

PURASORB® PDLG 8531

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Product data sheet

Description PURASORB PDLG 8531 is a GMP grade copolymer of DL-lactide and Glycolide in a 85/15 molar ratio and with an inherent viscosity midpoint of 3.1 dl/g. It is supplied in the form of white to light tan granules. PURASORB PDLG 8531 is primarily used for drug delivery applications and is suitable for all commonly used formulation techniques.

| Specification | Test | Method | Specification |
|---------------|--------------------|------------------------------------|-----------------------------|
| | Appearance | visual | white to light tan granules |
| | Identification | FTIR | conforms to reference |
| | DL-lactide content | HNMR | 83 - 87 mol% |
| | Glycolide content | HNMR | 17 - 13 mol% |
| | Inherent viscosity | CHCl ₃ , 25°C, 0.1 g/dl | 2.5 – 3.5 dl/g |
| | Residual monomer | GC | max. 2 wt. % |

For each batch a certificate of analysis is provided, showing the analytical data determined in our quality control laboratory. Additional analytical data can be made available upon request.

| Physical-chemical properties | Test | Method |
|------------------------------|---------------------|--|
| | Molecular formula | $(C_6H_8O_4 * C_4H_4O_4)_n$ |
| | Chemical name | 3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with 1,4-dioxane-2,5-dione |
| | CAS Registry number | 26780-50-7 |

Packaging PURASORB PDLG 8531 can be supplied in 1 or 5 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 PDLG 8531 keeps its initial properties for five years.

Current stability studies indicate that when stored in the original packaging at room temperature PURASORB PDLG 8531 keeps its initial properties for at least one year.

Allow the material to reach room temperature before opening the packaging. After opening the original packaging PURASORB PDLG 8531 is best stored in an inert atmosphere and at low temperatures (-15°C)