Efficacy Test Report Summary

Product description

Alcohol Free Surface Disinfectant Spray and Wipe

Date of revision: 05/10/20 v2.4

topdental™ Bossklein

Microorganism	Strain	Contact Time	Condition	Log Reduction	Lab / Report No
EN 14885 : 2015 Chemical disinfectants and antiseptics. Application of European Standards for chemical disinfectants and antiseptics.					
This European Standard specifies the below European Standards to which products have to conform in order to support the claims for microbicidal activity such as bactericidal etc. It is applicable to products to be used in the area of human medicine.					
BS EN 13727:2012 + A1:2013 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1).					
Pseudomonas aeruginosa	ATCC 15442	30 seconds	Dirty	>5.30	MelBec Microbiology Ltd Lab ref: 773.3
Staphylococcus aureus	ATCC 6538	30 seconds	Dirty	>5.34	MelBec Microbiology Ltd Lab ref: 773.3
Enterococcus hirae	ATCC 10541	30 seconds	Dirty	>5.46	MelBec Microbiology Ltd Lab ref: 773.3
VRE	NCTC 2201	1 minute	Dirty	>5.11	MelBec Microbiology Ltd Lab ref: 2281a
MRSA	NCTC 10442	1 minute	Dirty	>5.09	MelBec Microbiology Ltd Lab ref: 2281a
Legionella pneumophila	NCTC 11192	5 minutes	Dirty	>5.52	MelBec Microbiology Ltd Lab ref: 2281a
BS EN 13624:2003 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area – Test method and requirements (phase 2, step 1).					
Aspergillus niger	NCPF 2275	30 seconds	Dirty	>4.05	Abbott Analytical Certificate No 11B 061MF TOP 22/02/11
Candida albicans	NCPF 3179	30 seconds	Dirty	>4.19	Abbott Analytical Certificate No 11B 061MF TOP 22/02/11

BS EN 14348:2005 Chemical disinfectants and antiseptics. Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants. Test methods and requirements (phase 2, step 1)					
Mycobacterium avium	ATCC 15769	2 min	Clean	-	BluScientific Glasgow Certificate dated 14-11-2008 BS-TDL-001
BS EN 13704:2002 Chemical disinfectants. Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas. Test method and requirements (phase 2, step 1)					
Clostridium difficile (C-diff)	NCTC 11209	5 mins	Clean	4 86	Abbott Analytical Certificate No 08L022cd.TOP
BS EN 14476:2013 + A2:2019 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)					
Vaccinia virus	VR-1549 Elstree strain (P7)	2 mins	Dirty	>4	BluTest Laboratories Ltd. Lab code BT-TOP-23 A1

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Report for BS EN 13727:2012 + A1:2013

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1).

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Contact Name: Will Howell
Purchase Order Number: NA

Report Date: 24.04.16

Prepared By: Dawn Mellors

Date Tested: 19.04.16 & 20.04.16

Test Details:

	Product and Test Criteria	Product and Test Details
Product Details	Lab reference	**773.3**
	Name of Product(s)	**Ready to Use Alcohol Free Surface Cleaner**
	Manufacturer	Topdental
	Batch Code	**07/04/16**
	Storage Conditions	Ambient
	Active Substance	-
	Product Diluent	Not required. Product supplied as a Ready to Use product with concentration adjusted to compensate for dilution during testing.
Experimental Conditions	Method	BS EN 13727:2012 + A1:2013
	Neutraliser	Membrane Filtration for *Pseudomonas aeruginosa.* BU Broth for *Staphylococcus aureus* and *Enterococcus hirae.*
	Plating Method	Pour Plate using Tryptone Soy Agar
	Test Product Dilutions	Ready to Use
	Identification of the bacterial strains	*Pseudomonas aeruginosa* ATCC 15442 *Staphyloccocus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541
	Test Temperature	20°C ± 1°C
	Contact Times	30 second
	Interfering Substance	Dirty Conditions: 3.0g/l Bovine Albumin and 3ml/l sheep erythrocytes
	Incubation Temperature	36°C
	Product Dilutions	Client only requested testing on the product at one dilution.

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Requirements of the Standard:

The test product shall demonstrate at least a 5 decimal log (lg) reduction when tested in accordance with this standard.

Results:

Test Suspension: (N & N_0)

Pseudomonas aeruginosa ATCC 15442	N	V_c1	V_c2	ẋwm = 2.8×10^8 lgN = 8.45
	10^{-7}	27	29	N_0 = 2.8×10^7 lg N_0 = 7.45
				7.18 ≤ 7.45 ≤ 7.70
Staphyloccocus aureus ATCC 6538	N	V_c1	V_c2	ẋwm = 3.1×10^8 lgN = 8.49
	10^{-7}	30	32	N_0 = 3.1×10^7 lg N_0 = 7.49
				7.18 ≤ 7.49 ≤ 7.70
Enterococcus hirae ATCC 10541	N	V_c1	V_c2	ẋwm = 4.1×10^8 lgN = 8.61
	10^{-7}	43	38	N_0 = 4.1×10^7 lg N_0 = 7.61
				7.18 ≤ 7.61 ≤ 7.70

Test (N_a and lgR)

Na is the number of survivors per ml in the test mixture at the end of the contact time and before neutralisation.
lgR is the log reduction.

