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Research and Development

the plus of pure performance

BSE – TSE

mikrozid® AF liquid

BSE/ TSE Bestätigung	BSE/ TSE Confirmation
Schülke & Mayr GmbH bestätigt hiermit, dass das Produkt **mikrozid® AF liquid** nicht mit Rohwaren tierischen Ursprungs hergestellt wird und auch während der Herstellung nicht mit Rohwaren tierischen Ursprungs in Kontakt kommt.	Schülke & Mayr GmbH herewith declares that the product **mikrozid® AF liquid** does not contain any component of animal origin and is not in contact with materials of animal origin during the manufacturing process.

Schülke & Mayr GmbH
i.V.

Dr. Susanne Hendrich
Head of Regulatory Affairs Department
Schülke & Mayr GmbH

1. Sep. 2015

The information is to the best of our knowledge and has been compiled with the utmost reasonable care and no claims are made as to its completeness. The facts contained herein are based on our own examinations or have been provided to us by our suppliers and shall only be read as a comprehensive description of the quality of the respective product. Nothing herein shall be interpreted as a guarantee or whatsoever.

- This product information is not automatically updated -

Digitally signed by Ghereg Victor
Date: 2024.03.19 00:00:20 EET
Reason: MoldSign Signature
Location: Moldova

Schülke & Mayr GmbH
Robert-Koch-Str. 2 | D-22851 Norderstedt | Postal address: D-22840 Norderstedt
Phone: +49 40 521 00 -0 | Fax : +49 40 521 00 -577
mail@schuelke.com | www.schuelke.com

Declaration of Conformity

schülke

EC declaration of conformity

Medical Device name	**mikrozid® AF liquid**
Formulation No.	F05
Product group	Disinfectant, medical device surfaces
Product Category	05 - Hospital hardware
Intended Purpose	surface disinfectant
Risk Class according to Directive 93/42/EEC annex	II a IX
Standards applied	EN ISO 13485 additional standards see technical documentation Schülke & Mayr GmbH, Regulatory Affairs
Manufacturer according to Directive 93/42/EEC	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 according to Council Directive 93/42/EEC	Annex II excluding section 4
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 declation 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

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

06.05.2019

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

This Declaration is valid until an updated version has been issued, but not longer than 18.12.2023

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

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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.

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
Certificate unique ID: 170742365
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

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 and wound care products 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	170730505
Effective date	2018-12-19
Expiry date	2023-12-18
Frankfurt am Main	2018-12-19

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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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: 170730505
Effective date: 2018-12-19

Schülke & Mayr GmbH

Robert-Koch-Straße 2
22851 Norderstedt
Germany

Device	Class
Surface disinfectant for medical devices	IIa
Disinfectant for automated reprocessing of bedpans	IIa
Disinfectant for automated and manual reprocessing of medical instruments	IIb
Wound care products	IIb

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
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
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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.

Anastasija Schlicht
c/o
Labor LS SE & Co. KG
Mangelsfeld 4, 5, 6

97708 Bad Bocklet

07 October 2021

Schülke & Mayr GmbH
Robert-Koch-Str. 2
22851 Norderstedt

mikrozid AF liquid

L+S-No.: 170803-0057-001

Certificate

(Version 01)

for the evaluation of bactericidal efficacy within the quantitative suspension test according to EN 13727

1. Results of the in vitro-tests

(performed according to EN 13727 „Quantitative suspension test for the evaluation of bactericidal activity in the medical area according to EN 13727", dated: 12/2015).

In the quantitative suspension test according to EN 13727 the product **mikrozid AF liquid** showed the required activity of ≥ 5 log within the tested contact times of 30 seconds, 60 seconds and 2 minutes at clean conditions resp. dirty conditions against the test strains *S. aureus*, *E.coli*, *Ec. hirae* and *P. aeruginosa* at the below mentioned concentration-/time-relations in all cases (see test report of 20.10.2017; L+S-No.: 170803-0057-001).

The control tests proved the validity of the method in all cases.

2. Evaluation and recommendation for use

The product **mikrozid AF liquid** showed under in vitro-conditions, that it met the requirements of a suitable disinfectant.

For use of mikrozid AF liquid according to EN 13727 we recommend the following usage:

Bactericidal activity at clean conditions (0.03% albumin) according to EN 13727 at 20°C ± 1°C:

97%	30 sec, 60 sec, 2 min contact time
80%	30 sec, 60 sec, 2 min contact time
50%	30 sec, 60 sec, 2 min contact time

Bactericidal activity at dirty conditions (0.3% albumin + 0.3% sheep erythrocytes) according to EN 13727 at 20°C ± 1°C:

97%	30 sec, 60 sec, 2 min contact time
80%	30 sec, 60 sec, 2 min contact time
50%	30 sec, 60 sec, 2 min contact time

07. OKT. 2021

Anastasija Schlicht

Labor L+S AG Mangelsfeld 4, 5, 6 | 97708 Bad Bocklet-Großenbrach | Germany

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Akkreditiert nach ISO / IEC 17025 Zertifiziert nach DIN EN ISO 14001

Schülke & Mayr GmbH
Dr Peter Goroncy-Bermes
Robert-Koch-Str. 2

22851 Norderstedt
Germany

Durch die DAkkS Deutsche Akkreditierungsstelle GmbH nach DIN EN ISO/IEC 17025 akkreditiertes Prüflaboratorium.
Die Akkreditierung gilt für die in der Urkunde aufgeführten Verfahren.

Deutsche Akkreditierungsstelle
D-PL-14559-01-01
D-PL-14559-01-02

Bad Bocklet, 19 May 2017

Test report
(Version 02)

Sample: **mikrozid AF liquid** **L+S-No.: 150916-0224-001**

Order: **Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field-test) according to EN 16615**

Order of	11.08.2015
Period of testing	05.02.2016 – 24.03.2016

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.

