TECHNICAL PAPER

The case for FFKM sealing in life science applications

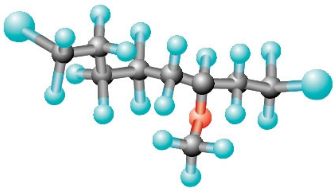
Mohammed Fiaz
Ryan McNulty

Precision Polymer Engineering

www.prepol.com

An introduction to polymers and elastomers

A polymer is a chemical compound with molecules bonded together in long, repeating chains. Because of their structure, polymers have unique properties that can be tailored for different uses.



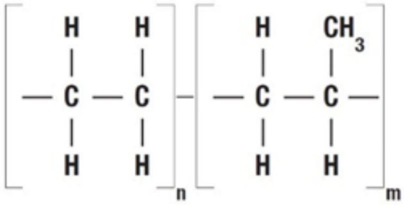
Polymers are both man-made and naturally occurring. Natural rubber, for example, is a natural polymeric material with excellent elastic qualities. Synthetic polymers include materials such as polyethylene, found in items from shopping bags to storage containers, and polystyrene, used to make packaging and disposable cups. Some synthetic polymers are pliable (thermoplastics), or permanently rigid (thermosets). Other polymers have rubber-like properties (elastomers).

Across the last seventy years, elastomer development has yielded a diverse set of materials each with unique properties, such as temperature range and chemical resistance. Elastomers derived from hydrocarbons include EPDM, nitriles and hydrogenated HNBRs (*Figure 1*). EPDM elastomers provide an outstanding resistance to water and steam, but are not compatible with oils. Nitrile elastomers have good resistance to oils, but are not suitable for water or steam applications. There are also elastomers where silica is the primary raw material, namely silicone. Silicone rubber has good low temperature resistance relative to other polymer materials, but its high gas permeability makes it unsuitable for some sealing applications.

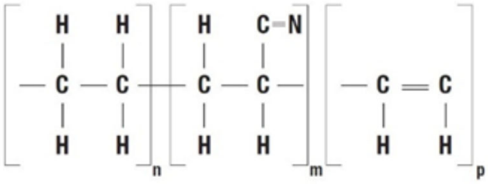
Another key set of these materials is fluoropolymers – a fluorocarbon-based polymer containing carbon-fluorine bonds. This family is characterised by a high resistance to solvents, acids and bases. The best known fluoropolymers are polytetrafluoroethylene (PTFE, plastic), fluoroelastomers (FKM) and perfluoroelastomers (FFKM).

Fluoroelastomers are widely used in sealing solutions for some of the most critical industries, including aerospace and semiconductor applications, because of their superior thermal and chemical resistance when measured against other polymer materials. There has been a recent surge in the popularity of fluoropolymer use for sealing in life science applications, including the production of food and pharmaceuticals. This progress has been facilitated through advances in filler and additive technologies, allowing these materials to pass the most stringent of industry standards and regulatory requirements demanded of life science components.

EPDM:



Nitrile Rubber (NBR) and hydrogenated nitrile (HNBR):



Silicone (methylvinylsilicone - VMQ):

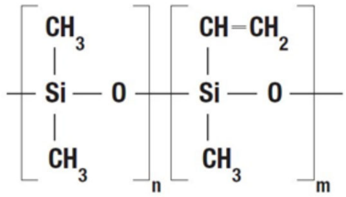


Figure 1 - Chemical structures of selected elastomer materials

Fluorocarbons: Strengths and weaknesses

Depending on the polymer composition, FKM rubber is available as a dipolymer Type 1 (according to ASTM D1418 standard) or terpolymer Type 2 and Type 3 (*Figure 2*). The type determines the fluorine content and thus the chemical resistance; Type 3 terpolymers are designed to provide improved low temperature flexibility, thus extending the minimum service temperature. FKM polymers can also be classified according to their vulcanization chemistry, namely bisphenol AF curing for better high temperature service and peroxide curing for improved resistance to aqueous environments, steam and additive containing lubricants.

