A guide to **Elastomer Seals**

for **Pharmaceutical, Lifescience, Food, Dairy** and **Water** industries

PPE

Precision Polymer Engineering Ltd

A Unit of IDEX Corporation IDEX CORPORATION

Precision Polymer Engineering Ltd

Precision Polymer Engineering (PPE) is a leading developer and manufacturer of high quality advanced sealing components, offering outstanding performance to the pharmaceutical, lifescience and food and dairy processing industries.

Pharmaceutical and food equipment presents some of the most demanding sealing applications. Unlike other industries where chemical or temperature resistance is the key seal selection criteria, food and pharmaceutical applications frequently have similar challenges and several more – for example the requirement never to use components which could impart taste onto the product. Elastomers used in process equipment, pumps, valves, pipe work, couplings, reaction vessels and bulk containers must be able to cope with a wide range of process media, potent active pharmaceutical ingredients (APIs) and aggressive cleaning and sterilising processes. In addition, seals must be compliant with a growing range of legislative manufacturing regulations and hygiene standards.

PPE offers a comprehensive range of sealing solutions compliant with the requirements of the Food and Drug Administration (FDA), United States Pharmacopeia - Class VI (USP Class VI) and 3-A Sanitary standards, as well as Good Manufacturing Practice (GMP) quality criteria. In addition, all PPE sealing materials are free from Animal Derived Ingredients (ADI FREE).

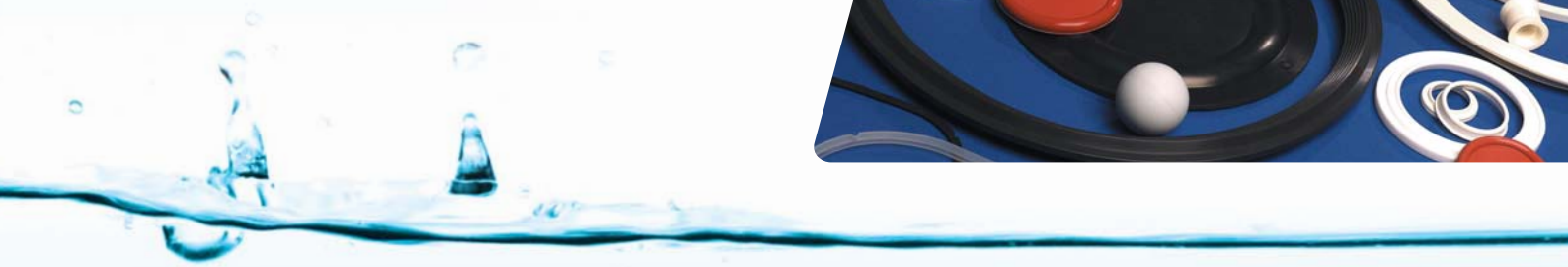
In addition to industry-standard elastomers such as EPDM and silicone, PPE has developed many new materials. One such material is the world-leading PERLAST® perfluoroelastomer, offering the widest range of chemical and temperature resistance of any perfluoroelastomer.

Seal design is an important factor in food and pharmaceutical processing. For example, O-rings are unsuitable in many cases due to the risk of bug traps. Instead, hygienic gaskets are preferred for ease of cleaning. PPE supports the guidelines for hygienic processing proposed by the European Hygienic Equipment Design Group (EHEDG) which look beyond the seal material and consider the seal in its operating environment.

With over 30 years experience of designing and manufacturing sealing components for food and pharmaceutical applications, PPE is well placed to advise on the best choice of seal material and design to meet legislative and manufacturing standards and ultimately to increase plant productivity.

Contents

PPE sets the standard in design, manufacture and materials:



Design

- Technical expertise to solve challenging sealing problems.
- Hygienic seal design and material selection for customised applications.
- Finite Element Analysis (FEA) modelling to simulate seal operation to optimise design.

Manufacture

- O-rings manufactured in all standard sizes (metric and imperial) and non-standard sizes from 0.25mm up to 2.5 metres (8ft) diameter as fully moulded components.
- Larger O-rings greater than 2.5 metres (8ft) diameter available with vulcanised joints.
- Custom hygienic seals, diaphragms, pipe couplings and gaskets.
- Custom parts moulded to customer designs or PPE-recommended solutions.
- CNC machined seals to standard seal profiles and custom-designs.
- Bonded and composite components.
- Small batch sizes and short manufacturing lead-times.

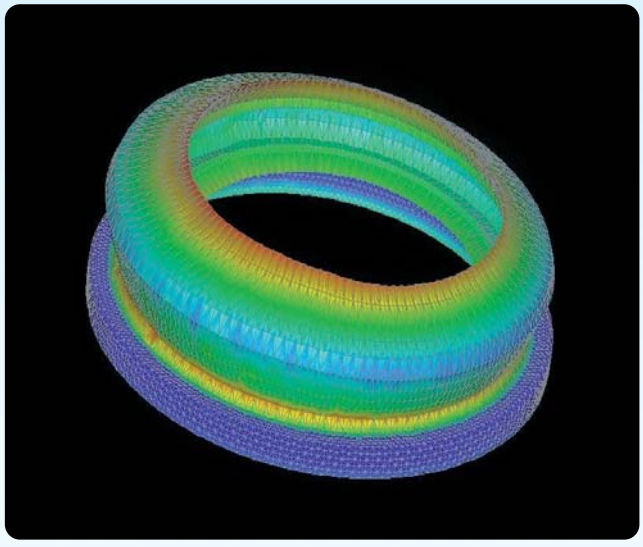
Materials

- A comprehensive range of elastomer materials and engineering plastics optimised for use in food, pharmaceutical and lifescience applications.
- Elastomer compounds to suit operating temperatures from -60°C to +310°C (-76°F to +590°F).
- Specially developed steam resistant FKMs.
- Materials compatible with virtually all process media, from standard EPDM and silicones, through to Perfluoroelastomers.
- Full traceability and certification to FDA, USP Class VI and 3-A Sanitary Standards.
- All PPE sealing materials are free from Animal Derived Ingredients (ADI-FREE).

High performance engineering plastics and elastomers

For components used in dynamic and static fluid sealing applications, PPE offers a complete sealing solution approach. With our technical expertise at your service, we can design complete sealing systems to meet your requirements, utilising a variety of engineering plastics, such as PTFE and PEEK, in addition to high performance elastomer compounds.

Certification for compliance to the appropriate specification/regulation is a pre-requisite. PPE's in-depth knowledge of elastomers and regulatory requirements ensures it is able to advise customers on the most appropriate certification.

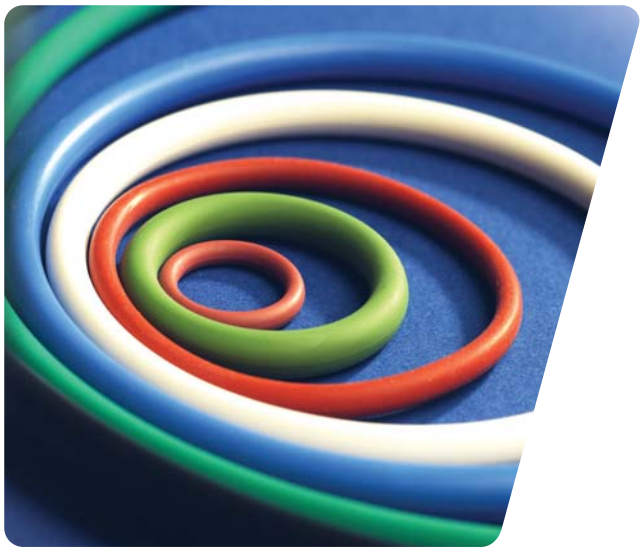


FEA model of an elastomer seal.