Organism	Conc. of product %	V_c Test 1	V_c Test 2	N_a ẋ x 10	lg N_a	lgR
Pseudomonas aeruginosa	100% (80%)	0 -1	0 -1	<140	<2.15	>5.30
	-	-	-	-	-	-
Staphyloccocus aureus	100% (80%)	0 -1	0 -1	<140	<2.15	>5.34
	-	-	-	-	-	-
Ent. hirae	100% (80%)	0 -1	0 -1	<140	<2.15	>5.46
	-	-	-	-	-	-

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Validation and Controls:

Pseudomonas aeruginosa

Validation Suspension (N_{v0})			Experimental Conditions Control (A)		
V_c1	50	$\dot{x}$ =4.35 x 10^1	V_c1	39	$\dot{x}$ =3.6 x 10^1
V_c2	37		V_c2	33	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

Validation Suspension (N_{vB})			Neutraliser Control (B)		
V_c1	50	$\dot{x}$ =4.35 x 10^4	V_c1	42	$\dot{x}$ = 3.8 x 10^3
V_c2	37		V_c2	34	
3.0 x 10^4 ≥N_{vB} ≤ 1.6 x 10^5			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_vB Yes		

Staphylococcus aureus

Validation Suspension (N_{v0})			Experimental Conditions Control (A)		
V_c1	69	$\dot{x}$ = 7.45 x 10^1	V_c1	72	$\dot{x}$ = 7.75 x 10^1
V_c2	80		V_c2	83	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

Validation Suspension (N_{vB})			Neutraliser Control (B)		
V_c1	92	$\dot{x}$ = 8.5 x 10^4	V_c1	78	$\dot{x}$ =8.7 x 10^3
V_c2	78		V_c2	96	
3.0 x 10^4 ≥N_{vB} ≤ 1.6 x 10^5			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_vB Yes		

Enterococcus hirae

Validation Suspension (N_{v0})			Experimental Conditions Control (A)		
V_c1	123	$\dot{x}$ = 1.16 x 10^2	V_c1	95	$\dot{x}$ = 9.6 x 10^1
V_c2	109		V_c2	77	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

Validation Suspension (N_{vB})			Neutraliser Control (B)		
V_c1	119	$\dot{x}$ = 1.1 x 10^5	V_c1	90	$\dot{x}$ =8.4 x 10^3
V_c2	101		V_c2	78	
3.0 x 10^4 ≥N_{vB} ≤ 1.6 x 10^5			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_vB Yes		

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Method Validation (C):

Pseudomonas aeruginosa			*Staphylococcus aureus*			*Ent hirae*		
V_c1	29	$\dot{x}$ = 3.2 x 10^1	V_c1	0	$\dot{x}$ = <10	V_c1	111	$\dot{x}$ = 5.9 x 10^2
V_c2	35		V_c2	0		V_c2	105	
$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 NO			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

Conclusion:

The test product has met the requirements (with a 30 second contact time) as specified in EN 13727 (5 log reduction) in dirty conditions as a Ready to Use product.

Please note that the neutralisation validation for the *Staphylococcus aureus* has not been successful using either neutralising diluent or membrane filtration. A full dilution of the neutraliser / product mix was carried out and no growth was observed at any dilution. When neutralisation is a problem and an organism has not been killed it will usually be observed on the 10^{-2} dilution as the active ingredient has been diluted enough to allow growth.

Report Authorised By:

Dawn Mellors

Technical Director

This is the end of the test report

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Report for BS EN 13727:2012 + A1:2013

Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of bactericidal activity in the medical area – Test method and requirements (phase 2, step 1).

Topdental
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Contact Name: Will Howell
Purchase Order Number: NA

Report Date: 12.03.17

Prepared By: Dawn Mellors

Date Tested: 23/02/17 & 24/02/17

Test Details:

	Product and Test Criteria	Product and Test Details
Product Details	Lab reference	**2281a**
	Name of Product(s)	**WH-10 Alcohol Free**
	Manufacturer	Topdental
	Batch Code	20/02/17
	Storage Conditions	Ambient
	Active Substance	-
	Product Diluent	Not required. Product supplied as a Ready to Use product with concentration adjusted to compensate for dilution during testing.
Experimental Conditions	Method	BS EN 13727:2012 + A1:2013
	Neutraliser	Membrane Filtration
	Plating Method	Pour Plate using Tryptone Soy Agar
	Test Product Dilutions	Ready to Use
	Identification of the bacterial strains	*E. coli* ATCC 10536 *Salmonella* Typhimurium NCTC 12023 VRE NCTC 2201 MRSA NCTC 10442 *Serratia marcescens* *Listeria monocytogenes* NCTC 7973 *Legionella pneumophila* NCTC 11192
	Test Temperature	20°C ± 1°C
	Contact Times	1 min & 5 min
	Interfering Substance	Dirty Conditions: 3.0g/l Bovine Albumin & Sheep erythrocytes

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	Incubation Temperature	36°C
Deviations	Product Dilutions	Client only requested testing on the product at one dilution. Timepoints chosen by client. Test organisms chosen by the client.

Requirements of the Standard:

The test product shall demonstrate at least a 5 decimal log (lg) reduction when tested in accordance with the standard.

