



Scheda Prodotto – Product Data Sheet

PDS-LN-010

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PTFE – FE1000

PTFE Vergine

Virgin PTFE

Date	Revision	Details of changes
October 2024	35	Regulation upgrade

Tipo di materiale – Material type		
A	Manicotti fascia grossa (spessore >15mm), tondi stampati, lastre e nastri sfogliati	Thick-walled molded tube (thick >15mm), Molded rod, skived sheet, and tape
B	Manicotti fascia sottile e lastre stampate	Thin-walled molded tube and sheet
C	Tondi e tubi estrusi	Extruded rod and tube

Caratteristiche Fisiche

Physical Properties

Caratteristica Property	Metodo di prova Test method	U.M Units	A Valore misurato Measured Values	B Valore misurato Measured Values	C Valore misurato Measured Values
Densità Density	ASTM D 792	g/cm ³	2.159	2.159	2.158
Carico di rottura Tensile strength	ASTM D 4894	MPa	27	25	23
Allungamento a rottura Elongation at break	ASTM D 4894	%	280	250	230
Durezza Hardness	ASTM D 2240	Shore D	61	58	55
Rigidità dielettrica Dielectric strength	ASTM D 149	kV/mm	38	34	30

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Caratteristica <i>Property</i>	Metodo di prova <i>Test method</i>	U.M <i>Units</i>	Valore tipico <i>Typical value</i>
Temperatura utilizzo <i>Working temperature</i>	-	°C	-200/+260
Coeff. dilatazione termica lineare <i>Coeff. Of linear thermal expansion</i>	ASTM 696	°C ⁻¹	13 · 10 ⁻⁵
Deformazione sotto carico <i>Deformation under load</i>	ASTM D 621	%	13
Deformazione sotto carico permanente <i>Permanent deformation</i>	ASTM D 621	%	7
Coefficiente attrito statico <i>Static friction coefficient</i>	ASTM D 1894	-	0.07
Coefficiente attrito dinamico <i>Dynamic friction coefficient</i>	ASTM D 1894	-	0.05
Resistenza compressione 1% deformazione <i>Compressive stress deformation 1% deformation</i>	ASTM D 695	N/mm ²	5
Comportamento alla fiamma <i>Flame behavior</i>	UL94	-	V0
Coefficiente di usura a PV <i>Wear factor</i>	ASTM D 3702	$\frac{\text{cm}^3 \cdot \text{min} \cdot 10^{-8}}{\text{kg} \cdot \text{m} \cdot \text{h}}$	-
Resistività di volume <i>Volume resistivity</i>	ASTM D 257	Ohm · cm	10 ¹⁷
Resistività di superficie <i>Surface resistivity</i>	ASTM D 257	Ohm	10 ¹⁶

Certificazioni/Certifications

Material conforms at: NSF61, KTW, ACS, WRAS, USP class VI.

Material conforms at food contact, in accordance with:

Italian regulations: DPR777, DL108, DM 34/73, DM174/04

EU regulations: 1935/2004/EU - 1895/2005/EU - 10/2011/EU and subsequent updating-2023/2006/EU

USA regulations: FDA 21 cfr § 177.1550

TSCA sezione 8(a)(7)

Gli articoli prodotti con questo materiale contengono politetrafluoroetilene, CAS 9002-84-0 in concentrazioni del 100%

TSCA section 8(a)(7)

Articles manufactured with this material contain polytetrafluoroethylene, CAS 9002-84-0, 100% in concentration

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		 LAB NP0066 L
RAPPORTO DI PROVA / TEST REPORT		
NUMBER 2319\FPM\FDC\21_1		ISSUE DATE 21/02/2022
BUSINESS AREA BA Product Conformity Assessment		LABORATORY Food Contact
SPECIMEN DESCRIPTION PTFE Vergine FE1000		
CUSTOMER GAPI SPA VIA MOLINARETTI, 2 24060 CASTELLI CALEPIO (BG)		
REFERENCE STANDARD D.P.R. 777 dated 23/08/1982, D.L. 108 dated 25/01/1992, D.M.34 dated 21/3/73 Regulation 1935/2004/EC GUCE L 338 dated 13/11/04. Regulation 10/2011/EU, GUUE L 12 dated 15/01/2011, and subsequent updatings. UNI EN 1186 1+15:2003 (see the overall migration test description for the identification of the technical standard part)		
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PTFE – FE1000

