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 QUALITY CONTROL DEPARTMENT
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 (Reg. Aut. F.V.G. decr. 150/art. 10/250)

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TECHNICAL DATA SHEET

SIFLEX[®] Medical Grade PVC Granulate
 Product code: SE0001EG

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

TEST

- Alkalinity
- Acidity
- UV absorption
- Reducing Substances
- Residue on Evaporation
- Cadmiun
- Heavy Metals
- Appearance
- Tin
- Zinc
- Vinychloride
- Barium
- Calcium

Limit Value

- 1,0 ml HCl 0,01 M
- 1,5 ml NaOH 0,01 M
- 0,25 250/370nm
- 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
- 0,0 %

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

- N/cm²
- %
- °C
- SH"A" (15"/48h)
- gr/cm³
- gr/(mq*day*bar)
- cm³/(mq*day*bar)

VALUE

- 1214
- 481
- 37° C
- 58 ± 2
- 1,168
- 4,9 to 23°C
- 440 to 23°C

PROCEDURE

- ASTM D-638
- ASTM D-638
- ASTM D-1043
- ISO 868
- ASTM D-792
- ASTM F-1249
- ASTM D-3985

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