Vorstand:
Dr. Frank Böttcher
Ärztl. Leiter:
PD Dr. med. Andreas Schwarzkopf

Aufsichtsrat:
Dipl. Kfm. Werner Wohnhas (Vors.)

Handelsregister HRB 2726
(Amtsgericht Schweinfurt)
USt-IdNr.: DE 814360374
EORI-Nr.: DE5184460

HypoVereinsbank Schweinfurt:
IBAN: DE10 7932 0075 0002 0110 00
BIC: HYVEDEMM451

LS|AG

Material and method

Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field-test) according to EN 16615 (dated: 06/2015)

0. Revision history

In its present Version 02 – compared with Version 01 – the batch number of the used product was added on page 2.

1. Laboratory

Labor L+S AG
Mangelsfeld 4, 5, 6

D - 97708 Bad Bocklet

2. Identification of the sample

Product name:	mikrozid AF liquid
Batch:	1287546
Active ingredients: (in 100 g solution)	25.0 g ethanol (94%) 35.0 g propan-1-ol
Appearance of the product:	colourless, liquid, clear
pH-value (100%):	5.00
Storage conditions:	room temperature

3. Quantitative test method according to EN 16615

Test strains:	*Staphylococcus (S.) aureus*	ATCC 6538
	Pseudomonas (P.) aeruginosa	ATCC 15442
	Enterococcus (Ec.) hirae	ATCC 10541
	Candida (C.) albicans	ATCC 10231
Test concentration:	undiluted	
Contact times:	1 min and 5 min	
Test surface:	PVC-floor	

Organic loading:	0.3% albumin + 0.3% sheep erythrocytes	
Incubation period:	bacteria *C. albicans*	40 h - 48 h, 36°C ± 1°C 40 h - 48 h, 30°C ± 1°C
Test temperature:	18°C - 25°C	
Inactivation combination:	CaSo-broth + 3.0% Tween 80 + 3.0% saponin + 0.1% histidine + 0.1% cysteine	
Wipes:	Product testing and water control with standardised wipe	
Relative humidity:	48% - 55%	

4. Requirements

According to EN 16615 a log reduction of ≥ 5 log against bacteria resp. of ≥ 4 log against yeasts is required.

5. Test results

The results are stated in tables A (overview) and 1a – 4d.

The results of the quantitative test method within the 4-field-test according to EN 16615 with the product **mikrozid AF liquid** after exposure times of 1 minute and 5 minutes under dirty conditions are stated in table A. Results, which passed the required microbial reductions are given in bold numbers (for detailed results see tables 1a - 4d).

Table A: Overview of the log-reductions of the quantitative test method

Product: mikrozid AF liquid Test concentration: undiluted Test surface: PVC-floor Organic loading: 0.3% albumin + 0.3% sheep erythrocytes Test temperature: 18°C - 25°C		
Test strain / Contact time	**1 min**	**5 min**
S. aureus	**> 5.83 / > 5.95 / > 5.95**	**> 5.78**
Ec. hirae	**> 5.74**	**> 5.75**
P. aeruginosa	**> 5.82**	**> 5.85**
C. albicans	**> 4.27 / > 4.23 / > 4.23**	**> 4.25**

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6. Conclusion

Within the quantitative test method with mechanical action employing wipes (4-field-test) according to EN 16615 the product **mikrozid AF liquid** showed under dirty conditions after contact times of 1 minute and 5 minutes the required microbial reductions of ≥ 5 log-levels resp. of ≥ 4 log-levels with reference to the test strains *S. aureus, P. aeruginosa, Ec. hirae* and *C. albicans* in all cases.

The results of the validation tests B and C proved the validity of the method.

19. MAI 2017

Dipl-Biol Anastasija Schlicht
- Manager Business Unit Services -

19. MAI 2017

Dr Frank Krieger
- Head of Department -

Dr. med. A. Sammann
Arzt für Mikrobiologie und Infektionsepidemiologie
Marckmannstr. 129 a, 20539 Hamburg
Tel: 040-42845-7900, Fax: 040-42845-7903
e-mail: Andreas.Sammann@hu.hamburg.de

Report based on the test report for Mikrozid AF liquid DIN EN 13624(2013) - 2017

Test of the disinfection product Mikrozid AF liquid from Schülke & Mayr in accordance with the DIN EN 13624 (Chemical disinfectants and antiseptics Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase2, step 1), dated 12-2013)

On behalf of Schülke & Mayr, 22840 Norderstedt, the product Mikrozid AF liquid was tested in the quantitative suspension test for Aspergillus brasiliensis with low and high organic load. As the use-concentration the undiluted concentrate should be used, the contact times should be 2 and 5 minutes. The request was received on 04.01.2017; the samples were received on 10.01.2017. The test period was March 2017. The batch number was 1304092, expiration date 02.2021.

Evaluation of the test results

Mikrozid AF liquid from Schülke & Mayr fulfils the requirements of the DIN EN 13624 for testing chemical disinfection procedures in the quantitative suspension test against Aspergillus brasiliensis.

Low and high organic load
For Aspergillus brasiliensis, a 97% concentration was required for a reduction by more than 4 log steps within 2 and 5 min.

Hamburg, March 28, 2017

Dr. med. A. Sammann
(Sci. director)

Labor L+S AG Mangelsfeld 4, 5, 6 | 97708 Bad Bocklet-Großenbrach | Germany

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E-Mail: labor@labor-ls.de Internet: www.labor-ls.de
Akkreditiert nach ISO / IEC 17025

Durch die DAkkS Deutsche Akkreditierungsstelle GmbH nach DIN EN ISO/IEC 17025 akkreditiertes Prüflaboratorium.
Die Akkreditierung gilt für die in der Urkunde aufgeführten Verfahren.

