

SIMETHICONE IN PHARMACEUTICAL APPLICATIONS

A row of small amber glass vials is shown on a white tray in a laboratory setting. The vials are arranged in a line, and the background is blurred, showing other laboratory equipment and a person in a white lab coat. The lighting is soft and focused on the vials.

SIMETHICONE IN PHARMACEUTICAL APPLICATIONS

Momentive offers a range of pharmaceutical-grade silicone antifoams (Simethicone) in compliance with US and European Pharmacopeia standards. Our solutions are versatile and deliver value to stakeholders across the pharmaceutical value chain, such as pharmaceutical ingredient manufacturers, finished dosage formulators, and end-users.

Simethicone is a composition of Silica and Polydimethylsiloxane. In Pharmaceutical applications, Simethicone is used as an Active Pharmaceutical Ingredient (API), Excipient, and Processing Aid.

ACTIVE PHARMACEUTICAL INGREDIENT

As an Active Pharmaceutical Ingredient (API), when formulated into a Finished Dose Form (FDF), Simethicone relieves the discomfort of excess gas in the gastrointestinal tract.

Momentive's cGMP-certified plant in the UK produces 100% active compounds and 30% active emulsions of Simethicone to satisfy the demands of various finished dose forms, including tablets, soft gel capsules, and liquid suspensions.

EXCIPIENT

Pharmaceutical excipients support the design of pharmaceutical formulation and are crucial to drug delivery within the body. Simethicone, as an excipient, delivers foam control, lubrication and facilitates the physiological absorption of the drug.

PROCESSING AID

Simethicone also finds use as a processing aid in the manufacture of API's, excipients, and pharmaceutical intermediates without participating in the chemical or biological reaction of a pharmaceutical process.

To support your success, Momentive has a team of experts with the technical and regulatory know-how to help solve your production and formulation challenges, leveraging over 30 years of expertise in manufacturing and delivering Simethicone solutions worldwide.

KEY FEATURES & BENEFITS



PHARMA INGREDIENT MANUFACTURERS

Processing Aid: used as an antifoam in the manufacturing process of pharmaceutical ingredients, APIs and excipients.

Used as antifoam in pharmaceutical bio-fermentation processes.

FINISHED DOSAGE FORMULATORS

API: active component of the final drug formulation. Functions as a non-systemic surfactant, decreasing the surface tension of gas bubbles in the gastrointestinal tract.

Excipient: improves the delivery and efficacy of APIs formulated into the Finished Dosage Form by providing foam control and lubrication.

Processing Aid: used as an antifoam in the manufacturing process of a Finished Dosage Form.



END USERS

Treats painful built-up gas in the digestive system and provides comfort.*

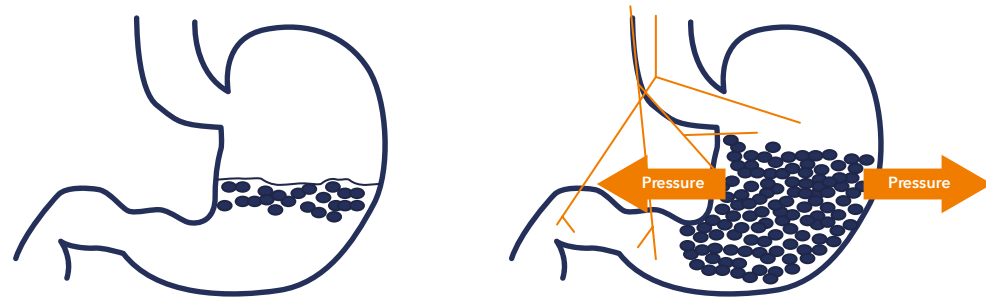
*Simethicone is only available as an API in the approved Finished Dosage Forms. Please refer to Novel & Parenteral use guidelines in Page 7.

HOW DOES SIMETHICONE WORK AS AN ACTIVE PHARMACEUTICAL INGREDIENT?

