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QUALITY ASSURANCE & CONTROL SYSTEMS

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

RES PHARMA INDUSTRIALE SRL

STUDY REPORT

2020-7887/20 23 00719

Disinfettante Superfici

SUSPENSION TEST
ACCORDING TO EN 1276:2019
(Phase 2 step 1)

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)

SEPTEMBER 2020

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

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SUSPENSION TEST ACCORDING TO 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 PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 1276:2019
CONTACT TIME	:	5 minutes
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00719

SCOPE

This document specifies a test method and the minimum requirements for bactericidal activity of chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water or - in the case of ready-to-use products - with water. 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.
This document applies to products that are used in food, industrial, domestic and institutional areas excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues except those for hand hygiene in the above considered areas

PRINCIPLE

A sample of the product as delivered and/or diluted with hard water (or water for ready-to-use products with the exception of handwash products whose first dilution is done in hard water is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at the chosen test temperature for the adopted contact time. At the end of this contact time, an aliquot is taken, and the bactericidal and/or the bacteriostatic activity in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used. The numbers of surviving bacteria in each sample are determined and the reduction is calculated.
The test is performed using Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and Enterococcus hirae as test organisms. For temperatures ≥ 40 °C only Enterococcus faecium shall be used. For testing of hand hygiene products, Pseudomonas aeruginosa, Escherichia coli K12, Staphylococcus aureus and Enterococcus hirae are used as test organisms.

A: 1 Antigonis str, 14451, Athens, Greece
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F: (+30) 210 2934606 | www.qacslab.com

TEST CONDITIONS

1. The following procedure was performed in water bath at 20 °C
2. The test product was tested at 5 minutes contact time
3. A final concentration of 0.3g/L bovine albumin was used for testing (clean conditions)
4. Neutralization Method used: Dilution neutralization.
5. Neutralizer used: LPT Dilution Broth containing polysorbate 80.
6. According to EN 1276, products shall be tested at a minimum of three different concentrations to include one concentration in the active range and one concentration in the non-active range. In this case the product was tested: Undiluted (80%), 50%, 1%.

TEST ORGANISMS

Pseudomonas aeruginosa	NCIMB 10421
Staphylococcus aureus	ATCC 6538
Escherichia coli	NCIMB 8879
Enterococcus hirae	NCIMB 8192

BACTERICIDAL ACTIVITY FOR GENERAL PURPOSES

The product shall be deemed to have passed the EN 1276 standard if it demonstrates in a valid test at least a 5 lg reduction, under the suitable test conditions for general purpose defined by this standard when the test organisms are Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus and Enterococcus hirae (E. faecium when the test temperature is ≥ 40 °C).

ASSAY ACCEPTANCE CRITERIA

1. Test Suspension (N) is between 1.5 to 5.0 X 10^8 CFU per mL ($8.17 \leq \log N \leq 8.70$)
2. No (N/10) is between 1.5 to 5.0 X 10^7 CFU per mL ($7.17 \leq \log No \leq 7.70$)
3. Validation Suspension=Nv is between 3.0 x 10^2 and 1.6 x 10^3.
4. Nvo (Nv/10) is between 30 and 160
5. Na is the number of survivors (cells) per ml in the test mixture at the end of contact time.
6. R (log reduction) = No - Na
7. Average recovery values for the experimental conditions control (A) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
8. Average recovery values for the Neutralizer control (B) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
9. Average recovery values for the Method Validation control (C) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
10. Control of weighted mean counts. Quotient is not lower than 5 and not higher than 15

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 for 5 years.

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TEST RESULTS FOR *Pseudomonas aeruginosa* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	2.03E+08
10^{-6}	194	213		
10^{-7}	21	19	log N	8.31
			No (N/10)	2.03E+07
			log No	7.31
			7,17 < = logNo < = 7,70	**Yes**

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Undiluted Product conc.: (80%)		
VC 1	42	**x mean**	VC 1	43	**x mean**	VC 1	51	**x mean**	VC 1	49	**x mean**
VC 2	47	**44.5**	VC 2	49	**46**	VC 2	45	**48**	VC 2	45	**47**
30<x mean of Nvo < 160?			x mean of A is > 0,5*x mean of Nvo?			x mean of B is > 0,5*x mean of Nvo or Nvo/1000?			x mean of C is > 0,5*x mean of Nvo?		
Yes			**Yes**			**Yes**			**Yes**		

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
Undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.31	> 5.16	≥ 5	**PASS TEST**
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.31	> 5.16	≥ 5	**PASS TEST**
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.31	< 2.79	≥ 5	**FAILS TEST**
		10^{-1}	> 330	> 330							

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TEST RESULTS FOR *Staphylococcus aureus* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	2.40E+08
10^{-6}	246	237		
10^{-7}	24	22	log N	8.38
			No (N/10)	2.40E+07
			log No	7.38
			7,17 < = logNo < = 7,70	**Yes**

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Undiluted Product conc.: (80%)		
VC 1	49	**x mean**	VC 1	52	**x mean**	VC 1	57	**x mean**	VC 1	48	**x mean**
VC 2	54	**51.5**	VC 2	59	**55.5**	VC 2	50	**53.5**	VC 2	52	**50**
30<x mean of Nvo < 160?			x mean of A is > 0,5*x mean of Nvo?			x mean of B is > 0,5*x mean of Nvo or Nv8/1000?			x mean of C is > 0,5*x mean of Nvo?		
Yes			**Yes**			**Yes**			**Yes**		

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
Undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.38	> 5.23	≥ 5	**PASS TEST**
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.38	> 5.23	≥ 5	**PASS TEST**
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.38	< 2.86	≥ 5	**FAILS TEST**
		10^{-1}	> 330	> 330							

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A: 1 Antigonis str, 14451, Athens, Greece
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TEST RESULTS FOR *Escherichia Coli* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	3.50E+08
10^{-7}	32	37		
10^{-8}	4	4	log N	8.54
			No (N/10)	3.50E+07
			log No	7.54
			7,17 < = logNo < = 7,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Undiluted Product conc.: (80%)		
VC 1	74	x mean	VC 1	77	x mean	VC 1	75	x mean	VC 1	75	x mean
VC 2	79	76.5	VC 2	69	73	VC 2	79	77	VC 2	86	80.5
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 or Nvo/1000? Yes			x mean of C is > 0,5*x mean of Nvo? Yes		

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
Undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.54	> 5.40	≥ 5	PASS TEST
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.54	> 5.40	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.54	< 3.03	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

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TEST RESULTS FOR *Enterococcus hirae* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	3.36E+08
10^{-7}	31	36		
10^{-8}	4	3	log N	8.53
			No (N/10)	3.36E+07
			log No	7.53
			7,17 < = logNo < = 7,70	**Yes**

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Undiluted Product conc.: (80%)		
VC 1	74	**x mean**	VC 1	77	**x mean**	VC 1	82	**x mean**	VC 1	84	**x mean**
VC 2	79	**76.5**	VC 2	84	**80.5**	VC 2	80	**81**	VC 2	92	**88**
30<x mean of Nvo < 160?			x mean of A is > 0,5*x mean of Nvo?			x mean of B is > 0,5*x mean of Nvo or Nvb/1000?			x mean of C is > 0,5*x mean of Nvo?		
Yes			**Yes**			**Yes**			**Yes**		

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
Undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.53	> 5.38	≥ 5	**PASS TEST**
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.53	> 5.38	≥ 5	**PASS TEST**
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.53	< 3.01	≥ 5	**FAILS TEST**
		10^{-1}	> 330	> 330							

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F: (+30) 210 2934606 | www.qacslab.com

CONCLUSION

TEST SUBSTANCE IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 1276:2019
CONTACT TIME	:	5 minutes
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00719

METHODOLOGY ABSTRACT

A test suspension of bacteria is tested against a product test solution at three different concentrations with the presence of interfering substance. The mixture is maintained at 20°C ±1°C for 5 minutes. 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 log reduction is calculated.

RESULT

The product under test: "Disinfettante Superfici" demonstrated bactericidal activity according to EN 1276:2019 (≥ 5 log reduction), under clean conditions for 5 minutes contact time, at 20 ± 1 °C, when tested at product concentrations:

Undiluted (80%) using as test organisms the reference strains: *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Escherichia coli* and *Enterococcus hirae*.

For the QACS Ltd Laboratory,

QACS Laboratories
1 Antigonis str 145 51 Metamorfossi Greece
VAT no EL 998709411, email: info@qacs.gr
Tel +30-2102934745 fax +30-210 2934606
www. qacs.gr

Signature date: 30/09/2020
Lagiopoulos Giorgos
Agronomist-Food Technologist M.Sc.
Study Manager

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

STUDY SUMMARY / ABSTRACT

SUSPENSION TEST ACCORDING TO 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)

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 1276:2019
CONTACT TIME	:	5 minutes
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00719

TEST MICROORGANISMS

Pseudomonas aeruginosa	NCIMB 10421
Staphylococcus aureus	ATCC 6538
Escherichia coli	NCIMB 8879
Enterococcus hirae	NCIMB 8192

RESULT

The product under test: “Disinfettante Superfici” demonstrated bactericidal activity according to EN 1276:2019 (≥ 5 log reduction), under clean conditions for 5 minutes contact time, at 20 ± 1 °C, when tested at product concentrations:

Undiluted (80%) using as test organisms the reference strains: *Pseudomonas aeruginosa*, *Staphylococcus aureus, Escherichia coli* and *Enterococcus hirae*.

Results refer to the sample as received and analyzed on the period specified above.

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 for 5 years.

