

Änderungsnummer / Change Master: C0489

Objektverknüpfungen / Object Links:

JBX 40010521 000 01 BPF Articare Cold Spray
JBX 40010521 000 02 BPF Articare Cold Spray
JBX 40010521 000 03 BPF Articare Cold Spray

Dokumentenstückliste / Document Structure:

JBN DIN EN ISO 9001 000 Qualitätsmanagementsysteme - Anforderung
JBN DIN EN ISO 9001 BER. 000 Quality managemant systems - Requirement
JBN ISO 9001 000 Quality management systems - Requirement
JBN DIN EN ISO 13485 000 Medizinprodukte - Qualitätsmanagementsys
JBN ISO 13485 000 Medical devices - Quality management sys
JBN ISO 13485 TECH CORR 1 000 Medical devices - Quality management sys

Status	Responsible	Date
IE in Erstellung	AEVERMANNM	22.04.2015
AF Freigabeanford.	AEVERMANNM	21.10.2015
FR freigegeben	STEINWEGM	21.10.2015

Product Safety Data Sheet

Document will not be automatically updated

1.0 Name of the product	Articare® Cold Spray		
2.0 Product description			
2.1 Description	Articare® Cold Spray is an aerosol spray providing instant cooling and pain relief of soft tissue injuries after contusions, distortions and strains. It is suitable for quick, on-the-spot treatment. In normal use, the product should be in contact with intact skin and is used by medical staff.		
2.2 Characteristics	<ul style="list-style-type: none"> - Immediate cooling and pain relief - Suitable for quick on the spot treatment - CFC free 		
2.3 Intended use	Articare® Cold Spray is used for instant cooling and pain relief after contusions, distortions and strains in unbroken skin.		
2.4 Instructions for use	Spray several times, in short bursts, from a distance of at least 15cm/6in (to avoid frostbite). For external use only		
2.5 CE-class GMDN - code	CE Class IIa , Rule 9 GMDN Code: 46557		
2.6 Composition	Material components: 38.5% Isopentane cosmetic, 1.2% Isopropanol cosmetic, 0.3% Menthol Ph Eur, 15% Propane-Butane mixture 3.5, 45% N-Butane USP XX111.		
2.7 Latex in product and packaging material	Product composition:	No latex content	
	Packaging material:	No latex content	
2.8 Duration of application / Period of use	Not applicable		
2.9 Phthalate in product and packaging material	Product composition:	No phthalate content	
	Packaging material:	No phthalate content	
2.10 Controls	Visual Characteristics		
2.11 Product range			
Reference	Size	Product name	Cans per shipper
47422-00	200 ml	Articare® Cold Spray	12

2.12 Storage conditions	Avoid heat and direct sunlight. Recommended storage temperature < 50°C. Protect from sunlight and do not expose to temperature exceeding 122°F/50°C
2.13 Shelf life/Storage time	3 years.
3.0 Safety information	
3.1 Warnings and precautions for use	<ul style="list-style-type: none"> - Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 122°F/50°C. - Do not pierce or burn, even after use. - Do not spray on a naked flame or any incandescent material. - Keep away from sources of ignition. - No smoking. - Keep out of reach of children. - Avoid contact with eyes, mucous membranes, and open wounds. - Not suitable for use on burns. - Articare Cold Spray has to be used in well-ventilated area. Do not intentionally inhale or ingest. Over application might cause frostbites and narcotic effects if used incorrectly. Use only short bursts of spray to ensure that frostbite does not occur.
3.2 Flammable or combustible properties	Combustible solid
3.3 Health Hazards	No health hazard is anticipated during normal handling of this product.
3.4 Contraindications	No contraindications known for this product.
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 First Aid	a) Inhalation: Not applicable b) Contact with skin: Not applicable c) Contact with eyes: Not applicable d) Ingestion: Not applicable
3.8 Disposal	The user has to follow the instructions of the respective laws, standards and guidelines for disposal of garbage coming from the medicinal field.



4.0 General information

4.1 Name, address and telephone number of legal manufacturer

BSN medical GmbH
Quickbornstrasse 24
20253 Hamburg

GERMANY

Tel. ++ 49 40 4909-909
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4.2 Certificates for Quality Management

ISO 9001 / DIN EN ISO 9001; ISO 13485 / DIN EN ISO 13485
(notified body: Dekra)

History

Version/Date	Page /Item	Description of Change
01 / 08.06.2011	Set up new document	
02/ 20.10.2015	All pages Page 2 / item 2.1 page 2 / item 2.3 page 3 / item 3.7 page 3 / item 3.8 page 3 / item 3.10	Revision of PSDS format Description changed Intended use changed Handling/ Use/ Protecting Clothing deleted Disposal description changed Additional information deleted