AITEX
INSTITUTO TECNOLÓGICO TEXTIL
PLAZA EMILIO SALA, 1
03801 ALCOY (ALICANTE) ESPAÑA, SPAIN

OEKO-TEX®
CONFIDENCE IN TEXTILES

CERTIFICATE

La sociedad

Torres Espic, S.L.
Polígono Industrial de Picassent.
Calle Nº 5; Casillero 86
46220 Picassent, SPAIN

OEKO-TEX®
CONFIDENCE IN TEXTILES
STANDARD 100
2002AN3765 AITEX,
Control de sustancias nocivas
www.oeko-tex.com/standard100

está autorizada para colocar, según el STANDARD 100 by OEKO-TEX® y nuestro informe de ensayo nº. **20160K1206**, la etiqueta OEKO-TEX®

en los artículos siguientes

Espumas de poliuretano flexible Bassic®, Resilén®, Resilén® Plus, Ikon®, Neropur®, Visco Neropur®, Viscoool® y espumas de poliuretano flexible con aceite de Soja. (Densidad: 20-60 Kg/m³). (Excepto espumas ignífugas). Altura max: 123cm.

Los ensayos han sido realizados según el STANDARD 100 by OEKO-TEX®**clase de productos I**, sobre los artículos mencionados anteriormente, resultando que éstos cumplen las condiciones en vigor, respecto a la ecología humana, del standard para artículos de bebé.

Los artículos certificados cumplen con los requisitos del anexo XVII del REACH(incluyendo el uso de colorantes azo, niquel etc...) así como también cumple con los requisitos americanos en cuanto al contenido total de plomo en artículos de niños (CPSIA no aplica para materiales de cristal).

El titular de este certificado se compromete con el instituto mediante una declaración de conformidad según la norma ISO 17050-1 a colocar la etiqueta OEKO-TEX® únicamente en los articulos que se correspondan con las muestras ensayadas. La conformidad se comprobará mediante auditorías.

El certificado 2002AN3765 es válido hasta el 15.12.2017

Alcoy, 09.01.2017

Silvia Devesa Valencia
Subdirectora Innovación

Isabel Soriano Sarrió
Jefa Área Innovación

HYGCEN®
Centrum für Hygiene
und medizinische Produktsicherheit

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

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

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

Torresespic
Poligono Industrial Picassent
c/No. 5 46220 Picassent (Valencia)

Espana

Cytotoxicity Test to DIN EN ISO 10993-5
SOP 09-001

2010-04-29

Test Protocol

Identification of the test laboratory:	SN 9913a
Delivery date:	20.01.2010
Product:	RESILÉN®
Customer:	Torresespic
Test method:	Cytotoxicity of eluates according to the DIN EN ISO 10993-5:2009-10 Biological evaluation of medical devices Part 5: tests for cytotoxicity: in vitro SOP 09-001
Test time period:	2010-03-01 – 2010-03-03
Test conditions:	Examining climate: 22,3 °C / 30 % rel. humidity Incubation: 24 hours The test was carried out after a standard washing procedure according EN ISO 6330:2000.

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Deutsche Apotheker- u. Ärztebank BLZ 300 606 01 Konto 0 005 578 698
Deutsche Bank AG Schwerin BLZ 130 700 24 Konto 3 184 645

Bei Überweisungen aus dem Ausland:
Deutsche Apotheker- u. Ärztebank IBAN DE 50 3006 0601 0005 5786 98
BIC DAAEDEDD

Geschäftsführerin: Dipl.-Ing. (FH) Margrit Werner Amtsgericht Schwerin HRB 4792 UST-Nr.: DE178599849 Steuer-Nr.: 090/110/03882

