EU Quality Management Certificate

This is to certify that the company

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

SRN: DE-MF-000005701

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	004567 MDR2017Q
Certificate ID	1000120979
Effective date	2023-05-17
Expiry date	2028-05-03
Frankfurt am Main,	2023-05-17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

Digitally signed by Ghereg Victor
Date: 2024.09.03 10:42:53 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120979

Device categories covered by this certificate:

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Cleaning and disinfection agent for chemo-thermal reprocessing

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Cleaning and disinfection agent for manual reprocessing of medical devices

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Disinfectant for suction unit surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Disinfectant medical devices

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIa
Intended purpose:	Disinfection of dental mouldings

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Risk classification:	IIb
Intended purpose:	Disinfectant of medical device surfaces at the endpoint of reprocessing

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120979

Examinations and tests performed:
004567 A209710MED MDR2017Q dated 2022-09-09

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-05-04	170779017	Addition of the Device category for the product Mikrozid® PAA wipes

EU Technical Documentation Assessment Certificate

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

SRN: DE-MF-000005701

has established and maintains the required Technical Documentation in accordance with

Annex IX, Chapter II of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Technical Documentation has been verified and confirmed in Conformity Assessment Procedures according to Article 52. The Technical Documentation is subject to regular surveillance. Limitations to this certificate are listed in the Annex.

For placing devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter I and III is required.

Devices of class IIa and IIb listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

Certificate registration no.	004567 MDR2017B
Certificate ID	1000120967
Effective date	2023-05-17
Expiry date	2028-05-03
Frankfurt am Main,	2023-05-17

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Device categories and variants covered by this certificate:

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Antifect AF (N)
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000016A9
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Antifect extra
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000017AB
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Aspirmatic
Models:	Aspirmatic, UnoDent Aspisept Daily, PremEco AS
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000018AD
Intended purpose:	Disinfectant for suction unit surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Dentavon
Models:	Dentavon, Perform ID, UnoDent Unoguard
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000019AF
Intended purpose:	Disinfection of dental mouldings

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Gigasept AF forte
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000035AD
Intended purpose:	Cleaning and disinfection agent for manual reprocessing of medical devices

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Gigasept instru AF
Models:	Gigasept instru AF, UnoDent Surgical Instru. Cleanser
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000037AH
Intended purpose:	Cleaning and disinfection agent for manual reprocessing of medical devices

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Gigazyme X-tra
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000039AM
Intended purpose:	Cleaning and disinfection agent for manual reprocessing of medical devices

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mikrozid AF
Models:	Mikrozid AF liquid, Mikrozid AF wipes, Terralin liquid, Mikrozid liquid, Mikrozid wipes, Antifect N liquid, Prem Eco Plus, UnoDent Unosept, UnoDent Unowipes, Terralin AF wipes
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC000000209Y
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mikrozid sensitive
Models:	Mikrozid sensitive liquid, Mikrozid sensitive wipes, Mikrozid alcohol free liquid, Mikrozid alcohol free wipes, Terralin sensitive wipes
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000021A2
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mikrozid universal
Models:	Mikrozid universal liquid, Mikrozid universal wipes, DESIFOR-ONE multi wipes, Pursept A Xpress S, Pursept UniSprint Wipes, Terralin universal wipes
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000022A4
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mucalgin
Models:	Mucalgin, Mucalgin dental
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000028AG
Intended purpose:	Disinfection of dental mouldings

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Perform
Models:	Perform, DESIFOR-ONE PROTECT
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000023A6
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Puresept
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651-BSC000000129Z
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Pursept AF
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000024A8
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Quartamon med
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000026AC
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Terralin protect
Models:	Terralin protect, TPH protect
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000027AE
Intended purpose:	Disinfectant and cleaner for medical device surfaces

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Thermosept NDR
Models:	n/a
Risk classification:	IIa
Basic-UDI-DI:	4032651BSC00000043AC
Intended purpose:	Cleaning and disinfection agent for chemo-thermal reprocessing

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Gigasept® powerTrio disinfection wipe
Models:	n/a
Risk classification:	IIb
Basic-UDI-DI:	4032651BSC00000014A5
Intended purpose:	Disinfectant of medical device surfaces at the endpoint of reprocessing

Device category:	**MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing**
Product name:	Mikrozid® PAA wipes
Models:	n/a
Risk classification:	IIb
Basic-UDI-DI:	4032651-BSC00000011-CP
Intended purpose:	Disinfectant of medical device surfaces at the endpoint of reprocessing

