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Schweiz / Switzerland

CUSTOMER NUMBER
324

DATE
January 11, 2021

REPORT 202630.VI

STABIMED ULTRA

SPORICIDAL ACTIVITY

EN 17126(2018)

Purpose

The sporicidal activity of the product formulation **Stabimed ultra** (B. Braun Medical AG, Sempach, Switzerland) should be evaluated by in vitro – tests in accordance with the European Standard **EN 17126 (2018)** against the spores of C. difficile, B. subtilis and B. cereus.

Test description

Order number:	A 191020
Manufacturer:	B. Braun Medical AG, Sempach, Switzerland
Test product:	Stabimed ultra
Batch number(s):	1903BH0014
Sample number(s):	P 197156
Date of manufacture:	n.p.
Best before:	03 / 2021
Appearance:	white fine-grained powder
Appearance of dilution(s):	bluish, turbid liquid; changing to clear after about 6 min + ultra sonic and to colourless after about 20 min
Odour:	product specific
pH-values (pH-meter):	2 %: 3.98 WSH: 6.97
Storage conditions:	Room temperature
Date of order:	December 10, 2019
Date of delivery:	December 10, 2019
Test date:	October 16, 2020 – November 06, 2020
Basis:	EN 17126 (2018) : 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)
Test organisms:	<i>Clostridium difficile</i> NCTC 13366 (spore batch: 06042020) <i>Bacillus subtilis</i> DSM 347 (spore batch: D) <i>Bacillus cereus</i> ATCC 12826 (spore batch: Bc-07102019-a)
Test solution(s):	2 %, 1 %, 0.1 %
Active ingredients in 100 g ¹ :	n. p.
Neutralizer:	<i>C. difficile</i> , <i>B. cereus</i> : 1 % Tween80 + 0.3 % Sodium Thiosulfate + 0.025 % Catalase; in 0.25M phosphate buffer (Neutralizer LX) <i>B. subtilis</i> : 6 % Tween80 + 0.2 % L-Histidine + 0.6 % Lecithin + 1 % Sodium Thiosulfate + 0.2 % Peptone + 1.7 % Sodium chloride + 1.8 % Disodium hydrogen phosphate + 0.3 % Potassium dihydrogen phosphate; in VE (Neutralizer XLIV)
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes (dirty conditions)
Test temperature:	20 ± 1 °C
Incubation temperature:	36 ± 1 °C

Test Method

Quantitative suspension test under dirty conditions

Testing is based on the European Standard **EN 17126** (2018). Validation and control procedures are therefore carried out in accordance with that standard, too.

For the test, a sample of the product **Stabimed ultra** (diluted with water of standardized hardness, if necessary) is added to a suspension of spore in a solution of the interfering substance. The mixture is maintained at 20 ± 1 °C for the required contact time. At the end of the contact time, an aliquot of 1 ml is taken; the microbicidal activity in this portion is immediately neutralized. The number of surviving test organisms in each sample is determined by spread plating 2 x 1 ml aliquots the neutralized test suspensions and its dilutions. The reduction is determined with respect to the corresponding test suspension N_0 . 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 the EN 17126. The tests were performed under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) using *Clostridium difficile*, *B. subtilis* and *B. cereus* as test-organisms. As a control for spore susceptibility, the test was also performed using a reference product containing 5 % of peracetic acid instead of the test product. Detailed results are presented in tables 1.1– 3.2.2

Results²


According to the **EN 17126 (2018)**, the batch 1903BH0014 of the product formulation **Stabimed ultra**, when applied at the concentration / contact time relation of at least **1 % / 5 min**, does **possess sporicidal efficacy against *C. difficile*** (\log_{10} RF ≥ 4) at 20 °C under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) for reference strain *C. difficile* (Tab. 1.1 – 1.2) .

According to the **EN 17126 (2018)**, the batch 1903BH0014 of the product formulation **Stabimed ultra**, when applied at the concentration / contact time relation of at least **1 % / 10 min** or **2 % / 5 min**, respectively, also possesses sporicidal efficacy (\log_{10} RF ≥ 4) at 20 °C under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) for reference strain *B. subtilis* (Tab. 2.1 – 2.2) ..