End of Test Report

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A: 1 Antigonis str, 14451, Athens, Greece
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F: (+30) 210 2934606 | www.qacslab.com

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STUDY REPORT

2020-7887/20 23 00720

Disinfettante Superfici

SUSPENSION TEST
ACCORDING TO EN 1650:2019
(Phase 2 step 1)

Chemical disinfectants and antiseptics
Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas - Test method and requirements (phase 2, step 1)

SEPTEMBER 2020

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

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T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

STUDY REPORT 2020-7887/20 23 00720

SUSPENSION TEST ACCORDING TO EN 1650:2019
Chemical disinfectants and antiseptics – evaluation of fungicidal or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (Phase 2 step 1)

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 1650:2019
CONTACT TIME	:	5 and 15 minutes
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale Srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale Srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00720

SCOPE

This document specifies a test method and the minimum requirements for yeasticidal or fungicidal activity of chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water or - in the case of ready-to-use-products - with water. 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.
This document applies to products that are used in food, industrial, domestic and institutional areas excluding areas and situations where disinfection is medically indicated and excluding products used on living tissues except those for hand hygiene in the above considered areas.

PRINCIPLE

A sample of the product as delivered and/or diluted with hard water (or water for ready-to-use products) is added to a test suspension of fungi (yeast cells or mould spores) in a solution of an interfering substance. The mixture is maintained at the chosen test temperature for the adopted contact time. At the end of this contact time, an aliquot is taken, and the yeasticidal and/or fungicidal activity in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used. The numbers of surviving yeasts in each sample are determined and the reduction is calculated.
The test is performed using only the vegetative cells of *Candida albicans* (yeasticidal activity) and the spores of *Aspergillus brasiliensis* (fungicidal activity) as test organisms.

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

TEST CONDITIONS

1. The following procedure was performed in water bath at 20 °C
2. The test product was tested at 5 and 15 minutes contact time
3. Interfering substance: A final concentration of 0.3 g/L bovine albumin was used for testing (clean conditions).
4. Neutralization Method used: Dilution neutralization.
5. Neutralizer used: LPT Dilution Broth containing polysorbate 80.
6. According to EN 1650:2019, products shall be tested at a minimum of three different concentrations to include one concentration in the active range and one concentration in the non-active range. In this test product was tested: Undiluted (80%), 50%, 1%

TEST MICROORGANISMS

Candida albicans	ATCC 10231
Aspergillus brasiliensis	ATCC 16404

FUNGICIDAL ACTIVITY FOR GENERAL PURPOSES

The product shall be deemed to have passed the EN 1650 standard if it demonstrates in a valid test a reduction of at least a 4 lg under the adopted test conditions with the chosen interfering substance simulating clean or dirty conditions defined by this European Standard when the test organisms are Candida albicans and Aspergillus brasiliensis.

YEASTICIDAL ACTIVITY FOR GENERAL PURPOSES

The product shall be deemed to have passed the EN 1650 standard (yeasticidal activity) if it demonstrates in a valid test a reduction of at least a 4 lg within the adopted test conditions with the chosen interfering substance simulating clean or dirty conditions defined by this European Standard when the test organism is Candida albicans.

ASSAY ACCEPTANCE CRITERIA

1. Test Suspension (N) is between 1.5 to 5.0 X 10^7 CFU per mL (7.17≤ log No ≤7.70).
2. No (N/10) is between 1.5 to 5.0 X 10^6 CFU per mL (6.17 ≤ log No ≤ 6.70).
3. Validation Suspension=Nv is between 3.0 x 10^2 and 1.6 x 10^3.
4. Nvo (Nv/10) is between 30 and 160.
5. Na is the number of survivors (cells) per ml in the test mixture at the end of contact time.
6. R (log reduction) = No - Na
7. Average recovery values for the experimental conditions control (A) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
8. Average recovery values for the Neutralizer control (B) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
9. Average recovery values for the Method Validation control (C) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
10. Control of weighted mean counts. Quotient is not lower than 5 and not higher than 15

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 for 5 years.

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TEST RESULTS FOR *Candida albicans* (YEASTICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	3.14E+07
10^{-6}	29	34		
10^{-7}	3	3	log N	7.50
			No (N/10)	3.14E+06
			log No	6.50
			6,17 < = logNo < = 6,70	**Yes**

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) undiluted Product conc.: (80%)		
VC 1	69	**x mean**	VC 1	72	**x mean**	VC 1	70	**x mean**	VC 1	66	**x mean**
VC 2	74	**71.5**	VC 2	75	**73.5**	VC 2	75	**72.5**	VC 2	74	**70**
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 or Nvo/1000? **Yes**			x mean of C is > 0,5*x mean of Nvo? **Yes**		

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	6.50	> 4.35	≥4	**PASS TEST**
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	6.50	> 4.35	≥4	**PASS TEST**
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	6.50	< 1.98	≥4	**FAILS TEST**
		10^{-1}	> 330	> 330							

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A: 1 Antigonis str, 14451, Athens, Greece
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F: (+30) 210 2934606 | www.qacslab.com

TEST RESULTS FOR *Aspergillus brasiliensis* (FUNGICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	1.82E+07
10^{-6}	17	19		
10^{-7}	2	2	log N	7.26
			No (N/10)	1.82E+06
			log No	6.26
			6,17 < = logNo < = 6,70	**Yes**

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) undiluted Product conc.: (80%)		
VC 1	36	**x mean**	VC 1	39	**x mean**	VC 1	41	**x mean**	VC 1	40	**x mean**
VC 2	42	**39**	VC 2	40	**39.5**	VC 2	44	**42.5**	VC 2	32	**36**
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 or Nvb/1000? **Yes**			x mean of C is > 0,5*x mean of Nvo? **Yes**		

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
undiluted (80%)	15 min	10^{0}	19	16	18	175	2.24	6.26	4.02	≥4	**PASS TEST**
		10^{-1}	2	3							
50%	15 min	10^{0}	> 165	> 165	> 1650	> 16500	> 4.22	6.26	< 2.04	≥4	**FAILS TEST**
		10^{-1}	> 165	> 165							
1%	15 min	10^{0}	> 165	> 165	> 1650	> 16500	> 4.22	6.26	< 2.04	≥4	**FAILS TEST**
		10^{-1}	> 165	> 165							

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

CONCLUSION

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 1650:2019
CONTACT TIME	:	5 and 15 minutes
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale Srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale Srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00720

METHODOLOGY ABSTRACT

A test suspension of fungi is tested against a product test solution at three concentrations with the presence of interfering substance. The mixture is maintained at 20 °C for 5 minutes for *Candida albicans* and 15 minutes for *Aspergillus brasiliensis*. At the end of this contact time, an aliquot is taken, and the fungicidal and/or yeasticidal activity in this portion is immediately neutralized or suppressed. The numbers of surviving fungi in each sample are determined and the reduction is calculated.

RESULT

The product under test: "Disinfettante Superfici" demonstrated yeasticidal activity (≥ 4 log reduction) according to EN 1650:2019, under clean conditions for 5 minutes contact time, at 20 ± 1 °C, when tested at product concentration:

Undiluted (80%) using as test organism the reference strains: *Candida albicans*.

The product under test: "Disinfettante Superfici" demonstrated fungicidal activity (≥ 4 log reduction) according to EN 1650:2019, under clean conditions for 15 minutes contact time, at 20 ± 1 °C, when tested at product concentration:

Undiluted (80%) using as test organism the reference strains: *Aspergillus brasiliensis*.

For the QACS Ltd Laboratory,

QACS Laboratories
1 Antigonis str 145 51 Metamorfossi Greece
VAT no EL 998709411, email: info@qacs.gr
Tel +30-2102934745 fax +30-210 2934606
www. qacs.gr

Signature date: 30/09/2020
Lagiopoulos Giorgos
Agronomist-Food Technologist M.Sc.
Study Manager

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

STUDY SUMMARY / ABSTRACT

SUSPENSION TEST ACCORDING TO EN 1650:2019

Chemical disinfectants and antiseptics – evaluation of fungicidal and/or yeasticidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (Phase 2 step 1)

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 1650:2019
CONTACT TIME	:	5 and 15 minutes
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale Srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale Srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00720

TEST MICROORGANISMS

Candida albicans	ATCC 10231
Aspergillus brasiliensis	ATCC 16404

RESULT

The product under test: “Disinfettante Superfici” demonstrated yeasticidal activity (≥ 4 log reduction) according to EN 1650:2019, under clean conditions for 5 minutes contact time, at 20 ± 1 °C, when tested at product concentration:

Undiluted (80%) using as test organism the reference strains: *Candida albicans*.

The product under test: “Disinfettante Superfici” demonstrated fungicidal activity (≥ 4 log reduction) according to EN 1650:2019, under clean conditions for 15 minutes contact time, at 20 ± 1 °C, when tested at product concentration:

Undiluted (80%) using as test organism the reference strains: *Aspergillus brasiliensis*.

End of Test Report

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

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STUDY REPORT

2020-7887/20 23 00721

Disinfettante Superfici

SUSPENSION TEST
ACCORDING TO EN 13727:2012+A2:2015
(Phase 2 step 1)

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)

SEPTEMBER 2020

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

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 2020-7887/20 23 00721

SUSPENSION TEST ACCORDING TO EN 13727:2012+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)

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13727:2012+A2:2015
CONTACT TIME	:	5 minutes
DILUTIONS	:	Undiluted (80%), 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00721

SCOPE

This European Standard specifies a test method and the minimum requirements for bactericidal activity of chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water, or - in the case of ready-to-use products - with water. Products can only be tested at a concentration of 80 % or less (97 % with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.
This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, surgical handrub, surgical handwash, instrument disinfection by immersion, and surface disinfection by wiping, spraying, flooding or other means.
This European Standard applies to areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care, for example:
— in hospitals, in community medical facilities and in dental institutions;
— in clinics of schools, of kindergartens and of nursing homes;
and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patients.

PRINCIPLE

A sample of the product as delivered and/or diluted with hard water (or water for ready-to-use products) is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at one of the temperatures for the adopted contact time. At the end of this contact time, an aliquot is taken; the bactericidal and/or the bacteriostatic action in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used. The numbers of surviving bacteria in each sample are determined and the reduction is calculated. Handwash products are always prediluted with hard water. The resulting solution is regarded as a ready-to-use product.