Results:

Test Suspension: (N & N_0)

E. coli	N	V_c1	V_c2	$\dot{x}wm = 1.87 \times 10^8$ lgN = 8.27
	10^{-7}	20	23	$N_0 = 1.87 \times 10^7$ lg N_0 = 7.27
	10^{-6}	170	199	$7.18 \leq 7.27 \leq 7.70$
Salmonella Typhimurium	N	V_c1	V_c2	$\dot{x} = 2.28 \times 10^8$ lgN = 8.36
	10^{-7}	19	18	$N_0 = 2.28 \times 10^7$ lg N_0 = 7.36
	10^{-6}	227	238	$7.18 \leq 7.36 \leq 7.70$
VRE	N	V_c1	V_c2	$\dot{x} = 1.84 \times 10^8$ lgN = 8.26
	10^{-7}	16	15	$N_0 = 1.84 \times 10^7$ lg N_0 = 7.26
	10^{-6}	179	194	$7.18 \leq 7.26 \leq 7.70$
MRSA	N	V_c1	V_c2	$\dot{x} = 1.53 \times 10^8$ lgN = 8.18
	10^{-7}	<14	16	$N_0 = 1.53 \times 10^7$ lg N_0 = 7.18
	10^{-6}	150	155	$7.18 \leq 7.24 \leq 7.70$
Legionella pneumophila	N	V_c1	V_c2	$\dot{x} = 4.65 \times 10^8$ lgN = 8.67
	10^{-7}	49	44	$N_0 = 4.65 \times 10^7$ lg N_0 = 7.67
	10^{-6}	>300	>300	$7.18 \leq 7.67 \leq 7.70$
Listeria monocytogenes	N	V_c1	V_c2	$\dot{x} = 4.65 \times 10^8$ lgN = 8.67
	10^{-7}	47	46	$N_0 = 4.65 \times 10^7$ lg N_0 = 7.67
	10^{-6}	>300	>300	$7.18 \leq 7.67 \leq 7.70$
Serratia marcescens	N	V_c1	V_c2	$\dot{x} = 2.64 \times 10^8$ lgN = 8.42
	10^{-7}	24	34	$N_0 = 2.64 \times 10^7$ lg N_0 = 7.42
	10^{-6}	254	268	$7.18 \leq 7.42 \leq 7.70$
Klebsiella pneumoniae	N	V_c1	V_c2	$\dot{x} = 3.8 \times 10^8$ lgN = 8.58
	10^{-7}	33	43	$N_0 = 3.8 \times 10^7$ lg N_0 = 7.58
	10^{-6}	>300	>300	$7.18 \leq 7.58 \leq 7.70$

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Test (N_a and lgR)

Na is the number of survivors per ml in the test mixture at the end of the contact time and before neutralisation.

lgR is the log reduction.

1 min

Organism	Conc. of product %	V_c Test 1	V_c Test 2	N_a ẋ x 10	lg N_a	lgR
E. coli	100% (80%)	0-1	0-1	<140	<2.15	>5.12
	-	-	-	-	-	-
Salmonella Typhimurium	100% (80%)	0-1	0-1	<140	<2.15	>5.21
	-	-	-	-	-	-
VRE	100% (80%)	0-1	0-1	<140	<2.15	>5.11
	-	-	-	-	-	-
MRSA	100% (80%)	0-1	0-1	<140	<2.15	>5.09
	-	-	-	-	-	-
Leg pneumophila	100% (80%)	60-4	74-4	6.7×10^5	5.83	1.84
	-	-	-	-	-	-
Klebsiella pneumoniae	100% (80%)	0-1	0-1	<140	<2.15	>5.43
	-	-	-	-	-	-
Listeria monocytogenes	100% (80%)	0-1	0-1	<140	<2.15	>5.52
	-	-	-	-	-	-
Serratia marcescens	100% (80%)	0-1	0-1	<140	<2.15	>5.26
	-	-	-	-	-	-

5 min

Organism	Conc. of product %	V_c Test 1	V_c Test 2	N_a ẋ x 10	lg N_a	lgR
E. coli	100% (80%)	0-1	0-1	<140	<2.15	>5.12
	-	-	-	-	-	-
Salmonella Typhimurium	100% (80%)	0-1	0-1	<140	<2.15	>5.21
	-	-	-	-	-	-
VRE	100% (80%)	0-1	0-1	<140	<2.15	>5.11
	-	-	-	-	-	-
MRSA	100% (80%)	0-1	0-1	<140	<2.15	>5.09
	-	-	-	-	-	-
Leg pneumophila	100% (80%)	5-1	6-1	<140	<2.15	>5.52
	-	-	-	-	-	-
Klebsiella pneumoniae	100% (80%)	0-1	0-1	<140	<2.15	>5.43
	-	-	-	-	-	-
Listeria monocytogenes	100% (80%)	0-1	0-1	<140	<2.15	>5.52
	-	-	-	-	-	-
Serratia marcescens	100% (80%)	0-1	0-1	<140	<2.15	>5.26
	-	-	-	-	-	

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Validation and Controls:

