

PURASORB® PDL 04A

Product specification data sheet

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Description PURASORB PDL 04A is an acid terminated GMP grade copolymer of DL-lactide with an inherent viscosity midpoint of 0.4 dl/g. It is supplied in the form of white to light tan granules. PURASORB PDL 04A is primarily used for drug delivery applications and is suitable for all commonly used formulation techniques.

Chemical composition	Poly(DL-lactide)
Item	1824021
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 = 0.5 g/dl	0.35 – 0.45 dl/g
Specific rotation	Polarimetry Chloroform, 20 °C	(-2) – (+2) °
Tg, second run	DSC, 10 °C	Report result
*Mw	GPC, Chloroform	For information purpose only
*Mn	GPC, Chloroform	For information purpose only
*Mw/Mn	GPC, Chloroform	For information purpose only
Water content	Coulometric titration	max. 0.5 %
Tin content	ICP	max. 50 ppm
Residual solvent, total	GC, headspace	max. 0.1 %
Residual solvent, toluene	GC, headspace	max. 890 ppm
Residual monomer, total	GC	max. 2 %
Acid number	Titration	Report result

Total microbial count	TAMC	max. 2×10^3 CFU/g
Yeast and moulds	TYMC	max. 2×10^2 CFU/g
Bacterial endotoxins	USP method 85	max. 6 EU/g

Packaging

PURASORB PDL 04A can be supplied in 1 kg packages. Normal packaging consists of an inner bag of clean room grade PE and an outer bag of aluminum coated polyester-PE laminate. The packed product is shipped in an additional bag of PE and in PE containers for added protection.

Storage & Handling

When stored in the original packaging at low temperatures (-15°C), PURASORB PDL 04A 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 04A 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 04A is best stored in an inert atmosphere and at low temperatures (-15°C).