

Testing of Disinfectant 70% in accordance with EN 1500: 1997

Identification of test laboratory:..... Plum A/S Laboratory

Identification of sample:

Product name..... Disinfectant 70%
Batch number..... 3700 1/05
Producer..... Plum A/S
Delivery date..... 03-03-2005
Storage requirements..... 0 – 30°C
Active ingredients and their concentration..... IPA 70%

Test method and its validation:

Method..... Dilution method
Neutraliser..... Tryptone Broth
Validated as per EN 12054

Test data:

Analysis period..... 15-06-2005
Product's test concentration..... Concentrated
Test temperature..... 20°C ±1°C
Contact time..... 60 sec.
Quantity..... 5 g
Culture technique..... Surface plating
Bacteria strain/Lot..... E. Coli K12, NTCT 10538, Lot: 67830.
Incubation temperature..... 36°C ±1°C

Test result:..... See appendices F-30-145-3C,
F-30-145-4C, F-30-145-5 and
F-30-145-6.

Conclusion: Disinfectant 70% satisfies the requirements for the effect of hygienic hand disinfectants in practice (phase 2 / step 2) in accordance with EN 1500 : 1997.

Assens, 30-06-2005

Jimmi Larsen

Responsible for test at Plum A/S

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K:glp\analyse og test\f-30-140-8

Plate counting form (EN 1500)

Concentration of test suspension								
	10 ⁷ Day 1	10 ⁸ Day 1	10 ⁹ Day 1	10 ⁷ Day 2	10 ⁸ Day 2	10 ⁹ Day 2	Control	Date tested
E. coli (K12), NCTC 10538	<u>23</u> , <u>240</u> (X = 24)	0, 1 (X = 1)	0, 0 (X = 0)	<u>23</u> , <u>30</u> (X = 27)	0, 1 (X = 1)	0, 0 (X = 0)	OK JL	15-06-05
Counting requirements: Plates with cfu < 300. Day 2: Only colonies where there is separation (free colonies) are counted. X = mean								

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K:glp\analyse og test\f-30-145-2

Plate counting form (EN 1500)

