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WALTHER-RATHENAU-STRASSE 49 A
17489 GREIFSWALD
DEUTSCHLAND - GERMANY

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

Büttner GmbH & Co. KG

Oberdorf 52

09518 Großrückerswalde

Deutschland / Germany

CUSTOMER NUMBER
2465

DATE
August 03, 2023

REPORT 231524.V1

BÜMEDES WIPES + TERRALIN® PROTECT

BACTERICIDAL AND YEASTICIDAL ACTIVITY

- 28 DAYS STANDING TIME -

4-FIELD-TEST - EN 16615 (2015)

Purpose

The bactericidal and yeasticidal activity of the surface disinfectant **terralin® protect (**Schülke & Mayr GmbH, Norderstedt, Germany) in combination with the **bümedes Wipes** (Büttner GmbH & Co. KG, Großrückerswalde, Germany) should be evaluated in tests simulating everyday use conditions in accordance with the **EN 16615 (2015)** after a storage time of 28 days (= $\mathbf{t}_{28\,d}$).

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HANDELSREGISTER: AMTSGERICHT STRALSUND HRB 5168

Test description

Order number:	A23-0786	
Sponsor:	Büttner GmbH & Co. KG, Großrückerswalde, Germany	
Product name:	**terralin® protect**	**bümedes Wipes**
Manufacturer	Schülke & Mayr GmbH	Büttner GmbH & Co. KG
Batch number:	1590604	Item number 1290
Sample number:	P 233587	P 233585
Date of manufacture:	09 / 2022	not provided
Best before:	08/2025	not provided
Odour:	fresh, product specific	/
Appearance:	clear, colourless, liquid	/
Appearance of dilution:	clear, colourless liquid	/
pH – value (pH-meter):	0.5 %: 8.10 (squeezed out of wipes) WSH: 6.83	/

Storage condition: room temperature

Product dilution: water of standardized hardness

Test date: July 31, 2023 – August 02, 2023 (date of soaking July 03, 2023)

Basis: **EN 16615 (2015)**: Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2)

Test organisms:

Staphylococcus aureus	ATCC 6538
Enterococcus hirae	ATCC 10541
Pseudomonas aeruginosa	ATCC 15442
Candida albicans	ATCC 10231

Active ingredients in 100 g[1]:

22 g alkyl (C12-16) dimethylbenzylammonium chloride
17 g 2-phenoxyethanol
0.9 g amines, N-C12-14 (even)alkyltrimethylenedi reaction products with chloroacetic acid

Test solution: 0.5 %

Wipe characterization: 100 % PET, 29 x 30 cm (folded to 14.5 cm), soaking volume 2000 – 2500 ml, 90 wipes / roll

Soaking volume: 2500 ml (residual quantity in the dispenser bucket 28 days after soaking: 374 g)

Bucket / dispenser system: dispenser bucket 3.4 l volume with star-shaped dispenser opening

Dwell time: 28 days ($t_{28\,d}$)

Carrier type: PVC (PUR-coated)

Neutralizer: 4.0 % Tween 80 + 3.0 % Saponin + 0.4 % Lecithin + 0.25 % SDS (Neutralizer XXIV)

Interfering substance: 0.3 % albumin + 0.3 % sheep erythrocytes (dirty conditions)

Test temperature: 20 ± 2 °C

Incubation temperature: 36 ± 1 °C / 30 ± 1 °C for *C. albicans*

Test Method

Surface disinfection, quantitative 4-Field carrier test according to EN 16615 (2015)

