


**RioCare India Private Limited**

 Plot No. R-940, TTC Industrial Area, MIDC Rabale, Navi Mumbai – 400 701, District: Thane,  
 Maharashtra, INDIA

**FINISHED PRODUCT SPECIFICATION**

Simethicone (Filix-110)	Effective Date : 22/06/2022	Reference
Specification No.: SPEC- FLX-01-08	Supersedes doc. : 01/04/2022	USP-NF 2022, Issue 1

<b>NAME</b>	: Simethicone [8050-81-5] $\alpha$ -(Trimethylsilyl)- $\omega$ -methylpoly[oxy(dimethylsilylene)], mixture with silicon dioxide.
<b>DEFINITION</b>	: Simethicone is a mixture of fully methylated linear siloxane polymers containing repeating units of the formula $[-(\text{CH}_3)_2\text{SiO-}]_n$ , stabilized with trimethylsiloxy end-blocking units of the formula $[-(\text{CH}_3)_3\text{SiO-}]$ and silicon dioxide. It contains NLT 90.5% and NMT 99.0% of Polydimethylsiloxane $([-(\text{CH}_3)_2\text{SiO-}]_n)$ , and NLT 4.0% and NMT 7.0% of silicon dioxide.
<b>DESCRIPTION AND RELATIVE SOLUBILITY</b>	: Translucent, gray, viscous fluid. The liquid phase is soluble in chloroform, in ether, and in benzene but silicon dioxide remains as a residue in these solvents. Insoluble in water and in alcohol.
<b>SPECTROSCOPIC IDENTIFICATION TEST</b>	: Infrared Spectroscopy. Meets the requirement.
<b>ASSAY FOR POLYDIMETHYLSILOXANE</b>	: 90.5 - 99.0%
<b>CONTENT OF SILICON DIOXIDE</b>	: 4.0 - 7.0%
<b>LOSS ON HEATING (200°C for 4 hrs.)</b>	: NMT 18.0%
<b>DEFOAMING ACTIVITY</b>	: Not more than 15 seconds.

	Prepared by	Checked by	Reviewed by	Approved by
Name	Vaishali Badekar	Leena Panchal	Meena Vaidya	Kalpaka Venkatesan
Designation	Sr. Officer -QC	Manager - QC	Manager - QA	Director
Signature and Date	 20/06/2022	 20/06/2022	 21/06/2022	 21/06/2022


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**VISCOSITY (at 25<sup>0</sup>C)**
**(BROOKFIELD VISCOMETER)**

: 500–700 cSt (LV2 Spindle at 30rpm/25°C)  
1000–1300 cSt (LV3 Spindle at 30rpm/25°C)  
2000 – 2500 cSt (LV3 Spindle at 30rpm/25°C)

**RETEST DATE**

: 4 years from the date of manufacture.

**STORAGE CONDITION**

: Store in air tight containers.  
Recommended temperature 25<sup>0</sup>C - 40<sup>0</sup>C.

**Reason for review:**

CCD No.: CC/20-22/054 dt. 23/03/2022 : Updated as per USP 44.  
CCD No.: CC/22-24/001 dt. 16/06/2022 : As per official USP notification the current version is changed from USP 44 to USP–NF 2022, Issue 1.

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