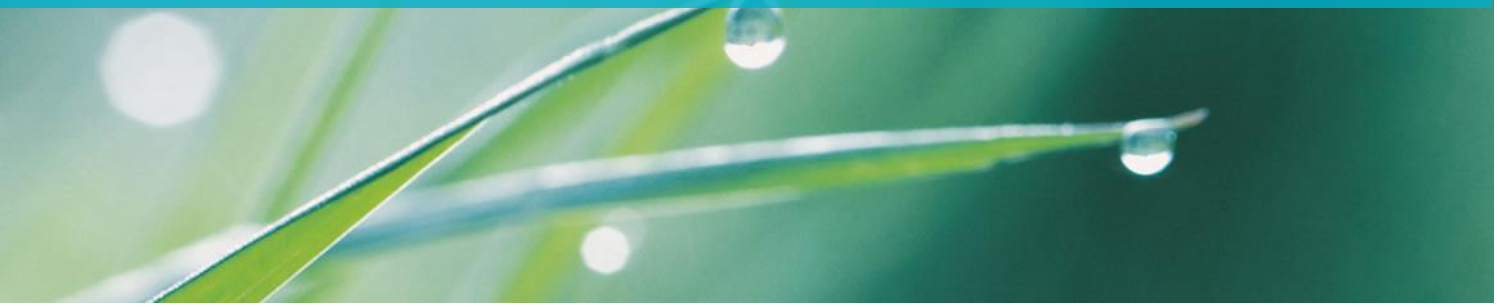
SenSura Mio 1p, Open and Closed



29. July 2021
Version 5.0

Safety Data Sheet

Based on template version 8.0

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

Product name:	SenSura Mio 1p, Open and Closed
Product code:	10401, 10406, 10411, 10412, 10413, 10414, 10416, 10421, 10422, 10423, 10424, 10426, 10428, 10431, 10436, 10441, 10442, 10443, 10444, 10446, 10451, 10452, 10453, 10454, 10456, 10458, 10461, 10471, 10472, 10473, 10474, 10475, 10476, 10477, 10478, 10479, 10480, 10481, 10482, 10483, 10484, 10485, 10486, 10487, 10488, 10489, 10490, 10491, 10492, 10493, 10494, 10495, 10496, 10670, 10671, 10672, 10673, 10674, 10681, 10683, 10684, 10685, 10691, 10870, 10871, 10872, 10873, 10874, 10881, 10883, 10884, 10885, 10891, 18370, 18371, 18372, 18373, 18375, 18376, 18377, 18378,18382, 18383, 13690
Product information:	Ostomy care product
Manufacturer:	Coloplast A/S Holtedam 1 DK-3050 Humlebaek Denmark Telephone +45 49111111 msds@coloplast.com

Hazards identification

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

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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.

The safety of this medical device has been evaluated according to the requirements in the European Union Medical Device Regulation (EU) 2017/745.

This product does not contain Substances of Very High Concern (SVHC) in concentrations above 0.1% w/w according to the candidate list, article 59 (10) European REACH regulation (EC) No. 1907/2006.

Main ingredients and packaging materials are listed below.

Chemical name	**CAS no.**
EVA/PVdC multilayer film	-
PU-EAA/EVA film	-
PP (Polypropylene)	9003-07-0
PE (Polyethylene)	9002-88-4
PET (Polyester)	-
EVA (Ethylene vinyl acetate)	24937-78-8
Ethene-1-octene copolymer	26221-73-8
Adhesive	-
Pigments	-
Filter	-
Packaging	
Corrugated cardboard	-

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 Conversation 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 SDS is supplied as an additional service to the customer. The product is a medical device, which is regulated under the European Union Medical Device Regulation (EU) 2017/745. 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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THIS PAGE SHOULD BE REMOVED BEFORE DISTRIBUTION/DISPLAY OF THE SDS TO CUSTOMERS OUTSIDE OF COLOPLAST

Change log

Version no.	Issue Date (Month Year)	Short description of and reason for change
2.0	February 2020	Update to a new template (version 7.0). Update items numbers and the composition.
3.0	February 2020	Correct Product Name.
4.0	April 2021	Update to a new template (version 8.0) – change references from MDD to MDR. The following item numbers have been added: 18370, 18371, 18372, 18373, 18375, 18376, 18377, 18378, 18380, 18381, 18382, 18383 Missing PE has been added.
5.0	July 2021	The following item numbers have been added: 13690 The following item numbers haven been deleted : 18380, 18381, these item numbers are no longer part of the Mio Max Cut project.