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 CONDITIONS

1. Product type: Surface Disinfection.
2. The following procedure was performed in water bath at 20 °C.
3. The test product was tested at 5 minutes contact time.
4. Interfering substance: A final concentration of 0.3g/L bovine albumin was used for testing (clean conditions).
5. Neutralization Method used: Dilution neutralization.
6. Neutralizer used: LPT Dilution Broth containing polysorbate 80.
7. According to EN 13727, products shall be tested at a minimum of three different concentrations to include one concentration in the active range and one concentration in the non-active range. In this case the product was tested: Undiluted, 50% 1%.

TEST ORGANISMS

Pseudomonas aeruginosa	NCIMB 10421
Staphylococcus aureus	ATCC 6538
Enterococcus hirae	NCIMB 8192

BACTERICIDAL ACTIVITY FOR SURFACE DISINFECTION PRODUCTS

The product shall be deemed to have passed the EN 13727 standard if it demonstrates in a valid test for surface disinfection products at least a 5 lg reduction within max. 5 min (or between 6 and 60 min for products used on surfaces which do not require an action within 5 min or shorter at) min 4 °C and max 30 °C with the chosen interfering substance (clean or dirty conditions) under the conditions defined by this standard when the test organisms are Pseudomonas aeruginosa, Staphylococcus aureus and Enterococcus hirae.

ASSAY ACCEPTANCE CRITERIA

1. Test Suspension (N) is between 1.5 to 5.0 X 10^8 CFU per mL ($8.17 \leq \log N \leq 8.70$)
2. No (N/10) is between 1.5 to 5.0 X 10^7 CFU per mL ($7.17 \leq \log No \leq 7.70$)
3. Validation Suspension=Nv is between 3.0 x 10^2 and 1.6 x 10^3.
4. Neutralizer control= N_{VB} is between 3.0 x 10^4 and 1.6 x 10^5.
5. N_{VO} (Nv/10) is between 30 and 160.
6. Na is the number of survivors (cells) per ml in the test mixture at the end of contact time.
7. R (log reduction) = No - Na
8. Average recovery values for the experimental conditions control (A) were equal to or greater than 0.5 times the Validation Suspension (Nvo).
9. Average recovery values for the Neutralizer control (B) were equal to or greater than 0.5 times the Validation Suspension (Nvo).
10. Average recovery values for the Method Validation control (C) were equal to or greater than 0.5 times the Validation Suspension (Nvo).
11. Control of weighted mean counts. Quotient is not lower than 5 and not higher than 15.

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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* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	2.03E+08
10^{-6}	194	213		
10^{-7}	21	19	log N	8.31
			No (N/10)	2.03E+07
			log No	7.31
			7,17 < = logNo < = 7,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: undiluted (80%)		
VC 1	44	x mean	VC 1	42	x mean	VC 1	41	x mean	VC 1	45	x mean
VC 2	49	46.5	VC 2	37	39.5	VC 2	46	43.5	VC 2	49	47
30<x mean of Nvo < 160?			x mean of A is > 0,5*x mean of Nvo?			x mean of B is > 0,5*x mean of Nvo or Nvb/1000?			x mean of C is > 0,5*x mean of Nvo?		
Yes			Yes			Yes			Yes		

Validation suspension (Nvb)		
VC 1	39	x mean
VC 2	46	42.5
30<x mean of Nvb < 160?		Yes

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.31	> 5.16	≥5	PASS TEST
		10^{-1}	0	0							
50%	5 min	10^{0}	4	6	< 14	< 140	< 2.15	7.31	> 5.16	≥5	PASS TEST
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.31	< 2.79	≥5	FAILS TEST
		10^{-1}	> 330	> 330							

QACS Ltd.
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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 *Staphylococcus aureus* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	2.32E+08
10^{-7}	24	22		
10^{-8}	2	3	log N	8.37
			No (N/10)	2.32E+07
			log No	7.37
			7,17 < = logNo < = 7,70	**Yes**

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: undiluted (80%)		
VC 1	48	x mean	VC 1	49	x mean	VC 1	56	x mean	VC 1	61	x mean
VC 2	45	**46.5**	VC 2	58	**53.5**	VC 2	54	**55**	VC 2	54	**57.5**
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 or NVB/1000?		**Yes**	x mean of C is > 0,5*x mean of Nvo?		**Yes**

Validation suspension (NVB)		
VC 1	52	x mean
VC 2	45	**48.5**
30<x mean of NVB < 160?		**Yes**

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.37	> 5.22	≥5	**PASS TEST**
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.37	> 5.22	≥5	**PASS TEST**
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.37	< 2.85	≥5	**FAILS TEST**
		10^{-1}	> 330	> 330							

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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 *Enterococcus hirae* (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	3.36E+08
10^{-7}	31	36		
10^{-8}	4	3	log N	8.53
			No (N/10)	3.36E+07
			log No	7.53
			7,17 < = logNo < = 7,70	**Yes**

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: undiluted (80%)		
VC 1	79	**x mean**	VC 1	82	**x mean**	VC 1	84	**x mean**	VC 1	79	**x mean**
VC 2	84	**81.5**	VC 2	80	**81**	VC 2	72	**78**	VC 2	80	**79.5**
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 or Nvb/1000?		**Yes**	x mean of C is > 0,5*x mean of Nvo?		**Yes**

Validation suspension (Nvb)		
VC 1	76	**x mean**
VC 2	82	**79**
30<x mean of Nvb < 160?		**Yes**

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.53	> 5.38	≥5	**PASS TEST**
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	7.53	> 5.38	≥5	**PASS TEST**
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.53	< 3.01	≥5	**FAILS TEST**
		10^{-1}	> 330	> 330							

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

SUSPENSION TEST ACCORDING TO EN 13727:2012+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)

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13727:2012+A2:2015
CONTACT TIME	:	5 minutes
DILUTIONS	:	Undiluted (80%), 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00721

METHODOLOGY ABSTRACT

A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at temperature θ (°C) and for the chosen contact time t. At the end of this contact time, an aliquot is taken; the bactericidal and/or the bacteriostatic action in this portion is immediately neutralized or suppressed by a validated method. The numbers of surviving bacteria in each sample are determined and the log reduction is calculated.

RESULT

The product under test: "Disinfettante Superfici", demonstrated Bactericidal activity for surface disinfection (> 5 log reduction), according to the EN 13727:2012+A2:2015, at 20±1 °C, under clean conditions for product dilution:

Undiluted (80%) for 5 minutes contact time using as test organisms the reference strains:
Pseudomonas aeruginosa, *Staphylococcus aureus* and *Enterococcus hirae*.

For the QACS Ltd Laboratory,

QACS Laboratories
1 Antigonis str 14451 Metamorfossi Greece
VAT no EL 998709411, email: info@qacs.gr
Tel +30-2102934745 fax +30-210 2934606
www. qacs.gr

Signature date: 30/09/2020
Lagiopoulos Giorgos
Agronomist-Food Technologist M.Sc.
Study Manager

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 13727:2012+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)

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13727:2012+A2:2015
CONTACT TIME	:	5 minutes
DILUTIONS	:	Undiluted (80%), 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00721

METHODOLOGY ABSTRACT

A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at temperature θ (°C) and for the chosen contact time t. At the end of this contact time, an aliquot is taken; the bactericidal and/or the bacteriostatic action in this portion is immediately neutralized or suppressed by a validated method. The numbers of surviving bacteria in each sample are determined and the log reduction is calculated.

RESULT

The product under test: “Disinfettante Superfici”, demonstrated Bactericidal activity for surface disinfection (> 5 log reduction), according to the EN 13727:2012+A2:2015, at 20±1 °C, under clean conditions for product dilution:

Undiluted (80%) for 5 minutes contact time using as test organisms the reference strains:
Pseudomonas aeruginosa, *Staphylococcus aureus* and *Enterococcus hirae*.

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 for 5 years.

End of Test report

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

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STUDY REPORT

2020-7887/20 23 00722

Disinfettante Superfici

SUSPENSION TEST
ACCORDING TO EN 13624:2013
(Phase 2 step 1)

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

SEPTEMBER 2020

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

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 2020-7887/20 23 00722

SUSPENSION TEST ACCORDING TO EN 13624:2013

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

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13624:2013
CONTACT TIME	:	5 and 15 minutes
DILUTIONS	:	Undiluted (80%), 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00722

SCOPE

This European Standard specifies a test method and the minimum requirements for fungicidal or yeasticidal activity of chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water, or - in the case of ready-to-use products - with water. Products can only be tested at a concentration of 80 % or less (97 % with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.
This European Standard applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, surgical handrub, surgical handwash, instrument disinfection by immersion, and surface disinfection by wiping, spraying, flooding or other means.
This European Standard applies to areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care, for example:
— in hospitals, in community medical facilities and in dental institutions;
— in clinics of schools, of kindergartens and of nursing homes;
and may occur in the workplace and in the home. It may also include services such as laundries and kitchens supplying products directly for the patients.

PRINCIBLE

A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test suspension of yeasts in a solution of an interfering substance. The mixture is maintained at the temperature (θ) and and for the chosen contact time (*t*). At the end of this contact time, an aliquot is taken; the yeasticidal action in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used. The numbers of surviving yeasts in each sample are determined and the reduction is calculated. Handwash products are always prediluted with hard water. The resulting solution is regarded as a ready-to-use product.

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 CONDITIONS

1. Product type: Surface Disinfection.
2. The following procedure was performed in water bath at 20 °C.
3. The test product was tested at 5 and 15 minutes contact time.
4. Interfering substance: A final concentration of 0.3g/L bovine albumin was used for testing (clean conditions).
5. Neutralization Method used: Dilution neutralization.
6. Neutralizer used: LPT Dilution Broth containing polysorbate 80.
7. According to EN 13624, products shall be tested at a minimum of three different concentrations to include one concentration in the active range and one concentration in the non-active range. In this case the product was tested: Undiluted, 50% 1%.

