

ERIKS sealing elements



- **High purity
FDA and USP class VI
compliant O-rings**

- **High purity elastomers
for pharmaceutical,
biochemical and food
industries**

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1. General introduction

Efficiently protecting process integrity is a challenge for all pharmaceutical manufacturers.

Today's pharmaceutical and biopharmaceutical manufacturing processes require the efficient handling of a wide range of process fluids under varying conditions of temperature and pressure. From basic chemical storage and handling to manufacturing and waste management, process lines and vessels must be resistant to a variety of fluids.

Many of these are toxic and corrosive, including raw materials, intermediate chemicals, active pharmaceutical ingredients (APIs), cleaning/sterilizing agents and by-products. What's more, during sterilization, temperatures can reach up to 160°C. Whatever the finished product, tablet, capsule, ointment or liquid suspension, the fluid-handling system plays a critical role.

Seal performance is paramount

Experience has shown that the weakest links in manufacturing processes are often the seals in couplings, flanges and other connection points in piping and equipment.

Degradation of these joint seals can result in:

- contamination of the final or intermediate products during manufacture and/or
- leakage that may require a process shutdown.

Even with the availability of specialty elastomers such as Viton® fluoroelastomer (FKM) or chemically-inert Teflon® polytetrafluoroethylene (PTFE), the problems of seal failure have not been solved. With increased awareness and stricter guidelines regarding product and environmental safety, selection of proper sealing materials is critical for maximizing production uptime. High-performance sealing materials should offer the chemical inertness and cleanliness of PTFE without sacrificing the resilience and associated sealing benefits of true elastomers.

Customer needs

ERIKS is focused on meeting customer needs and on assisting solving customer problems.

To respond to the higher needs of purity in pharma, biochemical and food industries, ERIKS developed a range of 'high purity' elastomers, described in this leaflet.

We developed a 'technical education program on 'legislation of FDA and USP' as well as on the theoretical and practical issues of migration of rubber substances.

More info on www.eriks.be.etoc

2. Classes of use FDA-USP

2.1. FDA compounds

FDA CFR § 21.177.2600 sets the standard for ensuring that foods are safe and sanitary; that human and veterinary drugs, biological products, medical devices are safe and effective.

FDA also ensures that these products are honest, accurate and are informatively represented to the public.

CFR 21.177.2600 sets out the relevant regulations for 'rubber articles intended for repeated use'. These list the ingredients that may form part of a rubber compound. The list includes elastomers, accelerators, plasticisers, fillers, emulsifiers, etc.

There are also certain quantitative limitations on different ingredients.

ERIKS FDA compounds are produced to meet class 1 for fatty foods. This means that the 'high purity' carbon black does not exceed 10%. All our compounds have been tested by an independent certified lab in Germany following the class 1 rules in n-hexane at reflex temperature. Certificates on demand.

2.2. USP compounds

USP class VI compounds are controlled by United States Pharmacopeia (USP), a non-governmental organisation that promotes the public health by establishing state-of-the-art standards to ensure the quality of medicines and other health care technologies.

The standards are published in the UP-NF which is officially recognised in FDA act (21 usc § 321 et seq.).

USP class VI compounds have undergone tests to:

- cytotoxicity
- hemolysis
- pyrogenicity
- sensitisation

Some elastomers are also formulated following the European Pharmacopeia.



3. Introduction to FDA-USP concept

3.1. General information on FDA

Since many years ERIKS has a leading role in the production and marketing of high quality seals.

ERIKS has also developed a vast range of elastomeric compounds that are formulated to comply with the regulations issued by the 'United States Federal Food and Drug Administration' (FDA). These regulations are stipulated in **Title 21, chapter 1, subchapter B, section 177.2600 of the 'Federal food and Cosmetic Act'**.

These regulations define which rubber polymers and compounding ingredients can be used in rubber articles, intended for repeated contact with food and preventing the use of dangerous substances that might cause cancer.

3.2. Types of FDA

Two important types (class 1 and class 2) of FDA exist, depending on the percentage of furnace carbon/black that is added to the compound.

Class 1: for edible oils, greasy media;

Class 2: for aqueous media.

3.3. Certification

ERIKS guarantees the 'conformity' by:

- strict production methods,
- an FDA-sticker which is put on the packaging,
- a certificate of conformity which can be obtained (on payment) with every delivery.

In general ERIKS guarantees that the FDA-materials are 'FDA-compliant' which means they are composed with ingredients according the FDA-regulations under 1.2. on this page.

3.4. Migration tests FDA

Some compounds have been tested by independent laboratories (for example 'Rapra' in England).

