Scientific Dossier
Dezfarm
Disinfectant for surfaces and carriers.

Disinfectant for the institutional area on the basis of cationic active ingredients, without the addition of aldehyde, for surface disinfection, wiping disinfection as well as disinfecting surface cleaning.
For application in hospitals, kindergartens, schools, foster homes, swimming pools and other public facilities for disinfection.
According to the application area of the medical product the surface is to rinse or wipe carefully after disinfection in order to remove product residues. Note batch number and expiry date separately printed on the packaging.

1. INTRODUCTION

DEZFARM+ is an effective cleaner and broad-spectrum disinfectant
(bactericidal, mycobactericidal, fungicidal and virucidal).
DEZFARM+ combines the microbiological effectiveness of a quaternary ammonium and
of an alkylamine.
The DEZFARM+ can be used on any type of surface, whether floors, walls,
sanitary facilities, but also the equipment, furniture and objects found in
the patient's environment.
DEZFARM can be used, with rinsing on surfaces likely to come into contact with
direct contact with foodstuffs (in accordance with the decree of September 8, 1999).
DEZFARM+ is used at a dose of 0.25%.

2. COMPOSITION

Active substance
- Didecyldimethylammonium chloride (CAS No: 7173-51-5)
- N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (CAS No: 2372-82-9)
-N-Alkyl-N-benzyl-N,N-dimethylammonium chlorideAlkyldimethylbenzylammonium chloride mixed
Non-ionic surfactants
EDTA and salts
Labelable allergen-free fragrance

3. ORGANOLEPTIC AND PHYSICO-CHEMICAL CHARACTERISTICS

Appearance: clear liquid
Colour: colorless to pale yellow*
Smell: specific
pH at 20°C (pure product): 9.1 +/- 0.3
pH at 20°C diluted to 0.25% (mains water): approximately 8.0
Density at 20°C (g/ml): 1.052 +/- 0.005

ATTESTATION OF EQUIVALENCE

I, Andrei Gogu, certify that the following products:

Microbac forte
And
BARRIER-TECH-MF-Sanitiser-Concentrate
And
Bacoban WB
And
Efficacy of five 'sporicidal' surface disinfectants against Clostridioides difficile spores in suspension tests and 4-field tests
And
Dezfarm

Has a similar formula.

This certificate is issued to serve and assert what is right.

Gogu
Andrei

4.Study about efficiency of the product.
Test of equivalence

Next we will make comparison of products:
Looking on the tests made before we can observe that presence of the active substances are the same .
Concluding this we can tell that Dezfarm have the similar formula with previous products used for disinfection.

Application area (1)	Organisms	Quantitative suspension test	Test conditions and time
Surface disinfection	Bacteria (and mycobacteria)	EN 1276 or EN 13727EN 13697 (and EN 14348)	1%- 5 min
	Yeast / Fungi	EN 1650 or EN 13624 EN 13697	1%-5min
	Bacteria	EN 1275	0.25% - 5min
	Spores Bactericidal /Yeasticidal	(EN 13727, EN 13624 & EN 16615 ,17126)	1% - 5 min 1% - 15 min 1% - 60 min 3% - 5 min dirty conditions
	Bacteria (and mycobacteria)	EN 13727 (and EN 14348)	0.25 - 30 min 0.5% - 15 min
	Yeast / Fungi	EN 13624	
	Spores (bacteria)	EN 13704 or EN 17126	
	Viruses	EN 14476 or DVV	
	Bacteria	EN 1276 or EN 13727	0.25% - 15min(dirty)
	Yeast / Fungi	EN 1650 or EN 13624	
	Viruses	EN 14476	0.25% - 15 min (dirty) 0.5% - 5 min (dirty) 1% - 5 min (dirty)

*The scientific file was developed in 2022.

HYGIENE NORD GMBH
C/O BIOTECHNIKUM
WALTHER-RATHENAU-STRASSE 49 A
17489 GREIFSWALD
DEUTSCHLAND - GERMANY

DAkkS
Deutsche
Akkreditierungsstelle
D-PL-18411-01-01
D-PL-18411-01-02

HYGIENE NORD GMBH

HYGIENE NORD GMBH, C/O BIOTECHNIKUM, W.-RATHENAU-STR. 49 A, D-17489 GREIFSWALD

Cleaning Box GmbH
Europaplatz 7
D-99091 Erfurt
Deutschland / Germany

CUSTOMER NUMBER	DATE
1592	October 08, 2019

REPORT 191428.V1

EINWEG-DESINFEKTIONS-MOPPS

4-FIELD-TEST (VAH / EN 16615)

BACTERICIDAL AND YEASTICIDAL EFFICACY

Purpose

Using the single-use mops **Einweg-Desinfektions-Mopps** (CleaningBox GmbH, Erfurt, Germany), the bactericidal and yeasticidal efficacy of the disinfectant / cleaner - combination **Microbac forte** + **PREMIUM Nº 1 PLUS** should be evaluated in the 4-Field-Carrier Test for surface disinfection with mechanical action in accordance with the **EN 16615** (2015).

HYGIENE NORD GMBH
W.-RATHENAU-STR. 49A
17489 GREIFSWALD
TELEFON: +49(0)3834-515520
TELEFAX: +49(0)3834-515525
E-MAIL: INFO@HYGIENE-NORD.DE
BANK: DEUTSCHE BANK GREIFSWALD
BLZ: 13070024 KONTO: 2245512OO
IBAN: DE14 13070024 0224551200
GESCHÄFTSFÜHRER: DR. TORSTEN KOBURGER-JANSSEN
UMSATZSTEUER-ID (VAT/TAX): DE211580653
SITZ DER GESELLSCHAFT: GREIFSWALD

Test description

Order number:	A 19665	
Manufacturer:	CleaningBox GmbH, Erfurt, Germany	
Product name:	**Einweg-Desinfektions-Mopps**	
Item number	CB 1162	
Description (mop):	1 Pack á 5 pieces; mops: blue, 42 cm x 13 cm; 3 layers: 75 g/m² cleaning layer of viscose; 280 g/m² disinfectant-storage layer of cellulose, 50 g/m² germ protective film of PP/CPP; absorption volume (according to manufacturer): max. 170 ml / mop	
Sample number:	P 194487	
Storage conditions:	Room temperature	
Disinfectant / Cleaner:	**Microbac® forte**	**PREMIUM Nº 1 PLUS**
Manufacturer:	Bode Chemie GmbH, Hamburg, Germany	Kleen Purgatis GmbH, Hidden-hausen, Germany
Ref:	975395	183.353
Batch number:	454639	120.9 E20l
Best before:	05/2024	not provided
Sample number:	P 194261	P 194779
Date of delivery:	August 05, 2019	August 28, 2019
Odour:	product specific	product specific, fresh
Appearance:	clear, colourless, slightly viscous liquid	clear, red liquid
App./working solution:	clear, colourless solution	clear, colourless solution
pH-value (pH-meter):	100 %: 8.12	100 %: 0.44
	5 %: n.d. 2.5 %: 7.64	0.5 %: 2.34
	1 %: n.d. 0.5 %: 7.71	WSH: 7.17
pH- value combinations:	2.5 % Microbac® forte + 0.5 % PREMIUM Nº 1 PLUS: 5.36	
	0.5 % Microbac® forte + 0.5 % PREMIUM Nº 1 PLUS: 2.73	
Active ingredients /100 g:	199 mg/g Bezyl-C12-18-alkyldimethylammonium chloride 50 mg/g N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamin	< 5 % nonionic surfactants Coumarin ALPHA-ISOMETHYL IONONE
Product dilution:	Water of standardized hardness (WSH)	
Date of order:	July 11, 2019	
Test date:	September 30, 2019 – October 04, 2019	

Table 1.1: Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)

Date:	October 02, 2019	**Order number:**	A 19665
Products:	**Microbac forte + PREMIUM Nº 1.**	**Sample Number:**	P 194261/-779
Mop:	**Einweg-Desinfektions-Mopp**	**Sample Number:**	P 194487
Test organism:	*S. aureus*	**Neutralizer:**	XXIII
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	**Incubation time:**	24 h - 48 h
Test suspension (N):	$2.67*10^9$ cfu/ml (9.43 log)	**Test temperature:**	20 ± 1 °C
Test suspension / carrier:	$1.20*10^8$ cfu (8.08 log)	**Drying time:**	17 min
Validation suspension (N_V):	$3.95*10^2$ cfu/ml (3.60 log)	**Rel. Humidity:**	73.5 %

1st run of testing - Contact time: 5 min

Concentration / Contact time: 2.5 % / 5 min

Product / field	Dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	$\log_{10}$ Na	$\log_{10}$ R
Field 1	4x0.5 ml (10^0)	0	0	0	0	0	0	0.00	**7.61**
	4x0.5 ml (10^{-1})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	0	0	0	0	0		
Field 3	4x0.5 ml (10^0)	0	0	0	0	0	0	∅ F2-F4 ≤ 50 ?	**OK**
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
WSH-Control (N_W)	4x0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-1})	42	37	44	39	79	83	3.59	**4.03**
Field 1	4x0.5 ml (10^{-2})	5	2	3	4	< 14	< 14		
Field 2	4x0.5 ml (10^0)	10	6	8	9	16	17		
Field 3	4x0.5 ml (10^0)	4	0	1	3	4	4	∅ F2-F4 ≥ 10 ?	**OK**
Field 4	4x0.5 ml (10^0)	1	4	2	2	5	4		
Control (T_0)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-5})	40	36	39	42	76	81	**7.59**	**0.02**
Control (T_t)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-5})	45	40	41	38	85	79	**7.61**	

	Mass in g:		
	Before test:	After test:	Difference
Product:	67.2	63.5	**3.7**
N_W:	19	18.1	**0.9**

Validation and Controls:

See table 1.2

Table 1.2: Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)

Date:	October 02, 2019	**Order number:**	A 19665
Products:	**Microbac forte + PREMIUM № 1.**	**Sample Number:**	P 194261/-779
Mop:	**Einweg-Desinfektions-Mopp**	**Sample Number:**	P 194487
Test organism:	*S. aureus*	**Neutralizer:**	XXIII
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	**Incubation time:**	24 h - 48 h
Test suspension (N):	$2.67*10^9$ cfu/ml (9.43 log)	**Test temperature:**	20 ± 1 °C
Test suspension / carrier:	$1.20*10^8$ cfu (8.08 log)	**Drying time:**	17 min
Validation suspension (N_V):	$3.95*10^2$ cfu/ml (3.60 log)	**Rel. Humidity:**	73.5 %

1st run of testing - Contact time: 60 min

Concentration / Contact time: 0.5 % / 60 min

Product / field	Dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	$\log_{10}$ Na	$\log_{10}$ R
Field 1	4x0.5 ml (10^0)	0	0	0	0	0	0	0.00	7.43
	4x0.5 ml (10^{-1})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	0	0	0	0	0		
Field 3	4x0.5 ml (10^0)	0	0	0	0	0	0	∅ F2-F4 ≤ 50 ?	OK
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
WSH-Control (N_W)	4x0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-1})	72	53	63	77	125	140	3.80	3.63
Field 1	4x0.5 ml (10^{-2})	7	9	6	5	16	< 14		
Field 2	4x0.5 ml (10^0)	14	13	9	12	27	21		
Field 3	4x0.5 ml (10^0)	4	7	6	9	11	15	∅ F2-F4 ≥ 10 ?	OK
Field 4	4x0.5 ml (10^0)	14	11	10	13	25	23		
Control (T_0)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-5})	40	36	39	42	76	81	7.59	-0.16
Control (T_t)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	266	292	253	271	558	524	7.43	
	4x0.5 ml (10^{-5})	25	26	29	27	51	56		

	Mass in g:		
	Before test:	After test:	Difference
Product:	67.2	63.2	4
N_W:	19	18.1	0.9

Validation and Controls:

Validation - Suspension (N_{VO})					Experimental condition control (A)					Neutralizer control (B)					Method validation (C); Product concentration: 2.5 %				
	cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$
V_{c1}	19	23	42	39.5	V_{c1}	31	38	69	67	V_{c1}	25	33	58	59.5	V_{c1}	39	34	73	67.5
V_{c2}	18	19	37		V_{c2}	35	30	65		V_{c2}	29	32	61		V_{c2}	29	33	62	
30 ≤ $\bar{x}$ of N_{VO} ≤ 160?					$\bar{x}$ of A is ≥ 0.5* $\bar{x}$ of N_{VO}?					$\bar{x}$ of B is ≥ 0.5* $\bar{x}$ of N_{VO}?					$\bar{x}$ of C is ≥ 0.5* $\bar{x}$ of N_{VO}?				
X Yes			No		X Yes			No		X Yes			No		X Yes			No	

Table 2.1: Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)

Date:	October 04, 2019	**Order number:**	A 19665
Products:	**Microbac forte + PREMIUM Nº 1.**	**Sample Number:**	P 194261/-779
Mop:	**Einweg-Desinfektions-Mopp**	**Sample Number:**	P 194487
Test organism:	*E. hirae*	**Neutralizer:**	XXIII
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	**Incubation time:**	24 h - 48 h
Test suspension (N):	$4.40*10^9$ cfu/ml (9.46 log)	**Test temperature:**	20 ± 1 °C
Test suspension / carrier:	$1.98*10^8$ cfu (8.30 log)	**Drying time:**	18 min
Validation suspension (N_V):	$3.21*10^3$ cfu/ml (3.51 log)	**Rel. Humidity:**	47.2 %

1st run of testing - Contact time: 5 min

Concentration / Contact time: 2.5 % / 5 min

Product / field	Dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	$\log_{10}$ Na	$\log_{10}$ R
Field 1	4x0.5 ml (10^0)	0	0	0	0	0	0	0.00	**7.30**
	4x0.5 ml (10^{-1})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	0	0	0	0	0		
Field 3	4x0.5 ml (10^0)	0	0	0	0	0	0	∅ F2-F4 ≤ 50 ?	**OK**
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
WSH-Control (N_W) Field 1	4x0.5 ml (10^0)	164	158	153	160	322	313	3.20	**4.10**
	4x0.5 ml (10^{-1})	16	18	15	17	34	32		
	4x0.5 ml (10^{-2})	2	1	1	2	< 14	< 14		
Field 2	4x0.5 ml (10^0)	31	21	20	23	52	43		
Field 3	4x0.5 ml (10^0)	31	37	31	35	68	66	∅ F2-F4 ≥ 10 ?	**OK**
Field 4	4x0.5 ml (10^0)	51	43	43	50	94	93		
Control (T_0)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	218	253	235	238	471	473	**7.38**	**-0.08**
	4x0.5 ml (10^{-5})	27	28	30	23	55	53		
Control (T_t)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	210	193	183	201	403	384	**7.30**	
	4x0.5 ml (10^{-5})	22	29	21	20	51	41		

