



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

schülke -t

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

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.



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

Schülke & Mayr GmbH

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22851 Norderstedt
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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
muccit® T	IIb
octenilin® wound gel	IIb
octenilin® wound irrigation solution	IIb
octenisan® md nasal gel	IIa
octenisept® Gel	IIb
octenisept® wound gel	IIb



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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

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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



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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.

Cygnat 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.

EC declaration of conformity

Declaration of Conformity

Medical Device name	mikrozid[®] AF wipes		
Formulation No.	F05		
Product group	Disinfectant, medical device surfaces		
Product Category	05 - Hospital hardware		
Intended Purpose	surface disinfectant		
Risk Class	II a		
according to Directive 93/42/EEC	annex	IX	
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH, Regulatory Affairs		
Manufacturer	Schülke & Mayr GmbH Robert-Koch-Str. 2 22851 Norderstedt Germany		
Notified Body	DQS Medizinprodukte GmbH August-Schanz-Str. 21 60433 Frankfurt am Main Germany Ident.No.: 0297		
Conformity Assessment Procedure	Annex II excluding section 4		
according to Council Directive 93/42/EEC			
Issued Certificates	Annex II 93/42/EEC	Cert. Reg. No.	004567 MR2
Version	8.0		

Schülke & Mayr GmbH herewith declares that the device covered by this declaration is in conformity with the Council Directive 93/42/EEC concerning medical devices.

Schülke & Mayr GmbH declares that Schülke & Mayr GmbH bears the sole responsibility for issuing this Declaration

Norderstedt

06.05.2019

06.05.2019



ppa. Dr. Peter Oltmanns
Director Research & Regulatory Affairs
Schülke & Mayr GmbH



ppa. Dr. Werner Weltgen
Director Quality and HSE
Schülke & Mayr GmbH



Ready to use disinfectant wipes
impregnated with an alcoholic solution.

mikrozid® AF wipes

Our Plus

- ready to use, impregnated disinfection wipes
- very broad biocidal activity within the shortest possible time
- dries rapidly
- wide range of wipe sizes and packaging

Application areas

Alcohol-based rapid disinfection of medical devices in all areas and all kinds of wipeable surfaces with an increased risk of infection and where short contact times are required, e.g.:

- Patient nearby surfaces
- Patient treatment units
- Examination couches
- Operating tables and nearby work surfaces
- Surfaces of medical equipment

Instructions for use

Thoroughly wipe the surface with the impregnated wipe and allow to take effect. Make sure to wet surfaces completely and keep them wet for the whole exposure time. Make sure that all visible dirt is removed prior to disinfection. When opening the lid and inserting the first cloth, make sure that hygiene requirements are maintained. Make sure to close the lid tightly after use. Do not treat surfaces that are sensitive to alcohol, e.g. acrylic glass. Not suitable for the disinfection of invasive medical devices. schülke guarantees, if used in the correct way, a shelf life of 3 months after the package has been opened.

Microbiological efficacy

Efficacy	Concentration	Contact time
bactericidal <i>in accordance with VAH Guidelines with short contact times</i>	ready-to-use	1 min.
MRSA	ready-to-use	1 min.
mycobactericidal <i>in accordance with VAH Guidelines with short contact times - dirty conditions</i>	ready-to-use	1 min.
levurocidal <i>in accordance with VAH Guidelines with short contact times</i>	ready-to-use	1 min.
enveloped viruses (incl. HIV, HBV, HCV) <i>in accordance with DVV (German Registered Association for Combating Viral Diseases)//RKI Guideline</i>	ready-to-use	30 sec.
Norovirus EN14476	ready-to-use	1 min.
Rotavirus	ready-to-use	30 sec.
Adenovirus (type 5) <i>in accordance with DVV (German Registered Association for Combating Viral Diseases)//RKI Guideline</i>	ready-to-use	5 min.

Certificates

- VAH certificate



Product data

Composition:
100g agent solution contain the following active ingredients:
25 g Ethanol (94 %), 35 g Propan-1-ol

Chemical-physical data

Color	colourless
Density	ca. 0,89 g/cm ³ / 20 °C
Flash point	27 °C / Method : DIN 51755 Part 1
Form	liquid
pH	Not applicable
Viscosity, dynamic	not determined

Special advice

Use disinfectants safely. Always read the label and product information before use.

The product is highly compatible with metals and synthetics (except acrylic glass and alcohol-sensitive varnishes). Please follow carefully any national fire and explosion protection guidelines when using alcohol-based disinfectants. Only treat small surfaces. The wiping range depends on the room temperature and on the structure of the surface to be disinfected. More information available on request.

