

## ATTESTATION

**SILBIONE FLD 70047V100, SILBIONE FLD 70047V200, SILBIONE FLD 70047V350,  
 MIRASIL DM 1000, SILBIONE FLD 70047V12 500, SILBIONE FLD 70047V30 000,  
 SILBIONE FLD 70047V300 000**

This is to certify that these products are polymeric substances described by CAS-No : 63148-62-9 and Chemical name : Siloxanes and Silicones, di-Me

◆ **Substances of Very High Concern (SVHC)**

The Article 33 of REACH requires suppliers of articles (manufacturers or importers) to inform European downstream users about the presence of substances of very high concern (SVHC) when their concentration exceeds 0.1% (w/w).

As a manufacturer of starting materials, in addition to the Safety Data Sheet, Elkem Silicones provides the information below in order to help our customers to fulfil their duty to communicate down the supply chain.

The above mentioned product does contain the following SVHC substances of the "Candidate List" for Authorisation, in force in Europe, since its last update published by ECHA on 2020 June 25th (<https://echa.europa.eu/candidate-list-table>).

Chemical name	CAS-No.	V100	V200	V350	MIRASIL DM 1000
Octamethylcyclotetrasiloxane (D4)	556-67-2	< 0,1	< 0,1	< 0,1	< 0,1
Decamethylcyclopentasiloxane (D5)	541-02-6	< 0,1	< 0,1	< 0,1	< 0,1
Dodecamethylcyclohexasiloxane (D6)	540-97-6	< 0,1	< 0,1	< 0,1	< 0,1

Chemical name	CAS-No.	V12 500	V30 000	V300 000
Octamethylcyclotetrasiloxane (D4)	556-67-2	< 0,1	< 0,1	< 0,1
Decamethylcyclopentasiloxane (D5)	541-02-6	≥ 0,25 - < 0,5	≥ 0,25 - < 0,5	≥ 0,1 - < 0,25
Dodecamethylcyclohexasiloxane (D6)	540-97-6	≥ 0,25 - < 0,5	≥ 0,25 - < 0,5	≥ 0,25 - < 0,5

◆ **Manufacturing Origin:**

- Synthetic.
- BSE-TSE or GMO requirements: comply because organic substances derived from animal or vegetable origin are not used in the formulation or manufacturing process.

◆ **RoHS:** We do not introduce as intentional ingredients or during the manufacturing process any of the substances listed in the DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) and its amendments

◆ **WEEE:** We do not introduce as intentional ingredients or during the manufacturing process any of the substances listed in the DIRECTIVE 2012/19/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 July 2012 on waste electrical and electronic equipment (WEEE).

◆ **ELV:** We do not introduce as intentional ingredients or during the manufacturing process any of the substances listed in DIRECTIVE 2000/53/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 September 2000 on end-of-life vehicles (ELV)

◆ **CONEG:** We do not introduce as intentional ingredients or during the manufacturing process any of the substances listed in Coalition of Northeastern Governors (CONEG) - Toxics in Packaging Legislation

◆ **Heavy Metals:** None of the heavy metals listed in the European standard EN 71.3 and European Directive 94/62/EEC are used in the manufacturing or formulation process.

◆ **Ozone-Depleting Substances (ODS):** We do not introduce as intentional ingredients or during the manufacturing process any of the any of the Ozone-Depleting Substances (ODS) listed in the REGULATION (EC) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

◆ **Biocides:** We do not introduce as intentional ingredients or during the manufacturing process biocidal substances (e.g. preservatives) as defined in REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products.

◆ **VOC:** We do not have in the formulation any substances (except traces of residual siloxane oligomers) considered as Volatile Organic Compounds (VOCs) according to the directive 2004/42/CE: boiling point  $\leq 250^{\circ}\text{C}$ .

◆ **CMR status:** does not contain substances classified in:

- TRGS 905: as carcinogenic (K1, K2), mutagenic (M1, M2), reprotoxic (RF1, RF2) teratogenic (RE1, RE2).
- The MAK Value List: as carcinogenic working materials (category 1 or 2) and germ-cell mutagenic working materials (category 1 or 2).

