Nordic Tersus
Laboratory

Test report No. 100/2016

EVALUATION OF YEASTICIDAL AND FUNGICIDAL ACTIVITIES OF A DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13624)

Name of the product:	**Des Insurance**
Batch number:	33050916
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	13.12.2016
Test material conditions:	no specific features, sample in the manufacturers tare
Storage conditions:	in room temperature, dark
Active substance – conc.:	5% Blend of quaternary ammonium compounds: benzyl-C12-18-alkyldimethyl chlorides and C12-14 alkyl [(ethylphenyl) methyl] dimethyl chlorides
Appearance of the product:	Transparent liquid
Test concentration:	0,5%; 1%
Contact time:	10 min, 15 min, 30 min
Interfering substance:	3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Rinsing liquid:	Tryptone 1 g/l + NaCl 9 g/l
Neutralizer:	-
Test organisms:	*Candida albicans* ATCC 10231
Testing method:	**EVS-EN 13624:2013** **Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area.**
Testing date:	14.12.2016 – 16.12.2016
Results:	look appendix 1-2

ACCREDITED LABORATORY. No L263. ISO/IEC 17025
NORDIC TERSUS LABORATORY OÜ
REPUBLIC OF ESTONIA

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Diana Kaare, MSc

Head of laboratory, microbiologist

Date of test report: 19.12.2016

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EESTI AKREDITEERIMISKESKUS
ESTONIAN ACCREDITATION CENTRE
Akrediteeritud L263

TEST RESULTS (yeasticidal suspension test)

EVS-EN 13624:2013; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: Tryptone 1 g/l + NaCl 9 g/l;
Test organism: *Candida albicans* ATCC 10231;
Test temperature: +20° C; Incubation temperature: +30° C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 14.12.2016 – 16.12.2016.
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{vo}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	28	$\bar{x}$ =30,5	V_{C1}	26	$\bar{x}$ = 27,5	V_{C1}	31	$\bar{x}$ = 29	V_{C1}	32	$\bar{x}$ = 31
V_{C2}	33		V_{C2}	29		V_{C2}	27		V_{C2}	30	
30 ≤ $\bar{x}$ N_{vo} ≤160 ? yes X; no □			$\bar{x}$ A is ≥ 0,5 $\bar{x}$ N_{vo}? yes X; no □			$\bar{x}$ **B** is ≥ 0,5 $\bar{x}$ N_{vo}? yesX; no □			$\bar{x}$ **C** is ≥ 0,5 $\bar{x}$ N_{vo}? yes X; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm}$ =1,58 x 10^7; log$N$ = 7,20
N and N_0	10^{-5}	**152**	**151**	N_0 = N/10; logN_0 = 6,20
	10^{-6}	**17**	**14**	6,17≤ logN_0≤6,70; yesX; no □

Experimental results

Concentration of the product	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
0,2%	-	>165	>165	>1650	>3,22	<2,98	10 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<2,98	15 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<2,98	30 min	dirty
0,5%	-	<14	<14	<140	<2,15	>4,05	10 min	dirty
0,5%	-	<14	<14	<140	<2,15	>4,05	15 min	dirty
0,5%	-	<14	<14	<140	<2,15	>4,05	30 min	dirty
1,0%	-	<14	<14	<140	<2,15	>4,05	10 min	dirty
1,0%	-	<14	<14	<140	<2,15	>4,05	15 min	dirty
1,0%	-	<14	<14	<140	<2,15	>4,05	30 min	dirty
3,0%	-	<14	<14	<140	<2,15	>4,05	10 min	dirty
3,0%	-	<14	<14	<140	<2,15	>4,05	15 min	dirty
3,0%	-	<14	<14	<140	<2,15	>4,05	30 min	dirty

Explanations:

V_C = count per ml (one plate or more)

x̄ = average of V_{C1} and V_{C2} (1. + 2. duplicate)

N = cfu/ml microbes in testsuspension

N_0 = cfu/ml at the start of the contact time (t=0)

N_{vo} = cfu/ml in the validation suspension (t=0)

Na = surviving microbes after the test

R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Interpretation:

Using the EN 13624 standard, there was tested product for instrument disinfection– **Des Insurance** (Batch nr. 33050916) under temperature conditions at 20 °C ± 1 °C, with the contact times: 10 min, 15 min and 30 min under the dirty conditions. The membrane filtration method was used for the testing of product effect against the microorganism: *Candida albicans* ATCC 10231. Under dirty conditions (one of the test regimes) tested product was active against the testorganism at 0,5% - 10 min, 15 min, 30 min and 1% - 10 min, 15 min, 30 min.

