Product Information
Healthcare

DOW CORNING

DOW CORNING® Q7-2243 LVA, Simethicone USP

FEATURES

- Specially formulated and processed to minimize low molecular weight silicone species
- Highly effective defoamer at low concentrations
- FDA Drug Master File (DMF)

BENEFITS

- Tested according to and complies with all United States Pharmacopeia (USP) requirements for Simethicone and European Pharmacopeia (EP) requirements for Simeticone[1]
- Low volatility allows for processing at a broader temperature range

COMPOSITION

- Simethicone USP
- A mixture of polydimethylsiloxane fluid and silicon dioxide

1. United States Pharmacopeia and European Pharmacopeia, current edition.

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

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[2]	Property	Unit	Value
	Simethicone USP content	%	100
0176	Appearance		Translucent, viscous gray liquid
0806	Silicon dioxide content	%	4.8
0208	Volatility, 15g, 4 hours, 200°C (392°F)	%	<1.0
0806	Polydimethylsiloxane content[3]	%	95.1
1169	Heavy metal content	ppm	<5
0003	Defoaming performance, at 20ppm	seconds	<15
	Typical properties of silicone fluid separated from the silicon dioxide:		
0004	Viscosity at 25°C (77°F)	centistokes	410
0001A	Specific gravity at 25°C (77°F)		0.975
0002	Refractive index at 25°C (77°F)		1.404

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 Q7-2243 LVA, Simethicone USP is a specially formulated low volatile silicone antifoam designed for use in various medical and pharmaceutical applications requiring foam suppression or inhibition.

DOW CORNING Q7-2243 LVA, Simethicone USP is formulated and manufactured so that the quantity of volatile, low-molecular-weight silicone species is minimal. This low volatility (1 percent maximum) is especially advantageous in the manufacture of antiflatulent or antiflatulent/antacid tablets and other products where processing conditions, such as drying by high surface area exposure at elevated temperatures, will result in loss of volatile silicone species and subsequent low assay results for silicone fluid.

REGULATORY STATUS

DOW CORNING Q7-2243 LVA, Simethicone USP complies with all monograph requirements for Simethicone 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.

DOW CORNING Q7-2243 LVA, Simethicone USP may also be used in non-standardized foods in amounts up to 10 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) and the European Pharmacopeia (EP). While these monographs 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 Q7-2243 LVA, Simethicone 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

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.

The height to which a foam will rise can be limited by applying DOW CORNING Q7-2243 LVA, Simethicone USP 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 Q7-2243 LVA, Simethicone USP 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 silicon dioxide.

Tableting

In some applications, DOW CORNING Q7-2243 LVA, Simethicone USP 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 antiflatulent and antiflatulent/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. 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 Q7-2243 LVA, Simethicone USP. Therefore, containers should be thoroughly mixed prior to use.

When stored in original unopened containers at ambient temperatures, DOW CORNING Q7-2243 LVA, Simethicone USP has a usable life of 24 months from the date of production.

PACKAGING

DOW CORNING Q7-2243 LVA, Simethicone 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 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 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.

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