	Mass in g:		
	Before test:	After test:	Difference
Product:	67	66	**1**
N_W:	18.9	17.9	**1**

Validation and Controls:

See table 2.2

Table 2.2: Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)

Date:	October 04, 2019	**Order number:**	A 19665
Products:	**Microbac forte + PREMIUM № 1.**	**Sample Number:**	P 194261/-779
Mop:	**Einweg-Desinfektions-Mopp**	**Sample Number:**	P 194487
Test organism:	*E. hirae*	**Neutralizer:**	XXIII
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	**Incubation time:**	24 h - 48 h
Test suspension (N):	$4.40*10^9$ cfu/ml (9.46 log)	**Test temperature:**	20 ± 1 °C
Test suspension / carrier:	$1.98*10^8$ cfu (8.30 log)	**Drying time:**	18 min
Validation suspension (N_V):	$3.21*10^3$ cfu/ml (3.51 log)	**Rel. Humidity:**	47.2 %

1st run of testing - Contact time: 60 min

Concentration / Contact time: 0.5 % / 60 min

Product / field	Dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	$\log_{10}$ Na	$\log_{10}$ R
Field 1	4x0.5 ml (10^0)	0	0	0	0	0	0	0.00	**7.15**
	4x0.5 ml (10^{-1})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	0	0	0	0	0		
Field 3	4x0.5 ml (10^0)	0	0	0	0	0	0	∅ F2-F4 ≤ 50 ?	**OK**
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
WSH-Control (N_W) Field 1	4x0.5 ml (10^0)	52	69	51	48	121	99	2.74	**4.41**
	4x0.5 ml (10^{-1})	5	3	6	4	< 14	< 14		
	4x0.5 ml (10^{-2})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	50	70	61	67	120	128		
Field 3	4x0.5 ml (10^0)	35	36	31	28	71	59	∅ F2-F4 ≥ 10 ?	**OK**
Field 4	4x0.5 ml (10^0)	41	49	43	36	90	79		
Control (T_0)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	218	253	235	238	471	473	**7.38**	**-0.23**
	4x0.5 ml (10^{-5})	27	28	30	23	55	53		
Control (T_t)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	150	112	153	138	262	291	**7.15**	
	4x0.5 ml (10^{-5})	20	16	15	13	36	28		

	Mass in g:		
	Before test:	After test:	Difference
Product:	67	64	3
Nw:	19	18.1	**0.9**

Validation and Controls:

Validation - Suspension (N_{VO})					Experimental condition control (A)					Neutralizer control (B)					Method validation (C); Product concentration: 2.5 %				
	cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$
V_{c1}	156	168	324	**321**	V_{c1}	176	172	348	**339.**	V_{c1}	152	134	286	**289**	V_{c1}	188	182	370	**348**
V_{c2}	160	158	318		V_{c2}	168	163	331		V_{c2}	151	141	292		V_{c2}	173	153	326	
30 ≤ $\bar{x}$ of N_{VO} ≤ 160?					$\bar{x}$ of A is ≥ 0.5* $\bar{x}$ of N_{VO}?					$\bar{x}$ of B is ≥ 0.5* $\bar{x}$ of N_{VO}?					$\bar{x}$ of C is ≥ 0.5* $\bar{x}$ of N_{VO}?				
X Yes *			No		X Yes			No		X Yes			No		X Yes			No	

* higher than 160 kbE, but OK, with regard to matching controls A, B and C

Table 3.1: Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)

Date:	October 01, 2019	**Order number:**	A 19665
Products:	**Microbac forte + PREMIUM Nº 1.**	**Sample Number:**	P 194261/-779
Mop:	**Einweg-Desinfektions-Mopp**	**Sample Number:**	P 194487
Test organism:	*P. aeruginosa*	**Neutralizer:**	XXIII
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	**Incubation time:**	24 h - 48 h
Test suspension (N):	$8.75*10^9$ cfu/ml (9.94 log)	**Test temperature:**	20 ± 1 °C
Test suspension / carrier:	$3.94*10^8$ cfu (8.60 log)	**Drying time:**	17 min
Validation suspension (N_V):	$1.49*10^3$ cfu/ml (3.17 log)	**Rel. Humidity:**	73.5 %

1st run of testing - Contact time: 5 min

Concentration / Contact time: 2.5 % / 5 min									
Product / field	**Dilution**	**cfu / plate 1**	**cfu / plate 2**	**cfu / plate 3**	**cfu / plate 4**	**V_{c1}**	**V_{c2}**	**$\log_{10}$ Na**	**$\log_{10}$ R**
Field 1	4x0.5 ml (10^0)	0	0	0	0	0	0	0.00	**7.72**
	4x0.5 ml (10^{-1})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	0	0	0	0	0		
Field 3	4x0.5 ml (10^0)	0	0	0	0	0	0	∅ F2-F4 ≤ 50 ?	**OK**
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
WSH-Control (N_W) Field 1	4x0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-1})	87	100	94	97	187	191	3.95	**3.77**
	4x0.5 ml (10^{-2})	4	8	9	7	< 14	16		
Field 2	4x0.5 ml (10^0)	63	72	59	67	135	126		
Field 3	4x0.5 ml (10^0)	35	50	44	49	85	93	∅ F2-F4 ≥ 10 ?	**OK**
Field 4	4x0.5 ml (10^0)	3	5	4	5	8	9		
Control (T_0)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-5})	105	104	99	106	209	205	**8.01**	**-0.30**
Control (T_t)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-5})	56	54	51	48	110	99	**7.72**	

	Mass in g:		
	Before test:	**After test:**	**Difference**
Product:	67.7	64.2	**3.5**
N_W:	19	18.1	**0.9**

Validation and Controls:

See table 3.2

Table 4.1: Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)

Date:	October 04, 2019	**Order number:**	A 19665
Products:	**Microbac forte + PREMIUM Nº 1.**	**Sample Number:**	P 194261/-779
Mop:	**Einweg-Desinfektions-Mopp**	**Sample Number:**	P 194487
Test organism:	*C. albicans*	**Neutralizer:**	XXIII
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	30 ± 1 °C	**Incubation time:**	48 h
Test suspension (N):	$1.06*10^9$ cfu/ml (9.03 log)	**Test temperature:**	20 ± 1 °C
Test suspension / carrier:	$4.77*10^7$ cfu (7.68 log)	**Drying time:**	20 min
Validation suspension (N_V):	$4.15*10^2$ cfu/ml (2.62 log)	**Rel. Humidity:**	46.6 %

1st run of testing - Contact time: 5 min

Concentration / Contact time: 2.5 % / 5 min

Product / field	Dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	$\log_{10}$ Na	$\log_{10}$ R
Field 1	4x0.5 ml (10^0)	0	0	0	0	0	0	0.00	**6.24**
	4x0.5 ml (10^{-1})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	0	0	0	0	0		
Field 3	4x0.5 ml (10^0)	0	0	0	0	0	0	∅ F2-F4 ≤ 50 ?	**OK**
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
WSH-Control (N_W) Field 1	4x0.5 ml (10^0)	1	0	0	0	1	0	0.40	**5.85**
	4x0.5 ml (10^{-1})	0	0	0	0	< 14	< 14		
	4x0.5 ml (10^{-2})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	0	0	0	0	0		
Field 3	4x0.5 ml (10^0)	0	0	0	0	0	0	∅ F2-F4 ≥ 10 ?	~~OK~~
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
Control (T_0)	4x0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-3})	162	200	213	178	362	391	**6.28**	**-0.04**
	4x0.5 ml (10^{-4})	29	20	23	17	49	40		
Control (T_t)	4x0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-3})	162	160	178	201	322	379	**6.24**	
	4x0.5 ml (10^{-4})	15	24	17	16	39	33		

	Mass in g:		
	Before test:	After test:	Difference
Product:	69	67	2
Nw:	19.1	18.1	1

Validation and Controls:

See table 4.2

Table 4.2: Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)

Date:	October 04, 2019	**Order number:**	A 19665
Products:	**Microbac forte + PREMIUM Nº 1.**	**Sample Number:**	P 194261/-779
Mop:	**Einweg-Desinfektions-Mopp**	**Sample Number:**	P 194487
Test organism:	*C. albicans*	**Neutralizer:**	XXIII
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	30 ± 1 °C	**Incubation time:**	48 h
Test suspension (N):	$1.06*10^9$ cfu/ml (9.03 log)	**Test temperature:**	20 ± 1 °C
Test suspension / carrier:	$4.77*10^7$ cfu (7.68 log)	**Drying time:**	20 min
Validation suspension (N_V):	$4.15*10^2$ cfu/ml (2.62 log)	**Rel. Humidity:**	46.6 %

1st run of testing - Contact time: 60 min

Concentration / Contact time: 0.5 % / 60 min

Product / field	Dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	log_{10} Na	log_{10} R
Field 1	4x0.5 ml (10^0)	0	0	0	0	0	0	0.00	**6.04**
	4x0.5 ml (10^{-1})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	0	0	0	0	0		
Field 3	4x0.5 ml (10^0)	0	0	0	0	0	0	∅ F2-F4 ≤ 50 ?	**OK**
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
WSH-Control (N_W) Field 1	4x0.5 ml (10^0)	0	0	0	0	0	0	0.00	**6.04**
	4x0.5 ml (10^{-1})	0	0	0	0	< 14	< 14		
	4x0.5 ml (10^{-2})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	0	0	0	0	0		
Field 3	4x0.5 ml (10^0)	0	0	0	0	0	0	∅ F2-F4 ≥ 10 ?	~~OK~~
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
Control (T_0)	4x0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-3})	162	200	213	178	362	391	**6.28**	**-0.24**
	4x0.5 ml (10^{-4})	29	20	23	17	49	40		
Control (T_t)	4x0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-3})	103	1< 14	121	101	217	222	**6.04**	
	4x0.5 ml (10^{-4})	7	12	10	11	19	21		

	Mass in g:		
	Before test:	After test:	Difference
Product:	67	65	2
Nw:	18.9	17.9	1

Validation and Controls:

Validation - Suspension (N_{VO})					Experimental condition control (A)					Neutralizer control (B)					Method validation (C); Product concentration: 2.5 %				
	cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$		cfu /plate 1 & 2		V_c	$\bar{x}$
V_{c1}	23	16	39	41.5	V_{c1}	22	28	50	49.5	V_{c1}	17	18	35	38	V_{c1}	21	20	41	40
V_{c2}	20	24	44		V_{c2}	26	23	49		V_{c2}	20	21	41		V_{c2}	21	18	39	
30 ≤ $\bar{x}$ of N_{VO} ≤ 160?					$\bar{x}$ of A is ≥ 0.5* $\bar{x}$ of N_{VO}?					$\bar{x}$ of B is ≥ 0.5* $\bar{x}$ of N_{VO}?					$\bar{x}$ of C is ≥ 0.5* $\bar{x}$ of N_{VO}?				
X Yes			No		X Yes			No		X Yes			No		X Yes			No	

Survival of the test organisms on the flooring throughout the contact time is controlled using a separate piece of flooring with two more contaminated test fields. One of them is sampled at the end of the drying time, i.e. immediately before starting the application of the test product - control T_0). The other one is sampled at the end of the contact time - control T_t). For the calculation of the reduction factor (RF), the number of test organisms recovered from the disinfected test fields is related to the number of test organisms recovered from the T_t control field.

The experimental conditions (control A), the non-toxicity of the neutralizer (control B) and the dilution-neutralization method (control C) are validated in accordance with **EN 16615 (2015)** requirements. Detailed results are presented in tables 1.1 – 4.2

Results

Quantitative carrier test – surface disinfection with mechanical action (4-Field-Test)

According to the European Standard **EN 16615 (2015)**, the test product **Einweg-Desinfektions-Mopps**, when soaked with **120 ml / mop** with the disinfectant / cleaner - combinations of **2.5 % Microbac forte + 0.5 % PREMIUM N° 1 PLUS** or **0.5 % Microbac forte + 0.5 % PREMIUM N° 1 PLUS**, possesses bactericidal and yeasticidal efficacy (log_{10} RF ≥ 5 or log_{10} RF ≥ 4, respectively on field 1; Ø < 50 cfu on fields 2 - 4) in **5 min** or **60 min**, respectively, at 20 °C under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) for reference strains *S. aureus*, *E. hirae*, *P. aeruginosa* and *C albicans*.

Results are considered validated in accordance with the requirements of the **EN 16615 (2015)**. However, the analysis of the efficacy against *C. albicans* was constrained by the high intolerance of those test organisms to (repeated) drying on surfaces and / or by them possibly getting wiped off the carrier too easily by the standard wipe. Possibly resulting deviations from the recovery requirements for the WSH-control are therefore attributed to insufficient experimental justification on the side of standard's developers for setting that parameter to that limit for these test organisms.

Greifswald, October 08, 2019

AKKREDITIERTES PRÜFLABOR HYGIENE NORD GMBH FRIEDRICH-LUDWIG-JAHN-STR. 49A 17489 GREIFSWALD DIN EN ISO/IEC 17025 DAKKS: PL-18411-01

Dr. rer. med. (Dipl. Biol.) T. Koburger-Janssen
- General Manager -

Prof. Dr. med. A. Kramer
- MD for Hygiene and Environmental Medicine -

BODE Chemie GmbH
A company of the HARTMANN GROUP
Melanchthonstr. 27
22525 Hamburg
Germany
T. +49 40 54006-0
F. +49 40 54006-200
bode-chemie.com
info@bode-chemie.de

EU-Declaration of Conformity for Medical Device Class IIa

Hamburg, 2023-02-07

Object of the declaration: **Mikrobac forte**

Mikrobac forte		
Pack size	Article number BODE	Article number HARTMANN
250 x 20 mL Sachet	975392	980434
5 L	975395	980435
200 L	975397	980437
640 L	975398	980438

We herewith declare under our sole responsibility that the medical devices listed above, first placed on the market by BODE Chemie GmbH, comply with the applicable provisions, in particular, the

- General Safety and Performance Requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5. April 2017 on medical devices.

The objects of the declaration have been identified as medical devices in risk class IIa according to classification rule 1 and rule 16 in Annex VIII of Regulation (EU) 2017/745.

The conformity assessment procedure according to Article 52 (6) and Annex IX has been performed and the Technical Documentation is kept available.

The conformity assessment procedure is under the supervision of the Notified Body:

MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2
20355 Hamburg
Germany
Identification No. 0482
Certificate No. 0523GB448210329A

Intended Purpose:
Disinfection of non-invasive medical devices

Basic UDI-DI: 40316783778MJ
Single Registration Number: DE-MF-000005851

BODE Chemie GmbH

ppa.

