

## PURASORB<sup>®</sup> PLDL 8058

### Product specification data sheet

Rev. No.1 / May 2019

**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>Item</b>	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 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 Chloroform, 25 °C, c = 0.1 g/dl	5.2 - 6.3 dl/g
Specific rotation	Polarimetry Chloroform, 20 °C	(-124) - (-128) °
Melting range	DSC, 10 °C/min	110 - 132 °C
Water	Coulometric titration	max. 0.5 %
Tin	ICP	max. 50 ppm
Residual solvent, total	GC, headspace	max. 0.1 %
Residual solvent, acetone	GC, headspace	max. 5000 ppm
Residual solvent, toluene	GC, headspace	max. 890 ppm
Residual monomer, total	GC	max. 0.1 %

<b>Test</b>	<b>Method</b>	<b>Specification</b>
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).