Testing is based on the **EN 16615 (2015)**: Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test) - Test method and requirements (phase 2, step 2). Validation and control procedures are therefore carried out in accordance with that standard. As indicated above PVC flooring (50 x 20 cm) is used as carrier surface. 4 Test fields (5 x 5 cm) are marked on the roll axis with 5 cm space in between. For the test, 1 ml of the 10fold concentrated stock solution of the interfering substance is mixed with 9 ml of the test organism suspension. 50 µl of that mixture are evenly distributed on the first of the 4 test fields, resulting in a contamination of 7.83 log – 8.35 log cfu on that test area. When the contamination is visually dry, but no longer than after 60 min, the test procedure continues with the application of the test- or the reference-product, respectively. For the standard reference test (Control N_w), the EN 16615 standard wipe (17.5 x 28 cm; 55 % Pulp + 45 % PET; "Tork Premium Spezial Tücher", Art.-Nr. 190491) was folded three times along the short axis and soaked in 16 ml of WSH in a closed Petri dish (ca. 8 cm in diameter) for 30 min. The wipe is then unfolded twice and fixed at the unitary weight used for the simulation of a defined wiping pressure. That construct is then placed on the carrier and moved across the 4 test fields without extra pressure, starting at the edge near the contaminated field 1, turning around at the other side and coming back to the starting point, all in about 2 s. With that being finished, the contact time starts.

In analogy to that, but with regard to the purpose of this study, the disinfectant **terralin® protect** is used in combination with the **bümedes Wipes** instead of the **EN 16615** standard wipe. As requested by the customer and simulating an original container of pre-soaked wipes, a roll of **bümedes Wipes** was to be soaked with **2.5 l** of **0.5 % terralin® protect** in the bemüdes dispenser bucket, pouring the liquid helically from the inside to the outside. The thereby prepared pre-soaked wipe systems were subjected to EN 16615 testing after having been stored for a service life / lifetime of 28 d (≙ $t_{28\,d}$). Wipes were taken from the box and used for the test immediately after that.

The contact time was set to 60 min. Each wipe was used folded twice in order to still enable complete coverage of the wiping surface of the unitary weight.

The weight of the wipes is recorded before and after the application. In accordance with **EN 16615 (2015)**, testing is performed with one carrier for each test strain and concentration.

At the end of the contact time, test areas are immediately sampled for remaining viable test organisms following the quantitative swabbing technique described by **EN 16615 (2015)**: The entire test surface is sampled once with a swab stick pre-moistened with neutralizer suitable for the disinfectant used. The swab stick is then vigorously agitated in a test tube containing 5 ml of the neutralizer, thereby releasing any test organisms sampled. It is then re-used for another sampling, after which the lower half is broken off and retained in the test tube with the neutralizer. Using a new and dry swab stick, the test surface is sampled once again. Both swab sticks are agitated in the same test tube in order to release recovered test organisms to the neutralizer solution. After a neutralization time of 5 min, aliquots of that solution or its dilutions are plated to nutrient plates. 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 the **EN 16615 (2015)** requirements. Detailed results are presented in tables 1 – 4.

Results and conclusion [2]

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

According to the **EN 16615 (2015)** requirements, the batch 1590604 of **terralin® protect** in combination with the **bümedes Wipes**, when applied at a product concentration / contact time- relation of at least **0.5% / 60 min** with a soaking volume of 2.5 l in the above mentioned dispenser system, **possesess** bactericidal efficacy (log_{10} RF ≥ 5 on field 1; Ø < 50 cfu on fields 2 – 4) at 20 ± 2°C under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) for reference strains *S. aureus*, *E. hirae* and *P. aeruginosa* **for service life / lifetime of up to 28 days** (Tab. 1 – 3).

According to the **EN 16615 (2015)** requirements, the batch 1590604 of **terralin® protect** in combination with the **bümedes Wipes**, when applied at a product concentration / contact time- relation of at least **0.5% / 60 min** with a soaking volume of 2.5 l in the above mentioned dispenser system, **possesess** yeasticidal efficacy (log_{10} RF ≥ 4, on field 1; Ø < 50 cfu on fields 2 – 4) at 20 ± 2°C under dirty conditions (0.3 % albumin + 0.3 % sheep erythrocytes) for reference strain *C. albicans* **for service life / lifetime of up to 28 days** (Tab. 4).

Results are considered validated in accordance with EN 16615 (2015) requirements.

