

# **ATTESTATION**

#### **MIRASIL CM 5**

### **Ingredient Status of Cosmetic Raw Material**

This is to certify that:

1) According to REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products

All the components of this product are listed in the International Nomenclature of Cosmetic Ingredients (INCI) - Section I of the Annex I of COMMISSION DECISION of 9 February 2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products (2006/257/EC)

Chemical name	Decamethylcyclopentasiloxane	
CAS No.	541-02-6	
EC (EINECS/ELINCS) no.	208-764-9	
INCI Name	Cyclopentasiloxane	
(Mean) molecular weight	370 Da	
Appearance (Form, Color, Odor, Physical state)	Slightly viscous, Colourless, Odorless, Liquid	

Composition with INCI name	CAS No.	EC (EINECS/ELINCS) no	Concentration
Cyclopentasiloxane	541-02-6	208-764-9	100%

Substances listed in the annexes of the Regulation (EC) No 1223/2009			
INCI name	CAS No.	EINECS No.	Concentration
Annex II			
Annex III			
Annex IV			
Annex V			
Annex VI			

We do not use in the formulation or the manufacturing process of this product any of the 26 allergenic substances or compounds listed in the Annex III of Regulation (EC) No 1223/2009.

This product, which is a polymer, has not been tested on animals, for the development of new cosmetic products in compliance with Regulation (EC) No 1223/2009.

The evaluation of the toxicological properties of this product is based on the available information for this product which has been historically developed for other markets and then tested for the assessment of safety in the workplace and protection of the environment.



Elkem Silicones, as a member of CES - SILICONES EUROPE and as a participant in their Alternative Method Task-Force, actively takes part in the development of in vitro alternative methods

2) This product is produced without using in the formulation or the manufacturing process any organic substance derived from animals; therefore, it complies with the REGULATION (EC) No 999/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies and updates (BSE/TSE):

Origin of starting material	☐ Plant (species and used parts) ☐ Synthetic ☐ Mineral
-----------------------------	--

If raw materials of vegetable origin are used, this product conforms to GMO requirements in compliance with the DIRECTIVE 2001/18/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC and updates.

3) Confédération Helvétique : Ordonnance sur la taxe d'incitation sur les composés organiques volatils (OCOV-RS 814.018) and amendements :

The formulation of this product does not contain any of the VOC substances subject to taxation, as listed in the Switzerland regulation annex 1.

4) The available toxicological data for this product are:

Information on skin irritation/ cytotoxicity	See SDS Section 11
Information on Het cam test	No data available
Information on skin sensitization	See SDS Section 11
Information on toxicity data	See SDS Section 11
Human closed Patch test	Human dermatological investigation: Clinically tested: Non-irritating

5) The available ecological data about this product are:

Water Hazard Class (WGK)	WGK 1
Information on ecotoxicity data	See SDS Section 12

6) Global inventory status for this product is:

Inventory	Status
Australia AICS	On or in compliance with the inventory
Canada DSL Inventory List	On or in compliance with the inventory



EINECS, ELINCS or NLP	On or in compliance with the inventory
Japan (ENCS) List	On or in compliance with the inventory
China Inv. Existing Chemical Substances	On or in compliance with the inventory
Korea Existing Chemicals Inv. (KECI)	On or in compliance with the inventory
Philippines PICCS	On or in compliance with the inventory
US TSCA Inventory	On or in compliance with the inventory
New Zealand Inventory of Chemicals	On or in compliance with the inventory
Taiwan Chemical Substance Inventory	On or in compliance with the inventory

- 7) We do not use in the manufacturing or formulation process any of the substances listed below:
  - Alkylphenolethoxylates (including nonylphenol ethoxylates)
  - Amido amines
  - Antioxidants
  - Benz[a]pyrene
  - Bisphenol A
  - Dioxins including polychlorinated dibenzodioxins (PCDD's)
  - DMAPA (Dimethylaminopropyl amine)
  - Endocrine disruptors
  - Ethylene oxide / propylene oxide
  - Formaldehyde
  - Free amines
  - Gluten
  - Glycol ethers
  - Hexachlorohexane isomers (HCH's)
  - Latex
  - Mono or dichloroacetic acid
  - Musk xylene

- Mykotoxins (Aflatoxins, trichothecenes or others)
- Nitrile, nitrosamines and/or nitrosamides
- Paraben
- Pentachlorophenol (PCP's)
- Pesticides
- Phthalate and alkyl phthalates
- Polyaromatic hydrocarbons (PAH's)
- Polychlorinated dibenzofurans (PCDF's)
- Polycyclic hydrocarbons
- Short chained chlorinated paraffins (SCCP's)
- Substances CMR (Carcinogen; mutagenic or reprotoxic) Cat 1; 2 except:
  - Octamethylcyclotetrasiloxane (D4) (CAS No 556-67-2) classified Repr.2, H361f (possible risk of impaired fertility) (See §10)
- Triclosan

Even though we do not have any analytical data, we do not have any reason to suspect the presence of the other substances listed at a significant level in this product.

