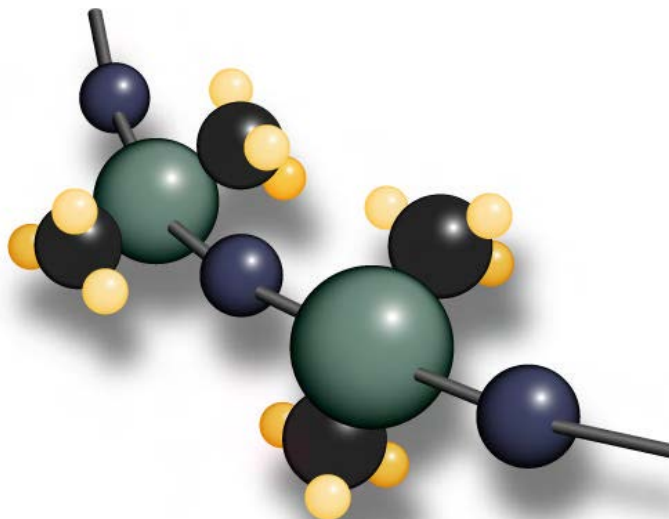


Polymer Systems Technology Limited

UK & Ireland Distributor



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Simethicone Emulsion

MED-349 (Antifoam 70462)

Description

- Designated by the FDA-OTC Antacid and Antiflatulent Review Panel as a safe and effective antiflatulent component of antacid and other gastrointestinal preparations
- May be diluted with water
- Effective over a broad range of pH
- Easy to use viscosity
- Produced in a registered drug facility according to criteria set by the U.S. Food and Drug Administration
- Produced in a facility compliant with Good Manufacturing Practices (FDA regulations 21 CFR Part 210 & 211 and ICH Q7)

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
- Defoaming and antifoaming agent in a wide range of applications
- Used in microbial fermentation processes
- Antacid / antigas preparations

Properties	Average Result	NT-TM
Appearance	White liquid	701
Viscosity	1,150 cP (1,150 mPas)	801
Simethicone Content	20%	-
pH	3 - 4.5	704
Defoaming Time	4 seconds	703
Heavy Metals (as Lead)	5 ppm maximum	706
Microbial Test Limits	Pass	715

The properties listed above are for reference only. 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.

Instructions for Use

Concentration and Dilution

Can be used as supplied or diluted to concentrations as low as 1% active. Dilute by slowly adding water to the emulsion while stirring continuously. Storage of diluted emulsion for greater than 24 hours is not recommended.

Shelf Life

MED-349 has a shelf life of 12 months from the date of manufacture when stored at ambient temperatures in original, unopened containers.

Packaging

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

Shelf Life

12 Months

Drug Master File (DMF)

A Drug Master File for MED-349 is currently being submitted to the United States Food and Drug Administration (USFDA). The DMF reference number shall be provided upon submittal of a request on company letterhead to NuSil Technology.

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.

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