

- Issue Date (From Astra Zeneca) 10.08.17
- Revision Date by Aspen Pharmacare – 15.05.18

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

#### **XYLOCAINE INJECTIONS WITH ADRENALINE**

Details of the supplier of the safety data sheet

: ASPEN PHARMACARE  
AUSTRALIA PTY  
34-36 CHANDOS  
STREET  
ST. LEONATDS NSW  
2065  
Tel: 02 8436 8300

Emergency Telephone  
Business hours  
+612 8436 8300  
After hours  
13 11 26

CAS No. : Not applicable

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Local anaesthetic solution for use in infiltration anaesthesia, intravenous regional anaesthesia and nerve blocks.

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## SECTION 2. HAZARDS IDENTIFICATION

### GHS Classification

Not a hazardous substance or mixture.

### GHS label elements

Not a hazardous substance or mixture.

### Other hazards which do not result in classification

May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.  
See Section 11.

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## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Lidocaine hydrochloride monohydrate	6108-05-0	>= 1 - < 10

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## SECTION 4. FIRST AID MEASURES

- If inhaled : Remove patient from exposure.  
Obtain medical attention if ill effects occur.
- In case of skin contact : Remove contaminated clothing.  
Wash skin with soap and water.  
If symptoms (irritation or blistering) occur obtain medical attention.
- In case of eye contact : Irrigate with eyewash solution or clean water, holding the

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- eyelids apart, for at least 10 minutes.  
Obtain medical attention.
- If swallowed : Wash out mouth with water and give 200-300ml of water to drink.  
Do NOT induce vomiting as a First-Aid measure.  
Obtain medical attention.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.  
For further detail consult the prescribing information.

#### **SECTION 5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : water spray, foam, dry powder or CO<sub>2</sub>.
- Unsuitable extinguishing media : -
- Specific hazards during firefighting : If involved in a fire, it may emit noxious and toxic fumes.
- Special protective equipment for firefighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages.  
See Section 8.
- Environmental precautions : Prevent entry into drains, sewers or watercourses.
- Methods and materials for containment and cleaning up : Clear up spillages.  
Wash the spillage area clean with water and detergent.  
Transfer to a container for disposal.

#### **SECTION 7. HANDLING AND STORAGE**

- Advice on safe handling : Avoid contact with skin and eyes.  
Avoid inhalation of vapour/mist.
- Conditions for safe storage : Keep container tightly closed.  
Protect from light.  
Do not freeze.
- Recommended storage temperature : < 25 °C

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**
**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Lidocaine hydrochloride monohydrate	6108-05-0	TWA	0.05 mg/m <sup>3</sup>	COM

**Engineering measures** : The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains, sewers or watercourses.

**Personal protective equipment**

- Respiratory protection** : Use a negative pressure air purifying respirator (half face mask) with filter class A if the risk assessment does not support the selection of other protection.
- Eye protection** : Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.
- Skin and body protection** : Avoid contact with skin. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.
- Protective measures** : Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	Aqueous solution
Colour	:	clear
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	3.3 - 5.0
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

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**SECTION 10. STABILITY AND REACTIVITY**

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Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Adrenaline is unstable in alkaline solutions when exposed to air or light.
Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	None known.
Hazardous decomposition products	:	No hazardous decomposition products are known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1.1 Acute toxicity

Not classified based on available information.

#### **Product:**

Acute oral toxicity	:	Remarks: Low acute oral toxicity.
Acute inhalation toxicity	:	Remarks: May cause effects as described under single exposure.(STOT)
Acute dermal toxicity	:	Remarks: No data available

#### **Components:**

##### **Lidocaine hydrochloride monohydrate :**

Acute oral toxicity	:	LD50 Oral (Rat): 159 - 773 mg/kg Remarks: Information refers to Lidocaine hydrochloride
Acute inhalation toxicity	:	Remarks: May cause tingling/numbness in exposed areas (paraesthesia).
Acute dermal toxicity	:	Remarks: No data available

### 11.1.2 Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

##### **Lidocaine hydrochloride monohydrate :**

Remarks: May cause numbness.

### 11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

##### **Lidocaine hydrochloride monohydrate :**

Remarks: May cause excessive watering of the eye (lachrymation).

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#### 11.1.4 Respiratory or skin sensitisation

##### **Skin sensitisation**

Not classified based on available information.

