Certification regulations and cleaning procedures

FDA compounds

- FDA sets the standard for ensuring that foods, 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'. This list contains the ingredients that may form part of a rubber compound. The list includes elastomers, accelerators, plasticisers, fillers, emulsifiers, etc.
- There are also certain quantative limitations on different ingredients.
- Most 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 reflux temperature.
- Certificates on demand.

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 temperature, shall yield total extractives not to exceed 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'.

FDA does not 'approve' products to CFR21.177.2600. It is the manufacturer's task and responsability to demonstrate compliance of the finished rubber product.

Introduction to FDA-USP concept

USP class VI standards 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 USP-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.

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 favourable gasket material for each application. The following criteria are used in determining correct sanitary gasket materials.

- USP Pharmacopoeia Class VI-XXII Certification
- Cytotoxicity Criteria
- CFR Title 21 Section 177.1550 (PTFE)
- CFR Title 21 Section 177.2600 (rubber)
- 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 Kalrez®.

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.

FDA Contact Notification (FCN)

The Food and Drug Administration (FDA) has regulatory oversight for substances added to food, including monitoring their safe use.

Section 309 of the Food and Drug Administration Modernisation Act (FDAMA) of 1997 now also establishes a Food Contact Notification (FCN) process as the primary method by which the FDA regulates substances that are classed as 'food contact substances' (FCS).

A FCS is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting or holding food, but is not an additive within the food.

DuPont Performance Elastomers

During the FCN process, the sealing material and its individual constituent ingredients undergo a significant amount of research, testing and analysis to evaluate the potential for food contamination.

Successful completion of the FCN process allows the following material grades to be used in a variety of food contact applications under the Food Contact number FCN000402.

The Food and Drug Administration Modernisation Act of 1997 provides a system whereby a manufacturer or supplier of food-contact material may submit a Food Contact Notification (FCN) to FDA regarding the identity and use of the new food contact substance, together with necessary date to demonstrate that the substance is safe for its intended use. FCN is a formal acceptance of a material by the FDA, so it is fundamentally different to self-certification to FDA CFR § 21.177.2600.

FCN application requires a detailed analysis of the compound, its constituents, toxicological effects and intended uses and is much more rigorous than the requirements of CFR § 21.177.2600. The complexity and high cost of the FCN process means that it is currently restricted to a limited range of very high performance perfluorelastomer materials that are used in very demanding applications.

Food Contact Notification Materials

Compound	*Hardness °RHD*	*Material*	*Colour*
FFKM Kalrez® 6221	70	perfluorelastomer	white
FFKM Kalrez® 6230	75	perfluorelastomer	black

AUTHORIZED DISTRIBUTOR Kalrez® perfluoroelastomer parts DuPont Performance Elastomers

3-A Sanitary Standards

ERIKS manufactures seals in accordance with 3-A Standard 18-03 which defines the requirements for food quality materials that must be suitable for cleaning and sanitising solutions.

All ERIKS 3-A Sanitary Standards compliant elastomers are FDA-compliant to FDA CFR § 21.177.2600 resistant to steam sterilisation, milk fat and water, acid and alkali cleaning solutions and chlorine sanitising solution.

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

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 N° 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 CFR § 21.177.2600 and also be resistant to steam sterilisation, milk fat, acid and alkali cleaning solutions and chlorine sanitising agents.

The European Hygienic Engineering & Design Group (EHEDG) is a consortium of equipment manufacturers, food industries, research institutes and public health authorities. It was founded in 1989 with the aim to promote hygiene during the processes 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.

ADI free (Animal Derived Ingredient free)

BSE (bovine spongiform encephalopathy) is a disease, which is caused by infectious proteins, so called prionics. These proteins are very resistant, it needs steam of 133°C, 3 bar and 20 minutes to destroy them. It is necessary to avoid to introduce any BSE prions into plants or food and beverage industry. Stearates, fatty acids or similar can be based on agricultural or animal production.

ERIKS has checked the standard qualities excluding the use of any animal derived ingredient in order to avoid the risk of contamination with BSE prions.

