

PURASORB® PDL 04A

Product specification data sheet

Rev. No.2 / March 2021

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.

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| Chemical composition | Poly(DL-lactide) |
| Material numbers | 1001018372 / 1001018397 / (1824021) |
| Molecular formula | (C ₆ H ₈ O 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 | (-2.0) – (+2.0) ° |
| 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. 0.50 % |
| Tin content | 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 % |
| Acid number | Titration | Report result |
| Total microbial count | USP 61 | max. 2 x 10 ³ CFU/g |



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|----------------------|---------------|----------------------------|
| Yeast and moulds | USP 61 | max. 2×10^2 CFU/g |
| Bacterial endotoxins | USP method 85 | max. 6.00 EU/g |

Packaging

PURASORB PDL 04A 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 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).
