

TRANSLATION

TÜV Product Service GmbH
Masurenweg 1 – 3

30163 Hannover

**Toxicity examination according to DIN EN ISO 10993-5
SOP 09-001**

Test Report

Sample no.:	SN 22001
Date of delivery:	10.09.2001
Product:	Skai sample black no. 5016/9 Skai sample grey no. 5016/5
Client:	TÜV Product Service GmbH
Manufacturer:	INVACARE Deutschland GmbH
Test method:	Toxicity of eluates in accordance with DIN EN ISO 10993-5, 1999-11 Biological assessment of medical products Part 5: Testing toxicity SOP 09-001
Test period:	10.09.2001 – 14.09.2001
Test conditions:	Climate: 22°C/25 % rel. Humidity Conditioning: 24 hours

Description of the test method

Conditions of extraction: 5 cm² material (approx. 1 g) in 4 ml MEM + 1 % serum + 1 % antibiotic solution at 37°C for 24 h = extraction medium

Methodic: Cell cultivation
FL-cells are a cell line of the human amnion. They are conserved in 250 ml-bottles (Greiner GmbH). All cells are filtered in 4 d. After the 100th filtration the reserve has been regenerated from the standard culture.
For test purposes the cells are put into culture tubes after having been separated.
The cultivation medium consists of 70 % lactalbuminhydrolysate and 30 % MEM with additives of 1 % antibiotic solution (final concentration: 100 IE Penicillin G and 100 µg streptomycin-sulfat/ml) and 8 % bovine serum.
The p_H-value was adjusted to 7,2 with M NaOH solution.

Exposition: After 72 hours cultivation the cells presented as monolayer, and a transfer to the incubation substrate was made. This consists of MEM + 1 % antibiotic solution + 1 % bovine serum (control), or above mentioned extraction medium directly has been used, respectively. For that purpose the medium was taken out and carefully replaced by the fresh medium (control or extraction medium), (1,5 ml per tube). A 24-hours incubation follows.

Removing/counting the cells: The medium was taken out, the cells were made wet equally by 0,3 ml enzym solution (0,05 % 1:250 trypsin and 0,02 % EDTA in Ca²⁺ and Mg²⁺ and free PBS) and the solution was taken off. After approx. 10 min incubation of the tubes at 37° the separated cells are suspended in each 1 ml MEM and 1 % serum, and the amount of cells comes out by means of the Universal-counter.

Analysis: The cell figure of 19 test samples has been determined and finally statistically evaluated.

HygCen
Centrum für Hygiene und medizinische Produktsicherheit

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skai

Palatexo NF

Materialaufbau

Gewicht 825 ± 50 gr/m²
 Dicke $1,30 \pm 0,2$ mm
 ca. 88 % PVC-Compound
 ca. 12 % BW-Gewirke

Eigenschaften

- lange Haltbarkeit
- flammenschutz geprüft nach NF M1, BS 5852 IS 0+1+5, EN 1021-1+2, DIN 53438, DIN 4102 (B2)
- besonders pflegeleicht
- angenehm weich
- guter Griff
- dehnfähig
- abriebfest
- reiß- und weiterrießfest
- urin- und blutbeständig
- desinfektionsmittelbeständig

Anwendungsgebiete

Alle Arten von Polsterungen und Bekleidungen. Besonders geeignet für den Einsatz in öffentlichen Gebäuden.

Verarbeitung

Problemlose Verarbeitung nach allen in der Polsterindustrie üblichen Verfahren (nähen, heften, kleben, nageln, HF-Schweißen). Keine Lösungsmittelkleber verwendet!

Reinigung

Keine materialerhaltende Pflege erforderlich. Bei ordentlicher Verschmutzung einfach mit feuchtem Tuch abwischen. Es kann auch handelsüblicher Trockenschwamm verwendet werden.

Composition

Weight 825 ± 50 g/sqm
 Thickness $1,30 \pm 0,2$ mm
 abt. 88 % PVC-compound
 abt. 12 % Cotton

Properties

- long service life
- flame retardant according to NF M1, BS 5852 IS 0+1+5, EN 1021-1+2, DIN 53438, DIN 4102 (B2)
- easy to clean
- soft, supple
- elastic touch
- elastic
- abrasion resistant
- tear-resistant
- urine and blood resistant
- resistant to disinfectants

Application

All kinds of upholstery and coverings. Particularly recommendable for the use in public buildings.

Processing

All usual processings possible (sewing, tacking, glueing, nailing, HF-welding). No use any solvent adhesives.

Maintenance

No special care necessary. In case of normal dirt with a damp cloth or use normal dry cleaning.

Composition

Poids 825 ± 50 g/m²
 Epaisseur $1,30 \pm 0,2$ mm
 env. 88 % composants PVC
 env. 12 % coton

Propriétés

- grande longévité
- résistance au feu selon les normes NF M1, BS 5852 IS 0+1+5, EN 1021-1+2, DIN 53438, DIN 4102 (B2)
- entretien facile
- souple
- toucher agréable
- élasticité
- résistance à l'abrasion
- résistance à la rupture et à la déchirure amorcée
- résistance à l'urine et au sang
- résistance aux produits désinfectants

Emploi

Article destiné à l'ameublement, au recouvrement de sièges et autres. Utilisation recommandée pour les établissements publics.

Façonnage

Sans problème pour les procédés habituels de fabrication dans l'ameublement (couture, agrafage, collage, clouage, soudure HF). Ne pas utiliser de colles en solution!

Entretien

Aucun entretien préventif nécessaire. Les salissures normales peuvent être éliminées à l'aide d'une éponge humide. L'utilisation d'une mousse sèche nettoiyante est également possible.

Composizione

Peso 825 ± 50 gr. al mq
 Spessore $1,30 \pm 0,2$ mm
 ca. 88 % PVC-compound
 ca. 12 % cotone

Caratteristiche:

- lunga durata
- ignifugo secondo NF M1, BS 5852 IS 0+1+5, EN 1021-1+2, DIN 53438, DIN 4102 (B2)
- di facile manuten. Zione
- morbido
- gradevole al tatto
- elastico
- resistente all'abrasione
- resistenza a trazione e allo strappo prolungato
- stabile all'urina e al sangue
- stabile ai disinfettanti

Campo d'impiego

Tutti i tipi di imbottiture e rivestimenti. Particolarmente adatto all'utilizzo negli ambienti pubblici.

Lavorazione

Lavorazione senza problemi secondo i soliti procedimenti della industria d'imbottitura (cucire, imbastitura, incollare, inchiodare, saldare ad alta frequenza). Non usare colla a base di solvente.

Pulitura

Non sono necessari accorgimenti particolari. Lo sporco normale si pulisce semplicemente con un panno umido. Si può anche usare la solita schiuma a secco che si trova in commercio.



* nach den gesetzlichen Bestimmungen
 prescribed by law
 in base alle disposizioni di legge
 prescription légale
 prescritto per ley

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