

Chemila, spol. s r.o., Za Dráhou 4386/3, Hodonín 69501, Phone +420518340919, chemila@chemila.cz
Chemical and Microbiological Laboratory, Testing Laboratory No. 1273 certified by Czech Accreditation Institute according to ČSN EN ISO/IEC 17025.

Copy No.: 1
Issue No.: 1

Test report No. D6-1/2017

**HYGIENIC HANDRUB (EN 1500) OF THE PRODUCT
VELODES SILK**

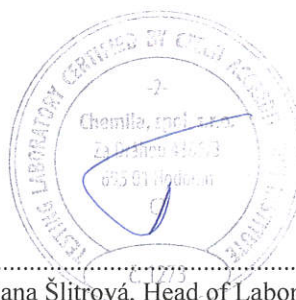
Sample ID: D6/2017
Sample name: **Velodes Silk**
Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Producer: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Page: 1
From pages: 7

Incoming date:
3.1.2017

Delivery date:
6.6.2017

Hodonín, 6.6.2017



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Ing. Jana Šlitrová, Head of Laboratory

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

Sample ID: D6/2017
Rep No: 44
Sample name: **Velodes Silk**
Sampled: by client
Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz
Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.12.2016
Sample delivered: 3.1.2017
Testing date: 9.2. – 10.2.2017
Delivered amount: 500 ml
Batch No: 20161109_102
Page: 2

Subject of testing:

Hygienic handrub.

Identification of the sample:

Name of the product: **Velodes Silk**
Batch number: 20161109_102
Date of manufacture: 09.11.2016
Expiry date: 09.11.2018
Manufacturer: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland
Incoming date: 3.1.2017
Storage conditions: at room temperature in dark
Active compounds and concentrations in 100 g:
CAS 64-17-5 Ethanol 63.7 g
CAS 67-63-0 Propan-2-ol 6.3 g

Experiment conditions:

Testing of disinfecting efficiency of chemical disinfecting and antiseptic agents by suspension method

SOP-M-19-00 (EN 1500:2013)

Period of analysis: 9.2. – 10.2.2017
Test temperature: 20 °C ± 1 °C
Test method: dilution neutralization method
Appearance of the products: colourless liquid
The test concentration: 100% (concentrated)
The volume of the product: 2 x 3 ml / person, the total application volume is 6 ml
The application time: 2 x 15 s, the total application time is 30 sec
The soap: soft soap from linseed oil 200 g/l
Reference item: 2-Propanol p.a., CAS 67-63-0, batch number: K47848134 623, expiry date: 2021/05/31, concentration: 60% (V/V)
The volume of the reference propan-2-ol used per person: 2 x 3 ml, according to reference handrub procedure, the total application volume is 6 ml
The application time: 2 x 30 s, according to reference handrub procedure, the total application time is 1 min
Test organism: *Escherichia coli* K 12 NCTC 10538 1.64 × 10⁸ CFU/ml
Neutralization medium: Dey-Engley Neutralizing Broth M 1062
Treatment procedure: hygienic handrub disinfection in accordance with the standard handrub procedure also include the instructions to keep hands wet with the product for a given time

Preparation of the test

1. Determination of the number of the microorganisms CFU/ml in the product
2. Preparation of the test suspension of *Escherichia coli*
3. Determination of the number of viable cells of *Escherichia coli*
4. Prevalue – number of cfu sampled after the contamination with *Escherichia coli*
5. Postvalue – number of cfu sampled after the treatment with the disinfectant
6. Reduction factor – ratio of prevalues and postvalues, generally expressed by decimal logarithms

The standard:

EN 1500:2013 Chemical disinfectants and antiseptics - Hygienic handrub - Test method and requirements (phase 2/step 2) April 2013

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The Number of CFU in the tested product: 0 CFU/ml

