

B. Braun Medical AG
Seesatz 17
CH – 6204 Sempach

Hamburg, 2 March 2011

Expert Report

Tuberculocidal Activity of **Meliseptol Foam pure**
in the Quantitative Carrier Test according to DIN EN 14563:2009 (Phase 2, Step 2)


The rapid disinfectant **Meliseptol Foam pure** was tested and evaluated according to DIN EN 14563:2009 "Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area – Test method and requirements (phase 2, step 2); German version EN 14563:2008".

According to test report no L 10/167 from Dr. Brill + Partner GmbH, the product showed tuberculocidal activity under clean conditions.

The use recommendation for the rapid disinfection **Meliseptol Foam pure** according to DIN EN 14563:2009 under low organic load is:

100 %

1 minute.



Dipl.-Biol. Florian H. H. Brill

Test Report No. L 10/167

Tuberculocidal Activity of Meliseptol Foam pure

in the Quantitative Carrier Test according to DIN EN 14563:2009 (Phase 2, Step 2)*

In accordance with your order, we tested the disinfectant **Meliseptol Foam pure** for its activity against *Mycobacterium terrae* in the quantitative carrier test according to DIN EN 14563:2009* under clean conditions.

1. General Information and Material

a) Client

- Client: B. Braun Medical AG, Seesatz 17, 6204 Sempach,
Switzerland, Mr Andreas Arndt
- Date of order: 24 November 2010

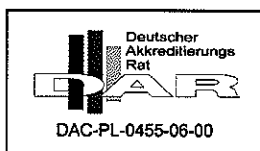
b) Identification of Test Laboratory

- Dr. Brill + Partner GmbH - Institute for Hygiene and Microbiology, Stiegstück 34, DE - 22339 Hamburg; Florian H. H. Brill, Henrik Gabriel, Dr. Jan-Hendrik Klock, Carmela Jänicke, Marion Korsch, Ulrike Ißleib.

c) Identification of Samples

- Name of product: Meliseptol Foam pure
- Batch no.: 0043M13
- Manufacturer: B. Braun Medical AG, Sempach, Switzerland
- Date of delivery: 20 December 2010
- Storage conditions: room temperature and darkness
- Appearance of concentrate: clear, colourless solution

L10/167-110302-V01-FB



*Test procedure accredited according to DIN EN ISO/IEC 17025. Test report issued by Dr. Brill + Partner GmbH, Stiegstück 34, DE - 22339 Hamburg, Telephone 040/557631-0, Telefax 040/557631-11, www.brillhygiene.com. No copying or transmission, in whole or in part, of this test report without the explicit prior written permission. The test results refer exclusively to the tested items. Information on measurement accuracy on request. © Dr. Brill + Partner GmbH 2011

- Odour: alcoholic, fresh
- Diluent recommended: drinking water
- Diluent used: water of standardised hardness (WSH)
- pH-value, 100 %: 7.50
- pH- value, 50 %, diluted with WSH: 7.35
- Active agents in 100 g test preparation: 17.0 g 1-propanol
0.23 g didecyl dimethyl ammonium chloride

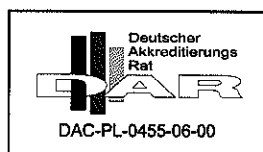
d) Test conditions

- Test period: 3 January 2011 – 24 January 2011
- Product test concentrations: 100, 75 and 50 volume-%
- Test temperature: $20^{\circ}\text{C} \pm 2^{\circ}\text{C}$
- Exposure times: 1, 3 and 5 minutes
- Organic load: clean conditions (0.03 % bovine albumin)
- Inactivation method: Membrane filtration and rinsing of membrane filter with an aqueous solution with 30 g/L Tween 80 and 3 g/L lecithin in order to inactivate possible rests of the active agent on the filter
- Incubation temperature: $36^{\circ}\text{C} \pm 1^{\circ}\text{C}$
- Test organism: *Mycobacterium terrae* ATCC 15755

2. Methods

The tests were carried out according to DIN EN 14563:2009 "Chemical disinfectants and antiseptics – Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area – Test method and requirements (phase 2, step 2); German version EN 14563:2008".

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3. Results

The test results are summarised in tables 1.

The test validation with the mentioned inactivation method was successful.

The sufficient effective concentration-time relationship (\geq RF 4) for the disinfectant Meliseptol Foam pure under clean conditions was:

100 %

1 minute.