Rubber articles intended for repeated use in contact with aqueous food shall meet the following specifications: 'The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with distilled water at reflux 20 milligrams per square inch during the first 7 hours of extraction, nor to exceed 1 milligram per square inch during the succeeding 2 hours of extraction'.

Rubber articles intended for repeated use in contact with fatty foods shall meet the following specifications: 'The food-contact surface of the rubber article in the finished form in which it is to contact food, when extracted with n-hexane at reflux temperature, shall yield total extractives not to exceed 175 milligrams per square inch during the first 78 hours of extraction, nor to exceed 4 milligrams per square inch during the succeeding 2 hours of extraction'.

3.5. USP

USP class VI was especially developed for the pharmaceutical industry. This information has been carefully prepared to help in selecting the correct elastomer or perfluorocarbon utilized in high purity sanitary hygienic seals where critical pure water, process fluids (both ambient and hot), and SIP environment exist.

The intention is to consider the different uses, applications and conditions to determine the most favorable gasket material for each application. The following criteria is used in determining correct sanitary gasket materials.



- USP Pharmacopoeia Class VI-XXII Certification
- Cytotoxicity Criteria
- CFR Title 21 Section 177.1550
- CFR Title 21 Section 177.2600
- Traceability: Lot and Batch
- Certification: Lot and Batch
- ASME-BPE Standards
- USD Standards
- 3-A Sanitary Standards
- Current Good Manufacturing Practices (CGMP)
- Manufacturer data and specifications
- Consultation with various pharmaceutical users

The gasket materials considered are Tef-Steel® (Teflon/Stainless Steel), Teflon® (PTFE), Silicone (platinum cured), Viton®, EPDM and Buna-N.

The 3 main goals are:

- To protect products from contamination, spalling, particulates and TOCs resulting from the use of improper sanitary gasket material.
- To protect facilities from unnecessary downtime associated with sanitary gasket failure and replacement from use of improper gasket material.
- To provide a standard of consistency of sanitary gaskets selection between multiple facilities.

Most decisions driving gasket type selection are based on chemistry, temperature, exposure limits, USP, FDA qualifications, and curing methods.

4. O-rings FDA-USP

4.1. Introduction

Since many years ERIKS has a leading role in the production and marketing of high quality seals.

ERIKS has also developed a vast range of elastomeric compounds that are formulated to comply with the regulations issued by the 'United States Federal Food and Drug Administration'.

These regulations are stipulated in Title 21, Chapter 1, subchapter B, section 177.2600 of the federal food and cosmetic Act.



4.2. Types of FDA 177.2600

Two important classes (class 1 and 2) of FDA 177.2600 exist, depending on the percentage of furnace black that is added to the compound.

Class 1:

for aqueous media, edible oils and greasy media (max. 10% furnace black)

Class 2:

for aqueous media only (max. 50% furnace black)



4.3. Migration tests foll. FDA 177.2600

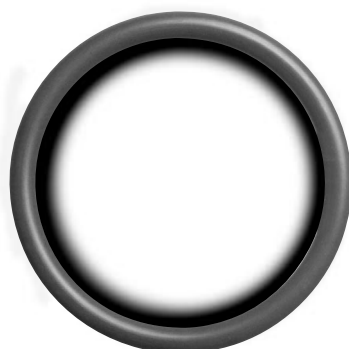
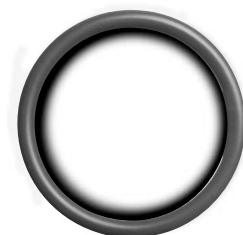
FDA regulations stipulate that FDA compounds have to be tested on migration. Indeed, rubberingredients tend to migrate into the system when brought in contact with media. Extraction of these particles is stipulated for class 1 and 2 FDA compliant elastomers.

Most ERIKS compounds are tested by independent labs and comply with these migration values (see certificate).

4.4. USP class VI-XXII

USP class VI stipulates that cytotoxicity-testes are carried out.

Our USP class VI compounds are also conform 3A, USDA, FDA and NSF51 regulations.



