Shandong Silico Silicone Materials Co., Ltd.
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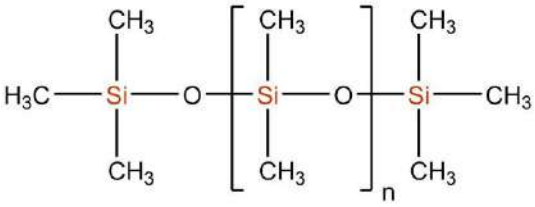
Silico® 350 cSt Medical-Grade Silicone Fluid (PDMS)

TECHNICAL DATA SHEET (TDS)

Chemical Structure



Product Overview

Silico® 350 cSt Medical-Grade Silicone Fluid is a high-purity linear polydimethylsiloxane (PDMS) specifically manufactured for regulated medical and pharmaceutical applications requiring:

- Controlled viscosity performance
- Excellent chemical inertness
- Low volatility and extractables
- Broad thermal stability
- Biocompatibility support

This 350 cSt silicone fluid is designed for use in medical device lubrication, siliconization processes, pharmaceutical processing, and precision damping systems, where purity, consistency, and regulatory documentation are critical.

Chemical Identification

Item	Description
Chemical Name	Polydimethylsiloxane
INCI Name	Dimethicone
CAS Number	63148-62-9
Molecular Structure	Linear PDMS polymer
Chemical Formula	$(–Si(CH_3)_2–O–)_n$
Product Type	Medical-Grade Silicone Fluid

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Typical Technical Properties

Property	Typical Value	Test Method
Viscosity @ 25°C	350 cSt	ASTM D445
Density @ 25°C	0.965 – 0.975 g/cm³	ASTM D1475
Refractive Index @ 25°C	1.402 – 1.406	ASTM D1218
Surface Tension @ 25°C	~21 mN/m	ASTM D1331
Flash Point (Closed Cup)	≥ 300°C	ASTM D92
Pour Point	≤ –50°C	ASTM D97
Volatile Content	≤ 0.2%	Gravimetric
Purity (PDMS Content)	≥ 99.0%	Internal Method

The above values represent typical properties and are not to be construed as specifications.

4. Key Performance Characteristics

High Purity & Controlled Manufacturing

Produced under controlled conditions to minimize residual catalysts, low molecular weight siloxanes, and potential extractables. Suitable for regulated medical environments.

Stable Rheological Behavior

The 350 cSt viscosity grade offers balanced flow and film-forming capability, making it ideal for controlled coating thickness and precision lubrication.

Chemical & Biological Inertness

PDMS is widely recognized for its non-reactivity toward metals, elastomers, glass, and engineering plastics. Properly processed grades may support ISO 10993 biocompatibility evaluations.

Excellent Thermal & Oxidative Stability

Maintains functional stability across a wide temperature range, with low volatility and high flash point suitable for sterilization-adjacent processes.

Low Surface Energy & Lubricity

Provides uniform spreading and consistent lubrication performance in medical device assemblies.

5. Application Areas

Silico® 350 cSt Medical-Grade Silicone Fluid is typically used in:

- Medical device lubrication (catheters, guidewires, syringes)
- Siliconization of glass and elastomer components

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- Pharmaceutical processing and equipment lubrication
- Biocompatible damping fluids in precision medical instruments
- Controlled coating and release systems

Selection for implantable or injectable applications requires additional validation and regulatory documentation.

6. Regulatory & Quality Support

Available documentation may include:

- Certificate of Analysis (CoA)
- Batch traceability records
- Extractables & Leachables data (upon request)
- ISO 10993 biocompatibility reference documentation
- USP / NF Dimethicone compliance support (if applicable)
- REACH and RoHS declarations

Regulatory compliance should be verified according to end-use requirements.

7. Packaging & Storage

Packaging Options:

1 kg bottles, 25 kg pails, 200 kg drums, 1000 kg IBC containers

Storage Conditions:

Store in original sealed containers at 5–35°C in a dry, well-ventilated area. Avoid contamination and exposure to strong oxidizing agents.

Shelf Life:

Typically 24–60 months under recommended storage conditions.

8. Handling Considerations

Although medical-grade PDMS silicone fluid is generally regarded as low hazard and chemically inert, standard industrial hygiene practices should be followed. Refer to the corresponding Safety Data Sheet (SDS) for complete safety information.