O-rings

PPE manufactures and supplies fully moulded O-rings in all standard sizes (metric and imperial) and non-standard sizes from 0.25mm to 2.5 metres (0.009“ to 8ft) outer diameter, and 0.8mm to 12mm (0.03” to 0.5“) cross section, both in small quantities and large volumes. For O-rings larger than 2.5 metres (8ft) in diameter, PPE offers jointed rings where the ends of lengths of cord are vulcanised to produce O-rings of limitless size.

All O-ring tooling is designed and manufactured in-house using the latest CAD and CNC machine techniques. We hold a comprehensive range of standard O-ring moulds to BS1806, BS4518, AS568 and ISO3601. For non-standard sizes we produce bespoke tooling rapidly (92% of O-ring tools are produced same day) providing cost effective solutions and a responsive service.



Encapsulated O-rings

An encapsulated seal consists of two, FDA-compliant, elements: an inflexible FEP (fluorinated ethylene propylene) or PFA (perfluoroalkoxy) jacket and a flexible internal core energiser elastomer designed to reduce the rigidity of the outer jacket and improve sealing.

Food manufacturers can select the most effective core material dependant on their particular requirements. Core materials include, VMQ Silicone, FKM fluoroelastomer, Perlast perfluoroelastomer (FFKM) and, where appropriate, hollow core silicon. Alternatively spring energised seals, utilising a high strength stainless steel core, are ideal for low temperature applications to -250°C (-418°F).

Hygienic O-ring Connectors (EHEDG)

O-ring seals for sterile screw-type connectors and flanges are manufactured to the DIN11864-1 “Form A” O-ring Union Seal (BS4825 / ISO2037 & ASME BPE 2002) standard in accordance with EHEDG guidelines.

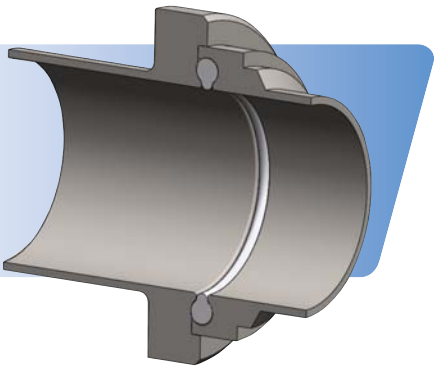
Seals for food process equipment often need to satisfy the requirements of the European Hygiene Equipment Design Group (EHEDG) for hygienic sealing. EHEDG is a consortium of equipment manufacturers, food industries, research institutes and public health authorities, founded in 1989, with the aim of promoting hygiene during the processing and packaging of food products. European legislation requires that handling, preparation, processing and packaging of food is done hygienically, with hygienic machinery in hygienic premises. EHEDG provides practical guidance on the hygienic engineering aspects of manufacturing safe and wholesome food, focusing particularly on equipment design and installation, cleanability and maintenance.

DIN11864 O-rings can be manufactured with off-set part lines to assist in achieving EHEDG approval.

DIN11864 Standard O-ring Sizes

Size Reference	Internal Diameter	Cross Section
1/2”	12	3.5
3/4”	18	3.5
1”	24	3.5
1 1/2”	37	5
2”	50	5
2 1/2”	62	5
3”	75	5
4”	100	5

Contact PPE for part number and ordering information.

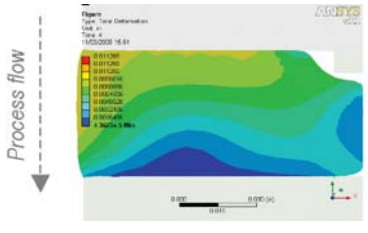


Hygienic Seal Design Advice

Hygienic seals are an integral part of food production plant and equipment. Maximising plant flexibility and reducing seal maintenance downtime is heavily dependent upon choosing the right sealing material and, of course, the seal design. PPE offers rapid prototyping, design and manufacturing technology that allows food engineers and equipment manufacturers to specify bespoke hygienic sealing solutions.

The use of finite element analysis (FEA) simulation techniques allows PPE to work closely with food engineers and equipment manufacturers to analyse, evaluate and fine tune the design of hygienic seals virtually before full production.

FEA Image 1
Seal is shown undeformed in hardware.



FEA Image 2
Total deformation plot of seal demonstrates flush sealing surface after compression and thermal expansion.

HyClamp™ Sanitary Gaskets

The **HyClamp™** range of hygienic gasket seals is specifically designed to meet the needs of pipe couplings in food, beverage and pharmaceutical process lines. Free from animal-derived ingredients, the range of **HyClamp™** elastomer materials meets various international sanitary standards and approvals, ensuring a material for every hygienic sealing application.

Engineered to deliver optimal chemical resistance to satisfy the requirements of aseptic conditions, CIP (clean-in-place) and SIP (sterilization-in-place) processes, **HyClamp™** seals provide excellent long-term sealing performance, therefore extending planned maintenance intervals and minimizing downtime.

HyClamp™ seals are manufactured to several clamp size standards conforming to current GMP (Good Manufacturing Practice) and supplied with full manufacturing batch traceability and certificates of conformity on request.

HyClamp™ elastomer seal gaskets:

- Compliant with FDA, USP Class VI and 3-A Sanitary Standards
- Free from animal-derived ingredients (ADI free)
- Optimal chemical and temperature resistance
- Excellent long-term sealing performance
- Available in 'Metal Detectable' materials
- Parts manufactured to BS4825, ISO2852 and DIN32676 standard sizes
- Tooling with non-wetted part lines to prevent bacterial build-up
- Full manufacturing batch traceability
- Certificates of conformity on request

PPE provides fast and responsive lead-times and hygienic seal design services, supported by expert material and engineering development teams.

FDA USP 3-A METAL DETECTABLE ADI-FREE

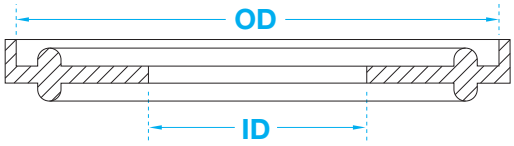
Part Number Definition

HyClamp™ part numbers are prefixed with SAN followed by four pieces of information; standard, type, size and material. This is defined as SANx-x-xxx-xxxx, for example: SANI - A - 21.3 - G75S

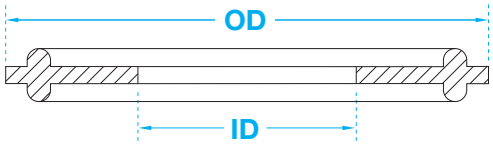
SAN	I-	A-	21.3-*	G75S
Sanitary seal prefix, non-changeable				
	Standard: I=ISO, B=BS, D=DIN, S=Special			
		Gasket model type: A=Type A, B=Type B		
			Standard nominal size* of pipe in mm (maximum 1 decimal place)	
				Material: changeable with material grade used

** For special (non-standard) parts this number should be the internal diameter of the pipe.*

Type A (lipped)



Type B (non-lipped)



BS 4825 (lipped)

