



## Dow Corning® 365, 35% Dimethicone NF Emulsion

### FEATURES & BENEFITS

- Excellent lubricating and release characteristics
- Good wetting characteristics
- The silicone fluid is tested according to and complies with all National Formulary (NF) requirements for dimethicone and European Pharmacopeia (EP) requirements for dimeticone

### COMPOSITION

- Polydimethylsiloxane emulsion
- Dimethicone fluid viscosity: 350 cs

Hydrophobic lubricant for medical devices.

### APPLICATIONS

- Water-borne silicone fluid for lubrication and siliconization of glass, metals, plastics and rubber.

### TYPICAL PROPERTIES

Specification Writers: These values are not intended for use in preparing specifications. Please contact your local Dow Corning sales office or your Global Dow Corning Connection before writing specifications on this product.

Test*	Property	Unit	Result
CTM 0176	Appearance		White liquid
CTM 0806	Dimethicone NF content	%	35
CTM 0001A	Specific gravity at 25°C (77°F)		0.99
CTM 0007	pH		5.0

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

### DESCRIPTION

Dow Corning® 365, 35% Dimethicone NF Emulsion is a water-dilutable emulsion containing non-ionic emulsifiers and 35% National Formulary dimethicone.

**The emulsion is not manufactured or tested to be pyrogen free.**

Advantages of this product include:

- Excellent lubricating and release characteristics
- Good wetting characteristics
- The silicone fluid meets the current National Formulary dimethicone and European Pharmacopeia dimeticone requirements

Dow Corning 365, 35% Dimethicone NF Emulsion may be used in a variety of applications where it is advantageous to deliver a lubricating silicone fluid in a water-dilutable delivery system.

### REGULATORY STATUS

The dimethicone component is qualification tested to requirements of the National Formulary and the European Pharmacopeia.

Dow Corning 365, 35% Dimethicone NF Emulsion is formulated with an emulsifier (Triton X-100, CAS #9036-19-5) which has been added to the REACh (Registration, Evaluation, Authorisation and Restriction of Chemicals) Authorisation List administered by the EChA (European Chemical Agency). Dow Corning does not intend to file with EChA for authorisation. Effective 04 July 2019, no new applications for such material in the European Union shall occur without EChA authorisation. EChA has communicated a sunset date of 04 January 2021 for the surfactant. In anticipation of these regulatory circumstances, Dow Corning has developed and made available a

similar product, *Dow Corning*<sup>®</sup> 366 35% Dimethicone NF Emulsion which is intended to replace *Dow Corning* 365, 35% Dimethicone NF Emulsion in most applications.

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**

Dow Corning neither represents nor tests this material for specific medical device or pharmaceutical applications. Purchaser is fully responsible to determine end-use suitability.

## **MANUFACTURING ENVIRONMENT**

*Dow Corning* 365, 35% Dimethicone NF Emulsion is manufactured, tested and packaged under strict quality control guidelines at the Healthcare Industries Materials Site (HIMS). The HIMS (Hemlock, Michigan) 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**

Before use, *Dow Corning* 365, 35% Dimethicone NF Emulsion must be mixed thoroughly to ensure that the emulsion is homogeneous. Depending on application, the product may be diluted to around 15% silicone with ambient temperature Water For Injection (WFI) water. The resulting solution may be applied to articles by spraying, brushing, wiping or using a dipping bath. After the water has evaporated, which can be accelerated with heat, the resultant coating is a

lubricious, hydrophobic film of polydimethylsiloxane fluid.

If the treated article can tolerate heat, the durability of the coating may be enhanced by baking; this step can be combined with the water evaporation step. Recommended baking conditions include a temperature less than 200°C (392°F) to avoid the possibility of oxidation and formaldehyde formation. A cloudy appearance on the surface of a treated article after baking may indicate excessive application or over-baking.

**HANDLING PRECAUTIONS PRODUCT SAFETY INFORMATION REQUIRED FOR SAFE USE IS NOT INCLUDED IN THIS DOCUMENT. BEFORE HANDLING, READ PRODUCT AND SAFETY DATA SHEETS AND CONTAINER LABELS FOR SAFE USE, PHYSICAL AND HEALTH HAZARD INFORMATION. THE SAFETY DATA SHEET IS AVAILABLE ON THE DOW CORNING WEBSITE AT DOWCORNING.COM, OR FROM YOUR DOW CORNING SALES APPLICATION ENGINEER, OR DISTRIBUTOR, OR BY CALLING DOW CORNING CUSTOMER SERVICE.**

## **USABLE LIFE AND STORAGE**

When stored in the original unopened container between 5°C and 40°C (41°F and 104°F), this product has a usable life of 36 months from the date of production.

Avoid freezing.

Separation/settling may occur during storage. Therefore, it is necessary that all containers be thoroughly mixed prior to use.

## **PACKAGING INFORMATION**

This product is supplied in 16 and 190 kg (35 and 419 lb) containers, net weight.

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

## **SHIPPING LIMITATIONS**

This product should not be shipped below 0°C (32°F). Freeze/thaw cycling may break emulsion.

## **LIMITATIONS**

This product is neither tested nor represented as suitable for medical or pharmaceutical uses.

## **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, [dowcorning.com](http://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 customer's tests to ensure that our 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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