

Biatain Ibu Soft-Hold Dressing



25. February 2015
Version 2.0

Safety Data Sheet

Based on template version 2.0

Identification of the substance/mixture and of the company/undertaking

Product name: Biatain Ibu Soft-Hold Dressing
Product codes: 34163, 34166, 34167, and 34169
Product information: Wound care product

Manufacturer: Coloplast A/S
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Denmark
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USA

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Europe

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Hazards identification

This product consists primarily of polymer materials. The products pose no immediate hazard.

Composition/information on ingredients

This product does not contain substances classified as hazardous under EC (REACH) or US OSHA regulations above 0.1 % (w/w). Main ingredients and packaging materials are listed below.

| Chemical name | CAS no. |
|---|------------|
| Wound dressing: | |
| Polyurethane film | - |
| Polyurethane foam | - |
| Ibuprofen* | 15687-27-1 |
| Adhesive | - |
| Siliconized polyethylene terephthalate film | - |
| Packaging: | |
| Foil of polyester/polyethylene | - |

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*Concentration of Ibuprofen corresponds to a content of 0.4-0.6 mg Ibuprofen per cm².

Disposal considerations

Dispose the device according to the recommended disposal technology at any approved facility. Under normal private use the product may be disposed of together with other household waste unless local regulations set special requirements. The disposal should always be in compliance with national, federal, state and local regulations. The product should not be discharged to the environment.

US

This product does not meet the criteria for hazardous waste as defined under the Resource Conservation and Recovery Act (RCRA) 40 CFR 261. Under normal private use the product may be disposed of together with other household waste per RCRA 40 RFT 261.4.B1.

European Union

Per The European Waste Catalogue (EWC), in accordance with EC Directive 75/422/ECC, the following Waste Code can be used: 18 01 04 00 wastes whose collection and disposal is not subject to special requirements in view of the prevention of infection (e.g. dressings, plaster casts, linen, disposable clothing, diapers). However, if the waste in view of the prevention of infection needs special requirements, other Waste Codes should be used. Under normal private use the product may be disposed of together with other household waste unless local regulations set special requirements.

Handling and storage

Handling: See instruction for use

Storage: Store until use as supplied and at room temperature unless other information is stated on the packaging or on the leaflet.

Other information

This MSDS is supplied as an additional service to the customer. The product is a medical device, which is regulated under the Council Directive 93/42/ECC, Medical Device Directive. The product has been evaluated according to the requirements of medical devices. According to current knowledge this product is considered non-toxic. For further information please contact Coloplast A/S.

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| Approved by | DKPLYM Peter Lynge Madsen Senior Biosafety Specialist Technical / Specialist 14-Aug-2015 10:23:01 GMT+0000 |
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