TEST MICROORGANISMS

Candida albicans	ATCC 10231
Aspergillus brasiliensis	ATCC 16404

FUNGICIDAL ACTIVITY FOR SURFACE DISINFECTION PRODUCTS

The product shall be deemed to have passed the EN 13624 Standard if it demonstrates in a valid test for surface disinfection products at least a 4 lg reduction within max. 5 min (or between 6 min and 60 min for products used on surfaces which do not require an action within 5 min or shorter) at min. 4 °C and max. 30 °C with the chosen interfering substance (clean or dirty conditions) under the conditions defined by this standard when the test organisms are *Aspergillus brasiliensis* and *Candida albicans*.

ASSAY ACCEPTANCE CRITERIA

1. Test Suspension (N) is between 1.5 to 5.0 X 10^7 CFU per mL ($7.17 \leq \log No \leq 7.70$)
2. No (N/10) is between 1.5 to 5.0 X 10^6 CFU per mL ($6.17 \leq \log No \leq 6.70$)
3. Validation Suspension=Nv is between 3.0 x 10^2 and 1.6 x 10^3.
4. Neutralizer control= N_{VB} is between 3.0 x 10^4 and 1.6 x 10^5.
5. Nvo (Nv/10) is between 30 and 160.
6. Na is the number of survivors (cells) per ml in the test mixture at the end of contact time.
7. R (log reduction) = No - Na
8. Average recovery values for the experimental conditions control (A) were equal to or greater than 0.5 times the Validation Suspension (Nvo)
9. Average recovery values for the Neutralizer control (B) were equal to or greater than 0.5 times the Validation Suspension (Nvo) or N_{VB}/1000.
10. Average recovery values for the Method Validation control (C) were equal to or greater than 0.5 times the Validation Suspension (Nvo)

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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 *Candida albicans* (YEASTICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	3.14E+07
10^{-6}	29	34		
10^{-7}	3	3	log N	7.50
			No (N/10)	3.14E+06
			log No	6.50
			6,17 < = logNo < = 6,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: Undiluted (80%)		
VC 1	69	x mean	VC 1	66	x mean	VC 1	67	x mean	VC 1	65	x mean
VC 2	74	71.5	VC 2	72	69	VC 2	72	69.5	VC 2	72	68.5
30<x mean of Nvo < 160?			x mean of A is >0,5*x mean of Nvo?			x mean of B is >0,5*x mean of Nvo or NvB/1000?			x mean of C is >0,5*x mean of Nvo?		
Yes			Yes			Yes			Yes		

Validation suspension (NvB)		
VC 1	65	x mean
VC 2	72	68.5
30<x mean of NvB < 160?		Yes

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
Undiluted (80%)	5 min	10^{0}	0	0	< 14	< 140	< 2.15	6.50	> 4.35	≥4	PASS TEST
		10^{-1}	0	0							
50%	5 min	10^{0}	0	0	< 14	< 140	< 2.15	6.50	> 4.35	≥4	PASS TEST
		10^{-1}	0	0							
1%	5 min	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	6.50	< 1.98	≥4	FAILS TEST
		10^{-1}	> 330	> 330							

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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 Aspergillus brasiliensis (FUNGICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	1.82E+07
10^{-6}	17	19		
10^{-7}	2	2	log N	7.26
			No (N/10)	1.82E+06
			log No	6.26
			6,17 < = logNo < = 6,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)			Neutralizer control (B)			Method validation (C) Product conc.: Undiluted (80%)		
VC 1	42	x mean	VC 1	40	x mean	VC 1	47	x mean	VC 1	49	x mean
VC 2	40	41	VC 2	46	43	VC 2	42	44.5	VC 2	42	45.5
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 or Nvb/1000?		Yes	x mean of C is > 0,5*x mean of Nvo?		Yes

Validation suspension (Nvb)		
VC 1	44	x mean
VC 2	45	44.5
30<x mean of Nvb < 160?		Yes

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
Undiluted (80%)	15 min	10^{0}	13	21	17.0	170	2.23	6.26	4.03	≥4	PASS TEST
		10^{-1}	1	2							
50%	15 min	10^{0}	> 165	> 165	> 1650	> 16500	> 4.22	6.26	< 2.04	≥4	FAILS TEST
		10^{-1}	> 165	> 165							
1%	15 min	10^{0}	> 165	> 165	> 1650	> 16500	> 4.22	6.26	< 2.04	≥4	FAILS TEST
		10^{-1}	> 165	> 165							

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
SUSPENSION TEST ACCORDING TO EN 13624:2013

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

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13624:2013
CONTACT TIME	:	5 and 15 minutes
DILUTIONS	:	Undiluted (80%), 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00722

METHODOLOGY ABSTRACT

A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test suspension of fungi in a solution of an interfering substance. The mixture is maintained at 20 °C for 5 and 15 minutes. At the end of this contact time, an aliquot is taken, and the fungicidal and/or yeasticidal activity in this portion is immediately neutralized or suppressed. The numbers of surviving fungi in each sample are determined and the reduction is calculated.

RESULT

The product under test: "Disinfettante Superfici" demonstrated yeasticidal activity for surface disinfection (> 4 log reduction) according to EN 13624:2013, at 20±1 °C, under clean conditions for product dilution:
Undiluted (80%) for 5 minutes contact time using as test organism the reference strain: *Candida albicans*.

The product under test: "Disinfettante Superfici" demonstrated fungicidal activity for surface disinfection (> 4 log reduction) according to EN 13624:2013, at 20±1 °C, under clean conditions for product dilution:
Undiluted (80%) for 15 minutes contact time using as test organism the reference strain: *Aspergillus brasiliensis*.

For the QACS Ltd Laboratory,

QACS Laboratories
1 Antigonis str 14451 Metamorfossi Greece
VAT no EL 998709411, email: info@qacs.gr
Tel +30-2102934745 fax +30-210 2934606
www. qacs.gr

Signature date: 30/09/2020
Lagiopoulos Giorgos
Agronomist-Food Technologist M.Sc.
Study Manager

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 13624:2013

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

TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13624:2013
CONTACT TIME	:	5 and 15 minutes
DILUTIONS	:	Undiluted (80%), 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	18/09/2020-21/09/2020
LAB ID	:	2020-7887/20 23 00722

TEST MICROORGANISMS

Candida albicans	ATCC 10231
Aspergillus brasiliensis	ATCC 16404

RESULT

The product under test: “Disinfettante Superfici” demonstrated yeasticidal activity for surface disinfection (> 4 log reduction) according to EN 13624:2013, at 20±1 °C, under clean conditions for product dilution:

Undiluted (80%) for 5 minutes contact time using as test organism the reference strain: *Candida albicans*.

The product under test: “Disinfettante Superfici” demonstrated fungicidal activity for surface disinfection (> 4 log reduction) according to EN 13624:2013, at 20±1 °C, under clean conditions for product dilution:

Undiluted (80%) for 15 minutes contact time using as test organism the reference strain: *Aspergillus brasiliensis*.

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 for 5 years.

End of Test Report

QACS LAB
QUALITY ASSURANCE & CONTROL SYSTEMS

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

STUDY REPORT

2020-7887/20 23 00723

RES PHARMA INDUSTRIALE SRL

Disinfettante Superfici

QUANTITATIVE NON-POROUS SURFACE TEST
ACCORDING TO EN 13697:2015+A1 2019
(phase 2/step2)

Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.
(phase 2, step 2)

SEPTEMBER 2020

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

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

STUDY REPORT 2020-7887/20 23 00723

Quantitative Non-Porous Surface Test According to EN 13697:2015+A1 2019 for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. (phase 2, step 2)

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13697:2015+A1 2019
CONTACT TIME	:	5 minutes
DILUTIONS	:	Undiluted, 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	22/09/2020-24/09/2020
LAB ID	:	2020-7887/20 23 00723

Test Method Principle

A test suspension of bacteria in a solution of interfering substances is inoculated onto a test stainless steel surface and dried. A prepared sample of the product under test is applied in a manner which covers the dried film. The surface is maintained at a specified temperature for a defined period of time. The surface is transferred to a previously validated neutralization medium so that the action of the disinfectant is immediately neutralized. The number of surviving organisms which can be recovered from the surface is determined quantitatively. The number of bacteria on the surface treated with hard water in place of the disinfectant is also determined and the reduction in viable counts attributed to the product is calculated by difference.

Activity on Non-Porous Surfaces for General Purposes

Bactericidal activity on surfaces for general purposes is characterized by the concentration of the tested product for which a 4 log or more reduction in viability is demonstrated under clean or dirty conditions when the test organisms are *Pseudomonas aeruginosa, Staphylococcus aureus, Enterococcus hirae* and *Escherichia coli*.

Test Conditions

1. The test plates were read and recorded after ~ 48 hours incubation time.
2. The following procedure was performed between 18°C ± 1°C and 25 °C ± 1 °C.
3. Interfering substance: A final concentration of 0.3g/L bovine albumin was used (clean conditions according to EN 13697 2015+A1 2019) for all micro-organisms under test.
4. Contact time: 5 minutes for all micro-organisms under test.
5. Incubation temperatures: Bacteria at 37 ° C ± 1 °C.
6. Appearance of product test solution: Homogeneous solution.
7. According to EN 13697 2015+A1 2019, products shall be tested at a minimum of three different concentrations to include one concentration in the active range and one concentration in the non-active range. In this case the product was tested: Undiluted, 50%, 1%.

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

Test Method

Dilution-Neutralization, plate count, pour plate method.

Neutralizer

Neutralizer used: LPT Dilution Broth containing polysorbate 80.