Nominal Pipe Size mm	Nominal Pipe Size inch	ID mm	ID inch	OD mm	OD inch
12.7	1/2"	10.1	3/8"	25.4	1"
19.1	3/4"	16.5	5/8"	25.4	1"
25.4	1"	22.8	7/8"	50.5	2"
38.1	1 1/2"	35.5	1 3/8"	50.5	2"
50.8	2"	48.2	1 7/8"	64	2 1/2"
63.5	2 1/2"	60.5	2 3/8"	77.5	3"
76.2	3"	73.2	2 7/8"	91	3 1/2"
101.6	4"	97.8	3 7/8"	119	4 1/2"
114.3	4 1/2"	110.5	4 3/8"	130	5 1/8"
127	5"	120.7	4 3/4"	139.7	5 1/2"
139.7	5 1/2"	135.9	5 3/8"	155	6 1/8"
152.4	6"	146.1	5 3/4"	165.1	6 1/2"
168.3	6 5/8"	163.3	6 3/8"	183	7 1/4"
203.2	8"	196.9	7 3/4"	215.9	8 1/2"
219.1	8 5/8"	214.1	8 3/8"	233.5	9 3/16"
254	10"	246.1	9 11/16"	266.7	10 1/2"
304.8	12"	296.9	11 11/16"	317.5	12 1/2"

BS 4825 (non-lipped)

Nominal Pipe Size mm	Nominal Pipe Size inch	ID mm	ID inch	OD mm	OD inch
12.7	1/2"	10.1	3/8"	25.4	1"
19.1	3/4"	16.5	5/8"	25.4	1"
25.4	1"	22.8	7/8"	50.5	2"
38.1	1 1/2"	35.5	1 3/8"	50.5	2"
50.8	2"	48.2	1 7/8"	64	2 1/2"
63.5	2 1/2"	60.5	2 3/8"	77.5	3"
76.2	3"	73.2	2 7/8"	91	3 1/2"
101.6	4"	97.8	3 7/8"	119	4 1/2"
114.3	4 1/2"	110.5	4 3/8"	130	5 1/8"
127	5"	120.7	4 3/4"	139.7	5 1/2"
139.7	5 1/2"	135.9	5 3/8"	155	6 1/8"
152.4	6"	146.1	5 3/4"	165.1	6 1/2"

ISO 2852 (lipped)

Nominal Size (mm)	ID	OD	Nominal Size (mm)	ID	OD
12	10.2	34	63.5	60.5	77.5
12.7	10.9	34	70	67	91
17.2	15.4	34	76.1	73.1	91
21.3	19.5	34	88.9	85.1	106
25	22.8	50.5	101.6	97.8	119
33.7	31.5	50.5	114.3	110.5	130
38	35.8	50.5	139.7	135.9	155
40	37.8	64	168.3	163.3	183
51	48.8	64	219.1	214.1	233.5

ISO 2852 (non-lipped)

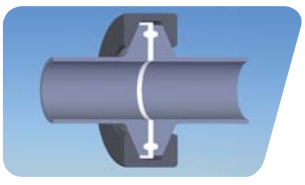
Nominal Size (mm)	ID	OD	Nominal Size (mm)	ID	OD
12	10.2	34	63.5	60.5	77.5
12.7	10.9	34	70	67	91
17.2	15.4	34	76.1	73.1	91
21.3	19.5	34	88.9	85.1	106
25	22.8	50.5	101.6	97.8	119
33.7	31.5	50.5	114.3	110.5	130
38	35.8	50.5	139.7	135.9	155
40	37.8	64	168.3	163.3	183
51	48.8	64	219.1	214.1	233.5

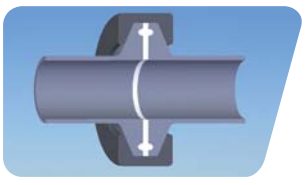
DIN 32676 (lipped)

Nominal Size (mm)	ID	OD	Nominal Size (mm)	ID	OD
10	10.2	34	65	66.2	91
15	16.2	34	80	81.2	106
20	20.2	34	100	100.2	119
25	26.2	50.5	125	125.2	155
32	32.2	50.5	150	150.2	183
40	38.2	50.5	200	200.2	233.5
50	50.2	64			

Type A (lipped)

Type B (non-lipped)



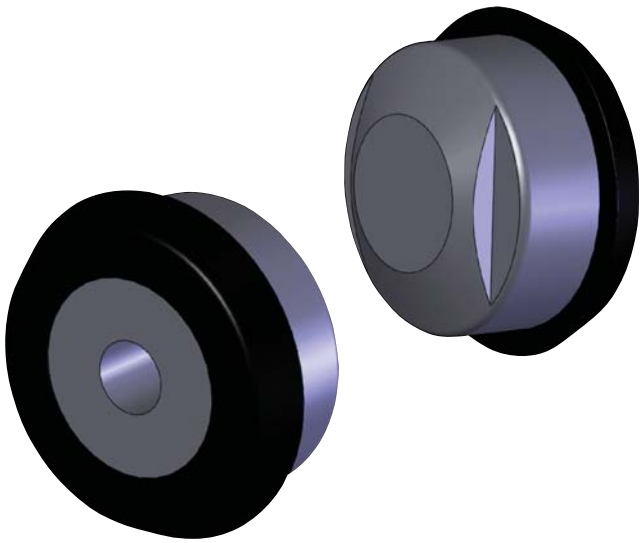


For non-standard sizes please contact our technical department for further information and advice.

Rubber-to-metal Bonded Seals

Very often in the food packaging industry, a cylinder with a varying bore diameter is used in hygienic dispensing applications. A piston operates inside the cylinder where there are small clearances and the seal interferes with the cylinder wall. During the cleaning cycle the piston is actuated to a region of the cylinder where the bore diameter is increased to ensure that there is clearance between it and the cylinder bore. This allows cleaning fluids to encompass the whole of the piston assembly and seal.

PPE offers turnkey piston assemblies where elastomer seals are moulded onto the piston to prevent bug traps. For split piston designs PPE also offers discrete solutions that are axially compressed to prevent bug traps.