Conclusion:

By the test results can be made conclusions that tested product **Des Insurance has yeasticidal effect in case of instrument disinfection under dirty conditions at 0,5% - 10 min, 15 min, 30 min and at 1% - 10 min, 15 min, 30 min**, as treated by the product the surviving microorganisms count was decreasing at least four grades.

ACCREDITED LABORATORY No L263, ISO/IEC 17025 NORDIC TERSUS LABORATORY OÜ REPUBLIC OF ESTONIA

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Diana Kaare, MSc

Head of laboratory, microbiologist

Nordic Tersus
Laboratory

Test report No. 101/2016

EVALUATION OF BACTERICIDICAL ACTIVITIES OF A DISINFECTANTS AND ANTISEPTICS USED IN THE MEDICAL AREA (EN 13727)

Name of the product:	**Des Insurance**
Batch number:	33050916
Manufacturer:	Chemi-Pharm Ltd.
Client, representative:	Chemi-Pharm Ltd., Põllu 132, Tallinn, 10917, ESTONIA Maris Millner, +372-51-77-090
Date of delivery:	13.12.2016
Test material conditions:	No specific features, sample in the manufacturers tare
Storage conditions:	In room temperature, dark
Active substance – conc.:	5% Blend of quaternary ammonium compounds: benzyl-C12-18-alkyldimethyl chlorides and C12-14 alkyl [(ethylphenyl) methyl] dimethyl chlorides
Appearance of the product:	Transparent liquid
Test concentration:	0,5%; 1,0%
Contact time:	10 min, 15 min, 30 min
Interfering substance:	3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Neutralizer:	-
Rinsing liquid:	Tryptone 1 g/l + NaCl, 9 g/l
Test organisms:	*Staphylococcus aureus* MRSA ATCC 33592 *Pseudomonas aeruginosa* ATCC 15442 *Staphylococcus aureus* ATCC 6538 *Enterococcus hirae* ATCC 10541
Testing method:	**EVS-EN 13727:2012+A2:2015** **Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)**
Testing date:	20.12.2016 – 22.12.2016
Results:	look appendix 1-5

ACCREDITED LABORATORY No L263 ISO/IEC 17025 NORDIC TERSUS LABORATORY OÜ

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Diana Kaare, MSc
Head of laboratory, microbiologist

Date of test report: 23.12.2016

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Appendix 1

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: tryptone, 1 g/l+ NaCl, 9 g/l;
Test organism: *Staphylococcus aureus* MRSA ATCC 33592;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 20.12.2016 – 22.12.2016
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{vo}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	49	$\bar{x} = 52$	V_{C1}	39	$\bar{x} = 42$	V_{C1}	42	$\bar{x} = 41$	V_{C1}	39	$\bar{x} = 37$
V_{C2}	55		V_{C2}	45		V_{C2}	40		V_{C2}	35	
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes X; no □			$\bar{x}$ A is $\geq 0{,}5\ \bar{x}\ N_{vo}$? yes X; no □			$\bar{x}$ **B** is $\geq 0{,}5\ \bar{x}\ N_{vo}$? yesX; no □			$\bar{x}$ **C** is $\geq 0{,}5\ \bar{x}\ N_{vo}$? yes X; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1{,}97 \times 10^8$; $\log N = 8{,}29$
N and N_0	10^{-6}	**197**	**187**	$N_0 = N/10$; $\log N_0 = 7{,}29$
	10^{-7}	**22**	**27**	$7{,}17 \leq \log N_0 \leq 7{,}70$; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
0,2%	-	>165	>165	>1650	>3,22	<4,07	10 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<4,07	15 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<4,07	30 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,14	10 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,14	15 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,14	30 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,14	10 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,14	15 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,14	30 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,14	10 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,14	15 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,14	30 min	dirty

Explanations:

V_C = count per ml (one plate or more)

x̄ = average of V_{C1} and V_{C2} (1. + 2. duplicate)

N = cfu/ml microbes in testsuspension

N_0 = cfu/ml at the start of the contact time (t=0)

N_{vo} = cfu/ml in the validation suspension (t=0)

Na = surviving microbes after the test

R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 2

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: tryptone, 1 g/l+ NaCl, 9 g/l;
Test organism: *Staphylococcus aureus* ATCC 6538;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 20.12.2016 – 22.12.2016
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{vo}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	45	$\bar{x} = 47,5$	V_{C1}	45	$\bar{x} = 48,5$	V_{C1}	49	$\bar{x} = 51$	V_{C1}	34	$\bar{x} = 32,5$
V_{C2}	50		V_{C2}	52		V_{C2}	53		V_{C2}	31	
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes X; no □			$\bar{x}$ A is $\geq 0,5\ \bar{x}\ N_{vo}$? yes X; no □			$\bar{x}$ **B** is $\geq 0,5\ \bar{x}\ N_{vo}$? yesX; no □			$\bar{x}$ **C** is $\geq 0,5\ \bar{x}\ N_{vo}$? yes X; no □		

Test suspension and test

Testsuspension: *N and N_0*	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 2,09 \times 10^8$; $\log N = 8,32$ $N_0 = N/10$; $\log N_0 = 7,32$ $7,17 \leq \log N_0 \leq 7,70$; yesX; no □
	10^{-6}	**212**	**207**	
	10^{-7}	**22**	**20**	

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
0,2%	-	>165	>165	>1650	>3,22	<4,10	10 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<4,10	15 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<4,10	30 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,17	10 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,17	15 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,17	30 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,17	10 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,17	15 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,17	30 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,17	10 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,17	15 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,17	30 min	dirty

Explanations:

V_C = count per ml (one plate or more)

x̄ = average of V_{C1} and V_{C2} (1. + 2. duplicate)

N = cfu/ml microbes in testsuspension

N_0 = cfu/ml at the start of the contact time (t=0)

N_{vo} = cfu/ml in the validation suspension (t=0)

Na = surviving microbes after the test

R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 3

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: tryptone, 1 g/l+ NaCl, 9 g/l;
Test organism: *Enterococcus hirae* ATCC 10541;
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 20.12.2016 – 22.12.2016
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{vo}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	60	$\bar{x} = 55,5$	V_{C1}	44	$\bar{x} = 41$	V_{C1}	35	$\bar{x} = 37$	V_{C1}	36	$\bar{x} = 36$
V_{C2}	51		V_{C2}	38		V_{C2}	39		V_{C2}	36	
$30 \leq \bar{x}\ N_{vo} \leq 160$? yes X; no □			$\bar{x}$ A is $\geq 0,5\ \bar{x}\ N_{vo}$? yes X; no □			$\bar{x}$ **B** is $\geq 0,5\ \bar{x}\ N_{vo}$? yesX; no □			$\bar{x}$ **C** is $\geq 0,5\ \bar{x}\ N_{vo}$? yes X; no □		

Test suspension and test

Testsuspension:	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1,74 \times 10^8$; $\log N = 8,24$
N and N_0	10^{-6}	**169**	**174**	$N_0 = N/10$; $\log N_0 = 7,24$
	10^{-7}	**20**	**19**	$7,17 \leq \log N_0 \leq 7,70$; yesX; no □

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
0,2%	-	>165	>165	>1650	>3,22	<4,02	10 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<4,02	15 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<4,02	30 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,09	10 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,09	15 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,09	30 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,09	10 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,09	15 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,09	30 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,09	10 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,09	15 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,09	30 min	dirty

Explanations:

V_C = count per ml (one plate or more)

x̄ = average of V_{C1} and V_{C2} (1. + 2. duplicate)

N = cfu/ml microbes in testsuspension

N_0 = cfu/ml at the start of the contact time (t=0)

N_{vo} = cfu/ml in the validation suspension (t=0)

Na = surviving microbes after the test

R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 4

TEST RESULTS (bactericidal suspension test)

