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Teijin's Materials for Medical Devices Exteriors

Unlocking Infinite Potential in Healthcare

TEIJIN LIMITED. Resin & Plastic Processing Business Unit

Introduction

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- Teijin has developed a number of resin businesses centered on the polycarbonate resin Panlite®, first commercialized by Teijin in Japan in 1960. Teijin has been researching and developing in the medical field for over 30 years.
- Based on the Company's pioneering spirit of making the impossible possible, Teijin provides solutions that support advanced medical care to meet the needs of its customers.

Wish to safe your devices from all disinfectants
Chemical resistance

Wish to use environment friendly materials
Halogen free flame resistant UL94 V-0

Wish to use safer materials
Biocompatibility (ISO 10993)

Wish to use safe and secure materials
Long term reliability

Wish to replace glass bottles with resin bottles
Airtightness

Wish to use materials that can withstand sterilization
Gamma-ray/ electron-beam sterilization

SUSTAINABLE DEVELOPMENT GOALS

PC alloy grade

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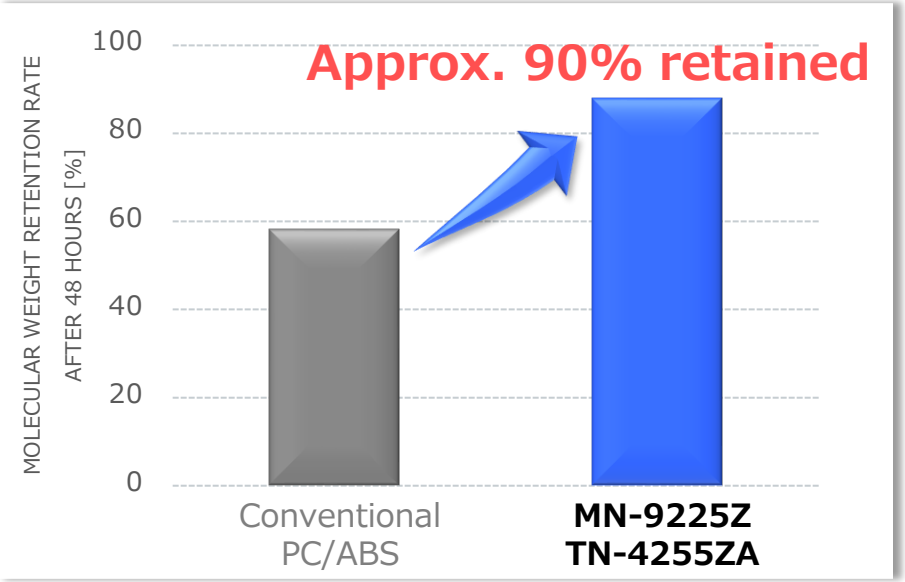
Features

- This grade is environment friendly, not using halogen flame resistant agents*.
  ＊Except for XJ-0878 and XJ-0879
- Compared to general flame resistance PC/ABS or flame resistance ABS products, products of this category excel in the balance between flame resistance and various properties.

Type	Grade	Biocompatibility	Flame resistance	UV	Hydrolysis resistance	Antiseptic resistance
High impact	TN-7500M	✓	✓			
long-term reliability	TN-4255ZA		✓	✓	✓	
	MN-9225Z	✓	✓	✓	✓	✓
	XJ-0878 (Development)		✓	✓	✓	✓

Long-term reliability grade



Compared to conventional PC/ABS products, products of this category made a significant improvement regarding hydrolytic deterioration; they are qualified for UL746C f1 and suitable for applications that require long-term reliability.

