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Issue No.: 1

Test report No. D109-3/2013

DETERMINATION OF MYCOBACTERICIDAL (EN 14348) ACTIVITY OF
THE PRODUCT **DENTIRO® Wipes Soaking Liquid** on *Mycobacterium avium*

Sample ID: D109/2013

Sample name: **DENTIRO® Wipes Soaking Liquid**

Client: OCC Switzerland, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland

Producer: OCC Switzerland, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland

Sampling point: OCC Switzerland, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland

Page: 1

From pages: 5

Incoming date:
13.6.2013

Delivery date:
15.5.2014

Hodonín, 15.5.2014



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Zuzana Matušková, Head of Laboratory

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Description: *Testing the efficacy of chemical disinfectants and antiseptics*

Sample ID: D109/2013	Sampling date: 12.6.2013
Rep No: 175	Sample delivered: 13.6.2013
Sample name: DENTIRO® Wipes Soaking Liquid	Testing date: 9.12.-30.12.2013
Sampled: by client	Delivered amount: 5 l
Sampling point: OCC Switzerland, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland	
Client: OCC Switzerland, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland	
Batch No: 8784	Page: 2

Subject of testing:

Determination of mycobactericidal activity of the product.

Identification of the sample:

Name of the product:	DENTIRO® Wipes Soaking Liquid
Batch number:	8784
Date of manufacture:	23.04.2013 10:53:44
Expiry date:	10/2015
Manufacturer:	OCC Switzerland, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland
Incoming date:	13.6.2013
Storage conditions:	at room temperature, in the dark, area with restricted access
Active compounds and concentrations in 100 g:	
CAS 64-17-5 Ethanol	31.3 g
CAS 67-63-0 2-Propanol	16.7 g

Experimental conditions:

	Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method SOP-M-19-00 (EN 14348)
Period of analysis:	9.12.2013 - 30.12.2013
Test temperature:	20 °C ± 1 °C
Test method:	dilution neutralization method
Neutralization medium:	Dey-Engley Neutralizing Broth M 1062
Technique:	pour plate technique
Appearance of the products:	colourless liquid
Test concentration:	100% (concentrated)*
Contact time:	1, 2, 5 a 10 min
Interfering substances:	0.3 g/l BSA (clean conditions)
Test organisms:	<i>Mycobacterium avium</i> ATCC 15769
Incubation conditions:	37 °C ± 1 °C, 21 days

Test procedure:

1. Preparation of test suspension
2. Preparation of product test solutions
3. Quantitative suspension test
4. Incubation and calculation
5. Expression and interpretation of results

Note:

Mycobactericidal activity – the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* and *Mycobacterium avium* under defined conditions by at least 4 orders (10^4).

Tuberculocidal activity - the capability of a product to produce a reduction in the number of viable cells of *Mycobacterium terrae* under defined conditions by at least 4 orders (10^4).

$R = N_0 / N_a$ nebo $\lg R = \lg N_0 - \lg N_a$ the reduction in viability

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

The standard:

EN 14348 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) January 2005

Description: Testing the efficacy of chemical disinfectants and antiseptics

Sample ID: D109/2013

Rep No: 175

Sample name: **DENTIRO® Wipes Soaking Liquid**

Sampled: by client

Sampling point: OCC Switzerland, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland

Client: OCC Switzerland, Oro Clean Chemie AG, Allmendstrasse 21, 8320 Fehraltorf, Switzerland

Batch No: 8784

Sampling date: 12.6.2013

Sample delivered: 13.6.2013

Testing date: 9.12.-30.12.2013

Delivered amount: 5 l

Page: 4

Interpretation:

Results of tests are in Tabs.

The tested concentrated* product **DENTIRO® Wipes Soaking Liquid**, batch No. 8784, in contact times 1, 2, 5 and 10 min under clean conditions at temperature $20\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ by the dilution-neutralization method **decreased** the number of alive microbes *Mycobacterium avium* ATCC 15769 by at least 4 (lg) orders (EN 14348).

* The product can only be tested at a concentration of 80% or less, as some dilution is always produced by adding the test organisms and interfering substance.

Conclusion:

The product **DENTIRO® Wipes Soaking Liquid** is capable of reducing the number of viable mycobacterial cells of the relevant organism under defined conditions to the declared values and, consequently, may be called mycobactericidal on *Mycobacterium avium*.

15.5.2014, Hodonín

