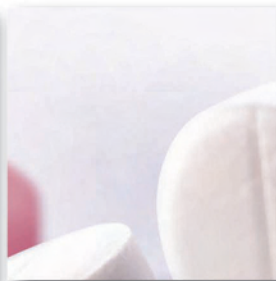
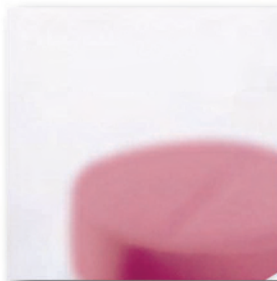
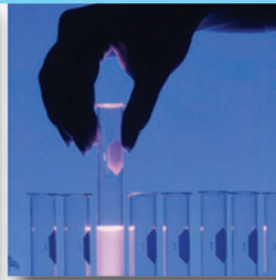




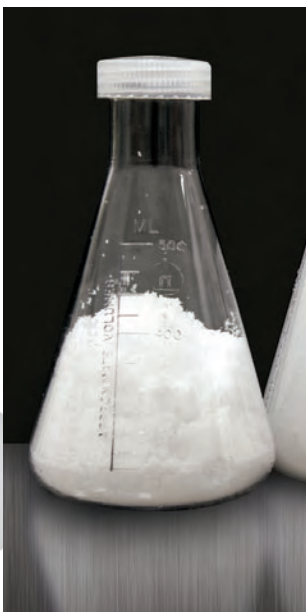
SILICONE  
TECHNOLOGY

Creative Partners in a Material World

Simethicone Materials Selection Guide



# SIMETHICONE MATERIALS GUIDE



Welcome to NuSil, a global manufacturer of silicone-based materials for a wide range of applications that include the healthcare and pharmaceutical industries. NuSil is comprised of hundreds of research, manufacturing, and engineering professionals, dedicated to perfecting silicone as the material of choice. Whether your challenge requires large or small quantities, we promise accurate and precise silicone formulations that will meet your requirements. ISO 9001-certified since 1994, NuSil operates state-of-the-art laboratories and processing facilities throughout the United States.

## Facilities:

Our Carpinteria corporate headquarters is located just outside Santa Barbara, California and covers more than 285,000 square feet of advanced research and manufacturing space, designed and built to formulate the world's most advanced silicone materials. NuSil has an additional manufacturing site in Bakersfield, California. This facility has been registered with the United States Food and Drug Administration (FDA) as a manufacturing site of active pharmaceutical ingredients (APIs). This 15 acre site currently covers more than 138,000 square feet of manufacturing space with ample room for expansion.

## API Products:

- Simethicone Fluids
- Simethicone Granular Solid

The simethicone product line is not only supported by the FDA registration of NuSil's manufacturing facility, but select products are supported by current Kosher and Halal certifications as well. "Residual Solvents" as listed in the current USP/NF and the Guideline for Residual Solvents (CPMP/ICH/283/95) are not used in the manufacture, handling, or storage of the simethicone products. All documentation and supporting processes are in compliance with ICH Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients. Certifications are available upon request.

## Simethicone Fluids:

### Description

NuSil's simethicone fluids offer outstanding pharmaceutical versatility with excellent properties including varying polymer viscosities, low volatility, and resistance to silica separation. They are made with superior bubble-coalescing activity and are highly effective for the elimination and control of foam in both aqueous and non-aqueous solutions.

- Low dose efficiency, of approximately 1 to 100 mg per kg of system to be defoamed
- Chemically inert with regard to the system to be defoamed
- Outstanding behavior in alkaline systems

### Applications

- The production of anti-gas tablets and antacid gels
- Treatment of ulcers
- Lubrication and bubble free application of topical preparations
- Anti-whitening properties in acne and other dermatological ointments, creams and lotions
- Antifoam in the manufacture of drug products made by microbial fermentations
- Listed in the INCI index for use in cosmetic and toiletry products
- Valuable for packaging and filling operations for such products as liquid soaps, shampoos and hair conditioners
- For a soft, silky feel in many hand creams and lotions, as it provides better cost efficiency and performance than dimethicone.

### Dilution Information

NuSil's simethicone fluids can be used as supplied or diluted/dispersed in non-polar aromatic, aliphatic, and chlorinated hydrocarbon solvents. In aqueous systems, simethicone fluids can be made water soluble or water dispersible in certain ketones, alcohols, or ethers. The end user is responsible for ensuring the solvent used complies with applicable regulatory agencies.