【Test method】 : An acceleration test was conducted in a hot and humid environment, and the level of deterioration of resin was measured from the apparent average molecular weights before and after treatment.
【Treatment condition】 : 120℃/100%RH

- Apparent molecular weight retention rate = molecular weight after treatment / molecular weight before treatment

Antiseptic resistance grade

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Classification	Sodium hypochlorite					Alcohol				
Chemical name	CLOROX Bleach Germicidal Wipes					70v/v% Isopropyl alcohol				
Stress(MPa)	0	9.8	13.7	18.0	31.0	0	9.8	13.7	18.0	31.0
MN-9225Z	1	1	1	1	1	1	1	1	1	3
Conventional PC/ABS	1	1	2	—	—	1	2	3	—	—

【Test details】
1. Stress is applied to the test piece by using a forcible three-point flexure jig. The specified chemical or wipe is made to contact the test piece, and the whole jig is wrapped.
2. A change in the appearance after treatment under the specified conditions is judged based on evaluation criteria.

【Test condition】 ASTM D543

【Evaluation criteria】

No.	1	2	3	4
Figure				
Evaluation	No effect	Craze	Crack	Break

In addition to "long-term reliability," MN-9225Z excels in resistance to various antiseptics used in medical institutions.

High antiseptic-resistant grade (New development product)

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Features

- ✓ Excellent resistance to antiseptics
- ✓ High thermal stability and excellent molding stability
- ✓ Excellent long-term reliability for UV resistance and resistance to dry heat
- ✓ Excellent impact resistance

Grade	Resistance to antiseptics	Dimensional stability for molding	Impact resistance	Long term reliability
XJ-0878	+++	+	++	+++
MN-9225Z	++	+	○	+++

+++ Excellent ++ very good + good ○ standard

Antiseptics resistance

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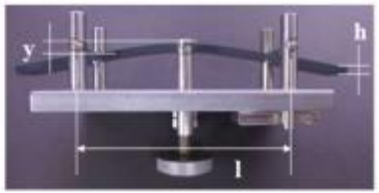
【Test details】

1. Distortion is caused to the test piece by using a forcible 3-point flexure jig shown in the figure. The specified chemical or wipe is made to contact the test piece.
2. A change in the appearance after treatment under the specified conditions is observed.
3. After the appearance is checked, a tensile test is conducted to calculate the tensile strength retention rate and rate of tensile strain at break.

【Test condition】 ASTM D543

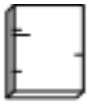
- Test piece: ISO dumbbell test piece
- Strain: 1%
- Test environment : 60℃×50%RH×7days



$\sigma = \varepsilon \cdot E$

σ : Stress(MPa)
ε : Strain in the outermost layer
E : Flexural modulus(MPa)

【Evaluation Criteria】

Symbol	+++ Excellent	++ Very Good	+ good	○ standard
Appearance evaluation	 No effect	 Craze	 Crack	 Break

Resistance to antiseptics (New development product)

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Antiseptics	Appearance evaluation	
	XJ-0878	MN-9225Z
PDI Sani-Cloth Bleach Germicidal Disposable Wipe	+++	+++
Super Sani Cloth Germicidal Wipe	+++	+++
PDI Sani-Cloth AF3　Germicidal Disposable Wipe	++	++
Sani-Cloth Plus Germicidal Disposable Cloth	+++	+++
Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes	+++	+
CLOROX Bleach Germicidal Wipes	+++	+++
CaviWipes 1	+++	++
Virex TB	++	+
CIDEX OPA Solution	+++	++
70v/v% Isopropyl alcohol	++	++
80v/v% Ethanol	+++	++

XJ-0878 excel in resistance to various antiseptics used in medical institutions.

