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Trans-textil GmbH

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



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13.08.2012

TESTREPORT

Identification of the test laboratory: SN 13795

Order: 2012-07-25

Date of delivery: 2012-07-26

Product: article P981

Manufacturer: Trans-textil GmbH

Test methods: Testing according see table 1

Period of analysis: 2012-07-27; 2012-07-31 – 2012-08-03

Test conditions: Reprocessed 1 time according
EN ISO 6330:2000
(washed and dried)

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Table 1: Test methods

Test description	Standard	SOP
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 10⁴/ml

Results of calculation:

	Test 1	Test 2	Test 3	Test 4	Test 5
I _B	6,000	6,000	6,000	6,000	6,000

Legend:

cfu = colony forming units

TSA = Nutrient agar

I_B = barrier index $I_B = 6 - (R_{CUM1} + R_{CUM2} + R_{CUM3} + R_{CUM4} + R_{CUM5})$

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: 10cm²

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_x = 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: $\leq 2 \log \text{CfU} / \text{dm}^2$

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.



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