



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 50% Powder (Simflo)	Effective Date : 01/04/2022	Reference
Specification No.: SPEC- SLO-04-12	Supersedes doc. : 01/11/2020	INH

NAME : Simethicone 50% Powder.

APPEARANCE : White, free flowing, odorless powder.

IDENTIFICATION : By Infrared absorption.

DEFOAMING ACTIVITY : Not more than 45seconds.

ASSAY AS PDMS (On dried basis) : 42.0% to 52.0%

LOSS ON HEATING (105⁰C for 2 hrs.) : NMT 6.0%

PARTICLE SIZE : 90% Particles less than 500 microns.

BULK DENSITY : 0.40g/cc to 0.80 g/cc

MICROBIAL ENUMERATION TEST

Total aerobic microbial count : Not more than 1000cfu/g

Mold and yeast : Not more than 100cfu/g

TESTS FOR SPECIFIED MICRO-ORGANISMS

Escherichia coli : Should be absent.

Salmonella spp. : Should be absent.

Pseudomonas aeruginosa : Should be absent.

Staphylococcus aureus : Should be absent.

EXPIRY DATE : 18 months from the date of manufacture

STORAGE CONDITION : Store in air tight containers.
Recommended temperature 25°C - 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
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Designation	Sr. Officer -QC	Manager - QC	Manager - QA	Director
Signature and Date	 28/03/2022	 29/03/2022	 30/03/2022	 30/03/2022