07/02/2023

Dr. Henning Mallwitz
Director Research & Development

Dr. Ralf Meier
Head of Quality Assurance

Valid until: 2025-02-07

DR. BRILL + DR. STEINMANN
INSTITUTE FOR HYGIENE AND MICROBIOLOGY

Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-AP-216.11.02

TEST REPORT

26/03/2019

Test report L19/0102aMV.2

Evaluation of the effectiveness of

Bacoban WB

Test virus: modified vaccinia virus Ankara (MVA)

Method: based on EN 14476:2013+A1:2015 (dirty conditions)

quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine

Sponsor:
ROPIMEX R. OPEL GmbH
Bildstocker Straße 12
DE - 66538 Neunkirchen

Norderoog 2, DE - 28259 Bremen
Tel.: +49 40-557631-0, Fax: +49 40-557631-11
info@brillhygiene.com, http://www.brillhygiene.com

1. Introduction

The objective of this study was to evaluate the virus-inactivating efficacy of Bacoban WB against modified vaccinia virus Ankara (MVA) using a quantitative carrier test based on the ASTM E2180 (1).

Ceramic tiles treated with Bacoban WB (and untreated controls) are contaminated with test virus suspension in an agar slurry. The ceramic tiles were incubated at room temperature for 5, 15 and 30 minutes. The inactivation of the test virus was studied in one run with three parallels for each exposure time. The ceramic tiles were checked after eluation for residual virus at the end of the experiment. The virus-inactivating properties of Bacoban WB under the chosen conditions can be calculated by comparing the virus titres of treated ceramic tiles with the controls (non-treated carriers).

2. Identification of test laboratory

Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology, Norderoog 2, DE - 28259 Bremen

3. Identification of sample

Manufacturer	ROPIMEX R. OPEL GmbH
Name of product	Bacoban WB
Confirmation no.	212558
Product diluent recommended by the manufacturer	-
Batch number	2002130
Application	surface disinfection
Production date	-
Expiry date	02/2022
Active compound (s) (100 g)	QAV
Appearance, odour	clear, yellow, viscous liquid product specific
pH-values	undiluted: 5.70 (20 °C) 1.0 %: 6.47 (20 °C)
Storage conditions	room temperature in the dark (area with restricted access)
Date of arrival in the laboratory	19/02/2020

4. Materials

4.1 Culture medium and reagents

- Eagle`s Minimum Essential Medium with Earle`s BSS (EMEM, Biozym Scientific GmbH, catalogue no. 880121)
- fetal calf serum (Biochrom AG, article no. S 0115)
- Aqua dest. (SG ultrapure water system, type Ultra Clear; serial no. 86996-1)
- PBS (Invitrogen, article no. 18912-014)
- Penicillin/ streptomycin (Sigma-Aldrich, article no. P-0781)
- BSA (Sigma-Aldrich-Chemie GmbH, article no. CA-2153)
- Agar-Agar (Carl Roth GmbH, article no. 5210.2)
- NaCl (Carl Roth GmbH, article no. 3957.1)
- Propan-2-ol (Carl Roth GmbH, article no. 6752.1)

4.2 Virus and cells

The modified vaccinia virus Ankara (MVA) originated from Dr. Manteufel, Institut für Tierhygiene und Öffentliches Veterinärwesen, DE - 04103 Leipzig. Before inactivation assays, virus had been passaged three times in *BHK 21-cells* (Baby Hamster Kidney).

BHK 21-cells (passage 104) originated from the Friedrich-Löffler-Institut, Bundesforschungsinstitut für Tiergesundheit (formerly Bundesforschungsanstalt für Viruskrankheiten der Tiere, isle of Riems).

The cells were inspected regularly for morphological alterations and for contamination by mycoplasmas. No morphological alterations of cells and no contamination by mycoplasmas could be detected.

4.3 Apparatus, glassware and small items of equipment

- CO_2 incubator, Nunc GmbH & Co. KG, model QWJ 350)
- Agitator (Vortex Genie Mixer, type G 560E)
- pH measurement 315i (WTW, article no. 2A10-100)
- Centrifuge (Sigma-Aldrich-Chemie GmbH, type 113)
- Microscope (Olympus, type CK 30)
- Centrifuge 5804 R (Eppendorf AG)
- Water bath (JULABO, Julabo U 3)
- Adjustable and fixed-volume pipettes (Eppendorf AG)

9. Conclusion

The ceramic tiles coated with Bacoban WB were able to demonstrate a significant ($P < 0,01$) log_{10} reduction of MVA after an exposure time of 5, 15 and 30 minutes.

Bremen, 14/04/2020

- Dr. Britta Becker -
Head of Laboratory

- Dr. Dajana Paulmann -
Scientific Project Manager

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Anerkannt durch/Recognized by Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-AP-216.11.02

TEST REPORT

07/11/2020

Test report L20/0285BC.5

Evaluation of the effectiveness of

BARRIER TECH MF Sanitiser Concentrate

Test virus: bovine coronavirus (BCoV) (surrogate of human coronaviruses)

Method: EN 14476:2013+A2:2019 (dirty conditions)

quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine (phase 2/ step 1)

Sponsor:
Teknologisk Institut
Kongsvang Allé 29
DK - 8000 Aarhus C

Norderoog 2, DE - 28259 Bremen
Tel.: +49 40-557631-0, Fax: +49 40-557631-11
info@brillhygiene.com, http://www.brillhygiene.com

1. Identification of test laboratory

Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology, Norderoog 2, DE - 28259 Bremen

2. Identification of sample

Manufacturer	Teknologisk Institut
Name of product	BARRIER TECH MF Sanitiser Concentrate
Confirmation no.	217044
Product diluent recommended by the manufacturer	-
Batch number	920810-1
Application	surface disinfection
Production date	-
Expiry date	-
Active compound (s) (100 g)	dodecyl-dimethyl ammonium chloride CAS No. 7173-51-5, 15% Alkyl (C12-16), di-methyl benzyl ammonium chloride, CAS No. 68424-85-1, 10%
Appearance, odour	clear, light blue liquid product specific
pH-values	undiluted: 6.51 (20 °C) 0.5 %: 7.32 (20 °C) 0.25 %: 7.36 (20 °C)
Storage conditions	room temperature in the dark (area with restricted access)
Date of arrival in the laboratory	20/03/2020

3. Materials

3.1 Culture medium and reagents

- Eagle's Minimum Essential Medium with Earle's BSS (EMEM, Biozym Scientific GmbH, catalogue no. 880120)
- fetal calf serum (Thermo Fisher, article no. CH30160.02)
- 1.4 % formaldehyde solution (dilution of Roti®-Histofix 4 %, Carl Roth GmbH)
- Aqua bidest. (SG ultrapure water system, type Ultra Clear; serial no. 86996-1)
- PBS (Invitrogen, article no. 18912-014)
- BSA (Sigma-Aldrich-Chemie GmbH, article no. CA-2153)
- sheep erythrocytes (Fiebig Nährstofftechnik).

3.2 Virus and cells

The bovine coronavirus strain L9 was obtained by Dr. G. Zimmer, Institute of Virology at the School of Veterinary Medicine Hannover (Tierärztliche Hochschule, DE - 30559 Hannover).

The *U373 cells* (passage 16) were as well obtained by Dr. G. Zimmer, Institute of Virology at the School of Veterinary Medicine Hannover (Tierärztliche Hochschule, DE - 30559 Hannover).

The cells were inspected regularly for morphological alterations and for contamination by mycoplasmas. No morphological alterations of cells and no contamination by mycoplasmas could be detected.

3.3 Apparatus, glassware and small items of equipment

- CO_2 incubator
- Agitator (Vortex Genie Mixer, type G 560E)
- pH measurement 315i (WTW, article no. 2A10-100)
- Centrifuge (Sigma-Aldrich-Chemie GmbH, type 113)
- Microscope (Olympus, type CK 30)
- Centrifuge 5804 R (Eppendorf AG)
- Water bath (JULABO, Julabo U 3)
- Adjustable and fixed-volume pipettes (Eppendorf AG)
- Polysterol 96-well microtitre plate (Nunc GmbH & Co. KG, Wiesbaden)
- Cell culture flask (Nunc GmbH & Co. KG, Wiesbaden)
- Sealed test tubes (Sarstedt AG & Co., Nümbrecht).

4. Experimental conditions

Test temperature	20 °C ± 1.0 °C
Concentration of test product	0.5 %, 0.25 % and 0.05 % (demonstration of non-active range) solutions
Appearance of product dilutions	no precipitation
Contact times	5 minutes
Interfering substance	3.0 g/l bovine serum albumin + 3.0 ml/l erythrocytes (dirty conditions, EN 14476)
Procedure to stop action of disinfectant	immediate dilution
Diluent	water of standardized hardness (WSH)
Stability of product in the mix with virus and interfering substance (0.5 % solution)	no clouding, no precipitation
Virus strain	bovine coronavirus strain L9
Date of testing	08/07/2020 – 27/10/2020
End of testing	07/11/2020

5. Methods

5.1 Preparation of test virus suspension

For preparation of test virus suspension, *U373* cells were cultivated in a 175 cm^2 flask with in EMEM supplemented with L-glutamine, non-essential amino acids and sodium pyruvate and 10 % fetal calf serum. Before virus infection, cells were washed two times with phosphate buffered saline (PBS), incubated for 3 h with EMEM without FCS and were washed once with EMEM supplemented with trypsin. For virus production, BCoV strain L9 was added to the prepared monolayer. After an incubation period of 24 to 48 hours (cells showed a constant cytopathic effect), cells were lysed by a rapid freeze/thaw cycle. Cellular debris was removed by low speed centrifugation. After aliquotation of the supernatant, test virus suspension was stored at –80 °C.

5.2 Preparation of disinfectant (dilutions)

The test product was tested as 0.5 %, 0.25 % and 0.05 % solutions under dirty conditions (1 part test virus suspension + 1 part interfering substance + 8 parts disinfectant). Due to the addition of interfering substance and test virus suspension the solutions had to be prepared by the factor 1.25.

These solutions were prepared with WSH immediately before the inactivation tests.

5.3 Infectivity assay

Infectivity was determined by means of end point dilution titration using the microtitre process. For this, samples were immediately diluted at the end of the exposure time with ice-cold EMEM with trypsin and 100 µl of each dilution were placed in eight wells of a sterile polystyrene flat bottomed plate with a preformed *U373* monolayer. Before addition of virus, cells were washed twice with EMEM and incubated for 3 h with 100 µl EMEM with trypsin. Incubation was at 37 °C in a CO_2-atmosphere (5.0 % CO_2 - content). Finally, cultures were observed for cytopathic effects for six days of inoculation. The infectious dose ($TCID_{50}$) was calculated according to the method of Spearman (2) and Kärber (3).

5.4 Calculation and verification of virucidal activity

The virucidal activity of the test disinfectant was evaluated by calculating the decrease in titre in comparison with the control titration without disinfectant. The difference is given as reduction factor (RF).

According to the EN 14476, a disinfectant or a disinfectant solution at a particular concentration is having virus-inactivating efficacy if the titre is reduced at least by 4 log_{10} steps within the recommended exposure period. This corresponds to an inactivation of ≥ 99.99 %.

5.5 Inactivation assay (end point titration)

Determination of virucidal activity has been carried out according to EN 5.5.

Immediately at the end of a chosen contact time, activity of the disinfectant was stopped by dilution to 10^{-6}.

Titrations of the virus control were performed at the beginning of the test and after the longest exposure time (EN 5.5.7). One part by volume of test virus suspension was mixed with one part interfering substance and eight parts by volume of WSH or Aqua bidest. (RTU products).

Furthermore, a cell control (only addition of medium) was incorporated.

Inactivation tests were carried out in sealed test tubes in a water bath at 20 °C ± 1.0 °C. Aliquots were retained after appropriate exposure times and residual infectivity was determined.

5.6 Inactivation assay following the large volume plating method (LVP)

Following the large volume plating method (EN 5.5.4.3) the inactivation assays were further diluted 1:1,000 in cell culture medium. The total volume was added (without any further dilution) to the permissive cells. By introducing such a huge dilution it is possible to eliminate cytotoxicity of the test product in order to demonstrate a 4 $\log_{10}$ reduction of virus titre. Calculation of virus titre follows formula of Taylor or Poisson (EN B.3). This method is necessary for those products which demonstrate a great cytotoxicity.

62.5 µl of the inactivation assay were added to 62.5 ml medium and then the total volume was distributed in 6 microtitre plates (108 µl / well, 576 wells total). After 6 days of inoculation cultures were observed for cytopathic effects.

5.7 Determination of cytotoxicity

Determination of cytotoxicity was performed according to EN 5.5.4.1.

5.8 Cell sensitivity to virus

For the control of cell sensitivity to virus two parts by volume of water were mixed with eight parts by volume of the lowest apparently non-cytotoxic dilution of the product. This mixture or PBS as control was added to the wells of the microtitre plates with a preformed monolayer of *U373 cells*. After at least one hour, a comparative virus titration was performed on the cells treated in such a manner or treated with PBS only.

5.9 Control of efficacy for suppression of disinfectant's activity

Furthermore, a control of efficiency for suppression of disinfectant's activity was included (EN 5.5.5).

5.10 Reference virus inactivation test

As reference for test validation a 0.7 % formaldehyde solution according to EN 5.5.6 was included. 5, 15, 30 and 60 minutes were chosen as contact times. In addition, cytotoxicity of formaldehyde test solution was determined based on EN 5.5.6.2 with dilutions up to 10^{-5}.

6. Verification of the methodology

The following criteria as mentioned in EN 5.7 were fulfilled:

a) The titre of the test virus suspension allowed the determination of a ≥ 4 $\log_{10}$ reduction (maximal virus reduction $\geq 5.36 \pm 0.35$, LVP)

b) The test product (0.5 %) showed cytotoxicity in the 1:100 dilutions thus allowing the detection of a 4 $\log_{10}$ reduction of virus titre.

c) The comparative titration on pre-treated (disinfectant) and non-pre-treated (PBS) cells showed no significant difference (< 1 $\log_{10}$; EN 5.7) of virus titre: 6.75 ± 0.33 (PBS, LVP) versus 7.00 ± 0.38 (1:1,000 dilutions of disinfectant as 0.5 % solution, LVP) $\log_{10}$ $TCID_{50}$/ml.

d) The control of efficacy for suppression of disinfectant's activity (0.5 %) showed no decrease (≤ 0.5 $\log_{10}$; EN 5.5.5.1) in virus titre (7.00 ± 0.38 versus 6.88 ± 0.37 $\log_{10}$ $TCID_{50}$/ml).

e) One concentration demonstrated a 4 $\log_{10}$ reduction and (at least) one concentration demonstrated a $\log_{10}$ reduction of less than 4.

