HygCen Centrum für Hygiene und medizinische Produktsicherheit

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Akkreditiert durch
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln
und Medizinprodukten
ZLG-P-715.98.13

SciCan
1440 Don Mills Road
Toronto, Ontario
Canada
M3B 3P9

2008-01-11
Prof. We/ku

OPTIM® 33TB
DIN EN 14348 (April 2005)
Mycobactericidal activity
phase 2, step 1

TEST REPORT

Identification of the test laboratory:	SN 7394
Test product:	OPTIM® 33TB
Batch number:	Lot. # 7379
Manufacturer:	SciCan
Date of order:	2007-12-04
Date of delivery:	2007-12-10
Storage conditions:	those of the manufacturer
Appearance:	clear colourless liquid
Odour:	aromatic
Active substance:	not indicated
pH-values (DIN 19266):	96%: 2.72

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Steuer-Nr.: 090/110/03882

Geschäftsführerin Dipl.-Ing. (FH) Umwelt- und Hygienetechnik Margrit Werner · Amtsgericht Schwerin HRB 4792 · UST.-Nr.: 178599849

test method:	**DIN EN 14348 (April 2005)** **Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants** **(phase 2, step 1)**
period of analysis:	2007-12-20 to 2008-01-10
test temperature:	20 °C ± 1 °C
product test concentrations:	96 % (v/v end concentration) Note: The product was prepared with a higher concentration of 120%, therefore the end concentration after dilution during the test (interfering substance and test suspension) was 96% (v/v).
contact times:	1, 5 and 10 minutes
interfering substances:	0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)
inactivation method:	dilution-neutralisation
neutralizer:	1.0 % polysorbate 80 + 3.0 % saponine + 0.3 % lezithine
counting procedure:	spread plate method
diluent used for product test solution:	distilled water
stability and appearance of the mixture during the procedure:	no precipitate or flocculent
incubation:	36 °C ± 1 °C – 21 d
test strains:	*Mycobacterium terrae* ATCC 15755 *Mycobacterium avium* ATCC 15769

Test results
with OPTIM® 33TB
according to DIN EN 14348

test strain: ***Mycobacterium terrae*** **ATCC 15755**

interfering substance: **0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)**

validation

Validation-suspension Nv and Nv_0	Contact time (min.)	Validation Control (A)	Control (B)	Control (C)
10^{-1} Vc1: 49+58 10^{-1} Vc2: 62+45 Nv_0: 107	1	Vc1: 67+43 Vc2: 70+46 A: 113	Vc1: 40+64 Vc2: 61+56 B: 110.5	Vc1: 62+50 Vc2: 51+54 C: 108.5
10^{-1} Vc1: 49+58 10^{-1} Vc2: 62+45 Nv_0: 107	5	Vc1: 52+56 Vc2: 60+56 A: 112	Vc1: 40+64 Vc2: 61+56 B: 110.5	Vc1: 48+68 Vc2: 42+58 C: 108
10^{-1} Vc1: 49+58 10^{-1} Vc2: 62+45 Nv_0: 107	10	Vc1: 52+66 Vc2: 48+47 A: 106.5	Vc1: 40+64 Vc2: 61+56 B: 110.5	Vc1: 48+48 Vc2: 49+54 C: 99.5

Verification:
Nv_0 is between 30 and 160 cfu/ml ($3.0x10^1$ and $1.6x10^2$)
A, B, C is equal to or greater than 0,5 x Nv_0,

Legend:
Nv_0 is number of cfu/ml of the test suspension in the validation test mixture
A is number of cfu/ml of the experimental condition control
B is number of cfu/ml of the neutralizer non-toxicity control
C is number of cfu/ml of the dilution neutralization test control

Test results
with OPTIM® 33TB
according to DIN EN 14348

test strain: ***Mycobacterium terrae*** **ATCC 15755**

interfering substance: **0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)**

test suspension and main test

test suspension N		
	Vc1	Vc2
10^{-7}	260+241	201+244
10^{-8}	34+31	26+39
N:	4.89×10^{9}	
N_0:	4.89×10^{8}	
lg N_0:	8.69	

Test proce-dure at concen-tration (v/v)		after contact time (min) 1		5		10	
				Vc1	Vc2	Vc1	Vc2
96%	10^{0}:	>330+>330	>330+>330	0+0	0+0	0+0	0+0
	10^{-1}:	>330+>330	>330+>330	0+0	0+0	1+0	0+0
	10^{-2}:	>330+>330	>330+>330	0+0	0+0	0+0	0+0
	10^{-3}:	96+41	28+120	0+0	0+0	0+0	0+0
	N_a:	1.42×10^{6}		<140		<140	
	lgN_a:	6.15		<2.15		<2.15	
	lgR:	2.54		>6.54		>6.54	

