EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

schülke

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

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

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Disinfectant for medical devices, wound care products and gel as listed in annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	004567 MR2
Certificate unique ID	170742365
Effective date	2020-06-09
Expiry date	2023-12-18
Frankfurt am Main	2020-06-09

DQS Medizinprodukte GmbH

Digitally signed by Dubalari Pavel
Date: 2022.01.18 10:23:44 EET
Reason: MoldSign Signature
Location: Moldova

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 004567 MR2
Certificate unique ID: 170742365
Effective date: 2020-06-09

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Device	Class
acryl-des® Gebrauchslösung	IIa
acryl-des® Desinfektionstücher	IIa
antifect® AF (N)	IIa
antifect® N liquid	IIa
antifect® extra	IIa
aspirmatic®	IIa
boots wound healing gel	IIb
dentavon®	IIa
dentavon® liquid	IIa
Essential+ Wipes	IIa
gigasept® AF	IIb
gigasept® AF forte	IIb
gigasept® FF (neu)	IIb
gigasept® Instru AF	IIb
gigasept® med	IIb
gigasept® pearls	IIb
gigasonic®	IIb
gigazyme® Xtra	IIb
mikrozid® AF liquid	IIa
mikrozid® AF wipes	IIa
mikrozid® alcohol free liquid	IIa
mikrozid® alcohol free wipes jumbo	IIa
mikrozid® liquid	IIa
mikrozid® PAA wipes	IIb
mikrozid® sensitive liquid	IIa
mikrozid® sensitive wipes	IIa
mikrozid® universal liquid	IIa
mikrozid® universal wipes	IIa
mikrozid® wipes	IIa
mucalgin®	IIa
mucadont® IS	IIb
mucapur® CD	IIa
mucocit® T	IIb
octenilin® wound gel	IIb
octenilin® wound irrigation solution	IIb
octenisan® md nasal gel	IIa
octenisept® Gel	IIb
octenisept® wound gel	IIb

Annex to certificate
Certificate registration No.: 004567 MR2
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Effective date: 2020-06-09

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Device	Class
perform®	IIa
pursept® AF	IIa
pursept® A Xpress liquid	IIa
pursept® A Xpress wipes	IIa
quartamon® med	IIa
rotasept®	IIb
septinol® SA	IIa
terralin® liquid	IIa
terralin® protect	IIa
thermosept® ED	IIb
thermosept® NDR	IIa
TPH® protect	IIa
SteraClar Daily	IIa
SteraDif Powder	IIa
SteraPex	IIb
SteraPex Rotary	IIb
SteraClens Alcohol Free	IIa
SteraClens	IIa
SteriWipe+ Alcohol Free	IIa
SteriWipe+	IIa
DESIMATIC-ID PLUS	IIb
DESIFOR-ONE multi wipes	IIa
DESIFOR-ONE PROTECT	IIa
B3	IIa

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 : 2016
ISO 13485 : 2016

Certificate registration no.	004567 MP2016
Certificate unique ID	170774693
Effective date	2021-06-27
Expiry date	2024-06-26
Frankfurt am Main	2021-06-27

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

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
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August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

410.90.en Version 1.0

Annex to certificate
Certificate registration No.: 004567 MP2016
Certificate unique ID: 170774693
Effective date: 2021-06-27

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Location	Scope
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.
Schülke & Mayr AG Sihlfeldstrasse 58 8003 Zürich Switzerland	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
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.
Schülke France S.A.R.L. 50 boulevard National 92250 La Garenne France	Sales of products for disinfection and cleaning of medical instruments, devices and surfaces as well as for wound treatment.
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.
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.
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.

This annex is only valid in connection with the above-mentioned certificate.

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

1.1 Product identifier

Trade name : desderman® pure

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

Use of the Substance/Mixture : Disinfectants and general biocidal products

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

E-mail address of person responsible for the SDS/Contact person : Application Department
+49 (0)40/ 521 00 8800
ADHI@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)

Flammable liquids, Category 2	H225: Highly flammable liquid and vapour.
Eye irritation, Category 2	H319: Causes serious eye irritation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

Precautionary statements : P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P403 + P233 Store in a well-ventilated place. Keep container tightly closed.
P501 Dispose of contents/ container to an approved waste disposal plant.

Further information : Use biocides safely. Always read the label and product information before use.

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.
Vapours are heavier than air and may spread along floors.
Take precautionary measures against static discharge.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Solution of the following substances with harmless additives.

