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SAGA APS

STUDY REPORT

2020-9159/20 23 00916

HAND/WET WIPES FORMULA 73%

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

Chemical disinfectants and antiseptics
Quantitative suspension test for the evaluation of yeasticidal 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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Chemical disinfectants and antiseptics – evaluation of 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	:	HAND/WET WIPES FORMULA 73%
SUBSTANCES AND THEIR CONCENTRATIONS	:	Ethanol 73% w/w
APPEARANCE OF THE PRODUCT	:	Liquid
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	Not Provided
METHOD	:	EN 1650:2019
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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SCOPE

This document specifies a test method and the minimum requirements for 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 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 yeasts (yeast cells) 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 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) 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 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

YEASTICIDAL ACTIVITY FOR HAND HYGIENE

The yeasticidal concentration for a hand hygiene is the concentration of the tested product for which a reduction of at least:
• lgR ≥ 4 for handrubs
or
• lgR ≥ 2 for handwashes at 50 % in test concentration or less.
is demonstrated in a valid test under the chosen test conditions in terms of interfering substance.

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	3.00E+07
10^{-6}	31	29		
10^{-7}	3	3	log N	7.48
			No (N/10)	3.00E+06
			log No	6.48
			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	62	**x mean**	VC 1	67	**x mean**	VC 1	76	**x mean**	VC 1	59	**x mean**
VC 2	69	**65.5**	VC 2	72	**69.5**	VC 2	70	**73**	VC 2	64	**61.5**
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**		

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	6.48	> 4.33	≥4	**PASS TEST**
		10^{-1}	0	0							
50%	30 seconds	10^{0}	0	0	< 14	< 140	< 2.15	6.48	> 4.33	≥4	**PASS TEST**
		10^{-1}	0	0							
1%	30 seconds	10^{0}	> 330	> 330	> 3300	> 33000	> 4.52	6.48	< 1.96	≥4	**FAILS TEST**
		10^{-1}	> 330	> 330							

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CONCLUSION

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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 yeasts 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, and the yeasticidal activity in this portion is immediately neutralized or suppressed. The numbers of surviving yeasts in each sample are determined and the reduction is calculated.

RESULT

The product under test: "HAND/WET WIPES FORMULA 73%" demonstrated yeasticidal activity according to EN 1650:2019 (≥ 4 log reduction), under clean conditions, at 20 ± 1 °C, when tested:

Undiluted (80%) for 30 seconds contact time using as test organism the reference strain: *Candida albicans*.

For the QACS Ltd Laboratory,

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End of Test Report