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SODEL

STUDY REPORT

2022-5141/22 23 00201_v03

F3320

SUSPENSION TEST
ACCORDING TO EN 13624:2021
(Phase 2 step 1)

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)

JUNE 2022

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SUSPENSION TEST ACCORDING TO EN 13624:2021

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	:	F3320
SUBSTANCES AND THEIR CONCENTRATIONS	:	Chlorhexidine 4.0% w/w
APPEARANCE OF THE PRODUCT	:	Liquid soap
STORAGE CONDITIONS	:	Room Temperature, Darkness
LOT	:	0224E017220420E
METHOD	:	EN 13624:2021
COMPANY NAME	:	SODEL
PRODUCT MANUFACTURER	:	SODEL
RECEIPT DATE	:	03/05/2022
STUDY PERIOD	:	24/05/2022-26/05/2022
LAB ID	:	2022-5141/22 23 00201_v03

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 fungi (yeast cells or mould spores) 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 fungicidal and/or the fungistatic 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 fungi in each sample are determined and the reduction is calculated. Handwash products are always prediluted with hard water. This solution simulates the addition of tap water in practice (1:1 in order to simulate real use conditions). Such a product is nevertheless regarded as a "ready-to-use product".

The test is performed using the vegetative cells of Candida albicans and the conidiospores of Aspergillus brasiliensis (fungicidal activity) or only the vegetative cells of Candida albicans (yeasticidal activity) as test-organisms. Other contact times and temperatures within the limits may be used. Additional interfering substances and test organisms may be used.

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TEST CONDITIONS

1. Product type: Hygienic handwash.
2. Test temperature: 20 °C.
3. Contact Time: 30 sec, 45 sec and 60 sec.
4. Interfering substance: 3g/L bovine albumin and 3 ml/l erythrocytes final concentration (dirty conditions).
5. Test Method: Dilution Neutralization Method - Pour Plate Technique.
6. Neutralizer used: LPT Dilution Broth containing 3% polysorbate 80.
7. Appearance of product test solutions: No precipitate during the test procedure (homogeneous solution)
8. Handwash products shall be tested at 50 % concentration as highest concentration (1:1 dilution, in order to simulate real use conditions). 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 at the following concentrations: 50%, 40, and 0.1%.

TEST MICROORGANISMS

Candida albicans ATCC 10231

YEASTICIDAL ACTIVITY FOR HANDRUB AND HANDWASH PRODUCTS

The product shall be deemed to have passed the EN 13624 Standard (yeasticidal activity) 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 organism is Candida albicans at least a:

- 4 lg reduction within 1 min under clean conditions (hygienic handrub);
- 4 lg reduction within 5 min under clean conditions (surgical handrub);
- 2 lg reduction within 1 min under dirty conditions (hygienic handwash);
- 4 lg reduction within 5 min under dirty conditions (surgical handwash).

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)
11. Control of weighted mean counts. Quotient is not lower than 5 and not higher than 15.
12. Vc values = Count per ml (one plate or more)
13. If the count on one plate for yeasts is higher than 330, the number is reported as "> 330".
14. If a Vc value is lower than 14, the number is reported "< 14"

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Test Results for Candida albicans

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	3.59E+07
10^{-6}	34	39	log N	7.56
10^{-7}	3	3	No (N/10)	3.59E+06
			log No	6.56
			6,17 < = logNo < = 6,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)				Neutralizer control (B)			Method validation (C) Product conc.: 50%			
Vc 1	74	x mean	Vc 1	70	C.time	x mean	Vc 1	81	x mean	Vc 1	70	C.time	x mean
Vc 2	79	76.5	Vc 2	76	30sec	73	Vc 2	72	76.5	Vc 2	73	30sec	71.5
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			
Validation suspension (N_{VB})			Vc 1	71	C.time	x mean				Vc 1	61	C.time	x mean
			Vc 2	73	45sec	72				Vc 2	72	45sec	66.5
VC 1	73	x mean	x mean of A is > 0,5*x mean of Nvo? Yes							x mean of C is > 0,5*x mean of Nvo? Yes			
VC 2	77	75											
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
50%	30sec	10^{-1}	204	186	1959.1	19591	4.29	6.56	2.26	≥ 2	PASS TEST
		10^{-2}	22	19							
40%	30sec	10^{-1}	> 330	> 330	3950.0	39500	4.60	6.56	1.96	≥ 2	FAILS TEST
		10^{-2}	36	43							
0.1%	30sec	10^{-1}	> 330	> 330	> 33000	> 330000	> 5.52	6.56	< 1.04	≥ 2	FAILS TEST
		10^{-2}	> 330	> 330							

