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TECHNICAL DATA SHEET

SIF-TUBE® Medical Grade PVC Tube

Product code: **0006T** (specific identification code)

Compound: **SIFLEX**® SE0006EG 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 zin 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

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

VALUE

In Conformity

 In Conformity
 In Conformity
 In Conformity
 In Conformity
 In Conformity
 In Conformity

PHYSICAL PROPERTIES

The physical properties listed below are referring to the Compound.

TEST

Tensile strength at break
 Elongation at break
 Break at low temperature
 Shore "A" durometer hardness
 Density

UNIT MEASURES

MPa
 %
 °C
 SH"A" (15"/23°C)
 gr/cm³

VALUE

17
 360
 - 14° C
 78 ± 2
 1,24 ± 0.02

PROCEDURE

ISO 527
 ISO 527
 ISO 458
 MAL 1-002
 MAL 1-001

Date: 20/10/2009 – revision: 10
 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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