##### **Respiratory sensitisation**

Not classified based on available information.

##### **Components:**

##### **Lidocaine hydrochloride monohydrate :**

Remarks: Repeated and/or prolonged contact may cause skin sensitisation in a small proportion of sensitive individuals.

#### 11.1.5 Germ cell mutagenicity

Not classified based on available information.

##### **Components:**

##### **Lidocaine hydrochloride monohydrate :**

Germ cell mutagenicity - : The substance is not considered to be genotoxic.  
Assessment

#### 11.1.6 Carcinogenicity

Not classified based on available information.

##### **Components:**

##### **Lidocaine hydrochloride monohydrate :**

Carcinogenicity - : No information available on this substance.  
Assessment

#### 11.1.7 Reproductive toxicity

Not classified based on available information.

##### **Components:**

##### **Lidocaine hydrochloride monohydrate :**

Reproductive toxicity - : There is no evidence of teratogenicity or embryotoxicity.  
Assessment

#### 11.1.8 STOT - single exposure

Not classified based on available information.

##### **Components:**

##### **Lidocaine hydrochloride monohydrate :**

Exposure routes: Inhalation

Remarks: High atmospheric concentrations may lead to anaesthetic effects.

May produce a reduced heart rate and reduction in blood pressure with a resulting feeling of dizziness.

Exposure routes: Oral

Remarks: May produce numbness of the tongue and anaesthetic effects on the stomach.

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#### 11.1.9 STOT - repeated exposure

Not classified based on available information.

##### Components:

##### **Lidocaine hydrochloride monohydrate :**

Remarks: Repeated exposure of animals to high levels produces adverse effects on the liver and central nervous system.

#### 11.1.10 Aspiration toxicity

Not classified based on available information.

##### Components:

##### **Lidocaine hydrochloride monohydrate :**

No data available

##### **Further information**

##### Product:

Remarks: This health hazard assessment is based on a consideration of the composition of this product.

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## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### Product:

#### **Ecotoxicology Assessment**

Acute aquatic toxicity : This product has no known ecotoxicological effects.  
Remarks: No information on this formulation.  
The following information refers to  
Lidocaine hydrochloride monohydrate

#### Components:

##### **Lidocaine hydrochloride monohydrate :**

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 106 mg/l  
Exposure time: 96 H  
Method: OECD Test Guideline 203  
Remarks: Low toxicity to aquatic organisms.

EC50 ((microtox test)): > 1,000 mg/l  
Exposure time: 15 MIN

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 112 mg/l  
Exposure time: 48 H  
Method: OECD Test Guideline 202

Toxicity to algae : EC50 (green algae): 780 mg/l  
Exposure time: 72 H

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Method: OECD Test Guideline 201

**Persistence and degradability**

**Components:**

**Lidocaine hydrochloride monohydrate :**

Biodegradability : Remarks: Not rapidly degradable.

**Bioaccumulative potential**

**Components:**

**Lidocaine hydrochloride monohydrate :**

Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

**Mobility in soil**

**Components:**

**Lidocaine hydrochloride monohydrate :**

Mobility : Remarks: No information available on this substance.

Distribution among environmental compartments : Remarks: No information available.

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : Disposal should be in accordance with local, state or national legislation.

Contaminated packaging : Empty container will retain residue. Observe all hazard precautions.

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**SECTION 14. TRANSPORT INFORMATION**

Not classified as dangerous in the meaning of transport regulations.

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## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

In order to comply with legal duties it is necessary to consult local and national legislation.

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

### The components of this product are reported in the following inventories:

REACH : Not listed

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Lidocaine hydrochloride monohydrate 6108-05-0

AICS : Not listed

ENCS : Not listed

ISHL : Not listed

IECSC : Not listed

TCSI : Not listed

TSCA : Not On TSCA Inventory

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM - In-house occupational exposure limit; CPR - Controlled Products Regulations; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HYG - Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican



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**MATERIAL SAFETY  
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Norm; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and

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Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects; STEL – Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); TSCA - Toxic Substances Control Act (United States); TWA – Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**Further information**

- Other information : The Safety Data Sheet has been updated to the SAP EH&S Standard template., This update affects all Sections of the Safety Data Sheet., New significant SHE information:, 8. New Occupational Exposure Limit Value, 11. Toxicological information, Minor changes:, 2, 6, 8, 9, 11
- Date format : dd.mm.yyyy

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