

Silicones Silbione[™]



Silbione[™] Medical Grade Silicone Fluids

High purity PDMS used in the siliconization of medical devices and pharmaceutical packaging components

Elkem Silicones has designed a range of medical and pharma-grade fluids to meet the demand of lubrication, hydrophobic coatings or demolding applications. Our product offering includes polydimethylsiloxanes (PDMS) fluids, emulsions and RTV lubricants.

This range of products is particularly known for its lubrication properties on pre-filled parenteral packaging such as vials, syringes, cartridges or needles, ensuring adequate medication for the patients:

Benefits of Silbione[™] medical grade silicone fluids

■ Siliconization of the needles is essential to prevent it sticking to the skin, thereby minimizing injection pain

■ Siliconization of packaging surfaces enables to deliver the right drug at a precise dose for the patients: lowest friction possible along the entire length of a syringe, hydrophobic deactivation of the surface, improving the containers' drainability, no interactions of typically hydrophilic biologics and drugs with the packaging

Siliconization of accessories (rubber stoppers...) enhances the performance for smooth operations and provides a better machineability

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Silbione[™] Medical Fluids Selector Table

Silbione[™] FLD 70047

Silbione[™] FLD 70047 are linear polydimethylsiloxanes used used for lubrication and siliconization of glass, metal, plastic, rubber or syringes.

	Silbione [™] product	Ph. Eur. 31.8 on "silicone oil used as lubricant"	Monography Ph. Eur. Dimeticone	Manufactured according to selected GMP principles*	Viscosity (mPa.s)	Shelf life (months)
Silbione™ FLD 70047 are linear polydimethylsiloxanes	FLD 70047 V100	-		-	100	36
	FLD 70047 V200	-	-	-	200	36
	FLD 70047 V350	-		-	350	36
	FLD 70047 V12 500		-	-	12 500	36
	FLD 70047 V30 000	•	-	-	30 000	36

*Production complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC

Silbione[™] Emulsion

Silbione[™] emulsion is used for lubrication and siliconization of glass, metal, plastic, rubber or syringes.

	Silbione [™] product	Ph. Eur. 3.1.8 on "silicone oil used as lubricant"	Monography Ph. Eur. Dimeticone**	Manufactured according to selected GMP principles*	Solid content (%)	Viscosity (mPa.s)	Shelf life (months)
Silbione™ EMULSION is a water-based emulsion of PDMS	EMUL 70001 SP	-	•		35 (Dimeticone oil)	300	24

*Production complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC **The silicone fluid in Silbione™ EMULSION is tested according to European Pharmacopeia (EP) requirements.

Silicones

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Silbione[™] DM

Silbione[™] DM GMP are linear polydimethylsiloxanes fluids which can be used as excipients or A.P.I:

	Silbione [™] product	Monography Ph. Eur. Dimeticone	Manufactured according to selected GMP principles*	Viscosity (mPa.s)	Shelf life (months)
	DM 300 GMP	•	•	300	36
Silbione™ DM are linear polydimethylsiloxanes	DM 500 GMP		•	500	36
	DM 1000 GMP	•	•	1000	36

*Production complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC

Silbione[™] RTV Lubricant

Silbione[™] RTV LUBRICANT is an aminofunctional silicone in solvent. It can be used for siliconization of metal and plastic components such as razor blades, scalpels or hypodermic needles. Extensive toxicology testing on Silbione[™] products has demonstrated their adequate biocompatibility and suitability for the recommended applications. Silbione[™] RTV Lubricant is biocompatible according to ISO10993.

	Silbione [™] product	Monography Ph. Eur. Dimeticone	Solid content (%)	Solvent	Viscosity (mPa.s)	Shelf life (months)
Silbione™ RTV LUBRICANT is an aminofunctional silicone in solvent	RTV Lubricant	•	30 (Aminofunctional dimethylsiloxane copolymer)	mixed aliphatic and isopropanol	30	24

The typical properties listed above are not intended for use in preparing specifications. For test methods and specifications, please contact an Elkem representative. User has sole responsibility to determine product suitability for intended uses and applications.

For detailed commercial contacts please visit our website: elkem.com

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Elkem supports you

We focus on developing state-of-theart application expertise to help our customers challenge their boundaries. At Elkem Silicones, we're more than just high quality silicone products.

We are dedicated people located around the globe committed to your success. From technical support to customized formulations and regulatory support, Elkem Silicones has the people in place when and where you need them.

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