QACS Ltd.
QUALITY ASSURANCE & CONTROL SYSTEMS

1 Antigonis str 14451 Metamorfosis, Athens, Greece
Tel : +30-210-2934745 | e-mail : info@qacs.gr
Fax : +30-210-2934606 | web : www.qacs.gr

Σ. ΚΟΥΖΟΥΝΑΣ ΚΑΙ ΣΙΑ ΕΕ ALCOFARM

STUDY REPORT 18 23 00024

SUSPENSION TEST
ACCORDING TO EN 1040
(Phase 1)

GERM KILL ALCOHOL

Chemical disinfectants and antiseptics
Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics. Test method and requirements
(Phase 1)

JANUARY 2018

QACS LTD, 1 Antigonis str, 144-51 Metamorfossi, Greece. Tel: +30-210-2934745,
fax: +30-210-2934606, email: info@qacs.gr website: www.qacs.gr

QACS Ltd.
QUALITY ASSURANCE & CONTROL SYSTEMS
1 Antigonis str 14451 Metamorfosis, Athens, Greece
Tel : +30-210-2934745 | e-mail : info@qacs.gr
Fax : +30-210-2934606 | web : www.qacs.gr

STUDY REPORT 18 23 00024

SUSPENSION TEST ACCORDING TO EN 1040:2005

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of basic bactericidal activity of chemical disinfectants and antiseptics. Test method and requirements (Phase 1)

PRODUCT NAME	:	GERM KILL ALCOHOL
PRODUCT TYPE	:	DISINFECTANT
ACTIVE SUBSTANCES AND THEIR CONCENTRATIONS	:	-
APPEARANCE OF THE PRODUCT	:	LIQUID
STORAGE CONDITIONS	:	ROOM TEMPERATURE, DARKNESS
LOT	:	-
METHOD	:	EN 1040
CONTACT TIME	:	5 minutes
DILUTIONS	:	AS IS, 50%, 1%
DILUENT RECOMENTED BY THE MANUFACTURER	:	HARD WATER
PRODUCT SUPPLIER	:	Σ. ΚΟΥΖΟΥΝΑΣ ΚΑΙ ΣΙΑ ΕΕ ALCOFARM
PRODUCT MANUFACTURER	:	Σ. ΚΟΥΖΟΥΝΑΣ ΚΑΙ ΣΙΑ ΕΕ ALCOFARM
STUDY PERIOD	:	17/01/2018-19/01/2018
LAB ID	:	2018-724/18 23 00024

OBJECTIVE

The objective of this study was to demonstrate the bactericidal activity of the test material under the requirements of European Standard EN 1040.

TEST SYSTEMS

Pseudomonas aeruginosa	:	NCIMB 10421 Lot: 02022005
Staphylococcus aureus	:	ATCC 6538 Lot: 4854821

TEST METHOD

European Standard EN 1040. Chemical disinfectants and antiseptics. Basic bactericidal activity

NOTES

A) Each test system was harvested off of the appropriate agar slants and diluted to the desired concentration using the appropriate diluent in order to have provided the desired level of inoculum.

B) The test substance was tested at **5 minutes** Contact Time

C) The test plates were read and recorded after ~ 2x24 hours of incubation.

1 Antigonis str 14451 Metamorfosis, Athens, Greece
Tel : +30-210-2934745 | e-mail : info@qacs.gr
Fax : +30-210-2934606 | web : www.qacs.gr

RESULT REPORTING – CALCULATIONS

As specified in the European Standard EN 1040 methodology, a Reduction in Viability (R) was calculated for each test system. Each of the 2 replicate counts for each test system's inoculum count (x 10-1) and treatment tube recovery count were averaged, and the Reduction in Viability was calculated.