Greifswald, August 03, 2023

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- deputy technical manager -

Table 1: **Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)**

Date:	August 02, 2023	**Order number:**	A23-0786
Product:	**terralin® protect**	**Sample number:**	P 233587, -85
Wipe:	**bümedes Wipes**	**Batch number:**	1590604 /-
Test organism:	*S. aureus*	**Neutralizer:**	XXIV
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	**Incubation time:**	48 h
Test suspension (N):	$3.04*10^9$ cfu/ml (9.48 log)	**Test temperature:**	20 ± 2 °C
Test suspension / carrier:	$1.37*10^8$ cfu (8.14 log)	**Drying time:**	26 min
Validation suspension (N_V):	$1.16*10^3$ cfu (3.06 log)	**Relative humidity:**	60.00 %

Test design: 1st run of testing; carrier 1 - $t_{28\,d}$ (= 28 d lifetime); soaking volume: 2.5 l

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	**7.89**
	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	1	0	0	1	0		
Water-Control (N_W)	4x0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-1})	> 330	> 330	> 330	> 330	> 660	> 660		
Field 1	4x0.5 ml (10^{-2})	212	197	199	218	409	417	5.31	**2.57**
Field 2	4x0.5 ml (10^0)	329	300	> 330	327	629	657		
Field 3	4x0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660	∅ F2-F4 ≥ 10 ?	**OK**
Field 4	4x0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660		
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})	83	90	89	87	173	176	**7.94**	**-0.06**
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})	72	80	79	76	152	155	**7.89**	

	Mass in g:		
	Before test:	**After test:**	**Difference**
Product:	22.5	21.6	**0.9**
N_W:	18.5	17.6	**0.9**

Validation and Controls:

Validation - Suspension (N_{VO})					Experimental condition control (A)					Neutralizer control (B)					Method validation Product concentration: 0.5 %				
	cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$
V_{c1}	55	60	115	**115.5**	V_{c1}	63	68	131	**129**	V_{c1}	39	44	83	**85.5**	V_{c1}	66	50	116	**112.5**
V_{c2}	59	57	116		V_{c2}	62	65	127		V_{c2}	45	43	88		V_{c2}	52	57	109	
$30 \leq \bar{x}$ of $N_{VO} \leq 160$?					$\bar{x}$ of A is $\geq 0.5^* \bar{x}$ of N_{VO}?					$\bar{x}$ of B is $\geq 0.5^* \bar{x}$ of N_{VO}?					$\bar{x}$ of C is $\geq 0.5^* \bar{x}$ of N_{VO}?				
[X] Yes		[ ] No			[X] Yes		[ ] No			[X] Yes		[ ] No			[X] Yes		[ ] No		

Table 2: **Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)**

Date:	August 02, 2023	**Order number:**	A23-0786
Product:	**terralin® protect**	**Sample number:**	P 233587, -85
Wipe:	**bümedes Wipes**	**Batch number:**	1590604 /-
Test organism:	*E. hirae*	**Neutralizer:**	XXIV
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	**Incubation time:**	48 h
Test suspension (N):	$4.65*10^9$ cfu/ml (9.67 log)	**Test temperature:**	20 ± 2 °C
Test suspension / carrier:	$2.09*10^8$ cfu (8.32 log)	**Drying time:**	23 min
Validation suspension (N_V):	$1.16*10^3$ cfu (3.06 log)	**Relative humidity:**	60.00 %

Test design: 1st run of testing; carrier 1 - $t_{28\,d}$ (= 28 d lifetime); soaking volume: **2.5 l**

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	**7.81**
	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	1	0	0	1	0	∅ F2-F4 ≤ 50 ?	**OK**
Field 4	4x0.5 ml (10^0)	0	0	0	0	0	0		
Water-Control (N_W)	4x0.5 ml (10^0)	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-1})	125	119	120	123	244	243	4.11	**3.70**
Field 1	4x0.5 ml (10^{-2})	25	14	23	21	39	44		
Field 2	4x0.5 ml (10^0)	158	175	163	167	333	330		
Field 3	4x0.5 ml (10^0)	115	118	117	123	233	240	∅ F2-F4 ≥ 10 ?	**OK**
Field 4	4x0.5 ml (10^0)	93	96	97	99	189	196		
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})	91	83	90	87	174	177	**7.94**	**-0.13**
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})	71	59	63	65	130	128	**7.81**	