Test Microorganisms

The bactericidal activity is evaluated using the following four strains:

Pseudomonas aeruginosa	NCIMB 10421
Staphylococcus aureus	ATCC 6538
Enterococcus hirae	NCIMB 8192
Escherichia coli	NCIMB 8879

Verification of Methodology

1. Test Suspension (N) for bacteria is between 6,57 ≤ N ≤ 7,10 Log
   (7,57 ≤ N ≤ 8,10 lg for P. aeruginosa under clean conditions)
2. Water control Nc ≥ 6,27 Logs for bacteria
3. Neutralizer control "NC" (verification of the absence of toxicity of the neutralizer) NC - Nc is not greater than ± 0,3 lg
4. Method validation "NT" (dilution-neutralization validation) NT - Nc is not greater than ± 0,3 lg
5. Test "Nd" – determination of microbicidal concentrations
6. The log reduction (R) is expressed in logarithm. R = Nc – Nd
7. Nts (number of cfu remaining on test surface) is less than 100 cfu/ml for active concentrations. If not, the recovery of microorganisms has not been sufficient. For non-active concentrations, Nts may be not countable.

Test Surfaces

Stainless steel discs (2 cm diameter discs) 304 with grade 2b finish on both sides (EN 10088-1). The surfaces are flat made. The surfaces are only used once and subsequently discarded.

Results

Quantitative non-porous surface test, EN 13697 for product under test.
The antimicrobial activity values are shown on the table below:

Microorganisms	Product dilutions			Contact time
	Undiluted	50%	1%	
Pseudomonas aeruginosa	**≥ 4 Pass**	**≥ 4 Pass**	< 4 Fail	5 minutes
Escherichia coli	**≥ 4 Pass**	**≥ 4 Pass**	< 4 Fail	5 minutes
Staphylococcus aureus	**≥ 4 Pass**	**≥ 4 Pass**	< 4 Fail	5 minutes
Enterococcus hirae	**≥ 4 Pass**	**≥ 4 Pass**	< 4 Fail	5 minutes

Results Criteria

The log10 viability reduction should be:
4 log10 or more for bacteria.

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

Conclusion

In accordance with EN 13697:2015+A1 2019, the product under test: "Disinfettante Superfici", possesses bactericidal activity on surfaces in 5 minutes contact time at 20°C under clean conditions at concentration:

Undiluted for referenced strains: *Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus* and *Enterococcus hirae*.

Results authenticity

The study concerned by this report was carried out according to the experimental protocol, under responsibility and quality plan of the QACS Ltd laboratory. All the observations and data recorded during this trial are reported in this study report.

For the QACS Ltd Laboratory

QACS Laboratories
1 Antigonis str, 145 51 Metamorfossi, Greece
VAT no EL 998709411, email: info@qacs.gr
Tel +30-2102934745 fax +30-210 2934606
www. qacs.gr

Signature date: 30/09/2020
Lagiopoulos Giorgos
Agronomist, Food Technologist M.Sc.
Study Manager

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 for 5 years

QACS LAB
QUALITY ASSURANCE & CONTROL SYSTEMS
A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

STUDY REPORT

2020-7887/20 23 00723

Disinfettante Superfici

QUANTITATIVE NON-POROUS SURFACE TEST
ACCORDING TO EN 13697:2015+A1 2019
(phase 2/step2)

STUDY SUMMARY
AND
APPENDICES

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

Study Summary / Abstract

Quantitative Non-Porous Surface Test According to EN 13697:2015+A1 2019 for the evaluation of bactericidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. (phase 2, step 2)

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13697:2015+A1 2019
CONTACT TIME	:	5 minutes
DILUTIONS	:	Undiluted, 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	22/09/2020-24/09/2020
LAB ID	:	2020-7887/20 23 00723

Test Microorganisms

The bactericidal activity is evaluated using the following four strains:

Pseudomonas aeruginosa	NCIMB 10421
Staphylococcus aureus	ATCC 6538
Enterococcus hirae	NCIMB 8192
Escherichia coli	NCIMB 8879

Result

In accordance with EN 13697:2015+A1 2019, the product under test: “Disinfettante Superfici”, possesses bactericidal activity on surfaces in 5 minutes contact time at 20°C under clean conditions at concentration:

Undiluted for referenced strains: *Pseudomonas aeruginosa, Escherichia coli, Staphylococcus aureus* and *Enterococcus hirae*.

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QUALITY ASSURANCE & CONTROL SYSTEMS

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

Appendix No 1: Compiled Raw

Test organisms	Bacterial Test Suspension			Validation Test				Water control : 20°C			Test procedure at concentrations %(V/V)			Test procedure at concentrations %(V/V)			Test procedure at concentrations %(V/V)		
				NT			NC	Nc			undiluted		5min	50%		5min	1%		5min
Pseudomonas aeruginosa				10-3			10-3	10-3	>330	>330	10^{-0}	0	0	10^{-0}	41	39	10^{-0}	>330	>330
	10-7	252	264	10-4	>330	>330	10-4	>330	10-4	>330	>330	10-4	>330	>330	10-1	0	0	10-1	5	4	10-1	>330	>330
	10-8	28	27	10-5	31	39	10-5	34	32	10-5	29	31	10-2	0	0	10-2	0	0	10-2	330	330
NCIMB 10421	10-9	3	3	10-6	4	3	10-6	4	4	10-6	3	3	Nd	<0.1		Nd	2.60		Nd	5.52	
	N	7.81		NT	7.54		NC	7.52		Nc	7.48		Nts	0		Nts	26		Nts	>100	
										Nts	>100		**R =**	**7.38**		**R =**	**4.88**		**R =**	**1.96**	
	7,57 ≤ N ≤ 8,10		VALID	**NT-Nc<0.3lg**		VALID	**NC-Nc<0.3lg**		VALID	Nc ≥ 6.27		VALID	PASS = R ≥ 4 log		PASS	PASS = R ≥ 4 log		PASS	PASS = R ≥ 4 log		FAIL
Staphylococcus aureus								10-3	>330	>330	10-0	0	0	10-0	4	6	10-0	>330	>330
	10-6	231	239	10-3	259	264	10-3	>300	>300	10-4	36	41	10-1	0	0	10-1	0	0	10-1	>330	>330
	10-7	21	24	10-4	24	29	10-4	32	36	10-5	4	3	10-2	0	0	10-2	0	0	10-2	330	330
ATCC 6538	10-8	3	3	10-5	3	3	10-5	4	4	10-6			Nd	<0.1		Nd	1.70		Nd	5.52	
	N	6.76		NT	6.42		NC	6.53		Nc	6.59		Nts	0		Nts	2		Nts	>100	
										Nts	>100		**R =**	**6.49**		**R =**	**4.89**		**R =**	**1.07**	
	6,57 ≤ N ≤ 7,10		VALID	**NT-Nc<0.3lg**		VALID	**NC-Nc<0.3lg**		VALID	Nc ≥ 6.27		VALID	PASS = R ≥ 4 log		PASS	PASS = R ≥ 4 log		PASS	PASS = R ≥ 4 log		FAIL
Escherichia coli								10-3	>330	>330	10-0	0	0	10^{-0}	19	24	10^{-0}	>330	>330
	10-6	>330	>330	10-3	>330	>330	10-3	>330	>330	10-4	54	59	10-1	0	0	10-1	2	3	10-1	>330	>330
	10-7	34	40	10-4	55	62	10-4	51	42	10-5	5	6	10-2	0	0	10-2	0	0	10-2	330	330
NCIMB 8879	10-8	4	3	10-5	5	6	10-5	4	4	10-6			Nd	<0.1		Nd	2.40		Nd	5.52	
	N	6.96		NT	6.77		NC	6.67		Nc	6.75		Nts	0		Nts	6		Nts	>100	
										Nts	>100		**R =**	**6.65**		**R =**	**4.35**		**R =**	**1.23**	
	6,57 ≤ N ≤ 7,10		VALID	**NT-Nc<0.3lg**		VALID	**NC-Nc<0.3lg**		VALID	Nc ≥ 6.27		VALID	PASS = R ≥ 4 log		PASS	PASS = R ≥ 4 log		PASS	PASS = R ≥ 4 log		FAIL
Enterococcus hirae								10-3	>330	>330	10-0	0	0	10-0	0	0	10-0	>330	>330
	10-6	>330	>330	10-3	>330	>330	10-3	>330	>330	10-4	31	34	10-1	0	0	10-1	0	0	10-1	>330	>330
	10-7	31	36	10-4	30	29	10-4	32	36	10-5	3	4	10-2	0	0	10-2	0	0	10-2	330	330
NCIMB 8192	10-8	4	4	10-5	3	3	10-5	3	4	10-6			Nd	<0.1		Nd	<0.1		Nd	5.52	
	N	6.93		NT	6.47		NC	6.53		Nc	6.51		Nts	0		Nts	0		Nts	>100	
										Nts	>100		**R =**	**6.41**		**R =**	**6.41**		**R =**	**0.99**	
	6,57 ≤ N ≤ 7,10		VALID	**NT-Nc<0.3lg**		VALID	**NC-Nc<0.3lg**		VALID	Nc ≥ 6.27		VALID	PASS = R ≥ 4 log		PASS	PASS = R ≥ 4 log		PASS	PASS = R ≥ 4 log		FAIL
Verification of Methodology	6,57 ≤ N ≤ 7,10 Logs for bacteria (7,57 ≤ N ≤ 8,10 lg for P.aeruginosa under clean conditions)							NC - Nc is not greater than ± 0,3 lg						Nts is less than 100 cfu/ml for active concentrations							
	5,57 ≤ N ≤ 6,10 Logs for fungi (6,57 ≤ N ≤ 7,10 lg for C.albicans under clean conditions)							NT - Nc is not greater than ± 0,3 lg						If not, the recovery of microorganisms has not been sufficient.							
	R = Nc – Nd, PASS ≥ 4 log for bacteria & ≥ 3 log for fungi													For non-active concentrations, Nts may be not countable							

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Appendix No 2: Tables

Table no 1: Microbial Suspensions

Test microorganisms	**Microbial test suspension**
	N in log 10 values
Pseudomonas aeruginosa NCIMB 10421	7.81
Staphylococcus aureus ATCC 6538	6.76
Escherichia coli NCIMB 8879	6.96
Enterococcus hirae NCIMB 8192	6.93

Table no 2: Validation of the neutralization

Test microorganisms	**Validation test:** log 10 values	
	NT	NC
Pseudomonas aeruginosa NCIMB 10421	7.54	7.52
Staphylococcus aureus ATCC 6538	6.42	6.53
Escherichia coli NCIMB 8879	6.77	6.67
Enterococcus hirae NCIMB 8192	6.47	6.53

Table no 3: Assays

Test microorganisms	N	Nc	Log reduction (R)		
	Inoculum	Water control	Product dilution undiluted	Product dilution 50%	Product dilution 1%
Pseudomonas aeruginosa NCIMB 10421	7.81	7.48	7.38	4.88	1.96
Staphylococcus aureus ATCC 6538	6.76	6.59	6.49	4.89	1.07
Escherichia coli NCIMB 8879	6.96	6.75	6.65	4.35	1.23
Enterococcus hirae NCIMB 8192	6.93	6.51	6.41	6.41	0.99

Results refer to the sample as received and analyzed on the period specified above.
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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 for 5 years.

