

Regulation EC No. 1935/2004

Static gaskets for use in the food industry

Regulation EC No. 1935/2004 related to “**materials and articles intended to come into contact with food.**”



The general requirements are outlined in Article 3, Paragraph 1:

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could

- a) endanger human health; or
- b) bring about an unacceptable change in the composition of the food; or
- c) bring about a deterioration in the organoleptic characteristics thereof.

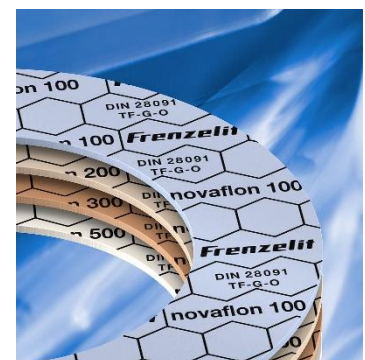
EC No. 1935/2004 does not explicitly describe test methods for gasket materials. Different sets of rules therefore have to be followed to make sure that the various product families satisfy the above requirements.

PTFE gaskets

Regulation EU No. 10/2011, that covers plastics and includes not only a formulation test but also migration tests with different food simulants (acetic acid, ethanol, vegetable oil and Tenax) based on a positive list, applies to the product line novaflon® (PTFE).

The following products comply with EC No 1935/2004 on the basis of the test specified in EU No. 10/2011:

- novaflon® 100
- novaflon® 200
- novaflon® 300 / novaflon® 300 WHITE
- novaflon® 500



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Fiber gaskets

Compliance with the requirements by products that contain rubber as a bonding agent is tested via BfR Directive XXI, which covers rubber products used in the food sector. A formulation test based on a positive list and, if necessary, migration tests with various media are necessary here too. The materials and articles are allocated to 4 different categories as well. Flat gaskets can be found in category 4, Paragraph 2.4.1/3:

“Gaskets for pipes, pumps, taps and Y-type valves etc. for liquid food products”



The following products comply with EC 1935/2004 on the basis of the test specified in BfR Directive XXI, category 4:

- **novapress® 850 / novaform® 2300**
- **novapress® 880**
- **novapress® UNIVERSAL**
- **novapress® BASIC**
- **novapress® AMBITION**
- **novapress® FLEXIBLE/815**
- **novatec® PREMIUM XP**
- **novatec® SPECIAL**
- **novaphit® 400 (graphite gasket)**

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EC No 1935/2004 and FDA

Both FDA and EC No 1935/2004 are regulations that rule the use of materials, including gasket materials, in the food industry. According to FDA and EC No 1935/2004 a formulation test is carried out on the basis of a positive list. In Europe neither EC No 1935/2004 nor FDA regulate applications in drinking water. Therefore further approvals, such as KTW or WRAS, are necessary. In order to govern the handling of different materials – rubber and plastics -, both regulations refer to so-called specific measures (see following chart).



FDA

The FDA regulation is applicable to US and foreign facilities, which produce, process, import, trade or cultivate food products in the USA for the US market. In the past the FDA was applied in Europe due to missing European regulation.

After the entry into force of Regulation EC No 1935/2004 FDA-conformity for applications within the European Union does not remain relevant.

Application engineering questions?

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