Before and after values for test product. Total.						
Test date: 15-06-2005 Test product: Disinfectant 70%						
Suspension concentration: 2.55×10^8						
		Before test values		After test values		
Proband No.		10 ⁴ Total	10 ⁵ Total	10 ⁰ Total	10 ¹ Total	10 ² Total
1	Right, Left	<u>229</u> , <u>291</u> (X = <u>260</u>)	<u>21</u> , <u>41</u> (X = <u>31</u>)	>300, >300 (X = >300)	<u>171</u> , <u>135</u> (X = <u>153</u>)	<u>28</u> , <u>12</u> (X = <u>20</u>)
2	Right, Left	<u>12</u> , <u>12</u> (X = <u>12</u>)	<u>0</u> , <u>1</u> (X = <u>1</u>)	>300, >300 (X = >300)	<u>34</u> , <u>58</u> (X = <u>46</u>)	<u>2</u> , <u>7</u> (X = <u>5</u>)
3	Right, Left	<u>184</u> , <u>194</u> (X = <u>189</u>)	<u>33</u> , <u>22</u> (X = <u>28</u>)	>300, >300 (X = >300)	<u>21</u> , <u>28</u> (X = <u>25</u>)	<u>0</u> , <u>1</u> (X = <u>1</u>)
4	Right, Left	<u>181</u> , <u>100</u> (X = <u>141</u>)	<u>52</u> , <u>11</u> (X = <u>32</u>)	>300, >300 (X = >300)	<u>15</u> , <u>21</u> (X = <u>48</u>)	<u>0</u> , <u>1</u> (X = <u>1</u>)
5	Right, Left	<u>184</u> , <u>159</u> (X = <u>172</u>)	<u>43</u> , <u>42</u> (X = <u>43</u>)	>300, >300 (X = >300)	>300, >300 (X = >300)	<u>54</u> , <u>53</u> (X = <u>54</u>)
6	Right, Left	<u>72</u> , <u>54</u> (X = <u>63</u>)	<u>11</u> , <u>12</u> (X = <u>12</u>)	>300, >300 (X = >300)	<u>72</u> , <u>35</u> (X = <u>54</u>)	<u>10</u> , <u>7</u> (X = <u>9</u>)
7	Right, Left	>300, >300 (X = >300)	<u>55</u> , <u>45</u> (X = <u>50</u>)	>300, >300 (X = >300)	<u>90</u> , <u>50</u> (X = <u>70</u>)	<u>9</u> , <u>10</u> (X = <u>10</u>)
8	Right, Left	<u>14</u> , <u>98</u> (X = <u>56</u>)	<u>0</u> , <u>5</u> (X = <u>3</u>)	>300, >300 (X = >300)	>300, >300 (X = >300)	<u>94</u> , <u>54</u> (X = <u>74</u>)
9	Right, Left	<u>114</u> , <u>131</u> (X = <u>123</u>)	<u>28</u> , <u>10</u> (X = <u>19</u>)	>300, >300 (X = >300)	<u>29</u> , <u>22</u> (X = <u>26</u>)	<u>0</u> , <u>4</u> (X = <u>2</u>)
10	Right, Left	<u>0</u> , <u>26</u> (X = <u>13</u>)	<u>0</u> , <u>2</u> (X = <u>1</u>)	>300, >300 (X = >300)	<u>41</u> , <u>182</u> (X = <u>112</u>)	<u>8</u> , <u>22</u> (X = <u>15</u>)
11	Right, Left	<u>165</u> , <u>166</u> (X = <u>166</u>)	<u>13</u> , <u>17</u> (X = <u>15</u>)	>300, >300 (X = >300)	<u>49</u> , <u>25</u> (X = <u>37</u>)	<u>6</u> , <u>5</u> (X = <u>6</u>)
12	Right, Left	>300 , <u>293</u> (X = <u>293</u>)	<u>45</u> , <u>43</u> (X = <u>44</u>)	>300, >300 (X = >300)	<u>141</u> , <u>32</u> (X = <u>87</u>)	<u>18</u> , <u>2</u> (X = <u>10</u>)
13	Right, Left	<u>88</u> , <u>249</u> (X = <u>169</u>)	<u>17</u> , <u>17</u> (X = <u>17</u>)	>300, >300 (X = >300)	<u>84</u> , <u>39</u> (X = <u>62</u>)	<u>10</u> , <u>6</u> (X = <u>8</u>)
14	Right, Left	<u>128</u> , <u>31</u> (X = <u>80</u>)	<u>4</u> , <u>4</u> (X = <u>4</u>)	>300, >300 (X = >300)	<u>26</u> , <u>28</u> (X = <u>27</u>)	<u>5</u> , <u>2</u> (X = <u>4</u>)
15	Right, Left	<u>81</u> , <u>185</u> (X = <u>133</u>)	<u>16</u> , <u>24</u> (X = <u>20</u>)	>300, >300 (X = >300)	<u>57</u> , <u>17</u> (X = <u>37</u>)	<u>10</u> , <u>4</u> (X = <u>7</u>)

Counting requirements:

Plates with cfu < 300.

Day 2: Only colonies where there is separation (free colonies) are counted.

Underlined = figures used in calculations

X = mean

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Plate counting form (EN 1500)

