Änderungsnummer / Change Master: W.030.998

Objektverknüpfungen / Object Links:

JBX 40003341 000 04 BPF Fixomull / Hypafix transparent

Dokumentenstückliste / Document Structure:

Status		Responsible	Date
IE	in Erstellung	PALLUCHB	14.01.2011
AP	Prüfanforderung	PALLUCHB	14.01.2011
AF	Freigabeanford.	SCHUBERTM	20.01.2011
FR	freigegeben	MATTHIESA	03.02.2011

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	**Hypafix® transparent**
2.0 Product description	
2.1 Description	Hypafix® transparent is a film dressing which consists of thin polyurethane film pattern coated with a thermal curing polyacrylate adhesive. The PU film is co-extrudated with a transparent polyethylene release film on top. The product is manufactured with a splitted, siliconized release paper on the adhesive side and a folded adhesive tape, made from polyvinylchloride, connects the release paper with the release film on one side of the product thus acting as an application aid. The product is finally rolled up on cardboard cores and packed according to working instructions.
2.2 Characteristics	- Transparent - Bacterial barrier - Wound is protected from all four sides against contamination - Good initial and permanent adhesion - Skin-friendly, well tolerated even by sensitive skin - Pliable and highly conformable, adapts well to body contours - Quick and easy application - Radio transparent - Waterproof - Allows the patient to shower and bathe without additional protection or dressing change - Permeable to water vapour, allows the skin to breathe, risk of maceration is reduced
2.3 Intended use	Wide area fixation of dressings, tubes, catheters, measuring devices and other instruments
2.4 Instructions for use	Instructions for use not necessary for class 1 product.
2.5 CE-class **GMDN - code**	Class 1 Rule 1, non-sterile GMDN Code: 34864
2.6 Composition	Substrate: Transparent polyurethane film Weight: 20 ± 3 g/m² Adhesive mass : Polyacrylate mass Weight: 22 ± 2,5 g/m²
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	One day to several days depending on the status of the wound and on the skin condition.

2.9 Phthalate in product and packaging	No content of phthalate in product. No content of phthalate in packaging.
2.10 Controls	**Raw materials:** Substrate:: Area weight Adhesive mass: Area weight **Finished product:** Quantitative control of adhesive mass Adhesive strength

2.11 Product range

Assortment		Packaging	Per shipper	Product code
5 cm x 10 m	on core	1 roll per box	12 boxes	72378-00
10 cm x 10 m	on core	1 roll per box	12 boxes	72378-01
15 cm x 10 m	on core	1 roll per box	12 boxes	72378-02
10 cm x 2 m	on core	1 roll per box	12 boxes	72378-03
10 cm x 2 m	on core	1 roll per box	12 boxes	72378-04

2.12 Storage conditions	Store under dry conditions. Keep away from sunlight and heat.
2.13 Shelf life/Storage time	5 years, printed on the packaging.

3.0 Safety information of Hypafix® transparent	
3.1 Recommendations / precautions for use	For securing dressings; not recommended for strong support. Do not use on patients with known intolerance with acrylic adhesive.
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	No known Contra Indications.
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**
01/21.2.2005	Item 7	See Change Control No.: 7_348
02/10.12.2008	General change from PD to PSDS Page 2 Page 4, item 11	All pages Add disclaimer Change of storage time from 5 years to 3 years
03/07.12.2010	General revision	All pages Change of storage time from 3 years to 5 years.