Refilling of the tin

First disinfect hands and wear new protective gloves. During the refilling process, please ensure that the gloves are not contaminated by other activities. On every refill, reprocess the lid closure. In reprocessing, subject the lid closure to disinfectant cleaning with an alcohol based surface disinfectant.

Following sizes are available:

- mikrozid® AF wipes (10 x 150 wipes 14 x 15 cm) Surface coverage*: approx. 0.3 m²
- mikrozid® AF wipes Refill (20 x 150 wipes 14 x 15 cm) Surface coverage*: approx. 0.3 m²
- mikrozid® AF wipes *Jumbo* (10 x 200 wipes 20 x 27 cm) Surface coverage*: approx. 0.5 m²
- mikrozid® AF wipes *Jumbo* Refill (12 x 200 wipes 20 x 27 cm) Surface coverage*: approx. 0.5 m²
- mikrozid® AF wipes *premium* (18 x 48 wipes 15,5 x 20 cm) Surface coverage*: approx. 0.5 m²

Information for order

Item	Delivery form	Item no.
mikrozid® AF wipes premium softpack (48 wipes)	18/Carton	on request
mikrozid® AF wipes Jumbo tin (200 wipes)	10/Carton	on request
mikrozid® AF wipes tin (150 wipes)	10/Carton	on request
mikrozid® AF wipes Jumbo refill (200 wipes)	1/Carton	on request
mikrozid® AF wipes refill (150 wipes)	1/Carton	on request

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

Accessories

Accessories	Item no.
wall bracket Jumbo tub	134421
Wall mounting for the dispenser (small)	134417

Related Products

- mikrozid® PAA wipes
- mikrozid® sensitive wipes
- mikrozid® universal wipes

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:

Customer Care

Phone: +49 40 52100-666

E-Mail: info@schuelke.com

* The surface coverage of one wipe depends on the surrounding conditions and the structure of the wiped surface.



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.



A company of the Air Liquide-Group

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SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

schülke 

mikrozyd® AF wipes **No Change Service!**

Version Revision Date: Date of last issue: 24.02.2016
05.02 06.09.2016 Date of first issue: 12.07.2001

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

1.1 Product identifier

Trade name : mikrozyd® AF wipes

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

Use of the Sub- : Disinfectants and general biocidal products
stance/Mixture

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 : Application Department HI
responsible for the +49 (0)40/ 521 00 8800
SDS/Contact person ADHI@schuelke.com
(Schülke & Mayr UK Ltd.: +44-1142543500)

1.4 Emergency telephone number

Emergency telephone num- : UK Poisons Emergency number: 0870 600 6266
ber

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 3	H226: Flammable liquid and vapour.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Specific target organ toxicity - single exposure, Category 3	H336: May cause drowsiness or dizziness.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :  

Signal word : Warning

Hazard statements : H226 Flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

Precautionary statements : P102 Keep out of reach of children.

SAFETY DATA SHEET

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P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P280 Wear protective gloves (e.g. Nitrile rubber) /eye protection.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.

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.

Has a degreasing effect on the skin.

SECTION 3: Composition/information on ingredients of the active solution

3.2 Mixtures

Chemical nature : Aqueous, alcohol containing solution on non-woven

Hazardous components

Chemical name	Index-Number CAS-No. EC-No. Registration number	Classification	Concentration (% w/w)
Propan-1-ol	603-003-00-0 71-23-8 200-746-9 01-2119486761-29-XXXX	Flam. Liq. 2; H225 Eye Dam. 1; H318 STOT SE 3; H336	35
Ethanol	603-002-00-5 64-17-5 200-578-6 01-2119457610-43-XXXX	Flam. Liq. 2; H225 Eye Irrit. 2; H319	25

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

If inhaled : If symptoms persist, call a physician.
In case of skin contact : Wash with water and soap as a precaution. If skin irritation persists, 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 : If accidentally swallowed obtain immediate medical attention.

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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, Carbon dioxide (CO₂),
Water spray jet

Unsuitable extinguishing media : Foam, High volume water jet

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Cool closed containers exposed to fire with water spray.

Specific risk from the substance or the product itself, its combustion products or evolved gases : No special risks known.

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 : Remove all sources of ignition. Avoid contact with eyes.

6.2 Environmental precautions

Environmental precautions : No special environmental precautions required.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Use mechanical handling equipment.

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 : Wear personal protective equipment.

Advice on protection against fire and explosion : Keep away from sources of ignition - No smoking.

Hygiene measures : Keep away from food and drink.