1. Preparation of the test suspension of *Escherichia coli* K 12 NCTC 10538 and verification of methodology

Tab No. 1.1 Verification of methodology

Validation of suspension (N _{v0})				Validation of suspension (N _{vB})				Neutralizer toxicity control (B)				Method validation (C)			
V _{c1}	46	Φ _{N_{v0}} = 48		V _{c1}	64	Φ _{N_{vB}} = 47.5		V _{c1}	42	Φ _B = 41.5		V _{c1}	40	Φ _C = 46	
V _{c2}	50			V _{c2}	31			V _{c2}	41			V _{c2}	52		
30 ≤ Φ _{N_{v0}} ≤ 160				30 ≤ Φ _{N_{vB}} (N _{vB} /1000) ≤ 160				Φ _B ≥ 0.0005 Φ _{N_{vB}}				Φ _C ≥ 0.5 Φ _{N_{v0}}			
x	yes		no	x	yes		no	x	yes		no	x	yes		no

Tab No. 1.2 Test suspension

Test suspension N				Weighted mean (Ø)					
Φ = 164 x 10 ⁶ = 1.64 x 10 ⁸				N	V _{c1}	V _{c1}	for N	5 ≤ Ø ≤ 15	8.03
lg 1.64 x 10 ⁸ = 8.21				10 ⁻⁶	164	157			
8.17 ≤ lg N ≤ 8.70				10 ⁻⁷	14	26			
				10 ⁻⁸	<14	<14			
x	yes		no						

