

Solutran[®] dop free

*Medical PVC phthalate-free for infusional sector:
container for peritoneal dialysis -
haemodialysis - infusional solution*

Solutran[®] dop free PVC GRANULE

Solutran[®] dop free is the Meditalia srl brand of granules, tubulars, tube and bags in PVC, phthalate-free (DOP FREE).

The non-toxic medical grade Solutran[®] dop free granule is to be used in peritoneal dialysis, hemodialysis and infusional solution sectors.

Meditalia Srl offers its customers a wide range of Solutran[®] dop free granules:
– from granules of a natural colour to those in light blue (crystal) in customized shades;
– granules from 60 to 90 Shore A of hardness, to be used in the extrusion process of both tubulars and tubes;

The Solutran[®] dop free granules are produced in a completely automated and sealed granulation plant guaranteeing the purity of the finished product, strictly using suitable raw materials certified for medical use.

The Solutran[®] dop free granules offer high-performance workability properties during the extrusion process.

Solutran[®] dop free PVC LAY FLAT TUBE, DOUBLE WOUND FLAT FILM AND TUBE

Solutran[®] dop free lay flat tubes, double wound flat film and tubes are the Meditalia srl answer to the market's demand for the production of bags to be used in the sectors of peritoneal dialysis, hemodialysis and infusional solutions that need to be DOP FREE, PHTHALATE-FREE.

Solutran[®] dop free offers high performance workability properties both during the extrusion process and in the thermoforming for the production of bags. Medical bags maintain at the same time optimal chemical stability as well as transparency after the steam sterilization process.

Together with the Meditalia offer for Solutran Plus[®] tubulars and tubes, we also supply our customers with:

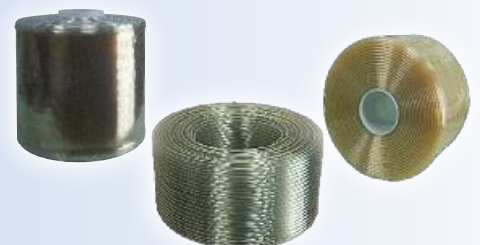
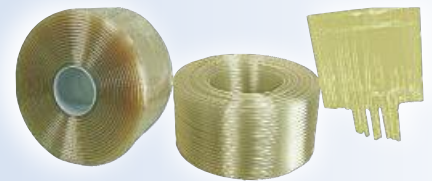
Tubulars

- from 0.30 to 0.40 mm in thickness (single layer)
- from 60 to 420 mm in width

Tubes

- in diameters and hardness requested by customers;
- rolling on coils or in precut pieces

The extrusion process (class ISO 8 white room) is performed with modern technologies which have been validated to guarantee chemical stability, constant and even coil rolling, absolute constancy in the dimension parameters. The laser detector provided with the tube extrusion plant guarantees the continuous size control of the external and internal diameter and of the thickness.



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Technical sheet

Medical grade PVC granule - lay flat tube - double wound flat film - tube - container
PHTHALATE FREE
for infusional solution - haemodialysis - peritoneal dialysis

CHEMICAL SPECIFICATIONS Eur. Ph. Sez. 3.1.1.1	
FORMULATION	
Poly(vinyl chloride)	> 55%
Plasticizer (DOP free)	< 40%
Epoxidised soya oil	< 5%
N,N'-diacylethylenediamines	< 1%
Calcium stearate	< 1%
TEST	
LIMIT VALUE	
Vinyl chloride	1,0 ppm
Appearance	Clear, colourless
Alkalinity	1,0 ml HCl 0.01 M
Acidity	1,5 ml NaOH 0.01 M
Reducing substances	2,0 ml Na ₂ S ₂ O ₃ 0.01 M
UV absorption	0,25 250-310nm
Residue on evaporation	0,3%
Barium	5,0 ppm
Cadmium	0,6 ppm
Heavy metals	50,0 ppm
Calcium	0,07%
Tin	20,0 ppm
Zinc	0,2%

PHYSICAL PROPERTIES Typical test results on 83 ShA tubular				
TEST	VALUE	UNIT	REFEREN.	
Appearance	Omogeneous granules			
	Omogeneous film			
	Natural colour			
	Crystal colour			
	Contamination free			
	Burned point free			
Hardness	83	Shore A	ISO 868	
Tensile strenght at break	170	Kg/cm ²	ISO R527	
Elongation at break	300	%	ISO R527	
Temperature of stiffening	-9	°C	ISO R458	
Density	1,24	g/cm ³	ISO R1183	

BIOLOGICAL REACTIVITY UNI EN ISO 10993	
TEST	IN CONFORMITY
Irritation	Yes
Cytotoxicity	Yes
Implantation	Yes
Hemolysis	Yes
Systemic toxicity	Yes

Small color differences depend only on the color tone of the resin

Search results for: 09-1892
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Regions searched: 3995.85-700.04