Ask for our FDA-USP technical manual

4. O-rings FDA-USP

4.5. Certificates

For every delivery we can send you following information on request:

- FDA sticker on the packaging
- FDA certificates with migration values
- USP sticker on the packaging



4.6. Extra Service

ERIKS offers you following extra services:

- Extra postcuring for optimal vulcanisation degree
- Cleaning with ionised water
- Custom packaging
- Barcoding



Certificate and datasheet examples:

The collage displays several key documents from ERIKS:

- Statement of Compliance:** A document from ERIKS Kalrez® (a product of DuPont Dow Elastomers) stating compliance with FDA regulations (21 CFR 177.2600) for Viton 514641. It includes technical information and a statement of compliance.
- Certificate of Certification:** A document certifying that the elastomer compounds EPDM, platinum cured silicone and Viton® from which parts are manufactured are in compliance with FDA Code of Federal Regulations (Title 21, paragraph 177.2600) and also meet the criteria of the USP Class VI material classification of the 3-A sanitary standards, USDA and Standard 51 of the N.S.F.
- Certificate of Conformity:** A document certifying that ERIKS Viton 514641 is formulated to comply with the regulations (Title 21, paragraph 177.2600) of the Federal Food and Drug Administration (FDA) for use in rubber articles intended for repeated contact with food. It lists FDA test results for various extraction methods.
- Technical Data Sheet:** A detailed document for Viton 514641, including physical properties, chemical resistance, and other technical specifications.

5. FDA-USP compounds, O-rings and mouldings

1. Moulded O-rings, class 1 (less than 10% furnace black)

These can be produced in all possible dimensions up to diameter 1400 mm internal. Table 1 shows our standard programme FDA compliant compounds which can be produced in a few days.

All O-rings are produced following DIN 3771 part 1-ISO 3601/1.

Note:

- Other FDA compounds in other hardnesses or qualities are also available in smaller quantities but with a slightly longer delivery time.
- USP XXII, class VI O-rings available in Silicone translucent. Other compounds on request.
- Black compounds are produced with less than 10% high purity furnace black.



2. Vulc-O-rings FDA class 1 (less than 10% furnace black) and moulded O-rings

Vulc-O-rings are produced in small quantities. Inside diameter from 30 mm up to 5.000 mm in different cross section diameters from 1,78 up to 25 mm. For silicone up to 40 mm diameter. No chemical additif is added in the bonding of the core-ends. Datasheet on request.

3. Kalrez®

The ultimate pure compound for SIP and CIP applications in pharma and food up to 275°C.

FDA and USP class VI compliant.

Note:

All O-rings are produced foll. DIN 3771 part 1 - ISO 3601/1

Table 1: Compounds FDA

Compound	Quality	Class	Hardness	Migration tested	Colour
Viton® 514670	Viton®	1	70	Yes	black
Viton® 514680	Viton®	1	80	Yes	black
Viton® 514690	Viton®	1	90	Yes	black
Viton® 514672	Viton®	1	70	Yes	white
Viton® 514674	Viton®	1	70	Yes	blue
Viton® 514694	Viton®	1	90	Yes	blue
Viton® 514676 USP class VI	Viton®	1	70	Yes	white
EPDM 559273 USP class VI	EPDM	1	70	Yes	black
EPDM 559274 USP class VI	EPDM	1	70	Yes	white
EPDM 559270	EPDM	2	70	Yes	black
EPDM 559272	EPDM	1	70	Yes	white
NBR 366470	NBR	1	70	Yes	black
NBR 366480	NBR	1	80	Yes	black
NBR 366490	NBR	1	90	Yes	black
NBR 366472	NBR	1	70	Yes	white
HNBR 886972	HNBR	2	70	Yes	black
Sil 714748	Silicone	1	40	Yes	red
Sil 714747	Silicone	1	40	Yes	transl.
Sil 714742	Silicone	1	40	Yes	white
Sil 714767	Silicone	1	60	Yes	transl.
Sil 714768	Silicone	1	60	Yes	red
Sil 714762	Silicone	1	60	Yes	white
Sil 714787	Silicone	1	80	Yes	transl.
Sil 714788	Silicone	1	80	Yes	red
Sil 714782	Silicone	1	80	Yes	white
Sil 714001 USP class VI	Silicone	1	70	Yes	transl.
Sil 714002 USP class VI	Silicone	1	70	Yes	transl.

Table 2: Compounds Vulc-O-ring FDA or USP

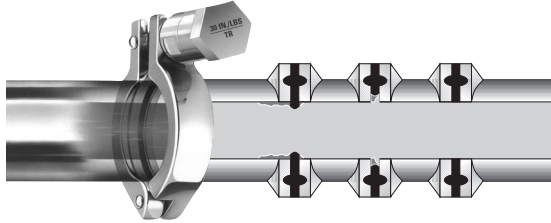
Compound	Quality	Class	Hardness	Migration tested	Colour
366185	NBR	1	75	Yes	black
514152	Viton®	1	75	Yes	black
559187	EPDM	1	75	Yes	black
714203	Silicone	1	75	Yes	red
329303	Neoprene®	1	75	Yes	black
Teflex / Silicone *	FEP/Silicone	1	-	Yes	red
714006 (3A)	Silicone	1	75	Yes	red
Teflex / Viton® *	FEP/Viton®	1	-	Yes	black
Teflex/EPDM	FEP/EPDM	1	-	Yes	white