Annex to EU Technical Documentation Assessment Certificate
SRN of Manufacturer: DE-MF-000005701
Certificate ID: 1000120967

Examinations and tests performed:
004567 A209710MED MDR2017B dated 2023-04-19
004567 A209710MED MDR2017B Mikrozid® PAA wipes dated 2023-05-08

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2023-05-04	170779018	Addition of Product Mikrozid® PAA wipes and new trade names Terralin AF , sensitive, universal wipes

CERTIFICATE

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:
Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2018
ISO 13485 : 2016

Certificate registration no.	004567 MP2016
Certificate unique ID	1000188322
Effective date	2024-07-20
Expiry date	2027-07-19
Frankfurt am Main	2024-07-20

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS IS A MEMBER OF
IQNET

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Szymon Kurdyn
Product Manager

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, info-med@dqs.de
The validity of the certification can only be verified by the QR-code.

414_90e Version 3.0

Annex to certificate
Certificate registration No.: 004567 MP2016
Certificate unique ID: 1000188322
Effective date: 2024-07-20

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Location	Scope
525120 **Schülke & Mayr GmbH** Robert-Koch-Straße 2 22851 Norderstedt Germany	Development, production and sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
249794 **Schülke & Mayr AG** Hungerbüelstrasse 22 8500 Frauenfeld Switzerland	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
068164 **Schülke & Mayr Ges. m. b. H.** Seidengasse 9 1070 Wien Austria	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
389168 **Schülke France S.A.R.L.** Route des Varennes 71100 Chalon sur Saône France	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
082146 **Schülke & Mayr UK Ltd.** Cygnet House, 1 Jenkin Road, Meadowhall Sheffield S9 1AT United Kingdom	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

Annex to certificate
Certificate registration No.: 004567 MP2016
Certificate unique ID: 1000188322
Effective date: 2024-07-20

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Location	Scope
226915 **Schülke & Mayr Benelux B.V.** Oudeweg 8d 2031 CC Haarlem Netherlands	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
515594 **Schulke Polska Sp. z o.o.** **Eurocentrum Office Complex** Budynek Delta al. Jerozolimskie 132 02-305 Warszawa Poland	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.

DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Date: 2023.12.18

Notified Body Confirmation Letter
Reference: 1000156054

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

SRN: DE-MF-000005701

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.
In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices. The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices

- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Hovsep Aro
Regulatory Affairs Manager

i.A. 

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
octenisan® md nasal gel	Class IIa	N/A	004567 MR2 NB 0297
octenilin® wound gel	Class IIb excluding Class IIb implantable non-WET	N/A	004567 MR2 NB 0297
octenilin® wound irrigation solution	Class IIb excluding Class IIb implantable non-WET	N/A	004567 MR2 NB 0297
octenisept® gel / octenisept® wound gel	Class IIb excluding Class IIb implantable non-WET	N/A	004567 MR2 NB 0297
thermosept® ED	Class IIb excluding Class IIb implantable non-WET	N/A	004567 MR2 NB 0297
gigasept® FF new / desimatic ID plus	Class IIb excluding Class IIb implantable non-WET	N/A	004567 MR2 NB 0297
rotasept®	Class IIb excluding Class IIb implantable non-WET	N/A	004567 MR2 NB 0297

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-12-18	1000156054	Initial issue
	Cert-ID	description of change (e.g. addition of device XYZ to Table 1)
	Cert-ID	description of change (e.g. removal of device XYZ from Table 2)

Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Schülke & Mayr GmbH
Manufacturer address and contact details	Robert-Koch-Str. 2 22851 Norderstedt Germany
Single Registration Number (SRN)	DE-MF-000005701

Notified body name	DQS Medizinprodukte GmbH
Notified body number	0297
Directive Certificate number to which this confirmation is made	004567 MR2
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	18.12.2023
End date of extended validity/transition period	31.12.2028

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

Schülke & Mayr GmbH
Robert-Koch-Str. 2 | 22851 Norderstedt | Postal address: 22840 Norderstedt | Germany
Phone.: +49 40 52100-0 | Fax: +49 40 52100-318
info@schuelke.com | www.schuelke.com
Trade register number: District court Kiel, HRB 38 21 NO
Managing Directors: Stefan Kukacka (Chairman), Hans-Christian Nehlsen

Banking details: Commerzbank AG Frankfurt/ Main
BSC 200 400 00 | Account: 42 46 757 00
SWIFT-BIC: COBA DE FFXXX | IBAN: DE20 2004 0000 0424 6757 00
VAT Reg.No.: DE 81 2065369
Creditor Identifier: DE10ZZZ00000006191

namely by fulfilling the following conditions:

- **Directive Certificate** as listed above or in the attached schedule
  - Directive Certificate covering the listed devices was issued after 25 May 2017, was valid on 26 May 2021 and has not been withdrawn afterwards.

