



S.I.F.R.A. EST S.P.A.
 QUALITY CONTROL DEPARTMENT
 APPROVED LABORATORY FOR APPLIED RESEARCH
 (Reg. Aut. F.V.G. decr. 150/art. 10/250)

S.I.F.R.A. EST S.P.A.
 tel.: +39 040 823602
 Fax: +39 040 280605
 e-mail: info@sifraest.com
<http://www.sifraest.com>

TECHNICAL DATA SHEET

SIFLEX[®] Medical Grade PVC Granulate
 Product code: SE0205EG

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% or 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
- Residue on Evaporation
- Cadmium
- Heavy Metals
- Appearance
- Tin
- Zinc
- Vinylchloride
- Barium
- Calcium

Limit Value

- 1,0 ml HCl 0,01 M
- 1,5 ml NaOH 0,01 M
- 0,25 250/310nm
- 2,0 ml Na₂S₂O₃ 0,01 M
- 0,3 %
- 0,6 ppm
- 50,0 ppm
- Clear, colourless
- 20,0 ppm
- 0,2 %
- 1,0 ppm
- 5,0 ppm
- 0,07 %

BIOLOGICAL REACTIVITY

USP XXIV

TEST

- Test for Cytotoxicity
- Implantation Test in the Rabbit
- Hemolysis test
- Bacterial Endotoxins Test (LAL Test)

VALUE

- In Conformity
- In Conformity
- In Conformity
- In Conformity

PHYSICAL PROPERTIES

TEST

- Tensile strength at break
- Elongation at break
- Break at low temperature
- Shore "A" durometer hardness
- Density
- Water vapour trans. rate
- Oxygen permeability

UNIT MEASURES

- MPa
- %
- °C
- SH"A" (15"/23°C)
- gr/cm³
- gr/(mq*day*bar)
- cm³/(mq*day*bar)

VALUE

- 16
- 380
- 14° C
- 75 ± 2
- 1,21 ± 0,02
- 4,9 to 23°C
- 440 to 23°C

PROCEDURE

- ISO 527
- ISO 527
- ISO 458
- MAL 1-002
- MAL 1-001
- ASTM F-1249
- ASTM D-3985

Date: 20/10/2009 – revision: 02
 Date of issued: 20/10/09
 Signature:

Date of verification: 20/10/09
 Signature:

Date of approval: 20/10/09
 Signature:

The information contained herein is to our knowledge accurate and reliable as of the date of publication.
 S.I.F.R.A. EST S.P.A makes no representations as to accuracy or completeness of the information contained herein and assumes no responsibility regarding the consequences of its use or for any printing errors. It is the customer's responsibility to inspect and test our products in order to satisfy himself as to the suitability of the product for the customer's particular purpose. The customer is also responsible for the appropriate, safe and legal use, processing and handling of our products.