

PURASORB[®] PLC 9538

Product specification data sheet

Rev. No. 1 / May 2019

Description PURASORB PLC 9538 is a GMP grade copolymer of L-lactide and ε-Caprolactone in a 95/05 molar ratio and with an inherent viscosity midpoint of 3.8 dl/g. It is supplied in the form of white to light tan granules. PURASORB PLC 9538 is primarily used for medical device applications and is suitable for all commonly used polymer processing techniques.

| | |
|-----------------------------|---|
| Chemical composition | 95/05 L-lactide/Caprolactone copolymer |
| Item | 1840506 |
| Molecular formula | $[(C_6H_8O_4)_x(C_4H_4O_4)_y]_n$ |
| Chemical name | (3S-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with 2-oxepanone |
| CAS Registry number | 65408-67-5 |

| Test | Method | Specification |
|-----------------------------|---|-----------------------------|
| Appearance | Visual test | White to light tan granules |
| Identity | FTIR spectroscopy | Conforms to reference |
| Monomer ratio, Lactide | NMR spectroscopy | 93 - 97 mol % |
| Monomer ratio, Caprolactone | NMR spectroscopy | 03 - 07 mol % |
| Inherent viscosity | Viscometry Chloroform, 25 °C, c = 0.1 g/dl | 3.3 - 4.3 dl/g |
| Specific rotation | Polarimetry Chloroform, 20 °C | Report data |
| Melting range | DSC 10 °C/min | Report data |
| Water | Coulometric titration | max. 0.5 % |
| Tin | ICP | max. 100 ppm |
| Residual solvent, total | GC, headspace | max. 0.1 % |
| Residual solvent, acetone | GC, headspace | max. 5000 ppm |
| Residual solvent, toluene | GC, headspace | max. 890 ppm |
| Residual monomer, total | GC | max. 0.5 % |
| Residual monomer, lactide | GC | max. 0.5 % |

| Test | Method | Specification |
|--------------------------------|----------------|----------------------|
| Residual monomer, caprolactone | GC | max. 0.5 % |
| Elemental impurities | USP method 232 | max. 10 ppm |

Packaging PURASORB PLC 9538 can be supplied in 1 kg packages. Our standardized packaging consists out of four protective layers, an inner layer of clean room grade PE bag, an outer bag of aluminum coated polyester-PE laminate, inserted in the additional bag of PE for extra protection and shipped in sealed PE containers.

Storage & Handling When stored in the original packaging at low temperatures (-15°C), PURASORB PLC 9538 keeps its initial properties for five years (expiry date).

Stability studies indicate that, when stored in the original packaging at room temperature, PURASORB PLC 9538 keeps its initial properties for at least one year.

Please refer to our current stability statement for most up to date information on storage stability.

Allow the material to reach room temperature before opening the packaging. After opening the original packaging PURASORB PLC 9538 is best stored in an inert atmosphere and at low temperatures (-15°C).