

# Simethicone Antifoam PD30S

## Description

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

## Product Features

- Highly effective at low concentrations
- Compatible with aqueous formulations
- Fully USP compliant
- Suitable for oral applications
- Kosher & Halal Certified
- Available in a variety of pack sizes

## Regulatory Status & Manufacturing Environment

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.

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.

## Applications

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 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, PD30S is mainly applied via liquid dose forms such as syrups and suspensions.

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.

## Method of Use

In the production of antacid liquids such as syrups or suspensions, the PD30S will mix easily with other ingredients used in this type of aqueous formulation. Since the simethicone in 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 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 100mg per dose, with levels of 30mg or less per dose, in a product designed for infants and children.

In situations where 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 & 100ppm

## Handling Precautions

Customers should consult the Product Safety Data Sheet for Simethicone PD30S and the pack label prior to using the product. Safety Data Sheets are freely available via our website at [www.baschem.co.uk](http://www.baschem.co.uk) or by contacting our Customer Service department at [csab@baschem.co.uk](mailto:csab@baschem.co.uk)

## Storage & Shelf Life

Since 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. If you wish to use the product beyond the stated shelf life, please contact us to discuss.

Simethicone USP content	30%
Appearance	White Emulsion
PDMS Assay	28.0 to 31.6%
pH	2.0 to 3.5
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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