DAkkS Deutsche Akkreditierungsstelle
D-PL-14559-01-01
D-PL-14559-01-02

Schülke & Mayr GmbH
Dr Peter Goroncy-Bermes
Robert-Koch-Str. 2

22851 Norderstedt
Germany

Bad Bocklet, 14 July 2017

Test report
(Version 01)

Sample: mikrozid AF liquid **L+S-No.: 160620-0092-002**

Order: Quantitative surface test for the evaluation of fungicidal activity according to EN 13697

(order of 16.06.2016)

The test was conducted in compliance with GMP guidelines. There were no test-related deviations.

The test results apply solely to the analysed sample.
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LS|AG

Material and Method

Quantitative surface test for the evaluation of fungicidal activity according to EN 13697 (June 2015)

1. Identification of the testing laboratory

Labor L+S AG
Mangelsfeld 4, 5, 6

D - 97708 Bad Bocklet

2. Identification of the sample

Product name:	mikrozid AF liquid
Identification:	Batch: 1303742
Manufacturer:	Schülke & Mayr GmbH
Active substances: (in 100 g product)	25 g Ethanol (94%) 35 g Propan-1-ol
Appearance of the product:	liquid, clear, colourless
pH-value (100%):	7.91
Delivery date:	20.06.2016
Storage conditions:	room temperature

3. Experimental conditions

Period of testing:	13.07.2016 – 30.09.2016	
Test strains:	*Candida (C.) albicans*	ATCC 10231
	Aspergillus (A.) brasiliensis – spores	ATCC 16404
Test concentrations:	97%, 50% and 25%	
Contact times:	*C. albicans* 1 min, 5 min and 15 min *A. brasiliensis* 1 min, 2 min, 5 min and 15 min	
Test surface:	Stainless steel	
Test temperature:	18°C – 25°C	

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Counting method: surface method

Incubation parameters: 48 h, 30°C ± 1°C (*C. albicans*)
4 - 5 days, 30°C ± 1°C (*A. brasiliensis*)

4. Test method and its validation

Test method: dilution-neutralisation

Inactivation combination: 3.0% Tween 80, 3.0% saponin, 0.1% histidine, 0.1% cysteine in casein-soy-broth

The results of the validation tests proved the validity of the method in all cases.

5. Test results

The results are stated in tables A (summary table) and 1 - 4.

Product: mikrozid AF liquid Organic loading: 0.03% albumin Test temperature: 18°C - 25°C Test surface: Stainless steel						
Contact time	**1 min**			**2 min**		
Test strain / Concentration	**25%**	**50%**	**100%**	**25%**	**50%**	**100%**
C. albicans	< 0.55	**> 5.97**	**> 5.97**			
***A. brasiliensis* - spores**	< 0.68	< 0.68	2.01	< 0.68	1.16	**3.37**
Contact time	**5 min**			**15 min**		
Test strain / Concentration	**25%**	**50%**	**100%**	**25%**	**50%**	**100%**
C. albicans	< 0.39	**> 5.81**	**> 5.81**	< 0.57	**> 5.99**	**> 5.99**
***A. brasiliensis* - spores**	< 0.77	1.06	**> 3.84**	< 0.77	1.18	**> 5.89**

14. JULI 2017

Dipl-Biol Anastasija Schlicht
- Manager Business Unit Services -

14. JULI 2017

Dr Frank Krieger
- Head of Department -

Anastasija Schlicht
c/o
Labor LS SE & Co. KG
Mangelsfeld 4, 5, 6

97708 Bad Bocklet

29 November 2021

Schülke & Mayr GmbH
Robert-Koch-Str. 2
22851 Norderstedt

mikrozid AF liquid

L+S-No.: 170803-0057-004

Certificate

(Version 01)

for the evaluation of mycobactericidal efficacy within the quantitative suspension test according to EN 14348

1. Results of the in vitro-tests

(performed according to EN 14348 „Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants according to EN 14348", dated: 04/2005).

In the quantitative suspension test according to EN 14348 the product **mikrozid AF liquid** showed the required activity of ≥ 4 log within the tested contact times of 30 seconds, 60 seconds and 2 minutes at clean conditions resp. dirty conditions against the test strains *M. avium* and *M. terrae* at the below mentioned concentration-/time-relations in all cases (see test report of 20.10.2017; L+S-No.: 170803-0057-004).

The control tests proved the validity of the method in all cases.

2. Evaluation and recommendation for use

The product **mikrozid AF liquid** showed under in vitro-conditions, that it met the requirements of a suitable disinfectant.

For use of mikrozid AF liquid according to EN 14348 we recommend the following usage:

Mycobactericidal activity at clean conditions (0.03% albumin) according to EN 14348 at 20°C ± 1°C:

97%	60 sec, 2 min contact time
80%	60 sec, 2 min contact time

Mycobactericidal activity at dirty conditions (0.3% albumin + 0.3% sheep erythrocytes) according to EN 14348 at 20°C ± 1°C:

97%	60 sec, 2 min contact time
80%	60 sec, 2 min contact time

Tuberculocidal activity at clean conditions (0.03% albumin) according to EN 14348 at 20°C ± 1°C:

97%	30 sec, 60 sec, 2 min contact time
80%	60 sec, 2 min contact time

Tuberculocidal activity at dirty conditions (0.3% albumin + 0.3% sheep erythrocytes) according to EN 14348 at 20°C ± 1°C:

97%	30 sec, 60 sec, 2 min contact time
80%	60 sec, 2 min contact time

29. NOV. 2021

Anastasija Schlicht

DR. JOCHEN STEINMANN

C/O DR. BRILL + PARTNER GMBH
INSTITUT FÜR HYGIENE UND MIKROBIOLOGIE
NORDEROOG 2, DE 28259 BREMEN
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DR. J. STEINMANN · C/O DR. BRILL + PARTNER GMBH · NORDEROOG 2 · DE-28259 BREMEN

Schülke & Mayr GmbH
Robert-Koch-Straße 2
DE – 22851 Norderstedt

Bremen, 27/09/2017

Expert opinion

Activity of mikrozid AF liquid against modified vaccinia virus Ankara (MVA) in a quantitative suspension test based on EN 14476:2013+A1:2015 under dirty conditions

This expert opinion is based on the test report L17/0474MV.2 dating 27.09.2017.

