

HygCen GmbH • Postfach 11 01 35 • D-19001 Schwerin

Trans-textil GmbH

Pommernstr. 11

83395 Freilassing



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
ZLG-P-715.98.13



Anerkannt durch/Recognized by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-AP-314.10.23

**AKS** Akkreditierung: AKS-PL-21301  
Verzeichnis: www.aks-hannover.de  
Staatliche Akkreditierungsstelle Hannover

13.08.2012

## TESTREPORT

<b>Identification of the test laboratory:</b>	SN 13795
<b>Order:</b>	2012-07-25
<b>Date of delivery:</b>	2012-07-26
<b>Product:</b>	article P981
<b>Manufacturer:</b>	Trans-textil GmbH
<b>Test methods:</b>	Testing according see table 1
<b>Period of analysis:</b>	2012-07-27; 2012-07-31 – 2012-08-03
<b>Test conditions:</b>	Reprocessed 1 time according EN ISO 6330:2000 (washed and dried )

SN 13795 page 1 of 11

**Table 1: Test methods**

<b>Test description</b>	<b>Standard</b>	<b>SOP</b>
Resistance to microbial penetration WET Penetration	EN ISO 22610	12-001
Resistance to liquid penetration Liquid penetration hydrostatic pressure with aqua dest	DIN EN 20811	12-004
Tensile Strength	EN 29073-3	12-006
Bursting Strength	EN ISO 13938 – 1	12-007
Tear resistance	EN 29073-4	12-005
Linting Linting Tendency “Particulate matter”	ISO 9073-10	12-011
Determination of a population of micro-organisms	EN 11737-1	07-014

**Results of Wet-Penetration according to EN ISO 22610 / SOP 12-001**

**Pressure:** 3 N  
**Test time:** 1 h 15 min  
**Room temp:** 26 °C      **rH:** 41%  
**Sample size:** 25 x 25 cm  
**Incubation:** 48 h at 36°C ± 1°C  
**Description of test sample:** article P981

Test date 30.07.2012		Test 1		Test 2		Test 3		Test 4		Test 5	
TSA	Testzeit	cfu	lg	cfu	lg	cfu	lg	cfu	lg	cfu	lg
1.	15 min	0	-	0	-	0	-	0	-	0	-
2.	30 min	0	-	0	-	0	-	0	-	0	-
3.	45 min	0	-	0	-	0	-	0	-	0	-
4.	1 h	0	-	0	-	0	-	0	-	0	-
5.	1 h 15 min	0	-	0	-	0	-	0	-	0	-
	Test specimens	127	2,10	118	2,07	112	2,05	116	2,06	101	2,00

cfu test suspension

*Staphylococcus aureus*      ATCC 29213      2,1 x 10<sup>4</sup>/ml

**Results of calculation:**

	Test 1	Test 2	Test 3	Test 4	Test 5
<b>I<sub>B</sub></b>	6,000	6,000	6,000	6,000	6,000

Legend:      cfu      =      colony forming units  
                  TSA      =      Nutrient agar  
                  I<sub>B</sub>      =      barrier index I<sub>B</sub> = 6-( R<sub>CUM1</sub>+R<sub>CUM2</sub>+R<sub>CUM3</sub>+R<sub>CUM4</sub>+R<sub>CUM5</sub>)  
                  rH      =      relative humidity

**Results of hydrostatic pressure test according to EN 20811 with Aqua dest / SOP 12-004**

**Increase in pressure:** 60 cm/min

**Description of test sample:** article P981

**Test date:** 2012-07-31

**Room temp:** 27 °C **rH:** 41%

**Test liquid:** Aqua dest

**Description of test sample:** article P981

Test	Aqua dest cm/WC
1.	> 500
2.	> 500
3.	> 500
4.	> 500
5.	> 500
Mean value	> 500

Legend: cm/WC = cm/Water column  
 Mean value = 5 tests  
 rH = relative humidity

**Results of tensile strength test according to EN 29073-3, dry and wet / SOP 12-006:**

**Description of test sample:** article P981

**Room temp:** 27 °C **rH:** 41%

**Test date:** 2012-07-31

direction	Fmax (N)	ε max (%)	Fbrk (N)	ε break (%)	Fmax (N)	ε max (%)	Fbrk (N)	ε break (%)
dry				wet				
machine	423,4	43,5	411,5	43,8	419,5	44,9	405,1	42,8
cross	206,0	141,4	195,0	141,5	225,2	141,7	216,7	141,8

**Standard deviation:**

	Fmax (N)	ε max (%)	Fbrk (N)	ε break (%)	Fmax (N)	ε max (%)	Fbrk (N)	ε break (%)
dry				wet				
machine	16,6	1,7	14,4	2,0	19,1	4,0	53,0	3,4
cross	13,5	8,6	10,5	8,6	12,2	7,3	13,7	7,3

**Percent coefficient of variation %:**

	Fmax (N)	ε max (%)	Fbrk (N)	ε break (%)	Fmax (N)	ε max (%)	Fbrk (N)	ε break (%)
dry				wet				
machine	3,94	4,07	3,50	4,61	11,72	9,07	13,09	7,57
cross	6,61	6,09	5,39	6,09	5,43	5,18	6,34	5,18

**Legend:**

ε max : maximally reached stretch material  
 ε break: Stretch of the material at break  
 Fmax: Maximum traction power  
 Smax= Maximum distance  
 Fbrk: Breaking stress  
 Sbrk: Distance to break  
 rH: relative humidity