Hazardous components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Ethanol	64-17-5 200-578-6 603-002-00-5 01-2119457610-43-XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319	78,2
Propan-2-ol	67-63-0 200-661-7 603-117-00-0 01-2119457558-25-XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336	10
Biphenyl-2-ol	90-43-7 201-993-5 604-020-00-6 - - -	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335 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

General advice	:	Take off all contaminated clothing immediately.
If inhaled	:	Move to fresh air. If symptoms persist, call a physician.
In case of eye contact	:	Rinse thoroughly with plenty of water, also under the eyelids. If eye irritation persists, consult a specialist.
If swallowed	:	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. If swallowed, seek medical advice immediately and show this container or label.

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 Alcohol-resistant 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	:	Vapours are heavier than air and may spread along floors. Cool closed containers exposed to fire with water spray.
Hazardous combustion prod-ucts	:	Vapours may form explosive mixtures with air.

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 : Ensure adequate ventilation.
Remove all sources of ignition.

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).
Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

6.4 Reference to other sections

see Section 8 + 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition - No smoking. Keep away from children.

Advice on protection against fire and explosion : The hot product gives off combustible vapours. Take measures to prevent the build up of electrostatic charge.

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. Keep at temperature not exceeding 25 °C.

Further information on storage conditions : Keep away from direct sunlight. Keep container tightly closed.

Advice on common storage : Do not store together with oxidising agents.

7.3 Specific end use(s)

Specific use(s) : none

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Ethanol	64-17-5	Permissible ex-	500 ppm	TRGS 900

		posure limit	960 mg/m3	
		Ceiling Limit Value	1.000 ppm 1.920 mg/m3	TRGS 900
		Permissible exposure limit	1.000 ppm 1.900 mg/m3	OSHA
Propan-2-ol	67-63-0	Permissible exposure limit	200 ppm 500 mg/m3	TRGS 900
		Ceiling Limit Value	400 ppm 1.000 mg/m3	TRGS 900
		Permissible exposure limit	400 ppm 980 mg/m3	OSHA

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Ethanol	Workers	Inhalation	Acute effects, Local effects	1900 mg/m3
	Workers	Skin contact	Chronic effects	343 mg/kg
	Workers	Inhalation	Chronic effects	950 mg/m3
Propan-2-ol	Workers	Skin contact	Long-term exposure, Systemic effects	888 mg/kg
	Workers	Inhalation	Long-term exposure, Systemic effects	500 mg/m3
Biphenyl-2-ol	Workers	Inhalation	Long-term systemic effects	19,25 mg/m3
	Workers	Dermal	Long-term systemic effects	21,84 mg/kg

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Ethanol	Fresh water	0,96 mg/l
	Marine water	0,79 mg/l
	Fresh water sediment	3,6 mg/kg
	Soil	0,63 mg/kg
Propan-2-ol	Fresh water	140,9 mg/l
	Marine water	140,9 mg/l
	Fresh water sediment	552 mg/kg
	Marine sediment	552 mg/kg
	Soil	28 mg/kg
	Intermittent use/release	140,9 mg/l
	Effects on waste water treatment plants	2251 mg/l
	Oral	160 mg/kg food
Biphenyl-2-ol	Fresh water	0,0009 mg/l
	Marine water	0,00009 mg/l
	Intermittent use/release	0,027 mg/l
	Sewage treatment plant	0,56 mg/l
	Fresh water sediment	0,1284 mg/kg
	Marine sediment	0,01284 mg/kg
	Soil	2,5 mg/kg

8.2 Exposure controls

Personal protective equipment

Eye protection	:	If splashes are likely to occur, wear: Safety glasses with side-shields conforming to EN166
Protective measures	:	Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	liquid
Colour	:	colourless
Odour	:	alcohol-like
Odour Threshold	:	not determined
pH	:	Not applicable
Melting point/freezing point	:	< -5 °C
Decomposition temperature		No data available
Boiling point/boiling range	:	ca. 80 °C
Flash point	:	16 °C Method: DIN 51755 Part 1
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit	:	15 %(V) Raw material
Lower explosion limit	:	3,1 %(V) Raw material
Vapour pressure	:	ca. 50 hPa (20 °C)
Vapour density	:	No data available
Relative density	:	ca. 0,83 g/cm3 (20 °C)
Solubility(ies)		
Water solubility	:	in all proportions (20 °C)
Partition coefficient: n-octanol/water	:	Not applicable
Flow time	:	< 15 s at 20 °C Method: DIN 53211
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 : Vapours may form explosive mixture with air.
Reaction with oxidising agents
Exothermic reaction with strong acids.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Strong acids and oxidizing agents

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Acute inhalation toxicity : Acute toxicity estimate: 40 mg/l
Acute dermal toxicity : Acute toxicity estimate: > 15.000 mg/kg

Skin corrosion/irritation

Product:

No skin irritation

Serious eye damage/eye irritation

Product:

Causes serious eye irritation., Calculation method

Respiratory or skin sensitisation

Components:

Ethanol:

Did not cause sensitisation on laboratory animals.Maximisation Test, Guinea pig
Propan-2-ol:
Did not cause sensitisation on laboratory animals.Buehler Test, Guinea pig
Biphenyl-2-ol:
Did not cause sensitisation on laboratory animals.Maximisation Test, Guinea pig, OECD Test Guideline 406

Germ cell mutagenicity

Components:

Ethanol:

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

Propan-2-ol:

Genotoxicity in vitro	:	Ames test, Mutagenicity (Escherichia coli - reverse mutation assay), Non mutagenic
Genotoxicity in vivo	:	Mouse, Mutagenicity (micronucleus test), Non mutagenic
Germ cell mutagenicity- Assessment	:	Not mutagenic in Ames Test

Biphenyl-2-ol:

Germ cell mutagenicity- Assessment	:	Not mutagenic in Ames Test

Carcinogenicity

Components:

Ethanol:

Carcinogenicity - Assessment	:	Did not show carcinogenic effects in animal experiments.

Propan-2-ol:

Carcinogenicity - Assessment	:	Based on available data, the classification criteria are not met.

Biphenyl-2-ol:
Rat, (male), Oral, 2 Years, No observed adverse effect level: 200

Carcinogenicity - Assessment	:	No data available

Reproductive toxicity

Components:

Ethanol:

Effects on foetal development	:	Rat, Oral, NOAEL: 2.000 mg/kg
Reproductive toxicity - Assessment	:	In animal testing, risk of impaired fertility was shown only after administration of very high doses of this substance.

Propan-2-ol:

Reproductive toxicity - Assessment	:	Based on available data, the classification criteria are not met.

Biphenyl-2-ol:

Effects on fertility	:	Rat, male and female, Oral, General Toxicity - Parent: No observed adverse effect level: 460 mg/kg body weight, General Toxicity F1: No observed adverse effect level: 460 mg/kg body weight
Reproductive toxicity - As-	:	No data available

sessment

STOT - single exposure

Components:

Ethanol:
No data available
Propan-2-ol:
May cause drowsiness or dizziness.
Biphenyl-2-ol:
Respiratory system, May cause respiratory irritation.

STOT - repeated exposure

Components:

Ethanol:
No data available
Propan-2-ol:
Based on available data, the classification criteria are not met.
Biphenyl-2-ol:
No data available

Repeated dose toxicity

Components:

Ethanol:
Rat, NOAEL: 1.730 mg/kg, LOAEL: 3.160 mg/kg, Oral90 d
Biphenyl-2-ol:
Rat, male, NOAEL: <= 1.000 mg/kg, Skin contact21 d
Rat, male, LOAEL: 200 mg/kg, Oral2 year

Aspiration toxicity

No data available

SECTION 12: Ecological information

12.1 Toxicity

Product:

Toxicity to microorganisms	:	EC50 : 4.000 mg/l Method: OECD 209

Components:

Ethanol:

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): 8.140 mg/l Exposure time: 48 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 5.000 mg/l Exposure time: 48 h
Toxicity to algae	:	IC50 (Scenedesmus quadricauda (Green algae)): > 100 mg/l Exposure time: 72 h

Propan-2-ol:

Toxicity to fish	:	LC50 (Leuciscus idus): > 100 mg/l Exposure time: 48 h Test Type: static test
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna): > 100 mg/l Exposure time: 48 h Test Type: static test
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 72 h Test Type: static test

Biphenyl-2-ol:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): 4,5 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna): 2,7 mg/l Exposure time: 48 h
Toxicity to algae	:	EC50 (Desmodesmus subspicatus (green algae)): 0,98 mg/l Exposure time: 72 h
M-Factor (Acute aquatic toxicity)	:	1
Toxicity to fish (Chronic toxicity)	:	NOEC: 0,036 mg/l Exposure time: 21 d Species: Pimephales promelas (fathead minnow)
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 0,009 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1

12.2 Persistence and degradability

Product:

Biodegradability	:	Result: Readily biodegradable. Method: OECD 301D / EEC 84/449 C6

Components:

Ethanol:

Biodegradability	:	Result: Readily biodegradable.

Propan-2-ol:

Biodegradability	:	Result: Readily biodegradable.

