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STUDY REPORT

2021-1701/21 23 00160

Active chlorine released from hypochlorous acid by electrochemical by activation

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)

MARCH 2021

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STUDY REPORT 2021-1701/21 23 00160

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)

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TEST PRODUCT IDENTIFICATION

PRODUCT NAME	:	Active chlorine released from hypochlorous acid by electrochemical by activation
ACTIVE SUBSTANCES	:	Active chlorine released from hypochlorous acid 0,05%
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room temperature, darkness
TEST CONDITIONS	:	Test conducted at 20ºC □ 1 ºC
LOT	:	02 – bacteria 1
METHOD	:	EN 1276:2019
RECEIPT DATE	:	17/02/2021
STUDY PERIOD	:	03/03/2021-05/03/2021
LAB ID	:	2021-1701/21 23 00160

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 dilutionneutralization. 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.

TEST CONDITIONS

1. The following procedure was performed in water bath at 20 °C.
2. The test product was tested at 15 seconds contact time.
3. Interfering substance: 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.

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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≤log N≤8.70) 2.

No (N/10) is between 1.5 to 5.0 X 10^7 CFU per mL (7.17≤log No≤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

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	2.28E+08
10 -6	217	241	log N	8.36
10 -7	23	21	No (N/10)	2.28E+07
			log No	7.36
			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	49	x mean	VC 1	42	x mean	VC 1	51	x mean	VC 1	47	x mean
VC 2	44	46.5	VC 2	40	41	VC 2	46	48.5	VC 2	49	48
30<x mean of Nvo < 160?		Yes	x mean of A is > 0,5*x mean of Nvo?		Yes	x mean of B is > 0,5*x mean of Nvo ?		Yes	x mean of C is > 0,5*x mean of Nvo?		Yes

Test Results

Product concentration (%)	Contact time	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 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.36	> 5.21	≥ 5	PASS TEST
50%	15 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.36	> 5.21	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	15 seconds	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.36	< 2.84	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

Test Results for Staphylococcus aureus

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	2.73E+08
10 -6	267	281	log N	8.44
10 -7	29	24	No (N/10)	2.73E+07
			log No	7.44
			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	61	x mean	VC 1	67	x mean	VC 1	54	x mean	VC 1	64	x mean
VC 2	64	62.5	VC 2	60	63.5	VC 2	62	58	VC 2	69	66.5
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 ?		Yes	x mean of C is > 0,5*x mean of Nvo?		Yes

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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
		10^{0}	0	0							
undiluted (80%)	15 seconds	10^{-1}	0	0	< 14	< 140	< 2.15	7.44	> 5.29	≥ 5	**PASS TEST**
50%	15 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.44	> 5.29	≥ 5	**PASS TEST**
		10^{-1}	0	0							
1%	15 seconds	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.44	< 2.92	≥ 5	**FAILS TEST**
		10^{-1}	> 330	> 330							

Test Results for Escherichia coli

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	3.45E+08
10^{-7}	31	37	log N	8.54
10^{-8}	4	4	No (N/10)	3.45E+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) Product conc.: undiluted (80%)		
VC 1	79	**x mean**	VC 1	74	**x mean**	VC 1	76	**x mean**	VC 1	81	**x mean**
VC 2	72	75.5	VC 2	82	78	VC 2	84	80	VC 2	84	82.5
30<x mean of Nvo < 16)?			x mean of A is > 0,5*x mean of Nvo?			x mean of B is > 0,5*x mean of Nvo ?			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
		10^{0} 0	0	0							
undiluted (80%)	15 seconds	10^{-1}	0	0	< 14	< 140	< 2.15	7.54	> 5.39	≥ 5	**PASS TEST**
50%	15 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.54	> 5.39	≥ 5	**PASS TEST**
		10^{-1}	0	0							
1%	15 seconds	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.54	< 3.02	≥ 5	**FAILS TEST**
		10^{-1}	> 330	> 330							

Test Results for Enterococcus hirae

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	3.95E+08

Validation and controls

Validation suspension	Experimental conditions (A)	Neutralizer control (B)	Method validation (C)

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PRODUCT NAME	:	Active chlorine released from hypochlorous acid by electrochemical by activation
ACTIVE SUBSTANCES	:	Active chlorine released from hypochlorous acid 0,05%
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room temperature, darkness
TEST CONDITIONS	:	Test conducted at 20ºC □ 1 ºC
LOT	:	02 – bacteria 1
METHOD	:	EN 1276:2019
RECEIPT DATE	:	17/02/2021
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10^{-7}	40	39	log N	8.60
10^{-8}	4	4	No (N/10)	3.95E+07
			log No	7.60
			7,17 < = logNo < = 7,70	Yes

(Nvo)									Product conc.: undiluted (80%)		
VC 1	91	x mean	VC 1	86	x mean	VC 1	74	x mean	VC 1	86	x mean
VC 2	81	86	VC 2	79	82.5	VC 2	82	78	VC 2	92	89
30<x mean of Nvo < 160?		Yes	x mean of A is > 0,5*x mean of Nvo?		Yes	x mean of B is > 0,5*x mean of Nvo ?		Yes	x mean of C is > 0,5*x mean of Nvo?		Yes

