

## BC Simethicone Antifoam C100LV

### Product Description

BC simethicone antifoam C100LV is a 100% active product designed specifically for suppression of foam in a variety of pharmaceutical applications. BC simethicone antifoam C100LV complies with the current monograph for Simethicone EP and Simethicone USP.

### Key Features and Typical Benefits

- Highly effective at low concentrations
- Low viscosity for ease of processing
- Fully EP and USP compliant
- Suitable for oral applications
- Kosher and Halal certified
- Available in a variety of pack sizes

### Storage and Shelf Life

Some settling of BC simethicone antifoam C100LV may occur during storage; therefore, it is recommended to mix containers before use. When stored in unopened containers at below 32 °C the product has a shelf life of 24 months from the date of manufacture stated on the label and the certificate of analysis.

Simethicone Content, %	100
Viscosity, cP	<800
PDMS Assay, %	90.5 to 99.0
Silica Assay, %	4.0 to 7.0
Volatile Content, %	<1.0
Heavy Metal Content, ppm	<5

Typical properties are average data and are not to be used as or to develop specifications.

### Potential Applications

BC simethicone antifoam C100LV is mainly used as an active ingredient in the production of dose forms such as antacids used in the treatment of gastrointestinal disorders. The BC simethicone antifoam C100LV alleviates symptoms such as bloating and discomfort caused by the build-up of gas in the gut. It was developed specifically for application via soft gel capsules where its low viscosity makes it easier to handle during the capsule filling process. It may also be applied via hard or chewable tablet dose forms and is often combined with other actives designed to combat different symptoms and complement the action of the simethicone.

BC simethicone antifoam C100LV may also be used in veterinary products to combat the same symptoms in animals. Notably the suppression of 'frothy bloat' in cattle. It is also used in some cases as a process antifoam or an excipient to control foaming in pharmaceutical manufacturing processes or products.

### General Considerations for Use

In production of soft gel capsules, the ingredients, including the simethicone, are often injected into the capsule at the point of encapsulation. In a fast-moving, precision process of this type, the viscosity of the liquid being filled into the capsule can be critical in maintaining accurate fill levels. BC simethicone antifoam C100LV is designed specifically for this kind of application.

In tableting the BC simethicone antifoam C100LV is usually premixed with a carrier powder such as a sugar, starch, or cellulose derivative before mixing with the rest of the tablet ingredients. Typical active content of simethicone in the finished antacid/anti-gas tablet would be between 80 and 125 mg per dose. If the product is being used in a production process as a defoamer or as an excipient to control foaming in a product, a typical level of use would be between 10 and 50 ppm.

### Regulatory Status and Manufacturing Environment

BC simethicone antifoam C100LV is manufactured in the UK as an API in a GMP certified plant by Basildon Chemical Co. Ltd. The plant is registered with the Medicines & Healthcare products Regulatory Agency (MHRA) in the UK and it is they who audit the plant to GMP standards.

The product is supported by a Certificate of Suitability (CEP) issued by the European Directorate for the Quality of Medicines (EDQM) and a Drug Master File (DMF) lodged with the US Food & Drug Administration (FDA).

The CEP certifies compliance of BC simethicone antifoam C100LV to the monograph for Simethicone EP and can be used to support license applications for finished dose forms in which it is being used.

The DMF supports compliance to the monograph for Simethicone USP.

The product is certified as Kosher and Halal by the relevant UK authorities.

### Technical and Regulatory Support

Our technical and regulatory departments are available to assist customers in working with our simethicone products and the regulatory environment which surrounds them. When you contact us, we will connect you with the appropriate person in our organization to discuss your needs and provide advice.

### Patent Status

Nothing contained herein shall be construed to imply the nonexistence of any relevant patents or to constitute the permission, inducement, or recommendation to practice any invention covered by any patent, without authority from the owner of the patent.

### Product Safety, Handling and Storage

Customers should review the latest Safety Data Sheet (SDS) and label for product safety information, safe handling instructions, personal protective equipment, if necessary, emergency service contact information, and any special storage conditions required for safety. Momentive Performance Materials (MPM) maintains an around-the-clock emergency service for its products. SDS are available at [www.momentive.com](http://www.momentive.com) or, upon request, from any MPM representative. For product storage and handling procedures to maintain the product quality within our stated specifications, please review Certificates of Analysis, which are available in the Order Center. Use of other materials in conjunction with MPM products (for example, primers) may require additional precautions. Please review and follow the safety information provided by the manufacturer of such other materials.

### Limitations

Customers must evaluate Momentive Performance Materials products and make their own determination as to fitness of use in their particular applications.



## Customer Service Centers

For additional information, please contact our Customer Service Team

<b>AMERICAS</b>	+1 800 295 2392 Toll Free* +704 805 6946 Direct Number
<b>LATIN AMERICA</b>	<b>BRAZIL</b> +55 11 4534 9650 Direct Number <b>MEXICO</b> +52 55 2169 7670 Direct Number *All American countries
<b>EMEI - EUROPE, MIDDLE EAST, AFRICA &amp; INDIA</b>	<b>EUROPE</b> +390510924300 Direct Number <b>INDIA, MIDDLE EAST &amp; AFRICA</b> +91 44 71212207 Direct Number* *All Middle Eastern countries, Africa, India, Pakistan, Bangladesh, Sri Lanka
<b>ASIA PACIFIC</b>	<b>CHINA</b> 800 820 0202 Toll Free +86 21 3860 4892 Direct Number <b>JAPAN</b> +81 3 5544 311 Direct Number <b>KOREA</b> +82 2 6201 4600 Direct Number <b>SOUTH EAST ASIA, AUSTRALIA &amp; NEW ZEALAND</b> +60 3 9206 1543 Direct Number* *All East Asia countries (Malaysia, Singapore, Thailand, Indonesia, Vietnam, Philippines, Cambodia, Myanmar / other countries located in Pacific region)
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260 Hudson River Road  
Waterford, NY 12188 USA  
[momentive.com](http://momentive.com)