

MED-340

Simethicone USP/EP

DESCRIPTION

- Designated by the FDA-OTC Antacid and Antiflatulent Review Panel as a safe and effective antiflatulent component of antacid and other gastrointestinal preparations
- Kosher and Halal certified
- Outstanding pharmaceutical versatility
- Excellent properties including low volatility and resistance to silica separation
- One of the fastest defoamers of any Simethicone made
- Produced in a registered drug facility according to criteria set by the U.S. Food and Drug Administration
- Demonstrates bubble-coalescing activity and lubricity
- Produced in a facility compliant with Good Manufacturing Practices (FDA regulations 21 CFR Part 210 & 211 and ICH Q7)
- Tested in accordance with and meets all the requirements of the United States Pharmacopeia (USP) for Simethicone and the European Pharmacopeia (EP) for Simeticone¹

1) Current edition of the United States Pharmacopeia and the European Pharmacopeia

APPLICATION

- 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
- 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)
- Provides lubrication for uniform and bubble-free application of topical preparations such as antibiotic ointments and contraceptive gels
- Effective in acne and other dermatological ointments, creams and lotions due to its lubricity and anti-whitening properties
- As an antifoam in the manufacture and separation of drug products made by microbial fermentation
- For use in enzyme digestive aids and as a stabilizer in making belladonna extract and in cod liver oil extraction
- Useful in packaging aqueous solutions such as prepared douches where foaming can impede operations
- Listed in the International Cosmetic Ingredient Dictionary as a material useful for the formulation of 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

PROPERTIES

Typical Properties	Average Result	NT-TM
Appearance	Translucent gray, viscous fluid	701
Viscosity	1,400 cP (1,400 mPas)	738
Simethicone, USP/EP Content	100%	-
Defoaming Test	3 seconds	703
Loss on Heating	0.25%	705
Heavy Metals (as Lead)	5 ppm maximum	784
Mineral Oils	Pass	757

The above 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

Concentration and Dilution

MED-340 is normally used at concentrations of between 1 and 100 mg per kg (or liter) of the system to be defoamed.

MED-340 may be used directly as supplied, or it may be diluted to a concentration of between 1% and 10% of active ingredient in compound-based silicone oil solvents.

The solvents must be soluble or dispersible in the system to be defoamed. For aqueous systems, consider diluents that are soluble or dispersible in water, such as alcohols (tert-butanol, 1-dodecanol, 2-ethyl hexanol), ketones (methylethyl ketone, methylisobutyl ketone), or ethers (ethyl ether, isopropyl ether). For anhydrous systems, consider aromatic, aliphatic or chlorinated hydrocarbons.

The given concentrations are for example only. The user is responsible for determining the concentration required for their specific application.

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.

Shelf Life

MED-340 has a shelf life of 36 months from the date of manufacture when stored at ambient temperature in original, unopened containers.

Packaging

5 Gallon Pail (18.0 kg)
Drum (200 kg)
Tote (1000 kg)

Warranty

36 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.

CERTIFICATION OF SUITABILITY (CEP)

A Certification of Suitability for MED-340 has been received by the European Directorate for the Quality of Medicines and Health (EDQM).

DRUG MASTER FILE (DMF)

A Drug Master File for MED-340 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.

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC (hereinafter "NuSil Technology") is 36 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.

WARNINGS ABOUT PRODUCT SAFETY

NuSil Technology believes, to the best of its knowledge, that the information and data contained herein are accurate and reliable. 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 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.

PATENT / INTELLECTUAL PROPERTY WARNING

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