End of Test Report

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STUDY REPORT

2020-7887/20 23 00724

RES PHARMA INDUSTRIALE SRL

Disinfettante Superfici

QUANTITATIVE NON-POROUS SURFACE TEST
ACCORDING TO 13697:2015+A1 2019
(fungicidal activity-phase 2/step2)

Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.
(phase 2, step 2)

SEPTEMBER 2020

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

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

STUDY REPORT 2020-7887/20 23 00724

Quantitative Non-Porous Surface Test According to EN 13697:2015+A1 2019 for the evaluation of fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. (phase 2, step 2)

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13697:2015+A1 2019
CONTACT TIME	:	5 and 15 minutes
DILUTIONS	:	Undiluted, 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	22/09/2020-24/09/2020
LAB ID	:	2020-7887/20 23 00724

Test Method Principle

A test suspension of fungi in a solution of interfering substances is inoculated onto a test stainless steel surface and dried. A prepared sample of the product under test is applied in a manner which covers the dried film. The surface is maintained at a specified temperature for a defined period of time. The surface is transferred to a previously validated neutralization medium so that the action of the disinfectant is immediately neutralized. The number of surviving organisms which can be recovered from the surface is determined quantitatively. The number of fungi on the surface treated with hard water in place of the disinfectant is also determined and the reduction in viable counts attributed to the product is calculated by difference.

Activity on Non-Porous Surfaces for General Purposes

- Fungicidal activity on surfaces for general purposes is characterized by the concentration of the tested product for which a 3 log or more reduction in viability is demonstrated under clean or dirty conditions, when the test organisms are *Candida albicans* and *Aspergillus brasiliensis*
- Yeasticidal activity on surfaces for general purposes is characterized by the concentration of the tested product for which a 3 log or more reduction in viability is demonstrated under clean or dirty conditions, when the test organisms are *Candida albicans*.

Test Conditions

1. The test plates were read and recorded after ~ 48 hours incubation time.
2. The following procedure was performed between 18°C ± 1°C and 25 °C ± 1 °C.
3. Interfering substance: A final concentration of 0.3g/L bovine albumin was used (clean conditions according to EN 13697 2015+A1 2019) for all micro-organisms under test.
4. Contact time: 5 for *Candida albicans* and 15 minutes for *Aspergillus brasiliensis*.
5. Incubation temperatures: Fungi at 30 °C ± 1 °C.
6. Appearance of product test solution: Homogeneous solution.
7. According to EN 13697 2015+A1 2019, products shall be tested at a minimum of three different concentrations to include one concentration in the active range and one concentration in the non-active range. In this case the product was tested: Undiluted, 50%, 1%.

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Test Method

Dilution-Neutralization, plate count, pour plate method.

Neutralizer

Neutralizer used: LPT Dilution Broth containing polysorbate 80

Test Microorganisms

The yeasticidal-fungicidal activity is evaluated using the following two strains:

Candida albicans	ATCC 10231
Aspergillus brasiliensis	ATCC 16404

Verification of Methodology

1. Test Suspension (N) for fungi is between 5,57 ≤ N ≤ 6,10 Logs
2. Test Suspension (N) for yeasts is between 5,57 ≤ N ≤ 6,10 Logs (6,57 ≤ N ≤ 7,10 lg for C. albicans under clean conditions)
3. Water control Nc ≥ 5,27 Logs for fungi
4. Neutralizer control "NC" (verification of the absence of toxicity of the neutralizer) NC - Nc is not greater than ± 0,3 lg
5. Method validation "NT" (dilution-neutralization validation) NT - Nc is not greater than ± 0,3 lg
6. Test "Nd" – determination of microbicidal concentrations
7. The log reduction (R) is expressed in logarithm. R = Nc – Nd
8. Nts (number of cfu remaining on test surface) is less than 100 cfu/ml for active concentrations. If not, the recovery of microorganisms has not been sufficient. For non-active concentrations, Nts may be not countable.

Test Surfaces

Stainless steel discs (2 cm diameter discs) 304 with grade 2b finish on both sides (EN 10088-1). The surfaces are flat made. The surfaces are only used once and subsequently discarded.

Results

Quantitative non-porous surface test, EN 13697 for product under test.
The antimicrobial activity values are shown on the table below:

Microorganisms	Product dilutions			Contact time
	Undiluted	50%	1%	
Candida albicans	**≥3 Pass**	**≥3 Pass**	<3 Fail	5 minutes
Aspergillus brasiliensis	**≥3 Pass**	<3 Fail	<3 Fail	15 minutes

Results Criteria

The log10 viability reduction should be:
3 log10 or more for fungi.

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F: (+30) 210 2934606 | www.qacslab.com

Conclusion

In accordance with EN 13697:2015+A1 2019, the product under test: "Disinfettante Superfici", possesses yeasticidal activity on surfaces in 5 minutes contact time at 20°C under clean conditions at concentration:

Undiluted using as test organisms the reference strains: *Candida albicans*.

In accordance with EN 13697:2015+A1 2019, the product under test: "Disinfettante Superfici", possesses fungicidal activity on surfaces in 15 minutes contact time at 20°C under clean conditions at concentration:

Undiluted using as test organisms the reference strains: *Aspergillus brasiliensis*.

Results authenticity

The study concerned by this report was carried out according to the experimental protocol, under responsibility and quality plan of the QACS Ltd laboratory. All the observations and data recorded during this trial are reported in this study report.

For the QACS Ltd Laboratory

QACS Laboratories
1 Antigonis str 145 51 Metamorfossi Greece
VAT no EL 998709411, email: info@qacs.gr
Tel +30-2102934745 fax +30-210 2934606
www. qacs.gr

Signature date: 30/09/2020
Lagiopoulos Giorgos
Agronomist, Food Technologist M.Sc.
Study Manager

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 for 5 years

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A: 1 Antigonis str, 14451, Athens, Greece
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STUDY REPORT

2020-7887/20 23 00724

Disinfettante Superfici

QUANTITATIVE NON-POROUS SURFACE TEST
ACCORDING TO EN 13697:2015+A1 2019
(fungicidal activity-phase 2/step2)

STUDY SUMMARY
AND
APPENDICES

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Study Summary / Abstract

Quantitative Non-Porous Surface Test According to EN 13697:2015 for the evaluation of fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. (phase 2, step 2)

PRODUCT NAME	:	Disinfettante Superfici
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 70.4% p/p
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	200728_01
METHOD	:	EN 13697:2015+A1 2019
CONTACT TIME	:	5 and 15 minutes
DILUTIONS	:	Undiluted, 50%, 1%
STUDY SPONSOR	:	INT.E.G.RA. srl
PRODUCT SUPPLIER	:	Res Pharma Industriale srl
PRODUCT MANUFACTURER	:	Res Pharma Industriale srl
RECEIPT DATE	:	05/08/2020
STUDY PERIOD	:	22/09/2020-24/09/2020
LAB ID	:	2020-7887/20 23 00724

Test Microorganisms

The yeasticidal-fungicidal activity is evaluated using the following two strains:

Candida albicans	ATCC 10231
Aspergillus brasiliensis	ATCC 16404

Result

In accordance with EN 13697:2015+A1 2019, the product under test: “Disinfettante Superfici”, possesses yeasticidal activity on surfaces in 5 minutes contact time at 20°C under clean conditions at concentration:

Undiluted using as test organisms the reference strains: *Candida albicans*.

In accordance with EN 13697:2015+A1 2019, the product under test: “Disinfettante Superfici”, possesses fungicidal activity on surfaces in 15 minutes contact time at 20°C under clean conditions at concentration:

Undiluted using as test organisms the reference strains: *Aspergillus brasiliensis*.

