

BC Simethicone Antifoam C100EP

Product Description

BC simethicone antifoam C100EP is a 100% active product designed specifically for suppression of foam in a variety of pharmaceutical applications. BC simethicone antifoam C100EP complies with the current monograph for Simethicone EP.

Key Features and Typical Benefits

- Highly effective at low concentrations
- Fully EP 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 C100EP 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 48 months from the date of manufacture stated on the label and the certificate of analysis.

Simethicone EP Content, %	100
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 C100EP is mainly used as an active ingredient in the production of dose forms, such as antacids, used in treatment of gastrointestinal disorders. The BC simethicone antifoam C100EP alleviates symptoms such as bloating and discomfort caused by the build-up of gas in the gut. It is mainly applied via solid dose forms such as hard or chewable tablets but can also be applied via dose forms such as soft gel capsules. It may be combined with other actives designed to combat different symptoms and complement the action of the simethicone.

BC simethicone antifoam C100EP 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 tableting the BC simethicone antifoam C100EP 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 C100EP 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).

The CEP certifies compliance of BC simethicone antifoam C100EP 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 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 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

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