Recoveries on the test plates represent a 10^{-1} dilution. A recovery of 67 CFU would result in a recovery of 6.7 x 10^2 CFU per mL. A recovery of 12 colonies results in a recovery reported as <1.5 x l02 CFU per mL, countable plates are those containing between 15 and 300 colonies as stated in the protocol. Test plates with greater than 300 colonies are reported as > 3.0 x 10^3CFU per mL.

Examples of a calculation have been shown below:

To determine the Reduction in Viabilitv (R), the following calculation was performed:

$$R = \frac{\text{Inoculum Count x 10-1}}{\text{Treatment Tube Recovery}}$$

An inoculum count of 4.87 x 10^8 CFU per mL and a recovery count of 1.5 x 10^2 CFU per mL would result in the following equation:

$$\frac{4.87 \text{ X } 10^8 \text{ x } 10\text{-}1}{1.5 \text{ X } 10^2}$$

Resulting in a Reduction in Viability (R) of 3.24 x 10^5.

ASSAY ACCEPTANCE CRITERIA

1. Average inoculum's counts of 1.5 to 5.0 X 10^8 CFU per mL were achieved for all test systems.
2. Average Bacterial Suspensions control counts of 6.0 x 10^2 to 3.0 x 10^3 CFU per mL were achieved for all test systems.
3. Average recovery values for the Neutralization Toxicity Validation control assays were equal to or greater than 0.05 times the bacterial suspension control count (i.e. 30 to 300 CFU per mL).
4. Average recovery values for the Experimental Conditions Validation control equal to or greater than 0.05 times the bacterial suspension control count (i.e. 30 - 300 CFU per mL).
5. Average recovery values for the Dilution Neutralization Validation control assay were equal to or greater than 0.5 times the recovery values obtained in the Neutralizer Toxicity Validation control assay (Le. 15 to 300 CFU per mL).

ARCHIVING

The laboratory book which contains all the information (raw data and results) regarding the study and the study reports are kept in the laboratory archives during 2 years.

QACS Ltd.
QUALITY ASSURANCE & CONTROL SYSTEMS

1 Antigonis str 14451 Metamorfosis, Athens, Greece
Tel : +30-210-2934745 | e-mail : info@qacs.gr
Fax : +30-210-2934606 | web : www.qacs.gr

TEST RESULTS FOR Pseudomonas aeruginosa

Test suspension

Test - suspension (N and Nvo)					
N	Vc1	Vc2	x mean		3.86E+08
10^{-7}	37	42			
10^{-8}	3	3	log N		8.59
			No	(N/10)	3.86E+07
			log No		7.59
			7,17 < = logNo < = 7,70		Yes

Validation and controls

Validation suspension (Nvo)				Experimental conditions (A)				Neutralizer control (B)				Method validation (C) Product conc.: as is (80%)			
Vc1	average:	123	x mean 120.5	Vc1	average:	113	x mean 117	Vc1	average:	112	x mean 107.5	Vc1	average:	104	x mean 98.5
	value1	value2			value1	value2			value1	value2			value1	value2	
	64	59			55	58			55	57			59	45	
Vc2	average:	118		Vc2	average:	121		Vc2	average:	103		Vc2	average:	93	
	value1	value2			value1	value2			value1	value2			value1	value2	
	58	60			59	62			53	50			46	47	
30<x mean of Nvo < 160? Yes				x mean of A is > 0,5*x mean of Nvo? Yes				x mean of B is > 0,5*x mean of Nvo? Yes				x mean of C is > 0,5*x mean of Nvo? Yes			

Test Results

Product concentration (%)	Contact time (min)	Vc1	Vc2	Average	log Na	log N	log Reduction (N-Na)	Criteria	Result
as is	5 min	0	0	140	2.15	7.59	5.44	>5	PASS TEST
50%	5 min	0	0	140	2.15	7.59	5.44	>5	PASS TEST
1%	5 min	54545	54545	54545	4.74	7.59	2.85	>5	FAILS TEST