Hamburg, 2 March 2011

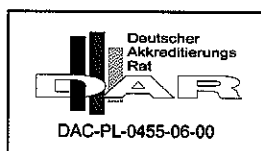


Dipl.-Biol. Florian H. H. Brill



DR. BRILL

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Test Report No L 10/167: Table 1.1: Validation and Controls (DIN EN 14563: 2009*)

Quantitative Carrier Test for the Evaluation of Tuberculocidal Activity (Phase 2, Step 2)

Test preparation (Batch): Meliseptol Foam pure (0043M13)
 Test organism: *Mycobacterium terrae*
 Organic load: clean conditions (0.03 % bovine albumin)
 Inactivation: Membrane filtration and rinsing of the filter with 3.0 % Tween and 0.3 % lecithin

NV0		A				B		C at 100 %			
		1 Minute		3 Minute				1 Minute		3 Minutes	
VC1	X	VC1	X	VC1	X	VC1	X	VC1	X	VC1	X
34		40		40		50		26		40	
VC2	36	VC2	40	VC2	40	VC2	35,5	VC2	30	VC2	41,5
38		40		40		21		34		43	

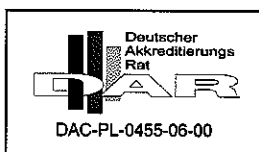
Evaluation of Test Validation and Controls

$30 \leq X \text{ of NV0} \leq 160 ?$	$X \text{ of A (1')} \geq 0.5 \times X \text{ of NV0} ?$	$X \text{ of A (3')} \geq 0.5 \times X \text{ of NV0} ?$	$X \text{ of B is } \geq 0.5 \times X \text{ of NV0} ?$	$X \text{ of C (1')} \geq 0.5 \times X \text{ of NV0} ?$	$X \text{ of C (3')} \geq 0.5 \times X \text{ of NV0} ?$
Yes	Yes	Yes	Yes	Yes	Yes

Key:

NV0 =	suspension for validation
A =	control of test conditions
B =	control of neutraliser
C =	validation of method at highest product concentration in %
VC =	number of viable cells per ml
X =	mean of VC1 and VC2

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Test Report No L 10/167: Table 1.2: Validation and Controls (DIN EN 14563: 2009*)Quantitative Carrier Test for the Evaluation of Tuberculocidal Activity (Phase 2, Step 2)

Test preparation (Batch): Meliseptol Foam pure (0043M13)
 Test organism: *Mycobacterium terrae*
 Organic load: clean conditions (0.03 % bovine albumin)
 Inactivation: Membrane filtration and rinsing of the filter with 3.0 % Tween and 0.3 % lecithin

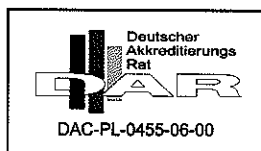
NV0		A 5 minutes		B		C at 100 % 5 minutes	
VC1 34	X	VC1 40	X	VC1 50	X	VC1 40	X
VC2 38	36	VC2 40	40	VC2 21	35,5	VC2 43	41,5

Evaluation of Test Validation and Controls

$30 \leq X \text{ of NV0} \leq 160 ?$	$X \text{ of A (5')} \geq 0.5 \times X \text{ of NV0} ?$	$X \text{ of B is } \geq 0.5 \times X \text{ of NV0} ?$	$X \text{ of C (5')} \geq 0.5 \times X \text{ of NV0} ?$
Yes	Yes	Yes	Yes

Key: NV0 = suspension for validation
 A = control of test conditions
 B = control of neutraliser
 C = validation of method at highest product concentration in %
 VC = number of viable cells per ml
 X = mean of VC1 and VC2

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Test Report No L 10/167: Table 1.3: Test Suspension (N), Water Control and Efficacy Test (DIN EN 14563: 2009*)

Quantitative Carrier Test for the Evaluation of Tuberculocidal Activity (Phase 2, Step 2)

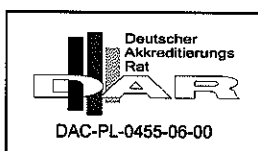
Test preparation (Batch): Meliseptol Foam pure (0043M13)
 Test organism: *Mycobacterium terrae*
 Organic load: clean conditions (0.03 % bovine albumin)
 Inactivation: Membrane filtration and rinsing of the filter with 3.0 % Tween and 0.3 % lecithin

N	Microbial count per plate				VC1	VC2	Xwm	lg N	Evaluation lg N sufficient?
1,0E-07	70	60	90	50	130	140	1,37E+09	9,14	No
1,0E-08	4	10	7	10	14	17	9,16 < lg N < 9,71		
Dilution	Microbial count per plate				VC1	VC2	lg Na	lg R	Use Concentration, Exposure time
1,0E+00	R		R		R	R	> 5.81	< 1.09	50 %, 1 minute
1,0E-02	R		R		R	R			
1,0E+00	R		R		R	R	> 5.81	< 1.09	75 %, 1 minute
1,0E-02	R		R		R	R			
1,0E+00	0		0		7	10	1,93	4,97	100 %, 1 minute
1,0E-02	0		0		0	0			
1,0E-04	70		0		80	75	6,90		WSH-control, 1 minute
1,0E-05	0		0		12	9			