EVS-EN 13727:2012+A2:2015; Phase 2, step 1;
Membrane filtration method;
Rinsing liquid: tryptone, 1 g/l+ NaCl, 9 g/l;
Test organism: *Pseudomonas aeruginosa* ATCC 15442
Test temperature: +20° C; Incubation temperature: +37 °C
Interfering substance: 3 g/l bovine albumin + 3 ml/l sheep blood erythrocytes = Dirty conditions
Nordic Tersus Laboratory LLC.; Date of test: 20.12.2016 – 22.12.2016
Responsible person: Diana Kaare

Validation and controls

Dirty conditions

Validation suspension N_{v0}			**Experimental conditions control (A)**			**Filtration control (B)**			**Method validation (C)**		
V_{C1}	44	$\bar{x} = 43$	V_{C1}	62	$\bar{x} = 58,5$	V_{C1}	49	$\bar{x} = 50$	V_{C1}	37	$\bar{x} = 38$
V_{C2}	42		V_{C2}	55		V_{C2}	51		V_{C2}	39	
$30 \leq \bar{x}\ N_{v0} \leq 160$? yes X; no □			$\bar{x}$ A is $\geq 0,5\ \bar{x}\ N_{v0}$? yes X; no □			$\bar{x}$ **B** is $\geq 0,5\ \bar{x}\ N_{v0}$? yesX; no □			$\bar{x}$ **C** is $\geq 0,5\ \bar{x}\ N_{v0}$? yes X; no □		

Test suspension and test

Testsuspension: *N and N_0*	N	V_{C1}	V_{C2}	$\bar{x}_{wm} = 1,90 \times 10^8$; $\log N = 8,28$ $N_0 = N/10$; $\log N_0 = 7,28$ $7,17 \leq \log N_0 \leq 7,70$; yesX; no □
	10^{-6}	**184**	**190**	
	10^{-7}	**25**	**18**	

Experimental results

Concentration of the product %	Dilution step	V_{C1}	V_{C2}	Na (=x̄*10)	log Na	logR	Contact time	Conditions
0,2%	-	>165	>165	>1650	>3,22	<4,06	10 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<4,06	15 min	dirty
0,2%	-	>165	>165	>1650	>3,22	<4,06	30 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,13	10 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,13	15 min	dirty
0,5%	-	<14	<14	<140	<2,15	>5,13	30 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,13	10 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,13	15 min	dirty
1,0%	-	<14	<14	<140	<2,15	>5,13	30 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,13	10 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,13	15 min	dirty
3,0%	-	<14	<14	<140	<2,15	>5,13	30 min	dirty

Explanations:

V_C = count per ml (one plate or more)

x̄ = average of V_{C1} and V_{C2} (1. + 2. duplicate)

N = cfu/ml microbes in testsuspension

N_0 = cfu/ml at the start of the contact time (t=0)

N_{vo} = cfu/ml in the validation suspension (t=0)

Na = surviving microbes after the test

R = reduction factor (R= N_0/ Na; LogR=LogN_0 - Log Na)

Appendix 5

Interpretation:

Using the EN 13727 standard, there was tested product for instrument disinfection – **Des Insurance** (33050916), concentrations 0,5% and 1% in temperature conditions at 20 °C ± 1 °C, with the contact times: 10 min, 15 min and 30 min. The membrane filtration method was used for the testing of product effect against the microorganisms: *Staphylococcus aureus* MRSA ATCC 33592, *Pseudomonas aeruginosa* ATCC 15442, *Enterococcus hirae* ATCC 10541, *Staphylococcus aureus* ATCC 6538. In dirty conditions tested product was active against all the testorganims at all tested contact times.

Conclusion:

By the test results can be made conclusions that tested product **Des Insurance has a bactericidal effect in case of a instrument disinfection under dirty conditions at 0,5% - 10 min 15 min, 30 min and at 1% - 10 min, 15 min, 30 min**, as treated by the product, the surviving microorganisms count was decreasing at least five grades.