QACS Ltd.
QUALITY ASSURANCE & CONTROL SYSTEMS
1 Antigonis str 14451 Metamorfosis, Athens, Greece
Tel : +30-210-2934745
Fax : +30-210-2934606
e-mail : info@qacs.gr
web : www.qacs.gr

TEST RESULTS FOR Staphylococcus aureus

Test suspension

Test - suspension (N and **Nvo**)				
N	Vc1	Vc2	x mean	3.18E+08
10^{-7}	28	34		
10^{-8}	3	5	log N	8.50
			No (N/10)	3.18E+07
			log No	7.50
			7,17 < = logNo < = 7,70	**Yes**

Validation and controls

Validation suspension (**Nvo**)				Experimental conditions (**A**)				Neutralizer control (**B**)				Method validation (**C**) Product conc.: as is (80%)			
Vc1	average:	**123**	**x mean 126**	Vc1	average:	**117**	**x mean 117**	Vc1	average:	**112**	**x mean 114**	Vc1	average:	**100**	**x mean 102.5**
	value1	value2			value1	value2			value1	value2			value1	value2	
	69	54			55	62			54	58			50	50	
Vc2	average:	**129**		Vc2	average:	**117**		Vc2	average:	**116**		Vc2	average:	**105**	
	value1	value2			value1	value2			value1	value2			value1	value2	
	65	64			59	58			59	57			49	56	
30<x mean of Nvo < 160? **Yes**				x mean of A is > 0,5*x mean of Nvo? **Yes**				x mean of B is > 0,5*x mean of Nvo? **Yes**				x mean of C is > 0,5*x mean of Nvo? **Yes**			

Test Results

Product concentration (%)	Contact time (min)	Vc1	Vc2	Average	log Na	log N	log Reduction (N-Na)	Criteria	Result
as is	5 min	0	0	140	2.15	7.50	5.36	>5	**PASS TEST**
50%	5 min	0	0	140	2.15	7.50	5.36	>5	**PASS TEST**
1%	5 min	54545	54545	54545	4.74	7.50	2.77	>5	**FAILS TEST**

QACS Ltd.
QUALITY ASSURANCE & CONTROL SYSTEMS

1 Antigonis str 14451 Metamorfosis, Athens, Greece
Tel : +30-210-2934745 | e-mail : info@qacs.gr
Fax : +30-210-2934606 | web : www.qacs.gr

CONCLUSION
TEST SUBSTANCE IDENTIFICATION

PRODUCT NAME	:	GERM KILL ALCOHOL
PRODUCT TYPE	:	DISINFECTANT
ACTIVE SUBSTANCES AND THEIR CONCENTRATIONS	:	-
APPEARANCE OF THE PRODUCT	:	LIQUID
STORAGE CONDITIONS	:	ROOM TEMPERATURE, DARKNESS
LOT	:	-
METHOD	:	EN 1040
CONTACT TIME	:	5 minutes
DILUTIONS	:	AS IS, 50%, 1%
DILUENT RECOMENTED BY THE MANUFACTURER	:	HARD WATER
PRODUCT SUPPLIER	:	Σ. ΚΟΥΖΟΥΝΑΣ ΚΑΙ ΣΙΑ ΕΕ ALCOFARM
PRODUCT MANUFACTURER	:	Σ. ΚΟΥΖΟΥΝΑΣ ΚΑΙ ΣΙΑ ΕΕ ALCOFARM
STUDY PERIOD	:	17/01/2018-19/01/2018
LAB ID	:	2018-724/18 23 00024

METHODOLOGY ABSTRACT
A test suspension of bacteria (*P. aeruginosa*, *S. aureus)* is tested against a product test solution (at concentration: **AS IS, 50%, 1%**). The mixture is maintained at (20 ± 1) °C for 5 min. At the end of this contact time, an aliquot is taken, and the bactericidal activity in this portion is immediately neutralized or suppressed. The numbers of surviving flora are determined and the reduction is calculated.

