

Application Number: E2.9_Fluororesins for medical device applications

Fluororesin used: PTFE (CAS No. 9002-84-0)

Product overview: Gasket for prefilled syringe (sliding stopper)

A fluororesin film is used in a gasket for a prefilled syringe for medical device applications.

A fluororesin film is used after heat-coating and processing. Since pharmaceuticals are filled into this and stored over a long period of time, it is necessary that the coated sliding stopper slides smoothly without substances being eluted therefrom.

For this reason, specifications such as slidability, heat resistance, elongation, purity, and inactivity are required, and a fluororesin is adopted as a material that satisfies all of these required specifications.

At present, a substitute product that satisfies all of the above-described requirements at the same time has not been found.

Since a prefilled syringe can be filled with a required amount in advance and stored over a long period of time, the work up to administration when in use is simplified and the risk of infection, foreign matter contamination, medical malpractice, and the like is reduced.

In addition, prefilled syringes in which films other than fluororesin films are used have insufficient lubricity and may interfere with safe inoculation work.

The global market size of prefilled syringes is expected to be USD 622.9 million in 2021 and is expected to grow at a compound annual growth rate of 10.9% from 2022 to 2030 (2030 forecast: USD 15.815 billion). In such a great need, it is thought that the shift to alternatives from fluororesins, which is very difficult to realize, will have a significant negative impact on the medical industry and humanity. As described above, permanent exemption from the proposed restrictions is proposed for this use.

Typical properties of fluororesins are shown in the following table.

List of fluororesin properties

△: Usable ○: Excellent
□: Very excellent ■: Superior than ◎

Properties	Unit	ASTM test method	PTFE	PFA	FEP	ETFE	PVDF	ECTFE	ECTFE
Physical									
Melting point	°C	—	327	310	260	270	156-170	245	220
Specific gravity	—	D792	2.14-2.20	2.12-2.17	2.12-2.17	1.30	1.75-1.76	1.68-1.69	2.1-2.2
Tensile strength	MPa	D638	27.4-34.3	24.5-34.5	21.6-31.4	65.1	34.3-65.1	48	30.9-41.2
Elongation	%	D638	200-400	200	250-300	100-400	60-200	300-300	80-200
Compressive strength	MPa	D695	11.8	16.7	15.2	49	86.6-96	—	31.4-51
Hardness	J/m	—	D2240	D50-35	D60	D55	D75	105-114	—
Hardness (Shore)	—	—	—	—	—	—	—	—	—
Tensile modulus of elasticity	MPa	D790	550	600-650	600	1400	2000-2400	600-650	—
Tensile modulus of elasticity (Shore)	MPa	D638	400-550	—	340	820	1100-1500	—	1000-2100
Dynamic friction coefficient	—	0.009MPa/200/20mm	0.10	0.2	0.3	0.4	0.32	—	0.37
Thermal									
Thermal conductivity	W/(m·K)	CT17	0.25	0.25	0.25	0.24	0.10-0.12	0.16	0.20-0.22
Specific heat	J/(g·K)	—	1.0	1.0	1.2	1.8-2.0	1.4	—	0.92
Linear expansion coefficient	10 ⁻⁵ /°C	D696	10	12	8.3-10.5	5.8	7-14	8	4.5-7.0
Softening point	°C	—	180	200	170	185	—	—	170
Ball Pressure Temperature	°C	—	55	30	30	74	87-115	77	—
Thermal stability	°C	—	121	74	72	104	149	116	126
Maximum operating temperature	°C	(No load)	200	260	200	150-180	150	165-180	177-200
Electrical									
Volume resistivity	Ω·cm	D149	>10 ¹⁴	>10 ¹⁴	>10 ¹⁴	>10 ¹⁴	>10 ¹⁴	>10 ¹⁴	>10 ¹⁴
Dielectric factor (tanδ)	—	D150	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002
Dielectric factor (tanδ) (frequency)	—	D150	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002
Dielectric factor (tanδ) (frequency)	—	D150	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002
Dielectric factor (tanδ) (frequency)	—	D150	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002
Dielectric factor (tanδ) (frequency)	—	D150	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002	<0.0002
Arc resistance	s	D495	>300	>300	>300	75	50-70	18	>300
Other									
Water absorption rate 24h	%	D570	<0.01	<0.01	<0.01	0.020	0.04-0.06	0.01	0.00
Conductivity at thickness of 1.2 mm	—	(UL-94)	V-0	V-0	V-0	V-0	V-0	V-0	V-0
Limit oxygen index	—	D2863	>35	>35	>35	30	44	60	>35
Direct sunlight effect	—	—	None	None	None	None	None	None	None
Acid	—	—	None	None	None	None	None	None	None
Alkali	—	—	None	None	None	None	None	None	None
Solvent	—	—	None	None	None	None	None	None	None

Elution test example of fluororesin

Eluent: Concentrated nitric acid Elution temperature: Room temperature
Elution time: 1+6+7 (days)
Processing method: PTFE Paste extrusion method
PFA Screw extrusion method
Analysis method: ICP-MS Method or flameless atomic absorption method Unit: ppb

Element	PTFE			PFA		
	1 day	6 day	7 day	1 day	6 day	7 day
Li	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Be	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Na	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Mg	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Al	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Ti	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Cr	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Mn	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Ni	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Cu	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Zn	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Co	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Ge	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Sr	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Zr	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Nb	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Mo	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Ag	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Cd	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Te	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Sa	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Sb	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Ba	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Ta	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Tl	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Pb	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Bi	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Fe	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Cu	0.2	<0.1	<0.1	<0.1	<0.1	<0.1
K	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1

Reference material: VALQUA Handbook Technical Section