


RioCare India Private Limited

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

FINISHED PRODUCT SPECIFICATION

Simeticone (Filix-110)	Effective Date : 01/04/2022	Reference
Specification No.: SPEC- FLX-03-07	Supersedes doc. : 05/08/2021	BP 2021

NAME	:	Simeticone.
DEFINITION	:	Mixture of α -trimethylsilyl [ω -methyl poly[oxy-(dimethylsilanediy)] and silicon dioxide. Simeticone is prepared by incorporation of 4% to 7% silica into poly(dimethylsiloxane) with a degree of polymerization between 20 and 400. It contains 90.5% to 99.0% of poly (dimethylsiloxane).
APPEARANCE	:	Viscous, greyish-white, opalescent liquid.
SOLUBILITY	:	Practically insoluble in water, very slightly soluble or practically insoluble in anhydrous ethanol, practically insoluble in methanol, partly miscible with ethyl acetate, with methylene chloride, with methyl ethyl ketone and with toluene.
IDENTIFICATION	:	A. By Infrared absorption. B. By Coloration. C. Reaction of Silicates.
ACIDITY	:	NMT 3.0 ml of 0.01M of NaOH.
DEFOAMING ACTIVITY	:	Not more than 15seconds.
MINERAL OILS	:	Fluorescence at 365 nm < 0.1 ppm of quinine sulfate R in 0.005M sulfuric acid.
PHENYLATED COMPOUNDS	:	Corrected absorbance is not greater than 0.2
VOLATILE MATTER (105°C FOR 2 HRS.)	:	NMT 1.0 %
ASSAY SILICA	:	4.0 to 7.0 %
POLY (DIMETHYLSILOXANE)	:	90.5 to 99.0%

	Prepared by	Checked by	Reviewed by	Approved by
Name	Vaishali Badekar	Leena Panchal	Meena Vaidya	Kalpakam Venkatesan
Designation	Sr. Officer -QC	Manager - QC	Manager - QA	Director
Signature and Date	 28/03/2022	 29/03/2022	 30/03/2022	 30/03/2022


RioCare India Private Limited

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

FINISHED PRODUCT SPECIFICATION

Simeticone (Filix-110)	Effective Date : 01/04/2022	Reference
Specification No.: SPEC- FLX-03-07	Supersedes doc. : 05/08/2021	INH

VISCOSITY (at 25⁰C)
(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 25-40°C.

Reason for review:

CCD No.: CC/20-22/054 dt. 23/03/2022 : Regular Updation.

	Prepared by	Checked by	Reviewed by	Approved by
Name	Vaishali Badekar	Leena Panchal	Meena Vaidya	Kalpakam Venkatesan
Designation	Sr. Officer -QC	Manager - QC	Manager - QA	Director
Signature and Date	 28/03/2022	 28/03/2022	 30/03/2022	 30/03/2022