PTFE Vergine
Virgin PTFE

  	
RAPPORTO DI PROVA / TEST REPORT	
NUMBER 2321\FPM\FDC\21	ISSUE DATE 21/02/2022
BUSINESS AREA BA Product Conformity Assessment	LABORATORY Food Contact
SPECIMEN DESCRIPTION PTFE Vergine FE1000	
CUSTOMER GAPI SPA VIA MOLINARETTI, 2 24060 CASTELLI CALEPIO (BG)	
REFERENCE STANDARD D.P.R. 777 dated 23/08/1982, D.L. 108 dated 25/01/1992, D.M.34 dated 21/3/73 Regulation 1935/2004/EC, GUCE L 338 dated 13/11/04 Regulation 10/2011/EU, GUUE L 12 dated 15/01/2011, and subsequent updates. DM 174/2004 - D.Lgs n. 31/2001 Directive 2015/1787/UE	
Pag. 1 di/ of 8	
GQ001 REV.00 CSI S.p.A. a socio unico SOCIETÀ AD ATTIVITÀ DIREZIONALE COORDINAMENTO DI IMV GROUP S.p.A. REA MI 1466310 E.I./C.F./P.I. 1136016013 Cap. Soc. € 1.040.000 Sede legale Italia 20030 Senago (MI) Cascina Traversagna 21 direzione-cs@legalmi.it info@csi-spa.com www.csi-spa.com	

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DIVISIONE: DIVISION:	FOOD PACKAGING MATERIALS	LABORATORIO: LABORATORY:	FOOD CONTACTS
RAPPORTO DI PROVA (Test Report)		Pag. 1 di/of	
		pag. 5	
N°	0999\FPM\FDC\14 Rev. 1	Data:	04/12/2015
IDENTIFICAZIONE E DESCRIZIONE DEL CAMPIONE: SPECIMEN DESCRIPTION:			
PTFE FE 1000			
DATI IDENTIFICATIVI DEL CLIENTE: CLIENT:			
GAPI SPA VIA MOLINARETTI, 2 24060 CASTELLI CALEPIO, 2 (BG)			
NORMA DI RIFERIMENTO: REFERENCE STANDARD:			
FDA 21 cfr. § 177.1550			
DISTRIBUZIONE ESTERNA: OUTSIDE DISTRIBUTION:		DISTRIBUZIONE INTERNA: INSIDE DISTRIBUTION:	
GAPI SPA Mrs. Giovanna Brizzolesi		Copy to Division Head	
ENTE DI ACCREDITAMENTO: ACCREDITATION BODY:			
		CSi S.p.A. Sede Legale Cascina Traversaglia, 21 20030 SENAGO (MI) Direzione - Uffici - Laboratori Viale Lombardia, 20 - 20021 BOLLATE (MI) Tel. +39 02 383301 - Fax +39 02 3503940 www.csi-spa.com	
		R.E.A. 1466818 Registro Imprese 352168/8620/18 C.R./P.L. (T)1368160151 Cap. Soc. € 1.040.000	

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DVGW certificate of conformity hygiene		CERT	
DVGW-Konformitätsbestätigung Hygiene		HW-0802DO0288	
		Registration Number Registriernummer	
Confirmation of Conformity based on type testing (simplified process) <i>Konformitätsbestätigung auf Basis einer Typprüfung (vereinfachtes Verfahren)</i>			
Owner of certificate <i>Zertifikatinhaber</i>	GAPI S.p.A. Via Molinaretti, 2, I-24060 Castelli Calepio (BG)		
Production plant <i>Fertigungsstätte</i>	GAPI S.p.A. Via Molinaretti, 2, I-24060 Castelli Calepio (BG)		
Product Category <i>Produktart</i>	Hygienic suitability based on a type testing: Components from plastic, product group P2 (0802)		
Product description <i>Produktbezeichnung</i>	Components from plastic, PTFE Seals		
Material/Model <i>Werkstoff/Modell</i>	PTFE Vergine FE 1000		
Test reports <i>Prüfberichte</i>	Certification report: from 20.09.2023 (ZGW)		
Test basis <i>Prüfgrundlagen</i>	DVGW CERT ZP 0800 (20.04.2022) UBA KTW-BWGL (07.03.2022) DIN EN 16421 (01.05.2015)		
Date of Expiry / File No. <i>Ablaufdatum / Aktenzeichen</i>	20.09.2028 / 21-0056-WHE		
			
