



QUALITY PRODUCT DOCUMENTATION  
EX-CELL<sup>®</sup> ANTIFOAM GI  
PRODUCT NUMBER 59920C





# PRODUCT REGULATORY DATASHEET

## 1. General Product Information

Product Name	EX-CELL® Antifoam GI
Product Number	59920C

## 2. Manufacturing, Packaging, Release Site and Supplier Information

Site of Manufacturing, Packaging, Testing and Product Release:  
3506 South Broadway  
St. Louis, MO 63118

The product is manufactured using Animal Component Free (ACF) raw materials and dedicated or disposable equipment.

Final Product Gamma Irradiated via Validated Process at:  
STERIS  
1880 Industrial Drive  
Libertyville, IL 60048

Or

Sterigenics U.S. LLC  
1700 N College Boulevard  
West Memphis, AR 72301

## 3. Chemical Information

### 3.1. Synonyms

Simethicone  
Simethicone Emulsion  
Polydimethylsiloxane (PDMS)

### 3.2. Linear Formula

A-(Trimethylsilyl)- $\pi$ -methylpoly[oxy(dimethylsilylene)], mixture with silicon dioxide

### 3.3. Molecular Formula

$[-(\text{CH}_3)\text{SiO-}]_n$

### 3.4. Origin

The product 59920C is manufactured using Animal Component Free material that is synthetically derived and mixed with water for injection (WFI) to product a known concentration of simethicone. Only synthetically derived raw materials are used in the manufacture of the product.

### 3.5. Manufacturing Process

The raw material is diluted in WFI and gamma irradiated to sterilize the product. The manufacturing and packaging utilizes dedicated and disposable equipment.



### **3.6. Specification**

Product specifications are outlined in the specification sheet on the product description webpage.

### **3.7. Batch Results**

Certificates of Analysis are available for each lot produced.

## **4. Regulatory Information**

### **4.1. Compendial Compliance**

No monographs available in Ph. Eur., USP/NF, or JP.

### **4.2. Master File**

Drug Master File (DMF) or EDQM Certificate of Suitability or other master file is currently not available. Please contact the company for further regulatory support.

### **4.3. BSE/TSE and Viral Risk Statement**

This product is produced using raw materials of synthetic origin.

This product is not produced using any bovine, ovine, or caprine tissue classified as Category A (per EMEA 410/01 or Specified Risk Material per USDA 9 CFR 310.22). BSE/TSE risk is negligible.

### **4.4. Allergen Information**

This product is not produced with any known major food allergens (as defined by the FDA and WHO).

### **4.5. GMO Information**

The product is not produced using GMOs and is considered GMO free.

### **4.6. Residual Solvents Information**

The product is produced without use of Class 1 – 3 organic solvents.

The raw material has less than 2% low-molecular-weight volatile silicone species.

### **4.7. Metal Catalyst and Metal Reagent Residues**

The product is produced without use of metal catalyst or metal reagent.

### **4.8. Kosher/Halal Status**

No status.

### **4.9. Melamine Statement**

This product is not recognized as high risk for melamine contamination.

## **5. Miscellaneous Product Information**

### **5.1. Explanation of the Lot/Batch Numbering System**

Each produced batch is identified by a single, specific lot number. Lot numbers are automatically generated to batches within the system. The batch number consists of 4 characters and 4 numbers (e.g. SLBB0001). The first two digits represent the location (SL for St. Louis); the following 2 letters are system generated sequential letters. The last four numbers are sequential numbers.

### **5.2. Expiration Date and/or Recommended Re-Evaluation Interval**

The expiration date is based upon real time stability testing of the product.

Product is maintained in appropriate storage conditions.

### **5.3. Handling, Shipping Conditions, and Long-term Storage Recommendation**

If stored in the original unopened container under specified conditions, no significant change of the material will be observed. Material is to be stored at ambient temperature. The material will be shipped at ambient temperature.



#### **5.4. Packaging**

Standard pack sizes of 1L and 5L.

Polyethylene (PE) bags are used to package the material.

#### **6. Revision History**

Updates are communicated to customers with change notification agreements only.

#### **7. Contact Information**

Please contact your local representative for more information.