

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:** *ATO MEPIVACAINE 3%*
- **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:**
SPECIALITES SEPTODONT Pty Ltd.,
Eclipse Tower, Level 16, 60 Station Street
Parramatta, NSW 2150
Australia
Telephone: 07 55224880
Fax: 07 5522 4128
msds@septodont.com
<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 to GHS, 5th Edition :**
- The product is not classified according to the GHS requirements
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC :** Not applicable.
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **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 and ADG** Not classified as hazardous for transport
- **Hazard pictograms** Not classified as hazardous for transport
- **Signal word** Not classified as hazardous for transport
- **Hazard statements** Not classified as hazardous for transport
- **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: 1722-62-9 EINECS: 217-023-9	mepivacaine hydrochloride  Xn R22 R52/53  Acute Tox. 4, H302; Aquatic Chronic 3, H412	2.5-10%
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- **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**
- **General information:** No special measures required.
- **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.
- **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.

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 :**
No dangerous substances are released.
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 measures required.
- **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:** None.
- **7.3 Specific end use(s) :** No further relevant information available.

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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:**
The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.
- **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:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:** Not required.
- **Gloves material :** -
- **Eye protection:** Goggles recommended during refilling

SECTION 9: Physical and chemical properties

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

Form:	Liquid
Colour:	Colourless
Odour:	Characteristic
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 6.4
- **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:** Not determined.
- **Density:** Not determined.
- **Relative density :** Not determined.
- **Vapour density :** Not determined.

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· Evaporation rate :	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Segregation coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
VOC (EC)	0.00 %
· 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:** No irritant effect.
- **Sensitisation:** No sensitising effects known.
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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.

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- **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 :** Smaller quantities can be disposed of with household waste.
- **Unused expired product:**
- **Recommendation:** Dispose of as pharmaceutical waste via certified handler - incineration with certification.

SECTION 14: Transport information

- | | |
|---|---|
| · 14.1 UN-Number | |
| · ADR, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.2 UN proper shipping name | |
| · ADR, ADN, IMDG, IATA | Not classified as hazardous for transport |
| · 14.3 Transport hazard class(es) | |
| · ADR, ADN, IMDG, IATA | |
| · Class | Not classified as hazardous for transport |
| · 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 | 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 a prescription only medicine, AUST R 150494. 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.

H412 Harmful to aquatic life with long lasting effects.

R22 Harmful if swallowed.

R52/53 Harmful 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)

Acute Tox. 4: Acute toxicity, Hazard Category 4

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