Typical properties for FKM include excellent resistance to heat, aliphatic and aromatic hydrocarbons, chlorinated solvents and petroleum fluids. Fluoroelastomers have a clear superiority in O-ring sealing force retention over most of other oil-heat resistant rubbers, except for perfluoroelastomers (FFKM). FKM do show poor resistance to ethers, ketones, esters, amines and hydraulic fluid based phosphate esters. Special compounds are required to provide suitable resistance to hot water, steam and wet chlorine. FKM are typically not recommended for alkaline fluids since a C-H bond next to a C-F bond in the polymer is highly acidic and would be attacked by alkaline species.

Base resistance of fluoroelastomers

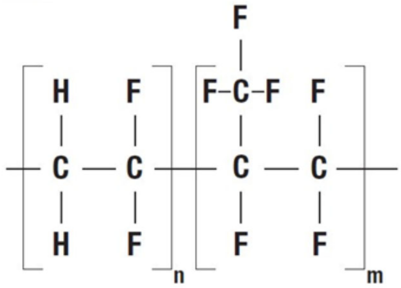
The FKM polymer consists of long chains of carbon atoms with a combination of fluorine and hydrogen atoms attached. The carbon fluorine bond is very strong but in comparison the carbon hydrogen bond is weaker. The fluorine atoms are electronegative, and want to attract all the electrons to themselves, making the electropositive hydrogen atom vulnerable to attack by any alkaline species (e.g amines or hydroxide groups). The hydrogen atom and a fluorine atom are lost via dehydrofluorination reaction, and a double bond is formed. This double bond is now a reactive site or weak point in the polymer chain and becomes more susceptible to subsequent chemical attack and to cross linking. Eventually it will result in the material becoming hard and losing elasticity.

The best base-resistant materials for use in these situations are FFKMs grades due to absence of acidic C-H bond in the polymer chain. An alternative polymer type which could be used for alkaline conditions is EPDM, but EPDM is limited considerably by temperature and the presence of oils and plasticisers which may severely inhibit seal performance.

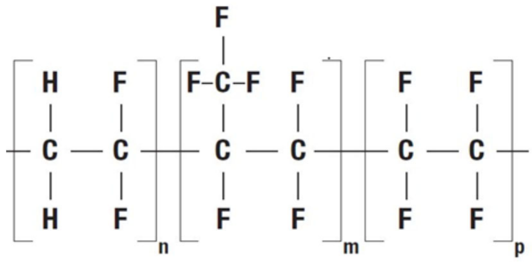
Typical applications for fluoroelastomers

Typical applications of FKM seals are valve stems, crankshafts and diesel engine cylinder O-rings in a range of industrial and automotive sectors. In life science applications, special compounds based on peroxide curable FKM would be the most suitable option, due to the steam and chemical resistance required for both process media and aggressive cleaning regimes.

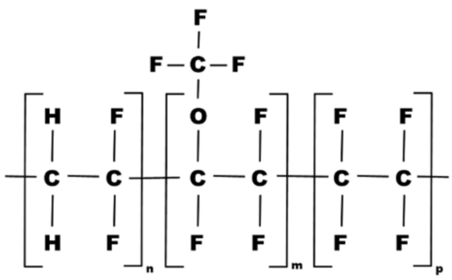
Very careful consideration is needed on specification of elastomer sealing solutions in life science, as the repercussions of 'getting it wrong' can be severe.



FKM Type 1



FKM Type 2



FKM Type 3

Figure 2 - Chemical structures of Type 1, Type 2 and Type 3 FKMs

Type	Fluorine Content	Advantages/Disadvantages
Type 1 Dipolymers (Bisphenol cured)	66%	• Contain two monomers (simple molecules from which polymer are built) • General purpose, most common, most widely used for sealing • Best compression set and good fluid resistance • Poor steam resistance • Least expensive
Type 2 Terpolymers (Bisphenol cured)	67–70%	• Contain three monomers • Better fluid and oil/solvent resistance than dipolymers but at the expense of worse compression set resistance and low temperature flexibility
Type 2 Terpolymers (Peroxide cured)	67–70%	• Contain three monomers • Better water, steam, acid and additive containing lubricants compared to the bisphenol cured FKM polymers (both Type 1 and 2)
Type 3 Terpolymers (Peroxide cured)	64-66%	• Contain three monomers with a special fluorinated vinyl ether monomer • Improved low temperature performance and similar fluid resistance as peroxide cured Type 2 FKM • Most expensive

