ECM Institute issues this

Certificate of Conformance

To:

Koyuncu Bilişim Teknolojileri San.Tic.Ltd.Şti
Nissa o2 Resi. 3/15 Bahçeşehir / Turkey
Biolustre, reod the presence of the Test Reports as evidence of its good monufocturing proctice
Finding it in conformonce with Regulotion (BPR) 528/2012
Hygienic Hondrub & Hondwosh, Surgi c9ı Hond Disinfection
For the following standards:

EN 14476 EN13627,EN13624.

In reference to:

Product Type : *Alcohol Wipes*

Product Reference : *Alcohol, Gel Biolustre*

Certificate of Conformance no. 5C200413.YCKTC00
Technical Construction File no. 20ZCTS0323066SP

Date of issuance : 13 April 2020
Expiration date : 12 April 2023

authorized by :

Luca Bedonni ECM Service Director

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Test Report: EN 14476 EN13727:2012+A2:2015

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1)

Identification of the test laboratory: 3263 Trade Center Drive
Riverside, CA 92507

Identification of the client: BIOLUSTRE

Identification of the sample:	20B/246
Name of the product:	Quadex International Alcohol Rub
Batch number/reference and expiry date (if available):	018
Date of delivery:	25 February 2020
Storage conditions:	Room temperature in darkness
Product diluent recommended by the manufacturer for use:	Not disclosed
Active substance(s) and their concentrations (s) (optional):	Not disclosed
Appearance of the product:	Clear viscous liquid

Notes:

1) The test results in this report relate only to the sample(s) tested.
2) This test report may not be reproduced except in full, adapted, altered or used to create a derivative work, without written approval from Abbott Analytical Ltd.

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Test method and its validation:

Method:	Dilution-neutralisation
Neutraliser:	30.0 g/l Polysorbate 80 + 5.0 g/l Lecithin + 1.0 g/l L-histidine + 1.0 g/l L-cysteine (Neutraliser A) or 100.0 g/l Polysorbate 80 + 30.0 g/l Lecithin + 30.0 g/l Tryptone Soya Broth + 5.0 g/l Sodium thiosulphate + 1.0 g/l L-histidine (Neutraliser B)
Neutraliser validation:	Validated in accordance with EN 13727:2012+A2:2015 (5.5.2)

Experimental conditions:

Period of analysis:	10 March 2020 to 13 March 2020
Product test concentration(s):	Neat
Diluent used for product test solution(s):	N/A
Contact time(s):	15 s ± 5 s
Test temperature(s):	20°C ± 1°C
Interfering substance:	0.3 g/l bovine albumin (clean conditions)
Temperature of incubation:	36°C ± 1°C
Identification of the bacterial strain(s) used:	*Pseudomonas aeruginosa* (NCIMB 10421) *Escherichia coli* K12 (NCIMB 10083) *Staphylococcus aureus* (NCTC 10788) *Enterococcus hirae* (NCIMB 8192)

Deviations:

1) Non-standard contact time (less than 30 s) used at client's request.

Remarks:

1) All test conditions are as requested by the client, irrespective of whether these are in accordance with EN 14476 EN13727:2012+A2:2015 (5.4.2) or EN 14476 EN13727:2012+A2:2015 (5.5.1.1).
2) Products can only be tested at a concentration of 80% or less as some dilution is always produced by adding the test organisms and interfering substance.

Requirements:

The product shall demonstrate at least a 5 decimal log (lg) reduction against every test organism.

Conclusion:

According to EN 14476 EN13727:2012+A2:2015, this sample of Quadex International Alcohol Rub possesses bactericidal activity against all of the referenced strains of *Pseudomonas aeruginosa*, *Escherichia coli* K12, *Staphylococcus aureus* and *Enterococcus hirae*, when tested neat with a contact time of 15 seconds at 20°C under clean conditions.

Report prepared by:

Signed:

Position: General Manager

Date: 13 March 2020

Approved by:

Signed:

Position: Laboratory Manager

Date: 13 March 2020

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Results: EN 14476 EN13727:2012+A2:2015

RST 004 (Issue 3)

Test organism:	*Pseudomonas aeruginosa*		(NCIMB 10421)
Date of test:	10 March 2020		
Test temperature:	20°C ± 1°C	Incubation temperature:	36°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates:	1 / ml
Neutraliser:	B	Test conditions:	Clean conditions