21.09.2023 Pz A-1/2 			
Date, Issued by, Sheet, Head of Certification Body Datum, Bearbeiter, Blatt, Leiter der Zertifizierungsstelle			
			
Deutsche Akkreditierungsstelle D-ZE-16028-03-02		DVGW CERT GmbH Zertifizierungsstelle Josef-Wimmer-Str. 1-3 53123 Bonn Tel. +49 228 91 88 - 888 Fax +49 228 91 88 - 993 www.dvgw-cert.com info@dvgw-cert.com	

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Approval Number 2208577 Test Report: J-00432511 & J-00432512 8th November 2022 Gapi S.p.s Via Molinarelli, 2, I-24060, Castelli Calepio (BG), Italy	  Water Regulations Approval Scheme Ltd. Unit 13, Willow Road, Pen y Fan Industrial Estate, Crumlin, Gwent, NP11 4EG
WATER REGULATIONS APPROVAL SCHEME LTD. (WRAS) MATERIAL APPROVAL The material referred to in this letter is suitable for contact with wholesome water for domestic purposes having met the requirements of BS6920-1:2000 and/or 2014 'Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water'. The reference relates solely to its effect on the quality of the water with which it may come into contact and does not signify the approval of its mechanical or physical properties for any use. POLYTETRAFLUOROETHYLENE (PTFE)- MATERIAL ONLY. 5295 'PTFE FE 1000'. White coloured, compression moulded PTFE material. For use with water up to 85°C. APPROVAL NUMBER: 2208577 APPROVAL HOLDER: GAPI S.P.A The Scheme reserves the right to review approval. Approval 2208577 is valid between August 2022 and August 2027 An entry, as above, will accordingly be included in the Water Fittings Directory on-line under the section headed, "Materials which have passed full tests of effect on water quality". The Directory may be found at: www.wrasapprovals.co.uk/approvals-directory/ Yours Faithfully  Ian Hughes WRAS Approvals Manager	
The Water Regulations Approval Scheme Ltd. Registered in England No. 1303284 Registered office: 6D Lowick Close, Hazel Grove, Stockport, SK7 5ED WRAS Appr-305P1 ver 2.0 Tel: +44(0)1456 244 888 Fax: +44(0)1456 244 888 Email: info@wrasapprovals.co.uk website: www.wrasapprovals.co.uk Page 1 of 9	

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Approval Number 2208576 Test Report: J-00432508 & J-00432509 8th November 2022 Gapi S.p.a Via Molinarelli, 2, I-24060, Castelli Calepio (BG), Italy	 Water Regulations Approval Scheme Ltd. Unit 13, Willow Road, Pen y Fan Industrial Estate, Crumlin, Gwent, NP11 4EG
WATER REGULATIONS APPROVAL SCHEME LTD. (WRAS) MATERIAL APPROVAL	
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POLYTETRAFLUOROETHYLENE (PTFE)- COMPONENTS.	5294
'PTFE FE 1000 Ring'. White coloured, extruded PTFE washer. For use with water up to 85°C.	
APPROVAL NUMBER: 2208576 APPROVAL HOLDER: GAPI S.P.A	
The Scheme reserves the right to review approval. Approval 2208576 is valid between August 2022 and August 2027	
An entry, as above, will accordingly be included in the Water Fittings Directory on-line under the section headed, "Materials which have passed full tests of effect on water quality".	
The Directory may be found at: www.wrasapprovals.co.uk/approvals-directory/	
Yours Faithfully 	
Ian Hughes WRAS Approvals Manager	
The Water Regulations Approval Scheme Ltd. Registered in England No. 1303284 Registered office: 5D Lowick Close, Hazel Grove, Stockport, SK7 8ED WRAS.App-305F1 ver 2.0 Tel: +44(0)1495 244 666 Fax: +44(0)1495 244 666 Email: info@wrasapprovals.co.uk website: www.wrasapprovals.co.uk	