E. coli

Validation Suspension (N_{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C):		
V_c1	47	$\dot{x}$ = 4.15 x 10^1	V_c1	59	$\dot{x}$ = 6.1 x 10^1	V_c1	59	$\dot{x}$ = 5.2 x 10^1	V_c1	41	$\dot{x}$ = 4.5 x 10^1
V_c2	36		V_c2	63		V_c2	45		V_c2	49	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

Salmonella Typhimurium

Validation Suspension (N_{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C):		
V_c1	50	$\dot{x}$ = 5.85 x 10^1	V_c1	58	$\dot{x}$ = 6.9x 10^1	V_c1	57	$\dot{x}$ = 5.3 x 10^1	V_c1	39	$\dot{x}$ = 4.2 x 10^1
V_c2	67		V_c2	80		V_c2	49		V_c2	45	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

Klebsiella pneumoniae

Validation Suspension (N_{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C):		
V_c1	82	$\dot{x}$ = 9.0 x 10^1	V_c1	63	$\dot{x}$ = 6.7x 10^1	V_c1	77	$\dot{x}$ = 7.45 x 10^1	V_c1	64	$\dot{x}$ 7.8 x 10^1
V_c2	98		V_c2	72		V_c2	71		V_c2	92	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

Listeria monocytogenes

Validation Suspension (N_{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C):		
V_c1	127	$\dot{x}$ = 1.09 x 10^2	V_c1	126	$\dot{x}$ = 1.39 x 10^2	V_c1	107	$\dot{x}$ = 1.01 x 10^2	V_c1	129	$\dot{x}$ = 1.37 x 10^2
V_c2	91		V_c2	151		V_c2	95		V_c2	145	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

VRE

Validation Suspension (N_{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C):		
V_c1	39	$\dot{x}$ =3.7 x 10^1	V_c1	54	$\dot{x}$ =4.8 x 10^1	V_c1	45	$\dot{x}$ = 4.3 x 10^1	V_c1	39	$\dot{x}$ = 3.3 x 10^1
V_c2	35		V_c2	42		V_c2	48		V_c2	27	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

MRSA

Validation Suspension (N_{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C):		
V_c1	38	$\dot{x}$ = 3.65 x 10^1	V_c1	27	$\dot{x}$ = 2.5 x 10^1	V_c1	28	$\dot{x}$ = 2.75 x 10^1	V_c1	20	$\dot{x}$ = 1.85 x 10^1
V_c2	35		V_c2	23		V_c2	27		V_c2	17	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

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Legionella pneumophila

Validation Suspension (N_{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C):		
V_c1	38	$\dot{x}$ = 4.15 x 10^1	V_c1	27	$\dot{x}$ = 2.5 x 10^1	V_c1	32	$\dot{x}$ = 3.45 x 10^1	V_c1	41	$\dot{x}$ = 3.7 x 10^1
V_c2	45		V_c2	23		V_c2	37		V_c2	33	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

Serratia marcescens

Validation Suspension (N_{v0})			Experimental Conditions Control (A)			Neutraliser Control (B)			Method Validation (C):		
V_c1	71	$\dot{x}$ = 8.6 x 10^1	V_c1	60	$\dot{x}$ = 5.65 x 10^1	V_c1	51	$\dot{x}$ = 5.45 x 10^1	V_c1	89	$\dot{x}$ = 9.5 x 10^1
V_c2	81		V_c2	53		V_c2	58		V_c2	101	
30 ≥N_{v0} ≤ 160			$\dot{x}$ of A is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of B is ≥ 0.5x $\dot{x}$ of N_v0 Yes			$\dot{x}$ of C is ≥ 0.5x $\dot{x}$ of N_v0 Yes		

Conclusion:

The test product met the requirements of the standard with a 1 minute contact time tested (5 log reduction) in dirty conditions as a Ready to Use product for the test organisms with the exception of *Legionella pneumophila.*

With a 5 minute contact time the test product met the requirements of the standard (5 log reduction) in dirty conditions as a Ready to Use product for the test organisms.

Report Authorised By:

Dawn Mellors

Technical Director

This is the end of the test report

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Efficacy Test Report Certificate

Abbott Analytical

Consulting Scientists to the Disinfectant Industry

Certificate of Analysis

Sample(s):	One sample of Mix Control Lot 102777		
Received from:	Topdental (Products) Ltd. Dental House, Steeton Grove Industrial Park, Steeton, West Yorkshire, BD20 6TT		
Date received:	14 February 2011	**Date tested:**	18 February 2011
Certificate no:	11B.061MF.TOP	**Certificate date:**	22 February 2011
Sample ref:	11B/061	**Page:**	1 of 2
Analysis required:	EN 13624, Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal and yeasticidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase 2, step 1)		

Product stored at:	Room temperature
Active substance:	Not declared
Test conditions:	Dirty
Interfering substance:	3.0g/l bovine albumin + 3.0ml/l sheep erythrocytes
Product test concentration:	8ml in 500ml of water
Product diluent used during test:	Sterile hard water 300mg/l $CaCO_3$
Contact time:	30 seconds
Test temperature:	20°C ± 0.5°C
Neutralising solution:	30g/l polysorbate 80, 3g/l lecithin, 1g/l histidine, 1g/l cysteine; in phosphate buffer
Incubation temperature:	30°C ± 1°C
Identification of fungal/yeast strain(s) used:	*Aspergillus niger* NCPF 2275 *Candida albicans* NCPF 3179

