

**SECTION 1 IDENTIFICATION OF THE MATERIAL AND SUPPLIER**

Product (material) name: Nopaine 2%  
Other names: None allocated  
Recommended use: For local and regional anaesthesia or area infiltration in cattle, deer, sheep and dogs.  
For diagnostic nerve blockade. For dehorning and deleveting procedures.  
Supplier Details: Phoenix Pharm Distributors Ltd  
3C Whetu Place, Rosedale  
AUCKLAND 0632  
NEW ZEALAND  
Contact Person: Graeme Webb  
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Emergency telephone number 0800 764 766 (0800 POISON) 24/7 for Poison Information Services  
111 for NZ emergency services

**SECTION 2 HAZARDS IDENTIFICATION**

Classification of Product:

This product is classified as a health hazard in accordance with the following classification criteria of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition.

Health hazards: Skin corrosion / irritation  
Germ cell mutagenicity  
Carcinogenicity  
Specific Target Organ Systemic Toxicity (Single and repeated exposure)

Skin corrosion / irritation: Category 3  
GHS label elements, including precautionary statements:  
Pictogram: Not required  
Signal word: Warning  
Hazard statements: Causes mild skin irritation  
Precautionary statements:  
Prevention: Keep out of reach of children  
Wear suitable protective clothing and gloves  
Do not eat drink or smoke when using this product  
Wash hands thoroughly after handling  
Response: If on skin wash with plenty of soap and water  
If skin irritation occurs get medical advice/attention

Germ cell mutagenicity: Category 2  
GHS label elements, including precautionary statements:  
Pictogram:



Signal word: Warning  
Hazard statement: Suspected of causing genetic defects  
Precautionary statements:  
Prevention: Obtain special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Use personal protective equipment as required.  
Response: If exposed or concerned, get medical attention / advice

Carcinogenicity: Category 2  
GHS label elements, including precautionary statements:  
Pictogram:



Signal word: Warning  
Hazard statement: Suspected of causing genetic defects  
Precautionary statements:  
Prevention: Obtain special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Use personal protective equipment as required.  
Response: If exposed or concerned, get medical attention / advice

Specific Target Organ Systemic  
Toxicity (Single and repeated exposure): Category 2  
GHS label elements, including precautionary statements:  
Pictogram:



Signal word: Warning  
Hazard statement: May cause damage to organs  
Precautionary statements:  
Prevention: Do not breathe fumes.  
Wash exposed parts thoroughly after handling.  
Do not eat, drink or smoke when using this product  
Response: Get medical advice / attention if you feel unwell.

### SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Cas No.	Proportion (% w/v)
Lignocaine* Hydrochloride	6108-05-0	2.0
Benzyl Alcohol	100-51-6	1.5
Sodium Hydroxide	1310-73-2	<0.1
Water	7732-18-5	To 100

[\* Also known as lidocaine and xylocaine]

### SECTION 4 FIRST AID MEASURES

**First Aid:**

If poisoning occurs, contact a doctor or Poisons Information Centre. Telephone Australia 131126; New Zealand 0800 764 766 (0800 POISON). If skin or hair contact occurs, remove contaminated clothing. Flush skin and hair with running water.

However, the following additional information is provided for assistance while implementing the recommended First Aid directions:

Inhalation: Remove patient from exposure.  
Eye: Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes.  
Ingestion: Wash out mouth with water and give 200-300ml of water to drink. Do not induce vomiting.

Advice to Doctor: Treat symptomatically.

### SECTION 5 FIRE FIGHTING MEASURES

Suitable extinguishing media: Water spray, foam, dry chemical or CO<sub>2</sub>  
Hazards from combustion products: May burn and emit noxious and toxic fumes  
Special protective precautions and equipment for fire fighters: Self contained breathing apparatus and suitable protective clothing should be worn in fire  
Hazchem Code: None allocated

### SECTION 6 ACCIDENTAL RELEASE MEASURES

Emergency procedures:  
Contain spills using inert absorbent materials. Wear self-contained breathing apparatus for cleaning up large spills. Prevent spilled material from entering drains, sewers or other waterways.

