

EXPANDED PTFE (SOFT-CHEM® / SEALEX®)

FDA Compliance

Expanded PTFE (ePTFE) is a soft, highly compressible, and long-lasting material. Its main ingredient is 100% pure polytetrafluoroethylene (PTFE) with no fillers, chemicals, or other ingredients that are extractable or leachable. Due to its inertness, PTFE does not support bacterial growth or cause product contamination.

Both KLINGER Thermoseal soft-chem® (unbranded) and SEALEX® have been deemed suitable for food contact and pharmaceutical applications. The base PTFE material is found in the US Food and Drug Administration's (FDA) indirect food additive listings.

The PTFE material is compliant with the requirements of the US FDA Code of Federal Regulations, Title 21, Chapter I, Section 177.1550. The Chemical Abstracts Registry Number (CAS#) for PTFE is 9002-84-0.

Additionally, SEALEX® utilizes a pressure sensitive adhesive tape backing for installation. This adhesive is also found in the FDA's indirect food additive listings and is compliant with the requirements of the US FDA Code of Federal Regulations, Title 21, Chapter I, Section 175.105.

Finally, these products do not contain any materials derived from animals and are therefore not governed by: *Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies* in Accordance with Chapter 1, Article 1, section 2(a).

Therefore, additional diseases within the transmissible spongiform encephalopathies (TSE) family and referenced in the regulation are also of no concern including Creutzfeldt-Jakob disease (CJD), bovine spongiform encephalopathy (BSE), chronic wasting disease (CWD) and transmissible mink encephalopathy (TME).

These products meet or exceed the requirements of the following regulations:

- » US FDA 21 CFR 177.1500
- » Council Regulation (EC)1935/2004
- » Council Regulation (EC) 2023/2006
- » Council Regulation (EC) 10/2011

The ability of a gasket to make and maintain a seal depends not only on the style and quality of the gasket material, but also on medium being sealed, the flange design, the amount of pressure applied to the gasket by the bolts and how the gasket is assembled onto the flanges and tightened. These factors are beyond the manufacturer's control.

KLINGER Thermoseal

2350 Campbell Road, Sidney, Ohio 45365
Tel: +1 937 498 2222

3803 S. Sam Houston Parkway W., Houston, Texas 77053
Tel: +1 713 997 8111