However, according to the **EN 17126 (2018)**, general sporicidal efficacy (\log_{10} RF ≥ 4) **cannot be claimed** for the batch 1903BH0014 of the product formulation **Stabimed ultra** up to a product concentration / contact time relation of 2 % / 30 min, as no sufficient efficacy was observed at 20 °C under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) for reference strain *B. cereus* (Tab. 3.1.1 – 3.2.2).

Results are considered validated in accordance to requirements of **EN 17126 (2018)**.

Greifswald, January 11, 2021


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

- General Manager -


Prof. Dr. med. A. Kramer

MD for Hygiene and Environmental Medicine -

Table 1.1: Results of the quantitative suspension test according to EN 17126 (2018)

Date:	October 21, 2020	Order number:	A19-1020
Product:	Stabimed ultra	Sample number(s):	P 197156
Test organism:	<i>C. difficile</i> (Spores)	Batch number(s):	1903BH0014
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	Neutralizer:	LX
Test suspension (N₀):	2.37*10 ⁷ cfu/ml (7.37 log)	Incubation time:	5 d
Validation Suspension (N_V):	5.35*10 ² cfu/ml (2.73 log)	Test temperature:	20 ± 1 °C

contact time: 5 min							
concentration	dilution	cfu / plate 1	cfu / plate 2	V _{c1}	V _{c2}	log ₁₀ Na	log ₁₀ R
2 %	2 x 1.0 ml (10 ⁰)	7	0	7	≤ 1	1.60	4.77 *
	2 x 1.0 ml (10 ⁻¹)	1	0	1	< 1		
1 %	2 x 1.0 ml (10 ⁰)	0	0	≤ 1	≤ 1	< 1.00	> 5.37 *
	2 x 1.0 ml (10 ⁻¹)	0	0	≤ 1	< 1		
0.1 %	2 x 1.0 ml (10 ⁰)	> 330	> 330	> 330	> 330		
	2 x 1.0 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 4.52	< 1.85

contact time: 10 min							
concentration	dilution	cfu / plate 1	cfu / plate 2	V _{c1}	V _{c2}	log ₁₀ Na	log ₁₀ R
2 %	2 x 1.0 ml (10 ⁰)	24	28	24	28	2.54	3.84 *
	2 x 1.0 ml (10 ⁻¹)	20	1	20	1		
1 %	2 x 1.0 ml (10 ⁰)	0	0	≤ 1	≤ 1	< 1.00	> 5.37 *
	2 x 1.0 ml (10 ⁻¹)	0	0	< 1	< 1		
0.1 %	2 x 1.0 ml (10 ⁰)	> 330	> 330	> 330	> 330		
	2 x 1.0 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 4.52	< 1.85

* questionable / inconsistent result in the remaining context; potential technical mistake. But also see our report 201901.V1 dated September 30, 2020, for confirmation of efficacy at 2 %, too.

Validation and controls:

Validation - Suspension (N _{VO})		Experimental condition control (A)		Neutralizer control (B)		Method validation (C); Product concentration: 2.0 %	
cfu /plate	\bar{x}	cfu /plate	\bar{x}	cfu /plate	\bar{x}	cfu /plate	\bar{x}
V _{c1}	55	V _{c1}	98	V _{c1}	41	V _{c1}	1
V _{c2}	52	V _{c2}	38	V _{c2}	34	V _{c2}	38
30 ≤ \bar{x} of N _{VO} ≤ 160?		\bar{x} of A is ≥ 0.5 * \bar{x} of N _{VO} ?		\bar{x} of B is ≥ 0.0005 * \bar{x} of N _{VO} ?		\bar{x} of C is ≥ 0.5 * \bar{x} of N _{VO} ?	
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input checked="" type="checkbox"/> yes <input type="checkbox"/> no		<input type="checkbox"/> yes <input checked="" type="checkbox"/> no	

Table 1.2: Results of the quantitative suspension test according to EN 17126 (2018) for the reference control with peracetic acid

