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TEST REPORT

Nº 2017TM0753

DATE OF RECEPTION: 07/06/2017

DATE TEST: Starting: 09/06/2017
Ending: 30/06/2017

APPLICANT

MOGUL TEKSTIL SANAYI VE TICARET LTD. STI.
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Att. ORKUN BAYRAM

DESCRIPTION AND IDENTIFICATION OF SAMPLES

SAMPLES REFERENCED:

-"MADALINE PRODUCT".

TESTS CARRIED OUT

- TEST METHOD FOR RESISTANCE TO DRY BACTERIAL BARRIER PENETRATION *
- RESISTANCE TO WET BACTERIAL PENETRATION*
- DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS
- LINTING IN THE DRY STATE*
- WATER PENETRATION RESISTANCE. TEST UNDER HYDROSTATIC PRESSURE
- BURSTING RESISTANCE
- DETERMINATION OF BREAKING STRENGTH AND ELONGATION

ENAC is a signatory to the Multilateral Agreement (MLA), (MRA Mutual Recognition Agreement) of the European Cooperation for Accreditation (EA) and the International Laboratory Accreditation Cooperation (ILAC), in testing.

ATTACHED --- SAMPLE(S) SEALED

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RESULTS

TEST METHOD FOR RESISTANCE TO DRY BACTERIAL BARRIER PENETRATION *

Standard: UNE-EN ISO 22612:2005.

Date: 14/06/2017 – 15/06/2017.

Principle:

The test is carried out on test pieces fixed each in a container. In each container except one a portion of talc contaminated with *Bacillus subtilis* is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at base of each container at a short distance below the test piece.

The apparatus supporting the containers is then brought into vibration by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate. The sedimentation plates are removed and incubated; the numbers of colonies produced are counted.

Equipment:

- 12 petri dishes of 9 cm diameter containing TGE agar
- 50 g of talc (95% $< 15\ \mu$).
- Purified spores of Bacillus subtilis in a concentration of $2{,}3 \cdot 10^8$ cfu/g talc.
- 12 test pieces 20x20 cm, of reference barrier material.

RESULTS

TEST METHOD FOR RESISTANCE TO DRY BACTERIAL BARRIER PENETRATION*

Results:

Reference*:* MADALINE PRODUCT

Test pieces	Nº of colonies CFU
1	0
2	0
3	0
4	0
5	0
6	0
7	0
8	0
9	0
10	0
Average	**0**

Remark:

In accordance with the standard UNE-EN 13795:2011+A1:2013, the results must be in the values of the following table, taking care of the application of the product:

Table of Performance requirements for surgical gowns and drapes

Characteristic	Unit	Requirement
Resistance to microbial penetration- Dry	**CFU**	**≤ 300[a]**

a→ Test conditions: challenge concentration 10^8 cfu/g talc and 30 minutes vibration time.

RESULTS

RESISTANCE TO WET BACTERIAL PENETRATION*

Standard*:* UNE-EN ISO 22610:2007

Principle:

A test specimen is put on a lidless agar plate on a rotating disk. On top of the test specimen, a piece of donor material and a piece of 10 µ HD polyethylene film of corresponding size are placed and fixed using a double steel ring.

An abrasion resistant finger is placed on top of the donor material to exert a specified force on the donor and test specimen to bring them into contact with the agar. The finger is applied to the material by a pivoted lever moved by an excenter cam in such a way that it moves over the entire surface of the plate within 15 minutes. The assemblage of materials is stretched by the weigth of the steel ring so that only a small area of the test specimen is brought into contact with the agar surface at a time. Due to the combined effect of rubbing and liquid migration bacteria may spread from the donor material through the test specimen down to the agar surface.

After 15 minutes of testing, the agar plate is replaced and the test repeated. With five periods of 15 minutes each, tests are performed with the same pair of donor material and test specimen. In that way the test allows for an estimation of the penetration over time.

Finally the remaining bacterial contamination on the test specimen is sampled using the same technique (turn the test specimen upside down and run the sixth plate).

The agar plates are incubated to visualise the bacterial colonies, which are then enumerated.

