

CRITICAL ISSUES REGARDING SILICONE SHEETING

Global demand for silicone sheeting and products is increasing in both the established and emerging markets. But some new suppliers to the industry are providing sheeting that is far below the exacting quality standards that we take for granted. Some production practices and end products in some countries are dangerous – to the workforce and the end user. Not all silicone sheeting is suitable for gaskets and other components used in the food and beverage industry and other critical environments.

In particular there are issues around Extractable Levels, Volatile Loss and FDA White List (Positive List).

Useful Definitions:-

Extractable Levels - are the amount of chemicals that can escape into a liquid from

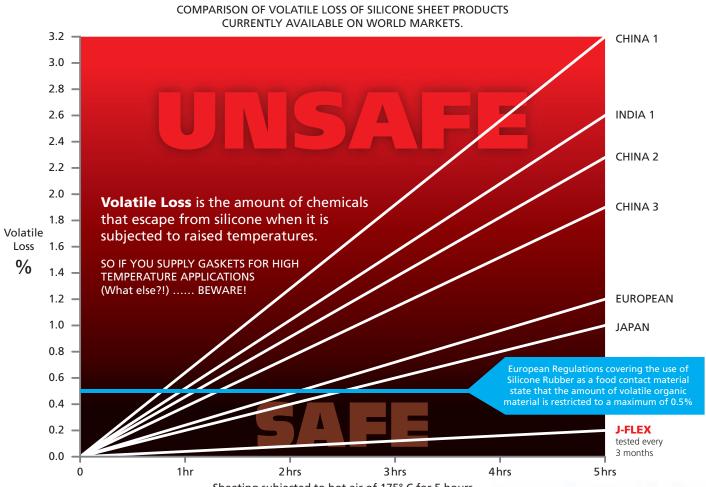
the silicone when it is in prolonged contact with that liquid.

Volatile Loss - is the amount of chemicals that escape from the silicone when

it is subjected to raised temperatures.

FDA White List (Positive List)

- list of permitted ingredients & the manufacturer has a legal obligation to use these white list ingredients.





INDEPENDENT TESTING RESULTS

J-Flex Silicone Sheet Products are independently tested and comply with the requirements issued by the US Federal Food & Drug Administration (FDA) Title 21, Chapter 1, sub-chapter 8, Section 177.2600. They also comply with the German Food Standards BfR Empfehlung XV and colour bleed test according to BfR Empfehlung part B11 + peroxide levels.

FDA Extraction Test	FDA Limit	Test Results	CONCLUSION:
1st Extraction distilled water 2nd Extraction distilled water	20.0mg/inch² 1.0mg/inch²	0.24mg/inch² 0.05mg/inch²	The silicone material tested meets the extractive requirements specified in FDA 21 CFR 177.2600 Class 1 - Rubber Article intended for repeated use in aqueous and fatty food contact (White List ingredients).
1st Extraction hexane 2nd Extraction hexane	175.0mg/inch ² 4.0mg/inch ²	47.84mg/inch ² 1.91mg/inch ²	

BfR Colour Bleed Test

Following tests in which Silicone samples were immersed in water, 10% aqueous ethanol; 3% aqueous acetic acid and Arachis oil. Test method MSG-LAB-SOP-PML-1006. The test summary reports that the Silicone materials pass the colour bleed test requirements of:

- No Detectable Bleed based on the specifications of the German Budesgesundheitsant (BfR) Empfehlung IX of Part 11.
- The Netherlands 'Verpakkingen-en-gerbruibsartenbesluit' of the Netherlands Werewet PartB, Section 7.
- The Belgium Moniteur Belg of 24th September 1976 Section 3 Migration d'un colorant au pigment

Under the Treaty of Rome the test covers all European Member States

The Silicone materials were also subjected to a test to determine levels of hydroxyl-peroxides as laid down in BfR XV Silicone 111 6. The test summary showed that the silicone materials pass the limit with 'No positive reaction for peroxide.'