D C Watson

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22 February 2011 Certificate No: 11B.061MX.TOP

Test results:

Test Organism		*Aspergillus niger*		*Candida albicans*	
Validation Suspension (Nv_c)		Vc1 238	Vc2 260	Vc1 228	Vc2 242
		x̄ = 249		x̄ = 235	
Experimental Control (A)		Vc1 224	Vc2 248	Vc1 216	Vc2 196
		x̄ = 236	≥ 0.5Nv_c	x̄ = 206	≥ 0.5Nv_c
Neutraliser Control (B)		Vc1 250	Vc2 216	Vc1 204	Vc2 220
		x̄ = 233	≥ 0.5Nv_c	x̄ = 212	≥ 0.5Nv_c
Method Validation (C)		Vc1 246	Vc2 222	Vc1 230	Vc2 196
		x̄ = 234	≥ 0.5Nv_c	x̄ = 213	≥ 0.5Nv_c
Test Suspension	10^{-6}	Vc1 192	Vc2 224	Vc1 234	Vc2 216
	10^{-5}	Vc1 31	Vc2 24	Vc1 15	Vc2 23
(N) **(N_o = 0.1N)**		N̄ = 2.14 x 10[illegible] lg N = 7.33 lg N_o = 6.33		N̄ = 2.19 x 10[illegible] lg N = 7.34 lg N_o = 6.34	
Results	10^{1}	Vc1 17	Vc2 21	Vc1 <14	Vc2 <14
(Na) **(R)**		10x̄ = 190 lg Na = 2.28 lg R = 4.05		10x̄ < 140 lg Na < 2.15 lg R > 4.19	
Pass: lg R ≥ 4		PASS		PASS	

Vc = plate count per ml
x̄ = average of Vc1 and Vc2
N̄ = weighted mean of x̄
R = reduction (lg R = lg N_o - lg Na)

Requirements & Conclusion:

This batch of Mix Control, when diluted 8ml in 500ml of water, passes the requirements of EN 13624 for fungicidal and yeasticidal activity in 30 seconds at 20°C under dirty conditions against the reference organisms detailed.

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BluScientific Test Data

Test Report BS EN 14348: 2005. Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants— Test method and requirements (phase 2, step 1)

Test Laboratory	**BluScientific Test Data** School of Life Sciences Glasgow Caledonian University GLASGOW G4 0BA
Identification of sample	
Name of the product	**MIX0007 Mix Control TM Disinfectant Spray Cartridge**
Batch Number	**LOT 1024456**
Manufacturer	TOPDENTAL (PRODUCTS) LTD, DENTAL HOUSE, STEETON GROVE INDUSTRIAL PARK, STEETON, WEST YORKSHIRE, BD20 6TT
Date of Delivery	14 July 2008
Project code	BS-TDL-001
Storage conditions	4°C and darkness
Active substances	Not known
Test Method and its validation	
Method	Filtration-neutralization
Neutralizer	Lecithin 3g/l, Polysorbate 80 30g/l, sodium thiosulphate 5g/l, L-histidine 1g/l, phosphate buffer 0.0025mol/l, sterilized by autoclave
Experimental Conditions	
Period of analysis	22 October to 11 November 2008
Product diluent used	Sterile hard water
Product test concentrations	7.9 ml to 492 ml distilled water
Appearance product dilutions	Colourless, clear product solution
Contact time	t = 2 min $\pm$ 10 s
Test temperature	20°C $\pm$ 1°C
Interfering substance	0.3 g/l bovine albumin
Stability of mixture	Precipitate absent throughout the test
Temperature of incubation	37°C $\pm$ 1°C
Identification of strain	*Mycobacterium Avium* ATCC 15769

Conclusion

According to EN 14348 (2005) the **MIX0007 Mix Control TM Disinfectant Spray Cartridge,** batch number LOT **1024456,** used as received from Topdental *possesses mycobactericidal activity* in 2 min at 20°C under **CLEAN** conditions (0.3 g/l bovine albumin) for reference strain *Mycobacterium Avium* ATCC 15769

Signed

Dr Chris Woodall, Director
BluScientific Test Data
Glasgow, UK, 14 November 2008

School of Life Sciences, Glasgow Caledonian University, Glasgow G4 0BA, Scotland, UK
[illegible]
[illegible]

GLASGOW CALEDONIAN UNIVERSITY

Efficacy Test Report Certificate

Abbott Analytical

Consulting Scientists to the Disinfectant Industry

24th November 2008

CERTIFICATE OF ANALYSIS.

Samples: One sample of Mix control Hard Surface Spray received from Topdental Products Ltd, Dental House, Steeton Grove Industrial Park, Steeton, West Yorkshire. BD20 6TT 13th November 2008

Certificate No: 08L.022cd.TOP

Page: 1 of 1

Sample Ref: 81 / 022

Analysis Required: BS EN 13704 Quantitative Suspension Test for the Evaluation of Sporicidal activity of chemical disinfectants.

Samples Tested: 19th November 2007

Product stored at room temperature.

