PURASORB ® PLC 9517

Product specification data sheet Rev. No. 1 / May 2019

Description

PURASORB PLC 9517 is a GMP grade copolymer of L-lactide and ε-Caprolactone in a 95/05 molar ratio and with an inherent viscosity midpoint of 1.7 dl/g. It is supplied in the form of white to light tan granules. PURASORB PLC 9517 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	1840505
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	1.4 - 2.0 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 9517 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 9517 keeps its initial properties for five years (expiry date).

Stability studies indicate that, when stored in the original packaging at room temperature, PURASORB PLC 9517 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 9517 is best stored in an inert atmosphere and at low temperatures (-15°C).