Application Number: E.2.9 (medical devices)
Fluororesin used: PTFE (CAS No. 9002-84-0)
Product Overview: endoscope cable

Fluororesin is used in cables for medical devices and cables of endoscope.

The application requires properties such as flexibility, insulation properties, and purity, and fluororesin is employed as a member satisfying required specifications. For example, for flexibility, the use of other polymer materials causes a quality risk for cables as the other polymer materials do not have sufficient properties for the required thickness.

As mentioned above, no alternative products have been found at this time because other polymer materials do not have sufficient properties and affect quality.

We believe that the regulatory exemption for this application from proposed restriction is reasonable.

Representative properties of fluororesin are shown in the following table.

Physical properties	Test method	Unit	PPS	PAR	PTFE	PSU		PES	
Classification and characteristics			GF40% Cross-linking type	Natural	Natural	Natural	GF30%	Natural	GF30%
Mechanical properties									
Tensile strength	ASTM D 638	MPa	150	70	27～34	71	108	84	140
Tensile break elongation	ASTM D 638	%	1.2	70	200～400	50～100	2	80	3
Bending strength	ASTM D 790	MPa	206	78	118(3)	108	157	129	190
Bending elastic modulus	ASTM D 790	GPa	13.7	1.9	0.34～0.62	2.6	7.6	2.5	8.3
Load impact strength with notches	ASTM D 256	J/m	69	245	157	69	78	88	78
Rockwell hardness	ASTM D 785	R scale	123	125	—	120	134	120	134
Thermal properties									
Load deflection temperature (1)	ASTM D 648								
: 0.45 Mpa load		℃	260	175	55	—	—	203	216
: 1.82 Mpa load		℃	—	—	121	174	181	210	—
Continuous use temperature (2)	UL746B	℃	200～220	140～160	180	140～160	140～160	180～190	180～190
Linear expansion coefficient	ASTM D 696	10^{-5}×K^{-1}	2.9	6.2	10	5.6	1.9	5.6	2.3
Flammability		—	V－0/5V	V－2	V－0	HB	V－0	V－0	V－0
Physical properties									
Specific gravity	ASTM D 792	—	1.67	1.21	2.14～2.20	1.24	1.49	1.37	1.60
Water absorption rate	ASTM D 570	%	0.05	0.26	<0.01	0.3	0.49	0.43	0.30
Molding shrinkage rate	ASTM D 955	mm/mm	0.0025	0.008		0.007	0.002	0.006	0.002
Electrical properties									
Volume resistivity	ASTM D 257	Ω·mm	1×10^{15}	2×10^{16}	$>10^{17}$	—	—	10^{16}	10^{15}
Dielectric breakdown strength	ASTM D 149	kV/mm	17.2	—	30～35	17	19	16	16
Dielectric constant (10^6 Hz)	ASTM D 150	—	3.8	3.0	<2.1	3.1	3.7	3.5	—
Dielectric tangent (10^6 Hz)	ASTM D 150	—	0.0014	0.01	0.0001	0.005	0.004	0.0035	—

Physical properties	Test method	Unit	LCP			PEEK		PEI	PAI	TPI
Classification and characteristics			GF30% Type I	GF30% Type II	GF30% Type III	Natural	GF30% High fluidity	Natural	Natural	Amorphous Natural
Mechanical properties										
Tensile strength	ASTM D 638	MPa	137	211	113	97	236	105	191	92
Tensile break elongation	ASTM D 638	%	1.7	2.2	3.8	80	5	60	15	90
Bending strength	ASTM D 790	MPa	157	250	176	142	330	145	240	137
Bending elastic modulus	ASTM D 790	GPa	13.3	14.7	12.6	3.7	21.1	3.3	5.0	2.9
Load impact strength with notches	ASTM D 256	J/m	108	137	118	88	—	49	147	88
Rockwell hardness	ASTM D 785	R scale	77	84(M)	69	126	124	109(M)	86(E)	129
Thermal properties										
Load deflection temperature (1)	ASTM-D-648									
: 1.82 Mpa load		℃	346	240	180	152	300	200	278	238
: 0.45 Mpa load		℃	—	—	—	—	—	210	—	—
Continuous use temperature (2)	UL746B	℃	240～280	～220	—	240	240	170～180	200～220	—
Linear expansion coefficient	ASTM D 696	10^{-5}×K^{-1}	1.2	—	—	4.6	—	5.6	3.1	5.5
Flammability		—	V－0	V－0	V－0	V－0	V－0	V－0/5V	V－0	V－0
Physical properties										
Specific gravity	ASTM D 792	—	1.60	1.62	1.60	1.30	1.44	1.27	1.42	1.33
Water absorption rate	ASTM D 570	%	<0.1	0.05	0.02	0.14	—	0.25	0.33	0.34
Molding shrinkage rate	ASTM D 955	mm/mm	—	—	0.025(4)	—	0.006	0.006	—	0.008
Electrical properties										
Volume resistivity	ASTM D 257	Ω·mm	1×10^{15}	3×10^{15}	5×10^{15}	10^{16}	—	10^{16}	2×10^{16}	—
Dielectric breakdown strength	ASTM D 149	kV/mm	25	43	—	19	—	30	24	—
Dielectric constant (10^6 Hz)	ASTM D 150	—	3.6	3.8	2.7	3.3	—	3.15	3.9	3.1
Dielectric tangent (10^6 Hz)	ASTM D 150	—	0.034	0.017	0.030	0.003	—	0.0013	0.031	0.0034

Note (1) Previous "heat distortion temperature"
(2) There are three items of mechanical strength (with or without impact) and electrical properties.
(3) compression strength
(4) Average value of MD and TD Actual value: MD/TD=0.0013/0.0033

Remarks The abbreviations and names of each resin are as follows.
PPS: Polyphenylene sulfide, PAR: Polyarylate, PTFE: Polytetrafluoroethylene,
PSU: Polysulfone, PES: Polyether sulfone, LCP: Liquid crystal polymer,
PEEK: Polyether ether ketone, PEI, Polyetherimide, PAI: Polyamideimide,
TPI: Thermoplastic polyimide, GF: Glass fibers

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