RESULT
The test substance: **GERM KILL ALCOHOL demonstrated** Bactericidal activity (> 1.0 x 10^5 Reduction in Viability or > 5 log reduction) in accordance with the EN 1040, within **5 minutes at 20±1 °C** when tested at concentrations:

AS IS using as test organisms the reference strains: ***P. aeruginosa*, *S. aureus***
50% using as test organisms the reference strains: ***P. aeruginosa*, *S. aureus***

Signature date: 30/01/2018

Q.A.C.S. L.T.D.
ΣΥΣΤΗΜΑΤΑ ΔΙΑΣΦΑΛΙΣΗΣ ΠΟΙΟΤΗΤΑΣ
ΚΑΙ ΕΛΕΓΧΟΥ Ε.Π.Ε.
ΥΠΗΡΕΣΙΕΣ ΠΑΡΟΧΗΣ ΣΥΜΒΟΥΛΩΝ ΕΠΟΧΕΩΝ
ΤΣΙΤΟΥΡΗ 5Α - ΧΑΛΑΝΔΡΙ
ΑΦΜ: 999708415 - ΔΟΥ: ΧΑΛΑΝΔΡΙΟΥ
ΤΗΛ.: 210 [illegible] - FAX: 210 2934606

Lagiopoulos Giorgos
Agronomist-Food Technologist M.Sc.
Study Manager

Results refer to the sample as received and analyzed on the period specified above.
The test report shall not be reproduced except in full, without written approval of the laboratory.
The samples will be stored by the laboratory during 1 month from the end test date.
The study report and raw data will be stored by the laboratory during 2 years.

QACS Ltd.
QUALITY ASSURANCE & CONTROL SYSTEMS

1 Antigonis str 14451 Metamorfosis, Athens, Greece
Tel : +30-210-2934745 | e-mail : info@qacs.gr
Fax : +30-210-2934606 | web : www.qacs.gr

STUDY SUMMARY / ABSTRACT

SUSPENSION TEST ACCORDING TO EN 1040/
Chemical disinfectants and antiseptics – Basic Bactericidal activity
Test methods and requirements (Phase 1)

TEST SUBSTANCE IDENTIFICATION

PRODUCT NAME	:	GERM KILL ALCOHOL
PRODUCT TYPE	:	DISINFECTANT
ACTIVE SUBSTANCES AND THEIR CONCENTRATIONS	:	-
APPEARANCE OF THE PRODUCT	:	LIQUID
STORAGE CONDITIONS	:	ROOM TEMPERATURE, DARKNESS
LOT	:	-
METHOD	:	EN 1040
CONTACT TIME	:	5 minutes
DILUTIONS	:	AS IS, 50%, 1%
DILUENT RECOMENTED BY THE MANUFACTURER	:	HARD WATER
PRODUCT SUPPLIER	:	Σ. ΚΟΥΖΟΥΝΑΣ ΚΑΙ ΣΙΑ ΕΕ ALCOFARM
PRODUCT MANUFACTURER	:	Σ. ΚΟΥΖΟΥΝΑΣ ΚΑΙ ΣΙΑ ΕΕ ALCOFARM
STUDY PERIOD	:	17/01/2018-19/01/2018
LAB ID	:	2018-724/18 23 00024

TEST SYSTEMS

Pseudomonas aeruginosa	:	NCIMB 10421 Lot: 02022005
Staphylococcus aureus	:	ATCC 6538 Lot: 4854821

RESULT

The test substance: **GERM KILL ALCOHOL demonstrated** Bactericidal activity (> 1.0 x 10^5 Reduction in Viability or > 5 log reduction) in accordance with the EN 1040, within **5 minutes at 20±1 °C** when tested at concentrations:

AS IS using as test organisms the reference strains: ***P. aeruginosa*, *S. aureus***
50% using as test organisms the reference strains: ***P. aeruginosa*, *S. aureus***

End of Test Report