



AB 815

TEST REPORT NR DZ/50/05/20 CONTAINS 6 NUMBERED PAGES

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**Evaluation of activity according to PN-EN 1500:2013-07 'Hygienic handrub'**

A. Laboratory:

LAB – TEST LABORATORIUM S.C. 40-868 KATOWICE, Poland

B. Identification of the sample:

1. Product tested.....**The Nordic Shield 75% Handsprit**
2. Batch.....na
3. Test sponsor.....The Army Painter
4. Date of delivery.....05.05.2020; sample delivered by the test sponsor
5. Storage conditions.....ambient
6. Active substances:.....na

C.1. Test method.....handrub according to PN-EN 1500:2013-07

D. Test conditions:

1. Test period.....05.05.2020 – 17.05.2020
2. Number of persons / hands in the test.....20 / 20x2
3. Test strain.....*Escherichia coli* K12 NCTC 10538
4. Neutralizer.....Tween 80, 100 g/l; lecithin 30 g/l; sodium thiosulphate 5 g/l, in TSB
5. Soft soap.....prepared according to PN-EN 1500:2013-07
6. Volume of product for single rub.....3,0 ml
7. Single handrub time.....30 s
8. Number of handrubs.....2
9. Handrub procedure.....according to annex A to PN-EN 1500:2013-07
10. Incubation.....37°C ± 1°C; 48 h

E. Test results..... tables 1 – 4

F. Conclusion:

Product: **The Nordic Shield 75% Handsprit** tested according to **PN-EN 1500:2013-07**, applied: 3 ml on dry hands, 30 s handrub, repeated, is not significantly worse than the reference procedure, and so meets the requirements of **PN-EN 1500:2013-07 'Hygienic handrub'**.

**TABLE 1**

**dilution – neutralization validation**

Product: **The Nordic Shield 75% Handsprit**

test strain	validation test		
	bacterial suspensions	neutralizer control	dilution-neutralization control
Escherichia coli K12 NCTC 10538	Vc: 10 <sup>-3</sup> : 60;67 Nv <sub>0</sub> : 6,4•10 <sup>1</sup> Nv <sub>B</sub> : 6,4•10 <sup>4</sup>	Vc: 52;63 B: 5,8•10 <sup>1</sup>	Vc: 34;39 C: 3,6•10 <sup>1</sup>

Nv - cfu/ml in the bacterial suspension in the dilution-neutralization control test, Nv<sub>0</sub>= Nv/10  
 Nv<sub>B</sub> - cfu/ml in the bacterial suspension in the neutralizer toxicity control test,

B - cfu/ml in neutralizer control test  
 C - cfu/ml in the dilution - neutralization control test

Validation criteria verification:

$3,0 \cdot 10^2 \leq N_v \leq 1,6 \cdot 10^3$	-	met	$C \geq 0,5 N_{v0}$	-	met
$3,0 \cdot 10^4 \leq N_{vB} \leq 1,6 \cdot 10^5$	-	met	$B \geq 0,0005 N_{vB}$	-	met



**TABLE 2 Reference handrub procedure – experimental results**

Reference product: 2-propanol 60% v/v  
 Application: 3 ml on dry hands; 30 s rub; performed 2 times  
 Test date: 15.05.2020  
 Test strain: *Escherichia coli* K12 NCTC 10538  
 Microbial suspension:  $3,3 \cdot 10^8$  cfu/ml