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2. Experimental results

Tab. No. 2.1 Hygienic handrub – experimental results for RP and PP

Propan-2-ol 60% (V/V) 2x3 ml/person (6 ml), 2x0.5 min (1 min) – RP							Velodes Silk, 2 x 3 ml/person, 2 x 15 s – PP									
Volunteer		Number of CFU/plate from dilution 10 ^x					Volunteer		Number of CFU/plate from dilution 10 ^x							
No.	Hand	Prevalues			Postvalues			No.	Hand	Prevalues			Postvalues			
		10 ⁻³	10 ⁻⁴	10 ⁻⁵	10 ⁰	10 ⁻¹	10 ⁻²			10 ⁻³	10 ⁻⁴	10 ⁻⁵	10 ⁰	10 ⁻¹	10 ⁻²	
1	left	>330	<u>44</u>	<14	>330	<u>52</u>	<14	1	left	>330	<u>65</u>	<14	>330	<u>66</u>	<14	
	right	>330	<u>54</u>	<14	>330	<u>66</u>	<14		right	>330	<u>79</u>	<14	>330	<u>74</u>	<14	
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	right	>330	<u>147</u>	14	>330	<u>35</u>	<14		right	>330	<u>74</u>	<14	>330	<u>65</u>	<14	
3	left	>330	<u>109</u>	<14	>330	<u>88</u>	<14	3	left	>330	<u>168</u>	<u>18</u>	>330	<u>95</u>	<14	
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	right	>330	<u>90</u>	<14	>330	<u>89</u>	<14		right	>330	<u>151</u>	<u>17</u>	>330	<u>89</u>	<14	
5	left	>330	<u>241</u>	23	>330	<u>229</u>	<u>20</u>	5	left	>330	<u>319</u>	<u>30</u>	>330	<u>138</u>	<u>15</u>	
	right	>330	<u>286</u>	23	>330	<u>236</u>	<u>23</u>		right	>330	<u>327</u>	<u>29</u>	>330	<u>160</u>	<u>17</u>	
6	left	>330	<u>138</u>	<u>15</u>	<u>313</u>	<u>36</u>	<14	6	left	>330	>330	<u>35</u>	>330	<u>69</u>	<14	
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	right	>330	<u>41</u>	<14	>330	<u>53</u>	<14		right	>330	<u>71</u>	<14	>330	<u>89</u>	<14	
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	right	>330	<u>40</u>	<14	<u>69</u>	<14	<14		right	>330	<u>51</u>	<14	<u>106</u>	<14	<14	
9	left	>330	<u>209</u>	<u>22</u>	>330	<u>33</u>	<14	9	left	>330	<u>162</u>	<u>17</u>	>330	<u>40</u>	<14	
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	right	>330	<u>158</u>	<u>20</u>	>330	<u>46</u>	<14		right	>330	<u>205</u>	<u>21</u>	>330	<u>83</u>	<14	
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	right	>330	<u>71</u>	<14	>330	<u>63</u>	<14		right	>330	<u>38</u>	<14	>330	<u>95</u>	<14	
12	left	>330	<u>51</u>	<14	>330	<u>72</u>	<14	12	left	>330	<u>272</u>	<u>28</u>	<14	>330	<u>92</u>	<14
	right	>330	<u>57</u>	<14	>330	<u>87</u>	<14		right	>330	<u>263</u>	<u>30</u>	<14	>330	<u>105</u>	<14
13	left	>330	<u>108</u>	<14	>330	<u>71</u>	<14	13	left	>330	<u>80</u>	<14	>330	<u>83</u>	<14	
	right	>330	<u>134</u>	<14	>330	<u>79</u>	<14		right	>330	<u>79</u>	<14	>330	<u>87</u>	<14	
14	left	>330	<u>133</u>	<u>15</u>	>330	<u>59</u>	<14	14	left	>330	<u>144</u>	<u>16</u>	>330	<u>71</u>	<14	
	right	>330	<u>145</u>	<u>17</u>	>330	<u>66</u>	<14		right	>330	<u>155</u>	<u>17</u>	>330	<u>84</u>	<14	
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	right	>330	<u>142</u>	<u>14</u>	>330	<u>74</u>	<14		right	>330	<u>34</u>	<14	>330	<u>93</u>	<14	
16	left	>330	<u>105</u>	<14	>330	<u>61</u>	<14	16	left	>330	<u>141</u>	<u>15</u>	>330	<u>65</u>	<14	
	right	>330	<u>131</u>	<14	>330	<u>83</u>	<14		right	>330	<u>160</u>	<u>15</u>	>330	<u>99</u>	<14	
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	right	>330	<u>71</u>	<14	>330	<u>44</u>	<14		right	>330	<u>98</u>	<14	<u>327</u>	<u>35</u>	<14	
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	right	>330	<u>72</u>	<14	>330	<u>62</u>	<14		right	>330	<u>161</u>	<u>19</u>	<u>73</u>	<14	<14	
19	left	>330	<u>36</u>	<14	>330	<u>61</u>	<14	19	left	>330	<u>44</u>	<14	>330	<u>30</u>	<14	
	right	>330	<u>40</u>	<14	>330	<u>75</u>	<14		right	>330	<u>58</u>	<14	>330	<u>39</u>	<14	
20	left	>330	<u>307</u>	<u>35</u>	<u>83</u>	<14	<14	20	left	>330	<u>141</u>	<u>16</u>	>330	<u>51</u>	<14	
	right	>330	<u>326</u>	<u>37</u>	<u>100</u>	<14	<14		right	>330	<u>178</u>	<u>16</u>	>330	<u>58</u>	<14	

underlined = count used for further computation, >330 = not countable

Prepared by: Mgr. Alena Rýdlová, Lab Technician

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Tab. No. 2.2 List of computed lg values (means of left and right hands) and lg reductions

