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To
ANTISEPTICA chem. -pharm. Produkte GmbH
Att.: Dr. H.-J. Molitor
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R 22/00

EXPERT OPINION

Based on your written order dated May 15, 2000, we have investigated your product **MANORAPID SYNERGY** for suitability for surgical hand disinfection as per EN 12791 (reference procedure: n-propanol 60 vol.%).

This disinfectant is a clear, colorless liquid which, as per information from you, contains as active ingredients 54.1% vol.% ethanol (100%) and 10.0 vol.% n-propanol (100%).

This product has already been tested for hygienic hand disinfection as per EN 1500 (results given in our Expert Opinion R 19/96) and was deemed suitable for this purpose. Surgical hand disinfection tests were performed therefore only under everyday conditions with 20 subjects.

1. Surgical Hand Disinfection Tests

The test methodology was based on Directive EN 12791, of which extracts are given here:

On beginning the tests, the hands were washed for 1 min with 5 ml 20% soft soap and thoroughly dried with disposable paper towels. After drying the fingertips of both hands,

including the thumbs, were each kneaded for 1 min on the bottom of a petri dish containing 10 ml trypticase soybean broth (TSB) without inactivator. The adhering broth was dried by rubbing the fingers together, followed immediately afterwards by hand disinfection using the reference procedure or the test product. As reference procedure, 3 ml n-propanol 60% (v/v) were poured into the dry hands and vigorously rubbed for 3 min using the standard rubbing technique. As many 3-ml portions as needed to keep the hands moist for 3 min were poured onto the hands. Using the test product **MANORAPID SYNERGY**, the hands were also kept moist for 3 min as per the manufacturer's instructions using $n \times 3$ ml. On expiry of the exposure time of the test or standard product, the postvalues were obtained for both hands in the same manner as the prevalues had been. From the various kneading liquids, decadic dilution series were prepared for quantitative cultures and incubated for 48 h at $36 \pm 1^\circ\text{C}$.

The 20 test subjects were randomly assigned to 2 groups, with one group first using the reference procedure and then crossing over to the test procedure in a repeat exercise; the second group conducted the tests in reverse order.

A product is deemed effective as per this Standard if the mean reduction factor obtained for the immediate effect of the test procedure is not significantly less than that of the reference procedure. If a sustained effect is required in addition, the mean reduction factor of the sustained effect must additionally be significantly greater than that of the reference procedure.

2. Results of the Surgical Hand Disinfection Tests

The results of the plate counts are given in the original lists (tables 1 and 2). The values used for further calculations are each marked with an asterisk. Tables 3 and 4 give the logarithmic pre- and postvalues as well as the log reduction factors of the test and reference procedure. At the bottom of the table are listed the associated mean values and standard deviations.

As the data from two subjects had to be discarded due to too low prevalues, the values from 18 subjects were used for evaluation.

Summary of results:

Product	Application	Mean log reduction factors \pm s	
		Immediate value	3-h value
MANORAPID SYNERGY	n x 3 ml / 3 min	2.40 \pm 1.06	1.93 \pm 0.84
n-propanol 60%	n x 3 ml / 3 min	2.80 \pm 1.16	1.70 \pm 0.82

Since the mean reduction factor of MANORAPID SYNERGY for the immediate effect is lower than that of the reference procedure, the difference had to be checked for statistical significance using the Wilcoxon matched pairs test. With N=18 and at a level $p=0.1$, the difference is not significant (see table 5). (Since there is no demand for a sustained effect, the corresponding values are not of importance here; the difference between the mean reduction factors is not significant (table 6).

3. Evaluation

The test product MANORAPID SYNERGY proved to be suitable for surgical hand disinfection on being tested as per prEN 12791:

(signature)

Grad. Eng. Miranda Lhotsky

(signature)

Univ. Prof. Dr. med. M. Rotter

Table 1:

SURGICAL HAND RUB

Original list of results

Agent number 1: MANORAPID SYNERGY

Application: n x 3 ml x / 3 min

Test period: 29.05 - 05.06.00

1000 = uncountable

V	Hand	Exponential dilutions and counts per ml and plate								
		Prevalues			Immediate Postvalue			3 h Postvalue Sustained		
		-1	-2	-3	0	-1	-2	0	-1	-2
1	l	1000	166*	23*				500	53*	5
1	r	1000	500	57*	5*	2	0			
2	l	1000	700	72*	9*	0	0			
2	r	1000	600	59*				133*	19*	2
3	l	1000	214*	22*	209*	31*	4			
3	r	1000	500	53*				1000	138*	18*
4	l	1000	1000	173*	1000	500	56*			
4	r	1000	700	71*				1000	131*	11
5	l	1000	1000	102*				1000	400	52*
5	r	1000	1000	162*	1000	143*	12			
6	l	1000	215*	31*	800	87*	10			
6	r	1000	154*	12				1000	400	42*
7	l	1000	1000	121*				1000	102*	11
7	r	1000	1000	151*	1000	1000	187*			
8	l	1000	1000	121*				52*	5	0
8	r	1000	1000	129*	1000	128*	3			
9	l	1000	1000	205*				1000	255*	25*
9	r	1000	1000	102*	350	37*	3			
10	l	1000	700	78*	1000	169*	15*			
10	r	1000	156*	17*				124*	15*	3
11	l	1000	182*	17*				229*	31*	3
11	r	1000	234*	22*	13*	3	0			
12	l	1000	1000	105*	131*	12	1			
12	r	1000	276*	29*				1000	500	52*
13	l	1000	1000	118*	1000	1000	166*			
13	r	1000	1000	198*				350	38*	2
14	l	1000	182*	18*				1000	206*	16*
14	r	1000	500	58*	1000	400	45*			
15	l	1000	600	72*	24*	2	0			
15	r	1000	1000	166*				1000	104*	12
16	l	1000	236*	24*				56*	5	0
16	r	1000	272*	25*	29*	4	1			
17	l	1000	246*	25*				6*	0	0
17	r	1000	187*	16*	38*	4	1			
18	l	1000	1000	171*	20*	1	0			
18	r	1000	143*	14				600	69*	8

Table 2:

SURGICAL HAND RUB

Original list of results

Agent number 2: 60 % n-propanol

Application: n x 3 ml / 3 min

Test period: 29.05 - 05.06.00

1000 = uncountable

V	Hand	Exponential dilutions and counts per ml and plate								
		Prevalues			Immediate Postvalue			3 h Postvalue Sustained		
		-1	-2	-3	0	-1	-2	0	-1	-2
1	l	1000	350	39*				350	37*	3
1	r	1000	1000	178*	1*	0	0			
2	l	1000	1000	122*	800	91*	9			
2	r	1000	500	47*				1000	216*	24*
3	l	1000	400	50*	12*	1	0			
3	r	1000	340	34*				1000	155*	14
4	l	1000	500	45*	400	46*	6			
4	r	1000	204*	23*				1000	700	69*
5	l	1000	1000	91*				800	85*	4
5	r	1000	1000	215*	1000	251*	16*			
6	l	1000	221*	29*	600	71*	4			
6	r	1000	106*	6				320	40*	1
7	l	1000	800	86*				600	76*	11
7	r	1000	1000	115*	98*	7	1			
8	l	1000	350	46*				38*	3	0
8	r	1000	327	36*	16*	2	0			
9	l	1000	600	61*				1000	211*	20*
9	r	1000	350	35*	94*	11	1			
10	l	1000	129*	10	1000	159*	22*			
10	r	1000	183*	24*				244*	33*	3
11	l	1000	134*	14				215*	29*	3
11	r	1000	350	35*	283*	36*	3			
12	l	1000	600	57*	244*	27*	3			
12	r	1000	400	41*				1000	243*	25*
13	l	1000	1000	111*	156*	29*	2			
13	r	1000	1000	92*				500	49*	5
14	l	1000	500	49*				1000	165*	12
14	r	1000	800	82*	400	44*	4			
15	l	1000	1000	172*	1*	0	0			
15	r	1000	1000	135*				1000	500	46*
16	l	1000	192*	21*				1000	123*	13
16	r	700	71*	8	0*	0	0			
17	l	1000	500	52*				9*	0	0
17	r	1000	167*	12	10*	0	0			
18	l	1000	254*	30*	172*	27*	1			
18	r	1000	153*	18*				1000	800	89*

Table 3:

SURGICAL HAND RUB

List of computed log values and log reduction factors

Agent number 1: MANORAPID SYNERGY

Application: n x 3 ml / 3 min

Test period: 29.05 - 05.06.00

V	Name	IgPRE	IgPOST	IgRF	IgPRE	IgPOST	IgRF
1	a	4.76	0.70	4.06	4.24	2.72	1.52
2	b	4.86	0.95	3.91	4.77	2.14	2.63
3	c	4.33	2.34	1.99	4.72	3.15	1.57
4	d	5.24	3.75	1.49	4.85	3.12	1.73
5	e	5.21	3.16	2.05	5.01	3.72	1.29
6	f	4.35	2.94	1.41	4.19	3.62	0.57
7	g	5.18	4.27	0.91	5.08	3.01	2.07
8	h	5.11	3.11	2.00	5.08	1.72	3.16
9	i	5.01	2.57	2.44	5.31	3.41	1.90
10	j	4.89	3.22	1.67	4.20	2.10	2.10
11	k	4.37	1.11	3.26	4.26	2.37	1.89
12	l	5.02	2.12	2.90	4.44	3.72	0.72
13	m	5.07	4.22	0.85	5.30	2.58	2.72
14	n	4.76	3.65	1.11	4.26	3.30	0.96
15	o	4.86	1.38	3.48	5.22	3.02	2.20
16	p	4.43	1.46	2.97	4.37	1.75	2.62
17	q	4.27	1.58	2.69	4.39	0.78	3.61
18	r	5.23	1.30	3.93	4.16	2.84	1.32
xq =		4.83	2.44	2.40	4.66	2.73	1.93
sd =		0.34	1.16	1.06	0.42	0.79	0.84