* : FEP encapsulated in FDA 177.1550 and USP XXII, class VI



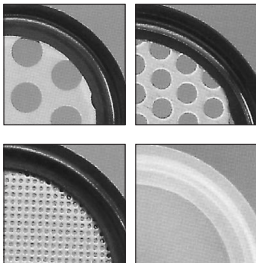


Table 3: Kalrez® FDA or USP

Compound	Quality	Class	Hardness	Migration tested	Colour
Kalrez® 6221	FFPM	1	70	Yes	white
Kalrez® 6230	FFPM	1	75	Yes	black

6. FDA-USP compounds, High Purity Seals Card



HIGH PURITY SEALS CARD

<i>PRODUCT SERVICES</i>	<i>TECHNICAL SUPPORT</i>	<i>PACKAGING</i>	<i>CERTIFICATES</i>	<i>INVENTORY SYSTEMS</i>
O-rings	Application Engineering	One by one	FDA 177.2600	Kanban
Oil seals	R & D	Clean Room	FDA 177.1550	Local branch
PTFE seals	Product Search	Barcode	USP class VI	In plant shop
Rubber parts	Technical Data	Your ID number	USDA	Express production
Clamp seals	Independant labs	FDA or USP labels on packaging	NSF	Kitting
Hydraulic seals			KTW-BGVV	e-business
Rubber profiles			KIWA	Just-in-time
			WRC-ACS	EDI
			Cytotoxicity testing	
			3A standards	
			Namsa	
			Full Traceability	
				

Ask for our High-Purity Triclovergaskets handbook

7. Approved compounds for potable water

Compound	Code	Approval	Approved Shore Hardness
NBR -25/+100°C	366320	DVGW-W270 KTW NSF61 ACS NF FDA 177.2600 WRC WRAS FDA 177.2600 DIN-EN 549 gas	70
EPDM (PEROX) -55/+150°C	559970	WRC WRAS for 85°C ACS NF KTW for 90°C NSF61 FDA for 82°C DVGW-W270 for drinking water EN681 WB FDA 177.2600	70
FKM (Viton®) -15/+200°C	714320	WRC WRAS FDA 177.2600 KTW DVGW NSF61 ACS DIN-EN549 for gas	70
SILICONE (VMQ) (*) (**) -60/+220°C	514320	WRC WRAS for 85°C KTW for 90°C NSF61 ACS NF FDA 177.2600 DVGW-W270 FDA 177.2600	70

- Many ERIKS compounds are produced following international norms (see addendum).
- Quality security in all production sites worldwide.
- EPDM 5599 to compound is specially compounded with very low lubricant % so that tensioncorrosion on plastic parts is excluded.
- Application in valves, fillings, couplings, fluidconnectors, pipesystems, etc.
- Optimal lifetime due to intensive compound research.

ERIKS compounds for potable water

	Food / Pharma FDA	Potable water KTW	Potable water ACS	Potable water WRAS	Potable water NSF61	Potable water DVGW W270
EPDM 55111	x	x	x	x	x	x
NBR 366320	x	x	x	x	x	x
FKM 814320		x	x	x	x	
Silicone 714320	x	x	x	x	x	x

7. Approved compounds for potable water

EPDM 559970 PC FDA - Technical Data Sheet

1. Introduction

The ERIKS compound EPDM 559970 PC FDA is a

2. Product Description

<i>Chemical Composition</i>	: Terpolymer ethylene / propylene
<i>Physical form</i>	: O-rings/mouldings
<i>Color</i>	: Black
<i>Storage stability</i>	: max. 10 years

3. Physical Properties

<i>Test Method</i>	<i>Norm</i>	<i>Test Values</i>
Hardness	DIN 53519	70° ± 5° IRHD
Specific Weight	ASTM D 1817	1,13
Elongation at break	ASTM D 412 C	160%
Tensile Strength at break	ASTM D 412 C	16 N/mm ²
Compression Set		
22h/150°C	ASTM 395B	9%
3.000h/110°C	DIN ISO 815 (in water)	10%
Change in air / 70h/100°C	ASTM D 471	
Hardness change		-1°
Volume change		+1,5%
Weight change		+1%

4. Temperature Resistance

- -55° to +150°C
- TR10 (low temp. resistance): -36°C

5. Chemical Resistance

Alkali	: very good
Alcohol	: good
Ethers	: fair
Fats	: unsatisfactory
Hydrocarbons	: unsatisfactory
Esters	: unsatisfactory
Air	: very good
Oils	: unsatisfactory
Ozon	: excellent
Water	: excellent
Steam	: good up to 130°