Volunteer	Chronological Sequence	Reference handrub (RP) (Propan-2-ol 60% V/V)			Handrub with tested product (PP) (Velodes Silk)		
		lg prevalues	lg postvalues	lg R	lg prevalues	lg postvalues	lg R
1	RP → PP	5.69	2.77	2.92	5.86	2.85	3.01
2	RP → PP	6.15	2.54	3.61	5.83	2.85	2.98
3	RP → PP	6.05	2.97	3.08	6.26	2.96	3.30
4	RP → PP	5.99	2.98	3.01	6.23	2.99	3.24
5	RP → PP	6.41	3.36	3.05	6.51	3.18	3.33
6	RP → PP	6.18	2.51	3.67	6.60	2.82	3.78
7	RP → PP	5.65	2.72	2.93	5.89	2.97	2.92
8	RP → PP	5.58	1.81	3.77	5.66	1.99	3.67
9	RP → PP	6.34	2.59	3.75	6.23	2.63	3.60
10	RP → PP	6.18	2.62	3.56	6.28	2.90	3.38
11	PP → RP	5.89	2.76	3.13	5.65	3.01	2.64
12	PP → RP	5.73	2.90	2.83	5.43	2.99	2.44
13	PP → RP	6.08	2.88	3.20	5.90	2.93	2.97
14	PP → RP	6.15	2.80	3.35	6.18	2.89	3.29
15	PP → RP	6.13	2.89	3.24	6.53	2.93	3.60
16	PP → RP	6.07	2.86	3.21	6.18	2.91	3.27
17	PP → RP	5.88	2.72	3.16	5.95	2.51	3.44
18	PP → RP	5.90	2.83	3.07	6.26	1.91	4.35
19	PP → RP	6.58	2.83	3.75	5.71	2.54	3.17
20	PP → RP	6.51	1.96	4.55	6.20	2.74	3.46
Ø	Overall	6.06	2.71	3.35	6.07	2.78	3.29
s		0.28	0.34	0.41	0.32	0.33	0.42
n		20	20	20	20	20	20
Ø	RP → PP	6.02	2.69	3.33	6.13	2.81	3.32
s		0.29	0.40	0.36	0.31	0.32	0.30
n		10	10	10	10	10	10
Ø	PP → RP	6.09	2.74	3.35	6.00	2.74	3.26
s		0.27	0.28	0.48	0.33	0.34	0.53
n		10	10	10	10	10	10

lg R = decimal log reduction; RP → PP sequence: first RP, second PP; PP → RP sequence: first PP, second RP;
 Ø = mean; s = standard deviation; n = number of values (= volunteers)

Difference of mean Rs (RP → PP): $3.33 - 3.32 = 0.01$; Difference of mean Rs (PP → RP): $3.35 - 3.26 = 0.09$;

Absolute difference of differences: $|0.01 - 0.09| = 0.08$ (hence less than 2.00)

Acceptance criteria for test results:

Only if the results of the test procedure fulfil the following requirements, they shall be accepted for further evaluation, otherwise the test shall be repeated:

- A complete set of results from at least 18 volunteers shall be available. All complete sets of results shall be used for further evaluation.
- The overall means of the lg prevalues for RP and PP shall be both at least 5.00.
- Not more than three individual lg reductions less than 3.00 shall occur in RP.
- The absolute difference of mean differences between lg reductions of RP and PP of group RP → PP and group PP → RP shall be less than 2.00.
- All quotients of weighted mean counts between 5 and 15.

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Tab. No. 2.3.1 Computation of individual differences of lg Rs of RP – PP

Volunteer	lg reduction (R)		Difference RP – PP
	Reference procedure (RP)	Product procedure (PP)	
1	2.92	3.01	-0.09
2	3.61	2.98	0.63
3	3.08	3.30	-0.22
4	3.01	3.24	-0.23
5	3.05	3.33	-0.28
6	3.67	3.78	-0.11
7	2.93	2.92	0.02
8	3.77	3.67	0.10
9	3.75	3.60	0.15
10	3.56	3.38	0.18
11	3.13	2.64	0.50
12	2.83	2.44	0.39
13	3.20	2.97	0.23
14	3.35	3.29	0.06
15	3.24	3.60	-0.35
16	3.21	3.27	-0.06
17	3.16	3.44	-0.28
18	3.07	4.35	-1.28
19	3.75	3.17	0.58
20	4.55	3.46	1.08