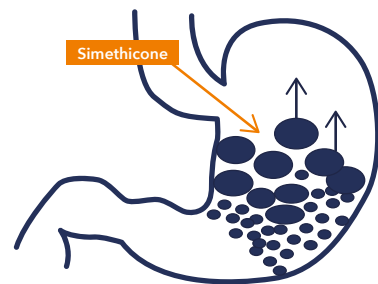


Gas is trapped as a foam in the stomach; foam levels increase by the regular activity of the stomach, which occurs due to the continuous mixing of food, known as segmentation.

Gas can become trapped when it is **finely** dispersed as small bubbles, this is difficult for the body to naturally expel. The buildup of foam causes **pressure** to increase in the stomach.



The action of the Simethicone breaks down the bubble walls and allows the smaller bubbles to form into larger ones which are much easier for the body to expel naturally.



BC SIMETHICONE C100F

BC Simethicone C100F Antifoam is a 100% active product designed specifically for suppression of foam in a variety of pharmaceutical applications. BC Simethicone C100F Antifoam complies with the current monograph for Simethicone USP.

KEY FEATURES & BENEFITS

Effective composition delivering maximum value to drug formulators.

- Low volatility and no silica separation on storage
- Highly effective at low concentration in drug formulations

Compatibility with multiple approved dose forms helps dosage formulators target diverse end-customer needs.

- Suitable for dose forms of hard tablets, chewable tablets, and powders used to treat gastrointestinal disorders

Robust regulatory and quality compliance enables dosage formulators to manufacture superior quality drug formulations aligned with US Pharmacopeia.

- Supported by a Drug Master File (DMF) lodged with the US Food & Drug Administration (FDA)
- Manufactured in the UK as an API in a cGMP certified plant by Basildon Chemical Co. Ltd, a Momentive Group Company
- Certified as Kosher and Halal by the UK authorities

BC SIMETHICONE C100EP

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

KEY FEATURES & BENEFITS

Effective composition delivering maximum value to drug formulators.

- Low volatility and no silica separation on storage
- Highly effective at low concentration in drug formulations

Compatibility with multiple approved dose forms helps dosage formulators target diverse end-customer needs.

- Suitable for dose forms of hard tablets, chewable tablets, and powders used to treat gastrointestinal disorders

Robust regulatory and quality compliance enables dosage formulators to manufacture superior quality drug formulations aligned with European Pharmacopeia.

- Supported by a Certificate of Suitability (CEP) issued by the European Directorate for the Quality of Medicines (EDQM)
- Manufactured in the UK as an API in a cGMP certified plant by Basildon Chemical Co. Ltd, a Momentive Group Company
- Certified as Kosher and Halal by the UK authorities

BC SIMETHICONE C100LV

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

KEY FEATURES & BENEFITS

Effective composition delivering maximum value to drug formulators.

- Low volatility and no silica separation on storage
- Highly effective at low concentration in drug formulations

Improves efficiency and accurate fill levels for soft gel dosages.

- Low viscosity improves the efficiency of the soft gel capsule filling process

Compatibility with multiple approved dose forms helps dosage formulators target diverse end-customer needs.

- Suitable for dose forms of soft gel capsules, hard tablets, chewable tablets and powders, used to treat gastrointestinal disorders

Robust regulatory and quality compliance enables dosage formulators to manufacture superior quality drug formulations aligned with US and European Pharmacopeia.

- Supported by a Drug Master File (DMF) lodged with the US Food & Drug Administration (FDA) and Certificate of Suitability (CEP) issued by European Directorate for the Quality of Medicines (EDQM)
- Manufactured in the UK as an API in a cGMP certified plant by Basildon Chemical Co. Ltd, a Momentive Group Company
- Certified as Kosher and Halal by the UK authorities

BC SIMETHICONE PD30S

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

KEY FEATURES & BENEFITS

Effective composition delivering maximum value to drug formulators.

