



EC1935/2004  
Components for direct contact with foods

know-how makes the difference

**ERIKS**



ERIKS is an industrial service provider with an extensive range of mechanical engineering components. Our company has expert knowledge of materials and applications, we also focus on service and reliability. ERIKS is part of the global ERIKS Group, with a workforce of more than 8000 employees on 450 sites in 21 countries.

### Core activities of ERIKS

- Power transmission and bearings
- Sealing and rubber technology
- Flow technology
- Industrial plastics
- Tools, maintenance and safety products

### Partner for the food industry

Ever since its establishment, ERIKS has supplied the food industry. From initially being a local supplier of seals for dairy products in the Netherlands, ERIKS has developed into a business partner for the food industry worldwide. Our customers come from all sectors of the food industry: from dairy products, beverages, alcohol, powders and raw materials to vegetable processing. Food safety and a reduction of the total cost of ownership are the starting points of ERIKS in its business activities in the food industry.

For each application, the right product is selected based on a number of criteria. ERIKS makes an inventory of the operating conditions under which the component must function and then puts forward a proposal. This saves you work and minimises risks, enabling you to focus on your core business.

### Why a separate product line for the food industry?

Past requirements for Food Contact Materials (FCM) differed considerably from country to country. In order to harmonise legislation within the EU member states, the European Commission decided to introduce a single piece of legislation for all member states. In 2004 work began on the drafting of this legislation, namely EC1935/2004, containing the requirements on materials for food contact applications.

ERIKS offers a defined range of EC1935/2004 compliant products and components.

### What is EC1935/2004?

EC1935/2004 is landmark European legislation for the food industry and covers materials and objects intended to come into contact with foods, namely so-called Food Contact Materials.

EC1935/2004 came into force on 1st April, 2009; Checking that there is compliance with this legislation in the Netherlands is the responsibility of the Netherlands Food and Consumer Product Safety Authority (NVWA).

Article 3 of EC1935/2004 sets out the general requirements on Food Contact Materials. Materials may not transfer substances to foods in quantities which:

- Represent a health risk to people
- Lead to an unacceptable change in the composition of the food
- Adversely affect the organoleptic properties of the food



EC1935/2004 prescribes that the migration of substances (contaminants) between the relevant materials and the food must remain within specific tolerances to avoid contamination and adverse taste changes. This legislation is the framework under which other requirements are defined.

These requirements concern:

- Materials
- Quality – Good Manufacturing Practice (EC2023/2006)
- Documentation
- Traceability



## What materials fall under the legislation?

EC1935/2004 covers the following materials:

- Active and intelligent materials and objects
- Adhesives
- Ceramics
- Cork
- Glass
- Metals and metal alloys
- Paper and cardboard
- Plastics
- Printing ink
- Regenerated cellulose
- Resins with ion exchangers
- Rubber
- Silicones
- Textiles
- Varnish and topcoats
- Wax
- Wood

## EU10/2011 in more detail

This part of the legislation, known as the Plastic Information Measure (PIM), came into force on 1st May 2011, replacing EC 2002/72. This legislation lays down the requirements on plastics. This also covers migration tests and a list of approved base materials as well as other supplementary requirements. In the Netherlands, EU10/2011 applies not only to industrial plastic materials, such as sheet materials and rods, but also to other products such as rubber seals, hoses, O-rings and valves. This is laid down in the Warenwet (Commodities Act) which was published in the Staatscourant (Government Gazette) of 27 March 2014.

## Migration tests

The test methods prescribe, based on the type of food with which a material comes into contact, the simulant which must be used for the migration test.

	Simulant	Type of food
A	10% ethanol	Watery food or non-alcoholic drinks
B	3% acetic acid	Foods with a pH of less than 4.5
C	20% ethanol	Alcohol-containing foods with an alcohol content up to 20%
D1	50% ethanol	Alcohol-containing foods with more than 20% alcohol and oil-in-water emulsions
D2	Vegetable/plant oil	Foods with free fat on the surface
E	MPPO (Tenax)	Dry foods
F*	Demineralised water	Water

\* Simulant F is not used in EU10/2011 which ERIKS applies for rubber. For applications in hot and cold water, rubber compounds are available which do not affect the odour and taste of water. For this reason we have added these and mentioned simulant F.

The duration of contact and the usage temperature are also important. Based on these parameters, for each material it is determined what substances are released and what quantities migrate into the food.



If the migration value stays within the legal limit, the material may be used in direct contact with the food.

## Overview of materials supplied by ERIKS

ERIKS supplies a wide range of EC1935/2004 approved materials:

- Bearings and lubricants
- Conveyor belts
- Flange gaskets
- Hoses
- Industrial plastics
- O-rings
- Seals
- Triclamps
- Valves

## Clear labelling

Labelling is mandatory on products that are not intended to come into contact with foods. Examples are hoses, flange gaskets and plastic products.



One of the above symbols can be found on EC1935/2004 approved articles from ERIKS. If no label can be placed on the article, for example an O-ring, the symbol is put on the packaging.



### Good Manufacturing Practice (EC2023/2006)

In order to ensure that no harmful actions are done to the material during its further processing, additional requirements are laid down. The GMP quality assurance system for production originally came from the pharmaceutical industry. This guarantees, amongst other things, full traceability of the processed materials. The GMP guidelines are in addition to the existing quality assurance system.

Furthermore, the following matters must be guaranteed during the production process:

- Full traceability of the material during production
- Clean workplaces with no possibility of contamination by other materials
- Use of approved lubricants
- Use of approved packaging materials

The relevant processes are prescribed in the ISO9001 quality system of ERIKS.