Nr	subject hand L left/ R right	Number of cfu / 1,0 ml TSB on plate from dilutions					
		pre-count			post-count		
		$10^{-3}$	$10^{-4}$	$10^{-5}$	$10^{-1}$	$10^{-2}$	$10^{-3}$
1	L	>330	<u>72</u>	8	<u>4</u>	0	0
	R	>330	<u>36</u>	2	<u>11</u>	1	0
2	L	<u>252</u>	<u>32</u>	4	<u>9</u>	1	0
	R	>330	<u>44</u>	6	<u>23</u>	3	0
3	L	>330	<u>84</u>	9	<u>3</u>	0	0
	R	>330	<u>149</u>	<u>15</u>	<u>24</u>	2	0
4	L	>330	<u>98</u>	10	<u>64</u>	7	1
	R	>330	<u>73</u>	9	<u>25</u>	3	0
5	L	>330	<u>104</u>	11	<u>31</u>	4	0
	R	>330	<u>45</u>	5	<u>18</u>	2	0
6	L	<u>167</u>	<u>21</u>	2	<u>10</u>	1	0
	R	<u>230</u>	<u>29</u>	4	<u>5</u>	1	0
7	L	<u>285</u>	<u>34</u>	4	<u>2</u>	0	0
	R	>330	<u>47</u>	6	<u>4</u>	0	0
8	L	>330	<u>106</u>	12	<u>50</u>	6	0
	R	>330	<u>97</u>	11	<u>72</u>	9	1
9	L	>330	<u>78</u>	10	<u>5</u>	1	0
	R	>330	<u>66</u>	8	<u>11</u>	1	0
10	L	>330	<u>126</u>	<u>14</u>	<u>62</u>	8	1
	R	>330	<u>183</u>	<u>22</u>	<u>81</u>	9	1
11	L	>330	<u>43</u>	5	<u>17</u>	2	0
	R	>330	<u>65</u>	8	<u>29</u>	3	0
12	L	>330	<u>109</u>	12	<u>39</u>	4	0
	R	>330	<u>152</u>	<u>18</u>	<u>10</u>	1	0
13	L	>330	<u>56</u>	6	<u>13</u>	1	0
	R	<u>282</u>	<u>36</u>	4	<u>4</u>	0	0
14	L	>330	<u>138</u>	<u>14</u>	<u>48</u>	4	0
	R	>330	<u>86</u>	9	<u>33</u>	3	0
15	L	>330	<u>95</u>	11	<u>21</u>	2	0
	R	>330	<u>54</u>	6	<u>16</u>	2	0
16	L	>330	<u>116</u>	<u>15</u>	<u>76</u>	8	1
	R	>330	<u>67</u>	4	<u>12</u>	1	0
17	L	>330	<u>113</u>	12	<u>65</u>	7	1
	R	>330	<u>80</u>	10	<u>11</u>	1	0
18	L	>330	<u>43</u>	4	<u>20</u>	2	0
	R	<u>177</u>	<u>23</u>	2	<u>8</u>	1	0
19	L	>330	<u>125</u>	13	<u>83</u>	7	0
	R	>330	<u>46</u>	5	<u>17</u>	3	0
20	L	>330	<u>77</u>	10	<u>14</u>	2	0
	R	>330	<u>92</u>	8	<u>51</u>	4	0



**TABLE 3 Handrub test procedure – experimental results**

Test product: **The Nordic Shield 75% Handsprit**  
 Application: 3 ml on dry hands; 30 s rub, performed 2 times  
 Test date: 15.05.2020  
 Test strain: *Escherichia coli* K12 NCTC 10538  
 Microbial suspension:  $3,3 \cdot 10^8$  cfu/ml

Nr	subject hand L left/ R right	Number of cfu / 1,0 ml TSB on plate from dilutions					
		pre-count			post-count		
		$10^{-3}$	$10^{-4}$	$10^{-5}$	$10^{-1}$	$10^{-2}$	$10^{-3}$
1	L	>330	<u>102</u>	13	<u>20</u>	3	0
	R	>330	<u>58</u>	6	<u>17</u>	1	0
2	L	>330	<u>45</u>	7	<u>28</u>	3	0
	R	>330	<u>62</u>	5	<u>42</u>	5	0
3	L	>330	<u>87</u>	11	<u>19</u>	2	0
	R	>330	<u>112</u>	13	<u>41</u>	4	0
4	L	<u>309</u>	<u>39</u>	5	<u>7</u>	1	0
	R	<u>108</u>	<u>14</u>	1	<u>3</u>	0	0
5	L	>330	<u>139</u>	<u>15</u>	<u>89</u>	9	1
	R	>330	<u>198</u>	<u>21</u>	<u>49</u>	6	1
6	L	<u>223</u>	<u>28</u>	4	<u>2</u>	0	0
	R	<u>137</u>	<u>18</u>	2	<u>6</u>	1	0
7	L	<u>218</u>	<u>24</u>	3	<u>11</u>	1	0
	R	<u>151</u>	<u>14</u>	1	<u>7</u>	0	0
8	L	>330	<u>83</u>	10	<u>56</u>	6	0
	R	>330	<u>112</u>	12	<u>14</u>	2	0
9	L	>330	<u>68</u>	7	<u>53</u>	5	1
	R	<u>224</u>	<u>28</u>	5	<u>8</u>	1	0
10	L	>330	<u>122</u>	13	<u>57</u>	6	1
	R	>330	<u>98</u>	8	<u>11</u>	2	0
11	L	<u>273</u>	<u>35</u>	4	<u>6</u>	1	0
	R	<u>187</u>	<u>24</u>	1	<u>15</u>	2	0
12	L	>330	<u>63</u>	8	<u>3</u>	0	0
	R	>330	<u>79</u>	8	<u>38</u>	4	0
13	L	>330	<u>115</u>	<u>16</u>	<u>61</u>	7	0
	R	>330	<u>71</u>	6	<u>59</u>	6	0
14	L	>330	<u>44</u>	5	<u>27</u>	3	0
	R	<u>263</u>	<u>29</u>	3	<u>21</u>	2	0
15	L	>330	<u>52</u>	4	<u>14</u>	2	0
	R	>330	<u>60</u>	8	<u>18</u>	3	0
16	L	>330	<u>94</u>	10	<u>53</u>	6	0
	R	>330	<u>51</u>	7	<u>26</u>	2	0
17	L	>330	<u>69</u>	6	<u>54</u>	7	1
	R	>330	<u>48</u>	5	<u>22</u>	2	0
18	L	>330	<u>105</u>	11	<u>32</u>	4	0
	R	>330	<u>88</u>	10	<u>55</u>	6	1
19	L	>330	<u>151</u>	<u>16</u>	<u>41</u>	5	0
	R	>330	<u>204</u>	<u>27</u>	<u>86</u>	8	1
20	L	>330	<u>53</u>	8	<u>20</u>	2	0
	R	<u>312</u>	<u>37</u>	4	<u>12</u>	1	0