6. Advantages

Very low compression set

7. Other Information

- In compliance with:
 - ACS
 - DVGW-W270
 - EN 681-1
 - following FDA 21 CFR 177.2600
 - KTW
 - NSF 51 and 61
 - WRC



8. The high purity Kalrez® O-ring concept

Kalrez® perfluoroelastomer parts improve sealing for today's processes

To meet the demand for greater sealing integrity while maintaining process purity, DuPont Dow Elastomers has a family of high-performance perfluoroelastomer sealing materials uniquely suited for pharmaceutical medical manufacturing. Similar to PTFE in cleanliness, heat and chemical resistance, Kalrez® has the resilience and compressive strength that are characteristic for frequently used materials such as ethylene propylene polymers (EPDMs), fluoroelastomers (FKMs) and silicone rubber.

With its combination of thermal/chemical performance and rubberlike sealing ability, Kalrez® offers the pharmaceutical industry a new level of protection against process contamination and seal failure. Multi-purpose Kalrez® seals increase process and equipment flexibility and may make it possible to standardize on a single seal material for all process environments.

Kalrez® compounds 6230 (black) and 6221 (white) have been developed to meet the unique sealing needs of today's high-speed, fully automated pharmaceutical and biopharmaceutical manufacturing processes. Kalrez® parts are manufactured by DuPont Dow Elastomers to ensure excellent quality, cleanliness and performance.

FDA and USP compliancy

The U.S. Food and Drug Administration (FDA) confirmed the compliance of Kalrez® 6221 and 6230 for repeated use in contact with food by Food Contact Notification (FCN) 000101. FCN 000101 was established through the FDA Premarket Notification Process for food contact substances as described in section 409(h) of the Federal Food, Drug, and Cosmetic Act 21U.S.C.348(h)) and is the primary method by which the FDA authorizes the use of food additives that are food contact substances. FCN 000101 requires materials to have extractable levels less than 0.2 mg/in². Kalrez® 6221 and 6230 have also been tested in accordance with United States Pharmacopeia Class VI (USP Class VI) and met those requirements.



8. The high purity Kalrez® O-ring concept

Providing new standards of protection against contamination and process interruption.

Unmatched resistance to aggressive process chemicals.

Kalrez® is unmatched in its resistance to a broad range of fluids, manufacturing chemicals and aggressive waters commonly used in pharmaceutical processes. Its near-universal compatibility with over 1800 chemicals provides added insurance against exposure to proprietary or unknown ingredients.

Acids, bases, solvents, and amines are among the many corrosive chemicals that can be safely handled by Kalrez® seals. Kalrez® does not readily absorb liquids or solids present in the process stream. This protects against premature seal failure due to swelling and loss of mechanical properties while minimizing the chance for product contamination due to chemical desorption of previously used chemicals from the elastomer seals.

Each type of elastomeric seal can be different depending on the grade of elastomer used as well as how it was formulated and manufactured. ‘Food Grade’ O-rings were obtained from the marketplace and tested along with Kalrez® 6230 and 6221 O-rings. It should be noted that EPDM can be less resistant to mineral oils and aromatic hydrocarbons; silicones to solvents, oils, concentrated acids and dilute sodium hydroxide; and FKM to amines, some bases and alcohols - depending on the formulation. Steam resistance can also be affected by te grade and formulation used.

Extremely low extractables

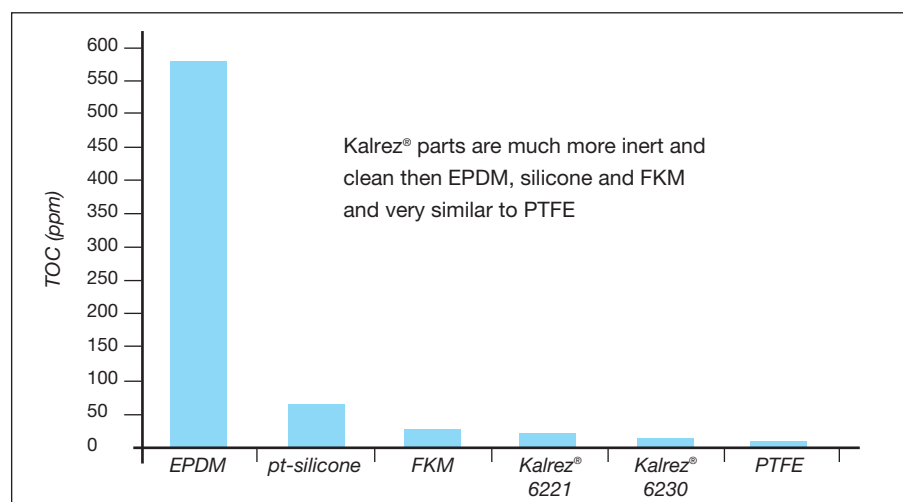
Kalrez® compounds contain fewer extractable materials (additives and fillers) than other elastomer seals. This significant difference reduces the risk of product contamination by ingredients leached from a sealed joint by the process flow. Total Organic Carbon (TOC) testing was used to show the levels of organic extractables of the various materials - Kalrez® parts are much more inert and clean than EPDM, silicone and FKM and very similar to PTFE.

