

# MED-342

## Simethicone GS

### 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
- Produced in registered drug facilities according to criteria set by the U.S. Food and Drug Administration

### APPLICATION

- 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
- Cited in FDA regulation 21 CFR 173.340 as being safe to use in food processing applications (refer to FDA regulation for allowable levels in specific food processing applications)
- 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

### PROPERTIES

Typical Properties	Average Result	NT-TM
<b>Uncured:</b>		
Appearance*	White, free flowing, granular solid	701
Simethicone, USP Content*	30%	712
Bulk Density	0.4 g/mL	-
Particle Size (95% passes through 20 mesh, U.S. standard sieve)	20-40 mesh (840-420 microns)	-
Percent Water*	4.5%	714

Properties are tested on a lot-to-lot basis. Do not use as a basis for preparing specifications. Please [contact](#) NuSil Technology for assistance and recommendations in establishing particular specifications.

## 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 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 12 months from the date of manufacture when stored at ambient temperatures in original, unopened containers.

## DRUG MASTER FILE (DMF)

A Drug Master File for MED-342 has been filed with the United States Food and Drug Administration. Customers interested in authorization to reference the Drug Master File should [contact](#) NuSil Technology LLC.

### Packaging

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

### Shelf Life

12 Months

## SPECIFICATIONS

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

## WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC (hereinafter "NuSil Technology") is 12 months from the date of shipment when stored below 40°C in original unopened containers. Unless NuSil Technology provides a specific written warranty of fitness for a particular use, NuSil Technology's sole warranty is that the product will meet NuSil Technology's then current specification. NuSil Technology specifically disclaims all other expressed or implied warranties, including, but not limited to, warranties of merchantability and fitness for use. The exclusive remedy and NuSil Technology's sole liability for breach of warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted. NuSil Technology expressly disclaims any liability for incidental or consequential damages.

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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 Sheet 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, the user is advised to obtain available product safety information and take the necessary steps to ensure safety of use.

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