Verification:
N is between 1.5×10^{9} and 5.0×10^{9} cfu/ml ($9.17 \leq lgN \leq 9.70$)
N_0 is between 1.5×10^{8} cfu/ml and 5.0×10^{8} cfu/ml ($8.17 \leq lg\ N_0 \leq 8.70$)

Legend:
N is number of cfu/ml of the test suspension
N_0 is number of cfu/ml of the test suspension in the test mixture
R is reduction of viability
N_a is number of cfu/ml of the test mixture

Test results
with OPTIM® 33TB
according to DIN EN 14348

test strain: ***Mycobacterium avium*** **ATCC 15769**

interfering substance: **0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)**

validation

Validation-suspension Nv and Nv_0	Contact time (min.)	Validation Control (A)	Control (B)	Control (C)
10^{-1} Vc1: 38+50 10^{-1} Vc2: 36+66 Nv_0: 95	1	Vc1: 88+80 Vc2: 78+68 A: 157	Vc1: 48+76 Vc2: 51+60 B: 117.5	Vc1: 49+64 Vc2: 38+50 C: 100.5
10^{-1} Vc1: 38+50 10^{-1} Vc2: 36+66 Nv_0: 95	5	Vc1: 74+40 Vc2: 68+48 A: 115	Vc1: 48+76 Vc2: 51+60 B: 117.5	Vc1: 50+74 Vc2: 46+62 C: 116
10^{-1} Vc1: 38+50 10^{-1} Vc2: 36+66 Nv_0: 95	10	Vc1: 60+70 Vc2: 59+60 A: 124.5	Vc1: 48+76 Vc2: 51+60 B: 117.5	Vc1: 48+46 Vc2: 44+37 C: 87.5

Verification:
Nv_0 is between 30 and 160 cfu/ml ($3.0x10^1$ and $1.6x10^2$)
A, B, C is equal to or greater than 0,5 x Nv_0,

Legend:
Nv_0 is number of cfu/ml of the test suspension in the validation test mixture
A is number of cfu/ml of the experimental condition control
B is number of cfu/ml of the neutralizer non-toxicity control
C is number of cfu/ml of the dilution neutralization test control

Test results
with OPTIM® 33TB
according to DIN EN 14348

test strain: ***Mycobacterium avium*** **ATCC 15769**

interfering substance: **0.3% albumine + 0.3% sheep erythrocytes (dirty conditions)**

test suspension and main test

test suspension N		
	Vc1	Vc2
10^{-7}	160+158	201+202
10^{-8}	18+46	27+38
N:	$3{,}91 \times 10^{9}$	
N_0:	$3{,}91 \times 10^{8}$	
lg N_0:	8.59	

Test proce-dure at concen-tration (v/v)		after contact time (min) 1		5		10	
				Vc1	Vc2	Vc1	Vc2
96%	10^{0}:	0+0	0+0	0+0	0+0	0+0	0+0
	10^{-1}:	0+0	0+0	0+0	0+0	0+0	0+0
	10^{-2}:	0+0	0+0	0+0	0+0	0+0	0+0
	10^{-3}:	0+0	0+0	0+0	0+0	0+0	0+0
	N_a:	<140		<140		<140	
	lgN_a:	<2.15		<2.15		<2.15	
	lgR:	>6.44		>6.44		>6.44	

Verification:
N is between 1.5×10^{9} and 5.0×10^{9} cfu/ml ($9.17 \leq lgN \leq 9.70$)
N_0 is between 1.5×10^{8} cfu/ml and 5.0×10^{8} cfu/ml ($8.17 \leq lg\ N_0 \leq 8.70$)

Legend:
N is number of cfu/ml of the test suspension
N_0 is number of cfu/ml of the test suspension in the test mixture
R is reduction of viability
N_a is number of cfu/ml of the test mixture

Conclusion: According to DIN EN 14348 (April 2005), the batch Lot. # 7379 of product OPTIM® 33TB possesses a mycobactericidal activity under dirty conditions at 20°C when diluted at 96% (v/v) for the referenced test strain *Mycobacterium terrae* in 5 minutes and for the referenced test strain *Mycobacterium avium* in 1 minute.

Archive: **The raw data with respect to this test and a copy of the report will be maintained by HygCen in the archive.**

Information: The test results are valid for the named test subject only. Reproduction of any part of this report requires the written permission HygCen GmbH.

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