The virus-inactivating properties of the surface disinfectant mikrozid AF liquid of Schülke & Mayr GmbH against modified vaccinia virus Ankara (MVA) were investigated by a quantitative suspension test based on EN 14476 under dirty conditions.

According to this norm, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99 %).

The surface didinfectant mikrozid AF liquid was examined undiluted at 20 °C. 30 and 60 seconds were chosen as exposure time. In summary, a virucidal activity against modified vaccinia virus Ankara (MVA) was measured as follows:

undiluted **30 seconds** **dirty conditions (3.0 g/l BSA + 3.0 g/l erythrocytes)**

Dr. Jochen Steinmann

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http://www.brillhygiene.com

Schülke & Mayr GmbH
Robert-Koch-Straße 2
DE – 22851 Norderstedt

Bremen, 27/09/2017

Summary: Virus-inactivating properties of mikrozid AF liquid of Schülke & Mayr GmbH according to EN 14476:2013+A1:2015/prA2:2016 under dirty conditions

This summary is based on the following test report of Dr. Brill + Partner GmbH for the surface disinfectant mikrozid AF liquid produced by Schülke & Mayr GmbH:

modified vaccinia virus Ankara test report L17/0474MV.2 dating 27/09/2017

The following concentration and exposure time are necessary for the inactivation of the test virus:

undiluted 30 seconds

in order to achieve a 4 $\log_{10}$ reduction (inactivation ≥ 99.99 %) under dirty conditions in a quantitative suspension test according to EN 14476:2013+A1:2015/prA2:2016.

After evaluation with modified vaccinia virus Ankara the surface disinfectant mikrozid AF liquid can be declared as having **"virucidal activity against all enveloped viruses"** according to EN 14476:2013+A1:2015 /prA2:2016.

The declaration **"virucidal activity against all enveloped viruses"** covers all enveloped humanpathogenic viruses like HBV, HCV, HIV and Ebola virus.

Dr. Jochen Steinmann

From Annex A in EN 14476
Examples of viruses which may contaminate human medical instruments, hands, surfaces (*Enveloped viruses are in bold*)

NOTE This list is not exhaustive.

Blood

Enterovirus
Filoviridae
Flavivirus
Herpesviridae
Hepatitis A Virus (HAV)
Hepatitis B virus (HBV)
Hepatitis C virus (HCV)
Hepatitis Delta virus (HDV)
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Parvovirus B 19

Respiratory tract

Adenovirus (Mast-)
Coronavirus
Enterovirus
Herpesviridae
Influenza Virus
Paramyxoviridae
Rhinovirus
Rubella Virus

Neural tissue, ear & nose, eye

Adenovirus (Mast-)
Enterovirus
Herpesviridae
Measles Virus
Human Immunodeficiency Virus (HIV)
Polyomavirus
Rabies Virus
Rubella Virus

Gastro-intestinal

Adenovirus (Mast-)
Caliciviridae
Coronavirus
Astrovirus
Enterovirus
Hepatitis A Virus (HAV)
Hepatitis E Virus (HEV)
Rotavirus

Skin, breast and/or milk

Enterovirus
Herpesviridae
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Papillomavirus
Poxviridae

Spleen and lymph nodes (see also „Blood")

Human T Cell Leukemia Virus (HTLV)
Human Immunodeficiency Virus (HIV)

Dental procedure

Adenovirus (Mast-)
Enterovirus
Herpesviridae
Hepatitis B virus (HBV)
Hepatitis C Virus (HCV)
Hepatitis Delta Virus (HDV)
Human Immunodeficiency Virus (HIV)

Urogenital tract

Hepatitis B Virus (HBV)
Herpesviridae
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Papillomavirus
Polyomavirus

Reference:
Van Regenmortel MHV et al., Eds.: Virus Taxonomy, Classification and Nomenclature of Viruses, seventh report of the international committee on taxonomy of viruses.
Academic Press, San Diego, 2000

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Schülke & Mayr GmbH
Robert-Koch-Straße 2
DE – 22851 Norderstedt

Bremen, 27/09/2017

Expert opinion

Activity of mikrozid AF liquid against modified vaccinia virus Ankara (MVA) in a quantitative suspension test based on EN 14476:2013+A1:2015 under clean conditions

This expert opinion is based on the test report L17/0474MV.1 dating 27.09.2017.

The virus-inactivating properties of the surface disinfectant mikrozid AF liquid of Schülke & Mayr GmbH against modified vaccinia virus Ankara (MVA) were investigated by a quantitative suspension test based on EN 14476 under clean conditions.

According to this norm, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99 %).

The surface disinfectant mikrozid AF liquid was examined undiluted at 20 °C. 30 and 60 seconds were chosen as exposure time. In summary, a virucidal activity against modified vaccinia virus Ankara (MVA) was measured as follows:

undiluted **30 seconds** **clean conditions (0.3 g/l BSA)**

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Schülke & Mayr GmbH
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Bremen, 27/09/2017

Summary: Virus-inactivating properties of mikrozid AF liquid of Schülke & Mayr GmbH according to EN 14476:2013+A1:2015/prA2:2016 under clean conditions

This summary is based on the following test report of Dr. Brill + Partner GmbH for the surface disinfectant mikrozid AF liquid produced by Schülke & Mayr GmbH:

modified vaccinia virus Ankara test report L17/0474MV.1 dating 27/09/2017

The following concentration and exposure time are necessary for the inactivation of the test virus:

undiluted 30 seconds

in order to achieve a 4 $\log_{10}$ reduction (inactivation ≥ 99.99 %) under clean conditions in a quantitative suspension test according to EN 14476:2013+A1:2015/prA2:2016.

