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)

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Scope

The standard method BS EN 1650 describes a suspension test for establishing whether a chemical disinfectant or antiseptic has fungicidal/yeasticidal activity. This laboratory test takes into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substance, i.e. conditions which may influence its action in practical situations. The conditions are intended to cover general purposes and to allow reference between laboratories and product types. Each utilization concentration of the chemical disinfectant or antiseptic found by this test corresponds to defined experimental conditions. However, for some applications the recommendations of use of a product may differ and therefore additional test conditions should be used.

Outline of Test Method (Obligatory Test Conditions)

A sample of the test product is diluted in synthetic hard water in products diluted at point of use or distilled water in the case of ready to use products. A test suspension of bacteria and interfering substance is then added to the dilutions and maintained at 20°C ± 1°C for 15 minutes ± 10 seconds. At the end of the contact time an aliquot is taken and the fungicidal/ fungistatic activity is immediately neutralised or suppressed by the validated method. The numbers of surviving bacteria in each sample are determined and the reduction is calculated.
The test is performed using *Candida albicans* and *Aspergillus brasiliensis (niger)* as standard organisms.

Acceptance Criteria

The product when tested as above shall demonstrate at least a 4 $\log_{10}$ reduction in viable yeast/fungal counts.

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Test information		Deviation
Name of Product	BioShield Guard 80	
Batch Number & Expiry Date	N/S	
Date of Delivery	01/05/2020	
Period of Analysis	06/05/2020-07/05/2020	
Manufacturer / Supplier	Sanglier Ltd	
Storage Conditions	Ambient	
Appearance of the Product	Clear Liquid	
Neutraliser	N6	
Neutralisation Method	Dilution	
Product Diluent	Distilled water	
Test Concentrations	Neat (80%), Mid-range (50%), Non active (0.1%)	
Experimental Conditions	Clean	
Interfering Substance	Clean 0.3g/l Bovine Albumin	
Test Temperature	20°C ± 1°C	
Temperature of Incubation	Fungi – 30°C ± 1°C for 24hr to 48hr	
Identification of the Fungal Strains:	*Candida albicans* (ATCC 10231)	
Contact Times	5min ± 10s	
Stability and Appearance During Test	No Change Observed	

Deviations from Standard Method

List deviations/There were no deviations from the standard method

Test Result Summary

The test product received has achieved a >4 log reduction against C.albicans when tested under the condition specified in this report.

See page 2 for acceptance criteria and raw data tables below for complete test results.

Validation and controls

Validation suspension (Nv_0)				Experimental condition controls (A)				Neutraliser or Filtration Control (B)				Method Validation (C)			
			$\bar{x}$ =				$\bar{x}$ =				$\bar{x}$ =				$\bar{x}$ =
Vc1	C.a	40		**Vc1**	C.a	45		**Vc1**	C.a	48		**Vc1**	C.a	42	
			C.a 40				C.a 43				C.a 57				C.a 42
Vc2	C.a	40		**Vc2**	C.a	41		**Vc2**	C.a	65		**Vc2**	C.a	42	
$30 \leq \bar{x}$ of $Nv_0 \leq 160$? Yes				$\bar{x}$ of A ≥ 0.5 Nv0 Yes				$\bar{x}$ of B ≥ 0.5 Nv0 Yes				$\bar{x}$ of C ≥ 0.5 Nv0 Yes			

Test Results

		Test Concentrations (W/V)		
Test Organism	**Suspension N**	Neat	**50%**	**0.1%**
Candida	10^5 188 ; 161	10^0 0 ; 0	10^0 0 ; 0	10^3 158 ; 205
albicans	10^6 17 ; 22	Na ; < 2.15	Na ; < 2.15	Na ; 6.26
ATCC 10231	N_0 : 6.25	R > 4	R > 4	R -0.01

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KEY

No	Log_{10} number of cfu/ml at the beginning of the contact time = *N*/10
Nvo	is the number of cfu/ml in the validation test suspension at the beginning of the contact time
A	is the verification of experimental conditions control
B	is the neutraliser toxicity control
C	is method validation
Vc	is the colony forming units counted per 1ml of sample
$\bar{x}$	is the average of Vc_1 & Vc_2
$\bar{x}$ *wm*	is the weighted mean of *N*
Na	Log_{10} number of surviving cfu/ml in the test mixture
R	(lg N_O – lg *Na* = lg *R*) is the calculation for reduction in viability
PASS	= lg *R* greater than or equal to 4
FAIL	= lg *R* less than 4
>	greater than
≥	equal to or greater than
<	less than
≤	equal to or less than