Since all criteria according EN 5.7 were fulfilled, examination with bovine coronavirus according to EN 14476 is valid.

7. Results

Results of examination are shown in tables 1 to 10. Tables 1 to 8 demonstrate the raw data, whereas tables 9 (a+b) and 10 give a summary of results.

The test product as 0.05 % solution was not active within 5 minutes of exposure time (table 1).

Table 1: Raw data for BARRIER TECH MF Sanitiser Concentrate (0.05 %) tested against bovine coronavirus at 20 °C (quantal test; 8 wells) (#6920)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
test product	0.05 %	dirty conditions	1	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			5	n.d.	n.a.	4444 4444	4444 4444	4444 4444	4000 0000	0000 0000	n.d.	n.d.
			10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			30	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	0.05 %	dirty conditions	n.a.	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	dirty conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0200 3400	0000 0000	0000 0000	n.d.
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0000 3034	0000 0000	0000 0000	n.d.

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

DR. BRILL + DR. STEINMANN
INSTITUTE FOR HYGIENE AND MICROBIOLOGY

Test report no: L20/0285BC.5
Author: DP Version 02 Date: 07/11/2020
Replaces Version 01
Product name: BARRIER TECH MF Sanitiser Concentrate
Method: EN 14476*

Table 2: Raw data for formaldehyde solution (0.7 %) tested against bovine coronavirus at 20 °C (quantal test; 8 wells) (#6920)

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log_{10})								
				1	2	3	4	5	6	7	8	9
formaldehyde	0.7 % (m/V)	PBS	5	tttt tttt	tttt tttt	tttt tttt	4434 4403	0000 0000	0000 0000	0000 0000	0000 0000	n.d.
			15	tttt tttt	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.
			30	tttt tttt	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.
			60	tttt tttt	tttt tttt	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.
formaldehyde cytotoxicity	0.7 % (m/V)	PBS	n.a.	tttt tttt	tttt tttt	tttt tttt	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	PBS	0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0200 0003	0000 0030	0000 0000	n.d.

n.a. = not applicable
n.d. = not done

0 = no virus present; t = cytotoxic
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

* Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Norderoog 2, DE – 28259 Bremen, Germany, Telephone +49. 40. 557631-0, Telefax +49. 40. 557631-11, www.brillhygiene.com. No copying or transmission, in whole or in part, of this test report without the explicit prior written permission. The test results exclusively apply to the tested samples. Information on measurement uncertainty on request.© Dr. Brill + Partner GmbH 2020

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ZLG-AP-216.11.02

Table 8: Inactivation of bovine coronavirus by BARRIER TECH MF Sanitiser Concentrate (0.25 %) at 20 °C (5 minutes) (LVP, 1:1,000) (#6920)

Interfering substance	Row	1	2	3	4	5	6	7	8	9	10	11	12
dirty conditions	plate 1/6	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444
	plate 2/6	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444
	plate 3/6	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444
	plate 4/6	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444
	plate 5/6	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444
	plate 6/6	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444

t = cytotoxic 0 = no virus detectable 1 to 4 = virus detectable (degree of CPE in 8 wells of a microtitre plate)

Table 6: Inactivation of bovine coronavirus by BARRIER TECH MF Sanitiser Concentrate (0.5 %) at 20 °C (5 minutes) (LVP, 1:1,000) (#6695)

Interfering substance	Row	1	2	3	4	5	6	7	8	9	10	11	12
dirty conditions	plate 1/6	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
	plate 2/6	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
	plate 3/6	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
	plate 4/6	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
	plate 5/6	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000
	plate 6/6	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000

t = cytotoxic 0 = no virus detectable 1 to 4 = virus detectable (degree of CPE in 8 wells of a microtitre plate)

Dr. rer. med. (Dipl. Biol.) Torsten Koburger-Janssen
c/o Hygiene Nord GmbH
Walther-Rathenau-Str.49a
D-17489 Greifswald

DR. T. KOBURGER-JANSSEN, W.-RATHENAU-STR. 49 A, D-17489 GREIFSWALD

ROPIMEX R. OPEL GmbH
Bildstocker Straße 12-14
66538 Neunkirchen
Deutschland / Germany

DATUM / *DATE*
28.11.2018 / *November 28, 2018*

GUTACHTERLICHE STELLUNGNAHME / *EXPERT'S REPORT*

BACOBAN® WB

FLÄCHENDESINFEKTION / SURFACE DISINFECTION

Von September bis November 2018 wurden durch die Hygiene Nord GmbH mit dem Prüfprodukt **Bacoban® WB**, einem Produkt zur Flächendesinfektion der Firma ROPIMEX R. OPEL GmbH, Neunkirchen, Germany) die im Folgenden aufgeführten Untersuchungen auf Basis der "Anforderungen und Methoden zu VAH-Zertifizierung chemischer Desinfektionsverfahren" (2015) und der EN 16615 (2015) durchgeführt:

*The efficacy of the surface disinfectant **Bacoban® WB**; manufactured by ROPIMEX R. OPEL GmbH, Neunkirchen, Germany) was evaluated by the testing laboratory Hygiene Nord GmbH, Greifswald, Germany. The following tests were performed between the months of September and November 2018 in accordance with the "Requirements and methods for VAH-certification of chemical disinfection processes" (2015) and the EN 16615 (2015):*

1. Bestimmung der **bakteriostatischen** und **levurostatischen Wirksamkeit** sowie geeigneter **Neutralisationsmittel**. Die Versuchsdurchführung und die Ergebnisse sind im Prüfbericht A 18466-2 der Hygiene Nord GmbH vom 28.11.2018 enthalten.

   *Determination of a suitable **neutralizer** and analysis of the bacteriostatic and yeaststatic actvity. Results are presented in the Hygiene Nord GmbH test report A 18466-2 (November 28, 2018).*

Dr. rer. med. (Dipl. Biol.) Torsten Koburger-Janssen
c/o Hygiene Nord GmbH
Walther-Rathenau-Str.49a
D-17489 Greifswald

2. Im **quantitativen Suspensionsversuch** wurde die bakterizide und levurozide Wirksamkeit des Prüfmusters **Bacoban® WB** unter hoher Belastung (0,3 % Albumin + 0,3 % Schaferythrozyten) bestimmt. Die Versuchsdurchführung und die Ergebnisse sind im Prüfbericht A 18466-2 der Hygiene Nord GmbH vom 28.11.2018 enthalten.

   *The bactericidal and yeasticidal activity of **Bacoban® WB** was evaluated in **quantitative suspension tests** under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes). Results are presented in the Hygiene Nord GmbH test report A 18466-2 (November 28, 2018).*

3. Im **quantitativen Keimträgertest zur Flächendesinfektion mit Mechanik (4-Felder-Test)** wurde die bakterizide und levurozide Wirksamkeit des Prüfmusters **Bacoban® WB** unter hoher organischer Belastung (0,3 % Albumin + 0,3 % Schaferythrozyten) bestimmt. Die Versuchsdurchführung und die Ergebnisse sind im Prüfbericht A 18466-1 der Hygiene Nord GmbH vom 28.11.2018 enthalten.

   *The bactericidal and yeasticidal efficacy activity of **Bacoban® WB** was evaluated by **quantitative carrier tests (surface disinfection with mechanical action, 4-Field-Test)** under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes). Results are presented in the Hygiene Nord GmbH test report A 18466-1 (November 28, 2018).*

Zusammenfassung / Summary

Nach Bewertung der Ergebnisse kann festgestellt werden, dass das Prüfprodukt **Bacoban® WB** den Anforderungen der "Anforderungen und Methoden zu VAH-Zertifizierung chemischer Desinfektionsverfahren" (2015) und der EN 16615 (2015) genügt, da folgende Wirkungen beobachtet wurden:

*Upon evaluation of the test results it can be concluded that **Bacoban® WB** complies with the "Requirements and methods for VAH-certification of chemical disinfection processes" (2015) and the EN 16615 (2015) as follows:*

- bakterizide und levurozide Wirksamkeit in den *in vitro* - Tests: In den **quantitativen Suspensionstests** unter hoher Belastung wurden die Prüfspezies *P. aeruginosa, P. mirabilis, E. coli, E. hirae, S. aureus* (Bakterizidie, RF ≥ 5 log) und *C. albicans* (Levurozidie, RF ≥ 4 log) bei den Konzentration/Zeit- Relationen 1 % / 5 min und 0,25 % / 15 min in einem ausreichenden Maße inaktiviert.

  *Bactericidal and yeasticidal activity in the in vitro tests: In the **quantitative suspension tests** under dirty conditions, the product possesses bactericidal (RF ≥ 5 log) and yeasticidal efficacy (RF ≥ 4 log) against the test organisms P. aeruginosa, P. mirabilis, E. coli, E. hirae, S. aureus and C. albicans, respectively, within the concentration / contact time – relations of 1 % / 5 min or 0.25 % / 15 min, respectively.*

Dr. rer. med. (Dipl. Biol.) Torsten Koburger-Janssen
c/o Hygiene Nord GmbH
Walther-Rathenau-Str.49a
D-17489 Greifswald

- Wirksamkeit unter praxisnahen Bedingungen: Im **quantitativen Keimträgertest zur Flächendesinfektion mit Mechanik (4-Felder-Test)** unter hoher Belastung wurden die Anforderungen für die Prüforganismen *P. aeruginosa, E. hirae, S. aureus* (Bakterizidie, RF ≥ 5 log) und *C. albicans* (Levurozidie, RF ≥ 4 log) bei denr Konzentration / Einwirkzeit - Relation 1 % / 5 min in einem ausreichenden Maße erfüllt.

  *Efficacy under conditions simulating practical conditions (**quantitative carrier test - surface disinfection with mechanical action – 4-Field-Test**): Under dirty conditions, the product possesses bactericidal (RF ≥ 5 log) and yeasticidal (RF ≥ 4 log) efficacy against the test organisms P. aeruginosa, E. hirae, S. aureus and C. albicans at the concentration/contact time – relation of 1 % / 5 min.*

Für die Aufnahme in die Desinfektionsmittelliste des VAH kann daher folgende Anwendungsempfehlung für **Bacoban® WB** als Mittel zur **Flächendesinfektion** (mit Mechanik) gegeben werden:

*It can therefore be recommended to include **Bacoban® WB** in the VAH List of Disinfectants as a product for **surface disinfection (with mechanical action)** as follows:*

Bacoban® WB

(hohe Belastung / *dirty conditions*):

Bakterizidie & Levurozidie:	**1 % / 5 min**
Bactericidal & yeasticidal efficacy:	

Greifswald, 28.11.2018 / *November 28, 2018*

Dr. rer. med. (Dipl. Biol.) T. Koburger-Janssen

Conclusion:

Making analysis on mor disinfectant we can make affirmation that as a disinfectant **Microbac forte** in concordance with EN 16615 is an effective cleaner and broad-spectrum disinfectant for E.Hirae C.Albicans , S.aureus , P.Aeruginosa for concentration 1-3% that confirms this disinfectant has also a broad spectrum against bacteria , yeast and fungi and if the concentration will be increased for 2 times so working concentration will be 0.5-1.5% for 5-60min in dirty conditions for EN 16615.

Bacoban WB dated 2018-12-19 (SN 26613, 2018-2688) quantitative non-porous surface test with mechanical action employing wipes according to EN 16615 as well as dated 2018-12-19 (SN 26613, 2018-2689) according to EN16615 Shows The efficacy of the disinfectant Bacoban WB in combination with the reference wipe was tested as surface disinfection with mechanical action employing wipes according to EN 16615 under dirty conditions against the test strains S. aureus, E. hirae, P. aeruginosa and C. albicans. The disinfectant shows sufficient reductions of ≥5lg units for bacteria and of ≥4lg units for C. albicans under dirty conditions in 1% within 1 and 5 minutes .The most lucrative concentration is :

EN 16615	**1%(dirty)**	**5 min**

Developer Gogu Andrei

Conclusion:

Bacoban WB combines the microbiological effectiveness of a quaternary ammonium in high concentration that is effective against viruses in concordance with EN 14476 also it proves on expert opinion following statement based on the results from the test reports dated 2018- 12-19 (SN 26613,2018-2685) qualitative suspension test according to VAH method 8, dated 2018-12-19 (SN 26613, 2018-2686) quantitative suspension test according to EN 13727, dated 2018-12-19 (SN 26613, 2018-2687) quantitative suspension test according to EN 13624,
BARRIER-TECH-MF-Sanitiser-Concentrate effective disinfectant with mixed QACs that shows effective action against viruses for a concentration 0.25-0.5% for 5 minutes in dirty conditions and clean conditions and looking on Bacoban thats have also QACs active component but in lower concentration at the similar working concentration 0.5% has virucidal action but exposed to 15 minutes and this is demonstration that increasing exposition time reduces concentration of active component and at the concentration of 0.25 at 15min we can obtain the same results. Another product with formula:- Didecyldimethylammonium chloride (CAS No: 7173-51-5)- N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (CAS No: 2372-82-9) -N-Alkyl-N-benzyl-N,N-dimethylammonium chlorideAlkyldimethylbenzylammonium chloride mixed,etc. Labelable allergen-free fragrance can have the same effect and can be used at the same concentrations.Disinfectant through tests can be used at a dose of 0.25% for 15 and 30 min for all disinfection and at 1% for advanced cleaning because concentration of active is higher and making comparison and if active components are 2 times higher we cân decrease working concentration.The most lucrative concentration is :

EN 14476 **0,25%(dirty)** **15 min**

Developer Gogu Andrei

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Efficacy of five 'sporicidal' surface disinfectants against *Clostridioides difficile* spores in suspension tests and 4-field tests

S. Gemein [a,b,*], R. Andrich [c], B. Christiansen [d], M. Decius [d], M. Exner [a], B. Hunsinger [b], E. Imenova [e], G. Kampf [f], T. Koburger-Janssen [g], K. Konrat [c], H. Martiny [b], M. Meckel [h], N.T. Mutters [a], F-A. Pitten [h], S. Schulz [e], I. Schwebke [c], J. Gebel [a,b]

[a] *Institute for Hygiene and Public Health, University Hospital Bonn, Bonn, Germany*
[b] *VAH Ring Trial Steering Committee of the Association for Applied Hygiene (VAH), Bonn, Germany*
[c] *Robert Koch-Institut, Abt. 1 Infektionskrankheiten, FG 14 Angewandte Infektions- und Krankenhaushygiene, Berlin, Germany*
[d] *ZE Medizinaluntersuchungsamt und Hygiene, University Hospital Schleswig-Holstein, Kiel, Germany*
[e] *HygCen Germany GmbH, Schwerin, Germany*
[f] *Institute for Hygiene and Environmental Medicine, University Medicine Greifswald, Greifswald, Germany*
[g] *Hygiene Nord GmbH, Greifswald, Germany*
[h] *IKI Institut für Krankenhaushygiene und Infektionskontrolle GmbH, Gießen, Germany*

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SUMMARY

Background: A sporicidal surface disinfection is recommended both for the outbreak and the endemic setting but a comparative evaluation on the efficacy of 'sporicidal' surface disinfectants using suspension tests and 4-field tests has not been performed.
Aim: To determine the efficacy of five 'sporicidal' surface disinfectants (three ready-to-use wipes (A, B, E), two concentrates (C, D) based on peroxides or aldehydes against *C. difficile* spores.
Methods: The efficacy was determined under clean conditions using a suspension test and the 4-field test. Each test was performed in duplicate in two separate laboratories. Wipes were wrung to collect the solution for the suspension tests.
Results: Product A (peracetic acid; 5 min), product C (peracetic acid; 2% solution in 15 min or 1% solution in 30 min) and product D (peracetic acid; only 2% solution in 15 min) were effective with at least a 4 $\log_{10}$-reduction of *C. difficile* spores in suspension and on surfaces. Product B (hydrogen peroxide) was not effective in suspension (0.9 $\log_{10}$ after 15 min; 3.2 $\log_{10}$ after 1 h) and on surfaces (2.8 $\log_{10}$ after 15 and 60 min). Product E based on glutaraldehyde, (ethylendioxy)dimethanol and DDAC demonstrated 0.9 $\log_{10}$ after 4 h in suspension and 4.5 $\log_{10}$ after 4 h on surfaces.
Conclusions: Not all surface disinfectants with a sporicidal claim were effective against *C. difficile* spores in standardized suspension tests and in the 4-field test. In clinical

* Corresponding author. Address: Institute for Hygiene and Public Health, University Hospital Bonn, Venusberg-Campus 1, 53127 Bonn, Germany.
E-mail address: stefanie.gemein@ukbonn.de (S. Gemein).