### Material processing at ERIKS

- Assembling of hoses
- Processing of plastics
- Assembling of valves
- Cutting of gaskets
- Vulcanisation of O-rings
- Vulcanisation and processing of elastomers

ERIKS puts much time and effort into applying GMP 2023/2006, meaning that our production processes are continually optimised. Indeed, ERIKS Plastics production processes are ISO22000 compliant, as certified by Lloyds.

### Declaration of Compliance

All relevant information can be found on the Declaration of Compliance of ERIKS. This includes the type of material, batch number, migration tests and test conditions. The materials themselves must bear the batch number, material name and various logos. Materials must be accompanied by a written Declaration of Compliance.

The Declaration of Compliance can be linked to your order number so as to guarantee the highest possible level of traceability. The Declaration of Compliance of ERIKS is suitable for submitting to inspection authorities.

**ERIKS**

Declaration of compliance

**DECLARATION OF COMPLIANCE**  
To FDA regulation CFR 21§177.2600  
To European legislation EC 1935/2004 EU10/2011

**Product/material** EPDM 70 COMPOUND 55985

**Date of declaration** 23-07-2015

We confirm that the above mentioned material is compliant to the above mentioned regulations and legislations. Products from this material are intended for repeated use in contact with the below listed type of foods.

This material has been evaluated according to the requirement of the Regulation EC 1935/2004, Annex I. Materials intended to come into contact, directly or indirectly, with food.

The safety of this material has been verified by testing against the migration requirements as described in EU10/2011 and in accordance with EN1186.

This material has been tested following the FDA regulation on extraction in hexane and boiling water as described in subparagraphs (e) and (f).

ERIKS guarantees that all products of this material are produced according to the directive for GMP (Good Manufacturing Practice) 2023/2006/EC, which is part of the guideline EC1935/2004.

The traceability of the products derived from this material is secured and the regulations for documentation and labelling protocol have been fulfilled.

Test	Requirements	Result
Extraction Hexane 7 hours	Max. 175 mg/lechl <sup>2</sup>	PASS
Extraction Hexane 2 hours	Max. 4 mg/lechl <sup>2</sup>	PASS
Extraction in boiling water 7 hours	Max. 20 mg/lechl <sup>2</sup>	PASS
Extraction in boiling water 2 hour supplementary	Max. 1 mg/lechl <sup>2</sup>	PASS

Simulant	Simulant media	Type of food	Time/Temperature	Ratio S/V
A	Ethanol 10%	Aqueous food	24 hours at 90°C	6
B	Acetic Acid 3%	Foods with pH <4.5	24 hours at 100°C	6
C	Ethanol 20%	Alcoholic beverages <20% alcohol	1 hour at 83°C	6
D1	Ethanol 50%	Alcoholic beverages >20% alcohol and oil in water emulsion	1 hour at 83°C	6
F	Distilled water	Aqueous food	24 hours at 100°C	6

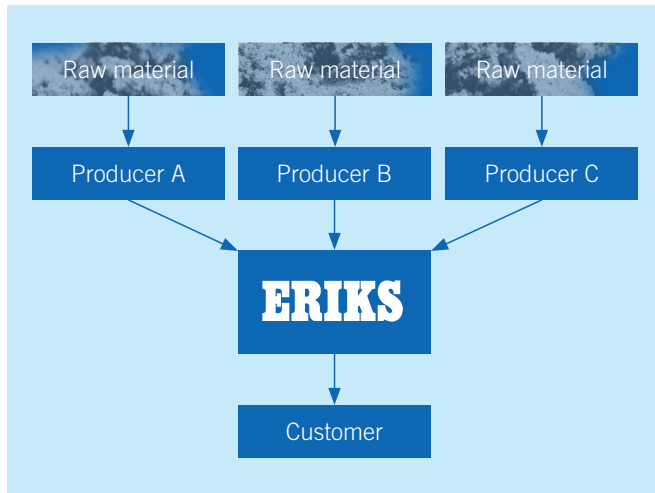
This declaration is not intended as technical documentation, the suitability of this product for a specific application should be verified with ERIKS.

Peter Laan  
QM Manager



## Traceability guaranteed

Traceability is always guaranteed at ERIKS throughout the whole production process. This facilitates product monitoring, recall of defective products and informing of customers. Traceability involves a chain of steps. Essential for this is assigning production numbers to products and materials.



## Specialism and engineering

The use of Food Contact Materials has increased enormously over recent years. However, the question remains when can a material be used and when not? And what is the most suitable material for your specific process? ERIKS helps you answer these questions.

For both OEM and MRO components, ERIKS has many years of experience selecting the right products. Besides ensuring there is the correct certification, it is essential to ensure the correct price/quality ratio. You can benefit from our expertise: For both standard applications and advanced customized applications where the correct choice of product is vital for the process.

Our Application Engineers work on just one of our product lines, meaning they have in-depth product and application knowledge in their field. Existing situations can often be improved by applying the correct materials or components. Existing Food Contact Materials which do not comply with EC1935/2004 are replaced by certified products.

ERIKS is also your partner for new developments and applications. Engineering with the aid of SolidWorks or other design programs can be undertaken. Rapid prototyping and the use of our 3D

printers during the product development phase shorten the route to a perfect end result.

Co-engineering and consultancy on material choice, strength, thermal stability, chemical resistance and other criteria complete our range of services.

## ERIKS offers comprehensive support

We are aware that many companies struggle with matters concerning the introduction or further improvement of EC1935/2004 within their processes. ERIKS can provide your company with concrete and practical support here:

- Presentations to enhance knowledge about EC1935/2004
- Practical help to make installations EC1935/2004 approved
- Production methods in accordance with GMP2023/2006
- A growing assortment of EC1935/2004 and EU10/2011 approved articles

For the food industry ERIKS is an unrivalled service provider in the area of technical components. We work with you to make your food production process even safer.



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