Product number - **MIX0007**

Experimental conditions:

Product test concentrations	-	Neat as received.
Interferring substance	-	0.3g/l Bovine serum
Contact time	-	5 mins
Test Temperature	-	20°C ± 0.5°C
Neutralising solution	-	3% Tween 80, 3% Saponin, 0.1% Histidine, 0.1% Cysteine
Temperature of incubation	-	30°C ± 1°C

Identification of bacterial strains used - **Clostridium difficile NCTC 11209**

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Efficacy Test Report Certificate

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19th November 2008

Certificate No 8L.022cd.TOP

Test Results

Validation test	Clostridium difficile
Bacterial suspension	Vc 310, 262 Nv 2.86×10^3
Experimental conditions	Vc 224, 270 A 2.47×10^2
Neutraliser control	Vc 200, 198 B 1.99×10^2
Dilution-neutralisation control	Vc 242, 270 C 2.56×10^2
Bacterial Test Suspension	10^{-6} 232 210 10^{-7} 29 33 N 2.65×10^8
Test results	
Neat Vc Na R	37 3700 7.16×10^4
Log reduction	4.86

Vc = Viable Count.
N = Number of cfu/ml of the bacterial test suspension.
Nv = Number of cfu in bacterial suspension.
R = Reduction in viability.
Na = Number of cfu/ml in the test mixture

Conclusion: According to EN13704 this batch of Mix Control Hard Surface Spray when used neat as received possesses satisfactory sporicidal activity in 5 minutes at 20°C under clean conditions (0.3g/l bovine albumin) for the reference organism detailed.

D C Watson

Efficacy Test Report Certificate

BluTest LABORATORIES LTD

Test Report: BS EN 14476:2013 + A2:2019 Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area- Test method and requirements (Phase 2/Step 1)

Test Laboratory	**BluTest Laboratories Ltd** 5 Robroyston Oval, Nova Business Park, Glasgow, G33 1AP
Identification of sample	
Name of the product	Alcohol Free BT-57
Batch number	2006081
Client	Top Dental Products Limited
Client Address	12 Ryefield Way, Silsden, West Yorkshire, BD20 0EF, UK
Project Code	BT-TOP-23 A1
Date of Delivery	24 June 2020
Storage conditions	Ambient
Active substances	DDAC/ BAC/ PHMB
Appearance	Liquid
Condition upon receipt	Undamaged
Test Method and its validation	
Method	1 part interfering substance + 1 part virus suspension + 8 parts biocide were mixed and incubated at the indicated contact temperature for the indicated contact times. Assays were validated by a cytotoxicity control, interference control, neutralisation control and a formaldehyde internal standard.
Neutralisation	Dilution-neutralisation/gel filtration Eagles Minimum Essential Medium + 5.0% v/v foetal bovine serum at 4°C
Experimental Conditions	
Period of analysis	11 August 2020 to 16 August 2020
Product diluents used	Sterile distilled water
Product test concentrations	10.0% v/v; 50.0% v/v; 80.0% v/v
Appearance product dilutions	No changes noted- stable
Appearance in test mixture	Sedimentation observed at 50.0% v/v and 10.0% v/v Turbidity observed at 10.0% v/v
Contact times (minutes)	2 ± 10s
Test temperature	20°C ± 1°C
Interfering substances	3.0 g/l bovine albumin + 3.0 ml/l erythrocytes
Temperature of incubation	37°C ± 1°C + 5% CO_2
Identification and passage (P) of virus	***Vaccinia virus*** **VR-1549 Elstree strain (P7)**
Identification and passage (P) of cells	Vero Cells (P 42)

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Company Registration Number: SC364409 VAT Registration Number: GB 979 1131 96 UKAS Number: 4597

BluTest

PROTOCOL SUMMARY

The basic virucidal efficacy test is set up with three concentrations of test product solution and a 2-minute contact time. Virus is exposed to disinfectant in 24-well plates, then neutralised, serially diluted and virus titred in 96-well tissue culture plates to determine the tissue culture infectious dose$_{50}$ ($TCID_{50}$) of surviving virus. *Vaccinia virus* VR-1549 Elstree strain / Vero cells are assayed in parallel in each test. $TCID_{50}$ is determined by the method of Karber[1].

Cytotoxicity control
The test product solution is measured for its effects on the host cells used to propagate the virus, to determine the sensitivity of the assay.

Interference control
The effect of the cells after treatment of the test product solution are verified to ensure the cells can show susceptibility for virus infection. This is compared against cells that have not been treated with test product.

Disinfectant suppression control VS1
Virus is added to the highest concentration of test product solution and then the mixture immediately removed and neutralised. The neutralised virus titre is then determined to assess the efficiency of the neutralisation procedure.

Disinfectant suppression control VS2
Internal control which adds virus to neutralised test product solution to assess the efficiency of the neutralisation procedure.

No column Control
Internal control on the highest contact time to assess any impact of the Microspin™ S 400 HR columns.

Virus recovery control
Virus titre is determined for virus in contact with sterile distilled water at t=0, t = 2 and at t =15. The virus titre after 2 minutes is then compared to the recovery of disinfectant-treated virus to measure the log reduction in virus titre. The virus titre at 15 minutes is compared to the reference virus inactivation control.