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practice preference should be given to products that reliably pass the efficacy criteria of both types of tests.

Introduction

A sporicidal surface disinfection is recommended both for the outbreak and the endemic setting [1] as one of many elements usually applied in bundles with the aim of controlling nosocomial transmission [2,3]. Only few biocidal agents such as peroxides, aldehydes or chlorine dioxide, sometimes in formulated products, have been described to be effective against spores of *Clostridioides difficile* in suspension or surface tests [4—8]. An effective treatment against spores on surfaces has been demanded to reduce the risk of *C. difficile* spore transmission in healthcare [9]. Some manufacturers of surface disinfectants claim a sporicidal activity of their product based on results obtained with spores of *Bacillus subtilis* in suspension tests. In the meantime, however, test protocols have been developed and approved to measure the sporicidal activity of surface disinfectants with spores of *C. difficile* in suspension tests and under practical conditions (4-field test) [6]. Both experimental designs have been described to yield reproducible efficacy data [6]. A comparative evaluation on the efficacy of 'sporicidal' surface disinfectants using both types of tests has, to our knowledge, never been performed. The aim of this study was therefore to determine the efficacy of five 'sporicidal' surface disinfectants against *C. difficile* spores in both suspension tests and 4-field tests.

Material and methods

Laboratories

Six laboratories participated in the study. All products were tested in laboratory 1 which has the largest experimental experience in sporicidal efficacy testing. A second test of each product was pereformed in one of the other five laboratories such that finally two data sets from different laboratories were available for each product.

Test organism and culture conditions

C. difficile NCTC 13366 was used in all experiments. It was chosen because of its clinical relevance (ribotype 027) and mostly lower susceptibility to disinfectants compared with other strains of the species [10]. Three spore suspensions were prepared centrally at Bonn University according to EN 17126 [11] and supplied to the participating laboratories. Briefly, a subculture was prepared from the stock culture by streaking on to BHIYT-L agar plates. After anaerobic incubation of the plates for 48 h at 36 °C an isolated colony was suspended in 5 mL pre-reduced Columbia broth and incubated in an anaerobic jar for 24 h at 36 °C. A 50 µL aliquot of the culture was inoculated into 20 mL of pre-reduced Columbia broth and incubated anaerobically for 20 h at 36 °C. The entire inoculum was then transferred into a 500-mL culture flask with the liquid sporulation medium. The flasks were incubated anaerobically for 10 d at 36 °C. Finally, the cells were washed, vegetative cells and debris digested enzymatically with trypsin and lysozyme. The spores were stored at 2 °C to 8 °C and were only used after a storage time of at least 8 weeks. The spore suspension adjusted to a cell count of 1.5—5.0 $\times$ 10^8/mL. The spore suspension was microscopically visually checked. Slight single debris was observed, the purity was approximately 97%. Laboratories were advised to keep the spore suspension at 2—8 °C.

Test products and sample size

Five products from German manufacturers with sporicidal claims were used and are described in Table I. Two of the products were from Ecolab Deutschland GmbH, one from Schülke & Mayr GmbH, one from Dr. Schumacher GmbH and one from Bode Chemie GmbH. Each product was tested twice on two different days and in two different laboratories. In addition, Bioban™ GA 50 Antimicrobial (Dow Chemical Company Ltd., Staines, UK, 50% glutaraldehyde) was used as glutaraldehyde standard. Lerasept® spezial (Stockmeier Chemie GmbH & Co. KG, Bielefeld, Germany, 4.9% peracetic acid and 25.5% hydrogen peroxide) was used as peracetic acid standard. The two standards were used to measure the susceptibility of the *C. difficile* spore preparation as described previously [6].

Determination of susceptibility of the prepared C. difficile spores for internal control

For internal quality-control purposes, a test using the validation solutions in its lower specified concentration 1% glutaraldehyde and 0.01% peracetic acid was performed at least once in each laboratory using a suspension test according to EN 17126 [11]. Briefly, 8 mL of the test product was thoroughly mixed with 1 mL of water of standard hardness and 1 mL of the test suspension (1.5—5.0 $\times$ 10^6 cfu/mL) controlled at 20 °C. Towards the end of the exposure time the tube contents were mixed again. After the exposure time of 15 min, an aliquot of 1 mL of the mixture was removed and transferred to a tube containing 9 mL of an appropriate neutralizer solution. Immediately afterwards, 10^{-1} and 10^{-2} dilutions were prepared in neutralizer solution. The following neutralizers were used: polysorbate 80 (10 g/L) with glycine (20 g/L) in 0.25 M phosphate buffer for glutaraldehyde, and polysorbate 80 (10 g/L) with sodium thiosulphate (3 g/L) in 0.25 M phosphate buffer for peracetic acid. The suitability of the neutralizers for the test products was validated with *C. difficile* spores according to VAH method 18 [18]. After a neutralization time of 5 min the solution was mixed again and 1 mL taken out in duplicate. The 1 mL samples were poured into separate Petri dishes. Fifteen to 20 mL of melted BHIYT-L agar was added and cooled to 45 °C. Plates were then incubated in anaerobic jars for five days at 36 °C followed by counting the colonies per plate, followed by calculating the number of cfu per mL on a $\log_{10}$ scale. The difference from the number of cells in the test mixture at the

Table I
Test products with a sporicidal claim from the manufacturer and validated neutralizing agents

Test product	Active biocidal ingredient(s)	Manufacturers sporicidal claim		Validated neutralizing agents
		2017	2021	
A*	Peracetic acid (0.06%, w/w)	Sporicidal in 15 min according to EN 13704**** Effective in 5 min against *C. difficile* spores****	Effective in 5 min against *C. difficile* spores according to EN 17126 under clean conditions	1% Tween 80, 0.3% sodium thiosulphate, 0.025% catalase
B*	Hydrogen peroxide (1.5%, w/w)***	Sporicidal in 60 min according to EN 13704 under clean conditions Effective in 15 min against *C. difficile* spores according to EN 13704under clean conditions Sporicidal in 15 min according to modified EN 16615 under clean conditions	Sporicidal in 60 min according to EN 17126 under clean conditions Effective in 60 min against *C. difficile* spores according to EN 17126 under clean and dirty conditions	1% Tween 80, 0.3% lecithin, 0.3% histidine, 0.3% sodium thiosulphate, 0.025% catalase
C**	Peracetic acid, made from a powder containing disodium carbonate, compound with hydrogen peroxide and citric acid; a 2% solution (w/v) contains > 0.1% peracetic acid	Sporicidal in 15 min at 2% according to EN 13704**** Effective in 10 min at 1% in a practical procedure*****	Sporicidal in 15 min at 2% and effective in 15 min at 1% against *C. difficile* spores according to EN 17126 under clean and dirty conditions	1% Tween 80, 0.3% lecithin, 0.3% histidine, 0.3% sodium thiosulphate
D**	Peracetic acid, made from a powder containing sodium percarbonate, citric acid and sodium carbonate; a 1% solution (w/v) contains >0.075% peracetic acid	Effective in 15 min at 2%, 30 min at 1% and 60 min at 0.5% against *C. difficile* spores according to EN 13704 under clean conditions	Effective in 5 min at 1.5% and 15 min at 1% against *C. difficile* spores according to EN 17126 under clean and dirty conditions Effective in 60 min at 0.5% against *C. difficle* spores according to a modified EN 16615 under clean and dirty conditions	1% Tween 80, 0.3% lecithin, 0.3% histidine, 0.3% sodium thiosulphate
E*	(Ethylendioxy)dimethanol (0.282%, w/w), didecyldimethylammoniumchloride (0.16%, w/w), glutaraldehyde (0.1%, w/w)	Effective in 4 h against *C. difficile* spores****	No updated information found	1% Tween 80, 0.3% lecithin, 0.3% histidine, 2% glycine

* Ready-to-use wipe.
** Powder concentrate.
*** Contains hydrogen peroxide (<8%) and acetic acid (1–5%) as additional ingredients.
**** No information on organic load.
***** No information on test method and requirements.

beginning of the contact time is reported as the $\log_{10}$ reduction. The susceptibility of the *C. difficile* test spores is considered to be validated if the mean $\log_{10}$ reduction is <1.5 with 1% glutaraldehyde and 0.01% peracetic acid.

Efficacy of test products in suspension tests

The efficacy of the surface disinfectants against *C. difficile* spores was determined with organic load (0.03% albumin w/v; 'clean conditions') in each laboratory in duplicate using a suspension test according to EN 17126 [11]. Clean conditions were chosen because most manufacturers provided sporicidal efficacy data only under clean conditions. Briefly, test products A, B and E were wrung inside the package in order to ensure that the ready-to-use surface disinfectant solution had no additional contact with other materials. The volume per package was sufficient to perform the suspension test and (typically 30 mL or more) was used within 1 h. Products C and D were diluted with water of standard hardness to the required use concentration. An 8 mL aliquot of the test product was then thoroughly mixed with 1 mL of 0.3% (w/v) sterile filtered albumin solution and 1 mL of the test suspension ($1.5–5.0 \times 10^7$ cfu/mL) controlled at 20 °C. Then 9.7 mL of the wrung ready-to-use solutions of A, B and E were mixed with 0.2 mL of 1.5% (w/v) albumin solution and 0.1 mL of the test suspension ($1.5–5.0 \times 10^8$ cfu/mL). Towards the end of the exposure time the tube content was mixed again. After the product-specific exposure time an aliquot of 1 mL of the mixture was removed and transferred to a tube containing 9 mL of an appropriate neutralizer solution. Immediately afterwards, 10^{-1} and 10^{-2} dilutions were prepared in neutralizer solution. The selected neutralizers are described in Table I. The suitability of the neutralizers for the test products was validated with *C. difficile* spores according to EN 17126 [11]. After a neutralization time of 5 min the solution was mixed again and a 1-mL solution was taken out in duplicate. The 1-mL samples were poured into separate Petri dishes, then 15–20 mL of melted BHIYT-L agar were added and cooled to 45 °C. Plates were then incubated in anaerobic jars for five days at 36 °C followed by counting the colonies per plate and calculating the number of cfu per mL on a $\log_{10}$ scale. The difference in the number of cells in the water control without product exposure and the number of cells after product exposure is described as the $\log_{10}$ reduction.

Efficacy of test products in the 4-field test

The efficacy of the surface disinfectants against *C. difficile* spores was determined using a practical test according to VAH method 19 [12] which is based on EN 16615 [11] because a European norm for sporicidal efficacy on surfaces with wiping is currently not available, only a work item (WI 000216139) which corresponds to VAH method 19. PVC pieces (20 × 50 cm; Forex classic, thyssenkrupp Plastics GmbH, Essen, Germany) were prepared simulating a surface to be treated with a surface disinfectant [13]. Four areas of 5 × 5 cm were marked. The first field was contaminated with 50 µL of a mixture containing 0.9 mL of the test suspension ($1.5–5.0 \times 10^7$ cfu/mL) and 0.1 mL of the organic load (0.03% albumin w/v; 'clean conditions'). Clean conditions were chosen because most manufacturers provided sporicidal efficacy data only under clean conditions (Table I). The inoculum was spread with a glass spatula and allowed to dry at room temperature for up to 60 min. Test products A, B and E were used directly. Test products C and D were diluted with water of standardized hardness to the appropriate use dilutions (Table I). A standard wipe (16.5 × 30 cm, TORK Low-Lint Cleaning Cloth, Essity Professional Hygiene Germany GmbH, Mannheim, Germany) based on 55% cellulose and 45% polyethylene terephthalate (PET) was used for products C and D. Each wipe was soaked for 30 min in 16 mL of the use dilutions of the disinfectant prior to the surface treatment following EN 16615. The volume of 16 mL for impregnating the standard wipe is a specification from EN 16615. The unitary weight (granite block, 2.5 kg) was covered with parafilm on the bottom. The soaked wipe, folded once, was placed on the protected area with parafilm and fixed with a rubber band. The hand pushed the weight over the test surface without applying additional pressure. The wiping procedure started in front of test field 1 and went on to fields 2, 3 and 4 within 1 s. Immediately afterwards it returned to field 1, crossing fields 4, 3 and 2 within another second (Figures 1 and 2). After the product-specific contact time, each test field was carefully swabbed using a cotton swab soaked with neutralizer in accordance with EN 16615 [14]. The suitability of the neutralizers for each test product was validated with *C. difficile* spores according to EN 17126, as described in Table I [11]. The entire test field 1 was wiped with a cotton swab moistened with neutralizer in a horizontal, vertical and diagonal direction. This recovery process was repeated using the same swab after it had been washed out in neutralizer. Subsequently, the lower half of the swab was transferred to the neutralizer test tube containing 5 mL of neutralizer by cutting it off at the edge of the neutralizer test tube. The recovery process was repeated once on the same test field with a second, dry cotton swab until the test field was visibly dry. The lower half of the swab was likewise transferred to the same neutralizer test tube and mixed. The recovery process took roughly 1 min per test field. The two cotton swabs used were combined in 5 mL of neutralizer per test field and vortexed thoroughly for approx. 1 min. Recovery from test fields 2 to 4 takes place in the same way. The swab was then put into a vial containing 5 mL of neutralizer. With a second dry swab the entire test field was carefully swabbed once more until the test field was visibly dry. This swab was put into the same neutralizer vial which was then vortexed for 1 min. After a 5-min neutralization time, aliquots of 1 mL were taken out in duplicate and poured into separate Petri dishes. For the sample obtained from the contaminated test field a

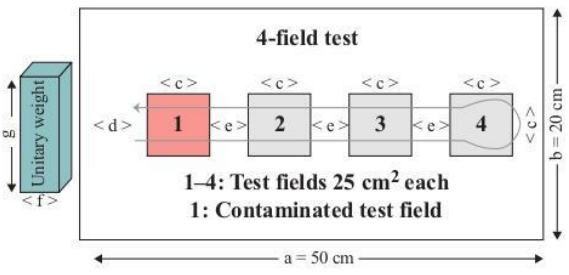

Figure 1. The 4-field test. Test surface (20 × 50 cm) with four test fields (5 × 5 cm) and stipulated wiping route of the wiping cloth. a = 50 cm, b = 20 cm, c = 5 cm, d = 10 cm, e = 5 cm, dimensions of the unitary weight f × g at least 8.6 cm × 12.1 cm.

