Compound GPlast™ 643 USP Class VI White (UV)
POLYMER TYPE: Perfluoroelastomer FFKM75 (+/-5°)

Physical Properties

Property	Test Method	Units	Typical Values
COLOUR			White
HARDNESS	ISO 48	°IRHD	78
TENSILE STRENGTH	ISO 37	MPa	13.9
MODULUS @ 100%	ISO 37	MPa	6.8
ELONGATION @ BREAK	ISO 37	%	162
TEAR STRENGTH	ISO 34	N/mm	19.4
TR10	ISO2921	°C	-2
SPECIFIC GRAVITY	ISO 2781	g/cm3	2.38
COMPRESSION SET VALUE IN AIR 25% STRAIN – 24HRS @ 204°C	ISO 815	%	18.1

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. This material does not contain any Animal Derived Ingredients (ADI's).

This material is tested to and complies with the following standards:

- USP <87> & USP <88> (USPVI)
- USP <88> Intracutaneous Injection.

This material is tested to the following standards:

- FDA 21 CFR 177.2600 (e) & (f)
- FDA 21 CFR 177.2400 (d1) & (d2)
- 3A 18-03

Do not use any GPlast™ grade with molten alkali metals. Service Temperatures: -17°C (+1°F) to +260°C (+500°F).

Chemical Resistance

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.

Chemical Group	Rating	Chemical Group	Rating
Aromatics / Aliphatic Oils	1	Ethers	1
Acids	2	Ethylene Oxide	1
Alkalis	1	Esters	1
Alcohols	1	Ketones	1
Aldehydes	1	Propylene Oxide	1
Amines	1	Steam/Hot Water	1
Amines > 70°C	2	Strong Oxidisers	1

More detailed information available on request.

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Extraction Results:

Property	Typical Values	Tolerance	Test Standard
Extraction test results to 21 CFR 177.2600 in distilled water			
7Hour Extraction (mg/inch²)	<0.01	≤20.0	21 CFR 177.2600 (e)
2Hour Extraction (mg/inch²)	<0.01	≤1.0	21 CFR 177.2600 (e)

Extraction test results to 21 CFR 177.2600 in n-hexane			
7Hour Extraction (mg/inch²)	0.02	≤175	21 CFR 177.2600 (f)
2Hour Extraction (mg/inch²)	0.03	≤4	21 CFR 177.2600 (f)

Extraction test results to 21 CFR 177.2400 in distilled water			
2Hour Extraction (mg/dm²) - Total Extractives	0.00	≤3.1	21 CFR 177.2400 (d1)
2Hour Extraction (mg/dm²) - Fluoride Extractives	0.01	≤0.47	21 CFR 177.2400 (d2)

Extraction test results to 21 CFR 177.2400 in 50% ethanol			
2Hour Extraction (mg/dm²) - Total Extractives	0.00	≤3.1	21 CFR 177.2400 (d1)
2Hour Extraction (mg/dm²) - Fluoride Extractives	0.01	≤0.47	21 CFR 177.2400 (d2)

Extraction test results to 21 CFR 177.2400 in n-heptane			
2Hour Extraction (mg/dm²) - Total Extractives	1.19	≤3.1	21 CFR 177.2400 (d1)
2Hour Extraction (mg/dm²) - Fluoride Extractives	0.00	≤0.47	21 CFR 177.2400 (d2)

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Biological Reactivity Testing:

United States Pharmacopeia (USP) Declaration:
GPlast 643 USP Class VI is in compliance with the requirements of USP Plastic Class VI as it passed the United States Pharmacopeia (USP) Biological Reactivity test (USP <88>) and the United States Pharmacopeia Cytotoxicity Evaluation (USP <87>). The following test regimes were evaluated:

- USP Cytotoxicity test in mouse fibroblast cells (In Vitro, extraction conditions of 121°C for 1Hours)
- USP Systemic Toxicity Study in the mouse (In Vivo, extraction conditions of 121°C for 1Hour)
- USP Intracutaneous Toxicity Study in the rabbit (In Vivo, extraction conditions of 121°C for 1Hour)
- USP Muscle Implantation Study in the rabbit (In Vivo, extraction conditions of 121°C for 1Hour)

Within the USP <87> test GPlast 643 USP Class VI scored the maximum grade of 0 (no response).

Within the USP <88> tests GPlast 643 USP Class VI:

- Showed no signs of toxicity or death in the systemic toxicity study
- Scored the maximum grade of 0 within the Intracutaneous toxicity study (no erythema or edema formation)
- Scored the maximum grade of 0 within the muscle implantation study (no capsule formation)

This material is supplied by Gapi Ltd 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 statuary, regulatory and health care industry requirements.

USP <87> Biological Reactivity Test. In Vitro (GLP):

Grading Results:

Test Article	24Hours	48Hours	% Stained (Lysed)
GPlast 643 USP Class VI	0.0	0.0	0%

The Grade 0 response to the sample preparation meets test acceptance requirements of no more than Grade 2 reactivity.

USP <88> Biological Reactivity Test. In Vivo (GLP):
Test results for GPlast 643 USP Class VI, intracutaneous injection test:
The difference between test article and control mean value is 0 for NaCL, 0 for Alcohol, 0 for PEG and 0 for cottonseed oil. Therefore the result is that there was no Erythema or Edema.

Test results for GPlast 643 USP Class VI, systematic injection test:
Under the conditions of this study the test article passes. No signs or symptoms of systematic toxicity was observed.

Test results for GPlast 643 USP Class VI, Intramuscular implantation test:
Under the conditions of this study the test article passes. There were no deaths or abnormal health observations during this study. Final macroscopic scores were 0 and 0.

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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
Tensie 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

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Additional Declarations:

ADI Statement:
The above material supplied by Gapi Ltd has been manufactured wholly from synthetic materials and does not contain any raw materials produced from substances derived from animal origin.

The manufacturing process does not use any ingredient of animal origin, nor does the product come into contact with animal products during storage and transportation. Therefore the above materials can be considered BSE/TSE Free.

(BSE – Bovine Spongiform Encephalopathy)
(TSE – Transmissible Spongiform Encephalopathy)

Restricted Ingredients:
GPlast 643 USP Class VI supplied by Gapi Ltd does not contain the following substances, nor has any of the below substances been intentionally added into the compound:

- Melamine
- Phthalates
- Bisphenol A
- Latex