

## PURASORB<sup>®</sup> PDL 04

### Product specification data sheet

Rev. No.3 / April 2022

**Description** PURASORB PDL 04 is a 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 04 is primarily used for drug delivery applications and is suitable for all commonly used formulation techniques.

<b>Chemical composition</b>	Poly(DL-lactide)
<b>Material numbers</b>	1001012300 / 1001012310 / (1824008)
<b>Molecular formula</b>	(C <sub>6</sub> H <sub>8</sub> O <sub>4</sub> ) <sub>n</sub>
<b>Chemical name</b>	poly[3,6-dimethyl-1,4-dioxane-2,5-dione]
<b>CAS Registry number</b>	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	0.32 – 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. 2.4 %
Elemental impurities	USP method 232	max. 10 ppm



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**Packaging**

PURASORB PDL 04 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.

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**Storage & Handling**

When stored in the original packaging at low temperatures (-15°C), PURASORB PDL 04 keeps its initial properties for at least five years (expiry date).

Current stability studies indicate that when stored in the original packaging at room temperature PURASORB PDL 04 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 04 is best stored in an inert atmosphere and at low temperatures (-15°C).

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