Änderungsnummer / Change Master: CM0159

Objektverknüpfungen / Object Links:

JBX 40004365 000 01 BPF Cutisoft wet swab
JBX 40004365 000 02 BPF Cutisoft wet swab
JBX 40004365 000 03 BPF Cutisoft wet swab

Dokumentenstückliste / Document Structure:

JBN DIN EN ISO 9001 000 Qualitätsmanagementsysteme - Anforderung
JBN DIN EN ISO 13485 000 Medizinprodukte - Qualitätsmanagementsys
JBN DIN EN ISO 14971 000 Medizinprodukte - Anwendung des Risikoma
JBN DIN EN 1644-1 000 Prüfungen für medizinische Vliesstoffkom
JBN DIN EN ISO 13934-1 000 Textilien-Zugeigenschaften von textilen

Status		Responsible	Date
IE	in Erstellung	KRUEGAN	26.07.2011
AP	Prüfanforderung	SOEHLE	25.11.2011
AF	Freigabeanford.	ARNETHA	28.11.2011
FR	freigegeben	SCHWANKED	29.11.2011

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	**Cutisoft® wipes** **Skin cleansing swabs**
2.0 Product description	
2.1 Description	Sachets containing a non woven swab impregnated with isopropyl alcohol 70% v/v
2.2 Characteristics	- For cleansing of skin - Easy and convenient way to cleanse the skin and help fight bacteria at the site of application, especially for pre-injection skin - Swabs are individually sealed and disposable for your safety and convenience - Ready to use
2.3 Intended use	Cutisoft® wipes are intended for cleansing of skin prior injection
2.4 Instructions for use	Instructions for use not necessary for class 1 product.
2.5 CE-class **GMDN - code**	Class 1 Rule 1 GMDN: P-47237
2.6 Composition	Material components: Non woven swab (70% Viscose / 30 % Polyester) impregnated with isopropyl alcohol 70 % v/v Sachets/Pouches made of aluminium foil laminated paper. Two pouches are cohering and can be separated by perforation.
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	**Finished product:** Appearance Weight Packaging Chemical characteristics Non woven with chemical characteristics acc. to EN 1644-1 and physical characteristics acc. to DIN EN 1644 (Annex B+C) and EN ISO 13934-1.
2.11 Product range	**Cutisoft® wipes** **Skin cleansing swabs**

Assortment	Packaging	Per shipper	Product code
1 swab per pouch	100 pouches per folding box (Two pouches are cohering and can be separated by perforation)	100 folding boxes	**72383-01**

2.12 Storage conditions	Store under dry conditions.
2.13 Shelf life/Storage time	4 years. Expiry Date is printed on packaging

3.0 Safety information of Cutisoft® wipes Skin cleansing swabs	
3.1 Recommendations / precautions for use	For topical administration on intact skin only. Keep out of the reach of children. Avoid contact with eyes or broken skin.
3.2 Physical & Chemical Properties	The non woven swab impregnated with isopropyl alcohol 70% v/v is flammable
3.3 Health Hazards	No health hazard is anticipated during normal handling of this product.
3.4 Contra Indications	Excessive use can cause drying of skin. Avoid contact with eyes or broken skin.
3.5 Fire Hazard and Emergency Action	In case of fire any standard fire extinguisher may be used.
3.6 Transport Precautions	Product is classed as flammable.
3.7 Handling/ Use/ Protecting Clothing	For topical administration on intact skin only. Withdraw from sachets only the correct number of wipes required. Handle in well ventilated area. PVC gloves may be worn to prevent drying of skin due to prolonged contact.
3.8 First Aid	a) Inhalation: *if excessive:* remove to fresh air, give oxygen if required. Seek medical aid. b) Contact with skin: *if excessive:* wash skin with water, cover the irritated skin with an emollient, seek medical attention if irritation develops c) Contact with eyes: Check for and remove any contact lenses. Immediately flush eyes with running water, keeping eyelids open. Cold water may be used. If required seek medical attention. d) Ingestion: wash out mouth with water. Do not induce vomiting. Seek medical aid.
3.9 Disposal	Discard used swabs safely away from sources of ignition. Controlled incineration / landfill according to local environmental health guidelines coming from medicinal field.
3.10 Additional Information	Not applicable

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
03 / 23.11.2011	Set up new document	PD and SD in one document PSDS