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TECHNICAL DATA SHEET

SIF-TUBE® Medical Grade PVC Tube

Product code: **0004T** (specific identification code)

Compound: **SIFLEX**® SE0004EG Medical Grade PVC Granulate

NOTE: Small color differences depend only on the color tone of the PVC resin.
 This technical information consists of typical product data and should not be used as a specification.

CHEMICAL SPECIFICATIONS

Eur. Ph. Ed. in force

FORMULATION

- Not less than 55% of poly(vinyl chloride)
- Not more than 40% of di(2-ethylhexyl)phthalate
- Not more than 1% of zinc octanoate (zinc 2-ethylhexanoate)
- Not more than 1% of calcium stearate or zinc stearate or 1% of a mixture of the two
- Not more than 1% of *N,N'* diacylethylenediamines (in this context acyl means in particular palmitoyl and stearoyl)
- Not more than 10% of one the following epoxidised oils or 10% of a mixture of the two
- Epoxidised soya oil of which the oxiran oxygen content is 6% to 8% and the iodine value is not greater than 6
- Epoxidised linseed oil of which the oxiran oxygen content is not greater than 10% and the iodine value is not greater than 7

TEST

Alkalinity
 Acidity
 UV absorption

 Reducing Substances
 Water extractable substances
 Appearance

Limit Value

0,5 HCl 0.01 M
 0,5 NaOH 0.01 M
 0,30 230/250nm
 0,15 251/360nm
 2.0 ml Na₂S₂O₃ 0.01 M
 1.5 mg
 Clear, colourless

GENERAL STATEMENT

We hereby confirm that this product meets the requirements of the European Pharmacopoeia of less than 50 ppm for total incidental Heavy Metals and less than 1.0 ppm for Vinyl chloride.

BIOLOGICAL REACTIVITY

USP XXIV

TEST	VALUE
Test for Cytotoxicity	In Conformity
Acute Systemic injection test in the Mouse	In Conformity
Intracutaneous Injection in the Rabbit	In Conformity
Implantation Test in the Rabbit	In Conformity
Hemolysis test	In Conformity
Bacterial Endotoxins Test (LAL Test)	In Conformity
Physicochemical tests - Plastics	In Conformity

PHYSICAL PROPERTIES

The physical properties listed below are referring to the Compound.

TEST	UNIT MEASURES	VALUE	PROCEDURE
Tensile strength at break	N/cm ²	1538	ASTM D-638
Elongation at break	%	431	ASTM D-638
Break at low temperature	°C	- 32° C	ASTM D-1043
Shore "A" durometer hardness	SH"A" (15"/48h)	70 ± 2	ISO 868
Density	gr/cm ³	1,205	ASTM D-792

Date: 20/10/2009 – revision: 07
 Date of issued: 20/10/09
 Signature:

Date of verification: 20/10/09
 Signature:

Date of approval: 20/10/09
 Signature:

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