MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

MARCAIN SOLUTION WITH ADRENALINE

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
Alma Road, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
Bupivacaine and Epinephrine solution

CAS No. : Not applicable
Use : Local anesthetic solution for use in infiltration anesthesia, peripheral and central nerve blocks.

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification UN GHS

Hazard class	Category	Hazard Statements
Acute toxicity	5	H303 # Refer to Section 16 'Other Information'

Label elements

Signal Word
Warning

Hazard Statements

H303 : May be harmful if swallowed.

Precautionary Statements

P280 : Wear protective gloves.

P312 : Call a POISON CENTER or doctor/ physician if you feel unwell.

P501 : Dispose of contents/ container to an approved incineration plant.

Other hazards
May cause tingling/numbness in exposed areas (paresthesia). May cause excessive watering of the eye (lacrimation).

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	**%**	**CAS No.**		
Bupivacaine hydrochloride monohydrate	0,25 - 0,75	14252-80-3		
	Hazard class #		**Category**	**Hazard Statements** #
	Acute toxicity		2	H300
	Acute aquatic toxicity		3	H402
	Chronic aquatic toxicity		3	H412
Component	**%**	**CAS No.**		
Epinephrine bitartrate	0,0005	51-42-3		
	Hazard class #		**Category**	**Hazard Statements** #
	Skin sensitization		1	H317
	Acute toxicity		2	H300
	Acute toxicity		2	H310
	Acute toxicity		2	H330
Component	**%**	**CAS No.**		
Sodium Metabisulphite	0,05	7681-57-4		
	Hazard class #		**Category**	**Hazard Statements** #
	Acute toxicity		4	H302
	Serious eye damage		1	H318

Refer to Section 16 'Other Information'

4. FIRST AID MEASURES

Description of first aid measures

Inhalation : Remove patient from exposure. Obtain medical attention if ill effects occur.
Skin Contact : Wash skin with soap and water.
Eye Contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects remain.
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.

Most important symptoms and effects, both acute and delayed
Refer to sections 2 and 11

Indication of any immediate medical attention and special treatment needed
Symptomatic treatment and supportive therapy as indicated. For further information consult the prescribing information.

5. FIRE FIGHTING MEASURES

Extinguishing Media (suitable) : water spray, foam, dry chemical or CO2.

Extinguishing Media (unsuitable)	:	-
Special hazards arising from the substance or mixture	:	If involved in a fire, it may emit noxious and toxic fumes.
Special protective actions for fire-fighters	:	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.
Environmental Precautions	:	Prevent entry into drains.
Methods and material for containment and cleaning up	:	Clear up spillages. Transfer to a container for disposal. Wash the spillage area with water.

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. Epinephrine is unstable in alkaline solutions when exposed to air or light. Do not freeze. Storage temperature : 2 - 15 °C
Specific end use(s)	:	Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Ingredients	Value	Control parameters	Comments
Bupivacaine hydrochloride	0,1 mg/m3	TWA	COM
Bupivacaine hydrochloride	1 mg/m3	STEL/CEILING(C)	COM
Sodium Metabisulphite			

Exposure 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.Prevent entry into drains.

Occupational exposure controls

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.

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.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

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.

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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form	:	aqueous solution
pH	:	3,3 - 5,5

Other information

No other data available

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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

Inhalation	:	May cause effects as described under single exposure.(STOT)
Skin Contact	:	May cause mild skin irritation.
Eye Contact	:	May cause excessive watering of the eye (lacrimation).
Ingestion	:	May be harmful if swallowed.
Specific Target Organ Toxicity (STOT)	:	**Single exposure** Routes of exposure: Inhalation May cause tingling/numbness in exposed areas (paresthesia)., High atmospheric concentrations may lead to anesthetic effects. Routes of exposure: Oral May produce numbness of the tongue and anaesthetic effects on the stomach. **Repeated exposure** Chronic effects are unlikely.
Sensitization	:	Unlikely to cause skin sensitization.
Carcinogenicity	:	No information available.
Mutagenicity	:	No information available.
Reproductive toxicity	:	No information available.

12. ECOLOGICAL INFORMATION

No information on this formulation. The following information refers to active ingredient: Harmful to aquatic life with long lasting effects.

Toxicity	:	EC50 (microtox test) 15 MIN > 1,000 mg/l EC50 Daphnia magna 48 H 39 mg/l No observed effect concentration Daphnia magna 48 H 7,5 mg/l
Effect on Effluent Treatment	:	No information available.
Persistence and degradability	:	Not rapidly degradable.
Bioaccumulative potential	:	No information available.
Mobility in soil	:	Water solubility >= 1 mg/l.
Other adverse effects	:	No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods	:	Disposal should be in accordance with local, state or national legislation. This material and/or its container must be disposed of as hazardous waste.
Contaminated Packaging	:	Empty container will retain product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

NOT RESTRICTED FOR TRANSPORT

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Hazard Statements	H300 : Fatal if swallowed. H302 : Harmful if swallowed. H303 : May be harmful if swallowed. H310 : Fatal in contact with skin. H317 : May cause an allergic skin reaction. H318 : Causes serious eye damage. H330 : Fatal if inhaled. H402 : Harmful to aquatic life. H412 : Harmful to aquatic life with long lasting effects.

GLOSSARY

COM	:	In-house occupational exposure lim
LTEL	:	Long-term exposure limit (8 hour TWA (time-weighted average))
STEL	:	Short-term exposure limit (15-minute TWA (time-weighted average))
TLV	:	Threshold Limit Value (ACGIH)
TLV-C	:	Threshold Limit Value - Ceiling limi
HYG	:	An in-house analytical method for occupational exposure monitoring is available
Sk	:	Can be absorbed through skin, thus contributing to systemic effe
Sen	:	Capable of causing respiratory sensitization

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.