Compound GPlast™ 643 USP Class VI HT (UW)
POLYMER TYPE: Perfluoroelastomer FFKM70 (+/-5°)

Physical Properties

Property	Test Method	Units	Typical Values
COLOUR			White
HARDNESS	ISO 48	°IRHD	70
TENSILE STRENGTH	ISO 37	MPa	16.5
MODULUS @ 100%	ISO 37	MPa	10.6
ELONGATION @ BREAK	ISO 37	%	154
TEAR STRENGTH	ISO 34	N/mm	24.1
TR10	ISO 2921	°C	-3
SPECIFIC GRAVITY	ISO 2781	g/cm3	2.45
COMPRESSION SET VALUE IN AIR 25% STRAIN – 24HRS @ 204°C	ISO 815	%	28.9

Description

This white 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 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). This material does not contain any Animal Derived Ingredients (ADI's). Tested to comply with the following standards; 21CFR177.2600 (e & f), USP <87> & USP <88> (USPVI), USP <88> Intracutaneous Injection. Do not use any GPlast™ grade with molten alkali metals. Service Temperatures +300°C (+572°F) to -18°C (-1°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
Aromatics / Aliphatic Oils	1
Acids	1
Alkalis	1
Alcohols	1
Aldehydes	1
Amines	1
Amines >70°C	2
Ethers	1
Ethylene	1
Esters	1
Ketones	1
Propylene Oxide	1
Steam/Hot Water	1
Strong Oxidisers	1

More detailed information available on request.

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FDA Statement:

GPlast 643 USP (FFKM) Class VI is intended for repeated use in food processing equipment and to be in contact with food types I through VII Table 1 - Types of Raw and Processed Food. The base perfluoroelastomer is registered in the FDA Inventory of Effective Food Contact Substances (FCS) Notifications, being the subject of Food Contact Notification (FCN #128).

Table 1--Types of Raw and Processed Foods

1) Non-acid, aqueous products; may contain salt or sugar or both (pH above 5.0).
2) Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of low- or high-fat content.
3) Aqueous, acid or non-acid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
4) Dairy products and modifications:
   A. Water-in-oil emulsions, high- or low-fat.
   B. Oil-in-water emulsions, high- or low-fat.
5) Low-moisture fats and oil.
6) Beverages:
   A. Containing up to 8 percent of alcohol.
   B. Non-alcoholic.
   C. Containing more than 8 percent alcohol.
7) Bakery products other than those included under Types VIII or IX of this table:
   A. Moist bakery products with surface containing free fat or oil. ·
   B. Moist bakery products with surface containing no free fat or oil.
8) Dry solids with the surface containing no free fat or oil (no end test required) .
9) Dry solids with the surface containing free fat or oil.

This material has also been formulated and tested to comply with the requirements of FDA 21 CFR 177.2600 e & f for repeated use in contact with aqueous and fatty foods.

EUROPEAN DIRECTIVE

The above material also complies with the requirements of EU directive REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004.

Exceptions

Article 3 (1) (C) bring about a deterioration in the organoleptic characteristics thereof.

Since the final conditions of use are outside of Gapi Ltd control we cannot test for deterioration in the organoleptic characteristics

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ADI Statement:

The above materials supplied by GAPI Ltd have been manufactured wholly from synthetic materials and do 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

USP Class VI Statement:

GPlast 643 USP (FFKM) Class VI is in compliance with the requirements of **USP Plastic Class VI** as it passed the United States Pharmacopoeia (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 37oC for 24Hours)
- USP Systemic Toxicity Study in the mouse (In Vivo, extraction conditions of 121oC for 1Hour)
- USP Intracutaneous Toxicity Study in the rabbit (In Vivo, extraction conditions of 121oC for 1Hour)
- USP Muscle Implantation Study in the rabbit (In Vivo, extraction conditions of 121oC for 1Hour)

Within the USP <87> test ***GPlast 643 USP (FFKM) Class VI*** scored the maximum grade of 0 (no response.)
Within the USP <88> tests ***GPlast 643 USP (FFKM) 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 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 statuary, regulatory and health care industry requirements.

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FDA Extraction Test results:

Extraction Test results for GPlast 643USP in Distilled Water

	Extractables (mg/inch2)	
Material Ref:	**7Hour Extraction**	**2Hour Extraction**
GPlast 643USP	<0.01	<0.01
FDA Specification	**20**	**1**

Extraction Test results for GPlast 643USP in N-Hexane:

	Extractables (mg/inch2)	
Material Ref:	**7Hour Extraction**	**2Hour Extraction**
GPlast 643USP	0.02	0.03
FDA Specification	**175**	**4**

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

Grading Test Results for GPlast 643USP:

	24Hours		48Hours		% Stained (lysed)
Test Article	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 643USP, 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 643USP, 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 643USP, 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.