COMPANY DETAILS

Company: Ceva Animal Health Pty Ltd
Address: 11 Moores Road
          Glenorie   NSW   2157  Australia

Telephone Number: +61 (02) 9652 7000
Facsimile Number: +61 (02) 9652 7001

Emergency Telephone Number: +61 (02) 9652 7000 (Business Hours)
Poisons Information Centre: 131126

SUBSTANCE IDENTIFICATION

Product Name: NV Mepivacaine Injection

Other Names: Mepivacaine

Synonyms for the active constituent (mepivacaine): Chlorocain, carbocaine

Manufacturer’s Product Code: MEP

UN Number: None allocated

Dangerous Goods Class and Subsidiary Risk: None allocated

Hazchem Code: None allocated

SUSDP Poisons Schedule Number: S4

Use: Non irritant local anaesthetic injection for horses. For animal treatment only.
Section 2 – Hazards Identification

Statement of Hazardous Nature:
Hazardous according to criteria of NOHSC Australia.

Risk Phrases: None

Safety Phrases:
S46 If swallowed, contact a doctor or Poisons Information Centre immediately and show this container or label.

Section 3 – Composition / Information on Ingredients

The substance is a complex mixture, including the following ingredients.

Ingredients:

* Chemical Name                     CAS Number  Proportion
Mepivacaine Hydrochloride          1722-62-9   2% (20 mg/mL)
Benzyal Alcohol                    100-51-6    less than 10%
Ingredients determined not to be hazardous to 100

Section 4 – First Aid Measures

Swallowed:
If poisoning occurs, contact a doctor or Poisons Information Centre (Phone 131126) and show doctor a copy of this MSDS.

Eye:
First aid is (not generally required). If in eyes, hold eyelids open and flush gently with copious quantities of water until substance is removed (up to 15 minutes).

Skin:
Remove contaminated clothing. Wash skin gently with water and non-abrasive soap.

Inhaled:
Not expected to be a significant route of exposure during normal use.

First Aid Facilities:
No specific first aid facilities required.

Advice to Doctor:
Treatment should be symptomatic and supportive, with attention to supporting ventilation and arresting convulsions. Diazepam or thiopentone sodium may be used to control convulsions.
Section 5 – Fire Fighting Measures

Fire/Explosion Hazard:
There is no risk of explosion from this product. The product is not readily combustible.

Flashpoint: Not applicable
Flammability Limits: Non-flammable.

Extinguishing Media:
No specific requirements. Use extinguishing media suited to the environmental materials involved in the fire.

Special Fire Fighting Procedures:
Wear self-contained breathing apparatus and full protective clothing in accordance with normal firefighting procedures.

Hazchem Code:
None allocated.

Section 6 – Accidental Release Measures

Emergency Procedures:
None prescribed.

Methods and Materials for Containment and Clean Up Procedures:
Prevent spill from spreading. Clean up spill using suitable adsorbent material. Dispose of waste in accordance with local, state and federal laws. Wash area with water and detergent.

Section 7 – Handling and Storage

Precautions for Safe Handling:
No specific protective clothing required. When handling this product, wash hands before eating, drinking, or touching face/eyes.

Storage:
Keep outer containers tightly closed and out of reach of children and unauthorised persons. Adhere to storage requirements as listed on label (STORE below 25°C [Air Conditioning]. Protect from light.).
Section 8 – Exposure Controls / Personal Protection

National Exposure Standards:
NOHSC has not listed exposure limits for mepivacaine.

Biological Limit Values:
No BLVs have been established for the ingredients in this product.

BLVs are reference values for the evaluation of potential health risks in the practice of industrial hygiene. Biological monitoring involves the measurement of substances in biological media (e.g., blood, urine, etc.) and the measurement of biological effects induced by the substance.

Engineering Controls:
No engineering controls allocated.

Personal Protective Equipment:
No specific protective clothing required for normal use.

Section 9 – Physical and Chemical Properties

Appearance:
Clear colourless aqueous solution in 100 mL or 10mL x 12 labelled amber glass vials with a rubber stopper and aluminium cap packaged in a labelled outer carton.

Odour:
Non-specific

pH:
No data

Vapour pressure:
Not determined.

Vapour density:
Not determined.

Boiling Point:
Expected to be ~100°C

Freezing / Melting Point:
Not determined.

Solubility:
Solution is water-based. 100% miscible in water.

Specific Gravity:
~1.00

Other Properties:
No other information.
Section 10 – Stability and Reactivity

Chemical Stability:
Product is not likely to react or decompose under normal storage conditions.

Conditions to Avoid:
No data.

Incompatible Materials:
No data.

Hazardous Decomposition Products:
No data.

Hazardous Reactions:
No hazardous reactions such as polymerization known.

Section 11 – Toxicological Information

Health Effects:
Acute poisoning is unlikely to occur under normal conditions of use. However, in cases of accidental or deliberate self-injection or if the product is swallowed, seek medical attention immediately.

In humans, mepivacaine has been used for all types of infiltration and regional nerve block anaesthesia and also for spinal anaesthesia. The dose in humans is up to 7 mg/kg BW (EMEA 1999)\(^1\).