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		Laboratoire habilité par le Ministère chargé de la santé en application de l'article R*. 1321-52 du code de la santé publique	
ATTESTATION DE CONFORMITE SANITAIRE (ACS) Certificate of sanitary conformity			
Conformément à l'arrêté du 29 mai 1997 modifié et aux circulaires du Ministère de la Santé DGS/VS4 n° 99/217 du 12 avril 1999 et DGS/VS4 n° 2000/232 du 27 avril 2000			
Coordonnées du demandeur / Contact details of the ACS owner : GAPI SPA Via Molinaretti 24060 Castelli Calepio Italy		Nom(s) commercial(aux) du produit fini / Commercial name(s) of the finished product : PTFE FE 1000	
Type de produit fini / Type of finished product : ☐ tube / pipe ☐ revêtement pour tubes / coating for pipes ☐ produit de jointoyage / sealing product ☐ Réservoirs / Storage systems ☐ Produits pour réservoirs / Products for storage systems ☐ raccord et manchon / fittings ☒ joint / seal, gasket, o-ring... ☐ composant d'accessoires / accessories components ☐ autre / other :			
Nature du matériau / Type of material : ☐ polychlorure de vinyl PVC ☐ PVC surchloré PVC-C ☐ polyéthylène PE ☐ polyéthylène réticulé PEX ☐ polypropylène PP ☐ polybutylène PB ☐ polyamide PA ☒ polytétrafluoroéthylène PTFE ☐ acrylonitrile-butadiène-styrène ABS ☐ à base de résine époxydique / epoxy resin ☐ éthylène-propylène EPDM ☐ butadiène-acrylonitrile NBR ☐ autre / other :			
Température(s) d'utilisation / Temperature(s) for the use : ☒ Eau froide / Cold water ☐ Eau chaude / Warm water ☐ Eau très chaude / Hot water			
Commentaires / Comments : Couleur du matériau / Material color : Naturel / Natural N° de dossier attribué par le laboratoire habilité / File reference : 22 MAT NY 118			
Formulation chimique / Chemical formulation : Vérifiée par le laboratoire et conforme aux listes positives / Checked by the laboratory and conform to the positive lists			
Essais de migration réalisés selon les normes NF EN 1420, NF EN 13052-1 & NF EN 12873-1 ou -2 : Migration tests performed according to the standards NF EN 1420, NF EN 13052-1 & NF EN 12873-1 or -2 : Rapport S/V testé / S/V tested ratio : 1,5 dm ⁻¹ selon NF EN 1420 et 13052-1 et 5,1 dm ⁻¹ selon NF EN 12873 Facteur de conversion associé / Associated conversion factor : 0,2 day/dm Date des essais / Tests date : du 12 décembre 2022 au 02 février 2023 / from December 12, 2022 to February 02, 2023. Commentaires : Les essais d'inertie n'ont fait apparaître aucune anomalie. Les résultats sont conformes aux critères d'acceptabilité fixés en annexe 1. Comments : The migration tests do not bring out any anomaly. The results are in accordance with the acceptance criteria set out in annex 1.			
Attestation délivrée par / Certificate issued by : Emilie Bailly Responsable Technique / Technical Manager A la date du / Date of issue : 27 mars 2023 Date d'expiration de l'ACS / Expiry date : 27 mars 2028 Commentaires / Comments : /			
Eurofins Dispositifs au Contact de l'Eau France Rue Lucien Cuénot - Site Saint Jacques II - 54320 Maxéville - France - T : +33 (0) 3 83 50 36 17 - F : +33 (0) 3 83 50 23 70 SAS au capital de 39 000 € RCS Nantes 844 974 014 TVA FR 05 844 974 014 - APE 7120B			
Référence : T-AM-FQ115564		Version : 1.1 Date publication : 18.12.2020	

