



TESTING LABORATORY ACCREDITED BY PCA (No. AB 079). MEMBER ANALYST OF FOSFA AND GAFTA

## REPORT OF ANALYSIS No. 8342/13/GDY

Client:  <b>ZAKŁAD PRODUKCJI SPRZĘTU MEDYCZNEGO "RAVIMED" SP. Z O.O.</b>  <b>UL. POLNA 54</b>  <b>05-119 ŁAJSKI K/LEGIONOWA</b>		Subject: <i>(according to declaration of the Client)</i>  <b>CHA-HA NON- IRRITATING ANTIBACTERIAL FLUID</b>  Marking of the sample: <b>CHA-HA NON- IRRITATING ANTIBACTERIAL FLUID</b> PET bottle with 75ml capacity
Sample received 2013-01-23	Analysis completed 2013-02-25	

TEST	METHOD	Unit	Result
Hygienic handwash	PN-EN 1499:2000/Ap1:2001	-	1)

1)

According to PN-EN 1499:2000/Ap1:2001 Chemical disinfectants and antiseptics. Hygienic handwash. Test method and requirements (phase 2/step 2) **CHA-HA Non- irritating antibacterial fluid** exhibits bactericidal activity against transitional microorganism used in hygienic handwash procedure - rubbing off the hands 5 ml of product for 30s

Results in Annexes:

TABLE 1  
TABLE 2  
TABLE 3  
TABLE 4

Laboratory: Chwaszczyńska 180, Gdynia, Poland

The results relate to the analysed samples only. Unless otherwise specified given measurement uncertainty was estimated for the coefficient k=2 and 95% confidence level.

Report date: 28.02.2013	Authorized with qualified electronic signature by:  <i>Małgorzata Stachowiak, Microbiology Laboratory Manager</i>
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**TABLE 1**

**A) IDENTIFICATION OF THE SAMPLE:**

Name of the product	<b>CHA-HA NON- IRRITATING ANTIBACTERIAL FLUID</b>
Manufacturer/Supplier	<b>Zakład Produkcji Sprzętu Medycznego "RAVIMED" Sp. z o.o. ul. Polna 54 05-119 Łajski k/Legionowa</b>
Active substance	Chlorhexidine Digluconate 0,2g

**B) TEST METHOD AND ITS VALIDATION:**

Method	PN-EN 1499:2000/Ap1:2001 Chemical disinfectants and antiseptics. Hygienic handwash. Test method and requirements (phase 2/step 2)
Neutralizer	Polisorbat 80, 30 ml/l, soponina 30g/l, histidine 1g/l cysteine, 1g/l

**C) EXPERIMENTAL CONDITIONS:**

Analysis period	23.01-25.02.2013
Appearance product dilutions	Clear solution
Product test concentrations (%V/V)	100%, rubbing off the hands 5 ml of product for 30s
Test temperature	20°C
Contact time	rubbing method- 30s
Temperature of incubation	37°C
Identification of the bacterial strains used	<i>E. coli</i> K12 NCTC 10538

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### E) Conclusions

According to PN-EN 1499:2000/Ap1:2001 Chemical disinfectants and antiseptics. Hygienic handwash. Test method and requirements (phase 2/step 2) **CHA-HA Non- irritating antibacterial fluid** exhibits bactericidal activity against transitional microorganism used in hygienic handwash procedure - rubbing off the hands 5 ml of product for 30s

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## REPORT OF ANALYSIS No. 8342/13/GDY