◆ **Do not use in the manufacturing or formulation process:**

- Any of the solvents listed in ICH guideline Q3C (R6) on impurities: guideline for residual solvents - Step 5 - 6 December 2016 - EMA/CHMP/ICH/82260/2006.
- Any of the elements listed in ICH guideline Q3D on elemental impurities - Step 5 - 25 July 2016 - EMA/CHMP/ICH/353369/2013.

◆ **Food Allergens:** We do not introduce as intentional ingredients or during the manufacturing process any of the substances or products causing allergies or intolerance listed in the Annex II of REGULATION (EU) No 1169/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

◆ **Skin Allergens:** We do not introduce as intentional ingredients or during the manufacturing process any of the 26 allergenic substances listed in the ANNEX III: LIST OF SUBSTANCES WHICH COSMETIC PRODUCTS MUST NOT CONTAIN EXCEPT SUBJECT TO THE RESTRICTIONS LAID DOWN of REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.

◆ **Skin contact:** Comply with the recommendations of standard NF EN ISO 10993 "Biological Evaluation of the Medical Devices – Part 1: Evaluation and testing" relating to the tests applicable to materials in contact with healthy skin and mucosal membranes and passed successfully the toxicological tests which show that these products are regarded as:

- NOT cytotoxic
- NOT irritating for the skin and the eyes
- NOT sensitizing

◆ **California Proposition 65:** None of the substances in the California Proposition 65 list of Chemicals Known to the State of California to cause Cancer or Reproductive Toxicity are contained in these products.

◆ The following substances are not used in the manufacturing or formulation process:

- 2,4-dimethyl-6-tertiary-butylphenol
- 2-bromo-2-nitropropane-1,3-diol
- 2-Nitropropane
- 4,4 Tetramethyldiaminobenzophenone
- Alcohol
- Alkylbenzolsulfonates
- Alkylphenol and derivatives
- Aluminium
- Amyl Cinnamal
- Amylcinnamyl Alcohol
- Antimony
- Antioxidants
- Aromatic amines
- Aromatic hydrocarbon Mineral Oil (MOAH)
- Arsenic
- Asbestos
- Azo Dyes
- Barium
- Benzyl Alcohol, Benzyl Benzoate, Benzyl Cinnamate, Benzyl Salicylate
- Beryllium
- Bis(hydrogenated tallow alkyl) dimethyl ammonium chloride (DTDMAC)
- Bismuth
- Bisphenol A (BPA)
- Brominated flame retardants (BFR)
- Butylated Hydroxyanisole (BHA)
- Butylated Hydroxytoluene (BHT)
- Cadmium
- Carboxylate
- Cashmeran
- Cetylpyridinium
- Chlorhexidine
- Chloride
- Chlorinated naphthalenes
- Chlorinated paraffins
- Chlorinated phenol and derivatives
- Chromium (VI & Total)
- Cobalt
- Color Pigments
- Copper
- Dehydroacetic acid
- Diaminostilbene and derivatives
- Diethylene triamine penta acetate (DTPA)
- Dimethyl Sulfoxide (DMSO)
- Dioxins
- Ethylene diamine tetra acetate (EDTA)
- Ethylene dioxide
- Fluorinated Compounds
- Formaldehyde
- Gluten
- Glycol ethers and derivatives (2-Ethoxyethanol, 2-Methoxyethyl acetate & 2-Ethoxyethyl acetate)
- Glycolic solvents (Ethoxyethanol, Ethoxyethanol acetate or Methoxyethanol)
- Halogen organic materials
- Hexachlorocyclohexane
- Hormones
- Hydrogen peroxides
- Iodine
- Iron
- Latex
- Lauryl sulfates
- Lead
- Limonene
- Linear Alkyl benzene Sulfonates (LAS)
- Majantol
- Manganese
- Mercury
- Methylene chloride
- Molybdenum
- Monochlorobenzene & Dichlorobenzene
- Nanoparticules
- Natural Rubber
- Nickel
- Nitromusks
- Nitrosamines
- N-Methyl-2-pyrrolidone (NMP)
- Organo-tin compounds
- Ortho-phenylphenol
- Oxalates & Oxalate Salts
- Parabens (Butyl, Ethyl, Iso Butyl, Iso propyl, Methyl, Propyl)
- Paraffines
- PEG-containing materials
- Perchloroethylene
- Peroxide
- Pesticides
- Phenols in general (Resorcinol, Naphthol, etc.) & Phenoxyethanol
- Phenylsalicylate
- Phosphates (Monocresyl, Monocresyl diphenyl phosphate & Tricresyl)
- Phthalates
- Plutonium
- Polybrominated Biphenyl (PBB)
- Polybrominated Diphenyl Ethers (PBDE)
- Polychlorinated biphenyls
- Polycyclic musks
- Polycyclic aromatic hydrocarbons (PAHs)
- Polyfluorinated Substances
- Potassium Sorbate
- Saturated hydrocarbon Mineral Oil (MOSH)
- Selenium
- Silver
- Sodium Benzoate
- Sodium chlorite
- Sodium picramate
- Tellurium
- Tertiary Butylhydroquinone (TBHQ)