RESULTS

RESISTANCE TO WET BACTERIAL PENETRATION*

Equipment:

- 1 set of 6 agar plates, 14 cm diameter, filled with agar to 3 ± 0.2 mm from the rim.
- 1 piece, 25 x 25 cm, of carrier material to produce donors that shall be wettable polyurethane polymer film of 30 µ thickness carried on paper.
- 1 piece, 25 x 25 c m, of 10 µ HD polyethylene film.
- *Staphylococcus aureus* suspension with a viable count of 28.000 cfu/ml.
- 5 test specimens, 25 x 25 cm, of material referenced.

Reference: MADALINE PRODUCT

Size:---

Batch nº (1): ---

Results:

Replica	1	2	3	4	5
Test time	**ufc**	**ufc**	**ufc**	**ufc**	**ufc**
15 min	15	10	2	10	5
30 min	21	12	7	18	9
45 min	20	21	6	12	10
1 h	31	20	17	25	21
1 h 15 min	42	22	30	42	36
Test specimen upside down	730	810	750	510	610

cfu/ plate maximum	42	22	30	42	36

Calculated barrier index Ib:

I_B	Replica 1	Replica 2	Replica 3	Replica 4	Replica 5	Average
	5,6	5,8	5,9	5,6	5,8	**5,7**

RESULTS

RESISTANCE TO WET BACTERIAL PENETRATION

Notes:

- In accordance with the standard UNE-EN 13795:2011+A1:2013, the results must be in the values of the following table, taking care of the application of the product:

Characteristic	Units	Standard performance		High performance	
		Critical area	Less critical area	Critical area	Less critical area
Resistance to microbial penetration- Wet	I_B	≥ 2,8 [b]	Not required	6,0 [b,c]	Not required

Remarks:

b→ The least significant difference (LSD) for BI when estimated using UNE EN ISO 22610:2007, was found to be 0,98 at the 95% confidence level. This is the minimum difference hended to distinguish between two materials thought to be different. Thus materials varying by up to 0,98 BI are probably not different; materials varying by more than 0,98 BI probably are different.

c→ Ib =6.0 for the purpose of this standard means: no penetration Ib= 6.0 is the maxium achievable value.

(1) Data provided by the Customer.

RESULTS

DETERMINATION OF A POPULATION OF MICROORGANISMS ON PRODUCTS

Standard: UNE-EN ISO 11737-1:2007 + UNE-EN ISO 11737-1:2007/AC:2009

Reference: MADALINE PRODUCT.

Batch number [(1)]**:** ---

Sample size (SIP): 100 cm^2

Replica number: 2

Expiry date: --

Test date: 09.06.17 - 14.06.17.

Test equipments: Incubators: 03068E05 and 03004E05

Results:

Parameter	Results		
	Replica 1 (ufc/100 cm^2)	Replica 2 (ufc/100 cm^2)	Average (ufc/100 cm^2)
Aerobic bacteria at 33 ± 2 ºC	168	127	148
Moulds and yeasts at 22 ± 2 ºC	27	21	24

Remarks:

- [(1)] Data provided by the Customer.

- The total count of microorganisms in the sample is 172 cfu / 100 cm^2

- In accordance with the standard UNE-EN 13795:2011+A1:2013, the results must be in the values of the following table:

Characteristic	Units	Requirement
Cleanliness microbial	cfu /100 cm^2	≤ 300

RESULTS

LINTING IN THE DRY STATE*

Standards

UNE-EN ISO 9073-10: 2005 ; UNE-EN 13795:2011+A1:2013

Number of specimens

5 each side

Reference: MADALINE PRODUCT

Side A and B

AVERAGE VALUES				
Periode	**3 µm**	**5 µm**	**>10 µm**	**summation > 3 µm**
1	68	4	1	73
2	90	7	1	97
3	101	4	0	105
4	101	3	0	104
5	96	3	0	100
6	99	3	0	101
7	103	2	0	105
8	96	3	0	98
9	95	2	0	97
10	97	2	0	100
Total	946	32	2	980
Total-Co	922	30	2	954
Standard deviation	158	16	1	173
CV	17	53	75	18
Particulate Matter Coefficient IPM	2,41	1,16	0,15	2,44
Coefficient off Linting C_L	2,96	1,48	0,23	2,98

Remark

Due to the requirements of the UNE-EN 13795:2011+A1:2013, the results obtained should be inside the values in the following table , based on the application of the product:

Table 1 and 2 - Characteristics for evaluation and performance requirements for surgical gowns and drapes