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Appendix No 1: Compiled Raw

Test organisms	Fungal Test Suspension			Validation Test						Water control : 20°C			Test procedure at concentrations %(V/V)			Test procedure at concentrations %(V/V)			Test procedure at concentrations %(V/V)		
				NT			NC			Nc			undiluted			50%			1%		
Candida albicans										10-3	>330	>330	10^{-0}	0	0	10^{-0}	0	0	10^{-0}	>330	>330
	10-6	>330	>330	10-3	>330	>330	10-3	>330	>330	10-4	51	60	10-1	0	0	10-1	0	0	10-1	>330	>330
	10-7	31	29	10-4	34	39	10-4	39	45	10-5	5	4	10-2	0	0	10-2	0	0	10-2	330	330
ATCC 10231	10-8	2	3	10-5	4	4	10-5	5	4	10-6			Nd	< 0.1		Nd	< 0.1		Nd	5.52	
5 minutes	N	6.87		NT	6.56		NC	6.62		Nc	6.74		Nts	0		Nts	0		Nts	>100	
										Nts	>100		**R =**	**6.64**		**R =**	**6.64**		**R =**	**1.23**	
	6,57 ≤ N ≤ 7,10		VALID	**NT-Nc<0.3lg**		VALID	**NC-Nc<0.3lg**		VALID	Nc ≥ 5,27		VALID	PASS = R ≥ 3 log		PASS	PASS = R ≥ 3 log		PASS	PASS = R ≥ 3 log		FAIL
Aspergillus brasiliensis				10-2	>165	>165	10-2	>165	>165	10-2			10^{-0}	20	18	10^{-0}	>165	>165	10^{-0}	>165	>165
	10-5	>165	>165	10-3	21	25	10-3	26	22	10-3	40	47	10-1	2	3	10-1	>165	>165	10-1	>165	>165
	10-6	20	17	10-4	3	2	10-4	3	3	10-4	5	3	10-2	0	0	10-2	165	165	10-2	165	165
ATCC 16404	10-7	2	2	10-5			10-5			10-5	0	0	Nd	2.28		Nd	5.22		Nd	5.22	
15 minutes	N	5.67		NT	5.36		NC	5.38		Nc	5.64		Nts	54		Nts	>100		Nts	>100	
										Nts	>100		**R =**	**3.36**		**R =**	**0.42**		**R =**	**0.42**	
	5.57 ≤ N ≤ 6.10		VALID	**NT-Nc<0.3lg**		VALID	**NC-Nc<0.3lg**		VALID	Nc ≥ 5,27		VALID	PASS = R ≥ 3 log		PASS	PASS = R ≥ 3 log		FAIL	PASS = R ≥ 3 log		FAIL
Verification of Methodology	6,57 ≤ N ≤ 7,10 Logs for bacteria (7,57 ≤ N ≤ 8,10 lg for P.aeruginosa under clean conditions)									NC - Nc is not greater than ± 0,3 lg						Nts is less than 100 cfu/ml for active concentrations					
	5,57 ≤ N ≤ 6,10 Logs for fungi (6,57 ≤ N ≤ 7,10 lg for C.albicans under clean conditions)									NT - Nc is not greater than ± 0,3 lg						If not, the recovery of microorganisms has not been sufficient.					
	R = Nc – Nd, PASS ≥ 4 log for bacteria & ≥ 3 log for fungi															For non-active concentrations, Nts may be not countable					

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Appendix No 2: Tables

Table no 1: Microbial Suspensions

Test microorganisms	Microbial test suspension
	N in log 10 values
Candida albicans ATCC 10231	6.87
Aspergillus brasiliensis ATCC 16404	5.67

Table no 2: Validation of the neutralization

Test microorganisms	Validation test: log 10 values	
	NT	NC
Candida albicans ATCC 10231	6.56	6.62
Aspergillus brasiliensis ATCC 16404	5.36	5.38

Table no 3: Assays

Test microorganisms	N	Nc	Log reduction (R)		
	Inoculum	Water control	Product dilution undiluted	Product dilution 50%	Product dilution 1%
Candida albicans ATCC 10231	6.87	6.74	6.64	6.64	1.23
Aspergillus brasiliensis ATCC 16404	5.67	5.64	3.36	0.42	0.42

Results refer to the sample as received and analyzed on the period specified above.
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The study report and raw data will be stored by the laboratory for 5 years.

End of Test Report

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Res Pharma Industriale srl

STUDY REPORT

2020 – 7887 / 20 23 00725

Disinfettante superfici

ANTIVIRAL ACTIVITY ACCORDING TO THE STANDARD EN 14476

OF THE PRODUCT "DISINFETTANTE SUPERFICI" AGAINST POLIOVIRUS,

ADENOVIRUS, MURINE NOROVIRUS AND INFLUENZA VIRUS A(H1N1) pdm09

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PRODUCT IDENTIFICATION

Product code/name	Disinfettante superfici
Study Sponsor	Res Pharma Industriale srl
Date of receipt	September 01st, 2020
Product Appearance	Clear, colorless liquid
Storage	At room temperature (20°C)
Concentration used in the test	97.0% of the received product
Active compounds	Ethanol 70.4 % v/v

EXPERIMENTAL CONDITIONS

Test Method	**14476:2013+A2:2019: "Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase2/Step 1)"**
Test period	September 2020
Strains of viruses	Adenovirus type 5 (ATCC VR-5) Poliovirus 1 Sabin strain, LSc-2ab (WHO) Murine Norovirus (Strain S99 Berlin) Influenza virus A(H1N1) pdm09 (The vaccine strain: A/Brisbane/02/2018)
Cell lines	Human epithelial type 2 (Hep-2) cells Human Rhabdomyosarcoma cells (RD) RAW 264.7 macrophage (ATCC) Madin-Darby canine kidney (MDCK)
Culture medium	DMEM (Dulbecco's Minimal Essential Medium)
Contact time	5 min
Test temperature	Water bath, 20±1°C
Interfering substance	BSA 0.3 g/L (clean conditions)
Inactivation process	Dilution 1/10 in ice cold maintenance medium
Technical supervisor	Pogka Vasiliki, Ph.D, Antonios Kalliaropoulos
Facilities	BSL-2 facility, Public Health Laboratories, Hellenic Pasteur Institute.

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1. Principle of the test

A 97% dilution of the product "Disinfettante superfici " was added to a test suspension of titrated viruses in bovine serum albumin solutions of 0.3 g/L (clean conditions). The mixtures were maintained at 20°C for 5 min. At the end of contact time, an aliquot was taken and the virucidal activity was suppressed by dilutions in ice-cold maintenance medium. The dilutions were then inoculated onto cell monolayers in 96-well culture plates for the titration of the remaining viruses. The titers of the viruses expressed in $TCID_{50}$ values, after 5-days incubation, were determined and expressed in log scale. Reduction of the viruses' infectivity was calculated from the differences of the log virus titers before (control) and after treatment with the product. According to the EN 14476 standard a product has antiviral activity when the reduction of the virus is at least 4 log.

2. Titration of the test viruses

The antiviral activity of the product was tested against three virus strains proposed by the Standard EN 14476, Adenovirus type 5, Poliovirus type 1 and Murine norovirus as well as against the influenza A(H1N1) pdm09. The viruses were propagated in the appropriate cell culture system to produce a high titer: Hep-2 monolayers for adenovirus titration, RD for poliovirus, RAW cell monolayers for M. norovirus titration and MDCK cell monolayers for influenza virus titration. Each virus was tested in decimal dilutions 10^{-3} up to 10^{-10}. Each dilution was inoculated 10x in wells of 96-well culture plates with the appropriate cell monolayer. The infected cells were incubated at 37°C in a 5% CO_2 atmosphere for 5 days. The Tissue Culture Infectious Dose ($TCID_{50}$) i.e. the infection dose of a virus suspension inducing a Cytopathic Effect (CPE) in 50% of cell culture units was estimated by the end-point Spearman-Karber method:

$$\textbf{Log } TCID_{50} = L - d(S - 0.5),$$

where *L* is the highest virus concentration used, *d* is the log difference of dilutions, *S* is the sum of % affected (CPE) at each dilution.

The standard error was calculated as follows:

$$\sigma_m^2 = d_f^2 \Sigma p_i(1-p_i)/(n_i-1)$$

where *d* is the logarithm of dilution factor, p_i was the observed reaction rate, *n* the number of test objects per dilution and σ_m standard error of the logarithmic titer.

CPE results of each virus on the appropriate cell line are presented in tables 1a, 1b, 1c and 1d respectively.

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Table 1a. Titration of the adenovirus on Hep-2 cells

Virus dilutions	CPE in cell culture wells of culture plate (*)										Cell control	
10^{-3}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-4}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-5}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-6}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-7}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-8}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-9}	0	0	0	4	0	0	0	0	4	0	0	0
10^{-10}	0	0	0	0	0	0	0	0	0	0	0	0

(*) CPE grading in each well: 0= no CPE, 1= 25% CPE, 2=50% CPE, 3= 75% CPE 4= 100% CPE

Table 1b. Titration of the Poliovirus on RD cells

Virus dilutions	CPE in cell culture wells of culture plate (*)										Cell control	
10^{-3}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-4}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-5}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-6}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-7}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-8}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-9}	0	4	0	4	4	0	4	0	0	4	0	0
10^{-10}	0	0	0	0	0	0	0	0	0	0	0	0

(*) CPE grading in each well: 0= no CPE, 1= 25% CPE, 2=50% CPE, 3= 75% CPE 4= 100% CPE

Table 1c. Titration of the Murine norovirus on RAW cells

Virus dilutions	CPE in cell culture wells of culture plate (*)										Cell control	
10^{-3}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-4}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-5}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-6}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-7}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-8}	4	4	4	4	0	4	4	0	4	4	0	0
10^{-9}	0	4	4	0	0	0	0	0	0	4	0	0
10^{-10}	0	0	0	0	0	0	0	0	0	0	0	0

(*) CPE grading in each well: 0= no CPE, 1= 25% CPE, 2=50% CPE, 3= 75% CPE 4= 100% CPE

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F: (+30) 210 2934606 | www.qacslab.com

Table 1d. Titration of the influenza A(H1N1) pdm09 virus on MDCK cells

Virus dilutions	CPE in cell culture wells of culture plate (*)										Cell control	
10^{-3}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-4}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-5}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-6}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-7}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-8}	4	4	4	4	4	4	4	4	4	4	0	0
10^{-9}	4	4	4	0	4	4	0	0	4	4	0	0
10^{-10}	0	0	0	0	0	0	0	0	0	0	0	0

(*) CPE grading in each well: 0= no CPE, 1= 25% CPE, 2=50% CPE, 3= 75% CPE 4= 100% CPE

By using of the Spearman-Karber formula on the aforementioned CPE results, the calculated $TCID_{50}$ of the Adenovirus, Poliovirus, the Norovirus and Influenza virus A(H1N1) pdm09 strains were $10^{-7.7}$, $10^{-8.0}$, $10^{-7.6}$ and $10^{-8.0}$ respectively. Taking into account the standard error of the above calculation, the titers of the four strains used in the tests were:

Initial titer of Adenovirus type 5	**Log $TCID_{50}$/0.1mL = 7.7±0.133**
Initial titer of Poliovirus type 1	**Log $TCID_{50}$/0.1mL = 8.0±0.167**
Initial titer of Murine norovirus	**Log $TCID_{50}$/0.1mL = 7.6±0.203**
Initial titer of influenza A(H1N1) pdm09	**Log $TCID_{50}$/0.1mL = 8.2±0.153**

3. Cytotoxic effect of the product

We determined the highest concentration of the product (97.0% final concentrations) not having toxic effect on the cells used for the virus culture. Dilutions 10^{-1} to 10^{-8} of the product in culture medium with 0.3 g/L BSA were incubated in ice-cold water for 30 min and then 100 µL of each dilution were inoculated onto monolayers of Hep-2, RD, RAW and MDCK cells in the wells of culture plates. Any microscopic changes in the cells after 5-days incubation were recorded.

