

MED-341

Simethicone Emulsion USP

Product Profile

NuSil Technology

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An ISO 9001 Certified Company

Description

- A 30% by weight emulsion of Simethicone, USP
- Easy-to-handle emulsion
- Highly stable over a broad pH range
- Kosher and Halal certified

Applications

- Cited in FDA regulations 21 CFR 332.10 and 21 CFR 332.15 as a safe and effective over-the-counter drug to alleviate the symptoms of gas associated with heartburn, sour stomach, acid indigestion and post operative gas pain
- For use in liquid antacids, antiflatulents and as a component of endoscopic diagnostic aids

Typical Properties	Result	Metric Conv.	ASTM	NT-TM
Appearance	Off-white liquid	-	-	701
Simethicone, USP content	30%	-	-	711
Viscosity @ 25°C	2,500 cP	2,500 mPas	-	-
Suitable Diluent	Water	-	-	-
pH @ 25°C	4.25	-	-	704

Instructions for Use

Handling

Keep containers tightly sealed to ensure that product quality is maintained. Storage at room temperature is preferred to prevent the contents from freezing.

Mark the date of receipt on containers to determine age and facilitate proper stock rotation.

Prolonged storage of the emulsion may result in some creaming. Creaming is the forming of a more concentrated silicone layer at the surface of the container. To ensure uniformity of the emulsion, any creaming can be easily dispersed by stirring gently under sanitary conditions before use. The same result can be achieved by gently rolling the drum prior to use.

Shelf Life

MED-341 has a shelf life of 18 months from the date of manufacture when stored at ambient temperatures in original, unopened containers.

Packaging

5 Gallon Pails (18.0 kg)
55 Gallon Drums (193.0 kg)

Shelf Life

18 Months

Warnings About Product Safety

NuSil Technology believes that the information and data contained herein are accurate and reliable. However, the user is responsible to determine the material's suitability and safety of use. NuSil Technology cannot know each application's specific requirements and hereby notifies the user that it has not tested or determined this material's suitability or safety for use in any application. The user is responsible to adequately test and determine the safety and suitability for their application and NuSil Technology makes no warranty concerning fitness for any use or purpose. NuSil Technology has completed no testing to establish safety of use in any medical application.

NuSil Technology has tested this material only to determine if the product meets the applicable specifications. (Please contact NuSil Technology for assistance and recommendations when establishing specifications.) When considering the use of NuSil Technology products in a particular application, review the latest Material Safety Data Sheets and contact NuSil Technology with any questions about product safety information.

Do not use any chemical in a food, drug, cosmetic, or medical application or process until having determined the safety and legality of the use. The user is responsible to meet the requirements of the U.S. Food and Drug Administration (FDA) and any other regulatory agencies. Before handling any other materials mentioned in the text, obtain available product safety information and take the necessary steps to ensure safety of use.

Specifications

Do not use the typical properties shown in this technical profile as a basis for preparing specifications. Please contact NuSil Technology for assistance and recommendations in establishing particular specifications.

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