Before and after values for reference product. Total.						
Test date: 15-06-2005 Reference product: 60% (by weight) 2-Propanol Suspension concentration: 2.55×10^8						
		Before test values		After test values		
Proband No.		10 ⁴ Total	10 ⁵ Total	10 ⁰ Total	10 ¹ Total	10 ² Total
1	Right, Left	<u>37</u> , <u>73</u> (X = <u>55</u>)	<u>2</u> , <u>2</u> (X = <u>2</u>)	>300, >300 (X = >300)	<u>39</u> , <u>42</u> (X = <u>41</u>)	<u>7</u> , <u>6</u> (X = <u>7</u>)
2	Right, Left	<u>23</u> , <u>66</u> (X = <u>45</u>)	<u>3</u> , <u>7</u> (X = <u>5</u>)	>300, >300 (X = >300)	<u>105</u> , <u>63</u> (X = <u>84</u>)	<u>7</u> , <u>7</u> (X = <u>7</u>)
3	Right, Left	<u>204</u> , <u>162</u> (X = <u>183</u>)	<u>53</u> , <u>55</u> (X = <u>54</u>)	>300, >300 (X = >300)	<u>24</u> , <u>20</u> (X = <u>22</u>)	<u>2</u> , <u>1</u> (X = <u>2</u>)
4	Right, Left	<u>180</u> , <u>274</u> (X = <u>227</u>)	<u>13</u> , <u>18</u> (X = <u>16</u>)	>300, >300 (X = >300)	<u>26</u> , <u>37</u> (X = <u>32</u>)	<u>6</u> , <u>5</u> (X = <u>6</u>)
5	Right, Left	<u>164</u> , <u>120</u> (X = <u>142</u>)	<u>25</u> , <u>17</u> (X = <u>21</u>)	>300, >300 (X = >300)	>300, >300 (X = >300)	<u>55</u> , <u>49</u> (X = <u>52</u>)
6	Right, Left	<u>10</u> , <u>33</u> (X = <u>22</u>)	<u>0</u> , <u>7</u> (X = <u>4</u>)	>300, >300 (X = >300)	<u>56</u> , <u>89</u> (X = <u>73</u>)	<u>5</u> , <u>33</u> (X = <u>19</u>)
7	Right, Left	<u>35</u> , <u>184</u> (X = <u>110</u>)	<u>4</u> , <u>26</u> (X = <u>15</u>)	>300, >300 (X = >300)	<u>92</u> , <u>118</u> (X = <u>105</u>)	<u>30</u> , <u>27</u> (X = <u>29</u>)
8	Right, Left	<u>210</u> , <u>135</u> (X = <u>173</u>)	<u>17</u> , <u>20</u> (X = <u>19</u>)	>300, >300 (X = >300)	>300, >300 (X = >300)	<u>246</u> , <u>127</u> (X = <u>187</u>)
9	Right, Left	<u>50</u> , <u>68</u> (X = <u>59</u>)	<u>4</u> , <u>6</u> (X = <u>5</u>)	>300, >300 (X = >300)	<u>22</u> , <u>16</u> (X = <u>19</u>)	<u>0</u> , <u>4</u> (X = <u>2</u>)
10	Right, Left	<u>16</u> , <u>12</u> (X = <u>14</u>)	<u>2</u> , <u>0</u> (X = <u>1</u>)	>300, >300 (X = >300)	<u>56</u> , <u>120</u> (X = <u>88</u>)	<u>3</u> , <u>17</u> (X = <u>10</u>)
11	Right, Left	<u>210</u> , <u>205</u> (X = <u>208</u>)	<u>30</u> , <u>24</u> (X = <u>27</u>)	>300, >300 (X = >300)	<u>104</u> , <u>208</u> (X = <u>156</u>)	<u>18</u> , <u>26</u> (X = <u>22</u>)
12	Right, Left	>300, >300 (X = >300)	<u>90</u> , <u>72</u> (X = <u>81</u>)	>300, >300 (X = >300)	<u>220</u> , >300 (X = <u>220</u>)	<u>18</u> , <u>22</u> (X = <u>20</u>)
13	Right, Left	<u>164</u> , <u>163</u> (X = <u>164</u>)	<u>36</u> , <u>15</u> (X = <u>26</u>)	>300, >300 (X = >300)	<u>199</u> , <u>241</u> (X = <u>220</u>)	<u>21</u> , <u>24</u> (X = <u>23</u>)
14	Right, Left	<u>16</u> , <u>27</u> (X = <u>22</u>)	<u>2</u> , <u>0</u> (X = <u>1</u>)	>300, >300 (X = >300)	<u>17</u> , <u>33</u> (X = <u>25</u>)	<u>1</u> , <u>3</u> (X = <u>2</u>)
15	Right, Left	<u>236</u> , <u>157</u> (X = <u>197</u>)	<u>5</u> , <u>17</u> (X = <u>11</u>)	>300, >300 (X = >300)	<u>49</u> , <u>45</u> (X = <u>47</u>)	<u>7</u> , <u>5</u> (X = <u>6</u>)