Methods and materials for containment and clean up:  
Absorb spilled materials with inert absorbent materials such as powdered clay, vermiculite, sand etc. Collect waste material and dispose of in accordance with local authority instructions.

### SECTION 7 HANDLING AND STORAGE

Precautions for safe handling:  
Avoid contact with eyes, skin, and clothing. Avoid prolonged or repeated exposure. Wash hands before eating drinking or smoking.

Conditions for safe storage, including any incompatibilities:  
Store below 30°C (Room Temperature)

### SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

National exposure standards: None allocated  
Biological limit values: None allocated  
Engineering controls:  
Ventilation: Not considered necessary during normal usage. For higher use, good general ventilation should be sufficient.  
Personal protective equipment: None considered necessary during normal usage. PVC or neoprene gloves and chemical safety glasses can be worn. Good Animal Handling Practice may require the use of surgical gloves.

### SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colourless liquid.  
Boiling Point [°C]: 100.0  
Vapour Pressure [mm of Hg at 20°C]: Not determined  
Per cent Volatiles: max 1.0  
Specific Gravity: 1.005  
Flash Point [°C]: Not determined  
Flammability Limits [%]: Not determined  
Autoignition temperature [°C]: Not determined

## SECTION 10 STABILITY AND REACTIVITY

Chemical stability:	Stable
Conditions to avoid:	Heat, exposure to strong oxidising agents
Incompatible materials:	Strong oxidising agents
Hazardous decomposition products:	Thermal decomposition of lignocaine hydrochloride may release toxic vapours
Hazardous reactions:	Hazardous polymerisation will not occur

## SECTION 11 TOXICOLOGICAL INFORMATION

### Routes of Exposure:

Nopaine 2% is an injectable product containing lignocaine (as the hydrochloride) as the active ingredient. It is considered that the most likely routes of exposure will be eye and skin contact and accidental injection.

### Signs and symptoms of exposure

Signs of toxicity include drowsiness; dizziness; disorientation; confusion; lightheadedness; tremulousness; psychosis; nervousness; apprehension; agitation; euphoria; tinnitus; visual disturbances including blurred or double vision; nausea; vomiting; paresthesia; sensations of heat, cold or numbness; difficulty swallowing; dyspnea; and slurred speech. Muscle twitching or tremors, seizures, unconsciousness, coma, and respiratory depression and arrest may also occur.

### Summary of Toxicology

#### Human

Adverse effects of the drug mainly involve the CNS because of its rapid entry in the brain. Shortly following the CNS effects, patients with lignocaine toxicity may also experience cardiovascular effects. If the patient is supported through this period, the drug rapidly distributes away from the heart, and spontaneous cardiac function returns.

#### Animal

In rats persistent functional impairment and histologic damage in the nerve roots and the spinal cord was less severe after epidural lidocaine than after intrathecal lidocaine. In 8 New Zealand Rabbits receiving 0.2 mL 1% lidocaine hydrochloride applied intracamerally to the lenses, had morphological abnormalities in both cornea and iris of the lidocaine injected eyes. Another experiment in rabbits with 2% lidocaine HCl applied intracamerally on the corneal endothelium found that lidocaine caused statistically significant corneal thickening and clinically significant corneal opacification. Lidocaine injection into the dorsal root ganglion of rats produced hyperalgesia, possibly due to activation of resident satellite glial cells. One-hour exposure of primary rabbit urothelial cells (PRUC) culture to 0.5 or 1.0% lidocaine decreased cell viability. Lidocaine rapidly crosses the placenta in pregnant guinea pigs. High concentrations are found in the fetal liver, heart, and brain. High myocardial levels of drug in the fetus may possibly account for marked depressant effects that local anesthetics produce. In another study, no significant effects were observed in offspring of rats administered lidocaine at by constant infusion for 2 weeks before mating and throughout pregnancy. Additionally, pregnancy did not enhance the CNS and cardiovascular toxic effects of lidocaine when studied in pregnant sheep receiving continuous IV drug infusion and compared to data from nonpregnant ewes. Lidocaine did not induce genotoxicity in the wing somatic mutation and recombination test in *Drosophila melanogaster*, which detects point and chromosomal mutations as well as recombination induced by the activity of genotoxins of direct and indirect action. Lidocaine 0.25% did decrease cell viability and caused DNA degradation in murine fibroblasts 3T6. Lidocaine was not oncogenic when administered topically weekly to the dorsal skin of mice for 26 weeks.

