

1. Description

Seplife® Gel 1x8C is a microcarrier independently developed by Sunresin suitable for adherent cell culture. These gel beads are made of polystyrene crossed linked with divinylbenzene gel and modified with positively charged quaternary amine groups.

Seplife® Gel 1x8C has the following properties:

- Density close to water making it easily suspended in cell culture media
- Quaternary amine positively charged surface groups for easy cell anchorage and growth promotion
- Mechanically stable in the harvest conditions
- Controlled particle size distribution for maximum uniformity
- Controlled chemical and microbiological impurities
- Can be sterilized by autoclave and gamma-irradiation.

Seplife® Gel 1x8C is currently used for large scale growth of mammalian cells; the main applications are in the production of vaccines and biologics.

2. Properties

Product	Seplife® Gel 1x8C
Appearance	Pale yellow spherical beads
Type	Microcarrier for cell culture
Matrix	Polystyrene/divinylbenzene
Ligand	Quaternary amine
Ion Exchange Capacity (mmol/g Cl ⁻)	≥3
Relative Density (g/ml)	1.05 - 1.15
Particle size	
160-200μm	≥75%
150-210μm	≥90%
Moisture Content (%)	40 -50
Volume Capacity (meq/ml Cl ⁻)	≥1.2

Microbial contamination (CFU/ml)	<20
Endotoxin Activity (EU/ml)	<0.25
Shipped as	Wet in Cl ⁻ form

3. Instructions

Guidelines of the instructions for use are presented below. The user should perform process optimization at all stages in the Seplife® Gel 1x8C usage.

3.1 Microcarrier pretreatment

Rinse the microcarriers with freshly prepared Ca²⁺ and Mg²⁺ free phosphate buffer, pH=7.4 for several times.

Sterilize the microcarrier solution by autoclaving (121°C, 30min, 15psi).

After sterilization, before use, add the suitable cell culture medium and rinse. Then, add sufficient cell culture medium to perform the microcarrier acclimation in a suitable vessel at optimal agitation rate. The cell culture medium should be suitable for the type of cell to be attached to the microcarriers. As a general rule, the microcarriers are to be mixed at the lowest speed that allows the formation of an uniform suspension throughout the culture vessel without settling. The acclimation process can take 30-120min in the optimum conditions.

3.2 Microcarrier culture

Add the digested cells into prepared microcarrier culture system and start culturing under controlled conditions.

Evaluate and document cell attachment after 4 hours of cells seeding. Sampling at specific time is essential to monitor cell growth throughout the culture.

3.3 Key points of microcarrier culture operation

- Attach period: ensure the cell culture is under a controlled environment. To obtain a uniform distribution of cells among microcarriers, it is essential to generate a robust, single-cell suspension that is free of aggregates and clumps. Trials for optimizing attachment condition should be done to ensure this period could be achieved as soon as possible to avoid cell aggregate. If small initial culture volume is applied, culture media should be added to the final volume at the end of this period.

- Culture period: Daily sampling for cell counts and morphology inspection is essential. As the cells

proliferate, the beads become heavier and the stirring speed might need to be increased. During the culture process, parameters such as pH, temperature, dissolved oxygen, should be monitored to keep the culture under optimized condition.

- Cell harvest: Discard the culture medium and rinse with Ca^{2+} and Mg^{2+} free phosphate buffer, pH=7.4, sterile at least once. Add dissociation enzyme such as trypsin (containing EDTA) to detach the cells from the surface of microcarriers, then use quench reagent to inhibit the activity of the enzyme. Use suitable cell strainer to separate cells from microcarrier beads.

In the case when the molecule of interest is secreted by cells in the medium or if the virus is released from cells, a proper filtration should be applied to separate microcarriers with cells from culture medium.

- Scale-up of microcarrier cell culture: large scale microcarrier cell culture can be achieved from small scale culture step by step through increasing of the culture volume with the same microcarrier concentration.

4. Storage

Store in closed containers at 4-30°C, in a dry, ventilated and clean place, away from direct sunlight.

5. Transportation

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

6. Precautions

This product should avoid contact with oxidants.

7. Ordering information

Product Name	References	Pack Size
Seplife® Gel1x8C	PS023C01	25g
	PS023C02	100g
	PS023C03	500g
	PS023C04	1kg
	PS023C05	2.5kg
	PS023C06	5kg

Production date: See label

Service life: 4 years, under proper storage conditions

Manufacturer: Sunresin New Materials Co. Ltd.

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