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Date: 29 June 2018

Our ref.: Za

From: Daniel Zahn

Test Report

Order No.: 8321/2 Page 1 of 6

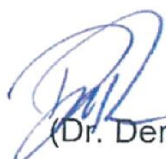
Client : CHTC JIAHUA NONWOVEN CO.,LTD
No.99,WaGou New Village,
Pengchang,Xiantao ,Hubei ,
CHINA


Date of order: 5 May 2018

Receipt of sample material: 11 May 2018

Origin of sample material: From CHTC Jiahua Nonwoven Co.,Ltd, No.99,WaGou
New Village, Pengchang,Xiantao ,Hubei ,China

Purpose: Analysis of a nonwoven sample according to EN868-2
and ISO 11607-1


(Dr. Derra)


(Zahn)
Manager
Physical Material Testing

The present report refers exclusively to the samples as laid out therein, Information and statistical data on the results can be obtained on request.

Sample Material

For analysis the following sample material was in hand:

Sample Material	Sample Designation
Nonwoven wrapping	Polypropylene SMS Blue Nonwoven 50 g/m ²

Carrying out of the Tests

Examination period: 12 May 2018 to 29 June 2018

The conditioning of the sample material and the examination of the physical characteristics took place in standard atmosphere according to ISO 187 at 23(+/-)°C and 50 (+/-2) % relative humidity.

The sterilization by steam(134°C), ethylene and H₂O₂-plasma(see section 2 and 3 of this test report) was performed in cooperation with a partner institute.

1. Determination of Physical and Chemical Properties

In order to show compliance to ISO 11607-1,section 5.1.6 c)“physical and chemical properties” as well as to the demands ISO 1107-1, section 5.1.7 b) to 5.1.7 f), the sample was examined according to EN868-2,section 4.2.1 “General requirements” and section 4.2.2.3 “specific requirements-Nonwoven”.

The test regulations are listed on page 3 of this test report

The number of individual values corresponds to the rules of the test regulations mentioned, regarding chemical analyses, a double determination was carried out.

Result:

The results of the tested parameters to show compliance to ISO11607-1, section 5.1.6 c) “physical and chemical properties” Are listed on the following page (page 3 of this test report).

Compliance to ISO 11607-1, section 5.1.6 c) "physical and chemical properties"

Examination according to EN868-2

Order number: 8321/2

Client: CHTC Jiahua Nonwoven Co., Ltd

Sample designation: Polypropylene SMS

Sample arrival date: 10 May 2018

Nonwoven 50 g/m²

Testing period: 11 May to 29 June 2018

Parameter	Test Regulation EN868-2	Test result	
		Average value	Standard deviation
General requirements			
Visual test	ISO 11607, sect.5.1.7 b) & d)	No objections	
Colour	Sect. 4.2.1.1, ISO6588-2	blue	
Grammage* -difference to nominal value	Sect. 4.2.1.2, DIN EN ISO 536	49.3 g/m ² -1.3%	1.82 g/m ²
Ph-value*	Sect. 4.2.1.3, ISO 6588-2	6.8	0.03
Mass portion -chloride* -sulphate*	Sect. 4.2.1.4, ISO 9197 Sect. 4.2.1.5, ISO 9198	<0.002% NaCl <0.002% Na ₂ SO ₄	--- ---
Fluorescent Substances* Brightening effect	Sect. 4.2.1.6, Annex B	No spots > 1mm/0.01m ² <1%	
Drapability* -side A -side B	Sect. 4.2.1.7, ISO 9073-9, Method A, $\Phi=36$ cm	83% 82%	2.7% 2.6%
Specific requirements-Nonwoven wrapping material			
Tearing resistance* -machine direction -cross direction	Sect. 4.2.2.3.1, ISO 1974	5211 mN ----- ²⁾ mN	875 mN -----mN
Bursting strength(dry)*	Sect. 4.2.2.3.2, DIN ISO 3689	>150 kPa	
Bursting strength (wet)*	sect. 4.2.2.3.3	>145 kPa	
Elongation at break(dry)* -machine direction -cross direction	Sect. 4.2.2.3.4, DIN EN ISO 1924-2	112% 92%	8.7% 14%
Hydrostatic pressure test ¹⁾ -side A -side B	Sect. 4.2.2.3.5, EN 20811	570 mm 529 mm	41.2 mm 101 mm
Tensile strength (dry)* -machine direction -cross direction	Sect. 4.2.2.3.6, DIN EN ISO 1924-2	2.07 kN/m 1.07 kN/m	0.06 kN/m 0.09 kN/m
Tensile strength (wet)* -machine direction -cross direction	Sect.4.2.2.3.7, DIN ISO 3781	2.08 kN/m 1.07 kN/m	0.16 kN/m 0.10 kN/m

1) This examination was performed in cooperation with a partner institute

2) Determination in cross direction not possible, All specimen only tear in machine direction.

2 . Determination of the Microbial Barrier

In order to show compliance to ISO 11607-1, section 5.1.6 a) "microbial barrier", the sample was examined according to ISO 11607-1, section 5.2.3, test method DIN 58 953-6 each after sterilization by steam (134°C), ethylene oxide and H₂O₂-plasma.