8) According to COMMISSION RECOMMENDATION of 18 October 2011 on the definition of nanomaterial (2011/696/EU), 'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.

Therefore, to the best of our knowledge, this product is not a 'nanomaterial' according to the definition of the REGULATION (EC) No 1223/2009, the French Decree n° 2012-232 and the French Arrete of August 6 2012.

9) This product complies with the requirements of ICH guideline Q3C (R6) on impurities: guideline for residual solvents - Step 5 - 6 December 2016 - EMA/CHMP/ICH/82260/2006 because none of the solvents listed under class 1, 2 or 3 are used in this product manufacturing process.

However, no research on the potential contamination by these solvents in our materials has been conducted.



10) COMMISSION REGULATION (EU) 2018/35 of 10 January 2018 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane ('D4') and decamethylcyclopentasiloxane ('D5'):

This commission issued restriction on D4 and D5: **Wash-off cosmetic products** shall not be placed on the market with a concentration equal to or greater than 0,1 % by weight of either substance, after 31 January 2020.

This product contains:

- Octamethylcyclotetrasiloxane (D4) (CAS No 556-67-2) content < 1 000 ppm</li>
- Decamethylcyclopentasiloxane (D5) (CAS No 541-02-6) content > 99%

#### 11) Heavy Metals:

We do not use in the manufacturing or formulation process any of the heavy metals listed below:

- Ni, Cr, Co, Cd, Hg, Pb, As, Sb
- Nor any of the elements listed in ICH guideline Q3D on elemental impurities Step 5 25 July 2016 EMA/CHMP/ICH/353369/2013.

Heavy metals < 5 ppm measured in Pb equivalent (EU pharmacopeia method)

- 12) This product has not been subject to a y-irradiation treatment.
- 13) REACH Status:

This product is a substance register under REACH. The REACH Registattion No. is 01-2119511367-43-0003

14) Substances of Very High Concern (SVHC)

The Article 33 of REACH requires manufacturers and importers to notify European users about the presence of substances of very concern (SVHC) when their concentration is or exceeds 0.1% (w/w).

We have to inform you that this 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 2018 June the 27<sup>th</sup> (https://echa.europa.eu/candidate-list-table), at a content greater or equal to 0.1% (w/w).

Chemical name	CAS-No.	% Content (w/w)
Decamethylcyclopentasiloxane (D5)	541-02-6	> 99 %
Dodecamethylcyclohexasiloxane (D6)	540-97-6	≥ 0,5 - < 1

Certified by Elkem Silicones' Product Stewardship Department Marie-Christine Cotting

Creation date: August 2018 Valid until: August 2021





Elkem Silicones France SAS 21 avenue Georges Pompidou 69003 Lyon France

🖣 NORTH AMERICA

Elkem Silicones USA Corp. Two Tower Center Blvd Suite 1601 East Brunswick, NJ 08816-1100 USA

## LATIN AMERICA

Elkem Silicones Brasil Ltda. Av. Duquesa de Goiás, 716 – 2º andar Cep. 05686-002. São Paulo/ SP Brazil

ASIA PACIFIC

Elkem Silicones Hong Kong Co., Limited 29/F, 88 Hing Fat Street Causeway Bay Hong Kong

This is a computer-generated document that is valid without a signature.

The information above is supplied in good faith and, to the best of our knowledge, is based on available sources believed to be reliable and accurate at the date of publication appearing above. This document and any information provided herein are for your guidance only.

This document shall be valid until the validity limit date indicated above. However, because use conditions and applicable regulations may change with time, the

requestor is responsible for determining whether the information is still appropriate and for asking for an update.

The conditions of use by the requestor are beyond Elkem Silicones' control; therefore, the responsibility for appropriate and safe use of the above information lies with the requestor. Elkem Silicones shall not be responsible for any misuse and/or misapplication of the information in this document