

# DOW CORNING® Antifoam M Compound

## FEATURES

- Specially formulated and processed to minimize low molecular weight silicone species
- Drug Master File and technical file available
- Tested according to and complies with current European Pharmacopoeia (Ph. Eur.) monograph requirements for Simeticone

## BENEFITS

- Highly effective defoamer at low concentrations
- Processable across a broad temperature range

## COMPOSITION

- A mixture of polydimethylsiloxane fluid and silicon dioxide

## Low-volatile silicone antifoam for use in medical and pharmaceutical applications requiring foam suppression or inhibition

### APPLICATION

- DOW CORNING Antifoam M Compound may be used as an antifoaming ingredient in antacid preparations, as a foam suppressant in pharmaceutical processes such as fermentation, maceration, percolation and mixing, and as an agent to improve the efficiency of ampoule and bottle filling when foaming is a problem.

### TYPICAL PROPERTIES

Specification writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales representative prior to writing specifications on this product.

CTM <sup>1</sup>	Simeticone monograph specification (PhEur #1470)	Property	Unit	Value
0176		Appearance; Light gray liquid, no suspended particulate contamination		Pass
0079	Identification A	Infrared identification		Pass
0051	Acidity	Acid number	mg KOH/g	<0.84
0003	Defoaming activity	Defoaming performance, at 20ppm	seconds	<15
1027	Mineral Oils	Fluorescence		Pass
0054	Phenylated compounds	Aromatic content	ABS	<0.2
1169	Heavy metals	Heavy metals content	ppm	<5
0208	Volatile matter	Volatility	%	<1
0600	Silica assay	Silicon dioxide content	%	4-7
0806	Dimeticone assay	Polydimethylsiloxane content	%	90.5-99.0
<b>Typical properties of silicone fluid separated from the silicon dioxide</b>				
0050		Viscosity at 25°C (77°F)	cSt	1000
0044		Specific gravity at 25°C (77°F)		0.970
0002		Refractive index at 25°C (77°F)		1.404

1. CTM: Corporate Test Method.

## DESCRIPTION

DOW CORNING Antifoam M Compound is a specially formulated low volatile silicone antifoam designed for use in various medical and pharmaceutical applications requiring foam control.

It is formulated and manufactured so that the quantity of volatile, low molecular weight silicone species is minimized. This low volatility is especially advantageous in the manufacture of antifatulent or antifatulent/antacid tablets and other products with high temperature processing conditions. This decreased volatility will help prevent the loss of silicone species and minimize the chance for a low assay result.

## REGULATORY STATUS

DOW CORNING Antifoam M Compound complies with all the requirements of the European Pharmacopoeia monograph for Simeticone. Dow Corning holds a European Drug Master file and a technical file to support regulatory filing in Europe and in other areas.

For current information regarding compliance with food regulations, please contact your local Dow Corning representative.

## IMPORTANT INFORMATION

This simeticone formulation is tested to comply with the requirements of the European Pharmacopoeia monograph for Simeticone. While this monograph can serve as a material screen, it is the user's responsibility to ensure the safety and efficacy of this product for each specific end-use pharmaceutical product, medical device or other application.

## MANUFACTURING ENVIRONMENT

DOW CORNING Antifoam M Compound is manufactured, tested and packaged under strict quality control guidelines at the Healthcare Industries Materials Site (HIMS) in Hemlock, Michigan, USA. The HIMS is dedicated to the production of silicone materials for healthcare applications. It is registered with the U.S. Food and Drug Administration (FDA) as a drug establishment (CFN 1816403). The Hemlock site operates according to applicable US FDA current Good Manufacturing Practices (cGMP), 21 CFR 210/211, and uses the International Committee on Harmonization's Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients (ICH Q7A). The site is also ISO registered by BSI.

## HOW TO USE

### Process Defoaming

In general, concentrations of 1 to 50 parts per million (ppm) are sufficient to suppress foaming in most systems. It is suggested that a concentration within this range be used initially. Adjustments in concentration may be desirable to determine the appropriate level to use for any particular process or product.

### Direct Application

The height to which a foam will rise can be limited by applying DOW CORNING Antifoam M Compound to processing equipment. For example, the defoamer is often wiped on nozzles of bottle-filling machines to knock down foam as it rises in the neck of the bottle. Similarly, if applied to the rim of a processing container, foam overflow can be prevented.

## Solvent Dispersion

In applications where solvents can be used, DOW CORNING Antifoam M Compound may be dispersed in a solvent and then sprayed on the foam or the solvent dispersion may be flushed through a system to remove remnants of foam. Dispersions may be made in an acceptable non-polar solvent. These dispersions require constant agitation to prevent settling of the silicon dioxide.

## Tableting

In some applications, DOW CORNING Antifoam M Compound may be premixed with a carrier material and this mixture subsequently added directly to the foaming system. This technique is commonly used in the manufacture of antifatulent and antifatulent/antacid tablets. For this application, the silicone antifoam compound is either dry- or wet-granulated with common carrier materials such as sugars, starches, or cellulose derivatives and then further processed into tablets.

## HANDLING PRECAUTIONS

Product safety information required for safe use is not included. Before handling, read product and safety data sheets and container labels for safe use, physical and health hazard information. The material safety data sheet is available on the Dow Corning website at [www.dowcorning.com](http://www.dowcorning.com). You can also obtain a copy from your local Dow Corning sales representative or Distributor or by calling your local Dow Corning Global Connection.

## USABLE LIFE AND STORAGE

Some settling may occur during storage of DOW CORNING Antifoam M Compound. Therefore, containers should be thoroughly mixed prior to use or testing.

When stored in original unopen containers at ambient temperatures, this product has a usable life of 18 months from the date of production.

## **PACKAGING**

This product is available in 190kg (418 lb) drums, 18kg (40 lb) pails and 454g (1 lb) bottles.

A certificate of analysis confirming that the product specifications have been met can be supplied upon request.

## **HEALTH AND ENVIRONMENTAL INFORMATION**

To support Customers in their product safety needs, Dow Corning has an extensive Product Stewardship organization and a team of Product Safety and Regulatory Compliance (PS&RC) specialists available in each area.

For further information, please see our website, [www.dowcorning.com](http://www.dowcorning.com) or consult your local Dow Corning representative.

## **LIMITED WARRANTY INFORMATION - PLEASE READ CAREFULLY**

The information contained herein is offered in good faith and is believed to be accurate. However, because conditions and methods of use of our products are beyond our control, this information should not be used in substitution for customers' tests to ensure that Dow Corning's products are safe, effective, and fully satisfactory for the intended end use. Suggestions of use shall not be taken as inducements to infringe any patent.

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Your exclusive remedy for breach of such warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted.

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