Date: October 21, 2020 **Order number:** -
Product: Lerasept Spezial (contains 5% PAA) **Sample number(s):** -
Test organism: *C. difficile* (Spores) **Batch number(s):** 11885895
Interfering substance: none
Incubation temperature: 36 ± 1 °C **Neutralizer:** LX
Test suspension (N₀): $4.55 \cdot 10^5$ cfu/ml (5.63 log) **Incubation time:** 24 h - 48 h
Validation Suspension (N_v): $4.85 \cdot 10^2$ cfu/ml (2.69 log) **Test temperature:** 20 ± 1 °C

concentration	dilution	Contact time: 15 min					
		cfu / plate	cfu / plate	V _{c1}	V _{c2}	log ₁₀ (x)	RF
0.01 %	2 x 1.0 ml (10 ⁰)	> 330	> 330	> 330	> 330		
	2 x 1.0 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 4.52	< 1.14

Validation and controls:

Validation - Suspension (N _{vo})			Experimental condition control (A)			Neutralizer control (B)			Method validation (C); Product concentration: 0.01 %		
	cfu /plate	\bar{x}		cfu /plate	\bar{x}		cfu /plate	\bar{x}		cfu /plate	\bar{x}
V _{c1}	52	48.5	V _{c1}	30	34	V _{c1}	19	25	V _{c1}	4	22
V _{c2}	45		V _{c2}	38		V _{c2}	31		V _{c2}	40	
30 ≤ \bar{x} of N _{vo} ≤ 160?			\bar{x} of A is ≥ 0.5 * \bar{x} of N _{vo} ?			\bar{x} of B is ≥ 0.0005 * \bar{x} of N _{vo} ?			\bar{x} of C is ≥ 0.5 * \bar{x} of N _{vo} ?		
<div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>			<div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>			<div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>			<div><input type="checkbox"/> yes <input checked="" type="checkbox"/> X no</div>		

Table 2.1: Results of the quantitative suspension test according to EN 17126 (2018)

Date:	October 20, 2020	Order number:	A19-1020
Product:	Stabimed ultra	Sample number(s):	P 197156
Test organism:	<i>B. subtilis</i> (Spores)	Batch number(s):	1903BH0014
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	Neutralizer:	XLIV
Test suspension (N₀):	3.95*10 ⁷ cfu/ml (7.60 log)	Incubation time:	24 - 48 h
Validation Suspension (N_v):	8.85*10 ² cfu/ml (2.95 log)	Test temperature:	20 ± 1 °C

contact time: 5 min									
concentration	dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V _{c1}	V _{c2}	log ₁₀ Na	log ₁₀ R
2 %	4 x 0.5 ml (10 ⁰)	0	1	1	2	1	3	1.30	5.30
	4 x 0.5 ml (10 ⁻¹)	0	0	0	0	< 1	< 1		
1 %	4 x 0.5 ml (10 ⁰)	77	71	75	74	148	149	3.24	3.36
	4 x 0.5 ml (10 ⁻¹)	23	23	19	21	46	40		
0.1 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	320	> 330	> 330	> 330	650	> 660	> 4.82	< 1.78

contact time: 10 min									
concentration	dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V _{c1}	V _{c2}	log ₁₀ Na	log ₁₀ R
2 %	4 x 0.5 ml (10 ⁰)	2	0	1	1	2	2	1.30	5.30
	4 x 0.5 ml (10 ⁻¹)	0	0	0	0	< 1	< 1		
1 %	4 x 0.5 ml (10 ⁰)	1	2	2	1	3	3	1.48	5.12
	4 x 0.5 ml (10 ⁻¹)	0	0	0	0	< 1	< 1		
0.1 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 1.78

Validation and controls:

Validation - Suspension (N _{Vo})					Experimental condition control (A)					Neutralizer control (B)					Method validation (C); Product concentration: 2 %				
	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}	40	47	87	88.5	V _{c1}	99	51	150	148	V _{c1}	38	49	87	85.5	V _{c1}	28	32	60	62.5
V _{c2}	44	46	90		V _{c2}	77	69	146		V _{c2}	45	39	84		V _{c2}	34	31	65	
30 ≤ \bar{x} of N _{Vo} ≤ 160?					\bar{x} of A is ≥ 0.5 * \bar{x} of N _{Vo} ?					\bar{x} of B is ≥ 0.0005 * \bar{x} of N _{Vo} ?					\bar{x} of C is ≥ 0.5 * \bar{x} of N _{Vo} ?				
<div><div>X</div>yes<div> </div>no</div>					<div><div>X</div>yes<div> </div>no</div>					<div><div>X</div>yes<div> </div>no</div>					<div><div>X</div>yes<div> </div>no</div>				

