

MATERIAL TEST DATA

TRP COMPOUND REFERENCE N°:
TRPlast® 643 USP Class VI



Polymer Type: Perfluoroelastomer (FFKM)

Description

This white material has been specifically developed for use with active pharmaceutical ingredients (API's), aggressive cleaning agents, steam-in-place (SIP) procedures and clean-in-place (CIP) procedures. It is intended for repeated use in food processing equipment and to be in contact with food. This material does not contain any Animal Derived Ingredients (ADI's).

Service Temperatures: 260°C (+500°F) to -17°C (+1°F). Do not use any TRPlast® grade with

molten alkali metals. This material is tested to and complies with the following standards:

- 21CFR177.2600 (e & f) (FDA).
- 3A Sanitary standards 18-03, Class 1.
- USP <87> & USP <88> (USPVI).
- USP <88> Intracutaneous Injection

TYPICAL PHYSICAL PROPERTIES	Property	Typical Values	Test Standard
	Colour	White	
	Hardness (°IRHD)	78	ISO 48
	Tensile Strength (MPa)	13.9	ISO 37
	Modulus @ 100% (MPa)	6.8	ISO 37
	Elongation @ Break (%)	162	ISO 37
	Tear Strength (N/mm)	19.4	ISO 34
	TR10 (°C)	-2	ISO 2921
	Specific Gravity (g/cm ³)	2.38	ISO 2781
	Compression Set Value in Air, 25% Strain, 24 hrs @ 204°C (%)	18.1	ISO 815

CHEMICAL RESISTANCE	Chemical Group	Rating	Chemical Group	Rating
	Aromatics/Aliphatic oils	1	Ethylene	1
	Acids	2	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™ 643 USP 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 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.

Data Sheet	Page	Issue Date	Issue No.	Issue By
MD395	1 OF 2	13.07.2021	2	CC

MATERIAL TEST DATA

TRP COMPOUND REFERENCE N^o: TRPlast[®] 643 USP Class VI (Page: 2 of 2)



Polymer Type: Perfluoroelastomer (FFKM)

3A Sanitary Test Results

Property	Typical Values	Class 1 Spec	Test Standard
Heat ageing in air, 166Hours @ 100°C			
Hardness change (°ShA)	0	+/-10	ASTM D573
Tensile Strength (MPa)	14.07	8.27	ASTM D573
Elongation @ Break (%)	164	100	ASTM D573
Change in Shore A hardness on immersion in liquid			
Distilled Water 22Hr @ 70°C	-1	+/-5	ASTM D471
Butter Oil 22Hr @ 70°C	-2	+/-5	ASTM D471
Nitric Acid (0.5%) 22Hr @ 82°C	-3	+/-5	ASTM D471
Alkaline Cleaner (1.0%) 22Hr @ 82°C	-3	+/-5	ASTM D471
Chlorine Sanitizer (200ppm) 22Hr @ 70°C	-2	+/-5	ASTM D471
Change in volume on immersion in liquid.			
Distilled Water 22Hr @ 70°C	0.6	+/-5	ASTM D471
Butter Oil 22Hr @ 70°C	0.4	+/-5	ASTM D471
Nitric Acid (0.5%) 22Hr @ 82°C	1.0	+/-5	ASTM D471
Alkaline Cleaner (1.0%) 22Hr @ 82°C	0.6	+/-5	ASTM D471
Chlorine Sanitizer (200ppm) 22Hr @ 70°C	0.4	+/-5	ASTM D471
Change in mass on immersion in liquid.			
Distilled Water 22Hr @ 70°C	0.3	+/-5	ASTM D471
Butter Oil 22Hr @ 70°C	0.1	+/-5	ASTM D471
Nitric Acid (0.5%) 22Hr @ 82°C	0.4	+/-5	ASTM D471
Alkaline Cleaner (1.0%) 22Hr @ 82°C	0.4	+/-5	ASTM D471
Chlorine Sanitizer (200ppm) 22Hr @ 70°C	0.3	+/-5	ASTM D471

The service limit provided on this datasheet is stated as 15°C below the TR10 value. It is generally accepted within the industry that an elastomer will seal to 15°C below the TR10 figure in static conditions, providing that compression of the seal takes place at ambient conditions. TRP Polymer Solutions Ltd. Recommends that seals are evaluated in service before specification.

TRPlast™643 USP 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 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.

Data Sheet	Page	Issue Date	Issue No.	Issue By
MD395	2 OF 2	02.02.2021	1	CC