After evaluation with modified vaccinia virus Ankara the surface disinfectant mikrozid AF liquid can be declared as having **"virucidal activity against all enveloped viruses"** according to EN 14476:2013+A1:2015 /prA2:2016.

The declaration **"virucidal activity against all enveloped viruses"** covers all enveloped humanpathogenic viruses like HBV, HCV, HIV and Ebola virus.

Dr. Jochen Steinmann

From Annex A in EN 14476
Examples of viruses which may contaminate human medical instruments, hands, surfaces (*Enveloped viruses are in bold*)

NOTE This list is not exhaustive.

Blood

Enterovirus
Filoviridae
Flavivirus
Herpesviridae
Hepatitis A Virus (HAV)
Hepatitis B virus (HBV)
Hepatitis C virus (HCV)
Hepatitis Delta virus (HDV)
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Parvovirus B 19

Respiratory tract

Adenovirus (Mast-)
Coronavirus
Enterovirus
Herpesviridae
Influenza Virus
Paramyxoviridae
Rhinovirus
Rubella Virus

Neural tissue, ear & nose, eye

Adenovirus (Mast-)
Enterovirus
Herpesviridae
Measles Virus
Human Immunodeficiency Virus (HIV)
Polyomavirus
Rabies Virus
Rubella Virus

Gastro-intestinal

Adenovirus (Mast-)
Caliciviridae
Coronavirus
Astrovirus
Enterovirus
Hepatitis A Virus (HAV)
Hepatitis E Virus (HEV)
Rotavirus

Skin, breast and/or milk

Enterovirus
Herpesviridae
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Papillomavirus
Poxviridae

Spleen and lymph nodes (see also „Blood")

Human T Cell Leukemia Virus (HTLV)
Human Immunodeficiency Virus (HIV)

Dental procedure

Adenovirus (Mast-)
Enterovirus
Herpesviridae
Hepatitis B virus (HBV)
Hepatitis C Virus (HCV)
Hepatitis Delta Virus (HDV)
Human Immunodeficiency Virus (HIV)

Urogenital tract

Hepatitis B Virus (HBV)
Herpesviridae
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Papillomavirus
Polyomavirus

Reference:
Van Regenmortel MHV et al., Eds.: Virus Taxonomy, Classification and Nomenclature of Viruses, seventh report of the international committee on taxonomy of viruses.
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Bremen, 10/10/2017

Expert opinion

Activity of mikrozid AF liquidagainst adenovirus type 5 in a quantitative suspension test according to the EN 14476:2013+A1:2015 under dirty conditions

This expert opinion is based on the test report L17/0474A.2 dating 10/10/2017.

The virus-inactivating properties of the surface disinfectant mikrozid AF liquid of Schülke & Mayr GmbH against adenovirus type 5 were investigated by a quantitative suspension test according to EN 14476 under dirty conditions.

According to EN 14476, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99 %).

The surface disinfectant mikrozid AF liquid was examined undiluted at 20 °C. 30 and 60 seconds were chosen as exposure time. In summary, a virucidal activity against adenovirus type 5 was measured as follows:

undiluted 30 seconds dirty conditions (3.0 g/l BSA + 3.0 g/l erythrocytes)

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Bremen, 10/10/2017

Expert opinion

Activity of mikrozid AF liquidagainst adenovirus type 5 in a quantitative suspension test according to the EN 14476:2013+A1:2015 under clean conditions

This expert opinion is based on the test report L17/0474A.1 dating 10/10/2017.

The virus-inactivating properties of the surface disinfectant mikrozid AF liquid of Schülke & Mayr GmbH against adenovirus type 5 were investigated by a quantitative suspension test according to EN 14476 under clean conditions.

According to EN 14476, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99 %).

The surface disinfectant mikrozid AF liquid was examined undiluted at 20 °C. 30 and 60 seconds were chosen as exposure time. In summary, a virucidal activity against adenovirus type 5 was measured as follows:

undiluted **30 seconds** **clean conditions (0.3 g/l BSA)**

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Schülke & Mayr GmbH
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Bremen, 26/09/2017

Expert opinion

Activity of mikrozid AF liquid against MNV in a quantitative suspension test according to the EN 14476:2013+A1:2015 under dirty conditions

This expert opinion is based on the test report L17/0474M.2 dating 26/09/2017.

The virus-inactivating properties of the surface disinfectant mikrozid AF liquid of Schülke & Mayr GmbH against murine norovirus (MNV) were investigated by a quantitative suspension test according to EN 14476 under dirty conditions.

According to EN 14476, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99 %).

The surface disinfectant mikrozid AF liquid was examined undiluted at 20 °C. 30 and 60 seconds were chosen as exposure time. In summary, a virucidal activity against MNV was measured as follows:

undiluted **30 seconds** **dirty conditions (3.0 g/l BSA + 3.0 g/l erythrocytes)**

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Bremen, 26/09/2017

Expert opinion

Activity of mikrozid AF liquid against MNV in a quantitative suspension test according to the EN 14476:2013+A1:2015 under clean conditions

This expert opinion is based on the test report L17/0474M.1 dating 26/09/2017.

The virus-inactivating properties of the surface disinfectant mikrozid AF liquid of Schülke & Mayr GmbH against murine norovirus (MNV) were investigated by a quantitative suspension test according to EN 14476 under clean conditions.

According to EN 14476, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99 %).