Parameters	**Unit**	**Requirements**			
		Standard Performance		**High Performance**	
		Critical area	**less critical area**	**Critical area**	**less critical area**
Cleanliness - Particulate matter	IPM	≤ 3,5	≤ 3,5	≤ 3,5	≤ 3,5
linting (particulate emissions)	Log_{10}(pelusa contada)	≤ 4,0	≤ 4,0	≤ 4,0	≤ 4,0

RESULTS

LINTING IN THE DRY STATE*

Standard
UNE-EN ISO 9073-10: 2005 ; UNE-EN 13795:2011+A1:2013

Number of specimens
5 each side

Reference: MADALINE PRODUCT

SIDE A

AVERAGE VALUES				
Periode	**3 µm**	**5 µm**	**>10 µm**	**summation > 3 µm**
1	59	4	2	65
2	76	4	0	81
3	89	2	0	91
4	92	1	1	94
5	81	2	0	84
6	91	1	0	92
7	92	1	0	93
8	89	2	0	90
9	89	1	0	90
10	90	2	0	92
Total	847	21	3	871
Total-Co	810	19	3	831
Standard deviation	371	10	1	373
CV	46	55	44	45
Coefficient off Linting C_L	2,91	1,27	0,41	2,92

RESULTS

LINTING IN THE DRY STATE*

Standard
UNE-EN ISO 9073-10: 2005 ; UNE-EN 13795:2011+A1:2013

Number of specimens
5 each side

Reference: MADALINE PRODUCT

SIDE B

AVERAGE VALUES				
Periode	**3 µm**	**5 µm**	**>10 µm**	**summation > 3 µm**
1	76	5	0	81
2	104	9	1	114
3	113	5	0	118
4	110	4	0	114
5	111	4	0	116
6	106	4	0	111
7	115	3	0	118
8	103	4	0	107
9	101	3	0	104
10	105	3	0	108
Total	1044	44	1	1090
Total-Co	1034	41	1	1076
Standard deviation	368	14	1	376
CV	36	34	185	35
Coefficient off Linting C_L	3,01	1,61	0,10	3,03

RESULTS

WATER PENETRATION RESISTANCE. TEST UNDER HYDROSTATIC PRESSURE

Standard

UNE-EN 20811:1993

Apparatus

Hydrostatic Head Tester

Atmosphere for conditioning and testing

Temperature	(20±2)ºC	**Relative humidity**	(65±4)%
Water temperature	20ºC	**Rate of increase of water pressure**	10cmH_2O/min
Surface exposed	External face		

The water pressure was applied from the upside of the test piece

Reference	Specimen	Pressure (cm/H_2O)	
MADALINE PRODUCT	1	29.2	
	2	30.1	
	3	30.9	**30.3**
	4	31.4	
	5	29.7	

Remark

Due to the requirements of the UNE-EN 13795:2011+A1:2013, the results obtained should be inside the values in the following table , based on the application of the product:

Table 1 - Characteristics for Evaluation and Performance Requirements for Surgical Gowns

Parameters	Unit	Requirements			
		Standard performance		High performance	
		Critical area	Less critical area	Critical area	Less critical area
Water Penetration Resistance	cm H_2O	≥ 20	≥ 10	≥ 100	≥ 10

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RESULTS

BURSTING RESISTANCE

Standard

UNE-EN ISO 13938-2:2000

Apparatus

Autoburst JAMES HEAL

Atmosphere for conditioning and testing

Temperature	(20±2) ºC
Relative humidity	(65±4) %

Test Chacateristics

Conditions	Wet specimen
Surface	50 cm^2
Duration	(20±5) s.

Number of specimens

Tested	5
Bursting in the proximity of the clamps	0
Rejected	0

Reference	Average resistance (kPa)	
MADALINE PRODUCT	210.9 194.0 228.6 212.4 231.5	**215.5**

Remarks

The test standard UNE-EN ISO 13938-1: 2000 hydraulic equipment used and the UNE-EN ISO 13938-2: 2000 pneumatic equipment usually reach 800kPa. Both standards specify that there is no significant difference between the two teams to 800kPa.

