

PURASORB[®] PDLG 5004A

Product specification data sheet

Rev. No 3 / March 2021

Description PURASORB PDLG 5004A is an acid terminated GMP grade copolymer of DL-lactide and Glycolide in a 50/50 molar ratio and with an inherent viscosity midpoint of 0.4 dl/g. It is supplied in the form of white to light tan granules. PURASORB PDLG 5004A is primarily used for drug delivery applications and is suitable for all commonly used formulation techniques.

Chemical composition	50/50 DL-lactide/Glycolide copolymer
Material numbers	1001013060 / 1001013050 / (1840426)
Molecular formula	$[(C_6H_8O_4)_x(C_4H_4O_4)_y]_n$
Chemical name	3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with 1,4-dioxane-2,5-dione
CAS Registry number	26780-50-7

Test	Method	Specification
Appearance	Visual test	White to light tan granules
Identity	FTIR spectroscopy	Conforms to reference
Monomer ratio, DL	NMR spectroscopy	47 - 53 mol %
Monomer ratio, G	NMR spectroscopy	47 - 53 mol %
Inherent viscosity	Viscometry Chloroform, 25 °C, c = 0.5 g/dl	0.32 - 0.48 dl/g
Specific rotation	Polarimetry Chloroform, 20 °C	(-2.0) - (+2.0) °
Water	Coulometric titration	max. 0.50 %
Tin	ICP	max. 50 ppm
Residual solvent, total	GC, headspace	max. 0.10 %
Residual solvent, toluene	GC, headspace	max. 890 ppm
Residual monomer, total	GC	max. 2.0 %
Residual monomer, DL-lactide	GC	max. 2.0 %
Residual monomer, Glycolide	GC	max. 2.0 %
Elemental impurities	USP method 232	max. 10 ppm
Acid number	Titration	min. 3.0 mg KOH/g

Test	Method	Specification
Total microbial count	USP method 61	max. 2×10^3 CFU/g
Yeast and moulds	USP method 61	max. 2×10^2 CFU/g
Bacterial endotoxins	USP method 85	max. 6.00 EU/g

Packaging PURASORB PDLG 5004A can be supplied in 1 kg packages. Our standard 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 an additional bag of PE and shipped in sealed PE containers.

Storage & Handling When stored in the original packaging at low temperatures ($-15\text{ }^{\circ}\text{C}$), PURASORB PDLG 5004A keeps its initial properties for at least three years. (retest date)

Stability studies indicate that, when stored in the original packaging at room temperature, PURASORB PDLG 5004A 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 PDLG 5004A is best stored in an inert atmosphere and at low temperatures ($-15\text{ }^{\circ}\text{C}$).