- Thallium
- Thorium
- Tin
- Titanium acetylacetonate (TAA), Pentane-2,4-dione (acetylacetone)
- Tocopherols
- Triclosan
- Triphenylphosphate
- Tungsten
- Uranium
- Vanadium
- Zinc

Please note that this information is not based on analytical data but is based on our knowledge of the manufacturing process and information provided by our suppliers. Therefore, we do not have any reason to suspect the presence of such substances as impurities at a significant level.

◆ Have chemical composition and physical properties that comply with the requirements of the following food contact regulations:

⇒US FDA

CFR 21	SILBIONE FLD 70047V100 SILBIONE FLD 70047V200	SILBIONE FLD 70047V350 MIRASIL DM 1000	SILBIONE FLD 70047V12 500 SILBIONE FLD 70047V30 000 SILBIONE FLD 70047V300 000
§173.340 – Defoaming Agents	No	Yes <sup>(1)</sup>	No
§175.105 - Adhesives	Yes	Yes	Yes
§175.300 – Resinous & Polymeric coatings	No	Yes	Yes
§176.170 – Components of Paper & Paperboard in contact with aqueous and fatty food	No	Yes	Yes
§176.180 - Components of paper and paperboard in contact with dry food	Yes	Yes	Yes
§176.200 – Defoaming agents used in coatings	Yes	Yes	Yes
§176.210 – Defoaming agents used in the manufacture of paper & Paperboard	Yes	Yes	Yes
§177.2260 – Filters, Resin-bonded	Yes	Yes	Yes
§177.2600 – Rubber articles intended for repeated use	Yes <sup>(2)</sup>	Yes <sup>(2)</sup>	Yes <sup>(2)</sup>
§177.2800 – Textiles and textiles fibers	Yes	Yes	Yes
§178.3570 – Lubricants with incidental food contact	No	Yes <sup>(1)</sup>	Yes <sup>(1)</sup>
§178.3910 – Surface lubricants used in the manufacture of metallic articles	No	No	No
§181.28 – Release agents	No	No	No

(1) Please refer to CFR documents to identify specific food limitations.

(2) Polydimethylsiloxanes meet the definition of silicone basic polymers. Please refer to CFR document about limitations of global migrations in food.

⇒German

Burr: Federal Institute for Risk Assessment	SILBIONE FLD 70047V100 SILBIONE FLD 70047V200	SILBIONE FLD 70047V350 MIRASIL DM 1000	SILBIONE FLD 70047V12 500 SILBIONE FLD 70047V30 000 SILBIONE FLD 70047V300 000
Chap XIV Plastics Dispersions	Yes (§)	Yes(§)	Yes(§)
Chap XV: Silicones	Yes (§)	Yes(§)	Yes(§)
Chap XXI: Commodities based on Natural & Synthetic Rubber	Yes (§)	Yes(§)	Yes(§)
Chap XXXVI: Paper and board for food contact	Yes (§)	Yes(§)	Yes(§)
Chap XXXVI/2: Paper and Paperboard for Baking Purposes	Yes (§)	Yes(§)	Yes(§)

(§) Please refer to BfR documents to identify specific limitations.

