

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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** SEPTOPACK**Article number / formula:** 282S**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.

58 rue du Pont de Creteil

94100 Saint Maur des Fosses

France

Téléphone: +33(0)149767000

Fax: +33(0)148855401

msds@septodont.com

http://www.septodont.com

1.4 Emergency telephone number:

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 : +44 (0)-870-190-6777 (CARECHEM24)

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

GHS05

Eye Dam. 1 H318 Causes serious eye damage.



GHS09

Aquatic Acute 1 H400 Very toxic to aquatic life.

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

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

GHS05 GHS09

Signal word Danger**Hazard-determining components of labelling:**

zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate)

(Contd. on page 2)

GB

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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

Trade name: SEPTOPACK

(Contd. of page 1)

· Hazard statements

- H318 Causes serious eye damage.
- H410 Very toxic to aquatic life with long lasting effects.

· Precautionary statements

- P264 Wash hands thoroughly after handling.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- 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: 1314-13-2 EINECS: 215-222-5 Index number: 030-013-00-7 RTECS: ZH 4810000 Reg.nr.: 01-2119463881-32	zinc oxide ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	25-50%
CAS: 7446-19-7 EINECS: 231-793-3 Index number: 030-006-00-9 RTECS: ZH 5300000 Reg.nr.: 01-2119474684-27-XXXX	zinc sulphate (hydrous) (mono-, hexa-and hepta hydrate) ⚠ Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Acute Tox. 4, H302	2.5-10%

- **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:** Provide fresh air; consult a doctor in case of medical complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **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.

GB

(Contd. on page 3)



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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

Trade name: SEPTOPACK

(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:**
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:**
Keep away from moisture
Keep container tightly sealed.
- **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: 1314-13-2 zinc oxide (25-50%)

MAK (Switzerland)	Short-term value: 3 a mg/m ³ Long-term value: 3 a mg/m ³ (Rauch)
-------------------	--

CAS: 7446-19-7 zinc sulphate (hydrus) (mono-, hexa-and hepta hydrate) (5-10%)

MAK (Switzerland)	Short-term value: 0.4a 4e mg/m ³ Long-term value: 0.1a 2e mg/m ³ SSc;als Zn
-------------------	---

(Contd. on page 4)

GB

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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

Trade name: SEPTOPACK

(Contd. of page 3)

CAS: 1309-37-1 diiron trioxide (<0.1%)

WEL (Great Britain)	Short-term value: 10* mg/m ³ Long-term value: 5* 10** 4*** mg/m ³ *fume (as Fe), **total respirable, ***respirable
MAK (Switzerland)	Long-term value: 3 a mg/m ³

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:

- Keep away from food, beverages and petfood.
- Immediately remove all soiled and contaminated clothing
- Wash hands before breaks and at the end of work.
- Avoid all contact with the eyes.
- Avoid contact with the eyes and skin.

Respiratory protection: Not required.

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Gloves material :

The selection of suitable gloves does not depend only on the material, but also on further marks of quality which may vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked before use.

Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:

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

pH-value: Not applicable.

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.

(Contd. on page 5)

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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

Trade name: SEPTOPACK

(Contd. of page 4)

· 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.

· **LD/LC50 values relevant for classification:**

CAS: 1314-13-2 zinc oxide

Oral	LD50	7950 mg/kg (mouse)
------	------	--------------------

CAS: 7446-19-7 zinc sulphate (hydrous) (mono-, hexa-and hepta hydrate)

Oral	LD50	2150 mg/kg (rat)
------	------	------------------

- **Primary irritant effect:**
- **On the skin:** Based on available data, the classification criteria are not met.
- **On the eyes:**
Causes serious eye damage.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.

(Contd. on page 6)

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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

Trade name: SEPTOPACK

(Contd. of page 5)

- **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:** No further relevant information available.
- **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.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water



Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms

- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects :** No further relevant information available.

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, IMDG, IATA** UN3077

(Contd. on page 7)

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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

Trade name: SEPTOPACK

(Contd. of page 6)

· 14.2 UN proper shipping name

· ADR

UN3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate), zinc oxide)

· IMDG

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate), zinc oxide), MARINE POLLUTANT

· IATA

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate), zinc oxide)

· 14.3 Transport hazard class(es)

· ADR



· Class

9 (M7) Miscellaneous dangerous substances and articles.

· Label

9

· IMDG



· Class

9 Miscellaneous dangerous substances and articles.

· Label

9

· IATA



· Class

9 Miscellaneous dangerous substances and articles.

· Label

9

· 14.4 Packing group

· ADR, IMDG, IATA

III

· 14.5 Environmental hazards:

Product contains environmentally hazardous substances: zinc oxide, zinc sulphate (hydrous) (mono-, hexa- and hepta hydrate)

· Marine pollutant:

Yes

· Special marking (ADR):

Symbol (fish and tree)
Symbol (fish and tree)

· 14.6 Special precautions for user

Warning: Miscellaneous dangerous substances and articles.

· Danger code (Kemler):

60

· EMS Number:

F-A,S-A

· Stowage Category

A

(Contd. on page 8)

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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

Trade name: SEPTOPACK

(Contd. of page 7)

· Stowage Code	SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· Transport category	3
· Tunnel restriction code	E
· IMDG	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (ZINC SULPHATE (HYDROUS) (MONO-, HEXA-AND HEPTA HYDRATE), ZINC OXIDE), 9, III

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.
- **Seveso category E1** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **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.
H318 Causes serious eye damage.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
- **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

(Contd. on page 9)



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

Printing date 09.06.2017

Version number 1

Revision: 09.06.2017

Trade name: SEPTOPACK

CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
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
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

(Contd. of page 8)

GB