

**Material Safety Data Sheet**  
**SIMETHICONE USP - 100 % (FILIX-110)**

**1. PRODUCT AND COMPANY IDENTIFICATION**

RioCare India Pvt. Ltd  
Plot No. R – 940, TTC Indl. Area,  
MIDC Rabale, Navi Mumbai – 400 701,  
District Thane, Maharashtra, India.

**24 Hour Emergency Telephone:**

0091 9820360036

MSDS No.: 104

Revision Date: 1<sup>st</sup> April 2022.

Description:  $\alpha$ -(Trimethylsilyl)- $\omega$ -methylpoly [oxy (dimethylsilylene)] mixture with Silicon Dioxide

Physical Form: Viscous Liquid

Color: Translucent gray

Odor: Odorless

NFPA Profile:

Health 0 Flammability 1 Instability/Reactivity 0

Note: NFPA = National Fire Protection Association

**2. HAZARD IDENTIFICATION**

Potential Health Effects:

Acute Effects

Eye: Direct contact may cause temporary redness and discomfort.

Skin: No significant irritation expected from a single short-term exposure.

Inhalation: No significant effects expected from a single short-term exposure.

Oral: Low ingestion hazard in normal use.

Prolonged/Repeated Exposure Effects

Skin: No known applicable information.

Inhalation: No known applicable information.

Oral: No known applicable information.

Signs and Symptoms of Overexposure

No known applicable information.

Medical Conditions Aggravated by Exposure.

No known applicable information

Signs and Symptoms of Overexposure:

No known applicable information.

The above listed potential effects of overexposure are based on actual data, results of studies performed upon similar compositions, component data and / or expert review of the product

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Composition:

Component Name	CAS Number	% by weight
Simethicone	8050-81-5	100



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**4. FIRST AID MEASURES**

Eye: Immediately flush with water for 15 minutes.

Skin: No first aid is needed.

Inhalation: No first aid is needed.

Oral: No first aid is needed.

**5. FIRE FIGHTING MEASURES**

Flash Point: > 321 °C / > 610 °F (Closed Cup)

Auto ignition Temperature: Not determined.

Flammability Limits in Air: Not determined.

Extinguishing Media: On large fires use dry chemical, foam or water spray. On small fires use carbon dioxide (CO<sub>2</sub>), dry chemical or water spray. Water can be used to cool fire exposed containers.

Fire Fighting Measures: Self-contained breathing apparatus and protective clothing should be worn in fighting large fires involving chemicals. Determine the need to evacuate or isolate the area according to your local emergency plan. Use water spray to keep fire exposed containers cool.

Unusual Fire Hazards: None.

Hazardous Decomposition Products: Thermal breakdown of this product during fire or very high heat conditions may evolve the following hazardous decomposition products: Carbon oxides and traces of incompletely burned carbon compounds Silicon dioxide, Nitrogen oxides, Formaldehyde.

**6. ACCIDENTAL RELEASE MEASURES**

Containment / Clean up:

Determine whether to evacuate or isolate the area according to your local emergency plan. Observe all personal protection equipment recommendations described in Sections 5 and 8. For large spills, sweep up and collect in appropriate containers for disposal. Clean area using solvents or detergents. Local laws and regulations may apply for disposal of this material, as well as those materials and items employed in the cleanup of releases.

Note: See section 8 for Personal Protective Equipment for Spills.

**7. HANDLING AND STORAGE**

Use with adequate ventilation. Avoid eye contact. Avoid breathing vapor, mist, dust, or fumes.

Keep container closed. Use reasonable care and store away from oxidizing materials.

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

Engineering Controls

Local Ventilation: Recommended.

General Ventilation: Recommended.

Personal Protective Equipment for Routine Handling

Eyes: Use proper protection - safety glasses as a minimum.

Skin: Washing at mealtime and end of shift is adequate.

Suitable Gloves: No special protection needed.

Inhalation: Use respiratory protection unless adequate local exhaust ventilation is provided or air sampling data show exposures is within recommended exposure guidelines.

Suitable Respirator: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits as determined by air sampling or are unknown, appropriate respiratory protection should be worn.



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**9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical Form: Liquid

Color: Translucent gray

Odor: Characteristic odor

Specific Gravity @ 25°C: 0.970 – 0.995

Viscosity: 500 – 3000 cSt

Freezing / Melting Point: Not determined.

Boiling Point: > 250°C / 482°F

Vapor Pressure @ 25°C: Not determined.

Vapor Density: Not determined.

Solubility in Water: Essentially Nil.

PH: Not determined.

Volatile Content: Not determined.

Note: The above information is not intended for use in preparing product specifications.

Contact RioCare India Pvt. Ltd before writing specifications.

**10. STABILITY AND REACTIVITY**

Chemical Stability: Stable.

Hazardous Polymerization: Hazardous polymerization will not occur.

Conditions to avoid: None.

Avoid: Keep away from direct sunlight, heat and source of ignition or moisture. Oxidizing material can cause a reaction.

**11. TOXICOLOGICAL INFORMATION**

It is a nonhazardous, nontoxic material.

**LD50 (Intravenous)(dog) –900mg/Kg**

**LD50 (Dermal) – NA**

**LD50 (Inhalation) – NA**

**LD50 (Oral) (rat) – 5000mg/Kg**

**12. ECOLOGICAL INFORMATION**

**Environmental Fate and Distribution**

Complete information is not yet available.

**Environmental Effects**

Complete information is not yet available.

**Fate and Effects in Waste Water Treatment Plants**

Complete information is not yet available.

**Eco toxicity Classification Criteria**

Hazard Parameters (LC50 or EC50) High Medium Low

Acute Aquatic Toxicity (mg/L) <=1 >1 and <=100 >100

Acute Terrestrial Toxicity <=100 >100 and <= 2000 >2000

This table is adapted from "Environmental Toxicology and Risk Assessment", ASTM STP 1179, p.34, 1993. This table can be used to classify the Eco toxicity of this product when Eco toxicity data is listed above. Please read the other information presented in the section concerning the overall ecological safety of this material.



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**13. DISPOSAL CONSIDERATIONS**

**RCRA Hazard Class (40 CFR 261)**

When a decision is made to discard this material, it is classified as a nonhazardous waste. No State or local laws may impose additional regulatory requirements regarding disposal.

**14. TRANSPORT INFORMATION**

Not classified as dangerous for transport in accordance with DOT, IMDG and IATA.

**15. REGULATORY INFORMATION**

**Regulatory Status:**

Simethicone USP complies with all, monograph requirements and acceptable under Food and Drug Administration Regulation.

**Manufacturing Environment:**

Simethicone USP is manufactured, tested and packaged under strict quality control guidelines. The site quality system for active pharmaceutical ingredient (APIs) is in compliance with current good manufacturing practices.

**16. OTHER INFORMATION**

Prepared by: RioCare India Private Limited.

These data are offered in good faith as typical values and not as product specifications. No warranty, either expressed or implied, is hereby made. The recommended industrial hygiene and safe handling procedures are believed to be generally applicable. However, each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate. RioCare disclaims liability for any incidental or consequential damages.

