

PURASORB® PDL 05

Product specification data sheet

Rev. No.3 / April 2022

Description PURASORB PDL 05 is a GMP grade copolymer of DL-lactide with an inherent viscosity midpoint of 0.5 dl/g. It is supplied in the form of white to light tan granules. PURASORB PDL 05 is primarily used for drug delivery applications and is suitable for all commonly used formulation techniques.

| | |
|-----------------------------|--------------------------------------------------------------|
| Chemical composition | Poly(DL-lactide) |
| Material numbers | 1001012322 / 1001012334 / (1824011) |
| 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 | 0.40 – 0.60 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 |



Packaging

PURASORB PDL 05 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 05 keeps its initial properties for at least five years (expiry date).

Stability studies indicate that, when stored in the original packaging at room temperature, PURASORB PDL 05 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 05 is best stored in an inert atmosphere and at low temperatures (-15°C).
