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Objektverknüpfungen / Object Links:

JBX 40012734 000 01 BPF Cutimed Sorbact WCL
JBX 40012734 000 02 BPF Cutimed Sorbact WCL

Dokumentenstückliste / Document Structure:

Status		Responsible	Date
IE	in Erstellung	PALLUCHB	12.04.2011
AP	Prüfanforderung	PALLUCHB	12.04.2011
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FR	freigegeben	EITELJ	04.05.2011

Product Safety Data Sheet

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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	**Cutimed® Sorbact® WCL**
2.0 Product description	
2.1 Description	The highly hydrophobic Cutimed® Sorbact® wound contact layer consists of an impregnated acetate fabric, treated with the fatty acid ester DACC (Dialkyl Carbamoyl Chloride) for water-repellence. Cutimed® Sorbact® wound contact layer decrease the number of microorganisms, cleanses the wound and creates the necessary conditions for a natural wound healing. Non folded wound contact layer.
2.2 Characteristics	- Sterile and non-adhesive - Is coated with DACC, a hydrophobic fatty ester acid - Wound contact layer with microbe binding action - Binds and reduces hydrophobic microbes in a moist environment - Effective infection prevention - Supports the natural wound healing process - Low allergy risk (in accordance with ISO 10993) - Easy product handling - Effective against antibiotic resistant microorganisms such as MRSA and VRE - Once bound, the microorganisms metabolism is slowed down and replication is minimised - Broad spectrum efficacy; Effective in gram positive and gram negative bacteria as well as fungi - Cleanses the wound by also binding pus and debris - No development of bacterial or fungal resistance - May not promote bacterial endotoxin release as microorganisms are bound but not destroyed - Reduces odour by reducing the microbial load - Reduces wound pain in infected wounds
2.3 Intended use	Cutimed® Sorbact® WCL can be used for all types of contaminated colonised or infected exudating wounds, regardless of their aetiology, such as: - Chronic wounds, e.g. venous, diabetic and pressure ulcers - Wounds after excision of fistulas and abscess cavities - Postoperative dehisced wounds - Traumatic wounds
2.4 Instructions for use	Yes, see leaflet JBR 06151.

2.5 CE-class **GMDN - code**	Class IIb Rule 4, sterile GMDN Code: 46855
2.6 Composition	Coloured acetate fabric coated with the fatty acid ester derivative DACC (dialkyl carbamoyl chloride).
2.7 Latex in product and packaging material	Product compositon: No latex content. Packaging material: No latex content.
2.8 Duration of application/ Period of use	The frequency of dressing changes depends on the exudate level and the degree of wound contamination. It is recommended to change the dressing every 1 to 3 days. In wounds that show clinical infection signs a high frequency of wound inspection is advisable. In these cases, an appropriate systemic treatment should be considered.
2.9 Phthalate in product and packaging	No content of phthalate in product. No content of phthalate in packaging.
2.10 Controls	**Finished product:** Weight Dimensions Appearance Microbiological control Packaging

2.11 Product range

Assortment	Dressing pads per Peel Pouch	Peel Pouches per Fold Box	Boxes per Shipping Case	Product code
5 cm x 7,5 cm	1	10	20	72662-00
10 cm x 10 cm	1	10	20	72662-01
10 cm x 12,5 cm	1	10	20	72662-02
10 cm x 20 cm	1	10	20	72662-03
15 cm x 15 cm	1	10	20	72662-04
20 cm x 20 cm	1	10	20	72662-05
10 cm x 20 cm	1	-	800 pieces	72662-06

2.12 Storage conditions	Store under dry conditions. Keep away from sunlight and heat. Storage and transport climatic zone II.
2.13 Shelf life/Storage time	5 years.

3.0 Safety information of Cutimed® Sorbact® WCL	
3.1 Recommendations / precautions for use	Yes, see leaflet JBR06151.
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	Yes, see leaflet JBR06151.
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	Controlled incineration/ landfill according to local environmental health guidelines.
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**
01/02.2011	All pages	Set up new document