Table 2.2: Results of the quantitative suspension test according to EN 17126 (2018) for the reference control with peracetic acid

Date: October 20, 2020
Product: Lerasept Spezial
Test organism: *B. subtilis* (Spores)
Interfering substance: none
Incubation temperature: 36 ± 1 °C
Test suspension (N_0): $7.58 \cdot 10^7$ cfu/ml (7.58 log)
Validation Suspension (N_V): $7.05 \cdot 10^2$ cfu/ml (2.85 log)
Order number: -
Sample number(s): -
Batch number(s): 11885895
Neutralizer: XLIV
Incubation time: 24 h - 48 h
Test temperature: 20 ± 1 °C

concentration	dilution	Contact time: 30 min							
		cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V _{c1}	V _{c2}	log ₁₀ (x)	RF
0.001 %	1.0 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	1.0 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 1.76

Validation and controls:

Validation - Suspension (N _{Vo})					Experimental condition control (A)					Neutralizer control (B)					Method validation (C); Product concentration: 0.001 %				
	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}	34	33	67	70.5	V _{c1}	52	36	88	85.5	V _{c1}	25	40	65	66	V _{c1}	40	39	79	78.5
V _{c2}	38	36	74		V _{c2}	44	39	83		V _{c2}	30	37	67		V _{c2}	42	36	78	
30 ≤ \bar{x} of N _{Vo} ≤ 160?					\bar{x} of A is ≥ 0.5 * \bar{x} of N _{Vo} ?					\bar{x} of B is ≥ 0.0005 * \bar{x} of N _{Vo} ?					\bar{x} of C is ≥ 0.5 * \bar{x} of N _{Vo} ?				
<div><div>X</div>yes<div></div>no</div>					<div><div>X</div>yes<div></div>no</div>					<div><div>X</div>yes<div></div>no</div>					<div><div>X</div>yes<div></div>no</div>				

Table 3.1.1: Results of the quantitative suspension test according to EN 17126 (2018)

Date: October 21, 2020 **Order number:** A19-1020
Product: Stabimed ultra **Sample number(s):** P 197156
Test organism: *B. cereus* (Spores) **Batch number(s):** 1903BH0014
Interfering substance: 0.3 % albumin + 0.3 % sheep erythrocytes
Incubation temperature: 36 ± 1 °C **Neutralizer:** XLIV
Test suspension (N₀): 9.30*10⁷ cfu/ml (7.97 log) * **Incubation time:** 24 - 48 h
Validation Suspension (N_v): 1.47*10³ cfu/ml (3.17 log) **Test temperature:** 20 ± 1 °C

contact time: 5 min									
concentration	dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V _{c1}	V _{c2}	log ₁₀ Na	log ₁₀ R
2 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 2.15 *
1 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	154	120	134	147	274	281	4.44	2.53
0.1 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 2.15

contact time: 10 min									
concentration	dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V _{c1}	V _{c2}	log ₁₀ Na	log ₁₀ R
2 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 2.15 *
1 %	4 x 0.5 ml (10 ⁰)	9	5	8	6	14	14	2.63	4.34 *
	4 x 0.5 ml (10 ⁻¹)	22	15	11	17	37	28		
0.1 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 2.15

* questionable / inconsistent results in the remaining context; potential technical mistake, but possibly having to do with N₀ exceeding requirements, too. See table 3.2.1 for verification.