Description of the method

Extraction conditions:	0,9 g test product were diluted with 9 ml MEM + 9 % serum +1 % antibiotic solution at 37°C for 24 h = **extraction medium**
cell culture	FI-cells are derived from the human amnion. The stock cultures were carried out into 250 ml culture flasks (Greiner GmbH). The cells were trypsinised all 4 days. Only cells up to 100 passages were used. Trypsinised cells were seeded in tissue culture plates. The culture medium consists of MEM (Minimum Essential Medium) supplemented with 9 % calf serum, 1 % antibiotic solution (Penicilline G, Streptomycin sulfate, Neomycin) and L-glutamine.
Exposition	After 24hours of cultivation the cells were available as monolayer. A medium change with extraction medium was accomplished. Therefore the culture medium was decanted and the extraction medium carefully pipetted into the wells (0.1 ml per well). An incubation for 24h is following.
Measuring principle	Vital cells incorporate the dye neutral red. Destroyed cells cannot incorporate the dye and remain unstained. The intensity of colour of the elution solution can be measured with a photometer.
Measurement	At the end of the incubation time the microtiterplate will be washed with PBS (Phosphate Buffered Saline). Culture medium containing the dye neutral red (50µg/ml) was given to the cells. After an incubation time of 3 hours the microtiterplate was washed again to remove the spare dye. With a special elution solution (1% acetic acid in 50% ethyle alcohol) the dye was solved out of the cells. After 1 hour of elution the photometric measurement was conducted.
Controls	As a negative control culture medium without a test solution was established. To verify the sensitivity of the test system a positive control (1.5mg/ml Sodiumdodecylsulfate) in culture medium was exposed in the cell culture system.
Evaluation	The optical density of 12 parallel tests was determined and used for statistical evaluation.

Results

Figure 1: box plot of the cellvitality

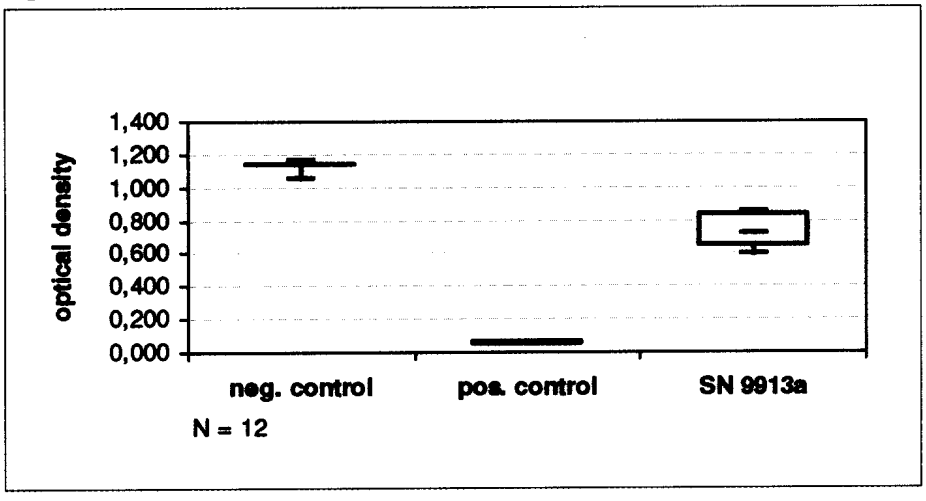

Table 1: Descriptive statistics (cellvitality)

	N	Mean	cell vitality (%)	minimum	maximum	Std. Deviation	p*
Negative control	9	1,126	100,00	1,056	1,166	0,035	-
Positive control	9	0,053	4,72	0,051	0,056	0,002	-
SN 9913a	12	0,736	65,42	0,591	0,850	0,106	0,8695

*U test (Man Whitney) vs. Control

HygCen
Centrum für Hygiene und medizinische Produktsicherheit

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

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Vice department manager

PROF. DR. MED. H. - P. WERNER
FACHARZT FÜR HYGIENE

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Espana

2010-04-29

RESILÉN

Judgement

After testing the Cytotoxicity of the RESILÉN® according to the DIN EN ISO 10993-5, 2009 -- test report of 2010-04-29 (Testreport SN 9913a) -- I give the following statement:

An evaluation of the scope of biological testing was carried out as per EN ISO 10993-1:2009.

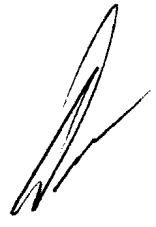
The intended use of the product, declared by the producer, involves contact with intact skin for a period of less than 24 hours. To evaluate the biocompatibility of the product, a cytotoxicity test as per EN ISO 10993-5 (2009) was therefore considered sufficient.

Any knowledge to be gained from further biocompatibility testing with this product would not justify the unnecessarily high level of harm to experimental animals involved. As per EN ISO 10993-1:2009, chapter 3.6 and EN ISO 10993-1: 2009, chapter 5.1 b) 7), such tests will therefore not be performed in these cases.

The type and scope of the tests performed complies with the specifications as per EN ISO 10993-1:2009.

From the tested material only minimal cytotoxic compounds were extracted at 37°C. The extract of the test material reduced the cell growth to 65.42% of control. This is statistically not significant. (Fig. 1 and Tab. 1).

Using the test material as mentioned before described by the manufacturer no cytotoxic effects should be expected.



Prof. Dr. med. H.-P. Werner