Biphenyl-2-ol:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: > 70 % Exposure time: 28 d Method: OECD 301B/ ISO 9439/ EEC 84/449 C5

12.3 Bioaccumulative potential

Components:

Ethanol:

Bioaccumulation	:	Remarks: Bioaccumulation is unlikely.
Partition coefficient: n-octanol/water	:	log Pow: -0,14 Method: Calculated value

Propan-2-ol:

Bioaccumulation	:	Remarks: No bioaccumulation is to be expected (log Pow <= 4).
Partition coefficient: n-octanol/water	:	log Pow: 0,05 (20 °C) Method: OECD Test Guideline 107

Biphenyl-2-ol:

Bioaccumulation	:	Bioconcentration factor (BCF): 22 Remarks: Bioaccumulation is unlikely.
Partition coefficient: n-octanol/water	:	log Pow: 3,18

12.4 Mobility in soil

Components:

Ethanol:

Mobility	:	Remarks: No data available

Propan-2-ol:

Mobility	:	Remarks: Mobile in soils

Biphenyl-2-ol:

Mobility	:	Remarks: No data available

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	:	EWC 070604
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	:	UN 1987
IATA (Cargo)	:	UN 1987

14.2 UN proper shipping name

IMDG	:	ALCOHOLS, N.O.S. (Ethanol, Propan-2-ol)
IATA (Cargo)	:	ALCOHOLS, N.O.S. (Ethanol, Propan-2-ol)

14.3 Transport hazard class(es)

IMDG	:	3
IATA (Cargo)	:	3

14.4 Packing group

IMDG

Packing group	:	II
Labels	:	3
EmS Code	:	F-E, S-D

IATA (Cargo)

Packing instruction (cargo aircraft)	:	364
Packing group	:	II
Labels	:	Flammable Liquid

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.

		Quantity 1	Quantity 2
P5c	FLAMMABLE LIQUIDS	5.000 t	50.000 t

Volatile organic compounds : Volatile organic compounds (VOC) content: 88,2 %
Remarks: 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.
Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

15.2 Chemical safety assessment

Exempt

SECTION 16: Other information

Full text of H-Statements

H225 : Highly flammable liquid and vapour.
H315 : Causes skin irritation.
H319 : Causes serious eye irritation.
H335 : May cause respiratory irritation.

H336	:	May cause drowsiness or dizziness.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute	:	Acute aquatic toxicity
Aquatic Chronic	:	Chronic aquatic toxicity
Eye Irrit.	:	Eye irritation
Flam. Liq.	:	Flammable liquids
Skin Irrit.	:	Skin irritation
STOT SE	:	Specific target organ toxicity - single exposure

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; 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

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) No. 1272/2008

Flam. Liq. 2, H225	:	On basis of test data.
Eye Irrit. 2, H319	:	Calculation method

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 guid-

ance 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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Declaration of Conformity

according Council Directive 98/8/EC concerning biocidal products

We herewith declare that the underneath described product corresponds by design, manufacture and labeling to the requirements of the EC directive concerning biocidal products.

Product	**desderman® pure**
Manufacturer	Schülke & Mayr GmbH, 22840 Norderstedt
Product group (Directive 98/8/EC, Annex V)	1 – Disinfectants and general biocidal products
Product type (Directive 98/8/EC, Annex V)	1 – Human hygiene biocidal product
Product category	Hand disinfectant
Relevant EC-guideline	Council Directive 98/8/EC concerning biocidal products
Applied harmonised standards	EN 1500 EN 12791 EN 14348 EN 14476 EN ISO 9001 OECD (toxicity; biodegradability)
Applied national standards and regulations	Methods for testing of microbiological efficacy according to: DGHM (German Society of Hygiene and Microbiology), DVV (German Society against Virus Diseases), RKI (Robert-Koch-Institute, previous BGA (Federal Office of Health))

24.02.2010 — Date

M. Schmidt — Signature

Schülke & Mayr Ges.m.b.H
schülke
the plus of pure performance

Version 2.0

schülke

EC declaration of conformity

according to Annex II - excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

DECLARATION OF CONFORMITY

Medical Device	**gigasept® pearls**
Manufacturer	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Ident.No.: 0297
Classification acc. to Directive 93/42/EEC, Annex IX, Rule 15	IIb
Product group	Disinfectant, surgical instrument
Product category	05 - Hospital hardware
Issued CE certificates by DQS Medizinprodukte GmbH/0297	EN ISO 9001 – Cert. Reg. No. 004567 QM08 EN ISO 13485 – Cert. Reg. No. 004567 MP2012 Annex II – Cert. Reg. No. 004567 MR2
Standards applied	Applied standards are listed in Sec. 2.3 of the technical documentation. Location of technical documentation: Schülke & Mayr GmbH, Reg. Affairs

We herewith declare that the described device corresponds to the essential requirements of the EEC directive concerning medical devices.

I, the undersigned, declare that Schülke bears the sole responsibility for issuing this Declaration

Norderstedt, 17.12.2015

ppa. Dr. W. Weltgen
Head of Quality Management
Schülke & Mayr GmbH

ppa Dr. P. Oltmanns
Head of Research & Development
Schülke & Mayr GmbH

This Declaration is valid until an updated version has been issued, but not longer than 2018-10-17.