

# Product Information

## EX-CELL® ANTIFOAM Gamma Irradiated

**CATALOG NO. 59920C**

### Description

EX-CELL ANTIFOAM is a USP Grade non-ionic emulsion (simethicone) designed for use in the pharmaceutical and veterinary biological industries to aid in the control of foaming typically associated with the use of culture medium in bioreactors. Through formulation optimization, utilization of a quantitative assay and an understanding of the nonspecific binding of simethicone, SAFC is able to report the actual simethicone concentration of the gamma irradiated finished material. As a result of this development, SAFC offers an optimized formulation, ensuring a consistent product with, at least, a 21-month shelf life.

Supplement EX-CELL ANTIFOAM into culture systems to prevent or eliminate foaming that occurs in culture medium due to mixing and shear forces.

This product is of non-animal origin formulated from a 30% simethicone emulsion from DOW Corning® Q7-2587.

### Features

Sterilized via a validated gamma irradiation process that ensures a known delivered dose to the product.

- Validated to a Sterility Assurance Level (SAL) of 10<sup>-6</sup>. Mitigates risk of raw material contamination to your process.
- Packaged in polyethylene (PE) media bags configured for sterile connection to bioreactors for direct addition to cell culture, reducing resources required for use.
- Performance assurance with a simethicone quantification assay that confirms the lot-specific concentration, assuring that your process will not be impacted by product performance failures to control and monitor required additions.
- Animal-component free raw materials and dedicated equipment used for manufacture, ensuring a regulatory-friendly product that can facilitate dossier approval for regulatory submissions.

### Intended use

This product is for further manufacturing use. This product is not intended for human or therapeutic use.

### Packaging

Part Number	Available Sizes
59920C-1B1357	1.0 L (in 1 L bag)
59920C-5B1357	5.0 L (in 5 L bag)

A Certificate of Analysis (CoA) is prepared for each manufactured lot. The approved CoA includes results of the Quality Control testing based on established release criteria.

### Stability

A minimum of 21 months stability has been established from date of manufacturing (DOM). Real-time stability studies are ongoing.

### Storage

Shipped under ambient conditions and stored at room temperature (15 to 30 °C). Do not use after the expiration date.

### Methods for use

Because simethicone emulsions are not true solutions, inherent separation of the product is expected depending on exposure to physical environments. During shipping and storage of the product, it is common for separation of the original components to occur.

To ensure product performance, EX-CELL ANTIFOAM should be mixed well prior to addition to the culture system.

To maintain maximum defoaming efficiency, EX-CELL ANTIFOAM should be vigorously mixed using a manual or mechanical rocking motion until a homogenous mixture is achieved (~1 - 5 minutes). Once thoroughly mixed, EX-CELL ANTIFOAM should be used immediately.

SAFC recommends that system-specific requirements be determined prior to use. To aid with downstream processing, EX-CELL ANTIFOAM should be added at the lowest concentration required to achieve effective results. Due to variability associated with individual systems and applications, the end user should titrate the optimal concentration of EX-CELL ANTIFOAM.

### Handling precautions

EX-CELL® ANTIFOAM is supplied as a sterile supplement and must be aseptically added to sterile media and/or culture systems. To avoid concerns with removal of simethicone, resulting in poor defoaming characteristics, DO NOT filter EX-CELL ANTIFOAM or the culture medium to which it has been added.

### Characteristics

Test	Specification
Assay, USP Simethicone Quantification	0.70 - 1.5%
Endotoxin (post irradiation)	Record (EU/mL)
Sterility (post irradiation)	No microbial growth detected
Defoaming activity (USP)	< 15 seconds
Irradiation Dose	25.0 - 35.0 kGy
Appearance	White to off-white liquid

### Sterilization information

EX-CELL ANTIFOAM is gamma sterilized at a dosage of 25 - 35 kGy via exposure to a Cobalt60 source. The gamma irradiation process has been validated to a Sterility Assurance Level (SAL) of 10<sup>-6</sup> and ensures a sterilization dose based on product bioburden populations prior to gamma radiation treatment.

The validation methodology was based on procedures outlined by the Association for the Advancement of Medical Instrumentation (AAMI), Technical Information Report No. 33:2005 (Sterilization of Healthcare Products - Radiation - Substantiation of a Selected Sterilization Dose - Method V<sub>Dmax</sub>).

SAFC has completed additional sterility evaluations in the form of challenge studies that determined gamma irradiation effectiveness on spiked samples. In these studies, SAFC was able to conclude that a sterilization dose of 25-35kGy is effective in achieving a >6 log reduction of *Bacillus pumilus*, *Candida albicans* and *Escherichia coli*.

#### Warranty, Limitation of Remedies

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