Key:

VC =	viable microbial count per ml
Xwm =	weighted mean of N
Na =	weighted mean of VC1 and VC 2
lg R =	reduction of microorganisms (lg R = lg WSH-control – lg Na)
R =	bacterial lawn (> 330 cfu)
WSH =	Water of Standardized Hardness

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Test Report No L 10/167: Table 1.4: Test Suspension (N), Water Control and Efficacy Test (DIN EN 14563: 2009*)

Quantitative Carrier Test for the Evaluation of Tuberculocidal Activity (Phase 2, Step 2)

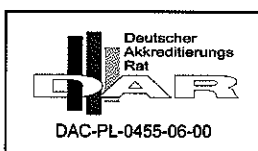
Test preparation (Batch): Meliseptol Foam pure (0043M13)
 Test organism: *Mycobacterium terrae*
 Organic load: clean conditions (0.03 % bovine albumin)
 Inactivation: Membrane filtration and rinsing of the filter with 3.0 % Tween and 0.3 % lecithin

N	Microbial count per plate				VC1	VC2	Xwm	Ig N	Evaluation Ig N sufficient?
1,0E-07	70	60	90	50	130	140	1,37E+09	9,14	No
1,0E-08	4	10	7	10	14	17	9,16 < Ig N < 9,71		
Dilution	Microbial count per plate				VC1	VC2	Ig Na	Ig R	Use Concentration, Exposure time
1,0E+00	R		R		R	R	> 5.81	< 0.87	50 %, 3 minutes
1,0E-02	R		R		R	R			
1,0E+00	R		R		R	R	> 5.81	< 0.87	75 %, 3 minutes
1,0E-02	R		R		R	R			
1,0E+00	0		0		0	0	u	> 5,58	100 %, 3 minutes
1,0E-02	0		0		0	0			
1,0E-04	40		52		40	52	6,68		WSH-control, 3 minutes
1,0E-05	8		5		8	5			

Key:

VC =	viable microbial count per ml
Xwm =	weighted mean of N
Na =	weighted mean of VC1 and VC 2
Ig R =	reduction of microorganisms (Ig R = Ig WSH-control – Ig Na)
R =	bacterial lawn (> 330 cfu)
U =	below detection limit
WSH =	Water of Standardized Hardness

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Test Report No L 10/167: Table 1.5: Test Suspension (N), Water Control and Efficacy Test (DIN EN 14563: 2009*)

Quantitative Carrier Test for the Evaluation of Tuberculocidal Activity (Phase 2, Step 2)

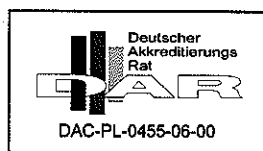
Test preparation (Batch): Meliseptol Foam pure (0043M13)
 Test organism: *Mycobacterium terrae*
 Organic load: clean conditions (0.03 % bovine albumin)
 Inactivation: Membrane filtration and rinsing of the filter with 3.0 % Tween and 0.3 % lecithin

N	Microbial count per plate				VC1	VC2	Xwm	lg N	Evaluation lg N sufficient?
1,0E-07	70	60	90	50	130	140	1,37E+09	9,14	No
1,0E-08	4	10	7	10	14	17	9,16 < lg N < 9,71		
Dilution	Microbial count per plate				VC1	VC2	lg Na	lg R	Use Concentration, Exposure time
1,0E+00	R		R		R	R	> 5.81	< 0.92	50 %, 5 minutes
1,0E-02	R		R		R	R			
1,0E+00	R		R		R	R	5,23	1,50	75 %, 5 minutes
1,0E-02	160		180		160	180			
1,0E+00	0		0		0	0	u	> 5,73	100 %, 5 minutes
1,0E-02	0		0		0	0			
1,0E-04	65		39		65	39	6,73		WSH-control, 5 minutes
1,0E-05	7		6		7	6			

Key:

VC =	viable microbial count per ml
Xwm =	weighted mean of N
Na =	weighted mean of VC1 and VC 2
lg R =	reduction of microorganisms (lg R = lg WSH-control – lg Na)
R =	bacterial lawn (> 330 cfu)
U =	below detection limit
WSH =	Water of Standardized Hardness

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