The surface disinfectant mikrozid AF liquid was examined undiluted at 20 °C. 30 and 60 seconds were chosen as exposure time. In summary, a virucidal activity against MNV was measured as follows:

undiluted 30 seconds clean conditions (0.3 g / l BSA)

Dr. Jochen Steinmann

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Schülke & Mayr GmbH
Robert-Koch-Straße 2
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Bremen, 10/10/2017

Summary: Virus-inactivating properties of mikrozid AF liquid of Schülke & Mayr GmbH according to EN 14476:2013+A1:2015/prA2:2016 under dirty conditions

This summary is based on the following test reports of Dr. Brill + Partner GmbH for the surface disinfectant mikrozid AF liquid produced by Schülke & Mayr GmbH:

adenovirus type 5 test report L17/0474A.2 dating 10/10/2017

murine norovirus (MNV) test report L17/0474M.2 dating 26/09/2017

The following concentration and exposure time are necessary for the inactivation of these test viruses:

undiluted 30 seconds

in order to achieve a 4 $\log_{10}$ reduction (inactivation ≥ 99.99 %) under dirty conditions in a quantitative suspension test according to EN 14476:2013+A1:2015/prA2:2016.

After evaluation with adenovirus type 5 and MNV the surface disinfectant mikrozid AF liquid can be declared as having **"limited spectrum virucidal activity"** according to EN 14476:2013+A1:2015 /prA2:2016.

The declaration **"limited spectrum virucidal activity"** covers the specified test organisms and all enveloped humanpathogenic viruses like HBV, HCV, HIV and Ebola virus.

Dr. Jochen Steinmann

From Annex A in EN 14476
Examples of viruses which may contaminate human medical instruments, hands, surfaces (*Enveloped viruses are in bold*)

NOTE This list is not exhaustive.

Blood

Enterovirus
Filoviridae
Flavivirus
Herpesviridae
Hepatitis A Virus (HAV)
Hepatitis B virus (HBV)
Hepatitis C virus (HCV)
Hepatitis Delta virus (HDV)
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Parvovirus B 19

Respiratory tract

Adenovirus (Mast-)
Coronavirus
Enterovirus
Herpesviridae
Influenza Virus
Paramyxoviridae
Rhinovirus
Rubella Virus

Neural tissue, ear & nose, eye

Adenovirus (Mast-)
Enterovirus
Herpesviridae
Measles Virus
Human Immunodeficiency Virus (HIV)
Polyomavirus
Rabies Virus
Rubella Virus

Gastro-intestinal

Adenovirus (Mast-)
Caliciviridae
Coronavirus
Astrovirus
Enterovirus
Hepatitis A Virus (HAV)
Hepatitis E Virus (HEV)
Rotavirus

Skin, breast and/or milk

Enterovirus
Herpesviridae
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Papillomavirus
Poxviridae

Spleen and lymph nodes (see also „Blood")

Human T Cell Leukemia Virus (HTLV)
Human Immunodeficiency Virus (HIV)

Dental procedure

Adenovirus (Mast-)
Enterovirus
Herpesviridae
Hepatitis B virus (HBV)
Hepatitis C Virus (HCV)
Hepatitis Delta Virus (HDV)
Human Immunodeficiency Virus (HIV)

Urogenital tract

Hepatitis B Virus (HBV)
Herpesviridae
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Papillomavirus
Polyomavirus

Reference:
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Schülke & Mayr GmbH
Robert-Koch-Straße 2
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Bremen, 10/10/2017

Summary: Virus-inactivating properties of mikrozid AF liquid of Schülke & Mayr GmbH according to EN 14476:2013+A1:2015/prA2:2016 under clean conditions

This summary is based on the following test reports of Dr. Brill + Partner GmbH for the surface disinfectant mikrozid AF liquid produced by Schülke & Mayr GmbH:

adenovirus type 5 test report L17/0474A.1 dating 10/10/2017

murine norovirus (MNV) test report L17/0474M.1 dating 26/09/2017

The following concentration and exposure time are necessary for the inactivation of these test viruses:

undiluted 30 seconds

in order to achieve a 4 $\log_{10}$ reduction (inactivation ≥ 99.99 %) under clean conditions in a quantitative suspension test according to EN 14476:2013+A1:2015/prA2:2016.

After evaluation with adenovirus type 5 and MNV the surface disinfectant mikrozid AF liquid can be declared as having **"limited spectrum virucidal activity"** according to EN 14476:2013+A1:2015 /prA2:2016.

The declaration **"limited spectrum virucidal activity"** covers the specified test organisms and all enveloped humanpathogenic viruses like HBV, HCV, HIV and Ebola virus.

Dr. Jochen Steinmann

From Annex A in EN 14476
Examples of viruses which may contaminate human medical instruments, hands, surfaces (*Enveloped viruses are in bold*)

NOTE This list is not exhaustive.

Blood

Enterovirus
Filoviridae
Flavivirus
Herpesviridae
Hepatitis A Virus (HAV)
Hepatitis B virus (HBV)
Hepatitis C virus (HCV)
Hepatitis Delta virus (HDV)
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Parvovirus B 19

Respiratory tract

Adenovirus (Mast-)
Coronavirus
Enterovirus
Herpesviridae
Influenza Virus
Paramyxoviridae
Rhinovirus
Rubella Virus

Neural tissue, ear & nose, eye

Adenovirus (Mast-)
Enterovirus
Herpesviridae
Measles Virus
Human Immunodeficiency Virus (HIV)
Polyomavirus
Rabies Virus
Rubella Virus

Gastro-intestinal

Adenovirus (Mast-)
Caliciviridae
Coronavirus
Astrovirus
Enterovirus
Hepatitis A Virus (HAV)
Hepatitis E Virus (HEV)
Rotavirus

Skin, breast and/or milk

Enterovirus
Herpesviridae
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Papillomavirus
Poxviridae

Spleen and lymph nodes (see also „Blood")

Human T Cell Leukemia Virus (HTLV)
Human Immunodeficiency Virus (HIV)

Dental procedure

Adenovirus (Mast-)
Enterovirus
Herpesviridae
Hepatitis B virus (HBV)
Hepatitis C Virus (HCV)
Hepatitis Delta Virus (HDV)
Human Immunodeficiency Virus (HIV)

Urogenital tract

Hepatitis B Virus (HBV)
Herpesviridae
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Papillomavirus
Polyomavirus

Reference:
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Schülke & Mayr GmbH
Robert-Koch-Straße 2
DE – 22851 Norderstedt

Bremen, 10/01/2018

Expert opinion

Activity of mikrozid AF liquid against Polyomavirus SV40 according to the Guideline of DVV/RKI dating 01/12/2014

This expert opinion is based on the test report L17/0779cS.1 dating 10/01/2018.