Kalrez® seals have low volume swell for better sealing functionality

Chemical	Temp (°C)	EPDM	pt-Si	FKM	Kalrez® 6230	Kalrez® 6221
Hexane	60	41	4	6	7	7
Acetic Acid	100	135	1	199	3	19
Acetone	50	-6 (*)	2	65	4	3
Ethanol	60	-9 (*)	10	18	1	1
Ethylene Carbonate	100	-3 (*)	0	64	0	0
Toluene	100	155	50	86	6	6
Glycerol	100	0	1	0	0	0
Benzyl Alcohol	100	-7 (*)	2	10	1	1
Ethyl Acetate	60	3	11	118	5	5
Methanol	60	-5 (*)	-2 (*)	67	1	1
20% Nitric	100	139	-2 (*)	309	1	10
15% NaOH	100	0	0	10	1	1

(*) = < 0% volume swell (desorption)

Kalrez® 6221 and 6230 have extractable levels compared to PTFE



EPA method 415; TOC tests performed on 1” sanitary seals, immersed in 50 ml of sterile WFI at 100°C/24hrs. The solution was then diluted to 100 ml and analysis.

8. The high purity Kalrez® O-ring concept

Delivering high-temperature stability and long-term elasticity

Properties:

Kalrez® seals based on 6230 and 6221 deliver outstanding performance in high-temperature service (up to 260°C), even after exposure to aggressive chemicals and fluids. This means that Kalrez® provides a measure of safety, because it can comfortably operate in the middle of its temperature range, rather than near its temperature limit.

Sealing force retention (force under constant stress) and compression set resistance are standard test methods used to predict seal longevity. Kalrez® seals have good compression set resistance in process fluids at elevated temperatures. In long-term testing of sealing force, Kalrez® and FKM retain their sealing force better than both EPDM and silicone at 140°C in hot air. FKM, however, can be limited in certain fluid and steam conditions, depending on the type and formulation.

Permanent deformation is the major draw-back of seals made from PTFE and other non-resilient thermoplastics. Over time, these materials will undergo compression set or ‘creep’, and lose their sealing force, even under moderate temperatures and loads. As a result, thermoplastic gaskets must be re-torqued to maintain a leak-proof joint. In most cases, plastic seals cannot be reused because surface deformation and leak paths are permanent. Kalrez® seals are made from a true elastomer; they maintain long-term sealing force and are inherently resistant to permanent deformation or compression set.

Kalrez® 6230 retains its sealability in harsh conditions

<i>Chemical</i>	<i>Temp (°C)</i>	<i>EPDM</i>	<i>pt-Si</i>	<i>FKM</i>	<i>Kalrez® 6230</i>
Acetic Acid	100	30	73 (*)	100 (*)	18
Acetone	50	27	-2	-121	23
Ethanol	60	28	5	14	26
WFI (water)	100	68 (*)	81 (*)	94 (*)	40
Benzyl Alcohol	100	54 (*)	21	27	22
Ethyl Acetate	60	11	-3	-109	11
Methanol	60	30	14	-84	25
20% Nitric	100	62 (*)	99 (*)	49	2
15% NaOH	100	52 (*)	75 (*)	60	25

(*) = > 30%

8. The high purity Kalrez® O-ring concept

A winning combination of cleanliness, integrity, quality and traceability

For over 30 years Kalrez® has demonstrated its value in critical applications in the chemical process, semiconductor, oil and gas recovery and aerospace industries. It has provided the most cost-effective solutions for high-performance sealing applications where other seals have failed.

The entire Kalrez® manufacturing process, from base polymer to finished seal, is controlled by one company, DuPont Dow Elastomers, under strictest standards of quality control (ISO 9001). This supply chain integration is unique among seal suppliers.

