

## BC Simethicone Antifoam PD30S

### Product Description

BC simethicone antifoam PD30S is a 30% active, simethicone emulsion, designed specifically for suppression of foam in a variety of pharmaceutical applications. BC simethicone antifoam PD30S complies with the current monograph for Simethicone Emulsion USP.

### Key Features and Typical Benefits

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

### Storage and Shelf Life

Since BC simethicone antifoam PD30S is an emulsion, it is recommended to mix or agitate containers before use to ensure the product is homogeneous. 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.

Simeticone USP Content, %	30
Appearance	White emulsion
PDMS Assay, %	28.0 to 31.6
pH	2.0 to 3.5
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 PD30S 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 PD30S alleviates symptoms such as bloating and discomfort caused by the build-up of gas in the gut. Because it is easily dispersible in aqueous media, BC simethicone antifoam PD30S is mainly applied via liquid dose forms such as syrups and suspensions.

BC simethicone antifoam PD30S 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 products. As a process antifoam it is ideally suited for use in biopharmaceutical applications such as cell culture fermentations.

### General Considerations for Use

In the production of antacid liquids such as syrups or suspensions, the BC simethicone antifoam PD30S will mix easily with other ingredients used in this type of aqueous formulation. Since the simethicone in BC simethicone antifoam PD30S is already emulsified, there is no need to apply high shear mixing when incorporating it into the formulation. Indeed, excessive high shear mixing when the BC simethicone antifoam PD30S is being diluted may affect the stability of the product by disrupting the particle size of the emulsified simethicone. The typical active content of simethicone in a finished antacid liquid would be 60 to 100 mg per dose, with levels of 30 mg or less per dose, in a product designed for infants and children.

In situations where BC simethicone antifoam PD30S 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 30 and 100 ppm.

### Regulatory Status and Manufacturing Environment

BC simethicone antifoam PD30S 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.

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The product is supported by a Drug Master File (DMF) lodged with the US Food & Drug Administration (FDA).

The DMF supports compliance to the monograph for Simethicone Emulsion 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

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