TABLE 2

### HYGIENIC HANDWASH TEST PROCEDURE

NAME OF PRODUCT: SOFT  
SOAP

ANALYSIS PERIOD : 25.01.2013

STRAIN OF BACTERIA: E. COLI K12 NCTC 10538

PREVALUE: 2,4X 10<sup>9</sup> JTK/G

NEUTRALIZER: POLISORBAT 80, 30 mL/L, SOPONINA 30G/L, HISTIDINE 1G/L

CYSTEINE, 1G/L

No.	PREVALUE				POSTVALUE				REDUCTION FACTOR
	HAND LEFT	HAND RIGHT	MEAN VALUE	Lg	HAND LEFT	HAND RIGHT	MEAN VALUE	Lg	
	1	2	3	4	5	6	7	8	
1	1500000	1700000	1600000	6,20	3400	2800	3100	3,49	2,71
2	2000000	1500000	1750000	6,24	4200	3900	4050	3,61	2,64
3	1700000	2000000	1850000	6,27	5200	4300	4750	3,68	2,59
4	1600000	1500000	1550000	6,19	7300	6500	6900	3,84	2,35
5	2600000	2300000	2450000	6,39	5300	4900	5100	3,71	2,68
6	1700000	1400000	1550000	6,19	1800	2600	2200	3,34	2,85
7	1500000	1100000	1300000	6,11	5800	7300	6550	3,82	2,30
8	2600000	1500000	2050000	6,31	3900	4300	4100	3,61	2,70
9	2300000	1400000	1850000	6,27	3000	5700	4350	3,64	2,63
10	1800000	1500000	1650000	6,22	7800	6500	7150	3,85	2,36
11	2300000	1500000	1800000	6,26	3900	8000	5950	3,77	2,50
12	2000000	2200000	2300000	6,36	9300	9000	9150	3,96	2,33

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## REPORT OF ANALYSIS No. 8342/13/GDY

TABLE 3

### HYGIENIC HANDWASH TEST PROCEDURE

NAME OF PRODUCT: **CHA-HA NON-IRRITATING ANTIBACTERIAL FLUID**

ANALYSIS PERIOD: 25.01.2013

STRAIN OF BACTERIA: *E. COLI* K12 NCTC 10538

PREVALUE:  $2,4 \times 10^9$  JTK/G

NEUTRALIZER: POLISORBAT 80, 30 mL/L, SOPONINA 30G/L, HISTIDINE 1G/L

CYSTEINE, 1G/L

No.	PREVALUE				POSTVALUE				REDUCTION FACTOR
	HAND LEFT	HAND RIGHT	MEAN VALUE	Lg	HAND LEFT	HAND RIGHT	MEAN VALUE	Lg	
	1	2	3	4	5	6	7	8	
1	980000	1100000	1040000	6,02	120	100	110	2,04	3,98
2	1200000	900000	1050000	6,02	150	150	150	2,18	3,85
3	1000000	820000	910000	5,96	150	190	170	2,23	3,73
4	890000	1200000	1045000	6,02	160	140	490	2,69	3,33
5	1200000	1400000	1300000	6,11	190	180	270	2,43	3,68
6	1300000	1490000	1395000	6,14	220	270	340	2,53	3,61
7	1000000	800000	900000	5,95	140	180	170	2,23	3,72
8	1130000	930000	1030000	6,01	120	160	297	2,47	3,54
9	1400000	1500000	1450000	6,16	150	170	214	2,33	3,83
10	1300000	1600000	1450000	6,16	130	180	210	2,32	3,84
11	1200000	1300000	1250000	6,10	140	178	214	2,33	3,77
12	1300000	1700000	1500000	6,18	413	412	110	2,04	3,96

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Table 4

### COMPARISON OF REDUCTION FACTORS

- 1.Reduction factor standard handwash - SOFT SOAP
- 2.Reduction factor standard handwash - **CHA-HA NON- IRRITATING ANTIBACTERIAL FLUID**

NO	1	2	difference 1-2
1	2,71	3,98	- 1,27
2	2,64	3,85	- 1,21
3	2,59	3,73	- 1,14
4	2,35	3,33	- 0,98
5	2,68	3,68	- 1,00
6	2,85	3,61	- 0,76
7	2,30	3,72	- 1,42
8	2,70	3,54	- 0,84
9	2,63	3,83	- 1,20
10	2,36	3,84	- 1,48
11	2,50	3,77	- 1,27
12	2,33	3,96	- 1,63
mean value	<b>2,55</b>	<b>3,74</b>	- <b>1,18</b>

#### Test validation:

- 1) the mean value of the logarithms of the prevalue > 5
- 2) the mean reduction factor for the preparation **CHA-HA NON- IRRITATING ANTIBACTERIAL FLUID** is significantly larger than that with soft soap

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