Counting requirements:

Plates with cfu < 300.

Day 2: Only colonies where there is separation (free colonies) are counted.

Underlined = figures used in calculations

X = mean

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Statistical calculation form (EN 1500)

Table for log reduction factors for test and reference.				Date: 15-06-2005		
Proband No.	Reference: 60 % (by weight) 2-Propanol			Test product: Disinfector 70%		
	log x	log y	log z	log x	log y	log z
1	6.18	3.35	2.83	6.45	3.24	3.21
3	6.55	2.92	3.63	6.37	2.19	4.18
4	6.89	3.26	3.63	6.36	2.15	4.21
5	6.25	3.71	2.54	6.48	3.73	2.75
6	6.09	3.72	2.37	6.56	3.46	3.10
7	6.72	3.29	3.43	6.70	3.53	3.17
9	6.34	2.89	3.45	6.80	2.96	3.84
11	6.98	3.88	3.10	6.80	3.29	3.51
12	6.91	3.32	3.59	7.17	3.57	3.60
13	6.93	3.35	3.58	6.83	2.85	3.98
14	5.81	2.95	2.86	6.38	3.13	3.25
15	6.78	3.33	3.45	6.82	3.33	3.49
X	6.54	3.33	3.21	6.66	3.11	3.52
S	0.39	0.32	0.45	0.26	0.53	0.47
N	12	12	12	12	12	12

log x = log before value X = mean
 log y = log after value S = standard deviation
 log z = log reduction factor N = number performed

Requirements: Unless all the reductions for the test are greater than for the reference, the results are checked in accordance with Wilcoxon (F-30-145-6). Mean before ref./test must be > log 5.00.

Proband Nos. 2, 8 and 10 were removed from the test because their reduction values were well below the requirement.

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Statistical calculation form (EN 1500)

Table for calculation of statistical significance.				Date: 15-06-2005	
Proband No.	log RF		Difference R-P	Enumeration of difference:	
	log R	log P		Without sign	With sign
1	2.83	3.21	- 0.38	5	- 5
3	3.63	4.18	- 0.55	10	- 10
4	3.63	4.21	- 0.58	11	- 11
5	2.54	2.75	- 0.21	3	- 3
6	2.37	3.10	- 0.73	12	- 12
7	3.43	3.17	+ 0.26	4	+ 4
9	3.45	3.84	- 0.39	6	- 6
11	3.10	3.51	- 0.41	9	- 9
12	3.59	3.60	- 0.01	1	- 1
13	3.58	3.98	- 0.40	8	- 8
14	2.86	3.25	- 0.39	7	- 7
15	3.45	3.49	- 0.04	2	- 2

log RF = log reduction factor
log R = log reduction factor reference
log P = log reduction factor test

Total enumeration (+): 4
Total enumeration (-): 74

Requirements: The total positive enumeration must not be greater than the figure looked up in Wilcoxon's table. The significance level has been set at 0.1 for disinfectants.

Result: 12 probands completed the test. The requirement for 12 probands is that the total positive rank must be ≤ 12 . As $4 \leq 12$, Disinfectant 70% is significantly more effective than the reference.

Wilcoxon's table			
Number performed	Significance level		
	0.1	0.05	0.01
12	12	17	9
13	26	21	12
14	31	25	15
15	36	30	19

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