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SAFETY DATA SHEET

CITANEST 0.5% prilocaine hydrochloride 250mg/50mL injection

Issue Date:	22nd July 2021
Sponsor:	Aspen Pharmacare Australia Pty Ltd
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1. IDENTIFICATION OF THE MATERIAL

Product Identifier:	Citanest 0.5% - prilocaine hydrochloride 250mg/50mL injection vial
Other means of identification:	N/A
Aspen product code/s:	AS-07576 CITANEST 0.5% 5X50ML
Recommended Use:	CITANEST solutions are indicated for the production of local or regional anaesthesia by infiltration techniques; intravenous regional anaesthesia; by peripheral nerve block techniques such as intercostal blocks; major plexus blocks such as brachial plexus blocks and by epidural and subarachnoid blocks.
Emergency phone number:	+(61 2) 8436 8300 Poisons Information Centre: 131 126 from anywhere in Australia, (0800 764 766 in New Zealand)

2. HAZARDS IDENTIFICATION/DATA

Hazard Classification:	Category 2A – Eye irritation
Hazard Information:	H319 - Causes serious eye irritation
Label Elements, including precautionary statements:	**Signal word:** Warning P264 - Wash hands thoroughly after handling. P280 - Wear eye protection/ face protection.

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P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 - If eye irritation persists: Get medical advice/ attention.

Other hazards which do not result in classification: May cause tingling/numbness in exposed areas (paraesthesia).

3. COMPOSITION

Chemical Ingredient	CAS No.	%
Prilocaine Hydrochloride	1786-81-8	0.5%
Excipients	Proprietary	withheld

Concentration Guide: Low (below 10%) Medium (10 to 60%) High (above 60%)

4. FIRST AID MEASURES

In case of Skin Contact: Wash skin with soap and water

In case of Eye: Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects remain.

In case of Ingestion: Wash out mouth with water and give 200-300ml of water to drink. Obtain medical attention if ill effects occur. Do NOT induce vomiting as a First-Aid measure.

Inhalation: Remove patient from exposure. Obtain medical attention if ill effects occur

Symptoms caused by exposure: Refer to sections 2 and 11

Medical attention and special treatment: Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Special hazards arising from the substance or mixture:	If involved in a fire, it may emit noxious and toxic fumes.
Advice for firefighters:	A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:	Ensure suitable personal protection during removal of spillages. See Section 8. Ensure adequate ventilation. Take care to avoid needles and broken containers.
Environmental precautions:	Prevent entry into drains.
Methods and materials for containment and cleaning up:	Clear up spillages. Wash the spillage area with water. Transfer spilled vials to a suitable container for disposal.

7. HANDLING AND STORAGE

Precautions for safe handling:	Avoid contact with skin and eyes.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed. Protect from light. Do not freeze. Store at the recommended storage conditions on the packaging.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters – Exposure standards, biological monitoring:	Prilocaine HCl – 1mg/m3 – LTEL 8hr TWA Prilocaine HCl – 5mg/m3 – STEL 15min
Engineering controls:	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. The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API).
Personal protective equipment	Avoid all unnecessary exposure.

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Eye protection:	Use goggles to protect against direct contact with the product if the risk assessment does not support the selection of other protection.
Skin 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.
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.

9. PHYSICAL & CHEMICAL PROPERTIES

Description of appearance (physical form, colour, shape):	Clear colourless solution
Odour:	Not available
Odour threshold:	Not available
pH:	5.0 - 7.0
Melting point/range:	Not available
Boiling point/range:	Not available
Flash point:	Not available
Evaporation rate:	Not available
Flammability:	Not available
Upper/lower flammability or explosive limits:	Not available
Vapour pressure:	Not available
Vapour density:	Not available
Relative density:	Not available
Solubility (ies):	Not available
Partition coefficient: n-octanol/ water:	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity:	Not available
Specific heat value:	Not available

Particle size:	Not available
Volatile organic compounds content:	Not available

10. STABILITY AND REACTIVITY

Reactivity:	No known reactivity hazard under normal conditions
Chemical stability:	Stable under normal conditions.
Conditions to avoid:	No conditions producing hazardous situations known.
Incompatible material and possible hazardous reactions:	None known
Hazardous decomposition products:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on routes of exposure:

Inhalation: May cause effects as described under single exposure. (STOT)

Skin Contact: May cause mild skin irritation.

Eye Contact: Causes serious eye irritation. May cause permanent damage if eye is not immediately irrigated.

Ingestion: Low acute oral toxicity.

Symptoms related to exposure:

Single exposure

Exposure routes: Oral
Target Organs: Gastrointestinal tract
May produce numbness of the tongue and anaesthetic effects on the stomach.

Exposure routes: Inhalation
Target Organs: Central nervous system High atmospheric concentrations may lead to anaesthetic effects. May cause tingling/numbness in exposed areas (paraesthesia).

Repeated exposure
Chronic effects are unlikely.

Numerical measures of toxicity:

Prilocaine Hydrochloride:

Skin mouse - LD50- 550 mg/kg

Intravenous mouse - LD50- 55 mg/kg

	Intravenous rat - LD50- 56.6 mg/kg Subcutaneous mouse - LD50- 632 mg/kg Subcutaneous rat - LD50- 790 mg/kg
Immediate, delayed and chronic health effects from exposure:	**Carcinogenicity:** No information available. **Mutagenicity:** There is no evidence of genotoxic potential in in vitro and in vivo tests. **Reproductive toxicity:** There is no evidence of a teratogenic potential or any other adverse effects on reproductive function.
Exposure levels:	No data available
Interactive effects:	No data available
Data limitations:	No data available

12. ECOLOGICAL INFORMATION

Ecotoxicity:	No information on this formulation. The following information refers to active ingredient: Harmful to aquatic life with long lasting effects. Toxicity: EC50 green algae 72 H 154 mg/l EC50 Daphnia magna 48 H 61 mg/l LC50 Zebra Fish 96 H 188 mg/l
Persistence, degradability & Persistence:	Not readily biodegradable.
Bioaccumulative potential:	The substance has low potential for bioaccumulation.
Mobility in Soil:	No information available.
Other adverse effects:	No information available.

13. DISPOSAL CONSIDERATIONS

Safe handling and disposal methods:	Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Dispose of contents/ container to an approved incineration plant.
Disposal of any contaminated packaging:	Empty container will retain product residue. Observe all hazard precautions.
Environmental regulations:	No data available

14. TRANSPORT INFORMATION

UN number:	NOT RESTRICTED FOR TRANSPORT

15. REGULATORY INFORMATION

Safety, health and environmental regulations specific for the product in question:	None at the time of writing
Poisons Schedule Number:	(S4) Prescription Only Medicine

16. OTHER INFORMATION

Date of preparation or review	22nd July 2021
Key abbreviations or acronyms used	CAS No. = Chemical Abstracts Service Number LD50= Lethal Dose EC50 = Half maximal effective concentration LTEL = Long-term exposure limit (8-hour TWA (time-weighted average)) STEL = Short-term exposure limit (15-minute TWA (time-weighted average)) STOT = Specific Target Organ Toxicity

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