eurofins | BioPharma Product Testing

REVISION JUSTIFICATION	The present revision supersedes the previous report released on April 16th, 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	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 *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Escherichia coli* 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, KH_2PO_4 3.6 g/L, Na_2HPO_4 7.2 g/L, Distilled water to 1000 ml) and another one by the membrane-filtration method. 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.		
TEST TEMPERATURE	20°C ± 1°C		

eurofins | BioPharma Product Testing

CONCENTRATION	80% (Neat) – 50% – 25% in test The item dilutions have been prepared 1.25 times higher the final tested concentrations, using water for injection
PRODUCT APPEARANCE	Transparent, light pink liquid
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	*Staphylococcus aureus* ATCC 6538 *Pseudomonas aeruginosa* ATCC 15442 *Escherichia coli* ATCC 10536 *Enterococcus hirae* ATCC 10541
INACTIVATION OF THE PRODUCT	Dilution- neutralization method - CEN neutralizer (for *E. hirae*): 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 *S. aureus, P. aeruginosa, E. coli*): 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		
S.aureus ATCC 6538	>5.39	>5.39	>5.39
P. aeruginosa ATCC 15442	>5.54	>5.54	>5.54
E. coli ATCC 10536	>5.42	>5.42	>5.42
E.hirae ATCC 10541	>5.18	>5.18	>5.18

See Addendum N.1

VALIDITY CRITERIA

N: is between $1.5x10^8$ and $5x10^8$ (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

eurofins | BioPharma Product Testing

	N_v = count in cfu/ml of the bacterial suspension in the preliminary assay **A** = count in cfu/ml of experimental conditions control **B** = count in cfu/ml neutraliser toxicity control/ filtration control **C** = count in cfu/ml neutraliser effectiveness/validation of membrane filtration method
INTERPRETATION OF RESULTS	The test item is considered bactericidal when a 5 decimal logarithm reduction is demonstrated under the test conditions for *general purpose disinfection*: 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 *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Escherichia coli*, *Enterococcus hirae* and *E. faecium* (only for temperatures ≥ 40°C). The recommended contact time for the use of the product is within the responsibility of the manufacturer. 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.
CONCLUSIONS	**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)
	It has not been identified a non-active concentration (i.e. causing a Log reduction less than 5), as required by the Reference Standard.
ADDENDA	N. 1: RAW DATA EXPERIMENTATION (*4 pages*)

Reviewed and electronically signed for Study Technical Supervisor Approval by
Camilla Carloni, employee
for Eurofins Biolab Srl, on 29-Apr-2020 09:30:07 UTC+02:00

eurofins | 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-IJE2-20-095-0C11:a

Microrganismi test ***(Test Microorganisms)***	**N**			**Nv**		**A**		**B**		**C**	
	Dil.	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*
Enterococcus hirae ATCC10541	10^{-6}	208	224	49	46	40	48	43	52	59	55
	10^{-7}	19	20								
	Log	8.33	VALIDO (VALID)	4.8E+02		4.4E+01		4.8E+01		5.7E+01	

N: conteggio sospensione batterica ufc/ml (N: count of the bacterial suspension cfu/ml)
Nv: conteggio sospensione batterica per il saggio preliminare ufc/ml (Nv: count of the bacterial suspension in the preliminary assay cfu/ml)
A: conteggio nella convalica delle condizioni sperimentali ufc/piastra (A: count in the experimental conditions verification solution cfu/plate)
B: conteggio nel controllo di tossicità del neutralizzante ufc/piastra (B: count in the neutraliser toxicity control cfu/plate)
C: conteggio nel controllo dell'efficacia del neutralizzante ufc/piastra (C: count in the neutraliser effectiveness control cfu/plate)

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

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

Sigla approvatore *e data (Approver signature and date)*: 15/04/2020

Approved document in ETQ

eurofins | 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-IJE2-20-095-0C11:a

Microrganismi test *(Test Microorganisms)*	**CONCENTRAZIONI E TEMPI DI CONTATTO ufc/piastra** *(CONCENTRATIONS AND CONTACT TIMES cfu/plate)*						
	Dil.	**80%**	**5 min**	**50%**	**5 min**	**25%**	**5 min**
Enterococcus hirae ATCC10541	10^0	0	0	0	0	0	0
	10^{-1}	0	0	0	0	0	0
	10^{-2}	0	0	0	0	0	0
	Log	**Na** < 2.15		**Na** < 2.15		**Na** < 2.15	
	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)*: 15/04/20

Sigla approvatore e data *(Approver signature and date)*: 15/04/2020

Revision: 2	**Local reference: Mod. PS/MIC/113.E**	Pagina 2 di 2
	Approved document in ETQ	

eurofins | 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)*: 10/04/20

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

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

ID. campione *(ID. sample)*: LV-MAT-IJE2-20-095-0C11:a

Microrganismi test *(Test Microorganisms)*		N		Nv		A		B		C	
	Dil.	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*	ufc/piastra *(cfu/plate)*
Staphylococcus aureus ATCC6538	10^{-6}	>330	>330	99	96	92	105	93	89	82	87
	10^{-7}	33	36								
	Log	8.54	VALIDO (VALID)	9.8E+02		9.9E+01		9.1E+01		8.5E+01	
Pseudomonas aeruginosa ATCC15442	10^{-6}	>330	>330	117	104	81	91	88	75	76	91
	10^{-7}	44	53								
	Log	8.69	VALIDO (VALID)	1.1E+03		8.6E+01		8.2E+01		8.4E+01	
Escherichia coli ATCC 10536	10^{-6}	>330	>330	92	79	78	66	73	77	65	70
	10^{-7}	35	39								
	Log	8.57	VALIDO (VALID)	8.6E+02		7.2E+01		7.5E+01		6.8E+01	

N: conteggio sospensione batterica ufc/ml (N: count of the bacterial suspension cfu/ml)
Nv: conteggio sospensione batterica per il saggio preliminare ufc/ml (Nv: count of the bacterial suspension in the preliminary assay cfu/ml)
A: conteggio nella convalida delle condizioni sperimentali ufc/piastra (A: count in the experimental conditions verification solution cfu/plate)
B: conteggio nel controllo di tossicità del neutralizzante ufc/piastra (B: count in the neutraliser toxicity control cfu/plate)
C: conteggio nel controllo dell'efficacia del neutralizzante ufc/piastra (C: count in the neutraliser effectiveness control cfu/plate)

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

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

Sigla approvatore *e data (Approver signature and date)*: 15/04/2020

eurofins | 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)*: 10/04/20

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

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

ID. campione *(ID. sample)*: LV-MAT-IJE2-20-095-0C11:a

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

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): 15/04/2020

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

Sigla approvatore *e data (Approver signature and date)*: 15/04/2020