

## PURASORB® PDL 45

### Product specification data sheet

Rev. No.1 / May 2019

**Description** PURASORB PDL 45 is a GMP grade copolymer of DL-lactide with an inherent viscosity midpoint of 4.5 dl/g. It is supplied in the form of white to light tan granules. PURASORB PDL 45 is primarily used for medical device applications and is suitable for all commonly used polymer processing techniques.

|                             |  |
|-----------------------------|--|
| <b>Chemical composition</b> | Poly(DL-lactide)                         |
| <b>Item</b>                 | 1824005                                  |
| <b>Molecular formula</b>    | $(C_6H_8O_4)_n$                          |
| <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<br>Chloroform, 25 °C, c = 0.1 g/dl | 3.5 – 5.5 dl/g              |
| Specific rotation         | Polarimetry<br>Chloroform, 20 °C              | (-2) – (+2) °               |
| Water                     | Coulometric titration                         | max. 0.5 %                  |
| Tin                       | 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 %                    |
| Elemental impurities      | USP method 232                                | max. 10 ppm                 |

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**Packaging**

PURASORB PDL 45 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.

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**Storage & Handling**

When stored in the original packaging at low temperatures (-15°C), PURASORB PDL 45 keeps its initial properties for five years (expiry date).

Stability studies indicate that, when stored in the original packaging at room temperature, PURASORB PDL 45 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 45 is best stored in an inert atmosphere and at low temperatures (-15°C).

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