Validation and controls:

Validation - Suspension (N _{Vo})					Experimental condition control (A)				Neutralizer control (B)					Method validation (C); Product concentration: 2 %					
	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}	62	73	135	146.	V _{c1}	129	140	269	271.	V _{c1}	115	104	219	219.5	V _{c1}	111	130	241	243
V _{c2}	88	70	158	5	V _{c2}	134	140	274	5	V _{c2}	109	111	220		V _{c2}	124	121	245	
30 ≤ \bar{x} of N _{Vo} ≤ 160?					\bar{x} of A is ≥ 0.5 * \bar{x} of N _{Vo} ?					\bar{x} of B is ≥ 0.0005 * \bar{x} of N _{Vo} ?					\bar{x} of C is ≥ 0.5 * \bar{x} of N _{Vo} ?				
<div><div>X</div><div>yes</div><div></div><div>no</div></div>					<div><div>X</div><div>yes</div><div></div><div>no</div></div>					<div><div>X</div><div>yes</div><div></div><div>no</div></div>					<div><div>X</div><div>yes</div><div></div><div>no</div></div>				

Table 3.1.2: Results of the quantitative suspension test according to EN 17126 (2018) for the reference control with peracetic acid

Date: October 21, 2020 **Order number:** -
Product: Lerasept Spezial **Sample number(s):** -
Test organism: *B. cereus* (Spores) **Batch number(s):** 11885895
Interfering substance: none
Incubation temperature: 36 ± 1 °C **Neutralizer:** XLIV
Test suspension (N_0): $1.01 \cdot 10^7$ cfu/ml (7.00 log) **Incubation time:** 24 h - 48 h
Validation Suspension (N_V): $1.62 \cdot 10^3$ cfu/ml (3.21 log) **Test temperature:** 20 ± 1 °C

concentration	dilution	Contact time: 30 min							
		cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	$\log_{10}(x)$	RF
0.05 %	1.0 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660		
	1.0 ml (10^{-1})	≥ 330	≥ 330	≥ 330	≥ 330	≥ 660	≥ 660	> 4.82	< 1.18

Validation and controls:

Validation - Suspension (N _{Vo})					Experimental condition control (A)					Neutralizer control (B)					Method validation (C); Product concentration: 0.05 %				
	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}	86	76	162	162	V _{c1}	94	87	181	180	V _{c1}	96	83	179	179	V _{c1}	63	80	143	147
V _{c2}	79	83	162		V _{c2}	91	88	179		V _{c2}	92	87	179		V _{c2}	74	77	151	
30 ≤ \bar{x} of N _{Vo} ≤ 160? <div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>					\bar{x} of A is ≥ 0.5 * \bar{x} of N _{Vo} ? <div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>					\bar{x} of B is ≥ 0.0005 * \bar{x} of N _{Vo} ? <div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>					\bar{x} of C is ≥ 0.5 * \bar{x} of N _{Vo} ? <div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>				

Table 3.2.1: Results of the quantitative suspension test according to EN 17126 (2018)

Date: November 06, 2020
Product: Stabimed ultra
Test organism: *B. cereus* (Spores)
Interfering substance: 0.3 % albumin + 0.3 % sheep erythrocytes
Incubation temperature: 36 ± 1 °C
Test suspension (N₀): 1.07*10⁷ cfu/ml (7.03 log) *
Validation Suspension (N_V): 1.60*10² cfu/ml (2.20 log)
Order number: A19-1020
Sample number(s): P 197156
Batch number(s): 1903BH0014
Neutralizer: LX
Incubation time: 24 - 48 h
Test temperature: 20 ± 1 °C

* not meeting the minimal requirements of 7.18 log

contact time: 10 min									
concentration	dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V _{c1}	V _{c2}	log ₁₀ Na	log ₁₀ R
2 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 1.21
1 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 5.33	< 0.69
0.1 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 1.21

contact time: 30 min									
concentration	dilution	cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V _{c1}	V _{c2}	log ₁₀ Na	log ₁₀ R
2 %	4 x 0.5 ml (10 ⁰)	35	40	39	37	75	76	2.88	3.15
	4 x 0.5 ml (10 ⁻¹)	4	5	5	4	9	9		
1 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 1.21
0.1 %	4 x 0.5 ml (10 ⁰)	> 330	> 330	> 330	> 330	> 660	> 660		
	4 x 0.5 ml (10 ⁻¹)	> 330	> 330	> 330	> 330	> 660	> 660	> 4.82	< 1.21