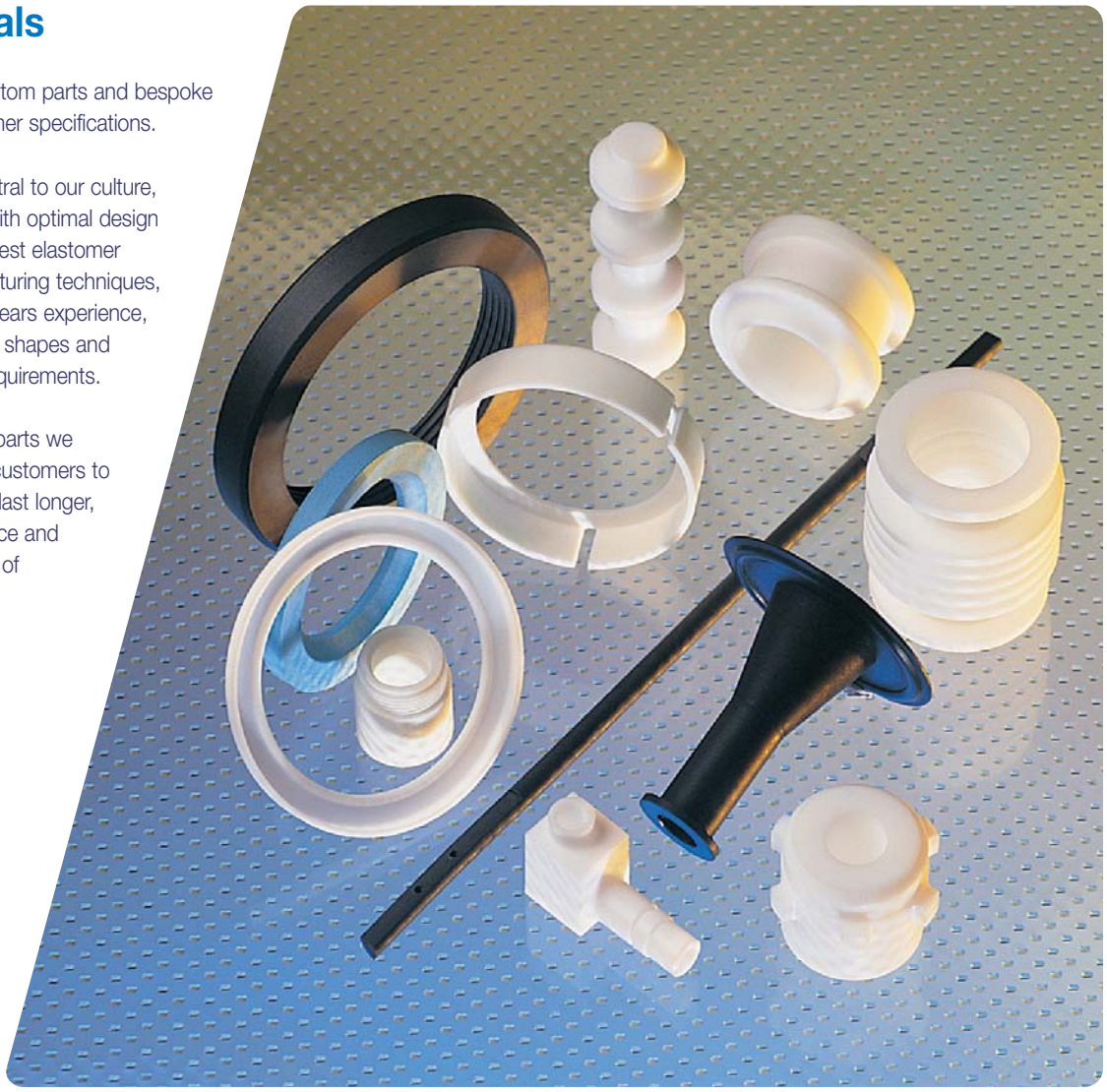


Custom Seals

PPE manufactures custom parts and bespoke components to customer specifications.

Problem solving is central to our culture, providing customers with optimal design solutions. Using the latest elastomer materials and manufacturing techniques, combined with many years experience, PPE produces custom shapes and profiles to meet any requirements.

In developing custom parts we work closely with our customers to develop solutions that last longer, require less maintenance and deliver the lowest cost of ownership.



Material Selection

Elastomer types are often referred to under standard designations/acronyms listed in ASTM D1418 and ISO 1629. The elastomer types listed below are commonly used in food, pharmaceutical and lifescience applications. The chemical resistance of various sealing materials varies greatly. The table below shows the compatibility of sealing materials with the most commonly used chemicals.

Material Type	Acids	Alkalis	Fats & Oils	Alcohol	Solvents	Amines	Steam
EPDM	2	1	4	1	2	2	1
FKM/FPM	1	4	1	1	2	4	1*
FFKM/FFPM	1	1	1	1	1	1	1
HNBR	3	2	1	2	3	3	3
Nitrile (NBR)	4	2	1	2	3	4	4
Silicone (VMQ)	4	2	2	1	4	2	3
PTFE	1	1	1	1	1	1	1
PEEK	2	1	1	1	1	1	1

Key: 1 = excellent, 2 = good, 3 = doubtful, 4 = do not use

* *Specialist steam resistant grades required.*

FFKM (Perfluoroelastomers)

Perfluoroelastomers exhibit outstanding high temperature properties and are the most chemically resistant elastomer type available. They are superior to FKM elastomers in terms of high temperature capability and are extremely chemically inert, exhibiting excellent resistance to the majority of chemicals that attack many other elastomers. Other notable properties include excellent resistance to high temperature steam and good long-term high temperature compression set resistance.

FKM (Fluoroelastomers)

This class of rubber is available as a copolymer, terpolymer or tetrapolymer; the type determines the fluorine content which directly affects chemical resistance. General properties include excellent resistance to heat, aliphatic and aromatic hydrocarbons and chlorinated solvents. Fluoroelastomers have a clear superiority in O-ring sealing force retention over most other oil-heat resistant rubbers. FKM materials can show poor resistance to ethers, ketones, esters and amines. Special compounds are required to provide suitable resistance to hot water, steam and wet chlorine.

NBR (Nitrile Rubber)

NBR copolymers consist of two monomers, acrylonitrile and butadiene. General characteristics of NBRs include excellent resistance to hydrocarbon oils, very low gas permeability, improved heat ageing and ozone resistance, high tensile and abrasion strength, hardness and low compression set.

HNBR (Hydrogenated Nitrile)

HNBR elastomers are a saturated version of NBR, showing superior heat resistance. General properties include excellent wear resistance, high tensile strength, high hot-tear resistance, low compression set and very good ozone and weathering resistance.

EPDM (Ethylene-Propylene)

EPDM rubbers are mainly available in two structures – as the copolymer (EPR), or as the terpolymer (EPDM). The properties for both types of rubber are very similar with the polymers exhibiting outstanding resistance to water and steam. These rubbers have good chemical resistance, but are not suitable for use with mineral oils. These rubbers can either be sulphur or peroxide cured. In general sulphur cured grades have superior mechanical properties and inferior high temperature properties and vice-versa for peroxide cured grades.

VMQ (Silicone)

Silicone rubbers are noted for their high and low temperature capability. They have good resistance to compression set at high temperatures. However they have poor gas permeability, tensile strength, low tear and abrasion resistance making them unsuitable for vacuum or dynamic sealing applications. Silicones exhibit high physiological inertness (tasteless, odourless and completely non-toxic) and are also resistant to bacteria, fungi and a range of chemical media. Platinum-cured silicones offer very enhanced levels of purity and low extractables making them ideal for pharmaceutical, biomedical and food & drink applications.

PTFE

Polytetrafluoroethylene is an extremely inert thermoplastic, unaffected by virtually all known solvents. It also exhibits this inert characteristic over a wide range of temperatures. Its hardness and lack of elasticity prevent its general use as an elastomeric sealing component, but it is often used as a back-up ring in high pressure environments.

PEEK

Polyetheretherketone is a semi-crystalline thermoplastic. PEEK provides high temperature performance, excellent wear and abrasion resistance properties, excellent chemical resistance and outstanding toughness and strength. PEEK is inert to all common organic and inorganic media, solvents and steam. It does, however, exhibit poor resistance to highly oxidising acids.

For further details of the chemical resistance of various elastomer materials, please consult our website **www.prepol.com** or a copy of our technical guide to elastomer compounds and chemical compatibility.

FDA-Compliant Seals

Selecting the right elastomer seal is a balance of material and design. In all cases compliance to FDA is a must. All PPE FDA-compliant compounds are produced only from FDA listed ingredients with a selection of these extraction tested for use in Aqueous and Fatty food applications.
FDA-compliant elastomers are available in the following grades:

FDA-COMPLIANT MATERIALS

ASTM Material Type	PPE Code	Hardness °IRHD	Material Description	Colour	Dry Food (A - D)	Dry and Aqueous (A - E)	Dry, Aqueous and Fatty (A - F)
NBR	N60W	60	Acrylonitrile Butadine Rubber	White	✓		
NBR	N70W	70	Acrylonitrile Butadine Rubber	White			✓
NBR	N70F	70	Acrylonitrile Butadine Rubber	Black			✓
NBR	XN7H	70	Detectaseal® Acrylonitrile Butadine Rubber	Black			✓
NBR	XN7A	70	Detectaseal® Acrylonitrile Butadine Rubber	Blue			✓
HNBR	Z70F	70	Hydrogentated Nitrile (peroxide cured)	Black			✓
EPDM	E50Q	50	Ethylene Propylene Rubber	Black			✓
EPDM	E60Q	60	Ethylene Propylene Rubber (peroxide cured)	Black	✓		
EPDM	E70Q	70	Ethylene Propylene Rubber	Black			✓
EPDM	E80Q	78	Ethylene Propylene Rubber (peroxide cured)	Black	✓		
EPDM	E60H	60	Ethylene Propylene Rubber	White		✓	
EPDM	E70H	70	Ethylene Propylene Rubber (peroxide cured)	White			✓
EPDM	E80H	80	Ethylene Propylene Rubber (peroxide cured)	White		✓	
EPDM	E81H	78	Ethylene Propylene Rubber (with PTFE)	White	✓		
EPDM	E85TMF*	85	Ethylene Propylene Rubber	Black	✓		
EPDM	XE7H	75	Detectaseal® Ethylene Propylene Rubber	Black			✓
EPDM	XE7A	70	Detectaseal® Ethylene Propylene Rubber	Blue			✓
VMQ	S40H	40	Silicone Rubber	White	✓		
VMQ	S50H	50	Silicone Rubber	White	✓		
VMQ	S60H	60	Silicone Rubber	White			✓
VMQ	S70H	70	Silicone Rubber	White			✓
VMQ	S80H	80	Silicone Rubber	White	✓		
VMQ	S70F	70	Silicone Rubber	Red	✓		
VMQ	S50T	50	Silicone Rubber	Translucent	✓		
VMQ	S75T	75	Silicone Rubber	Translucent			✓
VMQ	S71U	70	Silicone Rubber (platinum cured)	Translucent			✓
VMQ	S80U	80	Silicone Rubber (platinum cured)	Translucent			✓
VMQ	S85TMF*	85	Silicone Rubber	Translucent	✓		
VMQ	XS7H	75	Detectaseal® Silicone Rubber	Dark Grey			✓
FKM	V60H	60	Fluoroelastomer (copolymer)	Black			✓
FKM	V70H	70	Fluoroelastomer (copolymer)	Black			✓
FKM	V80H	80	Fluoroelastomer (copolymer)	Black			✓
FKM	V71H	70	Fluoroelastomer (copolymer)	Green			✓
FKM	V75W	70	Fluoroelastomer (copolymer)	White			✓
FKM	V70SW	70	Fluoroelastomer (terpolymer) steam-resistant	White			✓
FKM	V75SR	75	Fluoroelastomer (terpolymer) steam-resistant	Black			✓
FKM	V85TMF*	85	Fluoroelastomer (copolymer)	Brown	✓		
FKM	XV7H	74	Detectaseal® Fluoroelastomer	Black			✓
FKM	XV7A	70	Detectaseal® Fluoroelastomer	Blue			✓
FFKM	G60S	60	Perlast® Perfluoroelastomer	White			✓
FFKM	G74S	71	Perlast® Perfluoroelastomer	White			✓
FFKM	G75S	75	Perlast® Perfluoroelastomer	White			✓
FFKM	G80S	80	Perlast® Perfluoroelastomer	White			✓
PTFE	T99W	-	Virgin Polytetrafluoroethylene	White	✓		
PEEK	T55B	-	Virgin PEEK	Beige	✓		

Materials in blue are the most frequently specified.

* *Materials for machined parts.*

An up-to-date list of our current FDA materials can be found on our website: **www.prepol.com**
FDA certificates and material datasheets are also available to download.

The **Food and Drug Administration** is the US Federal Agency responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe.

Although the jurisdiction of the FDA is restricted to the United States, FDA regulations are commonly adopted as international control standards.

Through its Codes of Federal Regulations the FDA promulgates a list of materials and chemicals that are approved for contact with foodstuffs. CFR21.177.2600 describes the relevant regulations for 'Rubber articles intended for repeated use'. Paragraphs A - D list the ingredients, and any quantitative limits, that may be used in rubber compounds for moulded products intended for repeated use in all stages of dry food manufacture, preparation and transportation.

CFR21.177.2600 paragraphs E and F also specify limits on extractible products if the elastomer is to be used in contact with aqueous or fatty foods. The regulation specifies extraction test limits in water and n-hexane. It is important to note that for an elastomer to be compliant to these requirements, then this claim must be supported with appropriate documentation.

FDA does not 'approve' products to CFR21.177.2600. It is for the manufacturer of the finished rubber product to demonstrate compliance. It is also important to note that whilst a component may be made from a material that is suitable for food contact; this does not mean that the part is technically suitable for its intended application.

FDA ADI-FREE

Potable Water Grade Seals

WRAS

Materials approved for drinking water applications, must satisfy the requirement of BS 6920 for the **Water Regulations Advisory Scheme (WRAS)** in the United Kingdom. The testing regime for WRAS approval is different to FDA testing, in that it tests the 'Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water'. The test ensures sealing materials do not promote the propagation of bacteria or affect the colour, appearance and taste of drinking water.

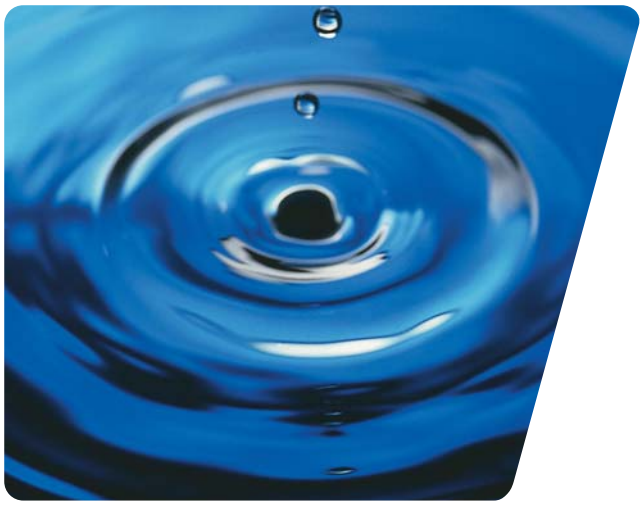
KTW

KTW specifies the requirements of elastomers in potable water as set out by the German Technical and Scientific Association for Gas and Water (DVGW) in regulation "KTW-Empfehlungen im Bereich Dicthungen D1 und D2".

PPE materials have been tested and approved in hot water (85°C). In accordance with the requirements of the KTW recommendations, the finished commodity is tested in respect of:

- its influence on the appearance quality of the water (e.g. odour, taste, colour)
- the release of its constituents into the water and
- its disinfectant demand (chlorine demand).

According to the Drinking Water Regulations (1990), drinking water shall not contain pathogens and therefore materials must be tested in hot and cold water to see if they are susceptible to the growth of bacteria and micro-organisms.



NSF / ANSI 61

NSF/ANSI Standard 61 is an American Standard issued by the National Sanitation Foundation which defines the acceptable levels of contaminating substances and impurities that may leach or migrate from components and devices into drinking water systems.

ACS XP P 41-250

Attestation de conformité sanitaire ACS XP P 41-250 is a system developed by the French health authorities to evaluate and certify the sanitary conformity and suitability of products which come into contact with drinking water destined for human consumption.

WRAS KTW ADI-FREE NSF/ANSI ACS

WATER APPROVED MATERIALS

ASTM Material	PPE Code	Hardness	Material Description	Colour	BS2494 Type'W' & WRAS BS6920		KTW D1/D2	NSF/ ANSI 61	ACS XP
					Cold water applications	Hot water applications			
EPDM	E72D	70	Ethylene Propylene Rubber	Black			✓		
EPDM	E85TMF*	85	Ethylene Propylene Rubber	Black			✓		
EPDM	E73D	70	Ethylene Propylene Rubber	Black	✓	up to 85° C	✓	✓	✓
FKM	V70Q	70	Fluoroelastomer	Black	✓	up to 70° C			
VMQ	S71U	70	Silicone Rubber	Translucent	✓	up to 85° C			
VMQ	S80U	80	Silicone Rubber	Translucent	✓	up to 70° C			

Materials in blue are the most frequently specified.