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: *Neat*		
*Vc*1	*41*	$\overline{n}$ =	*Vc*1	*44*	$\overline{n}$ =	*Vc*1	*41*	$\overline{n}$ =	*Vc*1	*40*	$\overline{n}$ =
*Vc*2	*47*	44	*Vc*2	*45*	44.5	*Vc*2	*38*	39.5	*Vc*2	*45*	42.5
$30 \le \overline{n}$ of $Nv_o \le 160$? ☒ yes ☐ no			$\overline{n}$ of $A \ge 0.5 \times \overline{n}$ of Nv_o ? ☒ yes ☐ no			$\overline{n}$ of $B \ge 0.5 \times \overline{n}$ of Nv_o ? (or Nv_B / 1000) ? ☒ yes ☐ no			$\overline{n}$ of $C \ge 0.5 \times \overline{n}$ of Nv_o ? ☒ yes ☐ no		

Validation suspension (Nv_B)		
*Vc*1	*40*	$\overline{n}$ =
*Vc*2	*43*	41.5
$30 \le \overline{n}$ of Nv_B / 1000 ≤ 160 ? ☒ yes ☐ no		

Test suspension (N and N_o):

N	*Vc*1	*Vc*2			
10^{-6}	*256*	*264*	$\overline{n}$ wm = 2.59×10^8 ;	lg N =	8.41
10^{-7}	*27*	*22*	$N_o = N / 10$;	lg N_o =	7.41
			$7.17 \le \lg N_o \le 7.70$?	☒ yes	☐ no

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	*Na* ($\overline{n}$ x 10 or $\overline{n}$ wm x 10)	lg *Na*	lg *R* (lg N_o - lg *Na*)
Neat	*15 s*	10^0	*0*	*0*	<140	<2.15	>5.26
		10^{-1}	*0*	*0*			

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Results: EN 14476 EN13727:2012+A2:2015

RST 004 (Issue 3)

Test organism:	*Escherichia coli* K12		(NCIMB 10083)
Date of test:	11 March 2020		
Test temperature:	20°C ± 1°C	Incubation temperature:	36°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates:	1 / ml
Neutraliser:	A	Test conditions:	Clean conditions

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: *Neat*		
*Vc*1	*94*	$\overline{n}$ =	*Vc*1	*87*	$\overline{n}$ =	*Vc*1	*94*	$\overline{n}$ =	*Vc*1	*90*	$\overline{n}$ =
*Vc*2	*91*	92.5	*Vc*2	*90*	88.5	*Vc*2	*91*	92.5	*Vc*2	*87*	88.5
$30 \le \overline{n}$ of $Nv_o \le 160$? ☒ yes ☐ no			$\overline{n}$ of $A \ge 0.5 \times \overline{n}$ of Nv_o ? ☒ yes ☐ no			$\overline{n}$ of $B \ge 0.5 \times \overline{n}$ of Nv_o ? (or Nv_B / 1000) ? ☒ yes ☐ no			$\overline{n}$ of $C \ge 0.5 \times \overline{n}$ of Nv_o ? ☒ yes ☐ no		

Validation suspension (Nv_B)		
*Vc*1	*93*	$\overline{n}$ =
*Vc*2	*91*	92
$30 \le \overline{n}$ of Nv_B / 1000 ≤ 160 ? ☒ yes ☐ no		

Test suspension (N and N_o):

N	*Vc*1	*Vc*2			
10^{-6}	*>330*	*>330*	$\overline{n}$ wm = 4.10×10^8 ;	lg N =	8.61
10^{-7}	*44*	*38*	$N_o = N / 10$;	lg N_o =	7.61
			$7.17 \le \lg N_o \le 7.70$?	☒ yes	☐ no

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	*Na* ($\overline{n}$ x 10 or $\overline{n}$ wm x 10)	lg *Na*	lg *R* (lg N_o - lg *Na*)
Neat	*15 s*	10^0	*0*	*0*	<140	<2.15	>5.46
		10^{-1}	*0*	*0*			

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Results: EN 14476 EN13727:2012+A2:2015

RST 004 (Issue 3)

Test organism:	*Staphylococcus aureus*		(NCTC 10788)
Date of test:	10 March 2020		
Test temperature:	20°C ± 1°C	Incubation temperature:	36°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates:	1 / ml
Neutraliser:	B	Test conditions:	Clean conditions

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: *Neat*		
*Vc*1	*63*	$\overline{n}$ =	*Vc*1	*64*	$\overline{n}$ =	*Vc*1	*59*	$\overline{n}$ =	*Vc*1	*65*	$\overline{n}$ =
*Vc*2	*58*	60.5	*Vc*2	*60*	62	*Vc*2	*69*	64	*Vc*2	*67*	66
30 ≤ $\overline{n}$ of Nv_o ≤ 160 ? ☒ yes ☐ no			$\overline{n}$ of A ≥ 0.5 x $\overline{n}$ of Nv_o ? ☒ yes ☐ no			$\overline{n}$ of B ≥ 0.5 x $\overline{n}$ of Nv_o ? (or Nv_B / 1000) ? ☒ yes ☐ no			$\overline{n}$ of C ≥ 0.5 x $\overline{n}$ of Nv_o ? ☒ yes ☐ no		

