

No. 1541

**Environment Management** 

**Customer:** 

LUMATECH PL 43-190 MIKOŁÓW ul. Żwirki i Wigury 65

**Material Designation** 

**Materialnumber:** 

skai Tundra

F646-

# **Properties**

Epikutan test (accredited Centrum für Hygiene und Medizinische Produktsicherheit HYGCEN)
Tests for irritation and sensitization (DIN EN ISO 10993-10:2010-12)
SOP 09-013

**Test method**: the patch test is a model designed to obtain proof of a primary irritative effect or contact allergy due to epicutaneous, local and lasting contact with the preparation under investigation.

To enhance absorption of the test substance, they are applied under occlusive conditions during the patch test. The sensitivity threshold must be crossed in order to elicit a positive reaction.

The product is applied to clinically healthy skin on the outside of the lower arms of 10 test volunteers and fixed there (Leukotest, Hartmann).

The test patch is removed after an exposure duration of 24 hours, 48 hours and 72 hours at which time an initial evaluation is done

**Testresult of the product above**: in all 10 test volunteers, no skin changes were recorded in the test patch area after 24, 48 and 72 hours.

Weissbach, 11 June 2014 Konrad Hornschuch AG

Birgit Kammerer Executive Vice President Research & Development

pp blue



No. 1542

**Environment Management** 

**Customer:** 

LUMATECH

PL 43-190 MIKOŁÓW

ul. Żwirki i Wigury 65

**Material Designation** 

**Materialnumber:** 

skai Tundra

F646-

### **Properties**

Cytotoxicity Test (accredited Centrum für Hygiene und Medizinische Produktsicherheit HYGCEN)

Cytotoxicity of eluates according to DIN EN ISO 10993-5:2009-10 Biological evaluation of medical devices Part 5: tests for cytotoxicity: in vitro SOP 09-001

#### Test conditions:

Incubation: 24 hours

The samples were checked in the delivery state.

### Testresult of the product above:

From the tested material only small amounts of cytotoxic compounds were extracted at 37°C.

Using the test material (contact with intact skin for a period of less than 24 hours) no cytotoxic effects should be expected.

Weissbach, 11 June 2014 Konrad Hornschuch AG

Birgit Kammerer Executive Vice President Research & Development



No. 1543

**Environment Management** 

**Customer:** 

LUMATECH

PL 43-190 MIKOŁÓW

ul. Żwirki i Wigury 65

**Material Designation:** 

Materialnumber:

**PVC- Upholstery-Material** 

skai Tundra

F646-

# Properties:

# Regulation (EC) 1907/2006 REACH Annex XVII

We confirm that the material above fulfils the demands of Regulation (EC) 1907/2006 of 18 December 2006 Annex XVII on Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles.

Weissbach, 11 June 2014 Konrad Hornschuch AG

Birgit Kammerer Executive Vice President Research & Development



No. 1544

**Environment Management** 

**Customer:** 

Lumatech

ul. Zwirki i Wigury 65 43-190 MIKOLOW

Material Designation:

Materialnumber:

**PVC- Upholstery-Material** 

skai Tundra

F646-

### **Properties:**

# PAH (polycyclic aromatic hydrocarbons)

According to our actually knowledge we are able to confirm you that PAH are **not** added during the production process for the material above. Therefore to our knowledge PAH are not present with exception optionally technical unavoidable traces or ultratraces PAH tests of comparably PVC materials show the following result: Benzoapyren < 1 mg/kg
Total PAH < 10 mg/kg
(Category 2)

Weissbach, 11 June 2014 Konrad Hornschuch AG

Birgit Kammerer Executive Vice President Research & Development



Confimation of special characteritics

TU FO 037.01

teritics Nr. 1545

**Environmental Management** 

**Customer:** 

Lumatech

ul. Zwirki i Wigury 65 43-190 MIKOLOW

**Material designation:** 

Material no.:

**PVC- Upholstery-Material** 

skai Tundra

F646-

### **Characteristics:**

EU Directive 2011/65/EC (RoHS) EU Directive 2002/95/EC

We hereby confirm that the abovementioned material does not exceed the limit values for Hg, Pb, Cd, CrVI, PBB and PBDE set out in Annex II of EU Directive 2011/65/EC.

Weissbach, June 11 2014 Konrad Hornschuch AG

Birgit Kammerer Executive Vice President Research & Development



<u>Confirmation</u> of Special Properties TU FO 132.01

No. 454

**Environment Management** 

**Customer:** 

Lumatech

ul. Zwirki i Wigury 65 43-190 MIKOLOW

**PVC- Upholstery-material** 

skai Tundra

F646-

REACH REGULATION (EC) No. 1907/2006 SVHC (Duty to provide information in accordance with Article 33) Candidate list 16 December 2013

We hereby confirm that the product above does not contain any substance included in the candidate list according to article 59(1) of regulation (EC) No. 1907/2006 ("REACH") in a concentration of more than 0.1 weight percent.

A substance included in the candidate list of 12/19/2012 is added as an additive in the parts-perthousand range, but this degrades during the manufacture of the material. Currently, the residual content of this substance is being tested. This testing can take months, as an assured analysis method must be created and verified.

If the material contains, contrary to expectations, more than 0.1 weight percent of this substance, you will naturally be informed of this immediately.

According to information available so far, the packaging for the product above does not contain any substance included in the current candidate list in a concentration of more than 0.1 weight percent. If we receive different information, we will inform you immediately and unsolicited.

In addition, we will immediately inform you of additions to the candidate list, if the product above or the packaging of the product is affected.

Weissbach, 11 June 2014 Konrad Hornschuch AG

Birgit Kammerer Executive Vice President Research & Development Dr. Roland Zwettler

Head of Safety & Environment Safety & Environment