    Expired/expires *after* 20 March 2023:

    Formal applications to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment have been made for the devices listed in the attached schedule and signed written agreements will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- **Quality Management System (QMS)**

  A notified body has issued a certificate for the MDR-compliant QMS.
- **Devices as listed in the attached schedule**
  - The devices continue to comply with MDD.
  - There are no significant changes in the design and intended purpose.
  - The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Schülke & Mayr GmbH Norderstedt 09.11.2023

Digital unterschrieben
von Dr. Susanne Hendrich
Datum: 2023.11.09
07:25:23 +01'00'

i.V. Dr. Susanne Hendrich

Senior Head of Regulatory Affairs

Schülke & Mayr GmbH
Robert-Koch-Str. 2 | 22851 Norderstedt | Postal address: 22840 Norderstedt | Germany
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VAT Reg.No.: DE 81 2065369
Creditor Identifier: DE10ZZZ00000006191

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the devices (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)**
thermosept® ED	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	**31.12.2028**	n/a
gigasept® FF new / Desimatic ID plus	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	**31.12.2028**	n/a
rotasept®	004567 MR2	18.12.2023	DQS Medizinprodukte GmbH 0297	DQS Medizinprodukte GmbH 0297	**31.12.2028**	n/a

Schülke & Mayr GmbH
Robert-Koch-Str. 2 | 22851 Norderstedt | Postal address: 22840 Norderstedt | Germany
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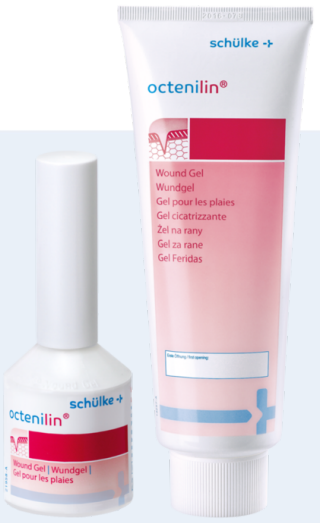
Trade register number: District court Kiel, HRB 38 21 NO
Managing Directors: Stefan Kukacka (Chairman), Hans-Christian Nehlsen

Banking details: Commerzbank AG Frankfurt/ Main
BSC 200 400 00 | Account: 42 46 757 00
SWIFT-BIC: COBA DE FFXXX | IBAN: DE20 2004 0000 0424 6757 00
VAT Reg.No.: DE 81 2065369
Creditor Identifier: DE10ZZZ00000006191



Wound gel for covering, moistening and cleansing of encrusted, contaminated and chronic wounds as well as burn wounds

octenilin® wound gel

Our Plus

- effectively moisturises and cleans wounds
- helps loosen wound coatings
- creates an ideal wound healing environment to support the natural healing process
- pain free, colourless and odour absorbent
- contains Octenidine as preservative, capable of inactivating pathogens in the gel to build a protective barrier against penetrating germs.

Application areas

- for moistening and cleansing of chronic wounds
- for the preservative moistening of wound dressings
- for loosening of coatings - even strongly encrusted coatings
- for the support of the natural healing process
- for the treatment of thermally induced large area wounds

Product Profile

Treament of second-degree burns octenilin® Wound Gel was used in a study on 107 subjects with grade IIa burns of the skin.
The moist dressing was easy to use and could be left on the wound for up to five days thanks to its antimicrobial preservative.
The pain was minimised and the number of required dressing exchanges reduced. 45 % of the subjects reported feeling comfortable or pain free with the first application.
No intolerance reactions within the meaning of allergic skin irriations, skin reddening etc. were observed.[1]
Non-irritating, non-sensitising, pain-free use, without tissue toxicity, no impairment of granulation or epithelialisation. The good tolerability of Octenidine has been confirmed by clinical experience over many years and by clinical studies also on chronic wounds.

