

	TIB Plastic Industries		
	Technical Data Sheet		PVC COMPOUND PELLETS FOR EXTRUSION FOR MEDICAL APPLICATIONS
	<i>Quality Control</i>		
Register No.	TIB/QC/TDS-03	Issue No. / Date	01 Dt. 01/11/2006

BFlex 56N

APPLICATION: Injection – connectors / gaskets

We evaluate our BFlex products in accordance with the US Pharmacopia 23rd Edition and as per recommendation of FDA.

BFlex 56N PVC compound is manufactured from FDA and BgVV approved components , being suitable for the manufacturing of medical devices.

If some particular compounds are required for special applications , please contact our Technical Services Department, who with pleasure will provide the more information.

SPECIFICATIONS

<i>Description</i>	<i>Control Limit</i>	<i>Unit</i>	<i>Test Method</i>
1. Hardness (6 mm, 23 ± 2 °C, 15")	56 ± 3	Shore-A	ISO 868
2. Density at 20 °C	1.19 ± 0.005	g/cm ³	TEST-01
3. Elongation at Break	≥ 400	%	EN ISO 527-2
4. Tensile strength at Break	≥ 8	MPa	EN ISO 527-2
5. Modulus at 100% Elongation	3 – 8	MPa	EN ISO 527-2
6. Modulus at 25% Elongation	0.5 – 2	MPa	EN ISO 527-2
7. Modulus at 10% Elongation	0.1 – 1	MPa	EN ISO 527-2
8. Buffering Capacity	≤ 10	mL	USP - XXIII
9. Residue on Evaporation	≤ 5	mg	USP - XXIII
10. Residue on Ignition	≤ 1.0	mg	USP - XXIII
11. Heavy Metals (as Pb)	≤ 0.1	ppm	USP - XXIII

RECOMMENDED PROCESSING PARAMETERS

The customers are recommended to determine optimum conditions by themselves , as these may vary with each particular type of machine. As a general guide, following are the typical processing parameters.

Zone 1 (Hopper End)	Zone 2	Zone 3	Die
135 °C	140 °C	145 °C	150 °C

Further processing information and recommendations can be obtained from our Technical Services Department

STORAGE CONDITIONS

1. Store under dark in cool and dry conditions; strictly secured from exposure to direct sunlight or artificial lights, and from prolonged ultraviolet or gamma radiations . Exposure to indirect light should also be avoided . For storage exceeding one year period, covering of the packed product with black UV barrier PE sheets is recommended
2. Storage of 25-kg bags over 5-layer stacked conditions for over a period of one year should be avoided to prevent the possibility of agglomerate formation , which though could be easily disintegrated by light pressures without affecting the overall product quality.
3. It is recommended to precondition / temprature-stabilize the material for 24 hours prior to use. Sudden change in temprature and humidity may generate the adhearance of moisture on the surface of granules.

The data and recommendations contained in this product information represent the current state of our knowledge and serve as guide only to our products and their potential applications. Therefore, no guarantee neither of specific properties of the products mentioned herein nor of their suitability or fitness for a particular purpose is implied.

The information given in this leaflet should be checked by preliminary trials because of conditions during processing , over which we have no control , especially where other companies' raw materials are also being used.