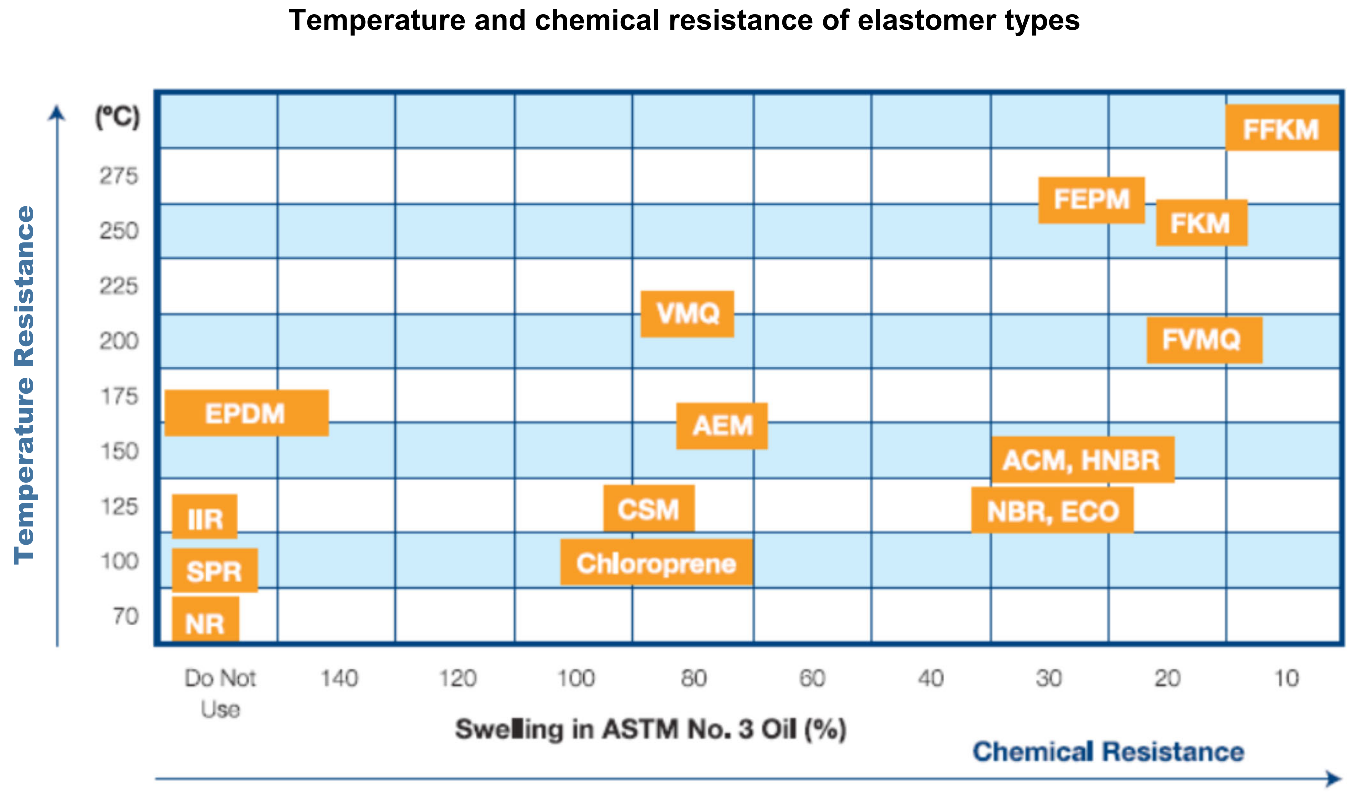


Figure 3 - Relative resistance of elastomer types in ASTM #No.3 Oil against temperature

