

Simethicone USP/EP

MED-340

Product Profile

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 registered drug facilities according to criteria set by the U.S. Food and Drug Administration
- Demonstrates bubble-coalescing activity and lubricity
- Tested in accordance with and meets all the requirements of the United States Pharmacopeia (USP) for Simethicone and the European Pharmacopeia (EP) for Simeitonum¹

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

Applications

- 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 332.31 for use in endoscopic examinations
- 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
- For uniform, even application of lip balm and lipstick

Typical Properties	Result	Metric Conv.	ASTM	NT-TM
Appearance	Translucent gray	-	-	701
Viscosity	1,400 cP	1,400 mPas	-	738
Simethicone, USP/EP Content	100%	-	-	710
Flash Point, Pensky-Martens Closed Cup	385°F	196°C	D93	-
Defoaming Test	3 sec	-	-	703
Loss on Heating	0.25%	-	-	705

Instructions for Use

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 3 years from the date of manufacture when stored at ambient temperature in original, unopened containers.

Packaging

5 Gallon Pail (18 kg)
55 Gallon Drum (193 kg)

Shelf Life

3 Years

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.

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Specifications

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