Test Report Number: GZHH00379018

Applicant: Orbel Health Limited
82 St John Street, London, England, EC1M 4JN

Date: Oct 26, 2020

Sample Description:

One (1) style of submitted sample said to be :

Item Name	:	**Orbel hand rub.**
Item Quantity	:	10 pcs 60mL units.
Item Batch	:	**PHA-O 04282020.**
Item Description	:	Alcohol based hand rub.
Manufacturer	:	Bath Concept Cosmetics (Dongguan) Co.,Ltd.
Country of Origin	:	China.
Date Sample Received	:	Sep 09, 2020

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Tests conducted:

As requested by the applicant, refer to attached page(s) for details.

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Intertek GM Testing Service Zhuhai Co. Ltd.

Sarah Xu
Asst. Manager
Healthcare and Beauty Products

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1 Disinfection Efficacy Test

With reference to standard test method BS EN 1500:2013 Chemical disinfectants and antiseptics-Hygienic handrub -Test method and requirements(phase 2/step2)

The testing procedure is as below:
a).Preparation of the contamination fluid
Grow the E.coli in two tubes each containing 5mL of TSB for 18h to 24h at (36±1) ℃. Inoculate these cultures into two bottles with 1L TSB each and incubate for 18h to 24h at (36±1) ℃. The contamination fluid is test bacterial suspension.

b).Application of the contamination fluid
Prepare the hands by washing for 1 min with 5mL diluted soft soap to remove natural transients. Dry them thoroughly on paper towels. Pour the contamination fluid into the container and immerse the hands up to the mid-metacarpals for 5s with fingers spread apart. Carefully allow surplus liquid to drain back into the container.

c).Allow the hands to dry in the air for 3 min, holding them in a horizontal position with the fingers spread out and rotating them to and fro to avoid the formation of droplets.

d).Prevalues
Immediately after drying, rub the fingertips(including that of the thumb) for 1min on the base of a Petri dish containing 10 mL of TSB without neutralizer, in order to assess the release of test organisms before treatment of the hands(prevalues). Use a separate Petri dish for each hand. Prepare dilutions of these sampling fluids of 10^{-3} and 10^{-4} in TSB. For each dilution, spread 0.1mL over the surface of a TSSA plate using glass spreaders.

e).Hygienic handrub procedure
e)(1). Immediately after sampling for the prevalues and without recontaminating the hands, the groups shall perform the handrub in accordance with either e)(2) or e)(3), as applicable.
e)(2).Reference handrub procedure R
Pour 3mL of propan-2-ol 60%(V/V) into the cupped dry hands and rub vigorously for 30s onto the skin up to the wrists in accordance with the standard handrub procedure, to ensure total coverage of the hands. Repeat with a further 3mL propan-2-ol, to give a total rubbing time of 60s.
e)(3).Handrub procedure with test product P
Pour 5mL of sample into the cupped dry hands and rub vigorously for 60s onto the skin up to the wrists in accordance with the standard handrub procedure, to ensure total coverage of the hands. Repeat with a further 5mL sample, to give a total rubbing time of 120s.

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f).Postvalues
Immediately afterwards, rub the fingertips and thumbtips on the base of a Petri dish containing 10mL TSB containing neutralizer for 1min. Use a separate Petri dish for each hand.

g). Incubation
Incubation all plates aerobically at (36±1) ℃ for 18h to 24h. Count the colony forming units and reincubate for a further 24h to detect any slow growing colonies.