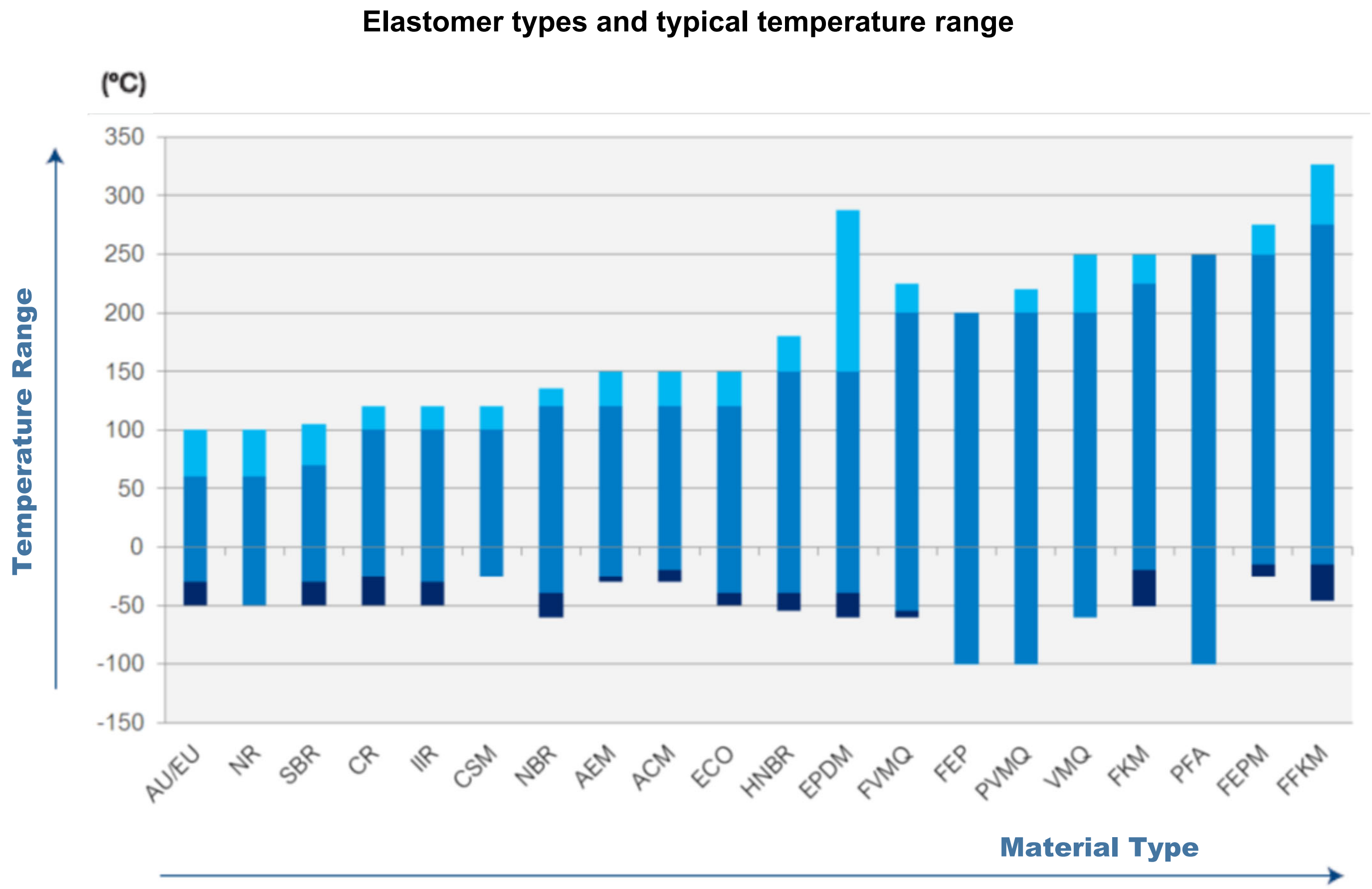


Figure 4 - Relative temperature resistance range for different elastomer types

FFKM: The next level in life science sealing?

We've seen that while FKM sealing materials can perform well under some operational conditions, they also have major limitations under others. In today's fast paced process lines, excellent sealing performance cannot be let down by unreliability, or even a sense of doubt that a sealing system might be sub-optimal.

While there are circumstances in which an FKM might fail, what is it about a perfluoroelastomer (FFKM) sealing material which produces a more reliable sealing solution?

