

PURASORB® PL 32

Product specification data sheet

Rev. No.1 / May 2019

Description

PURASORB PL 32 is a GMP grade homopolymer of L-lactide with an inherent viscosity midpoint of 3.2 dl/g. It is supplied in the form of white to light tan granules.

PURASORB PL 32 is primarily used for medical device applications and is suitable for all commonly used polymer processing techniques.

 $\begin{array}{lll} \mbox{Chemical composition} & \mbox{Poly(L-lactide)} \\ \mbox{Item} & 1820019 \\ \mbox{Molecular formula} & (C_6H_8O_4)_n \\ \end{array}$

Chemical name poly[(3S-cis)-3,6-dimethyl-1,4-dioxane-2,5-dione]

CAS Registry number 33135-50-1

Test	Method	Specification
Appearance	Visual test	White to light tan granules
Identity	FTIR spectroscopy	Conforms to reference
Inherent viscosity	Viscometry Chloroform, 25 °C, c = 0.1 g/dl	2.7 – 3.6 dl/g
Specific rotation	Polarimetry Chloroform, 20 °C	(-155) — (-160) °
Melting range	DSC 10 °C/min	170 – 200 °C
Water	Coulometric titration	max. 0.5 %
Tin	ICP	max. 50 ppm
Residual solvent, total	GC, headspace	max. 0.01 %
Residual solvent, acetone	GC, headspace	max. 5000 ppm
Residual solvent, toluene	GC, headspace	max. 890 ppm
Residual monomer, total	GC	max. 0.1 %
Elemental impurities	USP method 232	max. 10 ppm

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Packaging

PURASORB PL 32 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.

Storage & Handling

When stored in the original packaging at low temperatures (-15°C), PURASORB PL 32 keeps its initial properties for five years (expiry date).

Stability studies indicate that, when stored in the original packaging at room temperature, PURASORB PL 32 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 PL 32 is best stored in an inert atmosphere and at low temperatures (-15°C).

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