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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 container tightly closed. Keep away from direct sunlight.
Advice on common storage : Recommended storage temperature: 15 - 25°C
: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s) : The product falls under the regulation on biocide products (EU) 528/2012.
Product type: 2

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 exposure limit	500 ppm 960 mg/m ³	TRGS 900
		Ceiling Limit Value	1.000 ppm 1.920 mg/m ³	TRGS 900
		Permissible exposure limit	1.000 ppm 1.900 mg/m ³	OSHA
Propan-1-ol	71-23-8	Permissible exposure limit	200 ppm 500 mg/m ³	OSHA

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Propan-1-ol	Workers	Skin contact	Long-term exposure, Systemic effects	136 mg/kg
	Workers	Inhalation	Long-term exposure, Systemic effects	268 mg/m ³
	Workers	Inhalation	Short-term exposure, Systemic effects	1723 mg/m ³
Ethanol	Workers	Inhalation	Acute effects, Local effects	1900 mg/m ³
	Workers	Skin contact	Chronic effects	343 mg/kg
	Workers	Inhalation	Chronic effects	950 mg/m ³

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

Substance name	Environmental Compartment	Value
Propan-1-ol	Fresh water	10 mg/l
	Marine water	1 mg/l
	Soil	2,2 mg/kg
	Marine sediment	2,28 mg/kg

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

schülke 

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	Fresh water sediment	22,8 mg/kg
	Effects on waste water treatment plants	96 mg/l
	Intermittent use/release	10 mg/l
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

8.2 Exposure controls

Personal protective equipment

Hand protection : Prolonged contact: Nitrile rubber gloves e.g. Camatril (>120 Min., layer thickness: 0.40 mm) or butyl rubber gloves e.g. Butoject (>480 Min., layer thickness: 0.70 mm) made by KCL or gloves from other manufacturers offering the same protection.

Protective measures : Avoid contact with skin and eyes.

SECTION 9: Physical and chemical properties of the active solution

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	: 27 °C, DIN 51755 Part 1
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Upper explosion limit	: Propan-1-ol: 17,5 %(V)
Lower explosion limit	: Propan-1-ol: 2,1 %(V)
Vapour pressure	: ca. 50 hPa, 20 °C
Relative vapour density	: No data available
Density	: ca. 0,89 g/cm ³ , 20 °C
Solubility(ies)	
Water solubility	: in all proportions , 20 °C
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: Propan-1-ol: 412 °C
Viscosity	
Viscosity, dynamic	: not determined
Flow time	: < 15 s at 20 °C, DIN 53211
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2 Other information

No data available

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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

None reasonably foreseeable.

10.4 Conditions to avoid

Heat, flames and sparks.

10.5 Incompatible materials

Strong acids and oxidizing agents,

10.6 Hazardous decomposition products

None reasonably foreseeable.

SECTION 11: Toxicological information of the active solution**11.1 Information on toxicological effects****Acute toxicity****Product:**

Acute oral toxicity : Acute toxicity estimate: > 15.000 mg/kg
Acute inhalation toxicity : Acute toxicity estimate: > 50 mg/l
Acute dermal toxicity : Acute toxicity estimate: > 10.000 mg/kg

Skin corrosion/irritation**Components:****Propan-1-ol:**

No skin irritation

Ethanol:

Rabbit, No skin irritation

Serious eye damage/eye irritation**Product:**

Causes serious eye irritation. The toxicological data has been taken from products of similar composition., Expert judgement

Respiratory or skin sensitisation**Components:****Propan-1-ol:**

Does not cause skin sensitisation. Guinea pig, Maximisation Test

Ethanol:

Did not cause sensitisation on laboratory animals. Maximisation Test, Guinea pig

Germ cell mutagenicity**Components:****Propan-1-ol:**

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Germ cell mutagenicity- Assessment : Not mutagenic in Ames Test

Ethanol:

Genotoxicity in vitro : OECD Test Guideline 471, Not mutagenic in Ames Test

Genotoxicity in vivo : not mutagenic

Germ cell mutagenicity- Assessment : Tests on bacterial or mammalian cell cultures did not show mutagenic effects.

Carcinogenicity**Components:****Propan-1-ol:**

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

Ethanol:

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

Reproductive toxicity**Components:****Propan-1-ol:**

Effects on fertility : Rat, Inhalation, NOAEL: 8,6 mg/l

Effects on foetal development : Rat, Inhalation, NOAEL: 8,6 mg/l

Reproductive toxicity - Assessment : Animal testing did not show any effects on fertility.

Ethanol:

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.

STOT - single exposure**Product:**

May cause drowsiness or dizziness.

STOT - repeated exposure**Components:****Propan-1-ol:**

The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Repeated dose toxicity**Components:****Ethanol:**

Rat, NOAEL: 1.730 mg/kg, LOAEL: 3.160 mg/kg, Oral90 d

Aspiration toxicity

No data available

Further information**Product:**

The product has not been tested.

