

## **TECHNICAL DEPARTMENT COMMUNICATION**

Bulletin No.: FDA-003 (Document Circulation:  General;  Distributor;  Internal & confidential)

**PRODUCT: All *INERTEX*® 100% Expanded PTFE Products**

**SUBJECT: Compliance with FDA Regulations**

*INERTEX*® gasketing materials are 100% expanded virgin PTFE (polytetrafluoroethylene). The resins used meet the requirements of Section 177.1550 in Title 21 of the Code of Federal Regulations (21 CFR 177.1550). The code specifies the suitability of using perfluorocarbon resins as basic components of single and repeated use food contact surfaces. As stated in the Code, perfluorocarbon resins include those produced from homopolymerization of tetrafluoroethylene (i.e., PTFE) and they may be safely used as articles or components of articles intended to contact food, subject to the provisions in Section 177.1550. Chemical test results of the *INERTEX*® SQ-S gasket sheet and *INERTEX*® UHF Joint Sealant (available upon request) further confirm the compliance of the products to 21 CFR 177.1550.

*INERTEX*® UHF Joint Sealant and *INERTEX*® UHF Gasket Tape are backed with adhesive tapes to assist in installing these products. Inertech, Inc, offers a variety of adhesive tapes for different applications, including adhesive that meets the requirements of 21 CFR 175.105 for indirect food contact. The users should specify the needs for FDA compliance when ordering the *INERTEX*® UHF Joint Sealant and *INERTEX*® UHF Gasket Tape.

In addition, the *INERTEX*® SQ-S gasket sheet may be branded with the *INERTEX*® **SQ-S** trademark. All ingredients used in the branding ink are acceptable for direct contact with food and pharmaceutical products. However, the users may consider the use of unbranded sheets when such applications are involved.

In summary, the resins of the *INERTEX*® **SQ-S** gasket sheets comply with FDA requirements and the branding ink is acceptable for direct contact with food and pharmaceutical products. When requested, products with adhesive that meets the FDA requirements of 21 CFR 175.105 for indirect food contact can be supplied.

Reference:

1. "Code of Federal Regulations, Title 21 - Food and Drugs, Parts 170 to 199", revised as of April 1, 1996.
2. "Guide to the Safe Handling of Fluoropolymer Resins" (1992), by the Society of the Plastics Industry, Inc. Washington, D.C.
3. "Chemical Properties of TEFLON PTFE Fluoropolymer Resins", DuPont Polymers, Specialty Polymers, Wilmington, Delaware.

All information and recommendations contained in this publication are, to our best knowledge, correct. Since conditions of use are beyond our control, users should base their decision upon information verified through their own field testing as to whether products are suitable for the intended processes and uses. No warranty is given or implied with respect to information or recommendations herein. In any event or occurrence our liability is limited to our invoice value of the goods delivered to you by Inertech. Inertech reserves the right to change product design and properties without notice.

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**PREPARED BY: Inertech, Inc.**

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