Formulations of Kalrez® tend to be more polymer-rich than most other types of elastomer compounds, resulting in fewer ingredients to extract or leach into a process. Kalrez® assures that you get the same formulation every time. Other elastomers have several different grades or compositions. The combination of grade, filler, cure system, etc., can affect finished part performance (such as resistance to steam). Finding a reliable supplier willing to certify and provide documentation is important in the pharmaceutical industry. Every Kalrez® seal is packaged individually, bar coded and 100% traceable back to raw materials.

Versatility increases flexibility and standardization

A seal material with broad chemical and temperature capabilities not only minimizes contamination and production problems, but also helps reduce the costs of routine maintenance and inventory control. Standardization on a single sealing material may allow the exchange of equipment 'mini modules' without the need to retrofit seals. In new drug development programs or analytical laboratories involving the use of unknown or proprietary fluids, a sealing material with broad chemical versatility can be especially useful.



9. Elastoguard Anti-microbiological growth - problems and solutions

The most significant breakthrough ever in antimicrobial rubber technology

Imagine a situation where the rubber components you incorporate into your products; that form part of your production line; or you include in your plant specification; require much less costly labour-intensive, routine inspection and sterilisation treatment than they currently demand. Imagine rubber that inhibits the growth of any micro-organism; bacteria, fungi or algae and will deter it from contaminating or colonising its surface. Imagine the valuable, virtually unique marketing benefits and added value your products would enjoy.

Imagine the savings on downtime, lost production and maintenance costs. Just imagine how such a technically advanced antimicrobial rubber could improve your products, your productivity, your profitability.

Elastoguard is not imagination. It is reality. Available now.

Products:

- O-rings
- Oilseals
- Profiles
- Sheets
- Mouldings

Standard Elastoguard RX Types:

- Elastoguard RX EPDM 70 black
- Elastoguard RX Viton® 70 black
- Elastoguard RX Silicon 70 red

Elastoguard explained

The growth of microbes on rubber surfaces can lead to foul odours, discolouration, the formation of mildew and slime.

Another potential effect of microbial contamination on rubber components is serious surface degradation; a process that can significantly reduce the component's operational lifespan.

Traditional protection against microbial contamination involves thoroughly cleaning and washing with hot water and detergent. Such cleaning procedures, especially where the rubber components are sited in difficult to access locations, can be costly and time consuming. What's more, these procedures do not offer residual protection against further contamination.

Very often, to ensure compliance with health and hygiene regulations, rubber components are simply scrapped and replaced, frequently at significant expense.

Elastoguard is a pro-active antimicrobial rubber that provides residual protection against microbial contamination, thereby dramatically reducing the necessity for a traditional routine decontamination service agenda.

Innovative patent pending technology

Developed by Milliken Chemical Speciality Elastomers, Elastoguard's innovative patent pending technology can be produced in a wide range of specialist compounds to meet a broad spread of needs. It incorporates a **zirconium phosphate-based ceramic, ion-exchange resin containing silver**, which is acknowledged to be safe for human contact, and is recognised for its antimicrobial effectiveness against a broad spectrum of micro-organisms. Unlike most organic biocides, Elastoguard can be used in food contact situations and is designed for use in pharmaceutical and medical industries.



9. Elastoguard Anti-microbiological growth - problems and solutions

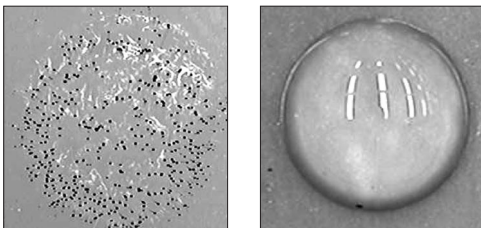
Non-leaching

This antimicrobial agent forms an integral part of the rubber compound. It is not simply a skin or liner, and therefore the antimicrobial properties always remain active. Furthermore, any abrasion or wear to the surface of the rubber actually increases the exposure of the silver and with it the efficacy of its antimicrobial qualities.

- Designed for use in pharmaceutical and food processing technology, water treatment, medical equipment, beverage production and dispensing, and for close human contact.
- Provides effective microbial protection against a broad spectrum of micro-organisms.
- Available in a wide range of technical rubber compounds.
- Can be incorporated as part of a customised compounding facility.
- Forms an integral part of the rubber compound, is durable and non-leaching.
- Does not affect colour stability of the compound.
- Has no taste. Contains no smell.
- Non-toxic, non-flammable, non-corrosive.

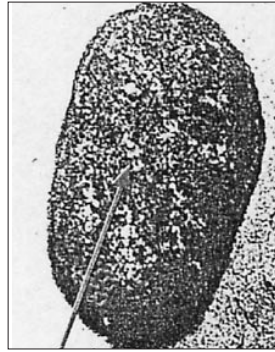
Proven Elastoguard efficiency is supported by substantial technical data

Pictures show contaminated water droplets. The sample on the left, which is on an untreated rubber surface, displays healthy growth of fungi. The sample on the right, exposed to silver ions in Elastoguard rubber, is virtually clear of any fungal contamination.