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
50%	45sec	10^{-1}	118	105	1145.5	11455	4.06	6.56	2.50	≥ 2	PASS TEST
		10^{-2}	13	16							
40%	45sec	10^{-1}	146	164	1545.5	15455	4.19	6.56	2.37	≥ 2	PASS TEST
		10^{-2}	12	18							
0.1%	45sec	10^{-1}	> 330	> 330	> 33000	> 330000	> 5.52	6.56	< 1.04	≥ 2	FAILS TEST
		10^{-2}	> 330	> 330							

Test Results for Candida albicans

Test suspension

Test - suspension			(N and No)	
N	Vc1	Vc2	x mean	3.59E+07
10^{-6}	34	39	log N	7.56
10^{-7}	3	3	No (N/10)	3.59E+06
			log No	6.56
			6,17 < = logNo < = 6,70	Yes

Validation and controls

Validation suspension (Nvo)			Experimental conditions (A)				Neutralizer control (B)			Method validation (C) Product conc.: 50%			
Vc 1	74	x mean	Vc 1	73	C.time	x mean	Vc 1	81	x mean	Vc 1	70	C.time	x mean
Vc 2	79	76.5	Vc 2	76	60sec	74.5	Vc 2	72	76.5	Vc 2	77	60sec	73.5
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			
Validation suspension (N_{VB})													
VC 1	73	x mean											
VC 2	77	75											
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
50%	60sec	10^{-1}	49	38	435.0	4350	3.64	6.56	2.92	≥ 2	PASS TEST
		10^{-2}	3	3							
40%	60sec	10^{-1}	116	139	1281.8	12818	4.11	6.56	2.45	≥ 2	PASS TEST
		10^{-2}	13	14							
0.1%	60sec	10^{-1}	> 330	> 330	> 33000	> 330000	> 5.52	6.56	< 1.04	≥ 2	FAILS TEST
		10^{-2}	> 330	> 330							

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LOT	:	0224E017220420E
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STUDY PERIOD	:	24/05/2022-26/05/2022
LAB ID	:	2022-5141/22 23 00201_v03

METHODOLOGY ABSTRACT

A sample of the product as delivered is added to a test suspension of yeasts in a solution of an interfering substance. The mixture is maintained at temperature 20°C and for 30, 45 and 60 seconds contact time. At the end of each 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.

CONCLUSION

The product under test: "F3320" demonstrated yeasticidal activity for hygienic handrub disinfection (≥ 4 log reduction) according to EN 13624:2021, at 20 ± 1 °C, under dirty conditions when tested at product concentration:

50% for 30, 45 and 60 seconds contact time using as test organisms the reference strain: *Candida albicans.*
40% for 45 and 60 seconds contact time using as test organisms the reference strain: *Candida albicans.*

The method is accredited according to EN ISO/IEC 17025:2017 (Cert. No 195).

For the QACS Ltd Laboratory

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ESYD
Testing
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STUDY SUMMARY / ABSTRACT

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TEST MICROORGANISMS

Candida albicans	ATCC 10231

CONCLUSION

The product under test: "F3320" demonstrated yeasticidal activity for hygienic handrub disinfection (≥ 4 log reduction) according to EN 13624:2021, at 20 ± 1 °C, under dirty conditions when tested at product concentration:

50% for 30, 45 and 60 seconds contact time using as test organisms the reference strain: *Candida albicans.*
40% for 45 and 60 seconds contact time using as test organisms the reference strain: *Candida albicans.*

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.

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