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Microbiological Report

RM-6D523-B

06 May 2016

EVALUATION OF E Klean50 HOCL SOLUTION IN ACCORDANCE WITH BS EN 1650:1998

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For:
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signed_____
on behalf of Donnington Laboratories Ltd

date _____

For:	Mark Staplehurst	Company:	ActivStorm Ltd
By:	John Reed	Date:	06/05/2016
Rept No:	**RM-6D523-B**	**EVALUATION OF E-Klean50 HOCL SOLUTION IN ACCORDANCE WITH BS EN 1650:1998**	

Sample details:

DLL ref	Description	Client Ref	Produced
M-6D523-1	hypochlorous acid		28/04/2106
Declared active system: hypochlorous acid			

Client: ActivStorm Ltd

Date received: 29/04/2016 **Date of test:** 30/04/2016 – 03/05/2016

Storage conditions: 20±2°C in dark

Test method: BS EN 1650: 1998 - *Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants & antiseptics used in food, industrial, domestic and institutional areas – Test method and requirements (phase2/step1)*.

Test performed under conditions simulating light and heavy organic soil.

Test organism(s):

Candida albicans	ATCC 10231	(CA)
Aspergillus brasiliensis	ATCC 16404	(AB)

Organisms derived from Selectrol discs and maintained on Tryptic Soy Agar slopes.

C albicans: suspensions for experimental purposes prepared from 48h/30˚C plate cultures on Sabouraud Dextrose Agar (Oxoid).

A brasiliensis: spores harvested from heavily sporing stock culture on Sabouraud Dextrose Agar incubated for 10d at 25±1°C.

Suspending medium: Maximum Recovery Diluent (Oxoid)

Interfering substances: 0.3% and 3.0% bovine serum albumen Cohn Factor V

Test product concentration: Neat **Test temperature:** 20 - 22°C

Contact time(s):

CA: 60±5s
AB: 60±5s + 15m±5s

Neutralising diluent: D/E neutralizing broth (Neogen)

Fungal enumeration: Sabouraud Dextrose Agar without additional neutralizer(s). Pour plates (1ml) prepared in duplicate at each dilution.

CA: plates incubated at 30±1°C for 24±2h and re-examined after a further 24±2h incubation at 30±1°C.

AB: plates incubated at 30±1°C for 48±4h and re-examined after a further 24±2h incubation at 30±1°C.

Note: Sabouraud Dextrose Agar substituted for Malt Extract Agar as recommended in standard.

Validation: Performed on neat test solution in accordance with BS EN 1650: 1998 Annex A.

Test product performance:

[A] Bacterial test suspension - cell density (N):

Organism	Target cell density cfu/ml	Actual cell density cfu/ml (N)	Verification	Inoculum level cfu/ml (N_0)
CA	1.5 – 5.0x10e7	1.64x10e07	complies	1.64x10e06
AB		1.49x10e07	complies	1.49x10e06

[B] Dilution : Neat - contact time 60±5s - 0.3% albumin:

Test Organism	Inoculum level cfu/ml	cfu/ml recovered after 60s	Log reduction factor	Log reduction factor ≥4.00	% Reduction
CA	1.64x10e06	<1.50x10e02	>4.04	Pass	>99.99
AB	1.49x10e06	>3.00x10e05	<0.70	Fail	<97.98

[C] Dilution : Neat - contact time 15m±5s - 0.3% albumin:

Test Organism	Inoculum level cfu/ml	cfu/ml recovered after 60s	Log reduction factor	Log reduction factor ≥4.00	% Reduction
AB	1.49x10e06	>3.00x10e05	<0.70	Fail	<97.98

[D] Dilution: Neat - contact time 60±5s – 3.0% albumin:

Test Organism	Inoculum level cfu/ml	cfu/ml recovered after 60s	Log reduction factor	Log reduction factor ≥4.00	% Reduction
CA	1.64x10e06	>3.00x10e05	<0.74	Fail	<98.17
AB	1.49x10e06	>3.00x10e05	<0.70	Fail	<97.98

[E] Dilution : Neat - contact time 15m±5s – 3.0% albumin:

Test Organism	Inoculum level cfu/ml	cfu/ml recovered after 60s	Log reduction factor	Log reduction factor ≥4.00	% Reduction
AB	1.49x10e06	>3.00x10e05	<0.70	Fail	<97.98

