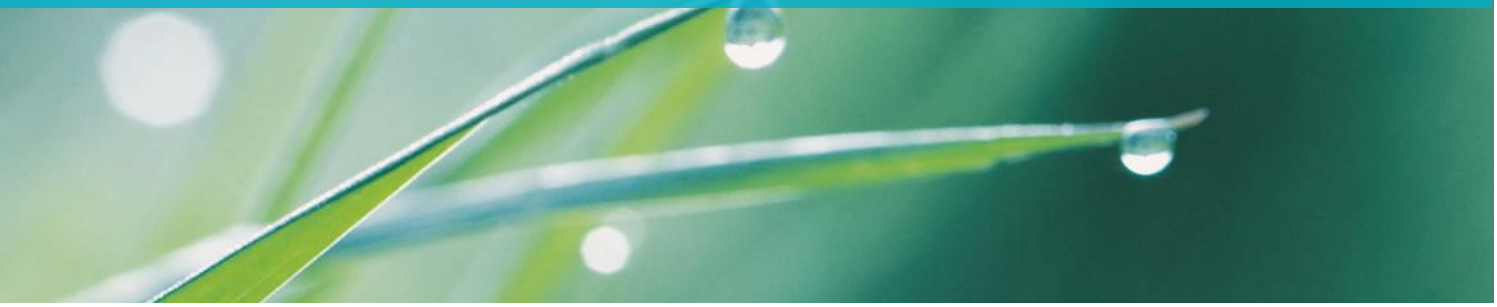
SpeediCath Compact Set Female



15. December 2023
Version 7.0

Safety and Disposal Sheet

Based on template version 9.0

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

Product name:	SpeediCath Compact Set Female
Product code:	28520, 28522, 28524
Product information:	Continence 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.

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.

USA
Coloplast Corp.
1601 West River Road N
Minneapolis, MN 55411
Telephone: +1-800-533-0464
www.us.coloplast.com

Canada
Coloplast Canada Corporation
1380 Creditstone Road, Unit 6&7
Concord, ON, L4K 0J1
Telephone: +1-888-880-8605
www.coloplast.ca

Europe
Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Telephone: +45 49 11 11 11
www.coloplast.com

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Main ingredients and packaging materials are listed below.

Chemical name	CAS no.
Catheter	
PU (Polyurethane)	-
PP (Polypropylene)	9003-07-0
Hydrophilic coating	-
Swelling medium	
PEG	25322-68-3
Bag	
PE/PP multilayer film	-
Packaging	
PP (Polypropylene)	9003-07-0
SEBS (Styrene-Ethylene-Butylene-Styrene)	-
Stainless steel	-

Disposal considerations

Disposal of products and packaging must always comply with local, national and regional regulations.
The product and packaging must not be discharged into the environment.

Product
Products used in private homes may be disposed of as regular mixed household waste. Because of the nature of the product and its intended use, the product is not considered recyclable.

Packaging
Primary packaging should be discarded as regular mixed household waste or sorted for recycling if it meets the criteria for local recycling guidelines. Retail and shipper boxes are made from cardboard and should be sorted for recycling, as cardboard is widely recyclable.

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 75/442/EEC, the following Waste Code can be used[1]:

18 01 04 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)

[1] Applicable waste codes might differ in some cases. It is the responsibility of the holder of the waste to determine the actual classification.

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Also, applicable if the product is or requires a wipe, cloth or similar*: Absorbent/cloth contaminated with the product. EWC code: 15 02 03 Absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02.*

Environmental awareness from the very start

At Coloplast we have a focus on continuously improving our products and packaging, incorporating environmental performance when developing new products. We strive to design our products and packaging to be renewable, recyclable and create less waste and environmental impact. Our efforts are strengthened by engaging with stakeholders throughout our value chain to identify and seize opportunities. Coloplast also supports the UN Sustainable Development Goals (SDGs) and the Business Ambition for 1.5°C in alignment with the Paris Agreement and we aim to reduce our carbon emissions through the Science-Based Targets Initiative.

Environmental Management System

Coloplast has implemented ISO 14001 certified environmental management at the manufacturing sites in Denmark, Hungary, France, Costa Rica, China, USA and plans to expand it to all its manufacturing sites.

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 Safety and Disposal Sheet 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.

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
3.0	April 2019	Updating to new template (version 5.0) and adding information about PEG (swelling medium)
4.0	December 2019	Update to a new template (version 7.0)
5.0	February 2023	Update to a new template (version 8.0) - change references from MDD to MDR. Update the composition – removal of PVP version; adding the bag composition. Update the primary packaging composition.
6.0	June 2023	Change name to Safety and Disposal Sheet (SADS), to be in compliance with legislations. The following changes have been made: • The template has been changed to version 9.0- change Safety Data Sheet/SDS to Safety and Disposal Sheet (SADS). • Update the section “Disposal consideration” to cover the current requirements. • The template is applicable for devices assessed according to MDR No changes to the composition.
7.0	December 2023	Removal of UV-328, due to the implementation of *Estane Change* project. Information about SVHC in the device has been removed.

Document Approvals

Approved Date: 2023-12-19

Approval Task Verdict: Approve	PLALWIN Aleksandra Witkowska-Nowak, Biosafety & Chemical Compliance Specialist (plalwin@coloplast.com) Technical / Specialist 19-Dec-2023 06:01:41 GMT+0000