

PURASORB® PDL 02A

Product specification data sheet

Rev. No. 1 / April 2021

Description PURASORB PDL 02A is a GMP grade copolymer of DL-lactide with an inherent viscosity midpoint of 0.2 dl/g. It is supplied in the form of white to light tan granules. PURASORB PDL 02 is primarily used for drug delivery applications and is suitable for all commonly used formulation techniques.

Chemical composition	Poly(DL-lactide)
Material numbers	1001012348 /1001012353 (1824012)
Molecular formula	$(C_6H_8O_4)_n$
Chemical name	poly[3,6-dimethyl-1,4-dioxane-2,5-dione]
CAS Registry number	26680-10-4

Test	Method	Specification
Appearance	Visual test	White to light tan granules
Identity	FTIR spectroscopy	Conforms to reference
Inherent viscosity	Viscometry Chloroform, 25 °C, c = 1 g/dl	0.16 – 0.24 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. 2.4 %
Elemental impurities	USP method 232	max. 10 ppm
Acid number	Titration	min. 6.0 mg KOH/g
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 PDL 02A 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 PDL 02A keeps its initial properties for at least three years (retest date).

Current stability studies indicate that when stored in the original packaging at room temperature PURASORB PDL 02A 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 PDL 02A is best stored in an inert atmosphere and at low temperatures (-15°C).