* *Materials for machined parts.*

An up-to-date list of our current potable water material grades can be found on our website: **www.prepol.com**

United States Pharmacopeia - Class VI (USP Class VI) Seals

USP Class VI-compliant elastomers are available in the following grades:

USP APPROVED MATERIALS

ASTM Material	PPE Code	Hardness	Material Description	Colour	USP Suffix 87	USP Class VI Suffix 88	
					37°C	70°C	121°C
EPDM	E50Q	50	Ethylene Propylene Rubber	Black	✓	✓	
EPDM	E70Q	70	Ethylene Propylene Rubber	Black	✓	✓	✓
EPDM	E70H	70	Ethylene Propylene Rubber	White	✓	✓	
FKM	V70SW	70	Fluoroelastomer (terpolymer) steam resistant	White		✓	
FKM	V75W	70	Fluoroelastomer (copolymer)	White	✓	✓	
FKM	V70H	70	Fluoroelastomer (copolymer)	Black	✓	✓	
FKM	V75SR	75	Fluoroelastomer (terpolymer) steam resistant	Black		✓	
VMQ	S60H	60	Silicone Rubber (peroxide cured)	White			✓
VMQ	S70H	70	Silicone Rubber (peroxide cured)	White	✓	✓	
VMQ	S71U	70	Silicone Rubber (platinum cured)	Translucent	✓		✓
VMQ	S75T	75	Silicone Rubber (peroxide cured)	Translucent	✓	✓	
VMQ	S80U	80	Silicone Rubber (platinum cured)	Translucent	✓	✓	
VMQ	XS7H	75	Metal Detectable Silicone Rubber	Dark Grey			✓
FFKM	G74S	71	Perlast® Perfluoroelastomer	White	✓		✓
FFKM	G75S	75	Perlast® Perfluoroelastomer	White	✓	✓	

Materials in blue are the most frequently specified.

The United States Pharmacopeia is the non-government organisation that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies.

Whilst this organisation is concerned with the pharmaceutical and bio-technology industries, many manufacturers of hygienic equipment will be designing multipurpose designs that may be used in a range of different industry sectors.

Standards are published in the United States Pharmacopeia and the National Formulary (USP -NF). Compliance to USP Class VI is often requested by end users. Testing for compliance involves an assessment of the effects of the material and extractables on tissue.

Two types of biological reactivity test are applicable to elastomers, plastics and polymeric materials; Suffix <87> involves in vitro testing and Suffix <88> involves in vivo testing.

USP ADI-FREE

An up-to-date list of our current USP material grades can be found on our website: **www.prepol.com**

3-A Sanitary Inc. approval for hygienic seals

PPE is one of a small number of seal manufacturers approved and audited in accordance with 3-A Standard 18-03. This standard defines the requirements for food quality materials that must be suitable for cleaning and sanitising solutions.

All of the PPE, 3-A Sanitary Standards compliant elastomers are FDA-compliant to FDA CFR21.177.2600, resistant to steam sterilisation, milk fat and water, acid and alkali cleaning solutions and chlorine sanitising solution.

The PPE elastomers meeting the 3-A standard include fluorocarbon, perfluoroelastomer, silicone, EPDM* and nitrile, allowing manufacturers to select the most appropriate elastomer to temperature, chemical and physical performance criteria.

3-A SANITARY APPROVED MATERIALS

PPE Code	Material Type	Hardness °IRHD	Colour	FDA 21.177.2600	USP Class VI	3-A 18-03 Standard	3-A 18-03 Maximum Product/Sterilisation Temp.	3-A 18-03 Maximum Chemical/Bactericidal Cleaning Temp.
V70H	FKM	75 IRHD	Black	Yes	Yes	Class I	149°C	82°C
V75SR	FKM	75 IRHD	Black	Yes	Yes	Class I	149°C	82°C
V70SW	FKM	70 IRHD	White	Yes	Yes	Class I	149°C	82°C
V75W	FKM	75 IRHD	White	Yes	Yes	Class I	149°C	82°C
S80U	Silicone	80 IRHD	Translucent	Yes	Yes	Class I	149°C	82°C
G74S	FFKM	71 IRHD	White	Yes	Yes	Class I	149°C	82°C
G75S	FFKM	75 IRHD	White	Yes	Yes	Class I	149°C	82°C
E70Q	EPDM*	75 IRHD	Black	Yes	Yes	Class II	121°C	82°C
E80Q	EPDM*	78 IRHD	Black	Yes	No	Class II	121°C	82°C
N70F	Nitrile	70 IRHD	Black	Yes	No	Class II	121°C	82°C
Z70F	HNBR	70 IRHD	Black	Yes	No	Class III	49°C	82°C

Materials in blue are the most frequently specified.

**EPDM recommended for use with maximum 8% milk fat concentration only.*

Formed by the US food and dairy industry, 3-A Sanitary Standards Inc. defines specifications and best practice for the design, manufacture, installation and use of hygienic equipment. As with FDA, the 3-A standards are adopted on a worldwide basis.

Standard no 18-03, '3-A Sanitary Standard for multiple-use rubber and rubber-like materials used in product contact surfaces in dairy equipment' describes requirements for food quality materials that must also be suitable for cleaning and sanitising.

To comply with the requirements of the Standard, the elastomer materials must comply with FDA CFR21.177.2600 and also be resistant to steam sterilisation, milk fat, acid and alkali cleaning solutions and chlorine sanitising agents.

3-A ADI-FREE

For more information or an up-to-date list of our current 3A material grades see our website: **www.prepol.com**

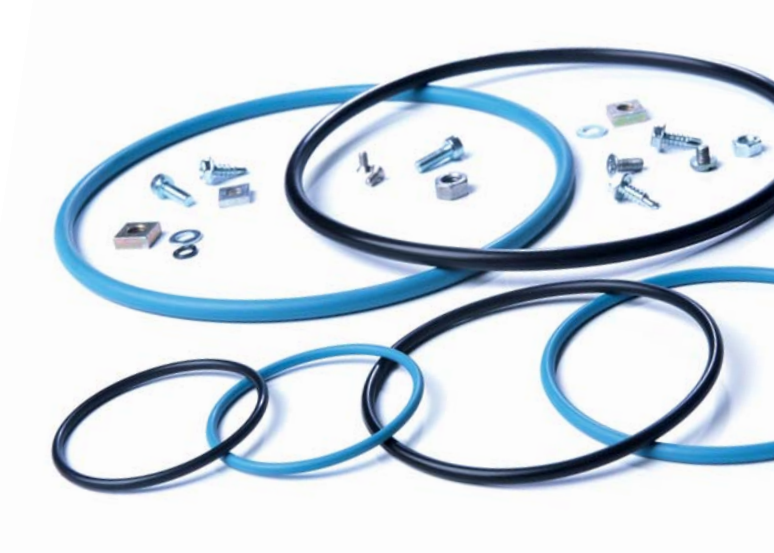
Detectaseal®

The latest advance in contamination detection and containment.

Detectaseal® provides a significant cost-effective advantage for the early detection of contamination from elastomer components. Using **Detectaseal®** can potentially save costly product recalls, damage to brand images, reputations and lost sales and profitability.

PPE has worked closely with leading industrial organisations to develop a range of **metal detectable elastomer compounds** designed specifically to meet the stringent demands of the pharmaceutical and food processing industries.