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Virgin PTFE



GAPI S.p.A.
Via Molinaretti, 2
Castelli Calepio (Bg) - Italy

Attention	Mr. Ryan Shinabery
Your Reference	011040
Report Number	ENB012354P-1
Author	Kimberly Hoffman
Date	February 17, 2011

Subject Evaluation of FE1000 Virgin PTFE per 3-A Sanitary Standard 20-27

Dear Mr. Shinabery:

Forty molded two inch diameter disks of polytetrafluoroethylene (PTFE), with a surface area of $7.00 \pm 0.10 \text{ in}^2$ as required by the 20-27 procedure, labeled FE1000 Virgin PTFE, were submitted for testing in accordance with 3-A Sanitary Standard Procedure No. 20-27 (latest revision). The 3-A Sanitary Testing Procedure subjects the specimens to accelerated use-simulating tests to determine the cleanability for use in dairy equipment.

The results from the cleanability response testing, in which specimens were subjected to a series of cleaning solutions, are indicated in Table 1. The results show that the samples had either no appreciable weight gains, or gains that were less than the maximum allowable limit. The maximum allowable limit for fluorocarbons including PTFE is 0.05%.

The results for the product treatment, where the samples were divided into two groups, are detailed in Table 2. The M-series set of specimens was placed in cream at room temperature for seven days, which resulted in either no appreciable weight gains, or gains that were less than the maximum allowable limit of 0.05%. The L-series of specimens was placed in a lactic acid solution at 155 °F for seven days. These specimens had either no appreciable weight gains, or weight gains less than the maximum allowable limit of 0.05%.

The results from the cleanability comparison testing, in which the surfaces appear better than the surface of polished 316 stainless steel, are presented in Table 3.

The results indicated that the PTFE samples, labeled FE1000 Virgin PTFE, met the requirements as specified in 3-A Sanitary Standard Procedure No. 20-27. The scope of this testing does not include verification of Section H5 of the Standard, regarding compliance with FDA regulations and/or FC&C Act requirements.

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GENEVA LABORATORIES		JN21E0367 CLASS-A TOX2019-1
FOR THE MEDICAL INDUSTRY WORLDWIDE		
P.O. Box 140 • 1001 Proctor Drive • Elkhorn, WI 53121-0140 Phone: (262) 723-5669 • Fax: (262) 723-4015 www.genevalabs.com		
REPORT TO:	Mr. Michael Rinaldi Gapi spa via Molinaretti 2 Castelli Calepio (BG), 24060 Italy	
TEST ARTICLE:	Virgin PTFE FE1000	
LOT NO:	Virgin PTFE FE1000	
P.O. NO.:	2	
DATE RECEIVED:	05-06-2021	
TEST INITIATION DATE:	05-26-2021	TEST COMPLETION DATE: 06-11-2021
TEST PROCEDURE:	Biological Reactivity Tests, In Vivo USP <88> Class Designation: VI	
Extraction Temperature:	50°C	Time: 72 Hours
According to the criteria outlined in the current USP <88>, the results of these studies indicates that the material <u>meets</u> the requirements for a USP Class <u>VI</u> .		
REFER TO REPORT NUMBERS:		
	Intracutaneous Injection: <u>TP17545</u> Systemic Injection: <u>TP17546</u> Implant: (7 Day Needle) <u>TP17547</u>	
ANALYST:	<u>Scott M. Robert</u>	DATE: <u>06-14-2021</u>
ACCEPTED BY:	<u>Jenny Tomoseth</u> Technical Reviewer	DATE: <u>06-14-2021</u>
Q.A. SIGNATURE:	<u>E. Jane Muloney</u>	DATE: <u>06-14-2021</u>
Total Number of Pages:	22	

The following results/conclusions relate only to the items tested. This result cannot be reproduced except in full without the written approval of the testing laboratory.

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