Independent test were carried out by Intertek MSG – Molecular Spectrosopy – The Wilton Centre, Redcar, TS10 4RF. Test report No. CHEMIST/W000424RL001 20th April 2010

In addition our materials are approved to UK WRAS Drinking Water Approval and meet the Framework Regulation (EC 1935/2004) which states that food contact materials shall be safe. They shall not transfer their components into the food in quantities that could endanger human health, change the composition of the food in an unacceptable way or deteriorate the taste or colour of foodstuffs.

ALL silicone sheet products supplied by J-Flex comply with these regulations











BANNED SUBSTANCE USE

IN SILICONE ELASTOMER PRODUCTS SUPPLIED BY J-FLEX

None of the following substances are contained in; or used in the production process of any of the silicone elastomer products (either solid or cellular) supplied by J-Flex Rubber Products.

Lead (Pb),cadmium (Cd), hexavalent chromium (Cr6+), mercury (Hg), phthalate based plasticisers, polycyclic aromatic hydrocarbons (PAH), Short chain chlorinated parafins (SCCP), polybrominated biphenyl ether and polybrominated diphenyl ether flame retardants (this includes octabromobiphenyl ether, pentabrombiphenyl ether and decabromodiphenyl ether). These products and associated production processes are free of any animal derivitives and are latex free.

None of the cellular silicone elastomer products supplied by J-Flex contain azodicarbonamide blowing agents.

None of the products supplied by J-Flex contain Perfluorooctane Sulfonates (PFOS).

All Silicone elastomer products produced by J-Flex Rubber Products and the processing methods used comply with the substance control requirements of the following directives:

GADSL V1.0 (formally known as ILRS List 101 and VDA list 232-101)

EC Directive 76/769/EC

EC Directive 2002/95/EC (RoHS)

EC Directive 2000/53/EC (ELV)

EC Directive 2003/11/EC

EC Directive 2004/1/EC

EC Directive 2006/122/EC

And any subsequent modifications to these core directives.



Conforming

to Food Safe standards:

All our Silicone Sheet Products are manufactured using European ingredients conforming fully to the requirements of REACH legislation.



Practical action from J-Flex to reassure you and all our customers

Positive responses can be confidently made to address the questions above when J-Flex supplies your silicone sheeting. To further reassure you of quality provenance we have taken the following additional measures which are now in place.

- All our silicone sheeting is regularly tested every three months and exceeds the minimum standards laid down by FDA, BfR, WRAS and EC Food Regulations
- All sheeting delivered to you will carry our quality guarantee label
- Your company will receive a J-Flex certificate of product guarantee with every order



Our J-Flex guarantee

J-Flex Rubber Products hereby declares that all supplied silicone sheeting is independently tested and conforms to the appropriate standards laid down by FDA, BfR, WRAS and EC Food Regulations with particular regard to food & beverage applications.





eusga European Seals and Gaskets Association





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As a valued J-Flex customer we hereby certify that **all** of our 40° / 50° / 60° / 70° Shore Silicone Sheet Products conform to the following Food Safe standards:

Dertificate

'Food & Drug Administration' (FDA) regulations as set out in paragraph 21 CFR 177.2600 (a-f) 'Rubber articles intended for repeated use'.

German Bundesgesundheitsant (BfR) Empfehlung XV Silicone 111,6 with no positive reaction for peroxide; extraction; migration and volatile loss.

WRAS U.K. Drinking Water Approvals (for Hot and Cold Water).

EC No.1935:2004 Framework Regulation - materials and articles intended to come into contact with food – manufactured.

Full details of extraction levels and test data available upon request.









We will only supply you with the Safest Sheet Products on the market



Signed by:

John S. Kirk Managing Director

Ben Woodward Quality Administrator



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J-Flex Rubber Products - www.j-flex.co.uk