By taking a detailed look at the comparative chemical structure of FFKM and FKM materials (*Figure 5*), note that in the FFKM we can observe a carbon-carbon polymer backbone surrounded by relatively large fluorine atoms. This structure gives a shielding effect, protecting the FFKM against virtually all types of chemical attack. We can also see the high bond dissociation energy C-F bond in the FFKM, in comparison to the weaker C-H bonds found in the FKM material. It is this more robust chemical makeup which gives FFKM materials their hallmark qualities of outstanding high temperature sealing capability, coupled with the best chemical resistance performance available on the market.

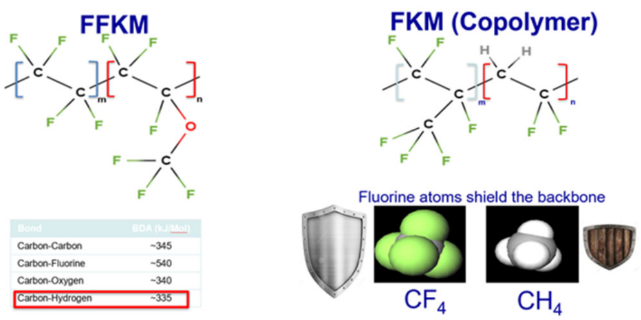


Figure 5 - Structures of FFKM and FFKM materials

It is the chemical formulation of FFKM which makes it a superior elastomer sealing option to its FKM counterpart – and particularly so in the case of life science applications. The key strengths of FFKM are a good match for the unique challenges faced by seals in food and pharmaceutical production; not only in terms of the variable thermal and chemical environments involved, but in the central importance of consumer health, and the required contribution of all process components to ensure an end product free of any contamination.

Benefits of FFKM in life science

Food and pharmaceutical manufacturing and processing is by no means the only industrial sector which places its sealing systems under such aggressive thermal and chemical pressures. Oil and gas is one such example. However, unlike other industries which also require their seals to deliver excellent long term performance in challenging environments, life science adds a human health consideration. When absolutely nothing can be left to chance, and the outcome of seal failure has a potential cost beyond the monetary, only an FFKM sealing material gives that total peace of mind to operators.

Elastomers used in life science process equipment – including pumps, valves, pipes, couplings, reaction vessels and bulk containers – must be able to cope with a wide range of process chemical media, potent active pharmaceutical ingredients (APIs) and aggressive SIP and CIP cleaning regimes. The representative table below illustrates some of the strengths and weaknesses of elastomer sealing materials in the face of common process media found in life science applications. As can be seen, the FFKM material has no chemical weakness in this respect.

Material Type	Acids	Alkalis	Fats and Oils	Alcohol	Solvents	Amines	Steam
FFKM	1	1	1	1	1	1	1
FKM	1	4	1	1	4	4	1*
EPDM	2	1	4	1	2	2	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

This table represents chemical compatibility for six prominent elastomeric sealing materials.

1 = Excellent (Volume change <10%)

2 = Good (Volume change 10-20%)

3 = Doubtful (Volume change 20-40%)

4 = Do Not Use (Volume change >40%)

* Some FKM grades are not suitable for use in steam — consult your sealing specialist for more information.

Food contact compliance

There is also the consideration of compliance. For industries with end products for human consumption, these are perhaps more exacting than any other industry. Food and pharmaceutical production is regulated by a robust legislature governing both manufacturing regulations and hygiene standards.

Sealing specialists at Precision Polymer Engineering have developed a white perfluoroelastomer (FFKM) called Perlast® G74S which is fully compliant with three of the most important industry standards in life science. These are the Food and Drug Administration (FDA), for solid, aqueous and fatty foods; the United States Pharmacopeia – Class VI <87> and <88>; and 3A 18-03 Sanitary Standard (Class 1) and its particular focus on dairy equipment.

The excellent gas and liquid permeation resistance, and good mechanical properties, are also key elements behind the suitability of FFKM grades for sealing solutions in life science applications. If material selection was purely a matter of sealing performance, an FFKM would be the best all-round choice. However, for many equipment operators when deciding on their material specification, performance is often beaten into second place by budgetary constraints. This is one area where FFKM struggles to compete with other elastomer options.

Why is FFKM so expensive?

FFKMs are the premium choice for applications demanding high-performance sealing with long term reliability. The chemical make-up of the FFKM material, with higher amounts of fluorine compared to standard FKM grades, gives near universal chemical compatibility to the FFKM, but it also serves to make the base material considerably more expensive. There is another key reason why FFKM materials cost more than the alternatives.

