

## 1. Description

rProtein A Seplife® Suno is an affinity chromatography resin based on agarose with affinity for the Fc region, designed for purification of mAbs and bispecific antibodies.

- rProtein A Seplife® Suno is based on a Sunresin proprietary genetically engineered protein A - derived ligand
- Providing good pressure flow characteristics
- High dynamic binding capacity of 70 mg/ml of IgG
- High stability to CIP ( cleaning in place) up to 1.0M NaOH
- Regulatory Support File (RSF) is available for rProtein A Seplife® Suno

rProtein A Seplife® Suno is an affinity chromatography resin based on 4% crossed linked agarose with high dynamic binding capacity and high tolerance to alkaline CIP, designed for purification of mAbs and bispecific antibodies and has a particle size range 40-100 micron.

## 2. Product Properties

### 2.1 Parameters

Product	rProtein A Seplife® Suno
Appearance	White spherical beads
Type	rProtein A affinity chromatographic resin
Matrix	Highly cross-linked 4% agarose
Ligand	Alkaline tolerant recombinant protein A (E.coli)
10% Dynamic binding capacity (mg /ml)**	≥70
Particle size range (µm)	40-100
pH stability	3-13 (operational), 2-14 (CIP)
Chemical Stability	Stable in all common aqueous buffers
Flow rate* (cm/h)	max 750cm/h
Shipped as	20% ethanol slurry

\*Testing conditions: Chromatography column 16mm×200mm; column bed height 20cm; temperature 25° C; mobile phase water.

\*\* Testing conditions: hlgG, RT=5min, Binding buffer: 20mm PB+0.15M NaCl, pH 7.4;elution buffer: 50mM Tris-HAc pH 3.5, Column 8mm\*100mm, room temperature.

### 3. Instructions

#### 3.1 Column packing

Column loading should be performed in accordance with standard operating procedures. It is important to ensure that each material is at its working temperature. r-Protein A Seplife® Suno can be loaded the same way conventional Seplife agarose media are loaded.

#### 3.2 Equilibration

Equilibrate the column with 3-5 CV of equilibration solution until the pH and conductivity remain unchanged.

#### 3.3 Sample feeding

Sample pretreatment: The sample needs to be filtered with a 0.45 μ m filter membrane before loading to avoid clogging the chromatographic column. The amount of sample loaded is determined according to the nature of the sample and the amount of chromatographic media. Generally, the DBC of the sample on the chromatographic column can be used as a reference for sample volume calculation.

#### 3.4 Elution

Generally, a low pH buffer is used for elution, and a buffer with a pH of 3.0-3.5 is selected: such as 0.1mol/L glycine-HCl, pH 3.0. The actual elution conditions can be optimized. After elution, it is recommended to adjust the pH of the mAb solution close to neutral. The neutralization solution could be 1mol/L Tris-HCl, pH 9- 10. Also, the chromatographic media should be returned to a higher pH.

The protein A leaching in the elution fraction can be quantified using Cygnus Protein A ELISA kit F610.

#### 3.5 Cleaning

CIP method:

r-Protein A Seplife® Suno is an alkaline-tolerant affinity resin, which can withstand cleaning with 0.1M-0.5M NaOH solution. Generally use more than 3CV of 0.1 – 0.5 M NaOH, and a contact time around 15 minutes; then rinse with 5CV of equilibration solution or until outlet pH and conductivity are same as inlet.

Note: The purification process of the fermentation broth may lead to impurities being adsorbed on the chromatographic media, resulting in an increase in pressure during CIP, an “up flow” CIP can be performed every cycle or after a certain number of cycles.

#### 3.6 Storage

Sealed and stored at 2-8° C (preservation solution is 20% ethanol) in a ventilated, dry and clean place, do not freeze.

### 3.7 Transportation

Avoid sunlight, rain, and heavy pressure during transportation. It is strictly forbidden to transport with toxic and hazardous materials.

## 4. Precautions

(1) After the chromatography media is taken out of the cold room or refrigerator, it is best to return it to room temperature, then shake it slowly and load it into the column to avoid air bubbles affecting the column efficiency.

(2) Generally, an optimum column bed height of rProtein A Seplife® Suno affinity resin is 15-25cm, but a suitable bed height should be determined according to the actual process.

(3) Perform clarification and filtration before loading the fermentation broth sample in order to prevent clogging of the chromatographic column.

(4) The elution time of the media with low pH buffer should be as short as possible, and the media should be washed to neutral pH as soon as possible after elution using neutralization buffer; this should prolong the service life of the resin.

## 5. Ordering information

Product Name	References	Pack Size
rProtein A Seplife® Suno	A4093101	5ml
	A4093102	25ml
	A4093103	100ml
	A4093104	500ml
	A4093105	1L
	A4093106	5L
	A4093107	10L

*Production date: See label*

*Expiry date: 5 years, under proper storage conditions*

**Manufacturer: Sunresin New Materials Co. Ltd.**

Add:No. 135, Jinye Rd, Xi'an

Hi-Tech Industrial Development Zone, Shaanxi, 710076, China

[www.seplite.com](http://www.seplite.com)    [www.sunresin.com](http://www.sunresin.com)

E-mail: [info.lifescience@sunresin.com](mailto:info.lifescience@sunresin.com)

All information set forth herein is for informational purposes only. This information is general descriptive(introductory) information of SUNRESIN and its related products, technologies and services. Neither shall constitute the guarantee of SUNRESIN and its affiliates to products, technologies and services in specific fields and specific application conditions results, unless otherwise expressly noted. SUNRESIN and its affiliates assumes no obligation or liability for the information in this document. Customer is responsible for judging whether the information is appropriate for Customer's concrete demand and are obliged to understand whether the use of these products, technologies and services is permitted by the laws and regulations of their countries and relevant regions. Unless expressly stated, no freedom from infringement of use any patent or trademark or intellectual property rights owned by SUNRESIN or its affiliated companies under this document is to be inferred.

**Manufacturer: Sunresin New Materials Co. Ltd.**

Add:No. 135, Jinye Rd, Xi'an

Hi-Tech Industrial Development Zone, Shaanxi, 710076, China

[www.seplite.com](http://www.seplite.com)    [www.sunresin.com](http://www.sunresin.com)

E-mail: [info.lifescience@sunresin.com](mailto:info.lifescience@sunresin.com)

All information set forth herein is for informational purposes only. This information is general descriptive(introductory) information of SUNRESIN and its related products, technologies and services. Neither shall constitute the guarantee of SUNRESIN and its affiliates to products, technologies and services in specific fields and specific application conditions results, unless otherwise expressly noted. SUNRESIN and its affiliates assumes no obligation or liability for the information in this document. Customer is responsible for judging whether the information is appropriate for Customer's concrete demand and are obliged to understand whether the use of these products, technologies and services is permitted by the laws and regulations of their countries and relevant regions. Unless expressly stated, no freedom from infringement of use any patent or trademark or intellectual property rights owned by SUNRESIN or its affiliated companies under this document is to be inferred.