⇒French

Brochure 1227	SILBIONE FLD 70047V100 SILBIONE FLD 70047V200	SILBIONE FLD 70047V350 MIRASIL DM 1000	SILBIONE FLD 70047V12 500 SILBIONE FLD 70047V30 000 SILBIONE FLD 70047V300 000
Instruction du 11 Avril 1990 – lubrification bouchons en liège	Yes(μ)	Yes(μ)	No
Arrêté du 2 janvier 2003 relatif aux matériaux et objets en matière plastique mis ou destinés à être mis au contact des denrées, produits et boissons alimentaires et Arrêté du 19 octobre 2006 modifiant l'arrêté du 2 janvier 2003	Yes(μ)	Yes(μ)	Yes(μ)
Arrêté du 25 Novembre 1992 – Objets en Silicones	Yes(μ)	Yes(μ)	Yes(μ)
Arrêté du 4 Novembre 1993 – Pellicule de cellulose régénérée	Yes(μ)	Yes(μ)	Yes(μ)

(μ) Please refer to Brochure 1227 documents to identify specific food limitations.

⇒Europe

Council of Europe	SILBIONE FLD 70047V100 SILBIONE FLD 70047V200	SILBIONE FLD 70047V350 MIRASIL DM 1000	SILBIONE FLD 70047V12 500 SILBIONE FLD 70047V30 000 SILBIONE FLD 70047V300 000
Regulation (EU) N°10/2011 - Plastic Materials (PM Ref: 76721)	Yes(b)	Yes(b)	Yes(b)
AP2004 (5) - Silicones used for food contact applications	Yes(α)	Yes(α)	Yes(α)

(α) Please refer to AP2004 (5) document to identify specific food limitations.

(b) Please refer to Regulation document to identify specific limitations.

According to (EC) 1935/2004 regulation, it is the user's responsibility to identify specific limitations for the application and to ensure that a suitable process is used to produce materials or articles that conform in every aspect to the above mentioned regulations, in particular for migration limitations and any restriction of use.

In addition, the final user must ascertain that the final material and the food in contact are mutually compatible and involve no modification of the organoleptic properties thereof.

◆ **SILBIONE FLD 70047V100 to V300 000 and MIRASIL DM 1000** cannot be considered or/and used as

- A food additive according to directive 95/2/CE and Directive 96/77/CE.
- A feed additive according to directive 70/524/CE and Regulation 1831/2003.
- A technological auxiliary according to the French Decree of 19 October 2006.

◆ Pharmacy:

**SILBIONE FLD 70047V100 to V300 000 and MIRASIL DM 1000** are not covered by any European Drug Master File according to the European pharmacopoeia monograph « Dimeticone ».

The following **SILBIONE FLD 70047** essentially meet the analytical requirements of European pharmacopoeia (EP) 3.1.8 on “Silicone oil used as a lubricant”:





- **SILBIONE FLD 70047 V12 500**
- **SILBIONE FLD 70047 V30 000**

For any more details contact our quality department.

It is the sole responsibility of the user to select the product in the Elkem Silicones range that meets any requirements for their applications.

Certified by Elkem Silicones' Product Stewardship Department

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 EUROPE	 NORTH AMERICA	 LATIN AMERICA	 ASIA PACIFIC
Elkem Silicones France SAS 21 avenue Georges Pompidou 69003 Lyon France	Elkem Silicones USA Corp. Two Tower Center Blvd Suite 1802 East Brunswick, NJ 08816-1100 USA	Elkem Silicones Brasil Ltda. Av. Duquesa de Goiás, 716 – 2º andar Cep. 05686-002. São Paulo/ SP Brazil	Elkem Silicones Hong Kong Co., Limited 29/F, 88 Hing Fat Street Causeway Bay Hong Kong

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