Tab. No. 2.3.2 Computation for Hodges-Lehmann 97.5% upper confidence limits

	Sorted differences	Mean pairwise differences (d _i +d _{ii})/2										
		1.08	0.63	0.58	0.50	0.39	0.23	0.18	0.15	0.10	0.06	
1	1.08	1.08 ¹										
2	0.63	0.86 ²	0.63 ⁸									
3	0.58	0.83 ³	0.61 ¹⁰	0.58 ¹²								
4	0.50	0.79 ⁴	0.57 ¹⁴	0.54 ¹⁶	0.50 ²⁰							
5	0.39	0.74 ⁵	0.51 ¹⁸	0.49 ²²	0.45 ²³	0.39 ³²						
6	0.23	0.66 ⁶	0.43 ²⁶	0.41 ²⁸	0.37 ³⁷	0.31 ⁴⁴	0.23					
7	0.18	0.63 ⁷	0.41 ²⁷	0.38 ³³	0.34 ⁴⁰	0.29 ⁴⁸	0.21	0.18				
8	0.15	0.62 ⁹	0.39 ³¹	0.37 ³⁶	0.33 ⁴²	0.27 ⁵¹	0.19	0.17	0.15			
9	0.10	0.59 ¹¹	0.37 ³⁵	0.34 ³⁹	0.30 ⁴⁶	0.25	0.17	0.14	0.13	0.10		
10	0.06	0.57 ¹³	0.35 ³⁸	0.32 ⁴³	0.28 ⁴⁹	0.23	0.15	0.12	0.11	0.08	0.06	
11	0.02	0.55 ¹⁵	0.33 ⁴¹	0.30 ⁴⁵	0.26	0.21	0.13	0.10	0.09	0.06	0.04	
12	-0.06	0.51 ¹⁷	0.29 ⁴⁷	0.26⁵³	0.22	0.17	0.09	0.06	0.05			
13	-0.09	0.50 ¹⁹	0.27 ⁵⁰	0.25	0.21	0.15	0.07	0.05				
14	-0.11	0.49 ²¹	0.26 ⁵²	0.24	0.20	0.14						
15	-0.22	0.43 ²⁴	0.21	0.18	0.14							
16	-0.23	0.43 ²⁵	0.20	0.18								
17	-0.28	0.40 ²⁹	0.18	0.15								
18	-0.28	0.40 ³⁰	0.18									
19	-0.35	0.37 ³⁴										
20	-1.28	-0.10										

The median is between the 10th and 11th value: $[0.06 + 0.02]/2 = 0.04$

The mean pairwise differences that do not exceed the median (here: 0.04) are computed. From table (see Table E.5 in EN 1500) of critical values for Wilcoxon's matched-pairs signed-ranks test the entry for n=20 and a one-sided 0.025 level of significance, the critical value of 52 is found. Hence $c=52+1=53$. The pairwise differences are sorted in descending order (small exponents). The 53rd value is 0.26. Hence the Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in lg Rs between RP and PP is 0.26, which is less than the agreed inferiority margin of 0.6. Therefore the hypothesis of inferiority of PP is rejected and it can be concluded the test preparation PP is non-inferior to RP.

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Sample name: **Velodes Silk**

Sampled: by client

Sampling point: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz

Client: Medi-Sept Sp. z o.o., Konopnica 159c, 210 30 Motycz, Poland

Sampling date: 23.12.2016

Sample delivered: 3.1.2017

Testing date: 9.2. – 10.2.2017

Delivered amount: 500 ml

Batch No: 20161109_102

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Interpretation:

Results of tests are in Tabs.

Hygienic handrub

The acceptance criteria for the test results were met.

The product **Velodes Silk**, batch No. 20161109_102, was tested according to EN 1500 under test conditions: application volume 2 x 3 ml/person and application time 2 x 15 s. The Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in lg Rs between RP and PP is smaller (**0.26**) than the agreed inferiority margin of 0.6. Therefore the hypothesis of inferiority of **Velodes Silk** is rejected and it can be concluded the test preparation **Velodes Silk** is non-inferior to **propan-2-ol 60%**.

Conclusion:

The product **Velodes Silk** is deemed suitable to be used as medical hygienic handrub under conditions: application volume 2 x 3 ml/person and application time 2 x 15 s.

6.6.2017, Hodonín

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Ing. Barbora Stoklásková, Leader of Study