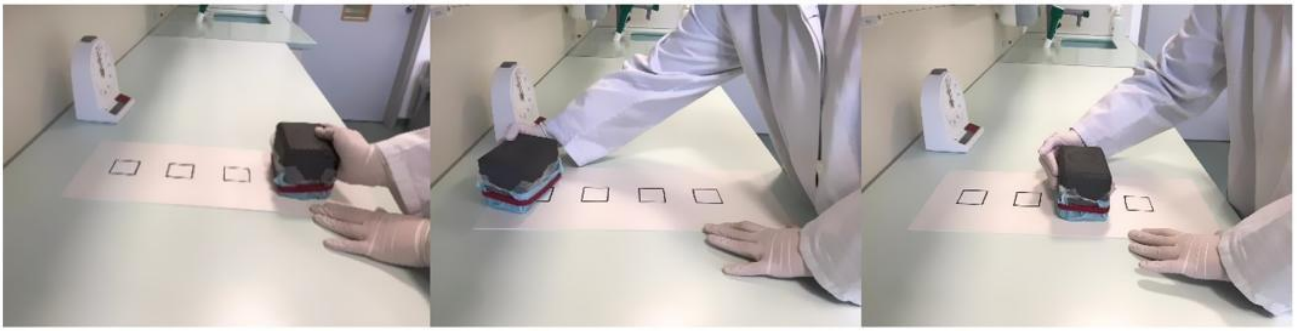

Figure 2. Wiping process in the 4-field test. The hand pushed the weight over the test surfaces without applying additional pressure.

1:10 dilution in neutralizer was prepared in addition. The samples were processed as described above for the suspension test. A $\log_{10}$ reduction of ≥ 4.0 on test field 1 is regarded as sufficient sporicidal activity. The numbers of cfu from the three other primarily uncontaminated test fields were also evaluated. A mean number of ≤ 50 cfu per 25 cm^2 was regarded as a sufficiently low residual contamination. An additional experiment using water of standardized hardness instead of the surface disinfectant revealed a mean number on test fields 2 to 4 of ≥ 10 cfu per 25 cm^2, demonstrating the lack of sporicidal activity. The applied volume of surface disinfectant was calculated by measuring the difference in weight of each wipe immediately before and after the wiping procedure.

Statistical evaluation

Colony counts between 1 and 330 were used for calculation. The mean and standard deviations were calculated for the $\log_{10}$-reductions per product, type of application and laboratory. The mean and median were calculated for the number of colonies on test fields 2 to 4 (4-field test results).

Results

The number of *C. difficile* spores in the test suspension used for the suspension tests was within the set limit for concentrates between 1.5 and 5.0×10^7 cfu/mL and ready-to-use products between 1.5 and 5.0×10^8 cfu/mL, as described in EN 17126 (laboratory 1: 3.0×10^7 resp. 3.3×10^8 cfu/mL; laboratory 2: 2.4×10^8; laboratory 3: 2.5×10^8; laboratory 4: 4.1×10^7; laboratory 5: 1.8×10^7; laboratory 6: 1.8×10^8). In the 4-field tests the mean number of cfu after the contact time (drying control 't') was 4.1×10^5 per 25 cm^2 (laboratory 1), 5.9×10^5 per 25 cm^2 (laboratory 2), 7.2×10^5 per 25 cm^2 (laboratory 3), 5.5×10^5 per 25 cm^2 (laboratory 4), 4.8×10^5 per 25 cm^2 (laboratory 5) and 1.1×10^5 per 25 cm^2 (laboratory 6).

Susceptibility of the C. difficile spore preparation

The internal quality control of the *C. difficile* test spores is considered to be valid if the mean $\log_{10}$ reduction is <1.5 with 1% glutaraldehyde and 0.01% peracetic acid [11]. This requirement was fulfilled in all laboratories with a mean $\log_{10}$ reduction of 0.59 with 1% glutaraldehyde (mean pH: 6.11 ± 0.77), a mean $\log_{10}$ reduction of 0.69 with 0.01% peracetic acid (mean pH: 4.92 ± 0.28) and a test suspension within the set limit between 1.5 and 5.0×10^6 cfu/mL.

Effect of water control

The water control led to a reduction in *C. difficile* spores between 1.68 and 3.14 $\log_{10}$ (mean: 2.14 $\log_{10}$; median: 2.10 $\log_{10}$). The residual contamination on the three non-contaminated test fields was ≥ 10 cfu/25 cm^2 in all laboratories (range of means: 28–518 cfu/25 cm^2).

Efficacy of test products

The solution of product A (ready-to-use wipes) reduced the *C. difficile* spore count in both laboratories by at least 4.0 $\log_{10}$ in the suspension tests in 5 min (Table II). In the 4-field test the wipes reduced the spore counts on field 1 in 5 min by at least 4.0 $\log_{10}$, on test fields 2 to 4 the spore count was consistently less than 50 cfu per 25 cm^2. The product solution and the wipe therefore fulfilled the efficacy criteria of both test methods and can be regarded as effective against *C. difficile* spores in 5 min under clean conditions. The applied amount was on average 0.37 mL.

The solution of product B (ready-to-use wipe) was not effective in the suspension tests and showed after 15 min a mean $\log_{10}$-reduction of 0.90 and after 60 min of 3.22 (Table II). In the 4-field tests the spore reduction on field 1 was similar after 15 min (2.82 $\log_{10}$) and 60 min (2.83 $\log_{10}$), suggesting that the additional 45-min exposure time did not add any sporicidal effect to the contaminated surface. On test fields 2 to 4 the spore counts were mostly above 50 cfu per 25 cm^2 indicating a substantial carry-over effect of the spores without a sufficient sporicidal effect. The product solution and the wipe therefore did not fulfil the efficacy criteria of both test methods and cannot be regarded to have sufficient efficacy against *C. difficile* spores in 15 or 60 min, respectively. The applied amount was on average 0.55 mL (15 min application time) and 0.41 mL (60 min application time).

Product C is a concentrate and reduced *C. difficile* spores in suspension by 5.40 $\log_{10}$ (2% solution, 15 min) and 5.03 $\log_{10}$ (1% solution, 30 min; Table II). In the 4-field test the product reduced the spore counts on field 1 by 5.16 $\log_{10}$ (2% solution, 15 min) and 4.36 $\log_{10}$ (1% solution, 30 min). On test fields 2 to 4 the spore count was consistently less than 50 cfu per 25 cm^2. The product at 2% and 1% therefore fulfilled the efficacy criteria of both test methods and can be regarded as effective under clean conditions against *C. difficile* spores in 15 or 30 min, respectively. The applied amount was on average 1.01 mL (15 min application time) and 0.94 mL (30 min application time).

Table II
Mean log_{10}-reductions obtained with five products against *Clostridioides difficile* spores in suspension tests and the 4-field test under clean conditions

Test product	Exposure time (min)	Laboratory	Suspension test	4-field-test	cfu per 25 cm^2 on fields 2 to 4 (mean/median)	Mean released liquid onto test surfaces (g; mean and SD)
			Log_{10}-reduction (mean and SD)	Log_{10}-reduction on field 1 (mean and SD)		
A*	5	1	5.60 ± 0.15	5.24 ± 0.42	10/8	0.39 ± 0.06
		2	5.36 ± 0.13	4.71 ± 0.47	1/0	0.35 ± 0.02
		Both	**5.48 ± 0.18**	**4.98 ± 0.50**	**5/3**	**0.37 ± 0.05**
B*	15	1	0.72 ± 0.47**	3.29 ± 0.31**	13**/10**	0.78 ± 0.43
		3	1.08 ± 0.15	2.35 ± 0.49	822/896	0.32 ± 0.06
		Both	**0.90 ± 0.37**	**2.82 ± 0.64**	**418/68**	**0.55 ± 0.36**
B*	60	1	3.43 ± 0.62	3.03 ± 0.18	83/81	0.49 ± 0.11
		3	3.01 ± 0.11	2.64 ± 0.09	401/419	0.32 ± 0.04
		Both	**3.22 ± 0.47**	**2.83 ± 0.25**	**242/101**	**0.41 ± 0.12**
C (2%)	15	1	5.29 ± 0.37	5.51 ± 0.07	3/3	1.08 ± 0.12
		4	5.52 ± 0.27	4.82 ± 0.73	8/7	0.93 ± 0.18
		Both	**5.40 ± 0.33**	**5.16 ± 0.61**	**6/3**	**1.01 ± 0.16**
C (1%)	30	1	5.25 ± 0.20	4.43 ± 0.40	7/3	0.92 ± 0.06
		4	4.80 ± 0.38	4.30 ± 0.18	5/5	0.96 ± 0.23
		Both	**5.03 ± 0.37**	**4.36 ± 0.30**	**6/4**	**0.94 ± 0.15**
D (2%)	15	1	5.42 ± 0.60	4.29 ± 0.28	0/0	0.78 ± 0.08
		5	5.27 ± 0.11	3.95 ± 0.08	20/21	0.89 ± 0.41
		Both	**5.35 ± 0.41**	**4.12 ± 0.26**	**10/8**	**0.83 ± 0.28**
D (0.5%)	60	1	5.09 ± 1.00	2.83 ± 0.16	19/18	0.86 ± 0.04
		5	5.33 ± 0.12	3.35 ± 0.15	73/75	1.08 ± 0.29
		Both	**5.21 ± 0.67**	**3.09 ± 0.31**	**46/43**	**0.97 ± 0.23**
E*	240	1	1.12 ± 0.00	5.05 ± 0.49	22/5	0.48 ± 0.06
		6	0.68 ± 0.14	3.89 ± 0.29	8/8	0.28 ± 0.10
		Both	**0.90 ± 0.25**	**4.47 ± 0.73**	**15/6**	**0.38 ± 0.13**

SD, standard deviation.
Bold: log10-reduction (mean and SD)obtained for both laboratories.
* Ready to use wipe.
** Based on $n = 3$.

Product D is also a concentrate and reduced *C. difficile* spores in suspension by 5.35 log_{10} (2% solution, 15 min) and 5.21 log_{10} (0.5% solution, 60 min; Table II). In the 4-field test the 2% product solution reduced the spore counts in 15 min on field 1 by 4.12 log_{10} although the mean log_{10}-reduction was just below 4.0 in one of the two laboratories. The 0.5% product was less effective in 60 min and reduced the spore counts by 3.09 log_{10}. On test fields 2 to 4 the overall spore count was consistently less than 50 cfu per 25 cm^2 for the 2% and 0.5% product solution although the counts were above 50 per 25 cm^2 for the 0.5% product solution in one laboratory. The 2% product solution (15 min) but not the 0.5% product solution therefore fulfilled the efficacy criteria of both test methods and can be regarded as having sufficient efficacy under clean conditions against *C. difficile* spores. The applied amount was on average 0.83 mL (15 min application time) and 0.97 mL (30 min application time).

Product E (ready-to-use wipe) revealed a mean log_{10}-reduction of 0.9 after 4 h in the suspension test (Table II). In the 4-field test the product reduced the spore counts in 4 h on field 1 by 4.47 log_{10} although the mean log_{10}-reduction was just below 4.0 in one of the two laboratories. On test fields 2 to 4 the spore count was consistently less than 50 cfu per 25 cm^2. The product solution therefore did not fulfil the efficacy criteria of both test methods and cannot be regarded as having sufficient efficacy against *C. difficile* spores in 4 h. The applied amount was on average 0.38 mL.

Discussion

Although the manufacturers of all five products claimed that their surface disinfectant has sporicidal activity, we found that only two of them (products A and C) had sufficient efficacy under clean conditions against *C. difficile* spores in suspension and under practical conditions. Product D at 2% (15 min) was also sufficiently effective but not at 0.5% (1 h). Product E fulfilled only the efficacy criteria after 4 h under practical conditions but not in the suspension tests. Product B did not fulfil the efficacy criteria of both test methods. Comparable results were found in two different laboratories and thus the study data are considered to be reliable. In addition, the spore suspensions were visually checked by microscopy, internal quality controls ensured the required chemical tolerance of the spores and valid neutralization. The results also show that a manufacturer's sporicidal claim often only based on suspension tests does not necessarily mean that the surface disinfectant exhibits sufficient sporicidal efficacy against *C. difficile* spores under practical conditions. That is why testing provides more reliable data [15]. A similar overall result with 10 different 'sporicidal' wipes has been described previously [16].

A major limitation of the study was that all experiments were performed under clean conditions. Clean conditions were chosen because most manufacturers provided sporicidal efficacy data under clean conditions. In clinical practice it is likely

that the surroundings of *C. difficile* patients are contaminated with some organic load with the spores. That is why it is uncertain whether the same efficacy can be assumed in the presence of organic load such as faeces. It has been described previously that the bactericidal efficacy is lower for 1.4 mM peroxynitric acid and 1.1 mM hypochlorous acid in the presence of protein [17]. The effect of ethanol, n-propanol or isopropanol against the murine norovirus, however, was not impaired in a carrier test under dirty conditions [18]. For clinical practice, however, efficacy data against *C. difficile* spores obtained under dirty test conditions are from our perspective more reliable and should preferably be used.