ACCREDITED LABORATORY, No L263, ISO/IEC 17025, REPUBLIC OF ESTONIA, NORDIC TERSUS LABORATORY OÜ

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Diana Kaare, MSc

Head of laboratory, microbiologist

Date of test report: 23.12.2016

Tervisekaitseinspektsioon • Health Protection Inspectorate
Mikrobioloogia Kesklabor • Central Laboratory of Microbiology

Akrediteeritud L013

MIKROBIOLOOGILINE UURING NR. 4591

Uuritav materjal: DES INSURANCE

Täiendavad andmed: valmistatud 06.01.2006

Suunav asutus, isik: AS Chemi-Pharm, laborijuhataja M. Millner, 6 778 806

Proovi võtmise koht: AS Chemi-Pharm Põllu 132 Tallinn 10917

Proovi võtmise kuupäev, kellaaeg: 06.01.2006

Uuringu eesmärk: Desinfitseerivate omaduste määramine EN 1040:1997 järgi

Laborisse saabumise aeg: 06.01.2006 kell 09.30

Proovi seisund laborisse saabumisel: Ilma iseärasusteta tootja pakend

Säilitamise tingimused: toatemperatuuril pimedas

Toimaine: kvaternaarsed ammooniumiühendid

Neutraliseerija: polüsorbaat 80 30 g/l, saponiin 30 g/l, L-histidiin 1 g/l, L-tsüsteiin 1 g/l lahustatuna trüptoon-soola lahuses

Katsetamise aeg: 06.02.- 10.02.2006

Uurimise tulemused: Vt lisa 1 ja 2

Kokkuvõte: Toode DES INSURANCE toimis bakteritsiidselt 1 % lahusena 10 min, 15 min ja 30 min jooksul *Escherichia coli* ATCC 10536, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 8043 ja *Pseudomonas aeruginosa* ATCC 15442 suhtes (reduktsioonifaktor oli suurem kui 10^5).

10.02.2006

Mikrobioloog K. Birk

* – EAK poolt akrediteerimata

Tervisekaitseinspektsioon • Health Protection Inspectorate
Mikrobioloogia Kesklabor • Central Laboratory of Microbiology

Akrediteeritud L013

MIKROBIOLOOGILINE UURING NR. 4591

Uuritav materjal: DES INSURANCE

Täiendavad andmed: valmistatud 06.01.2006

Suunav asutus, isik: AS Chemi-Pharm, laborijuhataja M. Millner, 6 778 806

Proovi võtmise koht: AS Chemi-Pharm Põllu 132 Tallinn 10917

Proovi võtmise kuupäev, kellaaeg: 06.01.2006

Uuringu eesmärk: Desinfitseerivate omaduste määramine EN 1040:1997 järgi

Laborisse saabumise aeg: 06.01.2006 kell 09.30

Proovi seisund laborisse saabumisel: Ilma iseärasusteta tootja pakend

Säilitamise tingimused: toatemperatuuril pimedas

Toimaine: kvaternaarsed ammooniumiühendid

Neutraliseerija: polüsorbaat 80 30 g/l, saponiin 30 g/l, L-histidiin 1 g/l, L-tsüsteiin 1 g/l lahustatuna trüptoon-soola lahuses

Katsetamise aeg: 06.02.- 10.02.2006

Uurimise tulemused: Vt lisa 1 ja 2

Kokkuvõte: Toode DES INSURANCE toimis bakteritsiidselt 1 % lahusena 10 min, 15 min ja 30 min jooksul *Escherichia coli* ATCC 10536, *Staphylococcus aureus* ATCC 6538, *Enterococcus hirae* ATCC 8043 ja *Pseudomonas aeruginosa* ATCC 15442 suhtes (reduktsioonifaktor oli suurem kui 10^5).

10.02.2006

Mikrobioloog K. Birk

* – EAK poolt akrediteerimata

Lisa 1

Metodoloogia verifitseerimine ja lahjendamis-neutraliseerimise meetodi valideerimine DES INSURANCE 1 % lahuse puhul

