Nordic Tersus
Laboratory

Test report No. 161022sd

EVALUATION OF SPORICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS USED IN FOOD, INDUSTRIAL, DOMESTIC AND INSTITUTIONAL AREAS (EN 13704)

Name of the product: STERISEPT WIPES

Batch number: 14190822

Date of test report: 12.01.2023

Digitally signed by Moraru Grigore
Date: 2025.12.17 15:59:50 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Client, representative:
Chemi-Pharm Ltd.
Tänassilma tee 11
Tänassilma küla, Saku vald
Harjumaa 76406
ESTONIA

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Test report No. 161022sd

EVALUATION OF SPORICIDAL ACTIVITY OF CHEMICAL DISINFECTANTS USED IN FOOD, INDUSTRIAL, DOMESTIC AND INSTITUTIONAL AREAS (EN 13704)

Name of the product*:	**STERISEPT WIPES**
Batch number*:	14190822
Order number:	20099
Manufacturer*:	Chemi-Pharm Ltd.
Client, representative*:	Chemi-Pharm Ltd., Tänassilma tee 11, Tänassilma küla, Saku vald, 76406, ESTONIA, Siimu Rom, +37253604748
Date of delivery:	05.09.2022
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	At room temperature
Active substance – conc.*:	Didecyl-Dimethyl-Ammonium Chloride (DDAC) 3.45g/100g; N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine 0.45g/100g
Appearance of the product:	Transparent liquid
Test concentration:	Ready to use
Contact time:	15 min
Interfering substance:	3.0 g/l bovine albumin (dirty conditions)
Neutralizer:	-
Rinsing liquid:	Tryptone 1g/l, NaCl 9g/l
Test organisms:	*Clostridium difficile* NCTC 13366 *Clostridium sporogenes* ATCC 19404
Testing method:	**EVS-EN 13704:2018** **Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.**
Testing period:	17.10.2022 – 21.12.2022
Results:	Look appendix 1 - 2
Interpretation and conclusion:	Look appendix 3

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NORDIC TERSUS LABORATORY OÜ
BERNHARD

Allar Laaneleht
Chief specialist
Date of issue: 12.01.2023

* - *Data provided by the customer*

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TEST RESULTS (suspension test)

EVS-EN 13704:2018; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: Tryptone 1g/l, NaCl 9g/l;
Test organism: *Clostridium difficile* NCTC 13366;
Test temperature: +20± 1° C; Incubation temperature: +37 ± 1° C
Interfering substance: 3.0 g/L bovine albumin;
Nordic Tersus Laboratory LLC.;
Date of test: 14.12.2022
Responsible person: Kerda Treksler

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
30	30	30	103	40	71.5	104	90	97	15	18	16.5
30 ≤ $\bar{x}$ N_{vo} ≤160?yes X; no □			$\bar{x}$ A is ≥ 0.5 $\bar{x}$ N_{vo}?yes X;no □			$\bar{x}$ B is ≥ 0.5 $\bar{x}$ N_{vo}? yesX; no □			$\bar{x}$ C is ≥ 0.5 $\bar{x}$ N_{vo}? yes X;no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1.51 x 10^6; log$N$ = 6.17
N and N_0	10^{-4}	150	148	$N_0 = N/10$; logN_0 = 5.17
	10^{-5}	20	15	5.17 ≤ logN_0 ≤ 5.70; yesX; no □

Experimental results

Concentration of the product	Dilution step	V_{C1}	V_{C2}	Na (=$\bar{x}$*10)	lg Na	LgR	Contact time	Conditions
80.0%	-	<14	<14	<140	<2.15	>3.02	15 min	Dirty
50.0%	-	>165	>165	>1650	>3.22	<1.95	15 min	Dirty
10.0%	-	>165	>165	>1650	>3.22	<1.95	15 min	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 2

TEST RESULTS (suspension test)

EVS-EN 13704:2018; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: Tryptone 1g/l, NaCl 9g/l;
Test organism: *Clostridium sporogenes* ATCC 19404;
Test temperature: +20± 1° C; Incubation temperature: +37 ± 1° C
Interfering substance: 3.0 g/L bovine albumin;
Nordic Tersus Laboratory LLC.;
Date of test: 14.12.2022
Responsible person: Allar Laaneleht

Validation and controls

Dirty conditions

Validation suspension N_{vo}			Experimental conditions (A)			Filtration control (B)			Method validation (C)		
V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$	V_{C1}	V_{C2}	$\bar{x}$
74	81	77.5	42	49	45.5	53	37	45	63	55	59
30 ≤ $\bar{x}$ N_{vo} ≤160?yes X; no □			$\bar{x}$ A is ≥ 0.5 $\bar{x}$ N_{vo}?yes X;no □			$\bar{x}$ **B** is ≥ 0.5 $\bar{x}$ N_{vo}? yesX; no □			$\bar{x}$ **C** is ≥ 0.5 $\bar{x}$ N_{vo}? yes X;no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ = 1.63 x 10^6; log$N$ = 6.21 N_0 = N/10; logN_0 = 5.21 5.17 ≤ logN_0 ≤ 5.70; yesX; no □
N and N_0	10^{-4}	**180**	**148**	
	10^{-5}	**14**	**16**	

Experimental results

Concentration of the product	Dilution step	V_{C1}	V_{C2}	*Na* (=$\bar{x}$*10)	lg *Na*	Lg*R*	Contact time	Conditions
80.0%	-	14	16	150	2.18	3.03	15 min	Dirty
50.0%	-	>165	>165	>1650	>3.22	<1.99	15 min	Dirty
10.0%	-	>165	>165	>1650	>3.22	<1.99	15 min	Dirty

Explanations:

V_C = count per ml (one plate or more)
$\bar{x}$ = average of V_{C1} and V_{C2} (1. + 2. duplicate)
N = cfu/ml microbes in testsuspension
N_0 = cfu/ml at the start of the contact time (t=0)
N_{vo} = cfu/ml in the validation suspension (t=0)
Na = surviving microbes after the test
R = reduction factor (R= N_0/ *Na;* LogR=LogN_0 - Log *Na*)

Appendix 3

Interpretation:

The sample of ready to use surface disinfection product **STERISEPT WIPES** (batch no 14190822) was tested according to the test method EVS-EN 13704:2018. The test was performed at 20 °C ± 1 °C, under dirty conditions during the contact time of 15 min. The membrane filtration method was used for testing the product's effectiveness against the reference strains *Clostridium difficile* NCTC 13366 and *Clostridium sporogenes* ATCC 19404. Under dirty conditions the 80.0% solution of the tested product was effective against the reference strains within the contact time tested.

Conclusion:

The surviving count of the reference strain showed at least 3 lg reduction meaning that **according to EVS-EN 13704:2018 under dirty conditions the sample of the ready to use surface disinfection product STERISEPT WIPES is effective against *C.difficile* NCTC 13366 and *C. sporogenes* ATCC 19404 within 15 minutes.**

This is the end of the test report.

NORDIC TERSUS LABORATORY OÜ

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Allar Laaneleht
Chief specialist
Date of issue: 12.01.2023