[F] Dilution : 50% dilution in hard water - contact time 60±5s - 0.3% albumin:

Test Organism	Inoculum level cfu/ml	cfu/ml recovered after 60s	Log reduction factor	Log reduction factor ≥4.00	% Reduction
CA	1.64x10e06	>3.00x10e05	<0.74	Fail	<98.17
AB	1.49x10e06	>3.00x10e05	<0.70	Fail	<97.98

[G] Dilution : 50% dilution in hard water - contact time 15m±5s - 0.3% albumin:

Test Organism	Inoculum level cfu/ml	cfu/ml recovered after 15m	Log reduction factor	Log reduction factor ≥4.00	% Reduction
AB	1.49x10e06	>3.00x10e05	<0.70	Fail	<97.98

[H] Dilution: 50% dilution in hard water - contact time 60±5s – 3.0% albumin:

Test Organism	Inoculum level cfu/ml	cfu/ml recovered after 60s	Log reduction factor	Log reduction factor ≥4.00	% Reduction
CA	1.64x10e06	>3.00x10e05	<0.74	Fail	<98.17
AB	1.49x10e06	>3.00x10e05	<0.70	Fail	<97.98

[I] Dilution : 50% dilution in hard water - contact time 15m±5s – 3.0% albumin:

Test Organism	Inoculum level cfu/ml	cfu/ml recovered after 15m	Log reduction factor	Log reduction factor ≥4.00	% Reduction
AB	1.49x10e06	>3.00x10e05	<0.70	Fail	<97.98

[J] Validation:

	Test strain	Validation suspension cfu/ml (Nv)	Experimental conditions control cfu/ml (A)	A ≥0.05Nv
Experimental Conditions	CA	1.64x10e03	1.30x10e02	complies
	AB	1.49x10e03	1.03x10e02	complies

	Test strain	Validation suspension cfu/ml (Nv)	Neutraliser toxicity control cfu/ml (B)	B ≥0.05Nv
Neutraliser toxicity	CA	1.64x10e03	1.32x10e02	complies
	AB	1.49x10e03	1.09x10e02	complies

	Test strain	Validation suspension cfu/ml (Nv)	Neutralisation-dilution control cfu/ml (C)	C ≥0.05Nv
Neutralisation-dilution	CA	1.64x10e03	1.30x10e02	complies
	AB	1.49x10e03	1.05x10e02	complies

Interpretation of results:

Pass: product achieves a reduction in viability of ≥1.0x10e4 (log reduction factor of ≥4.00) within the specified contact time at 20±1°C when the test organisms are Candida albicans ATCC 10231 and Aspergillus brasiliensis ATCC 16404.

Fail: product fails to achieve a reduction in viability of ≥1.0x10e4 (log reduction factor of <4.00) within the specified contact time at 20±1°C when the test organisms are Candida albicans ATCC 10231 and Aspergillus brasiliensis ATCC 16404.

Summary for hypochlorous acid solution

Test strain	**BS EN 1650:1998 **** Test method and requirements (phase2/step1)			
	R value – neat solution		R value – 50% dilution	
	BSA 0.3%	BSA 3.0%	BSA 0.3%	BSA 3.0%
Candida albicans ATCC 10231	Passes	Fails	Fails	Fails
Aspergillus brasiliensis ATCC16404	Fails	Fails	Fails	Fails

**BS EN 1650: 1998 - *Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants & antiseptics used in food, industrial, domestic and institutional areas*

Overall conclusion:

When tested at neat concentration in the presence of 0.3% albumin, the hypochlorous acid solution achieved the required 5 log reduction in the viability of Candida albicans within 60±5s at 20 - 22°C. However, after dilution to 50% in hard water and in the presence of the higher albumin level at both concentrations, the product failed to achieve the required 5 log reduction.

After 60s and 15m contact times, no significant activity was evident against Aspergillus brasiliensis at both test concentrations.

It is well established that organic materials and food residues decrease the antibacterial effectiveness of chlorine and that, in order to achieve effective disinfection, chlorine-based sanitisers should be used on clean or previously cleaned surfaces only as the final stage of an appropriate cleaning and sanitisation regime.