

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:** XYLONOR SPRAY**· Article number / formula:** 233S**· 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.

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· 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 : 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 :**

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

· 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**· Signal word** Danger**· Hazard statements**

H225 Highly flammable liquid and vapour.

· Precautionary statements

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

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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 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.*
Additional information:

EUH208 Contains l-carvone, (S)-p-mentha-1,8-diene. May produce an allergic reaction.

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: 64-17-5 EINECS: 200-578-6 Index number: 603-002-00-5 RTECS: KQ 6300000 Reg.nr.: 01-2119457610-43-xxxx	ethanol ⚠ Flam. Liq. 2, H225; ⚠ Eye Irrit. 2, H319	25-50%
CAS: 137-58-6 EINECS: 205-302-8	lidocaine ⚠ Acute Tox. 4, H302	10-25%
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	<1%
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	<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.

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SECTION 5: Firefighting measures

- **5.1 Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **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 :**
Wear protective equipment. Keep unprotected persons away.
- **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:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
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 :**
Keep receptacles tightly sealed.
Keep away from heat and direct sunlight.
- **Information about fire - and explosion protection:**



Keep ignition sources away - Do not smoke.

- Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **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.

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· 8.1 Control parameters

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

CAS: 64-17-5 ethanol (25-50%)

WEL (Great Britain)	Long-term value: 1920 mg/m ³ , 1000 ppm
MAK (Switzerland)	Short-term value: 1920 mg/m ³ , 1000 ppm Long-term value: 960 mg/m ³ , 500 ppm SSc;

CAS: 25265-71-8 Dipropylene glycol (isomer unspecified) (25-50%)

MAK (Switzerland)	Short-term value: 280 e mg/m ³ Long-term value: 140 e mg/m ³ SSc;
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CAS: 80-56-8 alpha-Pinene (<0.01%)

MAK (Switzerland)	Short-term value: 224 mg/m ³ , 40 ppm Long-term value: 112 mg/m ³ , 20 ppm H S;
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CAS: 5989-27-5 (R)-p-mentha-1,8-diene (<0.01%)

MAK (Switzerland)	Short-term value: 80 mg/m ³ , 14 ppm Long-term value: 40 mg/m ³ , 7 ppm S SSc;
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· DNELs

CAS: 64-17-5 ethanol

Dermal	DNEL Worker long-term systemic	343 mg/kg bw/d
Inhalative	DNEL Worker long-term systemic	950 mg/m ³
	DNEL Worker acute/short-term local effects	19 mg/m ³

· PNECs

CAS: 64-17-5 ethanol

PNEC STP	0.72 mg/L
PNEC aqua (fresh water)	0.96 mg/L
PNEC aqua (marine water)	0.79 mg/L
PNEC sediment (fresh water)	3.6 mg/kg
PNEC sediment (marine water)	2.9 mg/kg
PNEC soil	0.63 mg/kg

· 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

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

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· 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:	Liquid
Colour:	Clear
· Odour:	Characteristic
· Odour threshold:	Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	78 °C

· Flash point: 13 °C

· Flammability (solid, gas): Not applicable.

· Ignition temperature: 425 °C

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not self igniting.

· Explosive properties: Product is not explosive. However, formation of explosive air/vapour mixtures are possible.

· Explosion limits:

Lower:	3.5 Vol %
Upper:	15.0 Vol %

· Vapour pressure at 20 °C: 59 hPa

· Density at 20 °C: 0.91-0.92 g/cm³

· Relative density : Not determined.

· Vapour density : Not determined.

· Evaporation rate : Not determined.

· Solubility in / Miscibility with water: Fully miscible.

· Segregation coefficient (n-octanol/water): Not determined.

· Viscosity:

Dynamic: Not determined.

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Kinematic:	<i>Not determined.</i>
· Solvent content:	
COV :	45.5 %
VOC (EC)	45.46 %
· 9.2 Other information :	<i>No further relevant information available.</i>

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: 64-17-5 ethanol

Oral	LD50	7,060 mg/kg (rat)
Inhalative	LC50/4 h	20,000 mg/l (rat)

CAS: 137-58-6 lidocaine

Oral	LD50	500 mg/kg (ATE)
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CAS: 6485-40-1 l-carvone

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

CAS: 64-17-5 ethanol

EC50 72h	275 mg/l (Algae)
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EC50 48h 12,340 mg/l (daphnia)

EC50 96h 13,000 mg/l (fish)

- **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 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.

- **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 3 Flammable

HP 4 Irritant - skin irritation and eye damage

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

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN1170

- **14.2 UN proper shipping name**
- **ADR** UN1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
- **IMDG** ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
- **IATA** ETHANOL SOLUTION

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· 14.3 Transport hazard class(es)

· ADR



· Class 3 (F1) Flammable liquids.
· Label 3

· IMDG, IATA



· Class 3 Flammable liquids.
· Label 3

· 14.4 Packing group

· ADR, IMDG, IATA II

· 14.5 Environmental hazards:

· Marine pollutant: No

· 14.6 Special precautions for user

· Warning: Flammable liquids.
· Danger code (Kemler): 33
· EMS Number: F-E,S-D
· Stowage Category A

· 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: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml
· Transport category 2
· Tunnel restriction code D/E

· IMDG

· Limited quantities (LQ) 1L
· Excepted quantities (EQ) Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml

· UN "Model Regulation":

UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II

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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 P5c** FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 5,000 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 50,000 t
- **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**
- H225 Highly flammable liquid and vapour.
- H226 Flammable liquid and vapour.
- H302 Harmful if swallowed.
- H304 May be fatal if swallowed and enters airways.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H410 Very toxic to aquatic life with long lasting effects.

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

Flammable liquids	Bridging principles
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- **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

Flam. Liq. 2: Flammable liquids – Category 2

Flam. Liq. 3: Flammable liquids – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Asp. Tox. 1: Aspiration hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1