

Biatain Silicone

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Version 2.0

Material Safety Data Sheet

Based on template version 5.0

USA

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Canada

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

Product name: Biatain Silicone
Product code: 33434, 33435, 33436, 33437, 33438, 33400 and 33401
Product information: Wound care product
Manufacturer: Coloplast A/S
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DK-3050 Humlebaek
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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 is regulated as a medical device in European Economic Area (EEA). In other regions it may be regulated as a medical device, a cosmetic or not regulated.

This product does not contain substances classified as hazardous under EC Regulation No. 1272/2008/EC, Annex VI (EU) in concentrations above 0.1 % (w/w). Main ingredients and packaging materials are listed below.

Chemical name	CAS no.
Wound dressing:	
Polyurethane film	9009-54-5
Polyurethane foam	9009-54-5
Surfactant	-

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Acrylic adhesive	-
Sodium polyacrylate	9003-04-7
Polyethylene fibers	9002-88-4
Cellulose fibers	-
Silicone adhesive	-
Polyethylene film	9002-88-4

Packaging:

PE-coated paper	-
Polyester/ethylene vinyl acetate film	-

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 05-Jul-2016 11:58:42 GMT+0000
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