The virus-inactivating properties of the surface disinfectant mikrozid AF liquid of Schülke & Mayr GmbH against Polyomavirus SV40 strain 777 were investigated by a quantitative suspension test according to the Guideline of the Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (German Association for the Control of Virus Diseases) and of the Robert Koch-Institute (RKI).

According to this Guideline, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by ≥ 4 $\log_{10}$ (inactivation ≥ 99.99 %).

The surface disinfectant mikrozid AF liquid was examined undiluted at 20 °C. 5, 10 and 15 minutes were chosen as exposure times. In summary, a virucidal activity against Polyomavirus SV40 was measured as follows:

	undiluted	**5 minutes**

Dr. Jochen Steinmann

HVZ-Hamburg GmbH
Hygienisches Versorgungszentrum Hamburg
am Institut für Hygiene und Umwelt Hamburg
Dr. med. A. Sammann
Arzt für Mikrobiologie und Infektionsepidemiologie
Marckmannstr. 129a , 20539 Hamburg
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Report for mikrozid AF liquid based on the test report of TPH 5553 - 2018

Test of the product mikrozid AF liquid from Schülke & Mayr in accordance with the standard method of DIN EN 16615:2015 (Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2))

The product mikrozid AF liquid was tested in conjunction with the wipe system safe & easy bagless system for the disinfection of surfaces. The order date was 07.06.2018, the samples were received on 28.06.2018. The test period was July to August 2018 with batch numbers 1504726 for the disinfectant and 9353106 for the wipes, expiration dates 01/2023 for the disinfectant and 04/2023 for the wipes.

Use-recommendation

mikrozid AF liquid in combination with the wipe system safe & easy bagless system meets the requirements of the 4-field test according to DIN EN 16615 for a preparation for surface disinfection using a cloth dispenser system. The preparation and use of the cloths must be carried out according to the manufacturer's instructions.

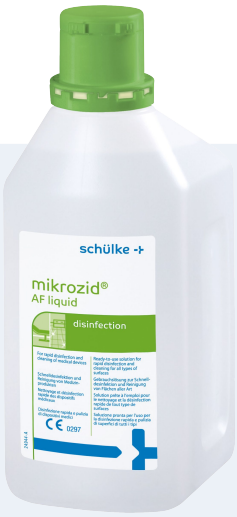
The product can be used for surface disinfection with bactericidal and yeasticidal activity.

Surface disinfection with dispenser system:

Under dirty conditions with a contact time of 1,0 minute

Hamburg, 29. August 2018

Dr. med. A. Sammann
(Sci. director)



Dezinfectant rapid pe bază de alcool pentru produse medicale non-invazive și alte suprafețe

mikrozid® AF liquid

Avantajele produsului nostru:

- soluție gata preparată
- activitate biocidă foarte extinsă, în cel mai scurt timp posibil
- uscare rapidă fără a lăsa urme

Aria de aplicare

Produsul este adecvat pentru dezinfecția dispozitivelor medicale și a altor suprafețe. Produsul nostru clasic printre cele pentru dezinfecția rapidă a suprefețelor este adecvat pentru dezinfecția suprafețelor din proximitatea pacienților care prezintă un risc ridicat de infecție și necesită un timp scurt de acțiune.

Instrucțiuni de utilizare

Aplicați produsul nediluat pe suprafețe, ștergeți și așteptați ca acesta să își facă efectul. Asigurați-vă că ați umezit complet suprafețele și păstrați-le umede pe întreaga durată a timpului de expunere. Coeficientul maxim de aplicare va fi de 50 ml/m pătrat. Asigurați-vă că ați îndepărtat toată murdăria vizibilă înainte de dezinfecție. Orice incident serios legat de produs trebuie raportat producătorului și autorităților competente. A nu se folosi pentru dezinfecția finală a echipamentelor medicale semi-critice și critice!

Eficiență microbiologică

Eficiență	Concentrație	Timp de contact
bactericid *EN13727, EN16615* *-condiții de murdărie*	Gata de utilizare	1 min.
tuberculocid *EN14348* *-condiții de murdărie*	Gata de utilizare	1 min.
levuricid *EN13727, EN16615* *-condiții de murdărie*	Gata de utilizare	1 min.
fungicid *EN13624, EN13697* *-condiții de murdărie*	Gata de utilizare	2 min.
virucid împotriva virusurilor capsulate *În conformitate cu DVV (Asociația Germană pentru Combaterea Bolilor Virale)// Instrucțiunile RKI*	Gata de utilizare	30 sec.
Norovirus *EN14476* *-condiții de murdărie*	Gata de utilizare	1 min.
Polioma SV40 *În conformitate cu DVV (Asociația Germană pentru Combaterea Bolilor Virale)// Instrucțiunile RKI*	Gata de utilizare	10 min.
Rotavirus *În conformitate cu DVV*	Gata de utilizare	30 sec.
Adenovirus (tip 5) *În conformitate cu DVV (Asociația Germană pentru Combaterea Bolilor Virale)// Instrucțiunile RKI*	Gata de utilizare	5 min.

