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SAGA APS

STUDY REPORT

2020-9159/20 23 00918

Hand Sanitizer Formula 73% Gel

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)

NOVEMBER 2020

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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	:	HAND SANITIZER FORMULA 73% GEL
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 73% w/w
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	Not Provided
METHOD	:	EN 1276:2019
CONTACT TIME	:	30 seconds
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
STUDY SPONSOR	:	Saga ApS
PRODUCT SUPPLIER	:	Saga ApS
PRODUCT MANUFACTURER	:	Saga ApS
RECEIPT DATE	:	21/09/2020
STUDY PERIOD	:	13/10/2020-15/10/2020
LAB ID	:	2020-9159/20 23 00918

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.

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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 30 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.
6. Neutralizer used: LPT Dilution Broth containing polysorbate 80.
7. 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 K12	NCTC 10538
Enterococcus hirae	NCIMB 8192

BACTERICIDAL ACTIVITY FOR HAND HYGIENE

The bactericidal concentration for hand hygiene is the concentration of the tested product for which at least a 5 lg reduction for hygienic handrub and 3 lg reduction for hygienic handwash (at 50 % in test concentration or less) is demonstrated in a valid test under the conditions defined by this standard when the test organisms are *Escherichia coli K12, 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. 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	2.30E+08
10^{-6}	237	222		
10^{-7}	22	24	log N	8.36
			No (N/10)	2.30E+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	42	x mean	VC 1	58	x mean	VC 1	48	x mean	VC 1	52	x mean
VC 2	59	50.5	VC 2	42	50	VC 2	46	47	VC 2	65	58.5
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 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%)	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.36	> 5.21	≥ 5	PASS TEST
		10^{-1}	0	0							
50%	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.36	> 5.21	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	30 seconds	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.36	< 2.84	≥ 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	3.77E+08
10^{-7}	35	40		
10^{-8}	4	4	log N	8.58
			No (N/10)	3.77E+07
			log No	7.58
			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	91	**x mean**	VC 1	100	**x mean**	VC 1	86	**x mean**	VC 1	91	**x mean**
VC 2	106	**98.5**	VC 2	92	**96**	VC 2	89	**87.5**	VC 2	94	**92.5**
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 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%)	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.58	> 5.43	≥ 5	**PASS TEST**
		10^{-1}	0	0							
50%	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.58	> 5.43	≥ 5	**PASS TEST**
		10^{-1}	0	0							
1%	30seconds	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.58	< 3.06	≥ 5	**FAILS TEST**
		10^{-1}	> 330	> 330							

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TEST RESULTS FOR *Escherichia Coli* K12 (BACTERICIDAL SUSPENSION TEST)

Test suspension

Test - suspension (N and No)				
N	Vc1	Vc2	x mean	4.27E+08
10^{-7}	40	46		
10^{-8}	3	5	log N	8.63
			No (N/10)	4.27E+07
			log No	7.63
			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	112	x mean	VC 1	114	x mean	VC 1	92	x mean	VC 1	96	x mean
VC 2	108	110	VC 2	98	106	VC 2	100	96	VC 2	102	99
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%)	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.63	> 5.48	≥ 5	PASS TEST
		10^{-1}	0	0							
50%	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.63	> 5.48	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	30 seconds	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.63	< 3.11	≥ 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	2.64E+08
10^{-6}	259	272		
10^{-7}	28	22	log N	8.42
			No (N/10)	2.64E+07
			log No	7.42
			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	58	x mean	VC 1	60	x mean	VC 1	52	x mean	VC 1	58	x mean
VC 2	59	58.5	VC 2	48	54	VC 2	59	55.5	VC 2	59	58.5
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%)	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.42	> 5.28	≥ 5	PASS TEST
		10^{-1}	0	0							
50%	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	7.42	> 5.28	≥ 5	PASS TEST
		10^{-1}	0	0							
1%	30seconds	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	7.42	< 2.90	≥ 5	FAILS TEST
		10^{-1}	> 330	> 330							

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CONCLUSION

TEST SUBSTANCE IDENTIFICATION

PRODUCT NAME	:	HAND SANITIZER FORMULA 73% GEL
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 73% w/w
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	Not Provided
METHOD	:	EN 1276:2019
CONTACT TIME	:	30 seconds
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
STUDY SPONSOR	:	Saga ApS
PRODUCT SUPPLIER	:	Saga ApS
PRODUCT MANUFACTURER	:	Saga ApS
RECEIPT DATE	:	21/09/2020
STUDY PERIOD	:	13/10/2020-15/10/2020
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METHODOLOGY ABSTRACT

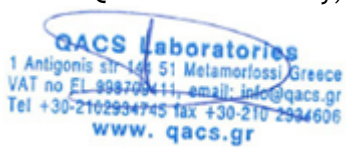
A sample of the product as delivered and/or diluted with hard water (or water for ready to use products) is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at 20 °C for 30 seconds. At the end of this contact time, an aliquot is taken; the bactericidal 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: "HAND SANITIZER FORMULA 73% GEL" demonstrated bactericidal activity according to EN 1276:2019 (≥ 5 log reduction) under clean conditions at 20 ± 1 °C, when tested:

Undiluted (80%) for 30 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,



Signature date: 05/11/2020
Lagiopoulos Giorgos
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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)

PRODUCT NAME	:	HAND SANITIZER FORMULA 73% GEL
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 73% w/w
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	Not Provided
METHOD	:	EN 1276:2019
CONTACT TIME	:	30 seconds
CONCENTRATION	:	Undiluted (80%), 50%, 1%.
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TEST MICROORGANISMS

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

RESULT

The product under test: “HAND SANITIZER FORMULA 73% GEL” demonstrated bactericidal activity according to EN 1276:2019 (≥ 5 log reduction) under clean conditions at 20 ± 1 °C, when tested:

Undiluted (80%) for 30 seconds contact time using as test organisms the reference strains: *Pseudomonas aeruginosa*, *Staphylococcus aureus, Escherichia coli K12* and *Enterococcus hirae*.

Results refer to the samples 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 for 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