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TECHNICAL DATA SHEET

SIF-TUBE[®] Medical Grade PVC Tube

Product code: 0201T (specific identification code)

Compound: **SIFLEX[®]** SE0201EG 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
- Blue ultramarine

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
 0,15 251/660nm
 2.0 ml $Na_2S_2O_3$ 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 Vinylchloride.

BIOLOGICAL REACTIVITY

USP XXIV

| TEST | VALUE |
|--|---------------|
| Test for Cytotoxicity 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 | 1214 | ASTM D-638 |
| Elongation at break | % | 481 | ASTM D-638 |
| Break at low temperature | °C | - 37° C | ASTM D-1043 |
| Shore "A" durometer hardness | SH"A" (15"/48h) | 58 ± 2 | ISO 868 |
| Density | gr/cm ³ | 1,168 | ASTM D-792 |

Date: 20/10/2009 – revision: 00
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 Signature:

Date of verification: 20/10/09
 Signature:

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 Signature:

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