Testing of the preservative properties of Octenidin in the gel

octenilin® Wound Gel shows excellent inactivation of pathogens after as early as 1 minute. The latter was determined in the quantitative suspension test with high protein exposure ('dirty conditions'). The results showed that the inactivation of pathogens in octenilin® Wound Gel was sufficient against all test organisms after a 1 minute application.[2]

Instructions for use

Wounds should always be irrigated and cleansed (e.g. octenilin® wound irrigation solution) to remove easily soluble encrustations before further treatment with octenilin® Wound Gel.
Bandages, gauze, compresses or other absorbent materials or wound-filling materials can be soaked or moistened before being applied to wounds.
octenilin® Wound Gel can remain on the wound until the next change of dressing. The frequency of dressing change depends on the nature of the wound and the amount of exudate and should be adapted to the current wound situation, but should be done after max. 3 days. If used with paraffin gauzes, the dressing is to be changed and the wound cleaned daily. Application should be repeated frequently until all encrustations or necrotic tissue are easily removed and the wound is clean on inspection.

CE 0297

octenilin® wound gel

Product data

Ingredients:
Aqua purificata, Propylene Glycol, Hydroxyethylcellulose, Octenidine HCl.
Original condition:
Sterile, sealed.
Stability at 5 - 25 °C, see stability information.

Chemical-physical data	
Color	nearly colourless
Density	ca. 1,01 g/cm3 / 20 °C
Flash point	> 61 °C / Method : ISO 2719
Form	viscous
pH	ca. 6,9 / 20 °C
Viscosity, dynamic	ca. 5.050 mPa*s

Special advice

Contraindications

octenilin® Wound Gel should not be used in patients with known or suspected allergy to one or more of the ingredients. If in doubt consult a physician.
To prevent possible tissue damage, octenilin® Wound Gel should not be used on hyaline cartilage, the eyes, ears, nose, urinary bladder and in the abdominal cavity! Do not use for infusion or injection! Not for oral use!
General safety information

- Use only intact and undamaged packs.
- Protect the product against exposure to direct sunlight.
- To prevent the introduction of bacteria when using octenilin® Wound Gel, ensure that the packaging does not come into contact with the wound!
- Do not use in combination with PVP-iodine, since this may cause discoloration and impair the antiseptic effect of the PVP-iodine
- Medical device - Keep out of the reach and sight of children!

For further information please read the package leaflet before use.

Information for order

Item	Delivery form	Item no.
octenilin Wound Gel 250 ml TB	6/Carton	on request
octenilin® wound gel	20/Carton	on request

These products are not available in every country. For more information please contact our local subsidiary or distributor.

Related Products

- octenilin® wound irrigation solution

Environmental information

schülke manufactures products economically and with advanced, safe and environmentally friendly production processes while at the same time maintaining out high quality standards.

Expert opinion and information

Please visit our website for an overview of all available literature/reports on the product: www.schuelke.com.
For individual questions:
Application Department
Phone: +49 40 52100-666
E-Mail: info@schuelke.com

1
C. Ottomann und B. Hartmann Unfallkrankenhaus Berlin Zentrum für Schwerbrandverletzte mit Plastischer Chirurgie Berlin, 9. Mai 2005
2
Dr. P. Goroncy-Bermes, Schülke & Mayr F&E, Norderstedt, 2. März 2007

Schülke & Mayr GmbH holds a Manufacturer's Authorisation according to sect 13 para 1 German Drug Law and Certificates of GMP Compliance for medicinal products.

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info@schuelke.com

#2044 / 910741-WORLD-en-04-08 2/2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : octenilin® wound gel

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Medical device

Recommended restrictions on use : Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Manufacturer/ Supplier : Schülke & Mayr GmbH
Robert-Koch-Str. 2

22851 Norderstedt
Germany
Telephone: +49 (0)40/ 52100-0
Telefax: +49 (0)40/ 52100318
mail@schuelke.com
www.schuelke.com

E-mail address of person responsible for the SDS/Contact person : Application Department
+49 (0)40/ 521 00 8800
ApplicationDepartment.SM@schuelke.com
(Schülke & Mayr UK Ltd.: +44-1142543500)

1.4 Emergency telephone number

Emergency telephone number : UK Poisons Emergency number: 0870 600 6266

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
Contact with eyes may cause irritation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : viscous liquid

Hazardous components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride	70775-75-6 274-861-8 - - - 01-2120750372-60-0000	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	< 0,1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of eye contact : Flush eyes with water as a precaution.
If eye irritation persists, consult a specialist.

If swallowed : Do NOT induce vomiting.
Drink water as a precaution.
Consult a physician if necessary.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : For specialist advice physicians should contact the Poisons Information Service.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Dry powder
Foam
Water spray jet
Carbon dioxide (CO2)

Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : No special precautions required.