Test mikroorganism	Eluvõimeliste mikroobide arv (CFU/ml)			
	Bakterite testimise suspensioon (N)	Valideerimis-suspensioon (N_v)	Neutraliseerija toksilisuse kontroll (N_x)	Lahjendus-neutraliseerimise kontroll (N_y)
Escherichia coli	$2{,}2 \times 10^8$	$2{,}8 \times 10^3$	$2{,}3 \times 10^2$	$1{,}2 \times 10^2$
Staphylococcus aureus	$5{,}0 \times 10^8$	$1{,}7 \times 10^3$	$2{,}7 \times 10^2$	$1{,}6 \times 10^2$
Enterococcus hirae	$2{,}0 \times 10^8$	$2{,}1 \times 10^3$	$2{,}1 \times 10^2$	$1{,}3 \times 10^2$
Pseudomonas aeruginosa	$3{,}0 \times 10^8$	$1{,}2 \times 10^3$	$2{,}0 \times 10^2$	$2{,}1 \times 10^2$
Testitud tüvede puhul: N : peab olema $1{,}5 \times 10^8$ CFU/ml kuni 5×10^8 CFU/ml; N_v : peab olema 6×10^2 CFU/ml kuni 3×10^3 CFU/ml; N_x : peab võrduma või olema suurem kui $0{,}05 \times N_v$; N_y : peab võrduma või olema suurem kui $0{,}05 \times N_v$.				
Neutraliseerimislahus on sobiv katsetatud toote 1 % lahuse neutraliseerimiseks ja testitud tüvede katsetamiseks				

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Lisa 2

Toote DES INSURANCE katsetamine lahjendamis-neutraliseerimise meetodil

Mikroorganism	Bakterite testimise suspensioon	Eluvõimeliste arv toote katsetamisel 1 % (V/V) lahusena		
		10 min	15 min	30 min
Escherichia coli	2,2 x 10^8	Kasv puudub	Kasv puudub	Kasv puudub
Staphylococcus aureus	5,0 x 10^8	Kasv puudub	Kasv puudub	Kasv puudub
Enterococcus hirae	2,0 x 10^8	Kasv puudub	Kasv puudub	Kasv puudub
Pseudomonas aeruginosa	3,0 x 10^8	Kasv puudub	Kasv puudub	Kasv puudub

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Labor on volitatud Põllumajandusministri käskkirjaga nr.203 29.06.2000 toidutoorme ja toidu järelvalveks võetud proovide analüüsimiseks

TEST REPORT NR. 814

Product name: DES INSURANCE

Manufacturer: AS Chemi - Pharm

Date of delivery: 02.01.2012

Storage conditions: room temperature, in the dark

Appearance of the product: colourless, clear liquid

Active substances: quaternary ammonium compounds

Delution neutralization method: EN 1275:1997*

Dates of testing: 04.01.2012 – 06.01.2012

Product concentration: 1%

Test temperature: 20 ± 1 ^{0}C

Contact time: 5 min, 10 min, 15 min

Neutralizer: 60 g/l TWEEN 80, 30 g/l Saponin, 1 g/l Cysteine, 1 g/l Histidine, 3g/l Lecithin

Test results: See annex 1 (attached). All controls and validation were within the basic limits.

Conclusion: According to EN 1275:1997* product DES INSURANCE (1%), possesses yeasticidal activity in 5 min, 10 min, 15 min at 20 ± 1 ^{0}C for referenced strain *Candida albicans* ATCC 10231.

Tallinn, 09.01.2012 Microbiologist J.Viktorova

Test results are valid for sample examined. Official report is to be copied in its entirety only.
*** - The method is not accredited.**

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EN 1275:1997
Lisa 1

Testi tulemused DES INSURANCE (nr. 814)

Test mikro-organism	Valideerimine ja kontrollimine			Test-suspensioon ja katse				
	Valideerimise suspensioon N_V; $N_{VO}=N_V/10$	Neutraliseerimise kontroll B	Meetodi valideerimine C	Test suspensioon N; $N_O=N/10$		Toote kontsentratsioon: **1% / 0,1%** toime aeg: 5 min katse tulemus	10 min katse tulemus	15 min katse tulemus
Candida albicans **ATCC 10231**	V_C: 115; 103 N_V: $1,1*10^3$ N_{VO}: $1,1*10^2$ $0,5N_{VO}$: 55	V_C: 154; 110 **B**: 132	$V_{C\ 1\%}$: 0; 0 $V_{C\ 0,1\%}$: 72; 60 **C**: 66	10^{-5}: 323; 280 10^{-6}: 40; 38 **N**: $3,1*10^7$ N_O: $3,1*10^6$	V_C N_a **R**	0, 0 <$1,5*10^2$ >$2,1*10^4$	0, 0 <$1,5*10^2$ >$2,1*10^4$	0, 0 <$1,5*10^2$ >$2,1*10^4$

