


REVISION JUSTIFICATION	The present revision supersedes the previous report released on April 16 th , 2020 and it is issued in order to change the product name, as per Sponsor request.		
SPONSOR	CHIMIVER PANSERI S.p.A. VIA BERGAMO 1401 24030 PONTIDA (BG) ITALY		
TEST METHOD	EN 1276:2019 / UNI EN 1276:2019 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)		
TEST ITEM			
PRODUCT NAME	VELUREX MULTI GEN		
MATRIX OF THE PRODUCT	Detergent / Household product (Cleaning solution for all hard surfaces)		
BATCH N.	30-03-20	CODE	VMLG000X
MANUFACTURING DATE	Not provided	EXPIRY DATE	30-Mar-21
MANUFACTURER	Chimiver Panseri S.p.A.		
ACTIVE INGREDIENT	Not provided		
MATERIAL ITEM ALIQUOT	LV-MAT-IJE2-20-095-0C11:a		
PARCEL REGISTRATION N.	IP-LV-2020093-AJM	RECEIVING DATE	02-Apr-20
STORAGE CONDITIONS	Room Temperature (10-25°C)		
ANALYSIS STARTING DATE	08-Apr-20	ANALYSIS ENDING DATE	14-Apr-20
EXPERIMENTAL CONDITIONS			
NOTE	<p>According to the Reference Standard, a first bactericidal assay (started on 08-Apr-20 and ended on 10-Apr-20) has been performed by dilution-neutralization method. This neutralizer, as demonstrated in the dilution-neutralization validation method "C", resulted invalid for <i>Staphylococcus aureus</i>, <i>Pseudomonas aeruginosa</i> and <i>Escherichia coli</i> so two additional bactericidal assays have been performed only for these microorganisms: one assay by dilution-neutralization method (Neutralizer composition: Lecithin 3g/L, Polysorbate 80 30g/L, L-histidine 1g/L, Casein peptone 1 g/L, NaCl 4.3 g/L, KH₂PO₄ 3.6 g/L, Na₂HPO₄ 7.2 g/L, Distilled water to 1000 ml) and another one by the membrane-filtration method.</p> <p>Also this second neutralizer, as demonstrated in the dilution-neutralization validation method "C", resulted invalid for the tested microorganisms, so, according to the Reference Standard, the membrane-filtration method was applied in place of the dilution-neutralization method.</p>		
TEST TEMPERATURE	20°C ± 1°C		

CONCENTRATION	80% (Neat) – 50% – 25% in test			
PRODUCT APPEARANCE	The item dilutions have been prepared 1.25 times higher the final tested concentrations, using water for injection			
CONTACT TIME	5 minutes			
INTERFERING SUBSTANCE	Bovine serum albumin (BSA) solution with a final concentration of 3 g/L (simulating dirty conditions)			
INCUBATION TEMPERATURE	37°C ±1°C			
TEST MICROORGANISMS	<i>Staphylococcus aureus</i>	ATCC 6538		
	<i>Pseudomonas aeruginosa</i>	ATCC 15442		
	<i>Escherichia coli</i>	ATCC 10536		
	<i>Enterococcus hirae</i>	ATCC 10541		
INACTIVATION OF THE PRODUCT	Dilution- neutralization method - CEN neutralizer (for <i>E. hirae</i>): Lecithin 3 g Polysorbate 80 30 ml Sodium Thiosulfate 5 g L-histidine 1 g Saponin 30 g Tryptone-treated water (q. s.) to 1000 ml Membrane Filtration method - Rinsing fluid (for <i>S. aureus</i> , <i>P. aeruginosa</i> , <i>E. coli</i>): Casein peptone 1 g NaCL 8.5 ml Polysorbate 80 1 g Distilled water (q. s.) to 1000 ml			
RESULTS	Log Reductions at concentrations and contact time			
		80%	50%	25%
		5 minutes		
	<i>S.aureus</i> ATCC 6538	>5.39	>5.39	>5.39
	<i>P. aeruginosa</i> ATCC 15442	>5.54	>5.54	>5.54
	<i>E. coli</i> ATCC 10536	>5.42	>5.42	>5.42
	<i>E.hirae</i> ATCC 10541	>5.18	>5.18	>5.18
	See Addendum N.1			
VALIDITY CRITERIA	N: is between 1.5×10^8 and 5×10^8 (8.17 Log and 8.70 Log) N _v : is between 3.0×10^2 and 1.6×10^3 A, B, C: is equal to, or 0.05 times higher than N _v Control of weighted mean counts: the quotient is ≥ 5 and ≤ 15 where: N = count in cfu/ml of the bacterial suspension			