These qualities are certified with the logo 'ADI free' (Animal Derived Ingredients free).

Cleaning procedures

Since sanitising programmes have been commonly established, cleaning and sanitising procedures have to be developed for all food processing equipment. The objective of cleaning and sanitising food contact surfaces is to remove food (nutrients) which bacteria requires so that it can grow, and to kill bacteria that already exists.

ERIKS has wide ranging experience in material and product design compatibility to overcome problems in the cleaning processes used in the food, beverage and pharmaceutical industries.

Cleaning definitions

- Clean: Free from dirt, stain, or impurities and generally unsoiled
- Sanitised: Free from elements that endanger health, reduction of micro-organisms
- Desinfect: Refers to inanimate objects and the destruction of all vegetative cells (not spores)
- Sterilize: Refers to the statistical destruction and removal of all living organisms

Manual cleaning procedures

These procedures could be done by clean-up personnel, using:

- buckets, brushes and hoses or
- HPLV-Systems (High Pressure Low Volume) via spray wands or
- by foaming (cleaning primarily by chemical action)

Mechanical cleaning procedures

System uses an agitated tank to clean components (equipment parts and short section of piping) disassembled and placed in the tank.

CIP (Clean-in-Place)

This cleaning process is usually accomplished via chemical action based on spray or pressure recirculation of the flush, wash, and rinse solutions under controlled conditions of time, temperature and chemical concentration. It involves the washing of processing and storage tanks, the piping systems and integrated equipment.

SIP (Sterilization-in-place)

The objective is to sterilize all sterile product contact equipment at its point of use to eliminate or reduce the need for aseptic additions or connections.

Requirements to seals

The requirements to the seals and plastic parts are:

- chemical resistance against the product
- chemical resistance against the used CIP media
- good cleanable and sterilizable sealing surface
- good resistance against abrasion and wear
- nontoxic sealing material
- installation without any dead spots (spaces)

Compatibility

In addition to the above mentioned requirements, the following parameters strongly influence the quality of the cleaning process as well as the life time of the seals:

- immersion period
- temperature
- type of cleaning media
- concentration of the cleaning solution

Chemical	*Example*	*Concentration*	*Temperature °C*	*Time*	*Cleaning procedure*
Chlorinated alkalies	Mild solution of caustic soda	max. 0,5%	55-70	5-22	CIP
Acidified rinse	Post rinse, fresh water, acid solution	pH 5,5-6,0	RT	-	CIP
Strong alkalies	Caustic soda	0,5-5%	up to 90	45-90	CIP
Strong acids	Phosphoric acid, nitric acid	pH-2	75-90	20-30	CIP
Sanitiser	Sodium hypochlorite	200 ppm active chlorine	cold	a couple of	CIP
Hot water	-	-	80-90	-	CIP
Steam	-	-	+130	-	SIP

Material	*Nitric acid* *85°C,2%*	*caustic soda* *85°C,3%*	*Aqua dest.* *100°C*	*Steam* *140°C*	*Sodium hypochlorite solution* *70°C,5%*	*Solution sodium hydroxide sodiumhypochlorite* *70°C,3%*	*Solution sodium hydroxide sodium carbonate* *70°C,3%*	*Solution hydrogen peroxide peracetic acid* *50°C,3%*	*3-A Sanitary standards 18-03*
PUR	+	+	+	-	+	+	+	+	Class 1,3**
NBR	(-)	+	+at 70°C	(-)	n.d.a.	n.d.a.	n.d.a.	n.d.a.	n.d.a.
H-NBR	(-)	+	+	-	n.d.a.	n.d.a.	n.d.a.	n.d.a.	n.d.a.
Silicone	-	(-)	+	(-)	n.d.a.	+	+	n.d.a.	n.d.a.
Viton®	(o)	o	o	-	o	+	+	+	Class 1

immersion period: 168 hours
n.d.a.: no data available
(+,o,-): n.d.a. supposed to be +, o or -
*** class 1,3: passed all tests for class 1, except the temperature of exposure to product of sterilization (possible up to 100°C)*
+ : resistant
o : limited resistance
- : not resistant