PC alloy grade Physical properties

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Property	Unit	Standard	Condition	High impact	Long-term reliability		
				TN-7500M	TN-4255ZA	MN-9225Z	XJ-0878※※
				—	General	Antiseptic resistance	High antiseptic-resistance
Density	kg/m³	ISO 1183	-	**1,170**	**1,180**	**1,240**	**1,300**
Tensile stress at yield	MPa	ISO 527-1 ISO 527-2	50mm/min	**60**	**60**	**55**	**53**
Tensile stress at break	MPa			**50**	**50**	**50**	**52**
Tensile strain at break	%			**100**	**80**	**110**	**123**
Flexural strength	MPa	ISO 178	2mm/min	**90**	**90**	**85**	**75**
Flexural modulus	MPa			**2,600**	**2,600**	**2,500**	**2,100**
Charpy impact strength	kJ/m²	ISO 179	notched	**30**	**35**	**14**	**58**
Heat deflection temperature	℃	ISO 75-1 ISO 75-2	1.80MPa	**80**	**96**	**78**	**87**
Mold shrinkage rate	%	In house method (4mmt)	parallel	**0.5～0.7**	**0.5～0.7**	**0.4～0.6**	**0.8～1.0**
			vertical	**0.5～0.7**	**0.5～0.7**	**0.4～0.6**	**0.8～1.0**
Flammability	-	UL94	-	**0.45mm/HB 0.8mm/V-2 1.2mm/V-1 1.5mm/V-0 1.8mm/5VB**	**0.7mm/V-2 1.0mm/V-1 1.5mm/V-0 2.0mm/5VB**	**0.7mm/V-2 1.5mm/V-0 2.0mm/5VB**	**1.5mm/V-0 2.5mm/5VA (equivalent)**

※ The values shown in the figure are representative values but not guaranteed values.
※※ Bromine flame resistant grade

Molding conditions

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Property	Unit	PC transparent grade	PC alloy grade			
			TN-7500M	TN-4225ZA	MN-9225ZA	XJ-0878
Molding temperature	℃	280~330	230~270	240~300	240~280	240~270
Mold temperature	℃	70~120	50~70	50~70	60~70	50~70
Injection molding pressure	MPa	98~147	59~147	59~157	59~157	59~147
Drying temperature	℃	120	80	90	80	90
Drying time	h	5~8	5~8	5~8	5~8	5~8
Temperature inside hopper	℃	120	80	90	80	90

※ Dehumidifying type dryers are recommended.

Molding condition & Caution

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(1) **Pre-drying**
For drying conditions, when a box type hot air dryer is used, make the pellet layer 3 cm or less, and refer to the table on the next page for the drying temperature and conditions. As shown in the following table, heat the hopper to keep pellets hot and prevent moisture absorption. If drying is not sufficient, resin deterioration occurs because of hydrolysis and thermolysis during the molding process. Conduct pre-drying sufficiently. When dying is performed by using a hopper dryer, a hopper dryer with a capacity big enough to perform molding for four hours or more is appropriate, and for the temperature inside the hopper, refer to the table on the next page.

(2) **Injection molding**
Select an injection molding machine whose injection capacity is 1.5 to 3 times as big as the weight of a molded item; for the cylinder temperature, die temperature, and injection pressure, consider that the ranges shown in the table on the next page are appropriate. If the resin temperature exceeds the molding temperature range, resin deterioration occurs and leads to the causes of poor appearance and degradation of physical properties. Be careful. In addition, for a back pressure, apply approx. 10–20 MPa and make air inclusion as little as possible.
Set the screw rotating speed as low as possible, and ensure that measurement is completed two to three seconds before the time of cooling completion.
Resin accumulation inside the cylinder causes poor appearance and degradation of physical properties. To pause or stop the molding machine for a long period of time, lower the cylinder temperature to a level near 150℃, and then perform purging before restarting the molding machine to remove the accumulated resin completely.

CAUTION

- The figures listed in this technical data are typical values obtained under standard test methods, and may not be applicable for products that are used under different application conditions.
- The combustion figures listed in this technical data are from small-scale test and may not be applicable for hazards during a major fire.
- Please refer to us for an advice regarding the application conditions for medical equipment, food service applications, and toys.
- When any kind of additives (such as anti-bacterial agents, stabilizers and flame retardants) or coloring agents are to be added to this resin, please be sure to consult with TEIJIN LIMITED, in advance.
  However, even after consultation, TEIJIN LIMITED will not guarantee nor bear responsibility in any form for usage of such additives.
- Please carefully consider all potential industrial property rights when considering applications introduced in this technical data.
- The contents of this technical data may be changed without prior notice.
- Please refer to the Safety Data Sheet (SDS) before use for other warnings in detail.