

Safety data sheet
According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

SECTION 1: Identification of the substance/mixture and of the company/undertaking**· 1.1 Product identifier****· Trade name:** Mariflex**· Article number / formula:** NA**· 1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.**· Application of the substance / the preparation :** dental product**· 1.3 Details of the supplier of the safety data sheet****· Manufacturer/Supplier:**

SEPTODONT.

Septodont Healthcare India Pvt. Ltd.

C-1/2, MIDC, Taloja, Tal, Panvel, Dist Raigad

410208- Maharashtra - INDIA

Tel. : +91 (22) 27 40 19 70 / 71

Fax : +91 (22) 27 40 19 72

· 1.4 Emergency telephone number:

France (ORFILA 24h/24) - Tel : +33 (0)1 45 42 59 59

Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24) France (INRS 24h/24) - Tel : +33 (0)1 45 42 59 59

Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24) EU Tel: 112

Belgique - Tel : 32 070/245 245

UK : Call NHS 999 in a medical emergency. If you urgently need medical help or advice but it's not a life-threatening situation, call 111 (24/7). The NHS 111 number is currently only available in certain areas. If you're outside of these areas, you should call NHS Direct on 0845 4647

SECTION 2: Hazards identification**· 2.1 Classification of the substance or mixture****· Classification according to Regulation (EC) No 1272/2008:**

Eye Irrit. 2 H319 Causes serious eye irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· 2.2 Label elements**· Labelling according to Regulation (EC) No 1272/2008**

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms

GHS07

· Signal word Warning**· Hazard-determining components of labelling:**

dipotassium hexafluorotitanate

· Hazard statements

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

(Contd. on page 2)

GB

Safety data sheet

According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

Trade name: Mariflex

(Contd. of page 1)

Precautionary statements

- P280 Wear protective gloves.
 P280 Wear eye protection / face protection.
 P302+P352 IF ON SKIN: Wash with plenty of water.
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards
Results of PBT and vPvB assessment

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

 · **Description:** Mixture: consisting of the following components.

Dangerous components:

CAS: 9005-36-1	Alginate acid, potassium salt ⚠ Eye Irrit. 2, H319	10-25%
CAS: 7778-18-9 EINECS: 231-900-3 Reg.nr.: 01-2119444918-26	calcium sulphate ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332	5-10%
CAS: 7722-88-5 EINECS: 231-767-1 Reg.nr.: 01-2119489794-17-0003	tetrasodium pyrophosphate ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302	≤2.5%
CAS: 16919-27-0 EINECS: 240-969-9	dipotassium hexafluorotitanate ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Skin Sens. 1, H317	≤1%

 · **SVHC** No

 · **Additional information:** For the wording of the listed risk phrases, refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures
After excessive inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient in a stable laying down side position for transportation.

 · **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

 · **After eye contact:** Rinse opened eye for several minutes under running water.

 · **After swallowing:** If symptoms persist consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed :

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed :

No further relevant information available.

(Contd. on page 3)

Safety data sheet
According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

Trade name: Mariflex

(Contd. of page 2)

SECTION 5: Firefighting measures

- **5.1 Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture :** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures :** Not required.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow the product to enter sewers/ surface water or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections :**
See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling :** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s) :** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 68855-54-9 Kieselguhr, soda ash flux-calcined (50-100%)	
MAK (Switzerland)	Long-term value: 0.3 a mg/m ³ SSc;
CAS: 7778-18-9 calcium sulphate (5-10%)	
MAK (Switzerland)	Long-term value: 3 a mg/m ³ SSc;
CAS: 1309-48-4 magnesium oxide (5-10%)	
WEL (Great Britain)	Long-term value: 10* 4** mg/m ³ (as Mg) *inhalable dust **fume and respirable dust

(Contd. on page 4)

Safety data sheet
According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

Trade name: Mariflex

(Contd. of page 3)

MAK (Switzerland)	Long-term value: 3 a mg/m ³ *SSc; *Magnesiumoxid	
CAS: 7722-88-5 tetrasodium pyrophosphate (≤2.5%)		
WEL (Great Britain)	Long-term value: 5 mg/m ³	
MAK (Switzerland)	Long-term value: 5 e mg/m ³	
· DNELs		
CAS: 7778-18-9 calcium sulphate		
Oral	DNEL Public long-term systemic	1.52 mg/kg bw/d
Inhalative	DNEL Public long-term systemic	mg/m ³
	DNEL Worker long-term systemic	21 mg/m ³
	DNEL Public acute/short-term local effects	3,811 mg/m ³
	DNEL Worker acute/short-term local effects	5,082 mg/m ³
· PNECs		
CAS: 7778-18-9 calcium sulphate		
PNEC STP	100 mg/L	

· **Additional information:**

The most current valid lists have been used as a basis for the production of this document.