Reference virus inactivation control
Virus is exposed to 0.7% W/V formaldehyde and the recovery of virus determined by $TCID_{50}$ after 5 and 15 minutes, in order to assess that the test virus has retained reproducible biocide resistance. In addition, the formaldehyde cytotoxicity of neutralised formaldehyde is determined, to measure assay sensitivity.

1Kärber, G.: Beitrag zur Kollektiven Behandlung Pharmakologischer Reihenversuche. Arch. Exp. Path. Pharmak. 162 (1931): 480-487.

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Vaccinia virus (VR-1549) Elstree strain Test Results

EN14476:2013 + A2:2019 Suspension test for the efficacy of Alcohol Free BT-57, BT-TOP-23 from Top Dental Products Limited against Vaccinia virus VR-1549 under DIRTY conditions

Test Results

Concentration	10.0% (v/v)		50.0% (v/v)		80.0% (v/v)	
Exposure Time	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml
t = 2 mins	3.00	3.16E+04	1.00	3.16E+02	0.00	3.16E+01
Raw Data	666000	3.16E+04	600000	3.16E+02	000000	3.16E+01
log		4.50		2.50		1.50
log difference		2.00		4.00		5.00

EN14476:2013 + A2:2019 Suspension test for the efficacy of Alcohol Free BT-57, BT-TOP-23 from Top Dental Products Limited against Vaccinia virus VR-1549 under DIRTY conditions

Summary Table

Product:	Interfering substance	Concentration	Level of cytotoxicity	lg $TCID_{50}$					>4 lg reduction after 'X' Min
				0 min	5 min	15 min	30 min	60 min	
Alcohol Free BT-57	3.0g/l BSA + 3.0ml/l erythrocytes	80.0% (v/v)	1.50	2.33	1.50	n.a.	n.a.	n.a.	<2 mins
		50.0% (v/v)	1.50	n.a.	2.50	n.a.	n.a.	n.a.	2 mins
		10.0% (v/v)	1.50	n.a.	4.50	n.a.	n.a.	n.a.	>2 mins
Alcohol Free BT-57	3.0g/l BSA	80.0% (v/v)	1.50	n.a.	1.50	n.a.	n.a.	n.a.	<2 mins
		50.0% (v/v)	1.50	n.a.	2.50	n.a.	n.a.	n.a.	2 mins
		10.0% (v/v)	1.50	n.a.	4.50	n.a.	n.a.	n.a.	>2 mins
Virus Control	DIRTY			6.33	6.50	6.17	n.a.	n.a.	n.a.
Virus Control	CLEAN			6.33	6.50	6.33	n.a.	n.a.	n.a.
							5 min	15 min	
Formaldehyde	PBS	0.7% (w/v)	2.50				4.67	2.50	>15 mins

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Vaccinia virus (VR-1549) Elstree strain Control Data

EN14476:2013 + A2:2019 Suspension test for the efficacy of Alcohol Free BT-57, BT-TOP-23 from Top Dental Products Limited against Vaccinia virus VR-1549 under DIRTY conditions

Controls

Virus Recovery 0 min		Virus Recovery 2 min		Virus Recovery 15 min		Cytotoxicity		Disinfectant Suppression VS		Disinfectant Suppression VS2	
raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
4.83	2.15E+06	5.00	3.16E+06	4.67	1.47E+06	0.00	3.16E+01	0.83	2.15E+02	5.17	4.64E+06
666650	2.15E+06	666660	3.16E+06	666640	1.47E+06	000000	3.16E+01	311000	2.15E+02	666661	4.64E+06
	6.33		6.50		6.17		1.50		2.33		6.67
									4.17		-0.17

Formaldehyde reference inactivation controls

Cytotoxicity		Exposure time	0.7% Formaldehyde			
			5 mins		15 mins	
raw data	$TCID_{50}$/ml		raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml
1.00	3.16E+02		3.17	4.64E+04	1.00	3.16E+02
600000	3.16E+02		666100	4.64E+04	600000	3.16E+02
	2.50	log		4.67		2.50
		log difference		1.50		3.67

No column Control 2 mins	
raw data	$TCID_{50}$/ml
5.17	4.64E+06
666661	4.64E+06
	6.67

Interference control	Virus dilution					
	-3	-4	-5	-6	-7	-8
PBS Control	1	1	1	1	0.33	0
	3.16E+02	3.16E+02	3.16E+02	3.16E+02	6.76E+01	3.16E+01
	2.50	2.50	2.50	2.50	1.83	1.50
Raw Data	6	6	6	6	2	0
Product	1	1	1	1	0.5	0
	3.16E+02	3.16E+02	3.16E+02	3.16E+02	1.00E+02	3.16E+01
	2.50	2.50	2.50	2.50	2.00	1.50
Raw Data	6	6	6	6	3	0
Log Difference	0.00	0.00	0.00	0.00	-0.17	0.00
Product Cyt Dilution	-1	-1	-1	-1	-1	-1
PBS Dilution	Neat	Neat	Neat	Neat	Neat	Neat

Stock Virus ($TCID_{50}$)
6.33
6.76E+07
6666662000

SOP 11000
SOP 8003 EN14476 Vaccinia REPORT TEMPLATE V01
Effective Date: 23 March 2020

BT-TOP-23 A1

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Vaccinia virus (VR-1549) Elstree strain Control Data

