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	PCTFE
Physical	Melting point	℃	—	327	310	260	270	156–170	245	220
	Specific gravity	—	D792	2.14–2.20	2.12–2.17	2.12–2.17	1.70	1.75–1.78	1.68–1.68	2.1–2.2
Mechanical	Tensile strength	MPa	D638	27.4–34.3	24.5–34.3	21.6–31.4	45.1	34.3–43.1	48	30.9–41.2
	Elongation	%	D638	200–400	300	250–330	100–400	80–300	200–300	80–250
	Compressive strength	MPa	D695	11.8	16.7	15.2	49	66.6–96	—	31.4–51
	Impact strength (Izod)	J/m	D256A	160	Undestroyed	Undestroyed	Undestroyed	160–374	Undestroyed	133–144
	Hardness (Rockwell)	—	D785	—	—	—	R50	R77–83	—	R75–95
	Hardness (Shore)	—	D2240	D50–55	D60	D55	D75	D75–77	D55	—
	Bending modulus of elasticity	MPa	D790	550	660–690	650	1400	2000–2480	660–690	—
	Tensile modulus of elasticity	MPa	D638	400–550	—	340	820	1320–1500	—	1050–2100
	Dynamic friction coefficient	—	0.60MPa 3m/min	0.10	0.2	0.3	0.4	0.39	—	0.37
Thermal	Thermal conductivity	W/(m·K)	C177	0.25	0.25	0.25	0.24	0.10–0.13	0.16	0.20–0.22
	Specific heat	J/(g·K)	—	1.0	1.0	1.2	1.9–2.0	1.4	—	0.92
	Linear expansion coefficient	10^{-5}/℃	D696	10	12	8.3–10.5	5.9	7–14	8	4.5–7.0
	Ball Pressure Temperature	℃	—	180	230	170	185	—	—	170
	Heat distortion temperature 1.81MPa	℃		55	50	50	74	87–115	77	—
	Heat distortion temperature 0.45MPa	℃		121	74	72	104	149	116	126
	Maximum operating temperature	℃	(No load)	260	260	200	150–180	150	165–180	177–200
Electrical	Volume resistivity	Ω—cm	ASTM D257 (50H,23℃)	$>10^{18}$	$>10^{18}$	$>10^{18}$	$>10^{16}$	2×10^{14}	$>10^{14}$	1.2×10^{16}
	Dielectric fracture strength (short period of time)	kV/mm (1.2 mm thick)	D149	19	20	20–24	16	10	20	20–24
	Dielectric constant 60Hz	—	D150	<2.1	<2.1	2.1	2.6	8.4	2.6	2.24–2.8
	Dielectric constant 10^3Hz	—	D150	<2.1	<2.1	2.1	2.6	8.4	2.6	2.3–2.8
	Dielectric constant 10^6Hz	—	D150	<2.1	<2.1	2.1	2.6	6.43	2.6	2.3–2.5
	Dielectric loss tangent 60Hz	—	D150	<0.0002	<0.0002	<0.0002	0.0006	0.049	<0.0005	0.0012
	Dielectric loss tangent 10^3Hz	—	D150	<0.0002	<0.0002	<0.0002	0.0008	0.018	0.0015	0.023–0.022
	Dielectric loss tangent 10^6Hz	—	D150	<0.0002	0.0003	<0.0005	0.005	<0.015	0.009–0.012	
	Arc resistance	s	D495	>300	>300	>300	75	50–70	18	>360
Durability and others	Water absorption rate 24h	%	D570	<0.01	<0.03	<0.01	0.029	0.04–0.06	0.01	0.00
	Combustibility at thickness of 3.2 mm	—	(UL–94)	V–0	V–0	V–0	V–0	V–0	V–0	V–0
	Limit oxygen index	—	D2863	>95	>95	>95	30	44	60	>95
	Direct sunlight effect	—	—	None	None	None	None	None	None	None
	Acid			◉	◉	◉	◎	○	◎	◎
	Alkali			◉	◉	◉	◎	○	◎	◎
	Solvent			◉	◉	◉	◎	△	◎	○

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 frameless atomic absorption method Unit: ppb

	PTFE						PFA					
	No.1			No.2			No.1			No.2		
Element	1 day	6 days	7 days	1 day	6 days	7 days	1 day	6 days	7 days	1 day	6 days	7 days
Li	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<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	<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	<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	<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	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Ti	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
V	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<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	<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	<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	<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	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Cu	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<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	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Ga	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<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	<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	<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	<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	<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	<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	<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	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
In	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05
Sn	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<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	<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	<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	<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	<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	<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	<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	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1
Ca	0.2	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1	0.1	<0.1	0.1
K	<0.1	<0.1	0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1

Reference material: VALQUA Handbook Technical Section