Due to the requirements of the UNE-EN 13795:2011+A1:2013, the results obtained should be inside the values in the following table , based on the application of the product:

Table 1 - Characteristics for Evaluation and Performance Requirements for Surgical Gowns

Parameters	Units	Requirements			
		Standard performance		High performance	
		Critical area	less critical area	Critical area	less critical area
Bursting Strenght -Wet	kPa	≥ 40	---	≥ 40	---

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RESULTS

BURSTING RESISTANCE

Standard

UNE-EN ISO 13938-2:2000

Apparatus

Autoburst JAMES HEAL

Atmosphere for conditioning and testing

Temperature	(20±2) ºC
Relative humidity	(65±4) %

Test Chacateristics

Conditions	Dry specimen
Surface	50 cm^2
Duration	(20±5) s.

Number of specimens

Tested	5
Bursting in the proximity of the clamps	0
Rejected	0

Reference	Average resistance (kPa)	
MADALINE PRODUCT	238.1 235.4 228.2 223.7 259.8	**239.0**

Remarks

The test standard UNE-EN ISO 13938-1: 2000 hydraulic equipment used and the UNE-EN ISO 13938-2: 2000 pneumatic equipment usually reach 800kPa. Both standards specify that there is no significant difference between the two teams to 800kPa.

Due to the requirements of the UNE-EN 13795:2011+A1:2013, the results obtained should be inside the values in the following table , based on the application of the product:

Table 2 - Characteristics for evaluation and performance requirements for Surgical Drapes

Parameters	Units	Requirements			
		Standard performance		High performance	
		Critical area	less critical area	Critical area	less critical area
Bursting strenght -Dry	kPa	≥ 40	≥ 40	≥ 40	≥ 40

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RESULTS

DETERMINATION OF BREAKING STRENGTH AND ELONGATION

Standard

UNE-EN 29073-3:1993

Apparatus

INSTRON Dynamometer

Conditioning date

15/06/2017

Test date

28/06/2017

Gauge length

200 mm.

Gauge length Lengthwise and Crosswise

100 mm/min

Mouting Laxo

Atmosphere for conditioning and testing

temperature (20±2) ºC **Relative humidity** (65±4) %

Nº of specimens

Tested 5 for each direction **Rejected** 0

Test conditions

Wet specimen. Immersion in water for 1 hour

Reference	MADALINE PRODUCT			
Direction	**Maximum average load (N)**	**C.V. (%)**	**Average elongation (%)**	**C.V. (%)**
Lengthwise	441.4	3.8	61.5	7.5
Crosswise	175.2	7.0	101.0	6.5

Remark

Due to the requirements of the UNE-EN 13795:2011+A1:2013, the results obtained should be inside the values in the following table, based on the application of the product:

Table 1 - Characteristics for evaluation and performance requirements for surgical gowns

Requisites

Parameter	**Unit**	**Standard performance**		**High performance**	
Tensile Strength - Wet	N	Critical area	Less critical area	Critical area	Less critical area
		≥ 20	It's not required	≥ 20	It's not required

_____///

RESULTS

DETERMINATION OF BREAKING STRENGTH AND ELONGATION

Standard

UNE-EN 29073-3:1993

Apparatus

INSTRON Dynamometer

Conditioning date

15/06/2017 – 23/06/2017

Test date

23/06/2017

Gauge length

200 mm.

Gauge length Lengthwise and Crosswise

100 mm/min

Mouting Laxo

Atmosphere for conditioning and testing

temperature (20±2) ºC **Relative humidity** (65±4) %

Nº of specimens

Tested 5 for each direction **Rejected** 0

Test conditions

Dry specimen

Reference	MADALINE PRODUCT			
Direction	**Maximum average load (N)**	**C.V. (%)**	**Average elongation (%)**	**C.V. (%)**
Lengthwise	462.2	6.7	62.0	10.0
Crosswise	179.8	2.7	101.5	3.5

Remark

Due to the requirements of the UNE-EN 13795:2011+A1:2013, the results obtained should be inside the values in the following table, based on the application of the product:

Table 1 - Characteristics for evaluation and performance requirements for surgical gowns

Requisites

Parameter	**Unid.**	**Standard performance**		**High performance**	
Tensile Strength - Dry	N	Critical area	Less critical area	Critical area	Less critical area
		≥ 20	≥ 20	≥ 20	≥ 20

>>>

Judit Sisternes
Head of Health and Hygiene products
Depart.

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