The **Detectaseal®** range includes FDA-compliant grades of EPDM, Nitrile and Fluorocarbon (FKM) compounds. Available in blue and black, **Detectaseal®** O-rings have been tested and proven in use at leading pharmaceutical and food manufacturing plants. Fragments of **Detectaseal®** as small as 2mm can be identified by in-line metal detection and X-ray equipment.



FDA METAL DETECTABLE ADI-FREE

Reduce the risk - Detectaseal® provides additional preventative measures and peace of mind.

Features of Detectaseal® materials:

- Early detection and containment of contamination
  - = Reduced product loss
  - = Increased productivity
- FDA-compliant elastomer materials
- Free from animal derived ingredients (ADI-free)
- Blue seals to assist in easy identification

Detectaseal® MATERIALS

Compound	Material Type	Colour	Hardness °IRHD	Temp Range °C	FDA A-F
XV7H	FKM	Black	74	-10 to +200°C (+14 to +392°F)	✓
XV7A		Blue	70	-20 to +200°C (-4 to +392°F)	✓
XN7H	Nitrile	Black	70	-40 to +120°C (-40 to +248°F)	✓
XN7A		Blue	70	-40 to +120°C (-40 to +248°F)	✓
XE7H	EPDM	Black	75	-40 to +150°C (-40 to +302°F)	✓
XE7A		Blue	70	-40 to +150°C (-40 to +302°F)	✓
XS7H	VMQ (Silicone)	Dark Grey	75	-60°C to +200°C (-76°C to +392)	✓

Key Materials Overview

PERLAST® G74S

FDA USP 3-A ADI-FREE

Perlast **G74S** is a white FDA, USP and 3A-compliant perfluoroelastomer (FFKM) that has been developed to provide the optimal combination of mechanical performance and solvent resistance at operating temperatures up to +260°C (+500°F). The all-round properties of Perlast **G74S** give process equipment makers and pharmaceutical manufacturers the opportunity to standardise with a single perfluoroelastomer. This allows for easier maintenance and simplified stockholding, thereby reducing costs.

The following tables show the results of immersion testing that was carried out over a period of 24 hours at room temperature in the most commonly used solvents seen in cleaning regimes and pharmaceutical processing environments.

Immersion test results showing percentage volume change: 24hrs @ 21°C (70°F).

PERLAST® G74S

Solvent	Volume Change
1-Methyl-2-Pyrrolidinone (NMP)	0.1%
4-Dimethylaminopyridine (DMAP)	0.1%
5-(Ethylthio)-1*H*-tetrazole	0.9%
Acetic Anhydribe	0.1%
Acetonitrile	0.4%
Acetone	0.2%
Amidite	0.3%
Chloroform	0.5%
Dichloromethane	1.5%
Diethanolamine (DEA)	0.1%
Dimethylformamide (DMF)	0.0%
Dimethylsulfoxide (DMSO)	0.0%
Ethylacetate	0.5%
Hexane	0.2%
Isopropyl Alcohol (IPA)	0.0%
Methanol	0.2%
Methylethylketone (MEK)	0.1%
Pyridine	0.3%
Tetrahydrofuran (THF)	1.0%
Toluene	0.3%
Trichloroacetic acid	0.3%
Trichlorobenzene (TCB)	0.0%

No negative values indicates no leachable ingredients.

PERLAST® G75S

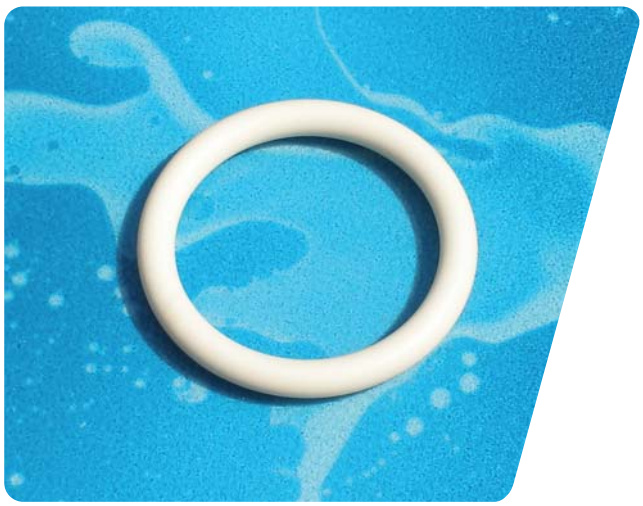
FDA USP 3-A ADI-FREE

Perlast **G75S** is a white, high temperature grade of FDA, USP and 3A-compliant perfluoroelastomer (FFKM) for operating temperatures up to +310°C (+590°F). Perlast **G75S** exhibits similar chemical resistance characteristics as Perlast **G74S** with the additional benefit of being thermally stable at higher temperatures, making it ideal for use in applications which require prolonged high temperature or steam exposure.

Immersion test results showing percentage volume change: 24hrs at elevated temperatures.

PERLAST® G75S

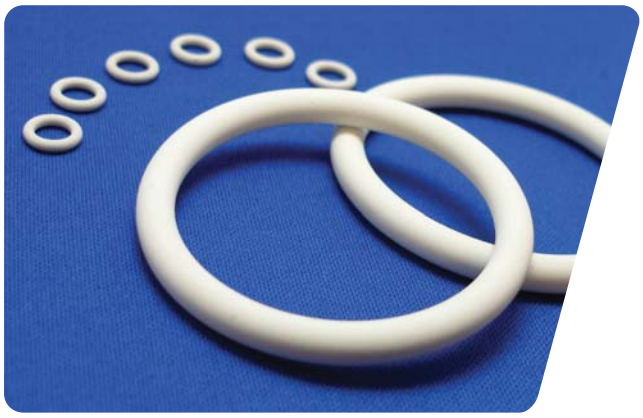
Solvent	Volume Change	Temperature
1-Methyl-2-Pyrrolidinone (NMP)	0.1%	50°C (122°F)
4-Dimethylaminopyridine (DMAP)	0.1%	21°C (70°F)
5-(Ethylthio)-1*H*-tetrazole	0.5%	21°C (70°F)
Acetic Anhydribe	0.2%	21°C (70°F)
Acetonitrile	0.1%	50°C (122°F)
Amidite	0.3%	21°C (70°F)
Dichloromethane	0.4%	35°C (95°F)
Diethanolamine (DEA)	0.8%	21°C (70°F)
Pyridine	0.4%	21°C (70°F)
Tetrahydrofuran (THF)	0.8%	45°C (113°F)
Toluene	1.3%	80°C (176°F)
Trichloroacetic acid (21°C / 70°F)	0.3%	21°C (70°F)
Steam	0.7%	120°C (248°F)



V70SW

FDA USP 3-A ADI-FREE

V70SW is a white, peroxide-cured, steam resistant, fluoroelastomer (FKM) material developed utilising the latest elastomer technology, to withstand steam-in-place (SIP) and clean-in-place (CIP) procedures within pipe work and vessels. V70SW provides optimised modulus and low compression set for maximum sealing efficiency and life. It also offers excellent resistance to a wide range of solvents & chemicals and superior steam resistance. V70SW is ideal for use in Stage II Sterilization processes which require exposure to steam up to +200°C (+392°F).