In clinical practice it will be relevant to avoid that the wiping itself contributes to the spread of the *C. difficile* spores on the treated surfaces [19]. That is why the results from test fields 2 to 4 have relevant practical implications. The wiping itself will carry over some of the local contamination to the neighbouring parts of the surface. That is why the disinfectant solution remaining on the treated surface should keep some sporicidal activity, which is considered and evaluated with this 4-field test [12].

Another limitation of our results may be the long exposure time of some products. EN 14885 specifies that the minimum efficacy should be proven for use on surfaces around the patient within 15 min, on other surfaces it may take up to 60 min [20]. A disinfectant requiring 240 min is therefore outside the maximum exposure time for this type of application. In particular, the use of higher concentrations with shorter contact times, however, requires the careful balancing of the advantage of a fast sporicidal efficacy with possible harms to the health of the cleaning staff and patients. A stronger sporicidal efficacy typically requires a higher concentration of the product with all possible side effects for occupational health. This aspect should be taken into account when evaluating suitable formulations for a sporicidal surface disinfection.

C. difficile-infected patients usually harbour between 1.5 and 5.5 $\times$ 10^6 *C. difficile* spores per g in their faeces [21]. It is therefore plausible to assume that the requirement for a 4 $\log_{10}$-reduction of spores is reasonable. The surface contamination in the direct surroundings of *C. difficile*-infected patients, however, has been described to be rather low with a mean of 5.1 cfu per swab [22]. Weber *et al.* reported in 2013 that surfaces were mostly contaminated with $<$1 to 2 $\log_{10}$ *C. difficile*. Two studies reported $>$2 $\log_{10}$ *C. difficile* on surfaces, of which one study that sampled different surfaces with a sponge found more than 1300 colonies [23]. No additional data were found. Even if the contamination level is low in some cases, Lawley *et al.* [24] found in an experiment with mice that 5—10 *C. difficile* spores per cm^2 (125—250 cfu/25 cm^2) are sufficient to infect 50% of the mice within 1 h of exposure. With this background, a practical consideration of the possible distribution of *C. difficile* spores in the environment is urgently expected and can be illustrated with this 4-field test [12]. For the human medical area, a 4 log reduction was set [11,12,25] and seems to be reasonable and sufficient in this context.

All three ready-to-use wipes used in our study released a rather small volume of the surface disinfectant solution (0.37—0.55 mL). When a standard wipe was soaked with 16 mL of a surface disinfectant solution, the release per wipe was higher at 0.83—1.10 mL. It has been shown previously that a larger volume of a disinfectant results in a higher $\log_{10}$-reduction on test field 1 [26]. It seems possible therefore that a larger volume of product per wipe may yield more favourable results for those products that failed to meet the efficacy requirements of the 4-field test.

'The results obtained with product E are somewhat confusing. The wrung product solution itself revealed consistently only a poor activity against *C. difficile* spores in suspension within 4 h. But when the wipe was applied in the 4-field test it demonstrated an overall sufficient sporicidal activity on the surface including the low carry-over effect shown in test fields 2 to 4. This discrepancy cannot be explained currently although it may be possible that a larger proportion of spores adhered to the tissues soaked with the slightly sticky product solution.

Another interesting observation was made with product B. The product solution showed a higher $\log_{10}$-reduction after 60 min in suspension compared with 15 min in suspension. This finding is expectable. At the same time, however, the wipe revealed no difference in efficacy on the surface whether spores were exposed for 15 min (2.82 $\log_{10}$) or for 60 min (2.83 $\log_{10}$). The data indicate that no additional sporicidal effect was achieved after 15 min. A possible explanation is that hydrogen peroxide requires the presence of water to act as a sporicidal substance.

Overall, product A (ready-to-use wipes, 5 min), product C (2% in 15 min or 1% in 30 min) and product D (2% in 15 min) were found to be effective against *C. difficile* spores in suspension and on surfaces. For surface disinfection of existing *C. difficile* infections, disinfectants with proven efficacy against *C. difficile* spores should be used [27]. This efficacy test should be carried out in a standardized manner according to VAH method 18 [25] or EN 17126 [11] and under practical conditions according to VAH method 19 [12].

In conclusion, not all surface disinfectants with a sporicidal claim from the manufacturer are effective against *C. difficile* spores in standardized suspension tests and in the 4-field test. In clinical practice, preference should be given to products that reliably pass the efficacy criteria of both types of tests.

Conflict of interest statement

The authors declare to have no conflict of interest related to the content of the manuscript.

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Hygiene - Information
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von: **MH/MHA** 12.May 2021
an: **Rundschreiben neodisher**
Export

neodisher endo SEPT PAC – Efficacy tests according to new European standards

To prove the disinfectant efficacy, the European standards of CEN /TC 216 "Chemical Disinfectants and Antiseptics" for testing the disinfectant properties of chemical disinfectants are suitable and harmonised throughout Europe.
These standards are subject to constant updates. In addition, new standards are added in order to close any gaps that may exist.

There are two new standards for the demonstration of the efficacy of instrument disinfectants:

EN 17111: 2018-12: Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area – Test method and requirements (phase 2, step 2); This test is to be used as a supplement to EN 14476 (phase 2, step 1).

EN 17126: 2019-2: Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area – Test method and requirements (phase 2, step 1)
This test replaces EN 13704 in the medical area.

In contrast to the previous standard, EN 17126 now allows for more differentiated claims:
Sporicidal against Clostridium difficile
and
Sporicidal (active against all bacterial spore formers, including C.difficile)

For sporicidal activity, higher reductions of the test organisms and other test organisms are required. Therefore, changes in application conditions may be possible.

neodisher endo SEPT PAC has been tested according to the two standards mentioned above.
The virucidal effectiveness does not change due to the additional testing according to EN 17111.

However, the test according to EN 17126 for sporicidal activity leads to changes in the claims:

Under the current application conditions of

1.0%, 5 minutes, 35°C
1.0%, 10 minutes, 25 °C

the product is now **sporicidal against C. difficile**.

C. dfficile is the only hygiene-relevant spore former in the reprocessing of flexible endoscopes, especially colonoscopes. It can therefore still be assumed that there is sufficient disinfection performance.

Conclusion :

In contrast to the previous standard, EN 17126 now allows for more differentiation claims:Sporicidal against Clostridium difficile and
Sporicidal (active against all bacterial spore formers, including C. difficile) For sporicidal activity, higher reductions of the test organisms and other test organisms has required. Therefore, changes in application conditions may be possible.Neodisher endo SEPT PAC has been tested according to the two standards mentioned above.
But for EN 17126 we establish an effectiveness of 1.0%, 5 minutes at 35°C and 1.0% at 10 minutes, 25°C according to neodisher endo SEPT PAC – Efficacy tests according to new European standards from May 12, 2021. The most lucrative concentration is :

EN 17126 **1%(dirty)** **10 min**

Developer Gogu Andrei

Prof. Dr. med. H.-P. Werner
Facharzt für Hygiene

c/o
HygCen Germany GmbH
Bornhövedstrasse 78
19055 Schwerin

Phone: +49 (0) 385 5682 65
Fax: +49 (0) 385 5682 67
Email: info@hygcen.de
Web: www.hygcen.de

[H.-P. WERNER | BORNHÖVEDSTRASSE 78 | 19055 SCHWERIN]

ROPIMEX R. OPEL GmbH
Bildstocker Str. 12-14

66538 Neunkirchen

2018-12-19

Bacoban WB
Surface disinfection with mechanical action
bactericidal and yeasticidal activity
dirty conditions

EXPERT OPINION

After testing the disinfectant **Bacoban WB in combination with the reference wipe** in accordance with

„Requirements and Methods for VAH-Certification of Chemical Disinfection Procedures" (status 2015)

I give the following statement based on the results from the test reports dated 2018-12-19 (SN 26613, 2018-2685) qualitative suspension test according to VAH method 8, dated 2018-12-19 (SN 26613, 2018-2686) quantitative suspension test according to EN 13727, dated 2018-12-19 (SN 26613, 2018-2687) quantitative suspension test according to EN 13624, dated 2018-12-19 (SN 26613, 2018-2688) quantitative non-porous surface test with mechanical action employing wipes according to EN 16615 as well as dated 2018-12-19 (SN 26613, 2018-2689) according to EN16615 – 3rd test run VAH.

Results of the in vitro-tests

On the basis of the results of the qualitative suspension test, the results with the test strains *S. aureus, E. hirae, P. aeruginosa* and *C. albicans* in the quantitative suspension tests were valid.
The quantitative suspension tests were carried out under **dirty conditions**.

Bacoban WB shows sufficient reductions of ≥5lg units for bacteria and of ≥4lg units for *C. albicans*

under **dirty conditions**

in **0.75%**	within	**2 minutes**
in **0.5%**	within	**5 minutes**

DAkkS Deutsche Akkreditierungsstelle

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-PL-13412-01-01 according to DIN EN ISO/IEC 17025:2018

Valid from: **03.01.2022**

Date of issue: 03.01.2022

Holder of certificate:

Dr. Brill + Partner GmbH
Institut für Hygiene und Mikrobiologie

Sites:
Stiegstück 34, 22339 Hamburg
Norderoog 2, 28259 Bremen
Am Hafen 10, 26548 Norderney (Institut für Antifouling und Biokorrosion)

Tests in the fields:

health care (hospital hygiene and infection prevention), pharmaceutical products and active agents, efficacy testing of disinfectants in the fields of pharmaceutical products and active agents, health care (hospital hygiene and infection prevention), veterinary medicine, food, industry and consumer goods by means of cultural microbiological tests,
microbiological testing of cosmetics, packaging, gases and air,
Efficacy testing of marine or limnic exposed materials (antifouling coatings) for ships, boats, port structures and other offshore structures on antifouling panels using biological test systems.

fields of testing: hygiene and infection prevention, biological pharmaceutical products, active agents and excipient analytic

For the test methods marked with **, the testing laboratory is permitted to modify and develop new test methods without obtaining prior notification and consent from Deutsche Akkreditierungsstelle GmbH.
The test methods listed are given by way of an example. The laboratory has an up-to-date list of all test methods within the flexible scope of accreditation

The management system requirements of DIN EN ISO/IEC 17025 are written in the language relevant to the operations of testing laboratories. Laboratories that conform to the requirements of this standard, operate generally in accordance with the principles of DIN EN ISO 9001.

The certificate together with the annex reflects the status as indicated by the date of issue.
The current status of any given scope of accreditation can be found in the directory of accredited bodies maintained by Deutsche Akkreditierungsstelle GmbH at https://www.dakks.de/en/content/accredited-bodies-dakks.

Abbreviations used: see last page

In-house method AA-00038 28.03.2018	Virucidal carrier test according to AOAC 991.47

Site Am Hafen 10, 26548 Norderney

Efficacy testing of marine or limnic exposed materials (antifouling coatings) for ships, boats, port structures and other offshore structures on antifouling panels using biological test systems

ASTM 6990-20 (2020)	Standard Practice for Evaluating Biofouling Resistance and Physical Performance of Marine Coating Systems
ASTM 3623-78a (2020)	Standard Test Method for Testing Antifouling Panels in Shallow Submergence
In-house method AA-00308 02.08.2021	Dynamic field testing of antifouling coatings using RotoMarin®
In-house method AA-00309 03.08.2021	Rapid Test on barnacle settlement (Rapid test for the settlement of barnacles in the field)

Abbreviations

AA	Standard opertating procedures / In-house method of KBS
ASTM	American Society for Testing and Materials
AOAC	Association of Official Agricultural Chemists
DIN	German Insitute for Standards (Deutsches Institut für Normung)
EN	European Standards (Europäische Norm)
ISO	International Organization for Standardization
DVG	German Society of Veterinary Medicine (Deutsche Veterinärmedizinische Gesellschaft)
DGHM	German Society for Hygiene and Microbiology
JIS	Japan Industrial Standard
Ph. Eur.	Pharmacopoeia Europaea
USP–NF	United States Pharmacopeia–National Formulary
VAH	Association for Applied Hygiene (Verbund für Angewandte Hygiene)

DIN EN 14476:2019-10	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1) *(no conformity assessment of medical devices)*
DIN EN 14675:2015	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirement (phase 2, step 1)
DIN EN 16777:2019-03	Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2, step 2) *(no conformity assessment of medical devices)*
DIN EN 17122:2020-02	Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements – (phase 2, step 2)
DIN EN 17272:2020-06	Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities
DVG Methode 5	Methods of testing chemical disinfectants for animal husbandry - DVG Test Guidelines; 4th edition, as of 27.07.2017 - Method description; V Animal husbandry (V.3 Virucidity test).
In-house method AA-00019 15.02.2019	Testing of the virucidal efficacy of chemical disinfectants with practice-like test models, quantitative testing of the virucidal activity of chemical disinfectants on non-porous surfaces (Carrier test according to OECD- 2010) (phase 2, Step 2)
In-house method AA-00020 30.12.2017	Testing of the virucidal efficacy of chemical disinfectants with practice-like test models, carrier test on treated materials (phase 2, stage 2)
In-house method AA-00024 12.07.2021	Virucidal efficacy testing according to a modification of EN 1500 on hands (phase 2, step 2)
In-house method AA-00025 29.06.2017	Testing of surface disinfectants for virus efficacy based on the draft of the CEN/TC216/WG 1 N (WI 00216104) (phase 2, step 2)
In-house method AA-00026 07.09.2018	Virucidal efficacy testing room decontamination (phase 2, step 2)
In-house method AA-00037 19.03.2018	Virucidal carrier test according to AOAC 955.15

Site Norderoog 2, 28259 Bremen

1. Field: Health care (Hospital hygiene and infection prevention)

1.1 Field of testing: Hygiene and infection prevention

1.1.1 Type of testing: microbiogical-hygienic testing**

Standard / date of issue In-house method /version	Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
ISO 21702:2019-05	Measurement of antiviral activity on plastics and other non-porous surfaces	Plastics, non-porous surfaces
In-house method AA-00032 09.07.2020	Measurement of antiviral activity on plastics and other non-porous surfaces based on JIS Z 2801/ISO 22196	Plastics, non-porous surfaces
ISO 18184:2019-06	Textiles — Determination of antiviral activity of textile products	Textile products
ASTM E 2149:2020	Standard Test Method for Determining the Antimicrobial Activity of Antimicrobial Agents Under Dynamic Contact Conditions	Fibre materials
ASTM E 2180:2018	Standard Test Method for Determining the Activity of Incorporated Antimicrobial Agent(s) In Polymeric or Hydrophobic Materials	Polymer surfaces, hydrophobic surfaces

