

MATERIAL TEST DATA

TRP COMPOUND REFERENCE N°:
TRPlast™ 643USP HT Class VI

Polymer Type: Perfluoroelastomer (FFKM)



Description

This white high temperature material has been specifically developed for use with a wide range of potent active pharmaceutical ingredients (API's) and aggressive cleaning agents, being especially suited to withstand steam-in-place (SIP) and clean-in-place (CIP) procedures. It has excellent temperature resistance -15°C (5°F) to +300°C (+572°F). This material is tested to requirements of FDA21 CFR 177.2600 (e) (f). It is intended for

repeated use in food processing equipment and to be in contact with food. It meets the requirements of USP Class VI, having passed the United States Pharmacopoeia (USP) Biological Reactivity test, IN VIVO. **Do not use any TRPlast™ grade with molten alkali metals.**

| TYPICAL PHYSICAL PROPERTIES | Property | Typical Values | Test Standard |
|-----------------------------|--|----------------|---------------|
| | Colour | White | |
| | Hardness (°IRHD) | 70 | ISO 48 |
| | Tensile Strength (MPa) | 16.1 | ISO 37 |
| | Modulus @ 100% | 2.0 | ISO 37 |
| | Elongation @ Break (%) | 296 | ISO 37 |
| | Tear Strength (N/mm) | 20.1 | ISO 34 |
| | Specific Gravity (g/cm ³) | 2.45 | ISO 2781 |
| | Compression Set Value in Air, 25% Strain, 24 hrs @ 204°C (%) | 24 | ISO 815 |

| CHEMICAL RESISTANCE | Chemical Group | Rating | Chemical Group | Rating |
|---------------------|--|--------|------------------|--------|
| | Aromatics/Aliphatic oils | 1 | Ethylene | 1 |
| | Acids | 1 | Esters | 1 |
| | Alkalis | 1 | Ketones | 1 |
| | Alcohols | 1 | Propylene Oxide | 1 |
| | Aldehydes | 1 | Steam/Hot Water | 1 |
| | Amines | 1 | Strong Oxidisers | 1 |
| | Ethers | 1 | Amines >70°C | 2 |
| | 1 Suitable, little or no effect. 2 Minor to moderate effect, not maximum resistance. 3 Moderate to severe effect-may be useful in some limited applications. 4 Unsuitable and not recommended-severe effect More detailed information available on request | | | |

TRPlast™ 643USP HT Class VI material has passed USP Systemic, USP Intracutaneous & USP Muscle Implantation studies when test article was extracted at 70°C for 24hrs. Although TRPlast™ 643 USP HT Class VI has passed the USP IN VIVO testing, this material is supplied by TRP Polymer Solutions LTD as an FDA grade product only for use in non-implant devices. It is for the developers of the finished product to determine the suitability of use of the material for its end application and that it complies with statutory, regulatory and health care industry requirements.

The properties given on this data sheet is derived from tests carried out by TRP Polymer Solutions Ltd. They should not be regarded as specifications, but only as typical properties of the material described. It is intended for use by persons having technical skills and understanding of the seal and gasket design. Since the conditions of use are outside our control, nor have we designed the product shape, we can make no warranties, express or implied and assume no liability in connection with any use of this information.

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