Validation suspension (Nv_B)		
*Vc*1	*64*	$\overline{n}$ =
*Vc*2	*65*	64.5
30 ≤ $\overline{n}$ of Nv_B / 1000 ≤ 160 ? ☒ yes ☐ no		

Test suspension (N and N_o):

N	*Vc*1	*Vc*2			
10^{-6}	*293*	*295*	$\overline{n}$ wm = 2.92×10^{8} ;	lg N =	8.47
10^{-7}	*29*	*26*	$N_o = N / 10$;	lg N_o =	7.47
			7.17 ≤ lg N_o ≤ 7.70 ?	☒ yes	☐ no

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	*Na* ($\overline{n}$ x 10 or $\overline{n}$ wm x 10)	lg *Na*	lg R (lg N_o - lg *Na*)
Neat	*15 s*	10^{0}	*0*	*0*	<140	<2.15	>5.32
		10^{-1}	*0*	*0*			

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Results: EN 14476 EN13727:2012+A2:2015

RST 004 (Issue 3)

Test organism:	*Enterococcus hirae*		(NCIMB 8192)
Date of test:	10 March 2020		
Test temperature:	20°C ± 1°C	Incubation temperature:	36°C ± 1°C
Dilution-neutralisation method:	Pour plate	Number of plates:	1 / ml
Neutraliser:	B	Test conditions:	Clean conditions

Validation and controls:

Validation suspension (Nv_o)			Experimental conditions control (A)			Neutraliser or filtration control (B)			Method validation (C) Product conc.: *Neat*		
*Vc*1	*41*	$\overline{n}$ =	*Vc*1	*40*	$\overline{n}$ =	*Vc*1	*36*	$\overline{n}$ =	*Vc*1	*41*	$\overline{n}$ =
*Vc*2	*42*	41.5	*Vc*2	*43*	41.5	*Vc*2	*39*	37.5	*Vc*2	*43*	42
$30 \le \overline{n}$ of $Nv_o \le 160$? ☒ yes ☐ no			$\overline{n}$ of $A \ge 0.5 \times \overline{n}$ of Nv_o ? ☒ yes ☐ no			$\overline{n}$ of $B \ge 0.5 \times \overline{n}$ of Nv_o ? (or Nv_B / 1000) ? ☒ yes ☐ no			$\overline{n}$ of $C \ge 0.5 \times \overline{n}$ of Nv_o ? ☒ yes ☐ no		

Validation suspension (Nv_B)		
*Vc*1	*41*	$\overline{n}$ =
*Vc*2	*42*	41.5
$30 \le \overline{n}$ of Nv_B / 1000 ≤ 160 ? ☒ yes ☐ no		

Test suspension (N and N_o):

N	*Vc*1	*Vc*2			
10^{-6}	*154*	*151*	$\overline{n}$ wm = 1.53×10^8 ;	lg N =	8.18
10^{-7}	*16*	*15*	$N_o = N / 10$;	lg N_o =	7.18
			$7.17 \le \lg N_o \le 7.70$?	☒ yes	☐ no

Test:

Conc. of the product	Contact time	Dilution step	*Vc*1	*Vc*2	*Na* ($\overline{n}$ x 10 or $\overline{n}$ wm x 10)	lg *Na*	lg *R* (lg N_o - lg *Na*)
Neat	*15 s*	10^0	*0*	*0*	<140	<2.15	>5.03
		10^{-1}	*0*	*0*			

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Explanations:

Vc	count per ml (one plate or more)
$\overline{n}$	average of *Vc*1 and *Vc*2 (1 + 2 duplicate)
$\overline{n}$ wm	weighted mean of $\overline{n}$
N	number of cells per ml in the test suspension
N_o	number of cells in the test mixture at the beginning of the contact time ($N_o = N / 10$)
Na	number of survivors per ml in the test mixture at the end of the contact time (before neutralisation or filtration)
R	reduction ($\lg R = \lg N_o - \lg Na$)
Nv	number of cells per ml in the validation suspension
Nv_o	number of cells in the validation mixtures at the beginning of the contact time ($Nv_o = Nv / 10$)
Nv_B	number of cells per ml in the neutraliser control validation suspension
A	number of survivors per ml in the experimental conditions control mixture
B	number of survivors per ml in the neutraliser or filtration control mixture
C	number of survivors per ml in the method validation mixture

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Alcohol Based Antibacterial Wet Towels

Safety Data Sheet

according to Regulation (EU) 2015/830
SDS Ref.: SDS-12052020-1
Issue date: 5/12/2020 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Article
Product name : Alcohol Based Antibacterial Wet Towels
Type of product : Cosmetic product