2. Efficacy testing of disinfectants in the fields of pharmaceutical products and active agents, health care (hospital hygiene and infection prevention), veterinary medicine, food, industry and consumer goods by means of cultural microbiological tests**

ASTM E 1052 – 20 (2020)	Standard Practice to Assess the Activity of Microbicides against Viruses in Suspension
ASTM E 1838 – 17 (2017)	Efficacy testing of chemical disinfectants on fingertips according to ASTM E 1838-17 (phase 2, step 2)
ASTM E 2011-13 (2013)	Efficacy testing of chemical disinfectants on the entire hand according to ASTM E 2011-13 (phase 2, step 2)
ASTM E 2197 – 17 (2017)	Standard Quantitative Disk Carrier Test Method for Determining Bactericidal, Virucidal, Fungicidal, Mycobactericidal, and Sporicidal Activities of Chemicals
ASTM E1053 – 20 (2020)	Standard Practice to Assess Virucidal Activity of Chemicals Intended for Disinfection of Inanimate, Nonporous Environmental Surfaces

4. Microbiological testing of cosmetics and packaging

DIN EN 15457:2014-11	Paints and varnishes - Laboratory method for testing the efficacy of film preservatives in a coating against fungi
DIN EN ISO 11930: 2019-04	Cosmetics - Microbiology - Evaluation of the antimicrobial protection of a cosmetic product
House method AA-00134 04.11.2020	Preservation test (Inoculation cycle test according to Brill)
In-house method AA-00143 04.11.2020	Agar diffusion test for water soluble substances
In-house method AA-00144 04.11.2020	Agar diffusion test for water insoluble substances
Ph. Eur. 10, (2020), 5.1.3	Testing of sufficient preservation (*Modifikation: here for cosmetics with formulations preserved with biocides)*
USP 30 NF 32 <51>, 2019	Antimicrobial effectiveness testing (*Modifikation: here for cosmetics with formulations preserved with biocides)*

PAS 2424:2014	Quantitative surface test for the evaluation of residual antimicrobial (bactericidal and/or yeasticidal) efficacy of liquid chemical disinfectants on hard non-porous surfaces
VAH - method 7 : 2019-06	Determination of bacteriostatic and levurostatic efficacy and appropriate neutralising agents
VAH - method 8 : 2019-06	Qualitative suspension test for determination of bactericidal and levurocidal activity
VAH - method 9 : 2019-06	Quantitative suspension test for determination of bactericidal, levurocidal, fungicidal, tuberculocidal or mycobactericidal activity
VAH - method 10 : 2019-06	Hygienic hand wash – practice-like test with volunteers
VAH - method 11: 2019-06	Hygienic hand disinfection – practice-like test with volunteers
VAH - method 12 : 2019-06	Surgical hand disinfection - practice-like test with volunteers
VAH - method 13 : 2019-06	Skin disinfection - practice-like test with volunteers
VAH - method 14.1 : 2019-06	Surface disinfection without mechanics - practice-like test
VAH - method 14.2 : 2019-06	Surface disinfection with mechanics - practice-like 4-field test
VAH - method 16 : 2019-06	Chemical-thermal textile disinfection – immersion-bath process (practice-like test)
VAH - method 17 : 2019-06	Chemical-thermal textile disinfection – single-bath process (practice-like test)

DIN EN 1656: 2019-12	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area
DIN EN 1657: 2016-11	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)
DIN EN 16615: 2015-06	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 1) *(no conformity assessment of medical devices)*
DIN EN 16616: 2015-10	Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2) *(no conformity assessment of medical devices)*
DIN EN 17126: 2019-02	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area - Test method and requirements (phase 2, step 1) (no conformity assessment of medical devices)
DIN EN 17272: 2020-06	Chemical disinfectants and antiseptics - Methods of airborne room disinfection by automated process - Determination of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal, virucidal and phagocidal activities
DVG 2000: IV.2, as of 2000	Dilution test for determination of bacteriostatic and fungiostatic efficacy as well as sufficient inactivation
DVG 2000: IV.3, as of 2015	Determination of the bactericidal, tuberculocidal and fungicidal activity within the suspension test
DVG 2000: IV.4, as of 2015	Determination of bactericidal, tuberculocidal and fungicidal activity within carrier test
DVG 2000: V.2.7, as of 2015	Suspension test: Qualitative suspension test (end point method), quantitative suspension test
DVG 2007: IV.2.1, 2.2, 2.3, 2.5, as of 2015	Methods for determining the minimal inibition concentration (MIC) and optimal neutralizer
DVG 2007: IX, as of 2015	Methods for testing chemical disinfectants for the area of commercial kitchens
DVG 2007: VII, as of 2015	Methods for testing chemical disinfectants for the area of meat production and of food of animal origin
DVG 2007: VIII, as of 2015	Methods for testing chemical disinfectants for milk production (except CIP)
House method AA-00049 24.07.2017	In-use stability wipe systems – Determiniation of disinfection power

DIN EN 13697: 2019-10	Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action *(no conformity assessment of medical devices)*
DIN EN 13704: 2018-09	Chemical disinfectants - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1) *(no conformity assessment of medical devices)*
DIN EN 13727: 2015-12	Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants in the medical area (phase2, step 1) *(no conformity assessment of medical devices)*
DIN EN 14204: 2013-02	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants and antiseptics used in the veterinary area - Test method and requirements (phase 2, step 1)
DIN EN 14347: 2005-08	Chemical disinfectants and antiseptics - Basic sporicidal activity (basic test) - Test method and requirements (phase 1) *(no conformity assessment of medical devices)*
DIN EN 14348: 2005-04	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1) *(no conformity assessment of medical devices)*
DIN EN 14349: 2013-02	Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action
DIN EN 1499: 2017-10	Chemical Disinfectants and antiseptics: Disinfecting hand wash
DIN EN 1500: 2017-10	Chemical Disinfectants and antiseptics: Hygienic hand disinfection
DIN EN 16437: 2019-12	Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in veterinary area on porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)
DIN EN 16438: 2014-07	Chemical disinfectants and antiseptics - Quantitative surface test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in the veterinary area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)
DIN EN 1650: 2019-10	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)

ASTM E1174-13 (2013)	Standard Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations
ASTM E1839-13 (2013)	Standard Test Method for Efficacy of Slimicides for the Paper Industry – Bacterial and Fungal Slime
ASTM E2197-17 (2017)	Standard Quantitative Disk Carrier Test Method for Determining Bactericidal, Virucidal, Fungicidal Mycobactericidal, and Sporicidal Activities of Chemicals
ASTM E2755-15 (2015)	Standard Test Method for Determining the Bacteria-Eliminating Effectiveness of Hand Sanitizer Formulations Using Hands of Adults
ASTM E2783-16 (2016)	Standard Test Method for Assessment of Antimicrobial Activity for Water Miscible Compounds Using a Time-Kill Procedure
ASTM E2799-12 (2012)	Standard Test Method for Testing Disinfectant Efficacy against *Pseudomonas aeruginosa* Biofilm using the MBEC Assay
ASTM E645-13 (2013)	Standard Practice for Evaluation of Microbiocides Used in Cooling Water Systems
DIN EN 1040: 2006-03	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic bactericidal activity (basic test) of chemical disinfectants and antiseptics - Test method and requirements (phase 1)
DIN EN 1275: 2006-03	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or levurocidal activity (basic test) of chemical disinfectants and antiseptics - Test method and requirements (phase 1) *(no conformity assessment of medical devices)*
DIN EN 1276: 2019-11	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal, fungicidal and sporicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1) *(no conformity assessment of medical devices)*
DIN EN 12791: 2018-01	Chemical Disinfectants and antiseptics: Surgical hand disinfectants
DIN EN 13610: 2003-06	Chemical disinfectants - Quantitative suspension test for the evaluation of virucidal activity against bacteriophages of chemical disinfectants used in food and industrial areas - Test method and requirements (phase 2, step 1) *(no conformity assessment of medical devices)*
DIN EN 13623: 2020-12	Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity against Legionella pneumophila of chemical disinfectants for aqueous systems - Test method and requirements *(no conformity assessment of medical devices)*
DIN EN 13624: 2013-12	Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase2, step 1). *(no conformity assessment of medical devices)*

Standard / date of issue In-house method /version	Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
In-house method AA-00125 19.02.2019	Testing of washing machines with bioindicators (Höller et al 1999).	Bioindicators

2. Field: Pharmaceutical products and active agents

2.1 Field of testing: biological pharmaceutical products, active agents and excipient analytic

2.1.1 Type of testing:
Testing for sufficient microbial preservation**

Standard / date of issue In-house method /version	Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
Ph. Eur. 10 (2020) 5.1.3	Testing for sufficient preservation	pharmaceutical products
USP 30 NF 32 <51> 2019	Antimicrobial Effectiveness Testing	pharmaceutical products

3. Efficacy testing of disinfectants in the fields of pharmaceutical products and active agents, health care (hospital hygiene and infection prevention), veterinary medicine, food, industry and consumer goods by means of cultural microbiological tests**

AOAC 955.14 2013	Testing Disinfectants against *Salmonella enterica* (Use dilution method)
AOAC 955.15 2013	Testing Disinfectants against *Staphylococcus aureus* (Use dilution method)
AOAC 955.17 2005	Fungicidal Activity of Disinfectants Using *Trichophyton mentagrophytes*
AOAC 964.02 2013	Testing Disinfectants against *Pseudomonas aeruginosa* (Use dilution method)
AOAC 991.47 2005	Testing Disinfectants against *Salmonella choleraesuis* (Hard Surface Carrier Test Method)
AOAC 991.48 2005	Testing Disinfectants against *Staphylococcus aureus* (Hard Surface Carrier Test Method)
AOAC 991.49 2005	Testing Disinfectants against *Pseudomonas aeruginosa* (Hard Surface Carrier Test Method)
ASTM E1153-14 (2014)	Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate, Hard, Nonporous Non-Food Contact Surfaces

Site Stiegstück 34, 22339 Hamburg

1. Field: Health care (Hospital hygiene and infection prevention)

1.1 Field of testing: Hygiene and infection prevention

1.1.1 Type of testing: microbiogical-hygienic testing**

Standard / date of issue In-house method /version	Title of the Standard or the in-house method (specify any deviations / modifications of standard method)	Test item
ASTM E2149-20 (2010)	Standard Test Method for Determining the Antimicrobial Activity of Immobilized Antimicrobial Agents Under Dynamic Contact Conditions	Plastics, metals
ASTM E2180-18 (2018)	Standard Test Method for Determining the Activity of Incorporated Antimicrobial Agent(s) In Polymeric or Hydrophobic Materials	Plastics
DIN EN 15457:2014-11	Paints and varnishes - Laboratory method for testing the efficacy of film preservatives in a coating against fungi	Coatings, varnishes
DIN EN ISO 20743:2013-12	Textiles - Determination of the antibacterial efficacy of textile products	Textiles
In-house method AA-00134 14.11.2020	Microbial challenge test (preservation test according to Brill)	Coatings, varnishes, cooling lubricants
In-house method AA-00140 04.11.2020	Service life of cloth systems - Determination of preservation	Disinfectants
In-house method AA-00144 14.11.2020	Agar diffusion test for water soluble substances and (based on DIN 58940:1989)	Disinfectants, cooling lubricants
In-house method AA-00143 14.11.2020	Agar diffusion test for water soluble substances and wound dressings (based on DIN 58940:2007)	Disinfectants, cooling lubricants
ISO 22196:2011-08	Measurement of antibacterial activity on plastics and other non-porous surfaces	Plastics, metals
JIS Z 2801/AMENDMENT 1: 2012-05-21	Antimicrobial products – Test for antimicrobial activity and efficacy	Plastics, metals
Ph. Eur. 10 (2020) 5.1.3	Testing on sufficient preservation	Disinfectants
USP 30 NF 32 <51> 2019	Antimicrobial effectiveness testing	Disinfectants
DIN EN 13060:2019-02	Small steam sterilizers	Bioindicators
In-house method AA-00124, 20.05.2021	Testing the sterilization performance of sterilizers with bioindicators DIN EN ISO 11138, DIN EN 13060, DIN EN ISO 18472	Bioindicators

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1:Efficacy of five ‘sporicidal’ surface disinfectants against Clostridioides difficile spores in suspension tests and 4-field tests S. Gemein a,b, *, R. Andrich c , B. Christiansen d , M. Decius d , M. Exner a , B. Hunsinger b , E. Imenova e , G. Kampff , T. Koburger-Janssen g , K. Konrat c , H. Martiny b , M. Meckel h , N.T. Mutters a , F-A. Pitten h , S. Schulz e , I. Schwebke c , J. Gebel a https://edoc.rki.de/bitstream/handle/176904/9618/1-s2.0-S0195670122000251-main.pdf?sequence=1&isAllowed=y

2: Test report L20/0285BC.5 Evaluation of the effectiveness of BARRIER TECH MF Sanitiser Concentrate Test virus: bovine coronavirus (BCoV) (surrogate of human coronaviruses) Method: EN 14476:2013+A2:2019 (dirty conditions) quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine (phase 2/ step 1)
https://www.barriertechsa.co.za/wp-content/uploads/2021/07/Teknologisk-BARRIER-TECH-MF-Sanitiser-Concentrate-L20-0285BC-5-BCoV-test-report-EN-14476-dirty-LVP-Version-02-27.11.2020-1.pdf

3: ROPIMEX R. OPEL GmbH Bildstocker Str. 12-14 66538 Neunkirchen 2018-12-19 **Bacoban WB**
Surface disinfection with mechanical action bactericidal and yeasticidal activity dirty conditions E X P E R T O P I N I O N
After testing the disinfectant **Bacoban WB in combination with the reference wipe** in accordance with „Requirements and Methods for VAH-Certification of Chemical Disinfection Procedures” (status 2015)

https://www.bacobaninternational.com/wp-content/uploads/2020/11/Expert_Opinion_Bac.WB_VAH2015_HygCen_EN.pdf

4: Gutachterliche stellungnahme expert report Bacoban WB

https://www.bacobaninternational.com/wp-content/uploads/2020/11/Experts_report_Bacoban-WB_VAH2015_Hygiene-Nord_EN.pdf

5:Annex to the Accreditation Certificate D-LP-13412-01-01 according to DIN EN ISO/IEC 17025 :2018 Dr.Brill+Partner GmbH

6 http://www.brama.lv/system/storage/download/Info-Weigert-neodisher%20endo%20SEPT%20PAC_05-21.pdf.mwLTIqeZo8AS9AvIA5OGOJk9XmUDzdZu