Test Results

Product concentration (%)	Contact time	Dilution step	Vc 1	Vc 2	Average of Vc1 and Vc2	Na= average x10	log Na	log No	log Reduction (No-Na)	Criteria	Result
		10^{0}	0	0							
undiluted (80%)	15 seconds	10^{-1}	0	0	< 14	< 140	< 2.15	7.60	> 5.45	≥ 5	PASS TEST
		10^{0}	0	0							
50%	15 seconds	10^{-1}	0	0	< 14	< 140	< 2.15	7.60	> 5.45	≥ 5	PASS TEST
		10^{0}	> 330	> 330							
1%	15 seconds	10^{-1}	> 330	> 330	> 3300	> 33000	> 4.52	7.60	< 3.08	≥ 5	FAILS TEST

CONCLUSION TEST SUBSTANCE IDENTIFICATION

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 15 seconds. 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.

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RESULT

The product under test: "Active chlorine released from hypochlorous acid by electrochemical by activation" demonstrated bactericidal activity according to EN 1276:2019 (≥ 5 log reduction), under clean conditions, at 20 □ 1 °C, when tested at product concentration:

PRODUCT NAME	:	Active chlorine released from hypochlorous acid by electrochemical by activation
ACTIVE SUBSTANCES	:	Active chlorine released from hypochlorous acid 0,05%
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room temperature, darkness
TEST CONDITIONS	:	Test conducted at 20ºC □ 1 ºC
LOT	:	02 – bacteria 1
METHOD	:	EN 1276:2019
RECEIPT DATE	:	17/02/2021
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TEST MICROORGANISMS

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

Undiluted (80%) for 15 seconds contact time using as test organisms the reference strains: *Pseudomonas aeruginosa*, *Staphylococcus aureus, Escherichia coli* and *Enterococcus hirae*.

For the QACS Ltd Laboratory,

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Signature date: 31/03/2021
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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)

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RESULT

The product under test: "Active chlorine released from hypochlorous acid by electrochemical by activation" demonstrated bactericidal activity according to EN 1276:2019 (≥ 5 log reduction), under clean conditions, at 20 □ 1 °C, when tested at product concentration:

Undiluted (80%) for 15 seconds contact time 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 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

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STUDY REPORT

2021-1701/21 23 00162

Active chlorine released from hypochlorous acid by electrochemical by activation

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)

MARCH 2021

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STUDY REPORT 2021-1701/21 23 00162

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)

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TEST PRODUCT IDENTIFICATION

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.

PRODUCT NAME	:	Active chlorine released from hypochlorous acid by electrochemical by activation
ACTIVE SUBSTANCES	:	Active chlorine released from hypochlorous acid 0,05%
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	02 – bacteria 1
METHOD	:	EN 13727:2012+A2:2015
CONTACT TIME	:	15 seconds
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
RECEIPT DATE	:	17/02/2021
STUDY PERIOD	:	03/03/2021-05/03/2021
LAB ID	:	2021-1701/21 23 00162

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.

TEST CONDITIONS

1. Product type: Hygienic handrub.
2. The following procedure was performed in water bath at 20 °C.
3. The test product was tested at 15 seconds 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.

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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 (80%), 50% 1%.

TEST ORGANISMS

Pseudomonas aeruginosa	NCIMB 10421
Staphylococcus aureus	ATCC 6538
Escherichia coli K12	NCTC 10538
Enterococcus hirae	NCIMB 8192

BACTERICIDAL ACTIVITY FOR HANDRUB AND HANDWASH PRODUCTS

The product shall be deemed to have passed the EN 13727 standard if it demonstrates in a valid test for handrub and handwash products at 20 °C under the conditions defined by this standard when the test organisms are: *Escherichia coli K12, Pseudomonas aeruginosa, Staphylococcus aureus* and *Enterococcus hirae* at least a:

a) 5 lg reduction within max. 1 min under clean conditions (hygienic handrub);
b) 5 lg reduction within max. 5 min under clean conditions (surgical handrub);
c) 3 lg reduction within max. 1 min under dirty conditions (hygienic handwash);
d) 5 lg reduction within max. 5 min under dirty conditions (surgical handwash).

ASSAY ACCEPTANCE CRITERIA

1. Test Suspension (N) is between 1.5 to 5.0 X 10^8 CFU per mL (8.17≤log N≤8.70) 2.

No (N/10) is between 1.5 to 5.0 X 10^7 CFU per mL (7.17≤log No≤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).

