

# SILBIONE DM 300 GMP, DM 500 GMP, DM 1000 GMP

**Description** **SILBIONE DM 300 GMP, DM 500 GMP and DM 1000 GMP** are linear polydimethylsiloxanes fluids available as a range with three viscosities.

**SILBIONE DM 300 GMP, DM 500 GMP and DM 1000 GMP** comply with:

- **European pharmacopoeia** requirements for Dimethicone.
- Production complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.
- **European Drug Master File available**

Refer to the regulatory attestation for the conformance to any regulated applications.

## Examples of applications

- Raw materials for Medical Devices
- Pharmacy
- Excipient in topical formulations,
- Antiflatulence and antacid preparations.

Warning: It is the sole responsibility of the user to select the product in the ELKEM SILICONES range that meets any requirements for their applications.

## Key benefits

- Chemically inert.
- Heat-resistant.
- Resistant to ageing by atmospheric agents (oxygen, ozone, water, light).
- Low surface tension.
- Non-toxic.

## Typical properties

<i>PropertiES</i>	<b>SILBIONE DM 300 GMP</b>	<b>SILBIONE DM 500 GMP</b>	<b>SILBIONE DM 1000 GMP</b>
<b>Aspect</b>	Clear liquid, colorless		
<b>Odour</b>	odourless		
<b>Viscosity at 25 °C (<i>mm<sup>2</sup>/s, approx.</i>)</b>	300	500	1000
<b>Volatile content (<i>2 h at 150°C, %</i>)</b>	< 0.3		
<b>Specific gravity (<i>at 25°C, approx.</i>)</b>	0.970		
<b>Refractive Index (<i>at 25°C, approx.</i>)</b>	1.403		
<b>Surface tension (<i>at 25°C, mN/m, approx.</i>)</b>	21.1		
<b>Pour point, (<i>°C, approx.</i>)</b>	-50		
<b>Flash point (<i>open cup, °C</i>)</b>	> 300		

### Compatibility

**SILBIONE DM 300 GMP, DM 500 GMP and DM 1000 GMP** are soluble in numerous solvents:

- Aliphatic hydrocarbon (e.g., hexane, heptane, mineral spirits)
- Aromatic hydrocarbon (e.g., toluene, xylene)
- Halogenated solvents: methylene chloride, chloroform, trichlorethane, chlorofluoro-alcanes...
- Ketones: methylethylketone.
- Ester: ethyl and butyl acetates, isopropyl palmitate, isopropyl myristate
- Ether: ethyl ether, isopropyl ether
- Higher alcohols: lauryl alcohol, ethyl-2 hexanol.

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They are insoluble in:

- Water.
- Lower alcohols: methanol, ethanol.
- Vegetable and animal oils, fatty acids.
- Glycols: ethylene glycol, propylene glycol.
- Glycerin.

Please note: The typical properties are not intended for use in preparing specifications. Please contact our local Sales Department for assistance in writing specifications.

<b>Instruction of use</b>	Please consult your local ELKEM SILICONES sales office.
<b>Regulation</b>	Extensive toxicology testing on SILBIONE® products has demonstrated their adequate biocompatibility and suitability for the recommended applications. SILBIONE DM 1000 GMP, SILBIONE DM 300 GMP and SILBIONE DM 500 GMP satisfies regulatory requirement in several countries and complies with a number of medical and pharmaceutical regulations. Contact Elkem Silicones for more detailed information.
<b>Limitations</b>	Please consult your local ELKEM SILICONES sales office.
<b>Packaging</b>	<ul style="list-style-type: none"> <li>• SILBIONE DM 1000 GMP is available in                             <ul style="list-style-type: none"> <li>○ Drum of 25 KG (55.13 LB)</li> <li>○ Drum of 200 KG (441 LB)</li> <li>○ Tote bin of 1000 KG (2205 LB)</li> </ul> </li> <li>• SILBIONE DM 300 GMP is available in                             <ul style="list-style-type: none"> <li>○ Drum of 25 KG (55.13 LB)</li> <li>○ Drum of 200 KG (441 LB)</li> <li>○ Tote bin of 1000 KG (2205 LB)</li> </ul> </li> <li>• SILBIONE DM 500 GMP is available in                             <ul style="list-style-type: none"> <li>○ Drum of 25 KG (55.13 LB)</li> <li>○ Drum of 200 KG (441 LB)</li> <li>○ Tote bin of 1000 KG (2205 LB)</li> </ul> </li> </ul>
<b>Storage and shelf life</b>	<p>When stored in its original packaging:</p> <p>SILBIONE DM 1000 GMP may be stored at temperatures between -20°C / -4°F and 50°C / 122°F for up to 36 months from its date of manufacturing.</p> <p>SILBIONE DM 300 GMP may be stored at temperatures between -20°C / -4°F and 50°C / 122°F for up to 36 months from its date of manufacturing.</p> <p>SILBIONE DM 500 GMP may be stored at temperatures between -20°C / -4°F and 50°C / 122°F for up to 36 months from its date of manufacturing.</p> <p>Comply with the storage instructions and expiration date marked on the packaging. Beyond this date, Elkem Silicones no longer guarantees that the product meets the sales specifications.</p>
<b>Safety</b>	Please consult the Safety Data Sheet of: SILBIONE DM 1000 GMP, SILBIONE DM 300 GMP and SILBIONE DM 500 GMP

Visit our website [www.elkem.com/silicones/](http://www.elkem.com/silicones/)

#### Warning to the users

The information contained in this document is given in good faith based on our current knowledge. It is only an indication and is in no way binding, particularly as regards infringement of or prejudice to third party rights through the use of our products. ELKEM SILICONES guarantees that its products comply with its sales specifications. This information must on no account be used as a substitute for necessary prior tests which alone can ensure that a product is suitable for given use. Determination of the suitability of product for the uses and applications contemplated by users and others shall be the sole responsibility of users. Users are responsible for ensuring compliance with local legislation and for obtaining the necessary certifications and authorisations. Users are requested to check that they are in possession of the latest version of this document and ELKEM SILICONES is at their disposal to supply any additional information.