2.1 Determination of Germ Proofness with Air Permeance*

The determination was performed according to DIN 58 953-6, subclause 4. Each after sterilization by steam (134°C), ethylene oxide and H₂O₂-plasma the sample material was contaminated with the test germ on both sides.

Result:

Sterilization-Test side	Number of CFU/specimen										
	1	2	3	4	5	6	7	8	9	10	Σ
Ethylene oxide-side A:	1	0	0	0	0	0	0	0	0	0	1
side B	1	1	0	1	0	0	1	0	0	0	4
H₂O₂-Plasma-side A:	1	0	0	0	0	0	0	0	0	0	1
side B	1	0	2	0	1	0	0	0	0	0	4

CFU=colony forming unit

2.2 Determination of Germ Proofness under Humidity*

The determination was performed according to DIN 58-983-6, subclause 3. Each after sterilization by steam (134°C), ethylene oxide and H₂O₂-plasma the sample material was contaminated with the test germ on both sides.

Result:

Sterilization-Test side	Number of CFU/agar plate					
	1	2	3	4	5	Σ
Ethylene oxide-side A:	0	0	0	0	0	0
side B	0	0	0	0	0	0
H₂O₂-Plasma-side A:	0	0	1	0	0	1
side B	0	0	0	0	0	0

CFU=Colony forming unit

According to DIN 58953-6, section 3.7.3,a re-examination had to be performed on side A of the material sterilized by H₂O₂-Plasma due to a total number of CFU between 1 and 5.

Result of the re-examination:

Sterilization- Test side	Number of CFU/ agar plate																				Σ
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	
H ₂ O ₂ -Plasma- side A:	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
side B	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

CFU=Colony forming unit

Evaluation of the Microbial Barrier:

The sample material submitted for analysis was examined for its germ proofness under humidity and with air permeance after sterilization by ethylene oxide and after sterilization by H₂O₂-Plasma and is evaluated as "sufficiently germ-proof" according to DIN 58 953-6, subclause 3.7 and subclause 4.7.6.

3. Determination of Compatibility with the Sterilization Processes

In order to show compliance to ISO 11607-1, section 5.1.6 e)"compatibility with respect to the intended sterilization processes", the sample was examined according to EN 868-2, section 4.2.2.3.4,4.2.2.3.6,4.2.2.3.7 and in analogy with DIN EN 646(without test simulants) each after sterilization by steam(134°C), ethylene oxide and H₂O₂-plasma.

Compliance to ISO 11607-1, section 5.1.6 e)
"compatibility with respect to the intended sterilization processes"
Examination according to EN 868-2

Order number:8321/2

Client: CHTC Jiahua Nonwoven Co., Ltd

Sample designation: Polypropylene SMS

Sample arrival date: 5 May 2018

Nonwoven 50 g/m²

Testing period: 6 May to 29 June 2018

Parameter	Test Regulation EN 868-2	Sterilization	Test result	
Visual test	ISO 11607-1 Sect. 5.1.7 b)&d)	Steam: Ethylene oxide: H ₂ O ₂ -Plasma	No objections No objection s No objections	
Colour fastness*	DIN EN 646 (without test simulants)	Steam: Ethylene oxide: H ₂ O ₂ -Plasma	5 ¹⁾ 5 ¹⁾ 5 ¹⁾	
			Average value	Standard dev.
Elongation at break(dry)* -machine direction	Sect. 4.2.2.3.4 DIN EN ISO 1924- 2	Steam: Ethylene oxide: H ₂ O ₂ -Plasma	43% 106% 105%	3.9% 7.9% 6.9%
-cross direction		Steam: Ethylene oxide: H ₂ O ₂ -Plasma	42% 89% 90%	4.6% 10% 12%

Tensile strength (dry)* -machine direction	Sect. 4.2.2.3.6 DIN EN ISO 1924- 2	Steam:	1.85 kN/m	0.10 kN/m
		Ethylene oxide:	2.00 kN/m	0.13 kN/m
-cross direction		H ₂ O ₂ -Plasma	2.03 kN/m	0.11 kN/m
		Steam:	0.93 kN/m	0.09 kN/m
		Ethylene oxide:	1.09 kN/m	0.09 kN/m
		H ₂ O ₂ -Plasma	1.08 kN/m	0.08 kN/m
Tensile strength (wet)* -machine direction	Sect. 4.2.2.3.7 DIN EN ISO 3781	Steam:	1.92 kN/m	0.12 kN/m
		Ethylene oxide:	2.16 kN/m	0.12 kN/m
-cross direction		H ₂ O ₂ -Plasma	2.07 kN/m	0.14 kN/m
		Steam:	0.93 kN/m	0.08 kN/m
		Ethylene oxide:	1.11 kN/m	0.06 kN/m
		H ₂ O ₂ -Plasma	1.07 kN/m	0.09 kN/m

1) Distinction is made between five evaluation grades, 1 means poor and 5 good fastness

The accreditation (Register no. D-PL-1416-01-10 and D-PI-1416-01-02) applies to the methods marked with* in the test report. **End of report.**