

Biological Tests on Sugi® material

Cytotoxicity (Project 98Z037, 1992)

Method:	ISO 10993-5 Biological evaluation of medical devices, Tests for <i>in vitro</i> Cytotoxicity.
Test Material:	SUGI® strips Dimension: 35 x 7.5 x 1.5 mm
Extract Production:	Extraction medium: phosphate buffered physiological saline solution, pH 7.4. Temperature and duration: 37°C, 72 hours
Cell Culture:	L 929 mouse fibroblasts
Controls:	Positive: Dilution series Negative: Extraction medium
Test Procedure:	6 parallel cultures per tested dilution of the extracts (100, 60, 30, 10, 3, 1 and 0.3 %). Dyed with crystal violet. Calculation of cell growth inhibition from the extinction values at 580 nm
Results:	Test sample and negative control showed no signs of reactivity (Grade 0)
Conclusion:	SUGI® (non-sterilized and sterilized) does not exhibit pronounced cytotoxicity

Sensitization (Report: IBR 10-05-0923/00-92, 1992)

Method:	ISO 10993-10 Biological evaluation of medical devices, Tests for irritation and skin sensitization.
Test Material:	SUGI® strips Dimension: 35 x 7.5 x 1.5 mm
Extract Production:	Extraction medium: phosphate buffered 0.9% saline solution, pH 7.4. Temperature and duration: 37°C, 72 hours
Test Population:	20 guinea pigs
Control Population:	10 guinea pigs
Test Procedure:	Induction exposure to undiluted extract of test material. After Extract production with surface to volume ratio 3cm ² /ml. Release 14 days afterwards, with this extract
Results:	After 24, 48 and 72 hours no allergic reaction, no toxic effects. Classification numbers for erythema and oedema = 0.
Conclusion:	SUGI® is non-sensitizing

Irritation – Skin (Report: IBR 10-03-0922/00-92, 1992)

Method:	ISO 10993-10 Biological evaluation of medical devices, Tests for irritation and skin sensitization.
Test Material:	Undiluted extract made of SUGI® strips
Test Population:	3 rabbits
Test procedure:	duration of contact: 4 hours
Results:	After 30 minutes, 1, 24, 48 and 72 hours p.a., no allergic reaction, no toxic effects. Irritation index for animals = 0.
Conclusion:	SUGI® is non-irritating to the skin

Irritation – Ocular (Report: IBR 10-03-0937/00-92, 1992)

Method:	ISO 10993-10 Biological evaluation of medical devices, Tests for irritation and skin sensitization.
Test Material:	Undiluted extract made of SUGI® strips
Test Population:	3 rabbits
Test Procedure:	duration of contact: 4 hours
Results:	After 1, 24, 48 and 72 hours p.a., no allergic reactions, no toxic effects or eye lesions. Classification number = 0.
Conclusion:	SUGI® is non-irritating to the ocular surface

Update biocompatibility

Cytotoxicity (Project 14Z057, 2014)

Method:	ISO 10993-5 Biological evaluation of medical devices, Tests for <i>in vitro</i> Cytotoxicity.
Test Material:	SUGI® macro swabs (34 mm, non-compressed), SUGI® sponge strips (35 x 7.5 x 1.5 mm, compressed)
Extract Production:	Sterile test items were transferred into the eluent (0.2 per milliliter cell culture medium containing 10% fetal calf serum) in consideration of absorption capacities: SUGI® macro swabs 14.8 ml/g, SUGI® sponge strips 15ml/g. Temperature and duration: 37°C, 24 hours.
Cell Culture:	L 929 mouse fibroblasts
Controls:	Positive: Dilution series of Dimethylsulfoxide Negative: Extraction medium
Test Procedure:	96 parallel cultures per tested dilution of the extracts (100, 30, 10, 3 %). After 4 hours incubation filled with dilution series and incubates for 72 hours at 37°C again. Dyed with crystal violet. Calculation of cell growth inhibition from the extinction values at 570 nm
Results:	Test samples and negative controls showed no signs of reactivity (Grade 0)
Conclusion:	SUGI® does not exhibit pronounced cytotoxicity

GC/MS Fingerprint (Project 14Y102, 2014)

Method:	ISO 10993-18 Biological evaluation of medical devices, Chemical characterization of materials.
Test Material:	SUGI® macro swabs (34 mm, non-compressed), SUGI® sponge strips (35 x 7.5 x 1.5 mm, compressed)
Sample Extraction:	Medium: water, isopropyl alcohol, n-hexane. Temperature and duration: 37°C, 72 hours. In closed glass vials
Controls:	Positive: solution of n-tetradecane dissolved in n-hexane Negative: Pure extraction
Test Procedure:	1 µl of each extract was injected into the GC (duplicate analysis per vial), separated on the capillary column and detected by MS (mass selective detector).
Results & Conclusion:	no semi-volatile organic compounds were detected above the analysis limit