Many sealing materials (e.g. EPDM, NBR, FKM) have low molecular weight species additives in the compounds. These additives are either part of the cure package, or have been incorporated to aid processing. At elevated temperature these low molecular weight species can be released from a seal, resulting in a hardening effect and a subsequent loss of elasticity and sealing. At ambient conditions the predominant leached substances are water vapor and hydrocarbons, with an increased rate of out-gassing or leaching at higher temperatures. This in turn increases the permeation rate, and can even initiate chemical reactions within the elastomer which release other gases. These substances can condense onto surfaces in the process equipment, or react with process chemicals and process media – unwelcome in all industries and applications, but particularly prohibitive in life science when the purity of the end product is paramount.

FFKM, on the other hand, is a markedly cleaner material than its alternatives. FFKM materials have very few, if any, low molecular weight species added during the compounding step of material production. With this material purity comes a much lower outgassing rate, as well as the outstanding chemical resistance demonstrated by FFKMs. This unrivalled purity of material is represented in the elevated cost of FFKM grades, relative to other elastomers.

FFKM – a cost-raiser or a cost-saver?

When choosing and specifying a seal material, particularly between FKM and FFKM grades, given a comparison matrix it is all too easy to be drawn to one column in particular – price. However, is a short term cost saving on FKM neglecting the long term savings on equipment downtime, unscheduled maintenance and increased contamination risk which comes with an incorrectly specified material grade.

FKM material grades are utilised in life science sealing systems, and when specified correctly by an experienced sealing specialist, they can provide many years of incident-free sealing performance. However, potential difficulty can arise when an FKM has been recommended as a material based on one performance metric, without a deep working understanding of how other factors (temperature, pressure, dynamic vs static etc) might impact that value. It is a complex calculation which costs time and money to get right. With an FFKM, there is a considerable safety buffer.

With the selection of a higher-rated FFKM in a life science sealing system, there is not only the peace of mind which comes with operating a safer process line, but the sizeable cost savings of increasing time between maintenance, replacement and overhaul windows.

We should also consider the cost benefits of standardising to FFKM from an organisational standpoint. Having a standardised sealing material able to be deployed in any temperature or chemical environment without increased risk of seal degradation can reduce the complexity of stock management significantly.

These medium to longer term cost savings with FFKM specification have seen the material become much more popular with food and pharmaceutical facilities. In life science especially, the reputational cost to a business if a seal does fail cannot be understated. The decision to go beyond the bare minimum when sealing a process line and choosing an FFKM over an FKM or alternative material, is an important step not only to safeguarding company profitability, but to safeguarding the health and wellbeing of consumers.

Conclusion

FFKM material grades are fast becoming a mainstream choice when sealing in life science applications, including food and pharmaceutical production. Outstanding chemical resistance and temperature range are the two main reasons for this. In terms of sealing performance, in virtually any industrial operating environment, FFKM materials perform better and more reliably than FKM materials.

While FFKM materials are initially more expensive than FKM, this expense is offset to a significant degree by medium to long term cost savings for the business. The core cost saving is through the relative reliability and longevity of an FFKM-based sealing solution, increasing time between maintenance, repair and overhaul windows. Sizeable cost savings are also enabled through the potential for users to rationalize onto a single material grade across all applications. Additionally, the reduced risk of process contamination through FFKM use reduces the large financial and reputational cost of batch loss and product recall, thus offering greater protection to the consumer.

Precision Polymer Engineering has developed Perlast® G74S specifically for the unique challenges of life science applications. Perlast® G74S is compliant with FDA, USP Class VI and 3-A, proven in both static and dynamic applications, and available in O-rings, hygienic gaskets and other custom profiles.

For further information, visit www.prepol.com/perlast.

Global Headquarters

Precision Polymer Engineering
Greenbank Road
Blackburn
BB1 3EA
England

T: +44 (0)1254 295 400
E: sales@idexcorp.com

Americas

Precision Polymer Engineering LLC
PPE, Brenham, USA
3201 S. Blue Bell Road
Brenham
TX 77833
USA

T: +1 979 353 7350
E: prepol.sales-usa@idexcorp.com

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