### Acute Toxicity:

#### LD<sub>50</sub> Oral

Rat:	317 mg/kg
Mouse:	292 mg/kg

#### LD<sub>50</sub> ip

Mouse:	105 mg/kg
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Rat	133 mg/kg
LD <sub>50</sub> iv Mouse	19.5 mg/kg
LD <sub>50</sub> sc Rat	335 mg/kg
Mouse	238 mg/kg

## SECTION 12 ECOLOGICAL INFORMATION

No ecological data are available for this material.

## SECTION 13 DISPOSAL CONSIDERATIONS

Disposal methods and containers:

Dispose of empty container by wrapping with paper and place in garbage.

Unused product should be disposed of in accordance with local authority instructions.

Special precautions for landfill or incineration:

Do not burn unused product or containers. Seek advice from local municipal authority before disposing of unused product in local authority landfill.

## SECTION 14 TRANSPORT INFORMATION

Not classified as dangerous goods under the United Nations Recommendations on the Transport of Dangerous Goods or the Australian Code for the Transport of Dangerous Goods by Road or Rail.

## SECTION 15 REGULATORY INFORMATION

New Zealand

Nopaine 2% Injection is registered as a veterinary medicine under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and Regulations.

Registration Number: **A006597**

For conditions of registration see [www.mpi.govt.nz/](http://www.mpi.govt.nz/)

HSNO approval number: HSR002330

Hazard classifications: 6.3B, 6.6B, 6.7B, 6.9B (All)

For full listing of controls see [www.epa.govt.nz/](http://www.epa.govt.nz/)

Australia

Lignocaine hydrochloride is a scheduled poison (Schedule 2 – Pharmacy medicine; Schedule 4 – Prescription Only Medicine, or Prescription Animal Remedy; Schedule 5 – Caution) under the Australian Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

Lignocaine hydrochloride has been identified as not requiring assessment under the Australian National Industrial Chemicals Notification and Assessment Scheme as it is controlled under legislation specific to human and animal health.

## SECTION 16 OTHER INFORMATION

SDS version:	2
Date of Revision:	May 2018
Update of sections:	Update to GHS

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**References:**

1. FAISD Handbook, Handbook of First Aid Instructions, Safety Directions, Warning Statements, and General Safety Precautions for, Agricultural and Veterinary Chemicals, (as updated), <https://apvma.gov.au/node/26586>
2. Model Code of Practice: Preparation of safety data sheets for hazardous chemicals, <https://www.safeworkaustralia.gov.au/doc/model-code-practice-preparation-safety-data-sheets-hazardous-chemicals>
3. AICS (Australian Inventory of Chemical Substances), Safework Australia, <https://www.nicnas.gov.au/forms/Australian-Inventory-of-Industrial-Substances>
4. APVMA Guidelines for registration of veterinary chemical products - <https://apvma.gov.au/node/6>
5. ADI [Acceptable Daily Intake] List, Commonwealth Department of Health & Aged Care, TGA, (as updated)
6. The Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) 7<sup>th</sup> Edition
7. The Poisons Standard (as updated), National Drugs and Poisons Schedule Committee, <https://www.tga.gov.au/publication/poisons-standard-susmp>
8. Hazardous Substances Information System, Safework Australia (as updated), <http://hcis.safeworkaustralia.gov.au/>
9. Globally Harmonized System of Classification and Labelling of Chemicals (GHS), Seventh Revised Edition, United Nations, New York and Geneva, 2017, [https://www.unece.org/trans/danger/publi/ghs/ghs\\_rev07/07files\\_e.html](https://www.unece.org/trans/danger/publi/ghs/ghs_rev07/07files_e.html)
10. NIOSH Pocket Guide to Chemical Hazards
11. Chemical Classification and Information Database (CCID) (as updated), New Zealand Environmental Protection Authority: <https://www.epa.govt.nz/database-search/chemical-classification-and-information-database-ccid/>
12. European Chemical Agency (ECHA), Information on Chemicals, <https://echa.europa.eu/information-on-chemicals>

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