

# Position Statement

## Title: Product Compliance – Silicone O-Rings

Parker Bioscience produce a range of air and gas filters for Food and Beverage and Bioscience applications. Some of these are fitted with O-rings which can be manufactured from either Silicone or EPDM.

Listed below are the regulatory approvals and recommendations applicable to the product and applications:

### Food contact compliance

FDA 21 CFR 177.2600	(including distilled water and hexane extractions)
Regulation (EC) 1935/2004	(compliance declared on the basis of FDA extraction data)
Regulation (EC) 1935/2004	(compliance declared on the basis of ResAP(2004) 5 positive lists)
Regulation (EC) 1935/2004	(compliance declared on the basis of EU10/2011 migration OML)

**Note 1** The material grade is a red compound, therefore contains a red pigment which is with FDA regulations 21 CFR 177.2600, 21 CFR 178.3297 Colourants for Polymers, and ResAP(2004)5 Silicones Used for Food Contact Applications.

### USP biocompatibility compliances

USP <88> Class VI extracted at 121°C

### Free from:

β-lactams (e.g. antibiotics such as penicillin)  
Sulphur / sulphur dioxide / sulphites  
Steroids  
Parabens  
Heavy Metals  
Alcohol  
Cytotoxins

### Animal derived ingredients:

Free from animal derived ingredients or components (ADI or ADC)

### Free from Allergens:

Peanuts / other nuts  
Eggs  
Milk  
Tree nuts  
Wheat  
Soy / soya beans  
Sesame seeds  
Seafood (fish, crustaceans, shellfish, molluscs)  
Mustard  
Celeriac  
Lupin  
Palm Oil  
Lanolin  
Formaldehyde  
Glycerine  
Protamine  
Iodine

**Additives - Does not contain:**

Latex  
Lactose  
Gluten  
Dioxin  
Epoxy derivatives  
Bisphenol A (BPA)  
Plasticisers  
Phthalates  
Polychlorinated biphenyl (PCB)  
Asbestos  
Melamine  
Dyes / Colour additives See note 2  
Preservatives  
Antioxidants  
Talc  
Quaternary Ammonium Compounds  
Dimethylfumarate (DMF)  
Genetically Modified Organisms (GMOs)

**EU - Country Specific Food Contact Recommendations**

Within the European Union, country specific recommendations, such as BfR XV, may be applied in the absence of a harmonised EU regulation. However, the silicone o-ring material meets the requirements of EU Regulation EC 1935/2004 according to the information in the Food Contact Compliance section above. For this reason, country specific recommendations are not required.

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