- Compatible with aqueous formulations and suitable for oral applications
- Highly effective at low concentration in drug formulations
- Suitable for liquid dose forms of syrups and suspensions used in the treatment of gastrointestinal disorders

Versatile Pharmaceutical grade with applications as a process antifoam.

- As a process antifoam ideally suited for use in biopharmaceutical applications such as cell culture formulations

Strong regulatory and quality compliance enables dosage formulators to manufacture superior quality drug formulations aligned with US Pharmacopeia.

- Supported by a Drug Master File (DMF) lodged with the US Food & Drug Administration (FDA)
- Manufactured in the UK as an API in a cGMP certified plant by Basildon Chemical Co. Ltd, a Momentive Group Company
- Certified as Kosher and Halal by the UK authorities



TECHNICAL PROPERTIES

	BC Simethicone C100F	BC Simethicone C100EP	BC Simethicone C100LV	BC Simethicone PD30S
Simethicone Level	100 %	100 %	100 %	30 %
Shelf Life (months)	48	48	24	24
Viscosity (cP)	Typically 1500 - 4500	Typically 2000 - 5000	Typically 500 - 800	Typically 4500 - 8000
Appearance	Translucent grey viscous liquid	Translucent grey viscous liquid	Translucent grey viscous liquid	Off white, viscous emulsion
Odour	Slight characteristic	Slight characteristic	Slight characteristic	Slight characteristic
pH	N/A	N/A	N/A	2.0 - 3.5
Defoaming Activity (seconds)	< 15	< 15	< 15	< 15
Silicon Dioxide Content (%)	4 - 7	4 - 7	4 - 7	Not Applicable+
Assay PDMS Content (%)	90.5 - 99.0	90.5 - 99.0	90.5 - 99.0	28.0 - 31.6
Loss on Heating (w/w %)	<18.0*	<1.0**	<1.0	Not Applicable+

* The Loss on Heating or volatile matter is tested using method, SO03 (USP) (15.0g for 4 hours at +20°C).
 ** The Loss on Heating or volatile matter is tested using method, SO09 (EP) (1.0g for 2 hours at +150°C).
 + All Simethicone products comply with respective and current pharmacopeia standards.
 Lab results; actual results may vary. Do not rely on lab results to make product specifications.

REGULATORY CAPABILITIES

	BC Simethicone C100F	BC Simethicone C100EP	BC Simethicone C100LV	BC Simethicone PD30S
cGMP API Certification	Yes	Yes	Yes	Yes
Halal Certification	Yes	Yes	Yes	Yes
Kosher Certification	Yes	Yes	Yes	Yes
Certificate of Suitability/CEP	Not Applicable	Yes	Yes	Not Applicable
FDA Drug Master File	Yes	Not Applicable	Yes	Yes
ISO 9001:2015	Yes	Yes	Yes	Yes
FDA Regulation 21 CFR 173.340	Yes	Yes	Yes	Yes

NOVEL & PARENTERAL USE GUIDELINES

Simethicone is normally used either solely (or in combination with other APIs) as the active pharmaceutical ingredient in medicines to control flatulence and bloating. It is also frequently incorporated into antacid products and is formulated into a variety of Finished Dosage Forms (FDFs) to be administered orally, such as:

- Chewable tablets
- Soft gel capsules
- Liquid drops

MOMENTIVE REQUIREMENTS FOR NOVEL USE

Momentive's product stewardship requires knowledge regarding any novel usage of simethicone APIs by the end-use customer where oral dosage forms are involved. For example, a potential customer may be interested in formulating the simethicone into a novel, new oral dosage form. In this scenario, we need to review and approve this before we can supply any simethicone.

If any doubt exists over a customer's potential use, please contact Momentive for further advice.

PARENTERAL USE OF SIMETHICONE

Momentive **does not support** the use of its simethicone APIs in any parenteral use applications e.g., injectable medicines.



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