

Safety data sheet

Version number 1

Printing date 14.08.2017

Revision: 14.08.2017

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

- **1.1 Product identifier**
- **Trade name:** **ZIAGEL LIDOCAINE**
- **Article number / formula:** 227S
- **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**
- **Supplier:**
SPECIALITES SEPTODONT Pty Ltd.
Eclipse Tower, Level 16, 60 Station Street
Parramatta, NSW 2150
Australia
Telephone: 07 55224880
Fax: 07 5522 4128
bmilsom@advantagempc.com.au
<http://www.septodont.com>
- **1.4 Emergency telephone number:**
13 11 26 – Poisons Information Line

SECTION 2: Hazards identification

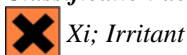
- **2.1 Classification of the substance or mixture**
- **Classification according GHS, 5th Edition :**



GHS05

Eye Dam. 1 H318 Causes serious eye damage.

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



Xi; Irritant

R36: Irritating to eyes.

- **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" .

- **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 GHS, 5th Edition ;**

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

- **Hazard pictograms**



GHS05

- **Signal word** Danger

- **Hazard-determining components of labelling:**

Trimethyltetradecyl-ammonium bromide

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- **Hazard statements**
H318 Causes serious eye damage.
- **Precautionary statements**
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.
- **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: 25322-68-3 NLP: 500-038-2	Polyethylene glycol	10-25%
CAS: 137-58-6 EINECS: 205-302-8	2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide ☒ Xn R22 ⚠ Acute Tox. 4, H302	2.5-10%
CAS: 1119-97-7	Trimethyltetradecyl-ammonium bromide ☒ Xn R20/22; ☒ Xi R37/38-41; ☒ N R50 ⚠ Eye Dam. 1, H318; ⚠ Aquatic Acute 1, H400; ⚠ Acute Tox. 4, H302; ⚠ Acute Tox. 4, H332; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335	2.5-10%

- **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; consult a doctor in case of 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.

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.

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SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** : Not required.
- **6.2 Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface 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).
- **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 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:**

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

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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- **Additional information:**
As a basis for the production of this document, the most current valid lists were used.
- **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 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

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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:** Pasty

· **Colour:** White

· **Odour:** Characteristic

· **Odour threshold:** Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· **Melting point/Melting range:** Undetermined.

· **Boiling point/Boiling range:** Undetermined.

· **Flash point:** Not applicable.

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

· **Ignition temperature:** Not applicable.

· **Decomposition temperature:** Not determined.

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

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

· **Explosion limits:**

· **Lower:** Not determined.

· **Upper:** Not determined.

· **Vapour pressure at 20 °C:** 59 hPa

· **Density:** Not determined.

· **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 at 20 °C:** 26000-49500 mPas

· **Kinematic:** Not determined.

· **Solvent content:**

· **VOC (EC)** 0.00 %

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· **9.2 Other information :** No further relevant information available.

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:**
- **Primary irritant effect:**
- **On the skin:** No irritant effect.
- **On the eyes:** Irritating effect.
- **Sensitisation:** No sensitising effects known.
- **Additional toxicological information:**
The product shows the following hazards according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

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.
- **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.

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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.

- **Unused expired product:**
- **Recommendation:** Dispose of as pharmaceutical waste via certified handler - incineration with certification.

SECTION 14: Transport information

- | | |
|---|---|
| · 14.1 UN-Number
· ADG, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.2 UN proper shipping name
· ADG, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.3 Transport hazard class(es)
· ADG, ADN, IMDG, IATA
· Class | Not classified as hazardous for transport |
| · 14.4 Packing group
· ADG, 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 MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | - |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
Registered as an OTC medicine, AUST R 128897. Hazard classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) and the Australian Code for the Transport of Dangerous Goods by Road and Rail (7th Edition).
Exposure limits according to "Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment [NOHSC:1003(1995)]"
S.D.S prepared in accordance with the National Code of Practice for the Preparation of Safety Data Sheets for Hazardous Chemicals, Dec 2011.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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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.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H332 Harmful if inhaled.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

R20/22 Harmful by inhalation and if swallowed.

R22 Harmful if swallowed.

R37/38 Irritating to respiratory system and skin.

R41 Risk of serious damage to eyes.

R50 Very toxic to aquatic organisms.

· **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)

Acute Tox. 4: Acute toxicity, Hazard Category 4

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

Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1

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