



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

Printing date 02.12.2017

Version number 3

Revision: 02.12.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** PHARMAETHYL
- **Article number / formula:** 235S
- **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 :**
Aerosol 3 H229 Pressurised container: May burst if heated.
Aquatic Chronic 3 H412 Harmful 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** Not classified as hazardous
- **Signal word** Warning
- **Hazard-determining components of labelling:**
l-carvone
(S)-p-mentha-1,8-diene
Menthone
- **Hazard statements**
H229 Pressurised container: May burst if heated.
H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P251 Do not pierce or burn, even after use.
P273 Avoid release to the environment.
P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
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.

(Contd. on page 2)

GB

Safety data sheet

According to 1907/2006/EC, Article 31

Printing date 02.12.2017

Version number 3

Revision: 02.12.2017

Trade name: PHARMAETHYL

 · **vPvB:** Not applicable.

(Contd. of page 1)

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture: consisting of the following components.

· Dangerous components:

CAS: 811-97-2 EINECS: 212-377-0 Reg.nr.: 01-2119459374-33	1,1,1,2-tetrafluoroethane ⚠ Press. Gas (Comp.), H280	50-100%
CAS: 115-10-6 EINECS: 204-065-8 Index number: 603-019-00-8 RTECS: PM 4780000 Reg.nr.: 01-2119472128-37	dimethyl ether ⚠ Flam. Gas 1, H220; Press. Gas (Comp.), H280	<5%
CAS: 6485-40-1 EINECS: 229-352-5 Index number: 606-148-00-8 RTECS: OS 8650000	l-carvone ⚠ Acute Tox. 4, H302; Skin Sens. 1, H317	≤2.5%
CAS: 5989-54-8 EINECS: 227-815-6 Index number: 601-029-00-7 RTECS: OS 8350000	(S)-p-mentha-1,8-diene ⚠ Flam. Liq. 3, H226; ⚠ Asp. Tox. 1, H304; ⚠ Aquatic Chronic 1, H410; ⚠ Skin Irrit. 2, H315; Skin Sens. 1, H317	<1%
CAS: 89-80-5 EINECS: 201-941-1	Menthone ⚠ Skin Irrit. 2, H315; Skin Sens. 1B, H317; Aquatic Chronic 3, H412	<0.25%

 · **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.

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.

(Contd. on page 3)

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

Printing date 02.12.2017

Version number 3

Revision: 02.12.2017

Trade name: PHARMAETHYL

(Contd. of page 2)

- **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:** Ensure adequate ventilation.
- **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 :** Ensure good ventilation/exhaustion at the workplace.
- **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:**
Observe official regulations on storing packagings with pressurised containers.
- **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: 811-97-2 1,1,1,2-tetrafluoroethane (50-100%)	
WEL (Great Britain)	Long-term value: 4240 mg/m ³ , 1000 ppm
MAK (Switzerland)	Long-term value: 4200 mg/m ³ , 1000 ppm SSc;
CAS: 115-10-6 dimethyl ether (<5%)	
WEL (Great Britain)	Short-term value: 958 mg/m ³ , 500 ppm Long-term value: 766 mg/m ³ , 400 ppm
IOELV (EU)	Long-term value: 1920 mg/m ³ , 1000 ppm
MAK (Switzerland)	Long-term value: 1910 mg/m ³ , 1000 ppm
CAS: 5989-27-5 (R)-p-mentha-1,8-diene (<0.1%)	
MAK (Switzerland)	Short-term value: 80 mg/m ³ , 14 ppm Long-term value: 40 mg/m ³ , 7 ppm S SSc;

- **Additional information:**
The most current valid lists have been used as a basis for the production of this document.

(Contd. on page 4)

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

Printing date 02.12.2017

Version number 3

Revision: 02.12.2017

Trade name: PHARMAETHYL

(Contd. of page 3)

- **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:**



In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

- **Protection of hands:**



Protective gloves

- **Gloves material :** Butyl rubber, BR
- **Eye protection:** Not required.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

· Form:	Aerosol
· Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
- **pH-value:** Not determined.
- **Change in condition**

· Melting point/freezing point:	Undetermined.
· Initial boiling point and boiling range:	-26 °C
- **Flash point:** Not applicable, as aerosol.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Not applicable, as aerosol.
- **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 at 20 °C:** 5716 hPa
- **Density:** Not determined.
- **Relative density :** Not determined.
- **Vapour density :** Not determined.