	Mass in g:		
	Before test:	**After test:**	**Difference**
Product:	22.6	22	**0.6**
N_W:	18.4	17.6	**0.8**

Validation and Controls:

Validation – Suspension (N_{VO})					**Experimental condition control (A)**					**Neutralizer control (B)**					**Method validation** Product concentration: 0.5 %				
	cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$
V_{c1}	52	63	115	**116**	V_{c1}	50	55	105	**107.5**	V_{c1}	77	58	135	**123.5**	V_{c1}	93	95	188	**184**
V_{c2}	60	57	117		V_{c2}	57	53	110		V_{c2}	53	59	112		V_{c2}	89	91	180	
$30 \leq \bar{x}$ of $N_{VO} \leq 160$?					$\bar{x}$ of A is $\geq 0.5 * \bar{x}$ of N_{VO}?					$\bar{x}$ of B is $\geq 0.5 * \bar{x}$ of N_{VO}?					$\bar{x}$ of C is $\geq 0.5 * \bar{x}$ of N_{VO}?				
X Yes		No			X Yes		No			X Yes		No			X Yes		No		

Table 3: **Surface disinfection - results of the quantitative carrier test with mechanical action - 4-Field Test – according to EN 16615 (2015)**

Date:	August 01, 2023	**Order number:**	A23-0786
Product:	**terralin® protect**	**Sample number:**	P 233587, -85
Wipe:	**bümedes Wipes +**	**Batch number:**	1590604 /-
Test organism:	*P. aeruginosa*	**Neutralizer:**	XXIV
Interfering substance:	0.3 % albumin + 0.3 % sheep erythrocytes		
Incubation temperature:	36 ± 1 °C	**Incubation time:**	24 h - 48 h
Test suspension (N):	$3.12*10^9$ cfu/ml (9.49 log)	**Test temperature:**	20 ± 2 °C
Test suspension / carrier:	$1.40*10^8$ cfu (8.15 log)	**Drying time:**	25 min
Validation suspension (N_V):	$8.85*10^2$ cfu (2.95 log)	**Relative humidity:**	60.00 %

Test design: 1st run of testing; carrier 1 - $t_{28\,d}$ (= 28 d lifetime); soaking volume: 2.5 l

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	**7.21**
	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		
Water-Control (N_W) Field 1	4x0.5 ml (10^0)	11	13	10	11	24	21	2.05	**5.16**
	4x0.5 ml (10^{-1})	2	1	2	1	< 14	< 14		
	4x0.5 ml (10^{-2})	0	0	0	0	< 14	< 14		
Field 2	4x0.5 ml (10^0)	0	4	3	2	4	5		
Field 3	4x0.5 ml (10^0)	6	2	5	3	8	8	∅ F2-F4 ≥ 10 ?	**OK**
Field 4	4x0.5 ml (10^0)	5	7	6	6	12	12		
Control (T_0)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	228	145	227	220	373	447	**7.32**	**-0.10**
	4x0.5 ml (10^{-5})	19	26	24	23	45	47		
Control (T_t)	4x0.5 ml (10^{-3})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-4})	162	167	169	165	329	334	**7.21**	
	4x0.5 ml (10^{-5})	13	16	12	15	29	27		

	Mass in g:		
	Before test:	**After test:**	**Difference**
Product:	22.8	21.8	**1**
N_W:	18.8	17.7	**1.1**

Validation and Controls:

Validation - Suspension (N_{VO})					Experimental condition control (A)					Neutralizer control (B)					Method validation Product concentration: 0.5 %				
	cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$
V_{c1}	48	42	90	**88.5**	V_{c1}	35	42	77	**79**	V_{c1}	46	49	95	**91.5**	V_{c1}	27	35	62	**65.5**
V_{c2}	44	43	87		V_{c2}	41	40	81		V_{c2}	45	43	88		V_{c2}	37	32	69	
$30 \leq \bar{x}$ of $N_{VO} \leq 160$?					$\bar{x}$ of A is $\geq 0.5 * \bar{x}$ of N_{VO}?					$\bar{x}$ of B is $\geq 0.5 * \bar{x}$ of N_{VO}?					$\bar{x}$ of C is $\geq 0.5 * \bar{x}$ of N_{VO}?				
X Yes			No		X Yes			No		X Yes			No		X Yes			No	