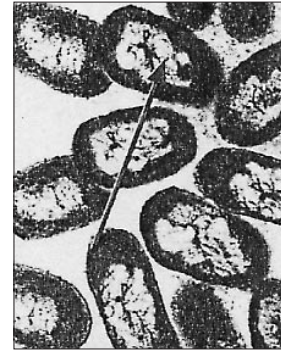


Ask for our technical programme in your company

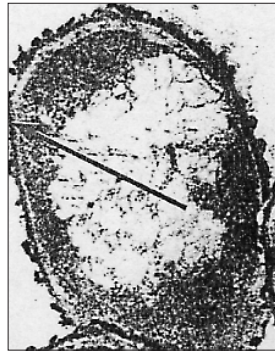
The effect of silver on healthy bacteria



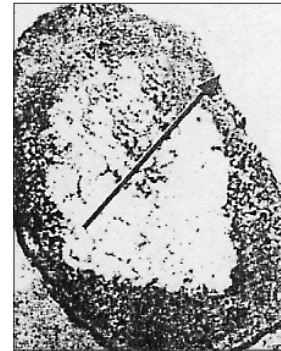
Healthy bacteria



DNA condenses on itself

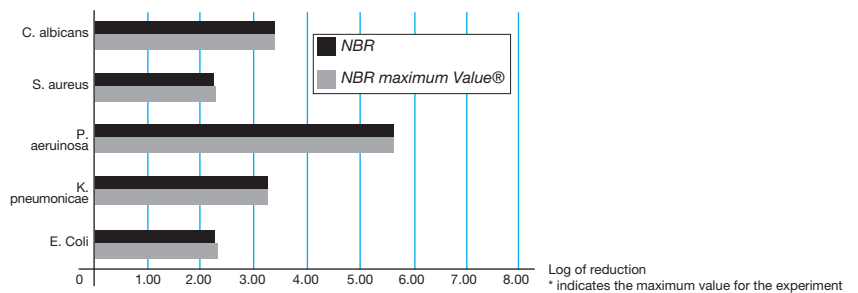


Formation of electron dense granulate

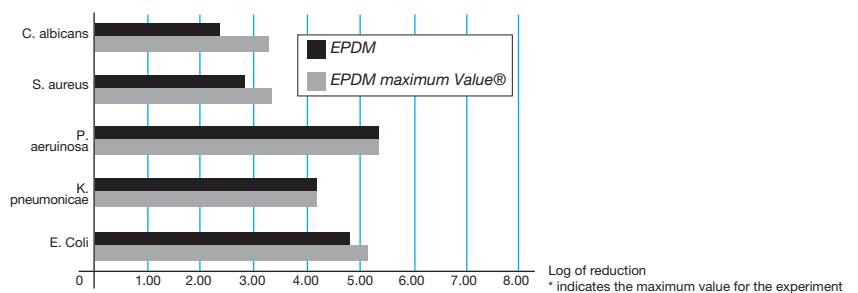


Cell wall decomposes

Elastoguard® NBR Rubber Exhibiting Safe and Durable Antimicrobial properties



Elastoguard® EPDM Rubber Exhibiting Safe and Durable Antimicrobial properties



10. Addendum

ADDENDUM				
<i>Certificates & Guidelines</i>	<i>Application</i>	<i>Standards</i>	<i>Tests</i>	<i>Legal Institution</i>
WRAS	Contact potable water	BS 6920 BS 2494	Microbiological Extraction	WRAS (Water Regulation Advisory Scheme)
ACS	Contact potable water	Afnor XP-P41-250	Microbiological Synoptic documents	ACS (Accreditation Conformité Sanitaire)
KTW	Contact potable water Cold, warm, hot water	BGVV part 1.3;13 Kunststoffe in Lebensmittel	Extraction Smell and taste	BGVV (Bundesinstitut für Gesundlichen Verbraucherschutz und Veterinärmedizin)
NSF	Food and Sanitary	NSF 51 NSF 61	Toxilogical Microbiological	NSF (National Sanitation Foundation)
FDA	Food, Sanitary and Pharma	White list Cfr 21 part 177.2600	Test white list Migration tests for acquous and fatty foods	FDA (Food and Drug Administration)
USP	US Pharmacopeia European Pharmacopeia	USP class VI	Cytotoxicity Hemolysis Pyrogenicity Sensitisation	NAMSA TOXICON