6.2 Environmental precautions

Environmental precautions : Avoid subsoil penetration.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).

6.4 Reference to other sections

See chapter 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : not required under normal use

Advice on protection against fire and explosion : No special protective measures against fire required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Store at room temperature in the original container.

Further information on storage conditions : Keep away from direct sunlight. Recommended storage temperature: -5 - 25°C

Advice on common storage : No materials to be especially mentioned.

7.3 Specific end use(s)

Specific use(s) : none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

none

8.2 Exposure controls

Personal protective equipment

Protective measures : No special precautions required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	viscous
Colour	:	nearly colourless
Odour	:	odourless
Odour Threshold	:	not determined
pH	:	ca. 6,9 (20 °C)
Melting point/freezing point	:	ca. 0 °C
Decomposition temperature		No data available
Boiling point/boiling range	:	ca. 90 °C
Flash point	:	> 61 °C Method: ISO 2719
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit	:	Not applicable
Lower explosion limit	:	Not applicable
Vapour pressure	:	ca. 25 hPa (20 °C) similar to water
Vapour density	:	No data available
Relative density	:	ca. 1,01 g/cm3 (20 °C)
Solubility(ies)		
Water solubility	:	in all proportions (20 °C)
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	ca. > 300 °C
Viscosity		
Viscosity, dynamic	:	ca. 5.050 mPa*s
Explosive properties	:	No data available

Oxidizing properties : No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

The product is chemically stable.

10.3 Possibility of hazardous reactions

Hazardous reactions : None reasonably foreseeable.

10.4 Conditions to avoid

Conditions to avoid : Keep at temperature not exceeding 25 °C.

10.5 Incompatible materials

Materials to avoid : Never mix concentrates directly.

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Acute oral toxicity	:	LD50 (Rat): > 800 mg/kg, OECD Test Guideline 401, Harmful if swallowed.
Acute inhalation toxicity	:	LC50 (Rat): > 4,0 mg/l, 4 h, OECD Test Guideline 403, 0,1 % solution
Acute dermal toxicity	:	No data available
Acute toxicity (other routes of administration)	:	LD50 intravenous (Rat): 10 mg/kg , OECD Test Guideline 401

Skin corrosion/irritation

Product:

No skin irritation

Serious eye damage/eye irritation

Product:

Contact with eyes may cause irritation.

Respiratory or skin sensitisation

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
Did not cause sensitisation on laboratory animals.Maximisation Test, Guinea pig, OECD Test Guideline 406

Germ cell mutagenicity

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Genotoxicity in vitro	:	Ames test, OECD Test Guideline 471, Non mutagenic
Germ cell mutagenicity- Assessment	:	Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

Carcinogenicity

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
Mouse, Dermal exposure, OECD Test Guideline 451, Based on available data, the classification criteria are not met.

Carcinogenicity - Assessment	:	Animal testing did not show any carcinogenic effects.

Reproductive toxicity

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Effects on fertility	:	Rat, Oral, Based on available data, the classification criteria are not met.
Effects on foetal development	:	Rat, Oral, OECD Test Guideline 414, Based on available data, the classification criteria are not met.
Reproductive toxicity - Assessment	:	No toxicity to reproduction

STOT - single exposure

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
No data available

STOT - repeated exposure

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
No data available

Repeated dose toxicity

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
Mouse, NOAEL: 32 mg/kg, Oral, OECD Test Guideline, 408

Aspiration toxicity

No data available

Further information

Product:

none

SECTION 12: Ecological information

12.1 Toxicity

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Toxicity to fish	:	LC50 (Brachydanio rerio (zebrafish)): 0,17 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0,007 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): 0,034 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Short-term (acute) aquatic hazard)	:	100
Toxicity to microorganisms	:	EC50 (activated sludge): 2,77 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,0056 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Long-term (chronic) aquatic hazard)	:	10
Toxicity to soil dwelling organisms	:	LC50: > 1.000 mg/kg Species: Eisenia fetida (earthworms) Method: OECD Test Guideline 207
Plant toxicity	:	LC50: > 1.000 mg/kg Species: Lactuca sativa (lettuce) Method: OECD Test Guideline 208
Toxicity to terrestrial organisms	:	EC50: > 1.000 mg/kg Method: OECD Test Guideline 216

12.2 Persistence and degradability

Product:

Biodegradability	:	Remarks: The methods for determining biodegradability are

not applicable to inorganic substances.

