
VULCAN ENGINEERING LIMITED

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Ref: Materials Regulatory Compliance

Issue: 12

Dated 10.02.14

Valid Until: Further Notice

Circ: All

VULCAN FEP/PFA ENCAPSULATED O-RINGS REGULATORY COMPLIANCE

SILICONE/VITON INNER CORE & FEP/PFA ENCAPSULATION

FEP/PFA Encapsulation

- FDA & NSF 61

The clear FEP/PFA Encapsulation of our CHEM-RING Encapsulated 'O' Ring complies with Part 177 of Title 21 of the Food and Drug Administration regulations for safe use as articles or components of articles for producing, manufacturing, processing, preparing, treating, packing, transporting or holding food in accordance with FDA regulation 21.CFR.177.1550.

The clear FEP/PFA Encapsulation of our CHEM-RING Encapsulated 'O' Ring is specified to be compliant to NSF 61 requirements.

- 3A® Sanitary Standard

Further, we can advise that Table One of number 20-22 3A® Sanitary Standard documents that FEP and PFA materials, to the previously mentioned FDA 21.CFR.177.1550 Compliance standard, is also compliant to this 3A® Sanitary Standard Number 20-22.

- USP Class VI

FEP/PFA fluoropolymers have been tested in accordance with USP Protocol and meet the requirements of a USP Class VI plastic. In that only the FEP/PFA Encapsulation comes into contact with the product, our FEP/PFA Encapsulated 'O' Rings are considered to be USP Class VI compliant. For information on our Core Materials, please see below;



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• EU VO 1935/2004 & 10/2011

Vulcan Engineering Ltd has researched and evaluated BFR documentation especially "Recommendations of the Federal Institute for Risk Assessment on Plastics intended to come in to contact with Food".

The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

On our Encapsulated 'O' Rings, the outer encapsulate is a FEP or PFA melt processable polymer of P.T.F.E. These material P.T.F.E polymers are highly inert and are utilised intensively in industrial Food Processing, and Domestic Food cooking equipment.

Vulcan FEP / PFA Encapsulated 'O' Rings Encapsulate materials and their manufacture are compliant with all relevant sections 1 to 21 of the E.C Regulation Number 1935/2004 and the subsequent Articles.

We are pleased to advise that FEP/PFA Encapsulated 'O' rings are compliant to EU VO 1935/2004 and 10/2011 certification.

• PFOA & PFOS

FEP/PFA fluoropolymers have been tested in accordance with US EPA 3550C:2007 protocol and meet the test conditions required. Test reports can be submitted upon request.

Silicone Core

• FDA

The Silicone core of our CHEM-RING Encapsulated 'O' Ring complies with Part 177 of Title 21 of the Food and Drug Administration regulations for safe use as articles or components of articles for producing, manufacturing, processing, preparing, treating, packing, transporting or holding food in accordance with FDA regulation 21.CFR.177.2600. Vulcan Chem-Rings with an FDA compliant Silicone core are supplied from stock as standard and at no extra charge.

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● Restriction of Hazardous Substances (ROHS)

The restrictions of the use of certain Hazardous Substances (ROHS) Directives 2002/95/EC and 2002/96/EG came into force on 1st July 2006. Vulcan recognise these requirements and declare that all Silicone Encapsulated 'O' rings sold by Vulcan Engineering Limited do comply with the European Directives.

● Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

The EU Regulations (EC 1907/2006) came into force on 1st June 2007. Vulcan Engineering Limited are familiar with the European Regulation on chemicals being the producer of products from raw materials. The elements of our product that could be considered chemical based are in actual fact rubber, being Silicone, and is classified in the Regulations as polymers and is therefore exempt.

Vulcan can confirm Fep Silicone complies according to the SVHC list from ECHA which was updated 16th December 2013.

● USP Class VI

The Silicone core of our CHEM-RING Encapsulated 'O' Ring is in accordance with USP Protocol and meets the requirements of a USP Class VI material.

Viton ® Core

● FDA

The Viton core of our CHEM-RING Encapsulated 'O' Ring complies with Part 177 of Title 21 of the Food and Drug Administration regulations for safe use as articles or components of articles for producing, manufacturing, processing, preparing, treating, packing, transporting or holding food in accordance with FDA regulation 21.CFR.177.2600. Vulcan Chem-Rings with an FDA compliant Viton core are supplied from stock as standard and at no extra charge.



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- **Restriction of Hazardous Substances (ROHS)**

The restrictions of the use of certain Hazardous Substances (ROHS) Directives 2002/95/EC and 2002/96/EG came into force on 1st July 2006. Vulcan recognise these requirements and declare that all Viton Encapsulated 'O' Rings sold by Vulcan Engineering Limited do comply with the European Directives.

- **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**

The EU Regulations (EC 1907/2006) came into force on 1st June 2007. Vulcan Engineering Limited are familiar with the European Regulation on chemicals being the producer of products from raw materials. The elements of our product that could be considered chemical based are in actual fact rubber, being Viton®, and is classified in the Regulations as polymers and is therefore exempt.

- **USP Class 3**

The Viton core of our CHEM-RING Encapsulated 'O' Ring is in accordance with USP Protocol and meets the requirements of a USP Class 3 material.

- **USP Class VI**

Vulcan can specifically manufacture our CHEM-RING FEP/PFA Encapsulated 'O' Rings with a Bisphenol Cured Viton compound that is compliant to the USP Class VI Protocol. However, this requires a special production run of the Viton Core which involves significant production minimums and a long lead time. Please enquire but also note that we have generally found that compliance of the Encapsulation has proved sufficient for our customers.

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