

## Simethicone USP

**Simethicone USP** Mixture of Polydimethyl siloxane fluid & silicone dioxide  
Silicone antifoam for use in pharmaceutical applications requiring foam suppression or inhibition.

### FEATURES

- Highly effective defoamer at low concentration.
- Tested according to and complies with Simethicone United state Pharmacopia.

### APPLICATIONS

**Simethicone USP** may be used as an antifoaming ingredient in antacid preparation, as a foam suppressant in pharmaceutical process such as mixing, percolation, fermentation, maceration & as an agent to improve the efficiency of ampoule & bottle filling when foaming is a problem.

### TYPICAL PROPERTIES

(REF-SIMETHICONE USP)

Simethicone USP	property	Value
Description	Translucent, grey, viscous liquid	Complies
Solubility	As per USP	Complies
Identification	IR identification	Complies
Loss of Heating	Loss after heating	Not more than 18 %
Heavy metal	Heavy metal content	Not more than 5 MCG per GM
Organic volatile impurity by Method IV	Organic impurity analysis by GLC	Complies
Defoaming activity	Defoaming performance	<15 sec
Assay of Polydimethyl siloxane	By IR absorption	Not less than 90.5 % & not more than 99 %
Assay of silicone dioxide	BY IR absorption <sup>1</sup> Typical Values – Should not be considered as specifications.	Not less than 4.0 % & not more than 7 %

<sup>1</sup>Typical Values – Should not be considered as specifications.

## IMPORTANT INFORMATION

This formulation is qualification tested to requirements of United state Pharmacopia (USP) It is the user 's responsibility to ensure the safety & efficiency of this product for each specific end use pharmaceutical product, medical device or other application.

## PACKING

35 & 50 HDPE carboys & 200 kg drums

## SHELF LIFE & STORAGE

Some settling may occur during storage .therefore containers should be thoroughly mixed prior to use or testing. When stored in unopened containers at ambient temperatures this product has a usable life of 48 month from the date of manufacturing.

## HANDLING

Product safety information required for safe use is not included. Before handling, read product & safety data sheet & container labels for safe use, physical health hazards information.

### Information please read carefully

The information provided to the customers in this data sheet is intended as a guideline and is provided in good faith. The Information is believed to be accurate. Changes may occur from system to system as methods of use and conditions are beyond our control, hence **users are requested to evaluate the recommendations before actual application to get desired performance.**

ELKAY CHEMICALS PVT. LTD. (ELKAY) Main Plant Office (MIDC, Bhosari) exclusively can provide you with a specific written warranty for a particular use. In the absence of this, ELKAY gives the sole **warranty that the product (or products) supplied will meet its sales specifications** (not provided on this sheet). ELKAY disclaims any other expressed or implied warranty. For current or required specifications, please contact your ELKAY distributor, representative or office. ELKAY does not warrant the recommendations given within for their fitness for use, performance, efficacy or safety. Users are responsible for certification of use of their product and for complying with local legislation. Suggestions of use shall not be taken as inducements to infringe any patents or grant any license under a valid patent and are provided for illustrative purposes only.

Internal References PS/Ref/03/04 DX30701