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Biodegradability	:	Result: Not biodegradable Method: OECD 301D / EEC 84/449 C6

12.3 Bioaccumulative potential

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Bioaccumulation	:	Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water	:	log Pow: 1,5 (23 °C) Method: OECD Test Guideline 123

12.4 Mobility in soil

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Mobility	:	Remarks: Adsorbs on soil.

12.5 Results of PBT and vPvB assessment

Product:

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

12.6 Other adverse effects

Product:

Additional ecological information	:	No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of the product according to the defined EWC (European Waste Code) No.
Contaminated packaging	:	Take empty packaging to the recycling plant.

Waste key for the unused product	:	European waste catalog (EWC) 070601
Waste key for the unused product(Group)	:	Waste material of HZVA from fats, lubricants, soaps, detergents, disinfectants and personal protection products.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable
For personal protection see section 8.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants	:	Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Volatile organic compounds	:	Remarks: none, Directive 2010/75/EC on the limitation of emissions of volatile organic compounds

Other regulations:

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.
Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values.

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statements

H302	:	Harmful if swallowed.
H315	:	Causes skin irritation.
H319	:	Causes serious eye irritation.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Irrit.	:	Eye irritation
Skin Irrit.	:	Skin irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Changes compared with the previous edition!!!

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Z_Z / EN

schülke

Wound irrigation solution for cleansing and moistening of chronic skin wounds.

octenilin® wound irrigation solution

Our Plus

- excellent cleaning performance
- especially well-tolerated by the skin and tissues
- for all wound situations
- for repeated and long-term use
- sterile

Application areas

- rapid, effective cleansing of wounds
- for the removal of wound crusts consisting of necrotic tissue, pathogens, biofilm and fibrinous films
- suitable for difficult to access areas, such as fissures and wound pockets
- for moistening and moisturisation of wounds
- for moisturisation of dressings and wound pads
- for gentle removal of difficult to remove, caked dressings/ wound pads
- for combined use with Negative Pressure Wound Therapy (V.A.C.Ulta, KCl)

Product Profile

Moisturising property

Due to its low surface tension, octenilin® Wound Irrigation Solution has excellent moisturising properties and thus cleansing properties on tissue surfaces, even difficult to reach surfaces, such as fissures and wound pockets.

Cleansing power to remove biofilms

Studies on the cleansing power against microorganisms in the biofilm revealed a good performance.
In comparison to wound irrigation solutions such as Ringer or isotonic saline solutions commonly used in hospitals, octenilin® Wound Irrigation Solution shows a significantly better cleansing power and, therefore, a better reduction of pathogens.

Conservation

octenilin® Wound Irrigation Solution is conserved as to considerably reduce the risk of germ conveyance into the adjacent surroundings during application. octenilin® Wound Irrigation Solution thus offers, if applied according to the instructions, an effective germ barrier between the wound and the treated person.

Tissue tolerability and biocompatibility

Non-irritating, non-sensitising, free of pain, without tissue toxicity, no impairment granulation and no impairment of the epithelialisation. The good tolerability of Octenidine has been confirmed by clinical experience over many years and by clinical studies on chronic wounds as well.

Instructions for use

Intensively irrigate and clean the wound with octenilin® Wound Irrigation Solution during each change of dressing (octenilin® Wound Irrigation Solution can be warmed up to body temperature immediately before application). Easily removable coverings can already be removed this way. Dressings and wound coverings additionally soaked with octenilin® Wound Irrigation Solution can be used to solvate fibrin coverings. The application should be repeated until all coverings and necroses can be removed and the wound is optically clean. Rinsing afterwards is generally not necessary. The wound can be further treated with octenilin® wound gel, if necessary.

Best before 8 weeks after the first use.

CE 0297

octenilin® wound irrigation solution

Product data

Ingredients:
Aqua valde purificata, Glycerol, Ethylhexylglycerin, Octenidine HCl
Original condition:
Sterile, sealed. Stability at room temperature, see stability information.
Use before:
8 weeks after first opening. The bottle must be closed after each use.

Chemical-physical data	
Color	colourless
Density	ca. 1,0 g/cm3 / 20 °C
Flash point	Not applicable
Form	liquid
pH	ca. 5,4 / 20 °C
Viscosity, dynamic	No data available

Special advice

Use with caked dressings, i. e. dressings that are difficult to remove

If the wound dressing is difficult to remove, soaking it with octenilin® Wound Irrigation Solution is recommended to facilitate the gentle removal of the dressing without traumatising the wound surface.

