

## DOW CORNING® Q7-2587, 30% Simethicone Emulsion USP

### FEATURES

- Emulsified Simethicone compound has less than 2% low-molecular-weight volatile silicone species

### BENEFITS

- Tested according to and complies with all United States Pharmacopeia (USP) requirements for Simethicone emulsion<sup>1</sup>
- Has a smooth consistency that allows the product to be poured or pumped

### COMPOSITION

- 30% Simethicone USP, stearate emulsifiers, sorbic acid, benzoic acid, thickeners and water

1. United States Pharmacopeia, current edition.

### Simethicone USP antifoam

#### 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>2</sup>	Property	Unit	Value
0176	Appearance		Off white, homogeneous liquid, no dark particulate contamination
0007	pH		2.6
0003	Defoaming performance, at 50ppm	seconds	<15
0806	Polydimethylsiloxane content <sup>3</sup>	%	30.4
1169	Heavy metals	ppm	<5

2. CTM: Corporate Test Method, copies of CTMs are available on request.

3. Because Simethicone USP contains both polydimethylsiloxane and silicon dioxide, the amount of polydimethylsiloxane in the product is less than the amount of simethicone.

#### DESCRIPTION

DOW CORNING Q7-2587, 30% Simethicone Emulsion USP is a water-dilutable, non-ionic emulsion containing 30% Simethicone USP by weight.

#### REGULATORY STATUS

DOW CORNING Q7-2587, 30% Simethicone Emulsion USP complies with all monograph requirements for Simethicone Emulsion USP and is acceptable under Food and Drug Administration Regulation 21 CFR 332.10 as a safe and effective over-the-counter drug for use as an anti-flatulent to alleviate the symptoms of gas associated with heartburn, sour stomach, and acid indigestion.

DOW CORNING Q7-2587, 30% Simethicone Emulsion USP can also be used in non-standardized foods in amounts up to 33.3 parts per million under FDA Regulation 21 CFR 173.340.

In any application involving the U.S. Food and Drug Administration or any other regulatory agency, it is the user's responsibility to ensure that use of the product complies with the requirements of these agencies.

#### IMPORTANT INFORMATION

This Simethicone formulation is qualification tested to requirements of the United States Pharmacopeia (USP). 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 Q7-2587, 30% Simethicone Emulsion USP is manufactured, tested and packaged under strict quality control guidelines at the Healthcare Industries Materials Site (HIMS). The HIMS (Hemlock, Mich.) 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 site quality system for active pharmaceutical ingredients (APIs) is in compliance with current Good Manufacturing Practices for Bulk Pharmaceutical Products. The site is also ISO registered by BSI.

## **HOW TO USE**

To ensure uniformity, DOW CORNING Q7-2587, 30% Simethicone Emulsion USP should be stirred gently prior to removing from shipping containers.

## **Diluting the antifoam**

To obtain maximum efficiency, DOW CORNING Q7-2587, 30% Simethicone Emulsion USP should be diluted before using. In diluting, add cool water slowly to the emulsion with continual low-shear mixing until a uniform liquid is attained.

Use diluted DOW CORNING Q7-2587, 30% Simethicone Emulsion USP within 8 hours for best results. If it is necessary to store the material for longer periods, stir frequently to maintain maximum defoaming efficiency.

## **Concentration**

In general, concentrations of 1 to 50 parts per million 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.

## **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**

When stored in original, unopened containers between 5 and 32°C (40 and 90°F), DOW CORNING Q7-2587, 30% Simethicone Emulsion USP has a usable life of 36 months from date of production. Avoid freezing. Freeze/thaw cycling may break emulsion.

## **PACKAGING**

DOW CORNING Q7-2587, 30% Simethicone Emulsion USP is available in 18 and 200kg (40 and 440 lb) containers, net weight.

A certification that the product specifications have been met will be supplied with each shipment upon request.

## **ORDERING**

For price information or to order, contact your local Dow Corning sales representative.

## **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.

Dow Corning's sole warranty is that the product will meet the Dow Corning sales specifications in effect at the time of shipment.

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.

**DOW CORNING SPECIFICALLY DISCLAIMS ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE OR MERCHANTABILITY.**

**DOW CORNING DISCLAIMS LIABILITY FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES.**

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