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Test Results for Pseudomonas aeruginosa

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	2.28E+08
10^{-6}	217	241	log N	8.36
10^{-7}	23	21	No (N/10)	2.28E+07
			log No	7.36
			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	47	x mean	VC 1	51	x mean	VC 1	47	x mean	VC 1	44	x mean
VC 2	49	48	VC 2	46	48.5	VC 2	50	48.5	VC 2	52	48
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	42	x mean						
			VC 2	46	44						
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
		10^{0}	0	0							
undiluted (80%)	15 seconds	10^{-1}	0	0	< 14	< 140	< 2.15	7.36	> 5.21	≥ 5	PASS TEST
50%	15 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.36	> 5.21	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	15 seconds	10^{-1}	> 330	> 330	> 33000	> 330000	> 5.52	7.36	< 1.84	≥ 5	FAILS TEST
		10^{-2}	> 330	> 330							

Test Results for Staphylococcus aureus

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	2.73E+08
10^{-6}	267	281	log N	8.44
10^{-7}	29	24	No (N/10)	2.73E+07
			log No	7.44
			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	61	x mean	VC 1	67	x mean	VC 1	69	x mean	VC 1	62	x mean
VC 2	54	57.5	VC 2	64	65.5	VC 2	54	61.5	VC 2	67	64.5
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	68	x mean 65						
			VC 2	62							
30<x mean of NVB <0? 16			Yes								

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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 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.44	> 5.29	≥ 5	**PASS TEST**
		10^{-1}	0	0							
50%	15 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.44	> 5.29	≥ 5	**PASS TEST**
		10^{-1}	0	0							
1%	15 seconds	10^{-1}	> 330	> 330	> 33000	> 330000	> 5.52	7.44	< 1.92	≥ 5	**FAILS TEST**
		10^{-2}	> 330	> 330							

Test Results for Escherichia coli

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	3.32E+08
10^{-7}	31	34	log N	8.52
10^{-8}	4	4	No (N/10)	3.32E+07
			log No	7.52
			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	74	x mean		VC 1	79	x mean		VC 1	74	x mean		VC 1	62	x mean	
VC 2	72	73		VC 2	72	75.5		VC 2	70	72		VC 2	71	66.5	
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	70	x mean									
				VC 2	64	67									
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
		10^{0}	0	0							
undiluted (80%)	15 seconds	10^{-1}	0	0	< 14	< 140	< 2.15	7.52	> 5.37	≥ 5	**PASS TEST**
50%	15 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.52	> 5.37	≥ 5	**PASS TEST**
		10^{-1}	0	0							
1%	15 seconds	10^{-1}	> 330	> 330	> 33000	> 330000	> 5.52	7.52	< 2.00	≥ 5	**FAILS TEST**
		10^{-2}	> 330	> 330							

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Test Results for Enterococcus hirae

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	3.95E+08
10^{-7}	40	39	log N	8.60
10^{-8}	4	4	No (N/10)	3.95E+07
			log No	7.60
			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	91	x mean		VC 1	93	x mean		VC 1	89	x mean		VC 1	87	x mean	
VC 2	82	86.5		VC 2	87	90		VC 2	82	85.5		VC 2	74	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 $N_{VB}/1000$?			Yes	x mean of C is > 0,5*x mean of Nvo?			Yes

Validation suspension (NVB)			
VC 1	86	x mean	
VC 2	92	89	
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
		10^{0}	0	0							
undiluted (80%)	15 seconds	10^{-1}	0	0	< 14	< 140	< 2.15	7.60	> 5.45	≥ 5	PASS TEST
50%	15 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.60	> 5.45	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	15 seconds	10^{-1}	> 330	> 330	> 33000	> 330000	> 5.52	7.60	< 2.08	≥ 5	FAILS TEST
		10^{-2}	> 330	> 330							

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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	:	Active chlorine released from hypochlorous acid by electrochemical by activation
ACTIVE SUBSTANCES	:	Active chlorine released from hypochlorous acid 0,05%
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	02 – bacteria 1
METHOD	:	EN 13727:2012+A2:2015
CONTACT TIME	:	15 seconds
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
RECEIPT DATE	:	17/02/2021
STUDY PERIOD	:	03/03/2021-05/03/2021
LAB ID	:	2021-1701/21 23 00162

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 20 °C for 15 seconds. 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: "Active chlorine released from hypochlorous acid by electrochemical by activation" demonstrated bactericidal activity for hygienic handrub disinfection (≥ 5 log reduction), according to the EN 13727:2012+A2:2015, at 20□1 °C, under clean conditions when tested at concentration:

Undiluted (80%) for 15 seconds contact time using as test organisms the reference strains:
Pseudomonas aeruginosa, *Staphylococcus aureus, Escherichia coli K12* and *Enterococcus hirae*.

For the QACS Ltd Laboratory,

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Signature date: 31/03/2021
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Agronomist-Food Technologist M.Sc. Study Manager

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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

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RECEIPT DATE	:	17/02/2021
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LAB ID	:	2021-1701/21 23 00162

TEST ORGANISMS

Pseudomonas aeruginosa	NCIMB 10421
Staphylococcus aureus	ATCC 6538
Escherichia coli K12	NCTC 10538
Enterococcus hirae	NCIMB 8192

RESULT

The product under test: “Active chlorine released from hypochlorous acid by electrochemical by activation” demonstrated bactericidal activity for hygienic handrub disinfection (≥ 5 log reduction), according to the EN 13727:2012+A2:2015, at 20□1 °C, under clean conditions when tested at concentration:

Undiluted (80%) for 15 seconds contact time using as test organisms the reference strains:
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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