Side effects

None observed.

Contraindications

octenilin® Wound Irrigation Solution should not be used in patients with known or suspected allergy to one or more of the ingredients. If in doubt consult a physician.octenilin® wound irrigation solution should not be used on hyaline cartilage, the eyes, ears, nose, urinary bladder and in the abdominal cavity! To prevent possible tissue injury, the product must not be injected or applied to tissues with pressure. Adequate drainage from wound cavities must be provided (e.g. for flexible drain tube).

General safety instructions

- Do not use for infusion or injection!
- Not for oral use!
- Only to be applied to the wound externally.
- Only flawless and undamaged container must be used.
- Use only intact and undamaged packs. Protect the product against exposure to direct sunlight.
- To prevent the introduction of bacteria when using octenilin® wound irrigation solution, ensure that the packaging does not come into contact with the wound.
- Medical device - Keep out of the reach and sight of children!

Information for order

Item	Delivery form	Item no.
octenilin wound irrigation 350 ml FL	10/Carton	on request

These products are not available in every country. For more information please contact our local subsidiary or distributor.

Related Products

- octenilin® wound gel

Environmental information

schülke manufactures products economically and with advanced, safe and environmentally friendly production processes while at the same time maintaining our high quality standards.

Expert opinion and information

Please visit our website for an overview of all available literature/reports on the product: www.schuelke.com.
For individual questions:
Customer Sales Service
Phone: +49 40 52100-666
E-Mail: info@schuelke.com

Schülke & Mayr GmbH holds a Manufacturer's Authorisation according to sect 13 para 1 German Drug Law and Certificates of GMP Compliance for medicinal products.

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#2098 / 910826-WORLD-en-01-13 1/2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : octenilin® wound irrigation solution

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Medical device

Recommended restrictions on use : Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Manufacturer/ Supplier :
Schülke & Mayr GmbH
Robert-Koch-Str. 2

22851 Norderstedt
Germany
Telephone: +49 (0)40/ 52100-0
Telefax: +49 (0)40/ 52100318
mail@schuelke.com
www.schuelke.com

E-mail address of person responsible for the SDS/Contact person :
Application Department
+49 (0)40/ 521 00 8800
ApplicationDepartment.SM@schuelke.com
(Schülke & Mayr UK Ltd.: +44-1142543500)

1.4 Emergency telephone number

Emergency telephone number : UK Poisons Emergency number: 0870 600 6266

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
No special risks known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Aqueous solution

Hazardous components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride	70775-75-6 274-861-8 - - - 01-2120750372-60-0000	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	< 0,1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

In case of eye contact : Flush eyes with water as a precaution.
If eye irritation persists, consult a specialist.

If swallowed : Do NOT induce vomiting.
Drink water as a precaution.
Consult a physician if necessary.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : For specialist advice physicians should contact the Poisons Information Service.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Dry powder
Foam
Water spray jet
Carbon dioxide (CO2)

Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting	:	No information available.

5.3 Advice for firefighters

Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions	:	No special precautions required.

6.2 Environmental precautions

Environmental precautions	:	Avoid subsoil penetration.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	:	Wipe up with absorbent material (e.g. cloth, fleece).

6.4 Reference to other sections

See chapter 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling	:	not required under normal use
Advice on protection against fire and explosion	:	No special protective measures against fire required.
Hygiene measures	:	Keep away from food and drink.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Store at room temperature in the original container.
Further information on storage conditions	:	Keep away from direct sunlight. Do not store at temperatures above 30°C.
Advice on common storage	:	No materials to be especially mentioned.

7.3 Specific end use(s)

Specific use(s)	:	none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

none

8.2 Exposure controls

Personal protective equipment

Protective measures : No special precautions required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	colourless
Odour	:	nearly odourless
Odour Threshold	:	not determined
pH	:	ca. 5,4 (20 °C)
Melting point/freezing point	:	ca. 0 °C
Decomposition temperature		No data available
Boiling point/boiling range	:	ca. 100 °C
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	ca. 25 hPa (20 °C) similar to water
Vapour density	:	No data available
Relative density	:	ca. 1,0 g/cm3 (20 °C)
Solubility(ies)		
Water solubility	:	in all proportions (20 °C)
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition temperature	:	No data available

Viscosity
Viscosity, dynamic : No data available

Explosive properties : No data available

Oxidizing properties : No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

The product is chemically stable.

