



BIOTECH TESTING SERVICES

TEST REPORT

LAB NO. : 2003248/ 1

DATE: 30/09/2020

NAME OF CUSTOMER : M/S. CHEMTEX SPECIALITY LIMITED
ADDRESS : Haute Street Corporate Park,
86-A, Topsia Road (S), Kolkata -700 046, India
REFERENCE : Letter Ref. Nil dated September 07, 2020
Kind Attention: Sumit Dasgupta
DATE OF RECEIPT : 07/09/2020
DATE OF INITIATION : 07/09/2020
DATE OF COMPLETION : 30/09/2020
SAMPLE DESCRIPTION : Test sample as labeled as-
Chemtex Bio – Bubble Coat
Batch No. 21190-10
DOM: August 2020
DOE: August 2022

Name of Test:

Chemical disinfectants and antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas - Test method and requirements without mechanical action (phase 2/step 2)

Test Method:

EN 13697:2015

Test Material:

Carrier : Ceramic Tiles (2.5 cm dia), washed, rinsed & sterilized by autoclaving
Test product : Ready to use
Interfering substances : **Dirty conditions** (3 g/L Bovine serum albumin)
Test Bacteria : *Staphylococcus aureus* ATCC 6538; *Escherichia coli* ATCC 10536;
Pseudomonas aeruginosa ATCC 15442; *Enterococcus hirae* ATCC 10541
Contact Period : 5 minutes at Room temperature
Medium : Trypticase soya agar
Neutralizer : 3% Polysorbate 80+3% + Saponin + 0.1% histidine + 0.1% Cysteine
Incubation for survivors : 37°C for 3 days



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Test Procedure:

Suspension of test organism was prepared in 3 g/L Bovine serum albumin (adjusted density app. $1 - 2 \times 10^5$ CFU/ml). Test organism 0.05 ml was dropped on carrier, dried at 35°C . This is carried out in triplicates. One set is a base line/ zero hours count. On the other sets, Test product at 1:50 dilution was placed on prepared carrier for a total contact period of 5 minutes at Room temperature. Carrier was transferred to neutralizer and Log of surviving population was determined by standard Plate count technique. Validation of Neutralizers was also carried out as per standard procedure. Average of three readings was used for calculation.

Test Procedure: Dilution - neutralisation

Interfering substance along with Test bacteria were kept in contact with Test product, for the contact time of 5 minutes. At the end of contact time, aliquots were withdrawn; neutralized and surviving viable organisms were estimated. Reduction in viability was calculated from the number of viable CFU/ml in Test suspension Before (N) and after exposure (N_a). Validation of dilution – neutralization was carried out as per standard protocol.

Validation and Records:

Neutralizer Validation and Records:

Validation Test			
Test Organism	Exptl. Condition Control (A) (CFU/ ml)	Neutralizer Toxicity Control (B) (CFU/ ml)	Dilution–neutralization Control © (CFU/ ml)
<i>Staph. aureus</i>	62	68	64
<i>Esch. coli</i>	72	78	76
<i>P. aeruginosa</i>	64	68	70
<i>Enterococcus hirae</i>	60	64	66

Where –

A=No. of CFU/ml of Test organism in Experimental condition validation

B=No. of CFU/ml of Test organism in Neutralizer Toxicity validation

C=No. of CFU/ml of Test organism in Dilution-Neutralization validation

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Results:

A: 5 minutes at Room temperature

Test Material	Test Organism	Pre-exposure Count (Nc)		Post-exposure Count (Nd)		Microbial Effect (ME)
		CFU/ carrier	Log	CFU/ carrier	Log	
Chemtex Bio – Bubble Coat Batch No. 21190-10 DOM: August 2020 DOE: August 2022	<i>Staph. aureus</i>	2.00×10^5	5.30	<10	<1	>4.30
	<i>Esch. coli</i>	2.40×10^5	5.38	<10	<1	>4.38
	<i>P. aeruginosa</i>	1.90×10^5	5.27	<10	<1	>4.27
	<i>E. hirae</i>	2.10×10^5	5.32	<10	<1	>4.32

Note:

ME value = Nc – Nd

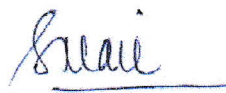
Bactericidal value = Concentration demonstrating > 4 log reduction

CONCLUSION:

Test product labeled as **Chemtex Bio – Bubble Coat, Batch No. 21190-10, DOM: August 2020, DOE: August 2022** is Effective on *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa* and *Enterococcus hirae* under Dirty conditions in 5 minutes contact on a carrier surface. **Chemtex Bio – Bubble Coat** conforms to standard EN 13697:2015.



For BIOTECH TESTING SERVICES



Dr Shilpa U. Nair
Quality Manager
(Authorized Signatory)

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