF	Freigabeanford.	STEINWEGM	01.03.2011
FR	freigegeben	SCHEIBB	01.03.2011

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Product Safety Data Sheet

For internal use only - Document will not be automatically updated

This document is thought as a data base which gives all information for promotion material, tender business applications and other marketing related activities.

EUROPEAN AND US REGULATIONS

The EU Chemical Agents Directive (98/24/EC) is the legislation designed to control the risk to users arising from exposure to harmful substances. The European Directive 1999/45/EC defines hazardous preparation and states the requirements for classification, packaging and labelling of dangerous preparations. The information within this Directive indicates that this medical device does not require a safety data sheet. Therefore, a Material Safety Data Sheet according to the Directive 91/155/EEC is not necessary for the product mentioned in this document.

The occupational Safety and Health (OSHA) regulation 29 CFR is the standard in the USA which ensures the hazards of chemicals are evaluated and that information regarding safety is communicated to employers and employees. Under the terms of this regulation (29CFR.1910.1200 b, c) this medical device is classed as an article based on the definition: " A substance which under normal conditions of use does not release more than very small quantities, e.g. minute or trace amounts of a hazardous chemical and does not pose a physical hazard or health risk to employees." Articles and Medical Devices do not require a Material Safety Data Sheet to comply with the requirements of Regulation 29CFR.


All relevant safety aspects are taken into consideration within the conformity process for CE-marking according to the Medical Device Directive 93/42/EEC. To fulfil these requirements, BSN medical runs a quality management system according to EN ISO 9001 und EN ISO 13485 and performs risk management according to EN ISO 14971 for all products.

The device when used as intended contains no substances which pose a risk to the health of the patient or user. The composition of the medical device is enclosed below so that you may review for your own risk assessment.

1.0 Name of the product	Physiopack®
2.0 Product description	
2.1 Description	Physiopack
2.2 Characteristics	<ul style="list-style-type: none">- Can be used hot or cold- Maintains conformability during cold application- The polystyrene box maintains the cooled Physiopack below 0°C/32°F for up to 5 hours.- The polystyrene box maintains the heated Physiopack above 42°C/107°F for up to 6 hours.
2.3 Intended use	Hot and cold therapy treatment of muscular, tendon or ligament injuries and swelling, muscle hypertonicity and rheumatoid arthritis, calming headaches, dental pains, menstrual cramps and stomach pain.
2.4 Instructions for use	Yes see leaflet JBR05266
2.5 CE-class GMDN - code	CE class 1 and rule of classification 1 GMDN – code number: P 37240
2.6 Duration of application / Period of use	One day to several days depending on the status of the medical conditions.

2.7 Composition	<p>Physiopack® is manufactured from a green gel in a soft plastic bag made of Polyamide/Polyethylene.</p> <p>The green gel consists of propylene glycol, carboxymethyl cellulose and filtered rain water.</p> <p>7 x 38 cm: 220 g 13 x 30 cm: 400 g 19 x 30 cm: 720 g</p> <p>Plastic made of co extruded plastic laminate PE/PA/PE 90µm alt. PE/PA/PP 100µm</p>		
2.8 Latex in product and packaging material	<p>Product composition: No latex content Packaging material: No latex content</p>		
2.9 Phthalate in product and packaging material	<p>Product composition: No phthalate content Packaging material: No phthalate content</p>		
2.10 Controls	<p>Visual characteristics (e.g. colour/ appearance, packaging/labelling)</p>		
2.11 Product range			
Size	Packaging	Per shipper	Product code
7cm x 38 cm	-	1 box of 12 pouches	72075-01
13cm x 30 cm	-	1 box of 12 pouches	72075-02
19 cm x 30 cm	-	1 box of 6 pouches	72075-04
7 cm x 38 cm	1 box of 1 pouch	12	72075-10
13 cm x 30 cm	1 box of 1 pouch	10	72075-11
19 cm x 30 cm	1 box of 1 pouch	8	72075-12
2.12 Storage conditions	<p>Dry and Clean, no specific requirements</p>		
2.13 Shelf life/Storage time	<p>5 years</p>		

3.0 Safety information of Physiopack®	
3.1 Recommendations / precautions for use	Please follow the treatment recommendations of your physician.
3.2 Physical & Chemical Properties	Combustible solid
3.3 Health Hazards	No health hazard is anticipated during normal handling of this product.
3.4 Contra Indications	Not applicable
3.5 Fire Hazard and Emergency Action	In case of fire any standard fire extinguisher may be used.
3.6 Transport Precautions	Not applicable
3.7 Handling/ Use/ Protecting Clothing	Not applicable
3.8 First Aid	a) Inhalation: Not applicable b) Contact with skin: Not applicable c) Contact with eyes: Not applicable d) Ingestion: Not applicable
3.9 Disposal	Landfill according to local regulations
3.10 Additional Information	Not applicable

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4.0 General information	
4.1 Name, address and telephone number of supplier	BSN medical GmbH Quickbornstraße 24 D-20253 Hamburg GERMANY Tel. ++ 49 40 4909-909 Fax ++ 49 40 4909-6666
4.2 Certificate	EN ISO 9001 / EN ISO 13485 (notified body: Dekra)

History

Version/Date	Page /Item	Description of Change
01 / 10.12.2009	Set up new document	