



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

REPORT OF ANALYSIS No. 8342/13/GDY

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

TEST	METHOD	Unit	Result
Hygienic hand disinfection	PN-EN 1500:2002	-	1)

1)
According to PN- EN 1500:2002 Chemical disinfectants and antiseptics. Hygienic handrub. Test method and requirements (phase 2/step 2) **CHA-HA Non- irritating antibacterial fluid** exhibits bactericidal activity against transitional microorganism used in hygienic hand disinfection procedure - rubbing off the hands 3 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	CHA-HA NON- IRRITATING ANTIBACTERIAL FLUID
Manufacturer/Supplier	Zakład Produkcji Sprzętu Medycznego "RAVIMED" Sp. z o.o. ul. Polna 54 05-119 Łąjski k/Legionowa
Active substance	Chlorhexidine Digluconate 0,2g

B) TEST METHOD AND ITS VALIDATION:

Method	PN-EN 1500:2002 Chemical disinfectants and antiseptics. Hygienic handrub. Test method and requirements (phase 2/step 2)
Neutralizer	Polisorbat 80, 30ml/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 3 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 1500:2002 Chemical disinfectants and antiseptics. Hygienic handrub. Test method and requirements (phase 2/step 2) **CHA-HA Non- irritating antibacterial fluid** exhibits bactericidal activity against transitional microorganism used in hygienic hand disinfection procedure - rubbing off the hands 3 ml of product for 30s

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TABLE 2

HYGIENIC HANDRUB TEST PROCEDURE

NAME OF PRODUCT:
PROPAN-2OL 60% (VOLUME
CONCENTRATION)

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 difference 4-8
	HAND LEFT	HAND RIGHT	MEAN VALUE	Lg	HAND LEFT	HAND RIGHT	MEAN VALUE	Lg	
	1	2	3	4	5	6	7	8	
1	1800000	2100000	1950000	6,29	280	246	263	2,42	3,87
2	1400000	1360000	1380000	6,14	156	125	140,5	2,15	3,99
3	1970000	1680000	1825000	6,26	240	378	309	2,49	3,77
4	1430000	1456000	1443000	6,16	198	198	198	2,30	3,86
5	2200000	1560000	1880000	6,27	123	144	133,5	2,13	4,15
6	1890000	1630000	1760000	6,25	240	211	225,5	2,35	3,89
7	1450000	1580000	1515000	6,18	147	223	185	2,27	3,91
8	2300000	1900000	2100000	6,32	245	189	217	2,34	3,99
9	1230000	1100000	1165000	6,07	136	147	141,5	2,15	3,92
10	1200000	2100000	1650000	6,22	287	278	282,5	2,45	3,77
11	2100000	1500000	1800000	6,26	198	156	177	2,25	4,01
12	2400000	2200000	2300000	6,36	136	120	128	2,11	4,25

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TABLE 3

HYGIENIC HANDRUB. 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 L/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	1160000	1000000	1080000	6,03	200	210	205	2,31	3,72
2	1000000	1180000	1090000	6,04	176	218	197	2,29	3,74
3	1100000	990000	1045000	6,02	270	267	268,5	2,43	3,59
4	1700000	1500000	1600000	6,20	210	480	490	2,69	3,51
5	1000000	1200000	1100000	6,04	245	110	270	2,43	3,61
6	1500000	1100000	1300000	6,11	210	360	340	2,53	3,58
7	1200000	1200000	1200000	6,08	130	128	170	2,23	3,85
8	1090000	900000	995000	6,00	120	245	297	2,47	3,53
9	1200000	1400000	1300000	6,11	110	210	214	2,33	3,78
10	1100000	1000000	1050000	6,02	125	132	210	2,32	3,70
11	1400000	1100000	1250000	6,10	145	178	214	2,33	3,77
12	1000000	1000000	1000000	6,00	413	412	110	2,04	3,96

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Table 4

COMPARISON OF REDUCTION FACTORS

- 1.Reduction factor standard hand disinfection-propan-2-ol 60%
- 2.Reduction factor standard hand disinfection- **CHA-HA NON- IRRITATING ANTIBACTERIAL FLUID**

NO	1	2	difference 1-2
1	3,87	3,72	0,15
2	3,99	3,74	0,25
3	3,77	3,59	0,18
4	3,86	3,51	0,35
5	4,15	3,61	0,54
6	3,89	3,58	0,31
7	3,91	3,85	0,06
8	3,99	3,53	0,46
9	3,92	3,78	0,13
10	3,77	3,70	0,07
11	4,01	3,77	0,24
12	4,25	3,96	0,30
mean value	3,95	3,70	0,25

Test validation:

- 1) the mean value of the logarithms of the prevalue > 5
- 2) the reduction factors R and P > 3
- 3) the mean reduction factor for the preparation **CHA-HA NON- IRRITATING ANTIBACTERIAL FLUID** is comparable to the reduction factor for the propan-2-ol 60%

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