Tähistused:
V_C – pesade arv ml-s;
N – mikroorganismide testimise suspensioon ($1,5*10^7$-$5,0*10^7$ PMÜ/ml);
N_V – mikroorganismide valideerimise suspensioon ($6,0*10^2$ – $1,5*10^3$ PMÜ/ml);
N_a – eluvõimeliste mikroorganismide hulk testitavas segus katseaja lõpus;
N_O - eluvõimeliste mikroorganismide hulk testitavas segus katseaja alguses;
R – reduktsioon (eluvõimeliste mikroorganismide hulga vähenemine);

Märkus:
$60 \leq N_{VO} \leq 150$
B, $C \geq 0,5\ N_{VO}$
$R = N_O/N_a$, peab olema $>10^4$

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Labor on volitatud Põllumajandusministri käskkirjaga nr.203 29.06.2000 toidutoorme ja toidu järelvalveks võetud proovide analüüsimiseks

MIKROBIOLOOGILINE UURING NR. 814

Uuritav materjal: DES INSURANCE

Tootja: AS Chemi - Pharm

Laborisse saabumise kuupäev: 02.01.2012

Säilitamise tingimused: toatemperatuuril pimedas

Toote välimus: värvitu läbipaistev vedelik

Toimiv aine: kvaternaarsed ammooniumühendid

Lahjendamis-neutraliseerimismeetod: EN 1275:1997*

Katsetamise aeg: 04.01.2012 – 06.01.2012

Toote kontsentratsioon: 1 %

Katsetamise temperatuur: 20 ± 1 ^{0}C

Kontaktajad: 5 min, 10 min, 15 min

Neutralisaator: 60 g/l TWEEN 80, 30 g/l Saponin, 1 g/l Cysteine, 1 g/l Histidine, 3g/l Lecithin

Uurimise tulemused: Vt lisa 1. Uuringu valideerimiste ja kontrollide tulemused vastasid käesoleva standardi kriteeriumitele.

Kokkuvõte: Vastavalt EN 1275:1997* nõuetele katsetamisel 20 ± 1 ^{0}C juures kontaktaegadega 5 min, 10 min ja 15 min omas DES INSURANCE (1%) pärmivastast toimet (reduktsioon oli suurem kui 10^4) referentstüvele *Candida albicans* ATCC 10231.

Tallinn, 09.01.2012 Vanemspetsialist J. Viktorova

Katsetulemused kehtivad uuritud proovide kohta. Protokolli tohib paljundada ainult tervikuna. Tärniga (*) tähistatud meetod ei kuulu akrediteerimisulatusse.

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EN 1275:1997
Annex 1

The results (yeasticidal suspension test)
Product name: DES INSURANCE (nr. 814)

Test organism	Validation and controls			Test suspension and Test				
	Validation suspension N_V; $N_{VO}=N_V/10$	Neutralizer control B	Method validation C	Test suspension N; $N_O=N/10$		Concentration of the product: **1% / 0,1%** contact time: 5 min test result	10 min test result	15 min test result
Candida albicans **ATCC 10231**	V_C: 115; 103 N_V: $1,1*10^3$ N_{VO}: $1,1*10^2$ $0,5N_{VO}$: 55	V_C: 154; 110 **B**: 132	$V_{C\ 1\%}$: 0; 0 $V_{C\ 0,1\%}$: 72; 60 **C**: 66	10^{-5}: 323; 280 10^{-6}: 40; 38 **N**: $3,1*10^7$ N_O: $3,1*10^6$	V_C N_a **R**	0, 0 <$1,5*10^2$ >$2,1*10^4$	0, 0 <$1,5*10^2$ >$2,1*10^4$	0, 0 <$1,5*10^2$ >$2,1*10^4$

Explanations:
V_C – viable count per ml;
N – number of cells per ml in the test suspension ($1,5*10^7$-$5,0*10^7$ cfu/ml);
N_V – number of cells per ml in the validation suspension ($6,0*10^2$ – $1,5*10^3$ cfu/ml);
N_O – number of viable cells per ml in the test mixture in the beginning of the test;
N_a – number of survivors per ml in the test mixture in the end of the test;
R – reduction in viability.

