Polymer Systems Technology Limited

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Creative Partners in a Material World

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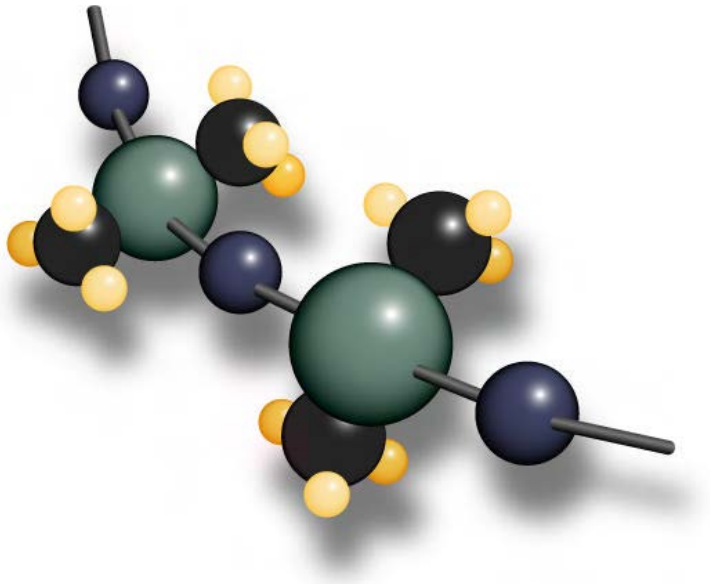

Product Profile

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An ISO 9001
Certified Company

Simethicone Emulsion

MED-348 (Antifoam 70460)

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
- Non-ionic and highly stable over a broad pH range
- Easy to disperse in most aqueous foaming systems
- Chemically inert, therefore does not alter the characteristics of material to be defoamed
- Effective in low doses such as 10 to 1000 mg per kg of material to be defoamed
- 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
- For prevention, control and elimination of foam in aqueous systems
- For use in treatments for stomach pain
- For use in antacid gels and radiological tracers
- For use in treatments for ulcers and gas due to abnormal swallowing

Properties	Average Result	NT-TM
Appearance	White liquid	701
Simethicone Content	30%	-
pH	3 - 5	704
Defoaming Time	5 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

MED-348 is normally used at concentrations of between 10 and 1000 mg per kg (or liter) of the system to be defoamed.

MED-348 may be used as supplied, or diluted in water or material to be defoamed. Predilution to an active ingredient content of approximately 1% may also be accomplished by slowly adding 29 parts water or material requiring defoaming to 1 part MED-348, while stirring.

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

Shelf Life

MED-348 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-348 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.

Warranty Information

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.

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