



FDA Silicone Sponge

Quality

The American Food and Drugs Administration (FDA) is the US Federal Agency who is responsible for ensuring foods are safe, wholesome and sanitary.

Silicone Engineering has produced another high quality silicone sponge material, this time the FDA range, which is compliant with the American Food and Drugs Administration (FDA) food contact materials regulation 21 CFR Section 177.2600: "Rubber articles intended for repeated use"

The sponge rubber is prepared using only ingredients that are permitted for use by FDA 21 CFR 177.2600.

The new material has been independently tested by Toxikon to analyse the total extractable substances, and proven to meet all criteria for extractables required by FDA 21 CFR 177.2600. See table:-

The composition of this product has also been positively assessed according to German BfR Recommendation XV on Silicone for food contact (BfR-Empfehlungen XV zu Silicone).

kSi™ FDA meets the following specification requirements

- IP65
- All FDA ingredients are used in kSiil FDA

Features & benefits



Closed cell white only



Food Industry



FDA Compliant



Manufactured in sheet/roll
1m x 1m/1m x 5m
(39"x39"/39"x156")



Beverage Industry



BfR Compliant



Thermally stable over a wide range of temperatures
-60°C (-76°F) to 230°C (450°F)



Pharmaceutical/ Medical Industry



Toxikon Approved

Table 1 - Results of Purified Water Extract

Reflux Time	Results	Evaluation Criteria	Meets Criteria
First 7 hours	0.0mg/in ²	≤20mg/in ²	Yes
Second 2 hours	0.0mg/in ²	≤1mg/in ²	Yes

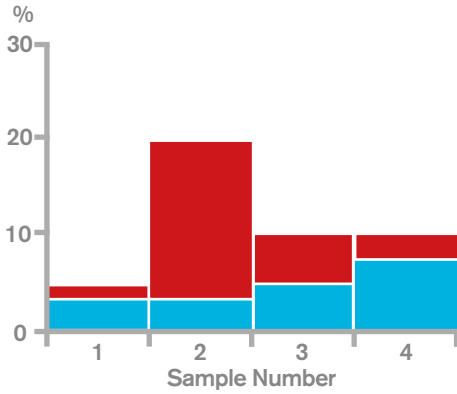
Table 2 - Results of Hexane Extract

Reflux Time	Results	Evaluation Criteria	Meets Criteria
First 7 hours	16.4mg/in ²	≤175mg/in ²	Yes
Second 2 hours	1.14mg/in ²	≤4mg/in ²	Yes

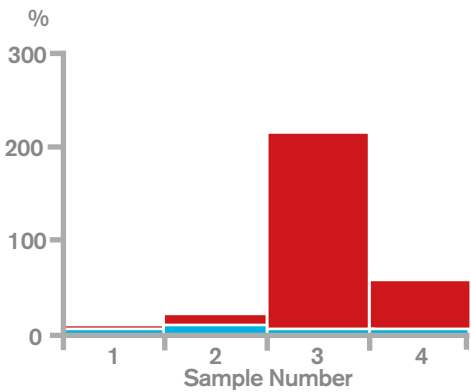


Technical Data

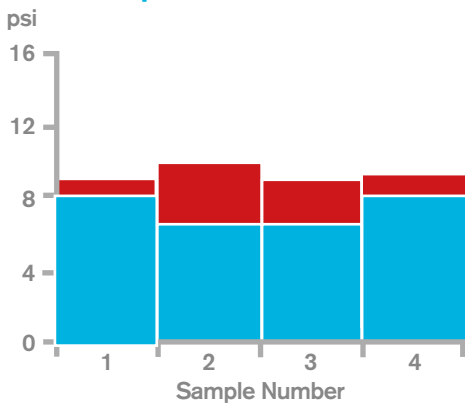
1 Compression Set



2 Water Absorption



3 Compression Stress Strain



Testing taken from different thicknesses

1 Low compression set demonstrates the ability of the rubber to return to its original thickness after prolonged compressive stresses at a given temperature and deflection

2 Lower water absorption of the kSi™ sponge means more closed cells in the material; this gives more consistent sealing performance and reduces the risks of liquid leakage in service.

3 Compression Stress Strain (often referred to as Compression Force Deflection) is a measure of how much force it takes to deform/displace the sponge specimen by given amount.

Summary Technical Data - kSi™ FDA 400

Property	Units	Typical Value
Density	kg.m ⁻³ (lb/ft ³)	420(26)
Compression Stress 25% Strain	kPa(psi)	55 (8)
Elongation to Failure	%	590
Compression Set 50% comp. 24hrs. recovery 22 hrs @ 70°C (158°F)	%	4.0
Temperature	°C (°F)	-60 to 230 (-76 to 446) and up to 250 (482) intermittent

Competitor FDA Sponge Samples

kSi™ FDA 400 Silicone Sponge

*Competitor samples collated from different continents around the world

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