Parallel Control Test												
Controls						Test Results						
Virus Recovery 0 min		Virus Recovery 2 min		Virus Recovery 15 min		Concentration	10.0% (v/v)		50.0% (v/v)		80.0% (v/v)	
raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	raw data	$TCID_{50}$/ml	Exposure Time	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml	data	$TCID_{50}$/ml
4.83	2.15E+06	5.00	3.16E+06	4.83	2.15E+06	t = 2 mins	3.00	3.16E+04	1.00	3.16E+02	0.00	3.16E+01
666650	2.15E+06	666660	3.16E+06	666650	2.15E+06	Raw data	664200	3.16E+04	600000	3.16E+02	000000	3.16E+01
	6.33		6.50		6.33	log		4.50		2.50		1.50
						log difference		2.00		4.00		5.00

SOP 11000
SOP 8003 EN14476 Vaccinia REPORT TEMPLATE V01
Effective Date: 23 March 2020
BT-TOP-23 A1

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CONCLUSION

Verification of the methodology

A test is only valid if the following criteria are fulfilled:

a) The titre of the test suspension of at least 10^8 TCID50 /ml is sufficiently high to at least enable a titre reduction of 4 lg to verify the method.

b) Detectable titre reduction is at least 4 $\log_{10}$.

c) Difference of the logarithmic titre of the virus control minus the logarithmic titre of the test virus in the reference inactivation test is between:
   - Between 0.75 and 3.5 after 5 min and between 2.0 and 4.0 after 15 min for Vaccinia virus

d) Cytotoxicity of the product solution does not affect cell morphology and growth or susceptibility for the test virus in the dilutions of the test mixtures which are necessary to demonstrate a 4 $\log_{10}$ reduction of the virus.

e) The interference control result does not show a difference of > 1.0 $\log_{10}$ of virus titre for test product treated cells in comparison to the non-treated cells.

f) Neutralisation validation. This is called the disinfectant suppression test in this protocol. The disinfectant was neutralised by column chromatography through an Illustra Microspin S-400 HR column to achieve the best possible neutralisation available for this test. The difference for virus is greater than 0.5 $\log_{10}$ indicating rapid irreversible virucidal activity of the disinfectant by dilution at a concentration of 80.0% v/v for VS1. This neutralisation validation has been verified by VS2, which shows the product has been successfully neutralised.

According to EN 14476:2013 + A2:2019, **Alcohol Free BT-57 POSSESSES VIRUCIDAL** activity at a concentration of **80.0% v/v** of the working concentration as tested after **2 MINUTES** at **20°C** under **DIRTY** conditions (3.0 g/l bovine albumin + 3.0 ml/l erythrocytes) against *Vaccinia virus* VR-1549 Elstree strain / Vero cells.

This product therefore is effective against all enveloped viruses as defined in EN 14476:2013 + A2:2019 Annex A*. This therefore includes all coronaviruses and SARS-CoV-2.

Authorised signatory

Dr Chris Woodall, Director
BluTest Laboratories Ltd
Glasgow, UK.
Date: 27 AUGUST 2020

DISCLAIMER

The results in this test report only pertain to the sample supplied.
BluTest (BT) has performed the testing detailed in this report using reasonable skill and care and has used reasonable endeavours to carry out the testing in accordance with an EN 14476 protocol. All forecasts, recommendations and results contained in this report are submitted in good faith. However, other than as expressly set out in this report, no warranty is given (i) in relation to the testing or the use(s) to which any results or deliverables produced in the course of the testing are or may be put by the Client or their fitness or suitability for any particular purpose or under any special conditions notwithstanding that any such purpose or conditions may have been made known to BT or (ii) that the intended results or deliverables from the testing can be achieved or (iii) that the Client can freely make use of the results or the deliverables without infringing any third party intellectual property rights and the Client will be deemed to have satisfied itself in this regard. BT shall have no liability (which is hereby excluded to the fullest extent permissible by law) in respect of any loss, liability or damage, including without limitation any indirect and/or consequential loss such as loss of profit or loss of business, market or goodwill, that the Client may suffer directly or indirectly as a result of or in connection with: (i) the performance of the testing; (ii) the use of any materials, samples or other information provided by the Client for use in the testing; and (iii) the Client's reliance upon or use of any results or deliverables provided as part of the testing.
Amendment 1: BT-TOP-23 EN14476 Vaccinia Report 25 Aug 20 LM CW: Batch number added. LM 27 August 2020

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***EN 14476 2013 + A2 2019 Annex A (informative – Enveloped viruses)**

Poxviridae
Herpesviridae
Filoviridae (e.g. Ebola, Marburg)
Flavivirus
Hepatitis C Virus (HCV)
Hepatitis Delta Virus (HDV)
Influenza Virus
Paramyxoviridae
Rubella Virus
Measles Virus
Rabies Virus
Coronavirus (e.g. SARS, MERS)
Human Immunodeficiency Virus (HIV)
Human T Cell Leukemia Virus (HTLV)
Hepatitis B virus (HBV)

Reference: Van Regenmortel MHV et al.,Eds.: Virus Taxonomy, Classification and Nomenclature of Viruses, seventh report of the international committee on taxonomy of viruses. Academic Press, San Diego, 2000

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