

Simethicone Antifoam C100EP

Description

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

Product Features

- Highly effective at low concentrations
- Fully EP compliant
- Suitable for oral applications
- Kosher & Halal Certified
- Available in a variety of pack sizes

Regulatory Status & Manufacturing Environment

Simethicone 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 Simethicone C100EP to the monograph for Simeticone EP and can be used to support licence applications for finished dose forms in which it is being used.

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

Applications

Simethicone C100EP is mainly used as an active ingredient in the production of dose forms, such as antacids, used in treatment of gastrointestinal disorders. The 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.

Simethicone 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.

Method of Use

In tableting the Simethicone 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 125mg 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 & 50ppm.

Handling Precautions

Customers should consult the Product Safety Data Sheet for Simethicone C100EP and the pack label prior to using the product. Safety Data Sheets are freely available via our website at www.baschem.co.uk or by contacting our Customer Service department at csab@baschem.co.uk

Storage & Shelf Life

Some settling of Simethicone 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 24 months from the date of manufacture stated on the label and the certificate of analysis. If you wish to use the product beyond the stated shelf life, please contact us to discuss.

Simeticone EP content	100%
PDMS Assay	90.5 to 99.0%
Silica Assay	4.0 to 7.0%
Volatile content	<1.0%
Heavy Metal Content	<5ppm

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 organisation to discuss your needs and provide advice.



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