10.3 Possibility of hazardous reactions

Hazardous reactions : None reasonably foreseeable.

10.4 Conditions to avoid

Conditions to avoid : Do not store at temperatures above 30°C.

10.5 Incompatible materials

Materials to avoid : Never mix concentrates directly.

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity : This information is not available.

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Acute inhalation toxicity : LC50 (Rat): > 4,0 mg/l, 4 h, OECD Test Guideline 403, 0,1 % solution

Acute dermal toxicity : No data available

Acute toxicity (other routes of administration) : LD50 intravenous (Rat): 10 mg/kg , OECD Test Guideline 401

Skin corrosion/irritation

Product:

No skin irritation

Serious eye damage/eye irritation

Product:

Contact with eyes may cause irritation.

Respiratory or skin sensitisation

Product:

Contains no substance or substances classified as sensitising. , May cause sensitisation of susceptible persons by skin contact.

Germ cell mutagenicity

Product:

Germ cell mutagenicity- Assessment	:	Contains no ingredient listed as a mutagen

Carcinogenicity

Product:

Carcinogenicity - Assessment	:	Contains no ingredient listed as a carcinogen

Reproductive toxicity

Product:

Reproductive toxicity - Assessment	:	Contains no ingredient listed as toxic to reproduction

STOT - single exposure

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
No data available

STOT - repeated exposure

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
No data available

Repeated dose toxicity

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:
Rat, NOAEL: 32 mg/kg, Oral, OECD Test Guideline, 408

Aspiration toxicity

No data available

Further information

Product:

No data is available on the product itself.

SECTION 12: Ecological information

12.1 Toxicity

Product:

Ecotoxicology Assessment

Short-term (acute) aquatic hazard	:	This product has no known ecotoxicological effects.

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Toxicity to fish	:	LC50 (Brachydanio rerio (zebrafish)): 0,17 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0,007 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): 0,034 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Short-term (acute) aquatic hazard)	:	100
Toxicity to microorganisms	:	EC50 (activated sludge): 2,77 mg/l Exposure time: 3 h Method: OECD Test Guideline 209
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,0056 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Long-term (chronic) aquatic hazard)	:	10
Toxicity to soil dwelling organisms	:	LC50: > 1.000 mg/kg Species: Eisenia fetida (earthworms) Method: OECD Test Guideline 207
Plant toxicity	:	LC50: > 1.000 mg/kg Species: Lactuca sativa (lettuce) Method: OECD Test Guideline 208
Toxicity to terrestrial organisms	:	EC50: > 1.000 mg/kg Method: OECD Test Guideline 216

12.2 Persistence and degradability

Product:

Biodegradability : Remarks: Not applicable

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Biodegradability : Result: Not biodegradable
Method: OECD 301D / EEC 84/449 C6

12.3 Bioaccumulative potential

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : log Pow: 1,5 (23 °C)
Method: OECD Test Guideline 123

12.4 Mobility in soil

Product:

Mobility : Remarks: No data available

Components:

N,N'-(decane-1,10-diyldi-1(4H)-pyridyl-4-ylidene) bis(octylammonium) dichloride:

Mobility : Remarks: Adsorbs on soil.

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

12.6 Other adverse effects

Product:

Additional ecological information : No data is available on the product itself.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of the product according to the defined EWC (Euro-

pean Waste Code) No.

Contaminated packaging	:	Take empty packaging to the recycling plant.
Waste key for the unused product	:	European waste catalog (EWC) 070601
Waste key for the unused product(Group)	:	Waste material of HZVA from fats, lubricants, soaps, detergents, disinfectants and personal protection products.

SECTION 14: Transport information

14.1 UN number

IMDG : -

IATA : -

14.2 UN proper shipping name

IMDG : -

IATA : -

14.3 Transport hazard class(es)

IMDG : -

IATA : -

14.4 Packing group

IMDG
Packing group : -

IATA (Cargo)
Packing group : -

IATA (Passenger)
Packing group : -

14.5 Environmental hazards

IMDG
Marine pollutant : no

14.6 Special precautions for user

Not applicable
For personal protection see section 8.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Volatile organic compounds : Remarks: none, Directive 2010/75/EC on the limitation of emissions of volatile organic compounds

Other regulations:

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.
Take note of Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values.

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statements

H302	:	Harmful if swallowed.
H315	:	Causes skin irritation.
H319	:	Causes serious eye irritation.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Irrit.	:	Eye irritation
Skin Irrit.	:	Skin irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical

Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Changes compared with the previous edition!!!

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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