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Intended for general public
Main use category : Consumer use
Use of the substance/mixture : All purpose cleaning wipe

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

AKGÜN ÇOCUK BEZİ VE KOZMETİK ÜRÜNLERİ SANATİ LTD.
ŞTİ. Akçaburgaz Mahallesi 3030 Sokak No: 7/1
Esenyurt
İstanbul - TÜRKİYE
T (0090) (850) 473 71 73 - (0090) (532) 291 75 17
info@biolustre.com.tr - www.biolustre.com.tr

1.4. Emergency telephone number

Country	Official advisory body	Address	Emergency number	Comment
Germany	Giftnotruf der Charité CBF, Haus VIII (Wirtschaftgebäude), UG	Hindenburgdamm 30 12203 Berlin	+49 30 19240	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2 H225

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS02

Signal word (CLP) : Danger
Hazardous ingredients : ALCOHOL

BIOLUSTRE,

TEST REPORT

Attention: ADVANCED DISINFECTING SERVICES
12 KING WILLOW CRESCENT
RANDJESFONTEIN

Lab number	526372
Order reference	386042/Q3168
Sample Date	12/04/2020
Submit Date	12/04/2020
Report Date	27/05/2020

SANS53727: Bactericidal activity of chemical disinfectants and antiseptics.
SANS53624: Fungicidal & Yeasticidal activity of chemical disinfectants and antiseptics.

Product information:	
Product name:	**Alcohol rub**
Batch number:	4
Expiry Date:	22/08/2020
Date received:	12-April-20
Storage conditions:	Ambient temperature
Recommended Diluent:	none
Active substances:	Ethanol
Appearance:	SUITABLE FOR TESTING

Test conditions:	
Date of test:	14/11/2018
Diluent used:	None
Test Concentration:	Neat
Appearance of dilution:	Homogenous suspension
Contact Time:	15 seconds
Test Temperature:	23°C
Interfering substance:	0.3% Bovine serum albumin
Solution appearance during test:	Homogenous suspension
Rinsing Liquid:	STERILE DISTILLED WATER
Bacterial strains used:	Escherichia coli ATCC10536 Staphylococcus aureus ATCC6538 Pseudomonas aeruginosa ATCC15442 Enterococcus hirae ATCC10541 Candida albicans ATCC10231 Listeria monocytogenes ATCC19115 Klebsiella pneumoniae Salmonella Typhimurium

Test results

Test Organism:	***Escherichia coli***
Initial bacterial load (cfu/ml):	8.10×10^7
Final Bacterial Load (cfu/ml)	0
% Kill rate	>99.999%
Log reduction	7.91
Compliance with requirement	**Pass**

Test Organism:	***Pseudomonas aeruginosa***
Initial bacterial load (cfu/ml):	1.22×10^8
Final Bacterial Load (cfu/ml)	0
% Kill rate	>99.999%
Log reduction	8.09
Compliance with requirement	**Pass**

Test Organism:	***Staphylococcus aureus***
Initial bacterial load (cfu/ml):	1.03×10^8
Final Bacterial Load (cfu/ml)	0
% Kill rate	>99.999%
Log reduction	8.01
Compliance with requirement	**Pass**

Test Organism:	***Enterococcus hirae***
Initial bacterial load (cfu/ml):	5.75×10^7
Final Bacterial Load (cfu/ml)	0
% Kill rate	>99.999%
Log reduction	7.76
Compliance with requirement	**Pass**

Test Organism:	***Candida albicans***
Initial bacterial load (cfu/ml):	1.39×10^9
Final Bacterial Load (cfu/ml)	0
% Kill rate	>99.999%
Log reduction	8.14
Compliance with requirement	**Pass**

Test Organism:	***Salmonella Typhimurium***
Initial bacterial load (cfu/ml):	1.10×10^9
Final Bacterial Load (cfu/ml)	0
% Kill rate	>99.999%
Log reduction	8.04
Compliance with requirement	**Pass**

Test Organism:	***Klebsiella pneumoniae***
Initial bacterial load (cfu/ml):	1.82 X 10^8
Final Bacterial Load (cfu/ml)	0
% Kill rate	>99.999%
Log reduction	8.26
Compliance with requirement	**Pass**

Test Organism:	***Listeria monocytogenes***
Initial bacterial load (cfu/ml):	7.15 X 10^7
Final Bacterial Load (cfu/ml)	0
% Kill rate	>99.999%
Log reduction	7.85
Compliance with requirement	**Pass**

CONCLUSION

Alcohol rub effectively killed all organisms tested against the product within 15 seconds.

The product achied a >7 log reduction against all organisms in 15 seconds.

Johan
Laboratory Services Manager - Hygiene Services