Mean value of 5 test pieces

Maximum break strength in Newton

Maximum expansion break strength

Test description of wet test: test sample 1 h in 0,1% polysorbate 80 solution

**Results of bursting strength test according to EN ISO 13938-1, dry and wet / SOP 12-007**

**Test surface:** 10cm<sup>2</sup>  
**Description of test sample:** article P981  
**Room temp:** 27 °C **rH:** 41%  
**Test date:** 2012-07-31

Mean value bursting strength [kPa] normal air- conditioned	Mean value bursting strength [mm] normal air- conditioned
671	28

Mean value bursting strength [kPa] wet	Mean value bursting strength [mm] wet
645	26

**Legend:**

Test description of wet test: test sample 1 h in 0,1% polysorbate 80 solution  
 Mean value 5 tests  
 rH: relative humidity

**Results of tear resistance test according to EN 29073-4, SOP 12-005:**

**Description of test sample:** article P981

**Room temp:** 26 °C **rH:** 44%

**Test date:** 2012-08-01

dry method

Number of test pieces	Mean value of load peak (N)	Fmean (N)	Coefficient of variation	Standard difference (N)
Test sample: machine				
1	28,1	33,0	10,54	3,48
2	37,2			
3	34,6			
4	31,1			
5	33,8			
Test sample: cross				
1	83,4	89,9	17,91	16,11
2	78,9			
3	77,2			
4	116,3			
5	93,8			

wet method

Number of test pieces	Mean value of load peak (N)	Fmean (N)	Coefficient of variation	Standard difference (N)
Test sample: machine				
1	37,6	60,9	52,93	32,24
2	37,2			
3	37,2			
4	95,9			
5	96,5			
Test sample: cross				
1	98,4	61,7	60,29	37,22
2	32,1			
3	34,1			
4	37,7			
5	34,7			

**Legend:**

Test description of wet test: test sample 1 h in 0,1% polysorbate 80 solution  
rH: relative humidity

**Result of linting test according to ISO 9073-10 / SOP 12-011**

**Description of test sample:** article P981

**Test date:** 2012-07-31

Measuring range (µm)	Particle content (Mean value of specimens)	High-difference	Coefficient of variation
	(n = 5)		
0,5-1	10689	2776	26
1-2	12387	2759	22
2-3	3880	1489	28
3-4	2041	1055	52
4-5	1884	1354	72
5-7	853	803	94
7-10	280	281	100
> 10	1978	2456	129
> 0,5 (cumulative)	33978	12432	38
10 – 15µm	392	415	106
15 – 25µm	1500	2001	133

**Result** 3,84 lg (6947) particle 3 µm - 25µm

**Result „Particulate matter“**

Calculation basis: Raw data to linting 2012-07-31 overall

Calculation formula:  $PM = C_{30} + C_{60} + C_{90}$

Measuring range: 3µm - 25µm

Result	PM =	3017
	IPM =	3,47 lg

Legend: PM = Particulate matter  
IPM = Index for Particulate matter  
C = particle  
C<sub>x</sub> = Measuring time



**Determination of a population of micro-organisms on products according EN 11737-1:2009, SOP Nr. 07-014**

**Result of the validation of the elution procedure using the method of repeated recovery**

**Product:** Article P981

**Date of testing:** 2012-07-30

**Dissolution procedure:** 10cm x10cm of the product were processed 5min in a stomacher by highest speed

**Incubation:** incubation of the membrane filter on blood agar, 48h at 36 ±1 °C

Number of tests	Volume Elution medium	CfU/testbody
1	100ml	0
2	100ml	2
3	100ml	1
4	100ml	0

Legend:

CfU = Colony forming units

TSB = Trypton Soya Broth

TSA = Trypton-Soya-Agar

**Calculation of the results**

Dissolution [%]: 0

Correction factor: -

Legend:

Dissolution [%] =  $\frac{\text{number of micro-organisms after the 1. Elution}}{\text{number of micro-organisms after Elution 1 - 4}} \times 100$

Correction factor:  $\frac{100}{\text{dissolution [%]}}$

**Determination of a population of micro-organisms on products according EN 11737-1:2009, SOP Nr. 07-014**

**Product:** Article P981

**Date of testing:** 2012-07-30

**Dissolution procedure:** 10cm x10cm of the product were processed 5min in a stomacher by highest speed

**Elution medium:** Tryptic Soy Broth (TSB)

**Incubation:** Membrane filter on blood agar 48h at 36 ± 1 °C

**Correction Factor\*:** -

Sample No.	Medium	Total count CfU/Testbody	Microbiological Differentiation	Total count x Correction factor*
Test 1	Blood agar	3		-
Test 2	Blood agar	0		-

Critical values:

Aerobe mesophile germ number <1000 CfU  
Yeasts and moulds <100 CfU  
Staphylococcus aureus <10 CfU  
Streptococcus <10 CfU  
Pseudomonade <10 CfU  
Enterobacteriaceae <10 CfU

**Result:** ≤ 2log CfU /dm<sup>2</sup>

Legend:

CfU = Colony forming units  
TSB = Trypton Soya broth  
n = not countable

**Archiving:** The raw data with respect to this test and a copy of the report will be stored in the archive of HygCen.

**Information:** The test results exclusively refer to the samples described above. Account of extracts of this test report is only possible by written approval from HygCen.



Prof. Dr. med. H.-P. Werner  
Manager of scientific-technical affairs



Monika Feltgen  
Department manager