



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

Printing date 02.11.2014

Version number 1

Revision: 02.11.2014

**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 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)  
EU Tel : 112

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

H229 Pressurised container: May burst if heated.

Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

**Classification according to Directive 67/548/EEC or Directive 1999/45/EC :**

R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

**Information concerning particular hazards for human and environment:**

The product has to be labelled in the latest valid version according to the calculation procedure of the "General Classification guideline for preparations of the EU".

Warning! Pressurised container.

**Classification system:**

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

**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 for transport**Signal word** Warning**Hazard statements**

H229 Pressurised container: May burst if heated.

H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements**

P251 Do not pierce or burn, even after use.

P273 Avoid release to the environment.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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.

(Contd. on page 2)

GB

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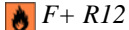
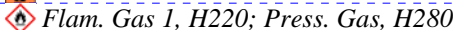
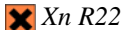
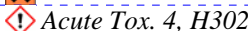

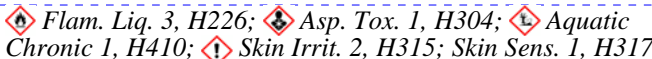
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- **Additional information:**  
 Contains (S)-p-mentha-1,8-diene. May produce an allergic reaction.  
 Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use.  
 3.4 % by mass of the contents are flammable
- **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: 115-10-6 EINECS: 204-065-8 Index number: 603-019-00-8 RTECS: PM 4780000 Reg.nr.: 01-2119472128-37	dimethyl ether  	2.5-10%
CAS: 6485-40-1 EINECS: 229-352-5 RTECS: OS 8650000	l-p-mentha-1(6),8-dien-2-one  	≤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  R10 	≤1%

- **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:**  
 CO<sub>2</sub>, 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

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Version number 1

Revision: 02.11.2014

**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 to enter sewers/ surface 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:**

**811-97-2 1,1,1,2-Tetrafluorethan (50-100%)**

WEL (Great Britain)	Long-term value: 4240 mg/m <sup>3</sup> , 1000 ppm
MAK (Switzerland)	Long-term value: 4200 mg/m <sup>3</sup> , 1000 ppm SSc;

**115-10-6 dimethyl ether (2.5-10%)**

WEL (Great Britain)	Short-term value: 958 mg/m <sup>3</sup> , 500 ppm Long-term value: 766 mg/m <sup>3</sup> , 400 ppm
IOELV (EU)	Long-term value: 1920 mg/m <sup>3</sup> , 1000 ppm
MAK (Switzerland)	Long-term value: 1910 mg/m <sup>3</sup> , 1000 ppm

**5989-27-5 (R)-p-mentha-1,8-diene (≤1%)**

MAK (Switzerland)	Short-term value: 80 mg/m <sup>3</sup> , 14 ppm Long-term value: 40 mg/m <sup>3</sup> , 7 ppm S SSc;
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- **Additional information:**  
As a basis for the production of this document, the most current valid lists were used.

(Contd. on page 4)

**Safety data sheet**  
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Printing date 02.11.2014

Version number 1

Revision: 02.11.2014

**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.

Use suitable respiratory protective device in case of insufficient ventilation.

- **Protection of hands:**



Protective gloves

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 only depend 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:** Not required.

**SECTION 9: Physical and chemical properties**

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

- **General Information**

- **Appearance:**

<b>Form:</b>	Aerosol
<b>Colour:</b>	According to product specification
<b>Odour:</b>	Characteristic
<b>Odour threshold:</b>	Not determined.

- **pH-value:** Not determined.

- **Change in condition**

<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	-26 °C

- **Flash point:** Not applicable, as aerosol.

- **Flammability (solid, gaseous):** Not applicable.

- **Ignition temperature:** Not applicable, as aerosol.

- **Decomposition temperature:** Not determined.

- **Self-igniting:** Product is not self igniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

<b>Lower:</b>	Not determined.
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(Contd. on page 5)

**Safety data sheet**  
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**Trade name: PHARMAETHYL**

(Contd. of page 4)

<b>Upper:</b>	<i>Not determined.</i>
<b>· Vapour pressure at 20 °C:</b>	5716 hPa
<b>· Density:</b>	<i>Not determined.</i>
<b>· Relative density :</b>	<i>Not determined.</i>
<b>· Vapour density :</b>	<i>Not determined.</i>
<b>· Evaporation rate :</b>	<i>Not applicable.</i>
<b>· Solubility in / Miscibility with water:</b>	<i>Not miscible or difficult to mix.</i>
<b>· Segregation coefficient (n-octanol/water):</b>	<i>Not determined.</i>
<b>· Viscosity:</b>	
<b>Dynamic:</b>	<i>Not determined.</i>
<b>Kinematic:</b>	<i>Not determined.</i>
<b>· Solvent content:</b>	
<b>VOC (EC)</b>	3.30 %
<b>· 9.2 Other information :</b>	<i>No further relevant information available.</i>

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity**
- **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:**

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

**115-10-6 dimethyl ether**

Inhalative	LC50/4 h	308 mg/l (rat)
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**6485-40-1 l-p-mentha-1(6),8-dien-2-one**

Oral	LD50	1640 mg/kg (rat)
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- **Primary irritant effect:**
- **On the skin:** *No irritant effect.*
- **On the eyes:** *No irritant effect.*
- **Sensitisation:** *No sensitising effects known.*

**SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** *No further relevant information available.*
- **12.2 Persistence and degradability :** *No further relevant information available.*

(Contd. on page 6)

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(Contd. of page 5)

- **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 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.  
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.

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

**SECTION 14: Transport information**

- |                                       |                         |
|---------------------------------------|-------------------------|
| · <b>14.1 UN-Number</b>               |                         |
| · <b>ADR, IMDG, IATA</b>              | UN1950                  |
| · <b>14.2 UN proper shipping name</b> |                         |
| · <b>ADR</b>                          | 1950 AEROSOLS           |
| · <b>IMDG</b>                         | AEROSOLS                |
| · <b>IATA</b>                         | AEROSOLS, non-flammable |

- **14.3 Transport hazard class(es)**

- **ADR**



- |                |             |
|----------------|-------------|
| · <b>Class</b> | 2 5A Gases. |
| · <b>Label</b> | 2.2         |

(Contd. on page 7)



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(Contd. of page 6)

· **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** Warning: Gases.
- **Danger code (Kemler):** -
- **EMS Number:** F-D,S-U

- **14.7 Transport in bulk according to Annex II of MARPOL73/78 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

- **UN "Model Regulation":** UN1950, AEROSOLS, 2.2

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
No further relevant information available.
- **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.

(Contd. on page 8)

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(Contd. of page 7)

*H317 May cause an allergic skin reaction.*

*H410 Very toxic to aquatic life with long lasting effects.*

*R10 Flammable.*

*R12 Extremely flammable.*

*R22 Harmful if swallowed.*

*R38 Irritating to skin.*

*R43 May cause sensitisation by skin contact.*

*R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.*

**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*

*Flam. Gas 1: Flammable gases, Hazard Category 1*

*: Flammable aerosols, Hazard Category 3*

*Press. Gas: Gases under pressure: Compressed gas*

*Flam. Liq. 3: Flammable liquids, Hazard Category 3*

*Acute Tox. 4: Acute toxicity, Hazard Category 4*

*Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2*

*Skin Sens. 1: Sensitisation - Skin, Hazard Category 1*

*Asp. Tox. 1: Aspiration hazard, Hazard Category 1*

*Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1*

*Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3*