**TABLE 4****Calculated logs (means for two hands) and reduction factors according to tables 2,3**

Test person/testing order		Reference procedure (R) 2 – propanol 60%			Test procedure (P) The Nordic Shield 75% Handsprit		
		Log x	Log y	Log z	Log x	Log y	Log z
1	PP/RP	6,71	1,82	4,89	6,89	2,27	4,62
2		6,53	2,16	4,37	6,72	2,54	4,18
3		7,05	1,93	5,12	6,99	2,45	4,54
4		6,93	2,60	4,33	6,27	1,66	4,61
5		6,84	2,37	4,47	7,22	2,82	4,40
6		6,30	1,85	4,45	6,25	1,54	4,71
7		6,57	1,45	5,12	6,26	1,94	4,32
8		7,01	2,78	4,23	6,98	2,45	4,53
9		6,86	1,87	4,99	6,60	2,31	4,29
10		7,19	2,85	4,34	7,04	2,40	4,64
11	RP/PP	6,72	2,35	4,37	6,37	1,98	4,39
12		7,11	2,30	4,81	6,85	2,03	4,82
13		6,60	1,86	4,74	6,96	2,78	4,18
14		7,04	2,60	4,44	6,53	2,38	4,15
15		6,86	2,26	4,60	6,75	2,20	4,55
16		6,95	2,48	4,47	6,84	2,56	4,28
17		6,98	2,43	4,55	6,76	2,54	4,22
18		6,45	2,10	4,35	6,98	2,62	4,36
19		6,88	2,57	4,31	7,25	2,77	4,48
20		6,93	2,43	4,50	6,61	2,19	4,42
<b>Total</b>							
X(m)		6,83	2,25	4,57	6,76	2,32	4,43
S		0,24	0,37	0,28	0,30	0,35	0,19
N		20	20	20	20	20	20
<b>Testing order: PP / RP</b>							
X(m)		6,80	2,17	4,63	6,72	2,24	4,48
S		0,27	0,47	0,36	0,36	0,4	0,18
N		10	10	10	10	10	10
<b>Testing order: RP / PP</b>							
X(m)		6,85	2,34	4,51	6,79	2,41	4,39
S		0,20	0,22	0,16	0,25	0,29	0,20
N		10	10	10	10	10	10
Log x = log of pre-count value Log y = log of post-count value Log z = log of reduction factor				S = standard deviation X(m) = mean N = number of subjects in the test			

Mean reduction for the product (4,43) is lower than for the reference procedure (4,57).





**TABLE 5**

Computation of individual differences of IgR for:  
 RP (reference procedure) and PP (test procedure for: The Nordic Shield 75% Handsprit)

person	Log RF for:		Difference RP-PP
	RP	PP	
1	4,89	4,62	0,27
2	4,37	4,18	0,19
3	5,12	4,54	0,58
4	4,33	4,61	-0,28
5	4,47	4,40	0,07
6	4,45	4,71	-0,26
7	5,12	4,32	0,80
8	4,23	4,53	-0,30
9	4,99	4,29	0,70
10	4,34	4,64	-0,30
11	4,37	4,39	-0,02
12	4,81	4,82	-0,01
13	4,74	4,18	0,56
14	4,44	4,15	0,29
15	4,60	4,55	0,05
16	4,47	4,28	0,19
17	4,55	4,22	0,33
18	4,35	4,36	-0,01
19	4,31	4,48	-0,17
20	4,50	4,42	0,08

Statistical comparison – sorting of individual differences and computation for Hodges-Lehmann  
 97,5% upper confidence limit test.

The agreed inferiority margin is 0,6.

Because only 7 mean-pair differences are larger than 0,6, for the critical value of 52 such differences  
 for 20 paired data different than 0, the hypothesis of inferiority of **PP (test procedure for: The Nordic  
 Shield 75% Handsprit)** to **RP (reference procedure)** is rejected with level of significance at least  
 0,25.

Signed off: Lab-test manager.....Date .....