## Simethicone Granular Solid

### Description

NuSil's MED-342 is a 30% simethicone granular solid. This product is produced using a patented process that applies the simethicone to maltodextrin without the use of solvents. The simethicone used in the formulation meets the USP monograph for simethicone and the EP monograph for simeticonum. It is the fastest granular simethicone defoamer on the market and a proven history of use in chewable and soft chew tablets currently on the market.

- A unique solid that allows for easy blending with other tablet ingredients
- Reduces cost of clean-up and additional equipment required for liquid addition of Simethicone active
- Fully assayed for simethicone content and uniformity. The assay of each lot is provided on the Certificate of Analysis to allow formulators to easily calculate the amount of granular simethicone required for specific products.
- Contains all Compendial grade components suitable for oral use
- Can be combined with flavors and lubricants

### Applications

- For the manufacture of single- or double-layer tablets
- For forming uniform compositions in any concentration required
- For effective, stable antiflatulence, even in the presence of aluminum and magnesium hydroxide

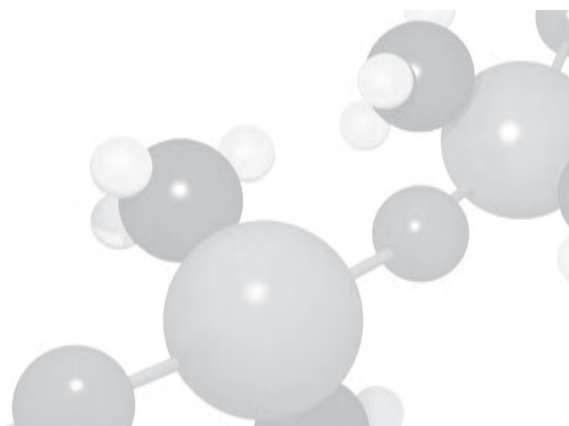
	MED-340	MED-342	MED-346	MED-347
<b>PRODUCT PROPERTIES</b>				
Description	Simethicone USP/EP	Simethicone GS	Simethicone	Simethicone
Appearance	Translucent gray liquid	White granular solid	Grey-white liquid	Grey-white liquid
Viscosity	1,600 cP	N/A	1,325 cP	2,775 cP
Simethicone Content	100%	30%	100%	100%
PDMS Content	95%	29%	95%	95%
Defoaming Test	3 Seconds	3 Seconds	3 Seconds	3 Seconds
Loss on Heating	0.25%	N/A	≤ 1%	≤ 1%
USP Microbial Limits	N/A	Pass	N/A	N/A
Heavy Metals	<5 ppm	<5 ppm	<5 ppm	<5 ppm
<b>PHARMACEUTICAL</b>				
Kosher Certified	Yes	Yes	No	No
Halal Certified	Yes	Yes	No	No
Water Soluble	No	No	No	No
Lubrication	Yes	No	Yes	Yes
Tableting	Yes	Yes	Yes	Yes
Process Defoamer	Yes	No	Yes	Yes
Endoscopic Aids	Yes	No	Yes	Yes
<b>COSMETICS/COSMECEUTICAL</b>				
INCI Listed	Yes	No	Yes	Yes
Creams & Lotions	Yes	Yes	Yes	Yes
Film Former	Yes	No	Yes	Yes
<b>REGULATORY INFORMATION</b>				
Certificate of European Pharmacopoeia (CEP)	Submission in process	N/A	Submission in process	Submission in process
Composition compliant with FDA 21 CFR 332.10*	Yes	Yes	Yes	Yes
Composition compliant with FDA 21 CFR 332.15*	Yes	Yes	Yes	Yes
Composition compliant with FDA 21 CFR 332.31**	Yes	No	Yes	Yes
BSE/TSE Compliant	Yes	Yes	Yes	Yes
USA FDA Drug Master File (DMF)	Yes	Yes	Yes	Yes
<b>OTHER</b>				
Shelf Life***	36 Months	12 Months	18 Months	18 Months
Packaging	5-Gallon Pail (18 kgs net) Drum (200 kgs net)	Drum (45 kgs net)	5-Gallon Pail (18 kgs net) Drum (200 kgs net) Tote (1000 kgs net)	5-Gallon Pail (18 kgs net) Drum (200 kgs net) Tote (1000 kgs net)

\*Classified 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

\*\*Classified as safe for use in endoscopic examinations

\*\*\*From the date of manufacture when stored at ambient temperature in original, unopened containers.

The properties listed above are for reference only. Do not use the properties shown in this table as a basis for preparing specifications. Please contact NuSil Technology for assistance and recommendations in establishing particular specifications.



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