	<p>N_v = count in cfu/ml of the bacterial suspension in the preliminary assay</p> <p>A = count in cfu/ml of experimental conditions control</p> <p>B = count in cfu/ml neutraliser toxicity control/ filtration control</p> <p>C = count in cfu/ml neutraliser effectiveness/validation of membrane filtration method</p>
INTERPRETATION OF RESULTS	<p>The test item is considered bactericidal when a 5 decimal logarithm reduction is demonstrated under the test conditions for <i>general purpose disinfection</i>: contact time shall be in a range from 1 min to 60 min (from 1 min to 5 min at intervals of 1 min and from 5 min to 60 min at intervals of 5 min); test temperature shall be in a range from 4 °C to 60 °C, in clean or dirty conditions, when the test organisms are <i>Staphylococcus aureus</i>, <i>Pseudomonas aeruginosa</i>, <i>Escherichia coli</i>, <i>Enterococcus hirae</i> and <i>E. faecium</i> (only for temperatures $\geq 40^{\circ}\text{C}$). The recommended contact time for the use of the product is within the responsibility of the manufacturer.</p> <p>In case of specific use conditions for which other contact times, temperatures, test organisms and interfering substances are applied instead of or in addition to the standard ones, the test item shall demonstrate at least 5 Log reduction under the chosen test conditions.</p>
CONCLUSIONS	<p>CAUSES A REDUCTION >5 log at the test item concentration of 25% after 5 minutes of contact, in the adopted test conditions, using a bovine serum albumin solution at the final concentration of 3 g/L (simulating dirty conditions)</p> <p>It has not been identified a non-active concentration (i.e. causing a Log reduction less than 5), as required by the Reference Standard.</p>
ADDENDA	N. 1: RAW DATA EXPERIMENTATION (4 pages)

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 The test results relate only to the tested items. Sampling, except specific indication on test report, is always intended to be made by the Sponsor. Characterization of the test sample is under Sponsor responsibility.*

 biolab	Prova quantitativa in sospensione per la valutazione dell'attività battericida dei disinfettanti chimici e antisettici usati in campo alimentare, industriale, domestico e istituzionale (Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas)	1-P-QM-TEM-9081590
	Norma (Standard): EN 1276:2019 / UNI EN 1276:2019 - phase2/step1	

Data inizio (Started on): 08/04/20

Data fine sperimentazione (Experimentation finished on): 10/04/2020

ID. studio (ID. Study): STULV20AA1759-1

ID. campione (ID. sample): LV-MAT-IJ2-20-095-0C11.a

Microorganismi test (Test Microorganisms)	CONCENTRAZIONI E TEMPI DI CONTATTO ufc/plastra (CONCENTRATIONS AND CONTACT TIMES cfu/plate)								
	Dil.	80% 5 min		50% 5 min		25% 5 min		5 min	
Enterococcus hirae ATCC10541	10 ⁰	0	0	0	0	0	0	0	0
	10 ⁻¹	0	0	0	0	0	0	0	0
	10 ⁻²	0	0	0	0	0	0	0	0
	Log	Na	<	2.15	Na	<	2.15	Na	<
Log	R	>	5.18	R	>	5.18	R	>	5.18

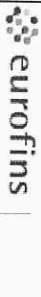
Na: numero di ufc/ml nella miscela test (Na: number of cfu/ml in the test mixture);
 R: riduzione della vitalità (R: vitality reduction)

Data verifica approvatore (approver verification date): 10/04/2020

Sigla tecnico e data (Technician signature and date): CS 15/04/20

Sigla approvatore e data (Approver signature and date): OE 15/04/20

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	Prova quantitativa in sospensione per la valutazione dell'attività battericida dei disinfettanti chimici e antisettici usati in campo alimentare, industriale, domestico e istituzionale <i>(Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas)</i>	1-P-QM-TEM-9081590
	Norma (Standard): EN 1276:2019 / UNI EN 1276:2019 - phase2/step1	

Data inizio (Started on):

10/04/20

Data fine sperimentazione (Experimentation finished on): 14/04/2020

ID. studio (ID. Study):

STULV20AA1759-1

ID. campione (ID. sample): LV-MAT-JE2-20-095-0C11:a

Microorganismi test (Test Microorganisms)	CONCENTRAZIONI E TEMPI DI CONTATTO UFC/PIASTRA (CONCENTRATIONS AND CONTACT TIMES cfu/plate)								
	Dil.	80%		50%		25%		5 min	
Staphylococcus aureus ATCC6538	10 ⁰	0	0	0	0	0	0	0	0
	Log	Na	< 2.15	Na	< 2.15	Na	< 2.15	Na	< 2.15
	Log	R	> 5.39	R	> 5.39	R	> 5.39	R	> 5.39
Pseudomonas aeruginosa ATCC15442	10 ⁰	0	0	0	0	0	0	0	0
	Log	Na	< 2.15	Na	< 2.15	Na	< 2.15	Na	< 2.15
	Log	R	> 5.54	R	> 5.54	R	> 5.54	R	> 5.54
Escherichia coli ATCC 10536	10 ⁰	0	0	0	0	0	0	0	0
	Log	Na	< 2.15	Na	< 2.15	Na	< 2.15	Na	< 2.15
	Log	R	> 5.42	R	> 5.42	R	> 5.42	R	> 5.42

Na: numero di ucf/ml nella miscela test (Na: number of cfu/ml in the test mixture);
R: riduzione della vitalità (R: vitality reduction)

Data verifica approvatore (approver verification date): 15/04/2020

Sigla tecnico e data (Technician signature and date): CS 15/04/20

Sigla approvatore e data (Approver signature and date): OP 15/04/20

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