· **8.2 Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· **Respiratory protection:** Not required.

· **Protection of hands:**



Protective gloves

· **Gloves material :** Butyl rubber, BR

· **Eye protection:**



Safety glasses

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Powder
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.

· **pH-value:** Not applicable.

(Contd. on page 5)



Safety data sheet
According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

Trade name: Mariflex

(Contd. of page 4)

· Change in condition Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not determined.
· Ignition temperature:	Not applicable.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not self igniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits: Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not applicable.
· Density:	Not determined.
· Relative density :	Not determined.
· Vapour density :	Not applicable.
· Evaporation rate :	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Segregation coefficient (n-octanol/water):	Not determined.
· Viscosity: Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content: VOC (EC)	0.00 %
· 9.2 Other information :	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions :** No dangerous reactions known.
- **10.4 Conditions to avoid :** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

(Contd. on page 6)

GB

Safety data sheet
According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

Trade name: Mariflex

(Contd. of page 5)

· LD/LC50 values relevant for classification:

CAS: 7778-18-9 calcium sulphate

Oral	LD50	>1,581 mg/kg (rat)
Inhalative	LC50/4 h	>2.61 mg/l (rat)

CAS: 7722-88-5 tetrasodium pyrophosphate

Oral	LD50	500 mg/kg (ATE)
------	------	-----------------

CAS: 16919-27-0 dipotassium hexafluorotitanate

Oral	LD50	500 mg/kg (ATE)
------	------	-----------------

· Primary irritant effect:

· **On the skin:** Based on available data, the classification criteria are not met.

· **On the eyes:**

Causes serious eye irritation.

· Respiratory or skin sensitization

May cause an allergic skin reaction.

· CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

· **Carcinogenicity** Based on available data, the classification criteria are not met.

· **Reproductive toxicity** Based on available data, the classification criteria are not met.

· **STOT-single exposure** Based on available data, the classification criteria are not met.

· **STOT-repeated exposure** Based on available data, the classification criteria are not met.

· **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

CAS: 7778-18-9 calcium sulphate

LC50 96h	>79 mg/l (fish)
EC50 72h	>79 mg/l (Algae)
EC50 48h	>79 mg/l (daphnia)

· **12.2 Persistence and degradability** : No further relevant information available.

· **12.3 Bioaccumulative potential** : No further relevant information available.

· **12.4 Mobility in soil** : No further relevant information available.

· Additional ecological information:

· General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· 12.5 Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Other adverse effects** : No further relevant information available.

GB

(Contd. on page 7)

Safety data sheet
According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

Trade name: Mariflex

(Contd. of page 6)

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation :**



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Not classified as hazardous for transport
· 14.4 Packing group · ADR, IMDG, IATA	Not classified as hazardous for transport
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Not classified as hazardous for transport

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
- H302 Harmful if swallowed.
- H317 May cause an allergic skin reaction.
- H318 Causes serious eye damage.

(Contd. on page 8)



Safety data sheet
According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 3

Revision: 09.04.2018

Trade name: Mariflex

(Contd. of page 7)

*H319 Causes serious eye irritation.**H332 Harmful if inhaled.***· Classification according to Regulation (EC) No 1272/2008***Serious eye damage/eye irritation
Skin sensitisation**The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.***· Abbreviations and acronyms:***ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)**IMDG: International Maritime Code for Dangerous Goods**IATA: International Air Transport Association**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**EINECS: European Inventory of Existing Commercial Chemical Substances**ELINCS: European List of Notified Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**VOC: Volatile Organic Compounds (USA, EU)**DNEL: Derived No-Effect Level (REACH)**PNEC: Predicted No-Effect Concentration (REACH)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**PBT: Persistent, Bioaccumulative and Toxic**SVHC: Substances of Very High Concern**vPvB: very Persistent and very Bioaccumulative**Acute Tox. 4: Acute toxicity – Category 4**Eye Dam. 1: Serious eye damage/eye irritation – Category 1**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**Skin Sens. 1: Skin sensitisation – Category 1*