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SECTION 12: Ecological information of the active solution**12.1 Toxicity****Components:****Propan-1-ol:**

Toxicity to fish : LC50 (Fish): 3.200 mg/l, 96 h
Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 3.642 mg/l, 48 h
aquatic invertebrates
Toxicity to algae : NOEC (Chlorella pyrenoidosa (aglae)): 1.150 mg/l, 48 h
Toxicity to daphnia and other : NOEC: > 100 mg/l , 21 d, Daphnia magna (Water flea), OECD
aquatic invertebrates (Chron- Test Guideline 211
ic toxicity)

Ethanol:

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

12.2 Persistence and degradability**Product:**

Biodegradability : Readily biodegradable., OECD 301D / EEC 84/449 C6
Chemical Oxygen Demand : 13.000 mg/l , 1 % solution
(COD)

Components:**Propan-1-ol:**

Biodegradability : Readily biodegradable.

Ethanol:

Biodegradability : Readily biodegradable.

12.3 Bioaccumulative potential**Components:****Propan-1-ol:**

Bioaccumulation : Bioaccumulation is unlikely.
Partition coefficient: n- : log Pow: 0,43
octanol/water

Ethanol:

Bioaccumulation : Bioaccumulation is unlikely.
Partition coefficient: n- : log Pow: -0,14, calculated
octanol/water

12.4 Mobility in soil**Components:****Propan-1-ol:**

Mobility : Mobile in soils

Ethanol:

Mobility : 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

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schülke 

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very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Additional ecological information : none

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Can be incinerated or landfilled together with household waste in compliance with the regulations, and after consultation with the waste disposal services.
Contaminated packaging : Take empty packaging to the recycling plant.

SECTION 14: Transport information

14.1 UN number

ADR : UN 3175
IMDG : UN 3175
IATA : UN 3175

14.2 UN proper shipping name

ADR : SOLIDS OR MIXTURES OF SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.
(Propan-1-ol, Ethanol)
IMDG : SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.
(Propan-1-ol, Ethanol)
IATA : Solids containing flammable liquid, n.o.s.
(Propan-1-ol, Ethanol)

14.3 Transport hazard class(es)

ADR : 4.1
IMDG : 4.1
IATA : 4.1

14.4 Packing group

ADR
Packing group : II
Classification Code : F1
Hazard Identification Number : 40
Labels : 4.1
Tunnel restriction code : E
IMDG
Packing group : II
Labels : 4.1
EmS Code : F-A, S-I

IATA

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Packing instruction (cargo aircraft) : 448
Packing group : II
Labels : Flammable Solid

14.5 Environmental hazards

ADR

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

For personal protection see section 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 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

Legislation on the control of major-accident hazards involving dangerous substances : Directive 96/82/EC does not apply

Volatile organic compounds : Volatile organic compounds (VOC) content: 60 %, of the active solution, 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.
H318 : Causes serious eye damage.
H319 : Causes serious eye irritation.
H336 : May cause drowsiness or dizziness.

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Full text of other abbreviations

Eye Dam.	: Serious eye damage
Eye Irrit.	: Eye irritation
Flam. Liq.	: Flammable liquids
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. 3, H226	: On basis of test data.
Eye Irrit. 2, H319	: Calculation method
STOT SE 3, H336	: 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 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

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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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ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
						mayr			
DM000305412	ȘERVEȚELE DEZINFECTANTE	MICROZID® AF WIPES	N50 Premium	70000808	Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000078	02-04-2021
DM000305425	DEZINFECTANT PENTRU INSTRUMENTE, PE BAZĂ DE OXIGEN ACTIV	GIGASEPT® PEARLS	1.5 KG	70000179	Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000078	02-04-2021
DM000305424	DEZINFECTANT PENTRU INSTRUMENTE, PE BAZĂ DE OXIGEN ACTIV	GIGASEPT® PEARLS	6 KG	70000178	Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000078	02-04-2021
DM000305416	ȘERVEȚELE DEZINFECTANTE	MICROZID® AF WIPES	N 150, 14 x 18 cm	109200	Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000078	02-04-2021
DM000305415	ȘERVEȚELE DEZINFECTANTE	MICROZID® AF WIPES	N 200, 20 x 20 cm, Jumbo Sensitive	109184	Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000078	02-04-2021
DM000305413	ȘERVEȚELE DEZINFECTANTE	MICROZID® AF WIPES	N 150, Rezerva	109205	Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000078	02-04-2021
DM000305414	ȘERVEȚELE DEZINFECTANTE	MICROZID® AF WIPES	N 200, 20 x 27 cm, Jumbo	109157	Germania	SCHÜLKE & MAYR GMBH	S.C. ENDO-CHIRURGIE S.R.L.	Rg04-000078	02-04-2021

✓ Conține ([Producatorul], 'mayr') și ([NameMake] Равно 'GIGASEPT® PEARLS' ИЛИ [NameMake]...