E70Q

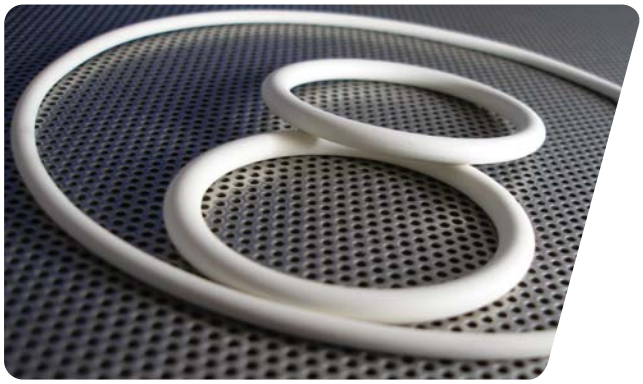
FDA USP 3-A ADI-FREE

E70Q is a black, peroxide-cured, ethylene propylene terpolymer (EPDM) that provides excellent water and steam resistance, with good compression set properties for long-term sealing performance. The thermal and chemical resistance of E70Q is superior to that of sulphur-cured EPDM materials, however its resistance to mineral oil is poor. Peroxide-cured EPDMs are normally better where retained sealing force is important, they are also considered cleaner for food and pharmaceutical applications.

S70H

FDA USP ADI-FREE

S70H is a white, peroxide-cured silicone rubber used primarily for dry heat static seals. Excellent heat resistance and low temperature flexibility make S70H effective over a wide operating temperature range -60°C to +250°C (-76°F to +482°F).



S71U

FDA USP ADI-FREE

S71U is a translucent, platinum-cured silicone rubber. Platinum-cured silicones are commonly used for seals in hygienic processing equipment as they offer higher levels of purity than peroxide and sulphur-cured materials. S71U provides excellent thermal stability over the temperature range of -60°C to +200°C (-76°F to +392°F). This high-purity, transparent grade has been developed for food contact situations plus potable water, pharmaceutical and biomedical applications.

Table of materials and physical properties

PPE Code	ASTM Material Type	FDA-Compliant	USP Class VI	Potable Water	3-A 18-03 Standard	Metal Detectable	Colour	Cure System	Hardness °IRHD	Temp range °C
E50Q	EPDM	A-F	87 & 88				Black	Peroxide	50	-40 to +150
E60Q	EPDM	A-D					Black	Peroxide	60	-40 to +150
E70Q	EPDM	A-F	87 & 88		Class II		Black	Peroxide	70	-40 to +150
E80Q	EPDM	A-D			Class II		Black	Peroxide	78	-40 to +150
E60H	EPDM	A-E					White	Sulphur	60	-40 to +150
E70H	EPDM	A-F	87 & 88				White	Peroxide	70	-40 to +150
E80H	EPDM	A-E					White	Peroxide	80	-40 to +150
E81H	EPDM	A-D					White	Peroxide	78	-40 to +150
E72D	EPDM	--		KTW			Black	Sulphur	70	-40 to +150
E73D	EPDM	--		Various			Black	Peroxide	70	-30 to +150
E85TMF*	EPDM	A-D		KTW			Black	-	85	-45 to +150
XE7H	EPDM	A-F				Yes	Black	Sulphur	75	-40 to +150
XE7A	EPDM	A-F				Yes	Blue	Sulphur	70	-40 to +150
N60W	NBR	A-D					White	Sulphur	60	-40 to +120
N70W	NBR	A-F					White	Sulphur	70	-40 to +120
N70F	NBR	A-F			Class II		Black	Sulphur	70	-40 to +120
XN7H	NBR	A-F				Yes	Black	Sulphur	70	-40 to +120
XN7A	NBR	A-F				Yes	Blue	Sulphur	70	-40 to +120
S40H	VMQ	A-D					White	Peroxide	40	-60 to +250
S50H	VMQ	A-D					White	Peroxide	50	-60 to +250
S60H	VMQ	A-F	88				White	Peroxide	60	-60 to +250
S70H	VMQ	A-F	87 & 88				White	Peroxide	70	-60 to +250
S80H	VMQ	A-D					White	Peroxide	80	-60 to +250
S70F	VMQ	A-D					Red	Peroxide	70	-60 to +250
S50T	VMQ	A-D					Translucent	Peroxide	50	-60 to +250
S71U	VMQ	A-F	87 & 88	WRAS			Translucent	Platinum	70	-60 to +200
S75T	VMQ	A-F	87 & 88				Translucent	Peroxide	75	-40 to +250
S80U	VMQ	A-F	87/88	WRAS	Class I		Translucent	Platinum	80	-60 to +250
XS7H	VMQ	A-F	88			Yes	Dark Grey	Platinum	75	-60 to +250
S85TMF*	VMQ	A-D					Translucent	-	85	-60 to +220
V60H	FKM	A-F					Black	Bisphenol	60	-20 to +200
V70H	FKM	A-F	87 & 88		Class I		Black	Bisphenol	70	-10 to +200
V80H	FKM	A-F					Black	Bisphenol	80	-10 to +200
V70Q	FKM	A-D		WRAS			Black	Bisphenol	70	-20 to +200
V75SR	FKM	A-F	88		Class I		Black	Peroxide	75	-10 to +200
V71H	FKM	A-F					Green	Bisphenol	70	-20 to +200
V70SW	FKM	A-F	88		Class I		White	Peroxide	70	-10 to +200
V75W	FKM	A-F	87 & 88		Class I		White	Bisphenol	70	-20 to +200
V85TMF*	FKM	A-D					Brown	-	85	-20 to +220
XV7H	FKM	A-F				Yes	Black	Bisphenol	74	-10 to +200
XV7A	FKM	A-F				Yes	Blue	Bisphenol	70	-20 to +200
Z70F	HNBR	A-F			Class III		Black	Peroxide	70	-40 to +180
G60S	FFKM	A-F					White	Peroxide	60	-15 to +260
G74S	FFKM	A-F	87/88		Class I		White	Peroxide	71	-15 to +260
G75S	FFKM	A-F	87/88		Class I		White	Peroxide	75	-15 to +310
G80S	FFKM	A-F					White	Peroxide	80	-15 to +260
T99W	PTFE	A-D					White	-	55 Shore D	-200 to +260
T55B	PEEK	A-D					Beige	-	-	-100 to +278

FDA Compliance: A-D = Dry Food, A-E = Dry and Aqueous Food, A-F = Dry, Aqueous and Fatty Food.

* *Materials for machined parts.*

Material datasheets can be downloaded from our website at **www.prepol.com**

Materials testing and analysis

Materials technology is at the core of the business ethos within PPE. The purpose-built **Material Characterisation Centre** includes a state-of-the-art laboratory and development cell and offers a comprehensive range of services for the development, characterisation, testing and analysis of polymeric materials.

A complete consultancy service

With the PPE Material Characterisation Centre at your disposal, we can provide a complete consultancy service including; specialist expertise, advice and assistance in material selection, material testing, sample analysis and problem-solving on any sealing matter.

Utilising the latest equipment and analytical techniques, PPE can provide detailed testing and analysis of materials. Services include failure analysis, chemical compatibility testing, thermo-mechanical evaluation and thermal performance analysis.

Elastomer sealing technology training courses

PPE conducts a range of professional development training courses, seminars and workshops throughout the year. These educational events are designed to increase the delegate's awareness of the important aspects of elastomer technology. The content of each course is industry specific and tailored to the attendees' requirements.

Events are held at PPE's purpose-built training centre in England, at delegates' own business premises (subject to a minimum group size) or at strategically located convention venues throughout Europe and the USA.

PPE training events are delivered by leading experts in the elastomer industry, ensuring that delegates receive the benefit of many years experience as well as the very latest technical know-how.

See the PPE website **www.prepol.com** for course outlines and upcoming dates.

A guide to **Elastomer Seals** for **Pharmaceutical, Lifescience, Food, Dairy** and **Water** industries

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02/11

Precision Polymer Engineering is a Unit of IDEX Corporation

Important note: This document was compiled in February 2011. Subsequent changes in legislation and other sectors may affect the validity of information herein contained. Readers are advised to check with PPE or other sources. While every effort is made to ensure accuracy, no responsibility can be taken for incorrect information.

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