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

Date:	August 02, 2023	**Order number:**	A23-0786
Product:	**terralin® protect**	**Sample number:**	P 233587, -85
Wipe:	**bümedes Wipes**	**Batch number:**	1590604 /-
Test organism:	*C. albicans*	**Neutralizer:**	XXIV
Interfering substance:	0.3 % albumin + 0.3 sheep erythrocytes		
Incubation temperature:	30 ± 1 °C	**Incubation time:**	48 h - 72 h
Test suspension (N):	$6.20*10^8$ cfu/ml (8.79 log) *	**Test temperature:**	20 ± 2 °C
Test suspension / carrier:	$2.79*10^7$ cfu (7.45 log)	**Drying time:**	18 min
Validation suspension (N_V):	$1.52*10^3$ cfu (3.18 log)	**Relative humidity:**	59.50 %

* slightly exceeding the required maximum of 8.70 log of N_0, but considered an acceptable deviation with regard to yeasticidal efficacy being achieved at 0.5 % / 60 min and controls are within the specified range

Test design: 1st run of testing; carrier 1 - $t_{28\,d}$ (= 28 d lifetime); soaking volume: 2.5 l

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	**6.24**
	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		
Water-Control (N_W) Field 1	4x0.5 ml (10^0)	6	3	5	3	9	8	1.63	**4.61**
	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)	4	1	2	3	5	5		
Field 3	4x0.5 ml (10^0)	4	9	6	7	13	13	∅ F2-F4 ≥ 10 ?	**OK**
Field 4	4x0.5 ml (10^0)	7	2	5	6	9	11		
Control (T_0)	4x0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-3})	355	294	312	327	649	639	**6.52**	**-0.28**
	4x0.5 ml (10^{-4})	47	38	39	39	85	78		
Control (T_t)	4x0.5 ml (10^{-2})	> 330	> 330	> 330	> 330	> 660	> 660		
	4x0.5 ml (10^{-3})	176	161	169	173	337	342	**6.24**	
	4x0.5 ml (10^{-4})	21	22	20	17	43	37		

	Mass in g:		
	Before test:	**After test:**	**Difference**
Product:	22.1	21.3	**0.8**
N_W:	18.3	17.3	**1**

Validation and Controls:

Validation - Suspension (N_{VO})					Experimental condition control (A)					Neutralizer control (B)					Method validation Product concentration: 0.5 %				
	cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$		cfu / plate1 & 2		V_c	$\bar{x}$
V_{c1}	78	73	151	**151.5**	V_{c1}	67	80	147	**149.5**	V_{c1}	79	68	147	**150**	V_{c1}	85	76	161	**161.5**
V_{c2}	75	77	152		V_{c2}	77	75	152		V_{c2}	75	78	153		V_{c2}	79	83	162	
$30 \le \bar{x}$ of $N_{VO} \le 160$?					$\bar{x}$ of A is $\ge 0.5 * \bar{x}$ of N_{VO}?					$\bar{x}$ of B is $\ge 0.5 * \bar{x}$ of N_{VO}?					$\bar{x}$ of C is $\ge 0.5 * \bar{x}$ of N_{VO}?				
X Yes			No		X Yes			No		X Yes			No		X Yes			No	

Legend:

[1]	=	as provided by the sponsor / manufacturer (unless stated otherwise)
[2]	=	According to EN 17025. § 7.8.2.1 l, 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.
$\bar{x}$	=	average value
RF	=	reduction factor
> 330	=	not countable
> 660	=	not countable
n.a.	=	not applicable
n.d.	=	not determined
n.p.	=	not provided
WFI	=	Water for injections
WSH	=	water of standardized hardness