(Contd. on page 5)

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

Printing date 02.12.2017

Version number 3

Revision: 02.12.2017

Trade name: PHARMAETHYL

(Contd. of page 4)

- **Evaporation rate :** *Not applicable.*
- **Solubility in / Miscibility with water:** *Not miscible or difficult to mix.*
- **Segregation coefficient (n-octanol/water):** *Not determined.*
- **Viscosity:**
 - Dynamic: Not determined.*
 - Kinematic: Not determined.*
- **Solvent content:**
 - VOC (EC)** *3.30 %*
- **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: 115-10-6 dimethyl ether

Inhalative	LC50/4 h	308 mg/l (rat)
------------	----------	----------------

CAS: 6485-40-1 l-carvone

Oral	LD50	1,640 mg/kg (rat)
------	------	-------------------

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

(Contd. on page 6)

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

Printing date 02.12.2017

Version number 3

Revision: 02.12.2017

Trade name: PHARMAETHYL

(Contd. of page 5)

- **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:** Harmful to 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.
Harmful to 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.

· **European waste catalogue**

HP 14 Ecotoxic

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

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN1950
- **14.2 UN proper shipping name**
- **ADR** UN1950 AEROSOLS
- **IMDG** AEROSOLS
- **IATA** AEROSOLS, non-flammable

(Contd. on page 7)

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

Printing date 02.12.2017

Version number 3

Revision: 02.12.2017

Trade name: PHARMAETHYL

(Contd. of page 6)

· **14.3 Transport hazard class(es)**

· **ADR**



· **Class** 2 5A Gases.
· **Label** 2.2

· **IMDG, IATA**



· **Class** 2.2
· **Label** 2.2

· **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**

· **Danger code (Kemler):** -
· **EMS Number:** F-D,S-U
· **Stowage Code** SW1 Protected from sources of heat.
SW22 For AEROSOLS with a maximum capacity of 1 litre: Category A. For AEROSOLS with a capacity above 1 litre: Category B. For WASTE AEROSOLS: Category C, Clear of living quarters.
· **Segregation Code** SG69 For AEROSOLS with a maximum capacity of 1 litre: Segregation as for class 9. Stow "separated from" class 1 except for division 1.4. For AEROSOLS with a capacity above 1 litre: Segregation as for the appropriate subdivision of class 2. For WASTE AEROSOLS: Segregation as for the appropriate subdivision of class 2.

· **14.7 Transport in bulk according to Annex II of**

Marpol and the IBC Code Not applicable.

· **Transport/Additional information:**

· **ADR**

· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E0
Not permitted as Excepted Quantity
· **Transport category** 3
· **Tunnel restriction code** E

· **IMDG**

· **Limited quantities (LQ)** 1L
· **Excepted quantities (EQ)** Code: E0
Not permitted as Excepted Quantity

(Contd. on page 8)

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

Printing date 02.12.2017

Version number 3

Revision: 02.12.2017

Trade name: PHARMAETHYL

(Contd. of page 7)

· UN "Model Regulation": UN 1950 AEROSOLS, 2.2

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.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- 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**

- H220 Extremely flammable gas.
- H226 Flammable liquid and vapour.
- H280 Contains gas under pressure; may explode if heated.
- H302 Harmful if swallowed.
- H304 May be fatal if swallowed and enters airways.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H410 Very toxic to aquatic life with long lasting effects.
- H412 Harmful to aquatic life with long lasting effects.

· **Classification according to Regulation (EC) No 1272/2008**

Aerosols	Bridging principles
Hazardous to the aquatic environment - long-term (chronic) aquatic hazard	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)
- 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
- Flam. Gas 1: Flammable gases – Category 1
- Aerosol 3: Aerosols – Category 3
- Press. Gas (Comp.): Gases under pressure – Compressed gas
- Flam. Liq. 3: Flammable liquids – Category 3
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- Skin Sens. 1B: Skin sensitisation – Category 1B
- Asp. Tox. 1: Aspiration hazard – Category 1
- Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3