

NuSil Technology

1050 Cindy Lane • Carpinteria, CA 93013

805/684-8780 • 805/566-9905 Fax

www.nusil.com

An ISO 9001 Certified Company

MED-342

Simethicone GS

Product Profile

Description

- A unique granular solid
- Kosher and Halal certified
- Easily blends with other tableting ingredients
- Eliminates the cost and clean-up of applying liquid Silicone antflatulents
- Contains all Compendial grade components suitable for oral use
- Can be combined with flavors and lubricants

Applications

- Cited in FDA regulations 21 CFR 332.10 and 21 CFR 332.15 as a safe and effective over-the-counter drug for use as an antflatulent to alleviate the symptoms of gas associated with heartburn, sour stomach, acid indigestion and post operative gas pain
- For the manufacture of single- or double-layer tablets
- For forming uniform compositions in any concentration required
- For effective, stable antflatulence, even in the presence of aluminum and magnesium hydroxide

Typical Properties	Result	Metric Conv.	ASTM	NT-TM
Appearance	White, free-flowing, granular solid	-	-	701
Simethicone, USP content	30%	-	-	712
Bulk Density	-	0.4 g/mL	-	-
Particle Size*	20-40 mesh	840-420 microns	-	-
Percent Water	4.8%	-	-	714

* 95% passes through 20 mesh, U.S. standard sieve

Instructions for Use

Blending/Tableting

For every 1 mg of Simethicone, USP desired use approximately 3.3 mg of MED-342. Blend with other solid tableting components, colors and lubricants in low-shear mixers such as ribbon mixers, planetary mixers, cubic mixers, cone mixers, etc. Mixing time should take approximately 20-25 minutes, depending on the amount added and the equipment used. Final formulated mixture can be compressed into tablets on standard one- or two-stroke tableting machines.

Storage

Outdoor storage or storage next to space heaters or radiators is not recommended, and cool storage temperatures are preferred. Keep cartons closed for protection from atmospheric moisture and other contaminants. Mark the date of receipt on containers to determine age and facilitate proper stock rotation.

Sampling/Handling

Some migration of Simethicone from the prepared substrate may occur when stored in non-tableted form. When sampling, it is recommended that a core sample be taken from the top and bottom and thoroughly mixed prior to testing. When separation occurs, it is recommended that full containers be blended before use to assure maximum uniformity.

Stability

Antacid tablets containing Simethicone and the product itself pass the USP defoam and antacid tests, both before and after aging for at least nine months at room temperature and elevated temperatures. There is no significant change in defoam

Packaging

100 lb. Net weight rectangular fiber-pack containers (45 kg)

Shelf Life

6 Months

activity, defoam time or acid neutralization, indicating that it can be tableted into antacid formulations with no loss in defoam activity over extended periods of time.

Shelf Life

MED-342 has a shelf life of 6 months from the date of manufacture when stored at ambient temperature in original, unopened containers.

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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