LD\(_{50}\) (i.v. mouse) and LD\(_{50}\) (i.v. rat) ranged from 35-44 mg/kg.

The common symptoms associated with administration of low doses of mepivacaine include stimulation of the cortical and other cerebral functions (e.g. hyperactivity, hyperreflectivity, tremors). At high doses, there is a progressive ascending depression of functions resulting in sleepiness, stupor, ataxia and eventual loss of consciousness. Nausea and vomiting may occur after systemic administration. Mepivacaine can also cause vasodilation and an increase in forearm blood flow.

The available pharmacological and toxicological studies are too limited to allow the establishment of an NOEL and therefore no ADI can be established.

Acute:

Swallowed: Toxicity following oral administration is unlikely. Effects associated with its anaesthetic action can be expected, for example numbing of gums and tongue may be anticipated.

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\(^1\) EMEA (1999) Mepivacaine Summary Report, European Agency for the Evaluation of Medicinal Products, Committee for Veterinary Medicinal Products.
LD50 (oral, mouse): 300 mg/kg

**Eye:** May cause transient irritation followed by numbing effect.

**Skin:** Absorption via intact skin is unlikely. May cause local numbing.

**Inhaled:** Not considered to be a significant route of exposure during normal use.

**Chronic:** No data are available concerning chronic health effects.

**Reproductive Effects:** There is no evidence that mepivacaine causes any reproductive effects (EMEA 1999).

**Teratogenic and mutagenic effects:** No evidence exists of any teratogenic effects. No data are available concerning possible mutagenic effects.

**Carcinogenic Effects:** Unknown. No carcinogenicity studies have been performed with mepivacaine.

**Toxicity to Other Domestic Species:** Administering low doses of mepivacaine to domestic species will give rise to effects associated with its anaesthetic action. High doses are expected to cause sleepiness, stupor, ataxia and eventual loss of consciousness.

### Section 12 – Ecological Information

**Ecotoxicity:** The main opportunity for residues to enter the environment will be via urine and excreta from treated animals. As the quantities involved will be very small, environmental impacts are expected to be negligible.

**Persistence / Degradability:** No data

**Mobility:** No data

### Section 13 – Disposal Considerations

**Disposal of empty or used containers:** Dispose of in accordance with Local, State, Federal and EPA (Environmental Protection Authority) waste regulations.

### Section 14 – Transport Information

**UN Number:** None allocated

**Dangerous Goods Class and Subsidiary Risk:** None allocated

**Hazchem Code:** None allocated

This product is not classified as a Dangerous Good. No special transport conditions.
Section 15 – Regulatory Information

SUSDP Poisons Schedule Number: 4
APVMA Approval Number: 47711

Section 16 – Other Information

This MSDS contains only information related to safety. For other data, see product literature.

Read all labels and package inserts carefully before using this product.

Glossary and Acronyms:

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADI</td>
<td>Acceptable Daily Intake, as listed in the Australian ADI List, August 2003.</td>
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<tr>
<td>CAS Number</td>
<td>Unique number assigned by the Chemical Abstracts Service, Columbus, Ohio, USA.</td>
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<td>EMEA</td>
<td>European Agency for the Evaluation of Medicinal Products – Committee for Veterinary Medicinal Products; 7 Westferry Circus, Canary Wharf, London E14 4HB, UK; ph (+44-171) 418 8400; fx (+44-171) 418 8416</td>
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<tr>
<td>Hazchem Code</td>
<td>Emergency action code of numbers and letters giving information to emergency services.</td>
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<tr>
<td>LD50</td>
<td>Lethal dose for 50% of a group of specified test animals.</td>
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<tr>
<td>MSDS</td>
<td>Material Safety Data Sheet (also called Safety Data Sheet in some countries).</td>
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<tr>
<td>NOEL</td>
<td>No Observable Effect Level, as listed in the Australian ADI List, August 2003.</td>
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<tr>
<td>NOHSC</td>
<td>National Occupational Health and Safety Commission</td>
</tr>
<tr>
<td>Risk Phrase</td>
<td>Standard phrase describing the hazard of a substance as provided in the NOHSC “Approved Criteria for Classifying Hazardous Substances [NOHSC:1008]”</td>
</tr>
<tr>
<td>Safety Phrase</td>
<td>Standard phrase describing the safe handling, storage or use of personal protective equipment for a material as provided in the NOHSC &quot;Approved Criteria for Classifying Hazardous Substances [NOHSC:1008]&quot;</td>
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<tr>
<td>SUSDP</td>
<td>Standard for the Uniform Scheduling of Drugs &amp; Poisons</td>
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<tr>
<td>TWA</td>
<td>Time Weighted Average</td>
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<td>UN Number</td>
<td>United Nations Number</td>
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CONTACT POINT

Ceva Animal Health Pty Ltd Regulatory Affairs Manager (02) 9652 7000.

This information has been collated by technical personnel employing data available from the prime manufacturer of the material. To the best of our knowledge it is true and accurate. It is not intended to be all inclusive and the manner and conditions of use and handling may involve other or additional considerations.