REQUIREMENT
Appearance product dilution: Light blue gel
Active ingredient in product: Alcohol
Application: rub in 5mL/60s, repeat once
Neutralizer: D/E Broth
Diluent (Tryptone Sodium Chloride Solution): Tryptone pancreatic digest of casein 1.0g/L, Sodium chloride8.5g/L
Medium:
Tryptone Soya Agar (TSA)
Tryptone Saya Selective Agar (TSSA)
TEST ORGANISMS
Escherichia coli K12 NCTC 10538 (5.0×10^{8}cfu/mL)

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TESTING RESULTS

Table 1 List of computed lg reductions and individual differences

Voluteers	Log reduction		Difference RP-PP
	Reference handrub (RP)	Product handrub (PP)	
1	4.62	5.12	-0.50
2	3.40	6.26	-2.86
3	4.55	5.35	-0.80
4	4.60	5.09	-0.49
5	4.48	4.47	0.01
6	4.57	4.88	-0.31
7	4.25	4.91	-0.66
8	3.28	4.44	-1.16
9	5.42	6.79	-1.37
10	4.54	4.64	-0.10
11	4.92	4.67	0.25
12	4.90	5.40	-0.50
13	3.50	4.30	-0.80
14	3.56	4.16	-0.60
15	3.94	6.13	-2.19
16	3.39	3.82	-0.43
17	3.56	4.26	-0.70
18	4.47	3.98	0.49
19	3.18	4.04	-0.86
20	5.24	3.65	1.59

RP: Propan-2-ol 60% V/V
PP: Test sample
A complete set of result from 20 volunteers are available and the acceptance criterias are fulfilled.

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Table 2 Sorting of individual difference and computation for Hodges-Lehmann 97.5% upper confidence limits

Computation sheet of mean pairwise differences (d1+d2)/2						
Sample No.	Sorted differences	1.59	0.49	0.25	0.01	-0.10
1	1.59	1.59 [1]				
2	0.49	1.04 [2]	0.49 [12]			
3	0.25	0.92 [3]	0.37 [17]	0.25 [19]		
4	0.01	0.80 [4]	0.25 [20]	0.13 [23]	0.01 [28]	
5	-0.10	0.75 [5]	0.20 [22]	0.08 [26]	-0.04 [33]	-0.10 [37]
6	-0.31	0.64 [6]	0.09 [25]	-0.03 [32]	-0.15 [42]	-0.21 [47]
7	-0.43	0.58 [7]	0.03 [27]	-0.09 [35]	-0.21 [48]	-0.27 [54]
8	-0.49	0.55 [8]	0.00 [29]	-0.12 [39]	-0.24 [51]	-0.30 [57]
9	-0.50	0.55 [9]	-0.01 [30]	-0.13 [40]	-0.25 [52]	-0.30 [58]
10	-0.50	0.55 [10]	-0.01 [31]	-0.13 [41]	-0.25 [53]	-0.30 [59]
11	-0.60	0.50 [11]	-0.06 [34]	-0.18 [45]	-0.30 [57]	
12	-0.66	0.47 [13]	-0.09 [36]	-0.21 [49]	-0.33 [64]	
13	-0.70	0.45 [14]	-0.11 [38]	-0.23 [50]		
14	-0.80	0.40 [15]	-0.16 [43]	-0.28 [55]		
15	-0.80	0.40 [16]	-0.16 [44]	-0.28 [56]		
16	-0.86	0.37 [18]	-0.19 [46]			
17	-1.16	0.22 [21]				
18	-1.37	0.11 [24]				
19	-2.19	-0.30 [60]				

The differences of the individual lg Rs of RP-PP from Table 2 are sorted in the second column and in the headline according to their size in descending order.

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Table 3 WILCOXON'S matched-pairs signed-ranks test

One-sided level of significance (directional test)			
Np	0.05	0.025	0.01
18	47	40	32
19	53	46	37
20	60	52	43
21	68	59	49
22	75	66	56

From Table 3 of critical values of 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. The 53rd value is -0.25. Hence the Hodges-Lehmann upper one-sided 97.5% confidence limit for the difference in lg Rs between RP and PP is -0.25, 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 that the test preparation PP is non-inferior to RP.

Conclusion:
Pass, n=20 at a one-sided 0.025 level of significance, c=52+1=53, the 53rd value is -0.25, <0.6. It can be concluded that the test sample is non-inferior to Propan-2-ol 60%(V/V) under hygienic handrub procedure.

Date sample received: Sep 25, 2020
Testing period: Sep 25, 2020 to Oct 22, 2020

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End of report

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