Remarks:
$60 \leq N_{VO} \leq 150$
B, $C \geq 0,5\ N_{VO}$
$R = N_O/N_a$, should be > 10^4

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TEST REPORT No 3379-3380 R **Koopia**

Name of the product: DES INSURANCE

Manufactured: Chemi-Pharm Ltd., Tallinn

Sampled by: Chemi-Pharm Ltd., R. Oltjer

Place of sampling: Chemi-Pharm Ltd., Serva 44a, Tallinn11618

Active substance(s) and its/their concentration(s): not indicated

Aim of the examination: detection of disinfecting properties

Date and hour of receipt: 21.08.2000 at 12.00

Storage condition: room temperature and darkness

Nature and characteristics of the sample: no deviation the packaging and the labelling

Period of analysis: 22.08.-26.08.2000

Condition of the examination: 40±1°C for application and 37° for incubation

Test method: in-house method dilution-neutralization of Central Laboratory of Microbiology* Dilutions of tested products were prepared with steriled drinking water from waterworks. Used neutralizer consists polysorbate 80 – 30 g/l, lecithin 3 g/l and L-histidine – 1 g/l.

Test results:

Concent-ration	Contact time	*Escheri-chia coli* ATCC 10538	*Staphylo-coccus aureus* ATCC 6538	*Streptococcus faecalis* ATCC 29212	*Pseudomonas aeruginosa* ATCC 15442	*Bacillus cereus* ATCC 11778	*Candida albicans* ATCC 10231
1%	5 min	0	0	0	0	0	0
0.3%r	10 min	0	0	0	0	0	0
Growth of tested strains		+	+	+	+	+	+

+ the growth of the organisms exists

0 the growth of the organisms is absent

The test results applies for the tested sample only

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Akrediteeritud L013

Conclusion: According to the in-house dilution-neutralization method of Central Laboratory of Microbiology, the tested product „ DES INSURANCE“ had the bactericidal effects in 1% dilutions during contact time 5 min and 0,3% dilutions during contact time 10 min to all referenced strains *Escherichia coli* ATCC 25922, *Staphylococcus aureus* ATCC 25923, *Streptococcus faecalis* ATCC 29212, *Pseudomonas aeruginosa* ATCC27853 and *Candida albicans* ATCC 10231

Microbiologist K. Birk

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MIKROBIOLOOGILINE UURING NR. 2488

Toote nimi: desinfektant DES Insurance

Tootja: AS Chemi-Pharm

Katsetamisele suunav asutus, isik: AS Chemi-Pharm, R. Oltjer

Proovi võtmise koht: AS Chemi-Pharm Põllu 132 Tallinn 10917

Proovi võtmise kuupäev, kellaaeg: 29.10.2001

Uuringu eesmärk: desinfitseerivate omaduste määramine

Laborisse saabumise aeg:29.10.2001 kell12.00

Proovi seisund laborisse saabumisel: ilma iseärasusteta proov

Laboris säilitamise tingimused: toatemperatuuril ja pimedas

Mikrobioloogilise uuringu algus: 29.10.2001

Uurimismeetod: lahjendamis-neutraliseerimismeetod
Katsetamise aeg: 29.10- 03.11.2001
Katsetingimused: Katsetatud temperatuuril 20±1^{0}C
Uuringu tulemused:

Lahuse kontsentratsioon	Toime-aeg	*Escherichia coli* ATCC 25922	*Staphylococcus aureus* ATCC 25923	*Streptococcus faecalis* ATCC 29212	*Pseudomonas aeruginosa* ATCC 27853	*Candida albicans* ATCC 10231
0	Testitava tüve kasvu kontroll	+	+	+	+	+
0,5 %	10 min	-	-	-	-	-
1 %	10 min	-	-	-	-	-

Tähistused: + Testkultuur kasvab, lahusel puudub bakteritsiidne toime
- Testkultuuri kasv puudub, lahus toimib bakteritsiidselt.

Uuringu tulemused kehtivad antud proovi kohta.

Katseprotokolli paljundamine on lubatud ainult tervikuna.

19.11. 2001

Arst-mikrobioloog .....K. Birk

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