Table 4:

SURGICAL HAND RUB

List of computed log values and log reduction factors

Agent number 2: 60 % n-propanol

Application: n x 3 m / 3 min

Test period: 29.05. - 05.06.00

V	Name	IgPRE	IgPOST	IgRF	IgPRE	IgPOST	IgRF
1	a	5.25	0.00	5.25	4.59	2.57	2.02
2	b	5.09	2.96	2.13	4.67	3.34	1.33
3	c	4.70	1.08	3.62	4.53	3.19	1.34
4	d	4.65	2.66	1.99	4.31	3.84	0.47
5	e	5.33	3.39	1.94	4.96	2.93	2.03
6	f	4.36	2.85	1.51	4.03	2.6	1.43
7	g	5.06	1.99	3.07	4.93	2.88	2.05
8	h	4.56	1.20	3.36	4.66	1.58	3.08
9	i	4.54	1.97	2.57	4.79	3.32	1.47
10	j	4.11	3.22	0.89	4.27	2.40	1.87
11	k	4.54	2.46	2.08	4.13	2.35	1.78
12	l	4.76	2.39	2.37	4.61	3.39	1.22
13	m	5.05	2.23	2.82	4.96	2.69	2.27
14	n	4.91	2.64	2.27	4.69	3.22	1.47
15	o	5.24	0.00	5.24	5.13	3.66	1.47
16	p	3.85	0.00	3.85	4.29	3.09	1.20
17	q	4.22	1.00	3.22	4.72	0.95	3.77
18	r	4.41	2.26	2.15	4.19	3.95	0.24
xq =		4.70	1.91	2.80	4.58	2.89	1.70
sd =		0.42	1.10	1.16	0.32	0.76	0.82

Table 5

WILCOXON matched pairs signed ranks test: IMMEDIATE VALUES

Agents used: MANORAPID SYNERGY

60% n-propanol

number of records = 18

0 records skipped due to identical or missing values

no	pno	rfs	rfm	diff.	rank
1	6	1.41	1.51	-0.10	1.00
2	5	2.05	1.94	.011	2.00
3	9	2.44	2.57	-0.13	3.00
4	4	1.49	1.99	-0.50	4.00
5	12	2.90	2.37	0.53	5.50
6	17	2.69	3.22	-0.53	5.50
7	10	1.67	0.89	0.78	7.00
8	16	2.97	3.85	-0.88	8.00
9	14	1.11	2.27	-1.16	9.00
10	11	3.26	2.08	1.18	10.00
11	1	4.06	5.25	-1.19	11.00
12	8	2.00	3.36	-1.36	12.00
13	3	1.99	3.62	-1.63	13.00
14	15	3.48	5.24	-1.76	14.00
15	18	3.93	2.15	1.78	15.50
16	2	3.91	2.13	1.78	15.50
17	13	0.85	2.82	-1.97	17.00
18	7	0.91	3.07	-2.16	18.00

T pos = 15.50

T neg = 115.50

One-sided testing with $\alpha=0.1$ for N=18

Since the tabular extreme values range from 55.00 to 116.00, T pos = 55.50 and T neg = 115.50 are within these limits:

no statistical significance at this level

Table 6:

WILCOXON matched pairs signed ranks test: 3 h VALUES

Agents used: MANORAPID SYNERGY

60% n-propanol

number of records = 18

0 records skipped due to identical or missing values

no	pno	rfs	rfm	diff:	rank
1	7	2.07	2.05	0.02	1.00
2	11	1.89	1.78	0.11	2.00
3	17	3.61	3.77	-0.16	3.00
4	3	1.57	1.34	0.23	4.50
5	10	2.10	1.87	0.23	4.50
6	8	3.36	3.08	0.28	6.00
7	9	1.90	1.47	0.43	7.00
8	13	2.72	2.27	0.45	8.00
9	1	1.52	2.02	-0.50	9.50
10	12	0.72	1.22	-0.50	9.50
11	14	0.96	1.47	-0.51	11.00
12	15	2.20	1.47	0.73	12.00
13	5	1.29	2.03	-0.74	13.00
14	6	0.57	1.43	-0.86	14.00
15	18	1.32	0.24	1.08	15.00
16	4	1.73	0.47	1.26	16.00
17	2	2.63	1.33	1.30	17.00
18	16	2.62	1.20	1.42	18.00

T pos = 111.00

T neg = 60.00

One-sided testing with $\alpha=0.1$ for N=18

Since the tabular extreme values range from 55.00 to 116.00, T pos = 110.00 and T neg = 60.00 are within these limits:

no statistical significance at this level