A cytotoxic effect on Hep-2, RD, RAW and MDCK cells was observed in dilutions 10^{-1} and 10^{-2} tested of a 97.0% final concentration of the product (Tables 2a, 2b, 2c and 2d). The cells incubated with the remaining dilutions did not present any signs of cytotoxicity and had similar appearance with the control cells.

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

Table 2a. Sub-cytotoxic concentration determination of the 97.0% concentration of the product in a 96 well culture plate of Hep-2 cells.

	Product dilutions	Presence or absence of cell cytotoxicity of the product (*)										Cell control	
	10^{-1}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-2}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-3}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-4}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-5}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-6}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0

(*) tox= cytotoxicity, 0 = absence of cytotoxicity

Table 2b. Sub-cytotoxic concentration determination of the 97.0% concentration of the product in a 96 well culture plate of RD cells.

	Product dilutions	Presence or absence of cell cytotoxicity of the product (*)										Cell control	
	10^{-1}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-2}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-3}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-4}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-5}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-6}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0

(*) tox= cytotoxicity, 0 = absence of cytotoxicity

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

Table 2c. Sub-cytotoxic concentration determination of the 97.0% concentration of the product in a 96 well culture plate of RAW cells.

	Product dilutions	Presence or absence of cell cytotoxicity of the product (*)										Cell control	
	10^{-1}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-2}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-3}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-4}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-5}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-6}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0

(*) tox= cytotoxicity, 0 = absence of cytotoxicity

Table 2d. Sub-cytotoxic concentration determination of the product in a 96 well culture plate of MDCK cells.

	Product dilutions	Presence or absence of cell cytotoxicity of the product (*)										Cell control	
	10^{-1}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-2}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-3}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-4}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-5}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-6}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0

(*) tox= cytotoxicity, 0 = absence of cytotoxicity

4. Reference test for virus inactivation

Formaldehyde 0.7% (w/v) was included as reference for test validation according to the Standard EN 14476. Cytotoxicity test as well as antiviral activity determination was performed on RD cells using serial dilutions of up to 10^{-8} of the aforementioned formaldehyde test solution. Contact times were 30 min and 60 min. The results of the cytotoxicity and the virus inactivation tests are presented in the tables 3 and 4 respectively (only the results for 30 min contact time are shown).

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

Table 3: Cytotoxicity test of formaldehyde solution tested on RD cells

	Product Dilutions	Presence or absence of cell cytotoxicity of the product (*)										Cell control	
	10^{-1}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-2}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-3}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-4}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-5}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-6}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0

(*) tox= cytotoxicity, 0 = absence of cytotoxicity

Table 4: Data of formaldehyde solution inactivation tested against Poliovirus

	Virus Dilutions	CPE in cell culture wells of culture plate (*)										Cell control	
	10^{-3}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-4}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-5}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-6}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-9}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-10}	0	0	0	0	0	0	0	0	0	0	0	0

(*) CPE grading in each well: 0= no CPE, 1= 25% CPE, 2=50% CPE, 3= 75% CPE 4= 100% CPE. Tox=cytotoxicity

A reduction of at least 2.5 log of the poliovirus titer was recorded in the presence of 0.7% (w/v) formaldehyde. Higher log reduction could not be observed due to toxicity of formaldehyde on RD cells. According to the EN 14476 standard, the difference between the logarithmic titer of the virus control and the logarithmic titer of the test organism in the reference inactivation test should be between 2 and 4.5 log after 30 min for poliovirus to verify the method.

5. Antiviral activity of the product

The antiviral activity of the product against the adenovirus, poliovirus, murine norovirus and influenza virus A(H1N1) pdm09 strains was determined for 5 min at 20±1°C in 0.3 g/L (clean conditions). Immediately at the end of contact time, a 1/10 dilution was made in ice-cold cell maintenance medium and 30 min later, subsequent serial dilutions (step 1:10) were inoculated onto cell culture monolayers. After incubation, the titer of each virus was calculated, and the

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

reduction of the virus infectivity was determined from the log differences of virus titers before and after treatment with the product. Results are presented in tables 5, 6, 7 and 8 for adenovirus, poliovirus, murine norovirus and influenza virus A(H1N1) pdm09, respectively.

Table 5: Adenovirus titration after a 5 min contact with 97.0% final concentration of the product in 0.3 % BSA

	Virus Dilutions	CPE in cell culture wells of culture plate (*)										Cell control	
	10^{-3}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-4}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-5}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-6}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-9}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-10}	0	0	0	0	0	0	0	0	0	0	0	0

(*) CPE grading in each well: 0= no CPE, 1= 25% CPE, 2=50% CPE, 3= 75% CPE 4= 100% CPE. Tox=cytotoxicity

The titer of the Adenovirus remaining after the treatment with the product is:

Log $TCID_{50}$after treatment: ≤3.5

Log difference=initial virus titer – virus titer after treatment = 7.7- (≤3.5) = ≥4.2

Table 6: Poliovirus titration after a 5 min contact with 97.0% final concentration of the product in 0.3 % BSA

	Virus Dilutions	CPE in cell culture wells of culture plate (*)										Cell control	
	10^{-3}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-4}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-5}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-6}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-9}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-10}	0	0	0	0	0	0	0	0	0	0	0	0

(*) CPE grading in each well: 0= no CPE, 1= 25% CPE, 2=50% CPE, 3= 75% CPE 4= 100% CPE. Tox=cytotoxicity

The titer of the Poliovirus remaining after the treatment with the product is:

Log $TCID_{50}$after treatment: ≤3.5

Log difference=initial virus titer – virus titer after treatment = 8.0- (≤3.5) = ≥4.5

A: 1 Antigonis str, 14451, Athens, Greece
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F: (+30) 210 2934606 | www.qacslab.com

Table 7: M. norovirus titration after a 5 min contact with 97% final concentration of the product in 0.3 % BSA

	Virus Dilutions	CPE in cell culture wells of culture plate (*)										Cell control	
	10^{-3}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-4}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-5}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-6}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-9}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-10}	0	0	0	0	0	0	0	0	0	0	0	0

(*) CPE grading in each well: 0= no CPE, 1= 25% CPE, 2=50% CPE, 3= 75% CPE 4= 100% CPE. Tox=cytotoxicity

The titer of the murine norovirus remaining after the treatment with the product is:

Log $TCID_{50}$ after treatment: ≤3.5

Log difference=initial virus titer – virus titer after treatment = 7.6- (≤3.5) = ≥4.1

Table 8: Influenza virus A(H1N1) pdm09 titration after a 5 min contact with 97% final concentration of the product in 0.3 % BSA

	Virus Dilutions	CPE in cell culture wells of culture plate (*)										Cell control	
	10^{-3}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-4}	tox	tox	tox	tox	tox	tox	tox	tox	tox	tox	0	0
	10^{-5}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-6}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-7}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-8}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-9}	0	0	0	0	0	0	0	0	0	0	0	0
	10^{-10}	0	0	0	0	0	0	0	0	0	0	0	0

(*) CPE grading in each well: 0= no CPE, 1= 25% CPE, 2=50% CPE, 3= 75% CPE 4= 100% CPE. Tox=cytotoxicity

The titer of the influenza virus A(H1N1) pdm09 remaining after the treatment with the product is:

Log $TCID_{50}$ after treatment: ≤3.5

Log difference=initial virus titer – virus titer after treatment = 8.2- (≤3.5) = ≥4.7

A: 1 Antigonis str, 14451, Athens, Greece
T: (+30) 210 2934745 | E: info@qacs.gr
F: (+30) 210 2934606 | www.qacslab.com

6. Method Requirements

The product under test shall demonstrate at least a decimal log (lg) reduction of 4 in virus titre when tested in accordance with EN 14476.

7. Conclusion

The antiviral activity of the product "Disinfettante superfici " against the Adenovirus type 5, Poliovirus type 1, Murine norovirus and Influenza virus A(H1N1)pdm09 was tested according to the EN 14476 standard: “Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area- test method and requirements (Phase2/Step1).” According to the EN 14476 standard a product has antiviral activity when a reduction of at least 4 log of the virus is observed.

The product under test tested when tested undiluted (97.0% final concentration), demonstrated:

- a ≥4.2 log reduction of the Adenovirus type 5 (ATCC VR-5) after 5 min contact time in the presence of 0.3 g/L BSA, at 20°C
- a ≥4.5 log reduction of the Poliovirus 1 Sabin strain, LSc-2ab (WHO) after 5 min contact time in the presence of 0.3 g/L BSA, at 20°C
- a ≥4.1 log reduction of the Murine Norovirus (Strain S99 Berlin) after 5 min contact time in the presence of 0.3 g/L BSA, at 20°C
- a ≥4.7 log reduction of the Influenza virus A(H1N1) pdm09 after a 5 min contact time in the presence of 0.3 g/L BSA, at 20°C

The product demonstrated antiviral activity against the non-enveloped DNA adenovirus, the non-enveloped RNA poliovirus, the non-enveloped RNA murine norovirus and the enveloped influenza virus A(H1N1) pdm09. According to the EN 14476 standard, products that have antiviral activity against the adenovirus, the poliovirus and the murine norovirus are considered active against all viruses (enveloped and non-enveloped).

Study Manager:

Lagiopoulos Giorgos
Technical Manager of Microbiological Dpt
Agronomist – Food Technologist, MSc
Pharmaceutical Microbiology PgCert
Date: 24/09/2020

End of Study Report