Certificate:

- Certificat VAH
- Înregistrat IHO
- Certificat ÖGHMP

CE 0297

mikrozid® AF liquid

Informații despre produs

Compoziție
100 g de soluție conține următoarele ingrediente active:
25 g etanol (94%) și 35 g propan-1-ol
Etichetare conform Reglementărilor (CE) Nr. 648/2004:
parfumuri

Informații de natură chimică/fizică:	
Culoare:	lichid incolor
Densitatea (20° C):	aprox. 0,89 g/cm³/20° C
Punct de inflamație:	27° C/ Metoda: DIN 51755 Partea I
Formă:	Lichidă
pH:	Nu se aplică
Vâscozitate, dinamică:	Nedeterminată

Recomandări speciale

Utilizați dezinfectantele în siguranță. Citiți întotdeauna prospectul și informațiile despre produs înaintea utilizării.
Produsul are o foarte bună compatibilitate cu metale și sintetice (cu excepția sticlei acrilice și a lacurilor sensibile la alcool). Nu tratați suprafețele sensibile la alcool (de ex. sticla acrilică). Vă rugăm să urmați cu strictețe orice instrucțiuni naționale cu privire la incendii și protecția împotriva exploziilor atunci când folosiți dezinfectanți pe bază de alcool. Păstrați la distanță de căldură şi surse de aprindere. Termenul de valabilitate a ambalajului deschis se regăseşte pe etichetă.

Informații pentru comandă

Articol	Forma de livrare	Nr. articol
Flacon spray 250 ml mikrozid® AF liquid	10/Bax	La cerere
Flacon 1 l mikrozid® AF liquid	10/Bax	La cerere
10 l mikrozid® AF liquid	1/Canistră	La cerere

Aceste produse nu sunt disponibile în toate țările. Pentru mai multe informații vă rugăm să contactați sucursala sau distribuitorul nostru local.

Accesorii

Accesorii	Nr. articol
Cheie canistră 5+10 l	135810
Robinet schülke pentru bidon de 5 l/ 10 l	135501
Pulverizator pentru 500/1000 ml	180124

Produse similare

- mikrozid® AF wipes
- mikrozid® sensitive liquid

Informații despre mediu

schülke fabrică produse într-un mod economic și prin procese de producție avansate, sigure și prietenoase cu mediul, păstrându-și, totodată, standardele înalte de calitate.

Părerile experților și informații

Vă rugăm vizitați site-ul nostru pentru o privire de ansamblu asupra întregii literaturi de specialitate/rapoarte asupra produsului: www.schuelke.com

Pentru informații individuale, contactați:
Serviciul Vânzări Clienți:
Telefon: +49 40 52100-666
E-mail: info@schuelke.com

EMAS GEPRÜFTES UMWELTMANAGEMENT REG.-NR. D-150-00003

Schükle & Mayr S.R.L. deține o Autorizație a Producătorului conformă cu secțiunea 13, paragraful 1 al Legii Germane pentru Medicamente și Certificate de Conformitate GMP pentru produse medicinale.

Producător: Schulke & Mayr GmbH
Str. Robert-Koch nr. 2,
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Fax: +49 (0) 40 – 52100 – 318
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www.intercoop.ro

Versiunea 6/2021

Verbund für Angewandte Hygiene (VAH)
Association for Applied Hygiene

– Desinfektionsmittel-Kommission im VAH –
Disinfectant Commission in VAH

Zertifikat / *Certificate*

über die Konformität der Wirksamkeitsprüfungen für / *for conformity of efficacy tests for*

mikrozid® AF liquid

mit den Anforderungen und Methoden zur VAH-Zertifizierung chemischer Desinfektionsverfahren – Stand 2.4.2015 - bzw. den Übergangsbestimmungen vom 2.4.2015
with the requirements and methods of VAH-certification for chemical disinfection procedures – as per 2 April 2015 - and the transitional provisions of 2 April 2015, respectively.

ANTRAGSTELLER / *APPLICANT*: **Schülke & Mayr GmbH**

22840 Norderstedt

WIRKSTOFFE nach Art und Menge bezogen auf 100 g: / *Quantity of active substances per 100 g:*

35 g 1-Propanol **25 g Ethanol (94%ig)**

Hiermit wird bestätigt, dass das o.g. Produkt für die prophylaktische Desinfektion in den aufgeführten Anwendungsbereichen in folgenden Konzentrations-Zeit-Relationen als wirksam eingestuft wird:
This is to confirm that the above product was found to be effective for prophylactic disinfection in the application domains listed below at the specified concentration/contact time ratios:

Flächendesinfektion zur Prophylaxe in Krankenhaus und Praxis (Bakterizidie und Levurozidie)
Surface disinfection for prophylaxis in hospital and primary healthcare (bactericidal activity and yeasticidal activity)

Flächeneinsatztyp / Type of Surface disinfectant :
Wischdesinfektion – ohne spezifizierte Tücher / Disinfectant wipes without specified wipe material

Wischen *Mechanical action*		Organische Belastung *Interfering substance*		Einwirkzeit in min *Contact time in min*				
mit/*with*	ohne/ *without*	gering/*clean conditions*	hoch/*dirty conditions*	5	15	30	60	240
X			X	konz.				

Das Zertifikat ist gültig vom 25.08.2020 bis zum 25.08.2023 (3 Jahre) /
Certificate is valid from 25.08.2020 until 25.08.2023 (3 years)

Der Antragsteller hat sich mit den Bedingungen der zum Zeitpunkt der Antragstellung gültigen Geschäftsordnung der Desinfektionsmittelkommission im VAH einverstanden erklärt und rechtsverbindlich bestätigt, dass das von ihm in Handel gebrachte Präparat in seiner Zusammensetzung identisch mit den für die Erstellung der Gutachten eingereichten Mustern ist. / *The applicant has agreed to the conditions laid down in the rules of the disinfectant commission in the VAH valid at the time of application and has legally binding confirmed that the distributed product is identical with the product used for the activity testing.*

Bonn, den **22.07.2020**
Place/Date

Der Vorsitzende der Desinfektionsmittel-Kommission im VAH /
The Chairman of the Disinfectant Commission in VAH Az.: *N20/141*

Desinfektionsmittel-Kommission im VAH, c/o Institut für Hygiene, Venusberg-Campus 1, D-53127 Bonn, www.vah-online.de, info@vah-online.de, Tel. 0228-2871 40220