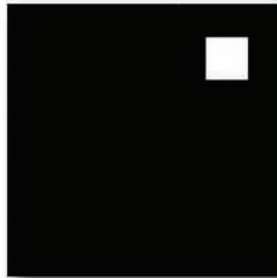
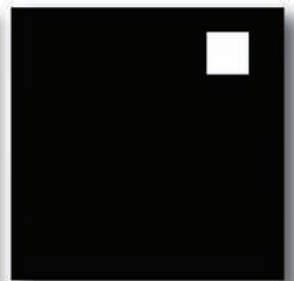
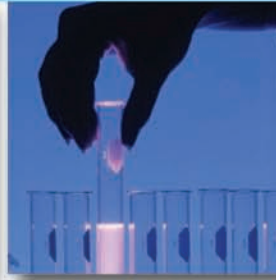




SILICONE  
TECHNOLOGY

Creative Partners in a Material World

Simethicone Materials Selection 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.

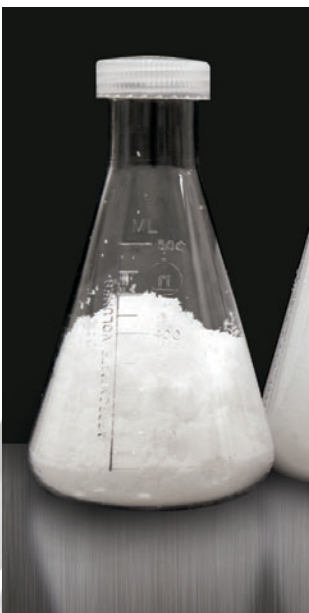
## Facilities:

Our Carpinteria corporate headquarters is located just outside Santa Barbara, California and covers more than 250,000 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 78,000 square feet of manufacturing space with ample room for expansion.



## API Products:

- Simethicone Fluids
- Simethicone Emulsions
- 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. NuSil Technology also confirms that materials used in the manufacturing process of the simethicone product line are not of human or animal origin. 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 Emulsions

### Description

NuSil's simethicone emulsions are easy to handle and highly stable over a broad range of pH levels. They are very fast and effective defoamers in both aqueous and non-aqueous solutions. Various active content formulations are available.

- Efficacious in low doses – from approximately 10 to 1000 mg per kg of the medium to be defoamed
- Chemically inert toward media to be defoamed
- Provides stability under high heat (<120 °C)

### Applications

- Active ingredient in liquid anti-gas and antacid gel products
- Anti-foam in aqueous processes
- Treatment of Ulcers
- Radiological tracers (tablets, powders, etc.)
- Biotechnologic processes such as bacteria, yeast, and enzyme fermentations and processes for the manufacture of antibiotics by fermentation.

### Dilution Information

NuSil's simethicone emulsions should be further diluted with water to customize the simethicone concentration for specific formulations. Additional dilutions are accomplished by adding cool water and gently stirring throughout the water addition process. Once diluted, mixing at the time of use will be required after prolonged storage.

For example, 30% simethicone can be diluted in water or in the medium to be defoamed to a concentration of 1% active ingredient by slowly adding 29 parts water or medium to be defoamed to 1 part simethicone emulsion. Doing this in reverse order is not recommended.





## 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 antifatulence, even in the presence of aluminum and magnesium hydroxide

	MED-340	MED-341	MED-342	MED-343	MED-344	MED-345	MED-346	MED-347	MED-348	MED-349
<b>PRODUCT PROPERTIES</b>										
Description	Simethicone USP/EP	Simethicone Emulsion USP	Simethicone GS	Simethicone Emulsion	Simethicone	Simethicone Emulsion	Simethicone	Simethicone	Silicone Antifoam Emulsion	Simethicone Emulsion
Appearance	Translucent gray liquid	Off-white liquid	White granular solid	White liquid	Off-white liquid	White to Off-white liquid	Grey-white liquid	Grey-white liquid	Off-white liquid	White liquid
Viscosity	1,600 cP	2,100 cP	N/A	185 cP	1,700 cP	55 cP	1,325 cP	2,775 cP	3,500 cP	1,150 cP
Simethicone Content	100%	30%	30%	27%	100%	27%	100%	100%	30%	20%
PDMS Content	95%	29%	29%	24%	95%	25%	95%	95%	27%	18%
Defoaming Test	3 Seconds	3 Seconds	3 Seconds	N/A	6 Seconds maximum	2 Seconds	3 Seconds	3 Seconds	5 Seconds	4 Seconds
Loss on Heating	0.25%	N/A	N/A	N/A	≤ 1%	N/A	≤ 1%	≤ 1%	N/A	N/A
USP Microbial Limits	N/A	Pass	Pass	Pass	N/A	Pass	N/A	N/A	Pass	Pass
Heavy Metals	<5 ppm	<5 ppm	<5 ppm	<5 ppm	<5 ppm	<5 ppm	<5 ppm	<5 ppm	<5 ppm	<5 ppm
<b>PHARMACEUTICAL</b>										
Kosher Certified	Yes	Yes	Yes	No	No	No	No	No	No	No
Halal Certified	Yes	Yes	Yes	No	No	No	No	No	No	No
Water Soluble	No	Yes	No	Yes	No	Yes	No	No	Yes	Yes
Lubrication	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Tableting	Yes	No	Yes	No	Yes	No	Yes	Yes	No	No
Process Defoamer	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Endoscopic Aids	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>COSMETICS/COSMECEUTICAL</b>										
INCI Listed	Yes	No	No	No	Yes	No	Yes	Yes	No	No
Creams & Lotions	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Film Former	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
<b>REGULATORY INFORMATION</b>										
Certificate of European Pharmacopoeia (CEP)	Submission in process	N/A	N/A	N/A	Submission in process	N/A	Submission in process	Submission in process	N/A	N/A
Composition compliant with FDA 21 CFR 332.10*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Composition compliant with FDA 21 CFR 332.15*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Composition compliant with FDA 21 CFR 332.31**	Yes	No	No	No	Yes	No	Yes	Yes	No	No
BSE/TSE Compliant	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
USA FDA Drug Master File (DMF)	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No	No
<b>OTHER</b>										
Shelf Life***	36 Months	18 Months	12 Months	12 Months	24 Months	15 Months	18 Months	18 Months	12 Months	12 Months
Packaging	5-Gallon Pail (18 kgs net) Drum (210 kgs net) Drum (200 kgs net)	5-Gallon Pail (18 kgs net) Drum (210 kgs net) Drum (200 kgs net)	Drum (45 kgs net)	5-Gallon Pail (18 kgs net) Drum (200 kgs net)	5-Gallon Pail (18 kgs net) Drum (200 kgs net)	5-Gallon Pail (18 kgs net) Drum (200 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)	5-Gallon Pail (18 kgs net) Drum (200 kgs net)	5-Gallon Pail (18 kgs net) Drum (200 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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