

## PURASORB® PLDL 8058

### Product specification data sheet

Rev. No.2 / March 2021

**Description** PURASORB PLDL 8058 is a GMP grade copolymer of L-lactide and DL-lactide in a 80/20 molar ratio and with an inherent viscosity midpoint of 5.8 dl/g. It is supplied in the form of white to light tan granules. PURASORB PLDL 8058 is primarily used for medical device applications and is suitable for all commonly used polymer processing techniques.

|                             |   |
|-----------------------------|---|
| <b>Chemical composition</b> | 80/20 L-lactide/DL-lactide copolymer  |
| <b>Material numbers</b>     | 1001012542 / (1840208)  |
| <b>Molecular formula</b>    | $[(C_6H_8O_4)_x(C_6H_8O_4)_y]_n$  |
| <b>Chemical name</b>        | (3S-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione, polymer with<br>3,6-dimethyl-1,4-dioxane-2,5-dione |
| <b>CAS Registry number</b>  | 52305-30-3  |

| Test                      | Method  | Specification               |
|---------------------------|---|-----------------------------|
| Appearance                | Visual test                                   | White to light tan granules |
| Identity                  | FTIR spectroscopy                             | Conforms to reference       |
| Monomer ratio, L          | Polarimetry, 20 °C                            | 77 - 83 mol %               |
| Monomer ratio, DL         | Polarimetry, 20 °C                            | 17 - 23 mol %               |
| Inherent viscosity        | Viscometry<br>Chloroform, 25 °C, c = 0.1 g/dl | 5.20 - 6.30 dl/g            |
| Specific rotation         | Polarimetry<br>Chloroform, 20 °C              | (-124.0) - (-128.0) °       |
| Melting range             | DSC, 10 °C/min                                | 110.0 – 132.4 °C            |
| Water                     | Coulometric titration                         | max. 0.50 %                 |
| Tin                       | ICP   | max. 50 ppm                 |
| Residual solvent, total   | GC, headspace                                 | max. 0.10 %                 |
| Residual solvent, acetone | GC, headspace                                 | max. 5000 ppm               |
| Residual solvent, toluene | GC, headspace                                 | max. 890 ppm                |
| Residual monomer, total   | GC  | max. 0.10 %                 |



| Test                 | Method         | Specification |
|----------------------|----------------|---------------|
| Elemental impurities | USP method 232 | max. 10 ppm   |

**Packaging** PURASORB PLDL 8058 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 PLDL 8058 keeps its initial properties for five years (expiry date).

Stability studies indicate that, when stored in the original packaging at room temperature, PURASORB PLDL 8058 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 PLDL 8058 is best stored in an inert atmosphere and at low temperatures (-15°C).