Validation and controls:

Validation - Suspension (N _{Vo})					Experimental condition control (A)					Neutralizer control (B)					Method validation (C); Product concentration: 2 %				
	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}	11	3	14	16	V _{c1}	9	7	16	16.5	V _{c1}	9	10	19	18	V _{c1}	2	5	7	9
V _{c2}	9	9	18		V _{c2}	8	9	17		V _{c2}	9	8	17		V _{c2}	6	5	11	
30 ≤ \bar{x} of N _{Vo} ≤ 160?					\bar{x} of A is ≥ 0.5 * \bar{x} of N _{Vo} ?					\bar{x} of B is ≥ 0.0005 * \bar{x} of N _{Vo} ?					\bar{x} of C is ≥ 0.5 * \bar{x} of N _{Vo} ?				
<div><div>(X)</div>yes * <div></div>no</div>					<div><div>X</div>yes <div></div>no</div>					<div><div>X</div>yes <div></div>no</div>					<div><div>X</div>yes <div></div>no</div>				

* Ok, with regard to decreased N₀

Table 3.2.2: Results of the quantitative suspension test according to EN 17126 (2018) for the reference control with peracetic acid

Date: November 06, 2020
Product: Lerasept Spezial
Test organism: *B. cereus* (Spores)
Interfering substance: none
Incubation temperature: 36 ± 1 °C
Test suspension (N_0): $1.64 \cdot 10^6$ cfu/ml (6.21 log)
Validation Suspension (N_V): $1.65 \cdot 10^2$ cfu/ml (2.22 log)

Order number: -
Sample number(s): -
Batch number(s): 11885895
Neutralizer: LX
Incubation time: 24 h - 48 h
Test temperature: 20 ± 1 °C

concentration	dilution	Contact time: 30 min							
		cfu / plate 1	cfu / plate 2	cfu / plate 3	cfu / plate 4	V_{c1}	V_{c2}	$\log_{10}(x)$	RF
0.05 %	1.0 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660		
	1.0 ml (10^{-1})	230	204	210	212	434	422	4.63	0.58

Validation and controls:

Validation - Suspension (N _{Vo})					Experimental condition control (A)					Neutralizer control (B)					Method validation (C); Product concentration: 0.05 %				
	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}	9	8	17	16.5	V _{c1}	9	8	17	16.5	V _{c1}	7	7	14	14	V _{c1}	13	6	19	18
V _{c2}	7	9	16		V _{c2}	7	9	16		V _{c2}	8	6	14		V _{c2}	9	8	17	
30 ≤ \bar{x} of N _{Vo} ≤ 160?					\bar{x} of A is ≥ 0.5 * \bar{x} of N _{Vo} ?					\bar{x} of B is ≥ 0.0005 * \bar{x} of N _{Vo} ?					\bar{x} of C is ≥ 0.5 * \bar{x} of N _{Vo} ?				
<div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>					<div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>					<div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>					<div><input checked="" type="checkbox"/> X yes <input type="checkbox"/> no</div>				

Legend:

1	=	as provided by the sponsor / manufacturer (unless stated otherwise)
2	=	According to EN 17025, § 7.8.2.1 I. we are required to state that the results presented in this report relate to the item(s) tested only. That is quite obvious in the first place. anyway. And it is also ridiculous. of course. with regard to these tests and reports typically being used for a product's generalized efficacy evaluation and market authorization. Which. as such. is then fully acceptable by all other relevant authorizing and responsible parties (other than EN 17025). too. Which therefore is why this disclaimer is only to be found at the very back end of this report.
MW	=	average value
x	=	average value
\bar{x}	=	average value
RF	=	reduction factor
< 14	=	not supposed to be counted more precisely
> 165	=	not countable
> 330	=	not countable
> 660	=	not countable
n.a.	=	not analysable
n.d.	=	not determined
n.p.	=	not provided
Co 1	=	Control 01
Co 2	=	Control 02
Co 3	=	Control 03
WFI	=	Water for injections
WSH	=	Water of standardized hardness