ISSUED: 27 November 2018

SAFETY DATA SHEET

Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

Product Name:	**Buprelieve Injection (currently registered and previously marketed as Bupredyne Injection)**
Product Identifier:	0.3 mg/mL Buprenorphine (as hydrochloride), an analgesic injection for dogs and cats
Product Code:	504410 (10 mL) – Bupredyne Injection 504411 (10 mL) – Buprelieve Injection
Recommended Use:	An analgesic injection for dogs and cats.
Restrictions on Use:	For animal treatment only.
Company Identification:	Jurox Pty Limited
Address:	85 Gardiner Street, Rutherford, NSW 2320 Australia
Email:	customerservice@jurox.com.au
Customer Centre:	1800 023 312
National Poisons Information Centre:	13 1126 (24 hrs)
Emergency Telephone Number:	1800 023 312 (9am – 5pm, Monday to Friday)

Section 2: HAZARDS IDENTIFICATION

GHS Hazard Classifications: This product has been assessed according to GHS and is classified as non-hazardous. However, buprenorphine hydrochloride is a potent narcotic drug and is a Schedule 8 controlled substance. Buprenorphine hydrochloride may cause physical and/or psychological dependence, can harm the developing foetus, and affects the central nervous system and digestive system.

GHS Label Elements:

Signal word: None.

GHS Pictograms: None.

Precautionary statements: None.

Section 3: COMPOSITION / INFORMATION on INGREDIENTS

INGREDIENT	CAS No.	CONTENT
Buprenorphine hydrochloride	53152-21-9	0.032%
Ingredients not contributing to the hazards	-	> 90%

Section 4: FIRST AID MEASURES

General Information: Consult the National Poisons Centre on 13 1126 or a doctor immediately in every case of suspected chemical poisoning. Never give fluids or induce vomiting if a patient is unconscious or convulsing regardless of cause of injury. If medical advice/attention is needed, have this SDS, product container or label at hand.

Symptoms and Effects of Exposure: Signs of an acute overdose of buprenorphine include: sedation, nausea, vomiting, slowed breathing, hallucinations, extreme weakness, hypotension, fainting, coma, and cold, clammy skin.

Inhalation: Is unlikely to present an inhalation problem. If respiratory symptoms do occur, remove patient to fresh air. Lay patient down and keep warm and rested.

Ingestion: If swallowed do NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Contact a doctor or the National Poisons Centre on 13 1126 immediately.

Skin: If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

Eye: If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. If eye irritation persists, get medical advice/attention.

Recommended First Aid Facilities: Ready access to running water and soap is required. Accessible eyewash is required.

Advice to Doctor: Buprelieve Injection contains buprenorphine, a potent opioid analgesic that can produce sedation and respiratory depression. Naloxone may not be effective in reversing the respiratory depression produced by buprenorphine hydrochloride. Therefore, the primary management of overdose should be the reestablishment of adequate ventilation with mechanical assistance of respiration, if required.

Section 5: FIRE FIGHTING MEASURES

Flash Point: No data. Product is predominantly water and non-combustible.

Hazardous Combustion Products: If involved in a fire, may emit noxious and irritant fumes.

Extinguishing Media: There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

Protective Equipment: Protective gloves and breathing apparatus.

HAZCHEM Code: None.

Section 6: ACCIDENTAL RELEASE MEASURES

Spills and Disposal: No special protective clothing is normally necessary. For small spills, wash area well with excess water. For large spills, exclude non-essential people from the area. Contain spill and absorb with inert material such as soil, sand or absorbent granules and place in a sealable waste container. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely in an approved landfill.

Protective Clothing: For appropriate personal protective equipment see section 8.

Environmental Precautions: Prevent from entering drains, waterways or sewers. If spill does enter waterways contact local authority.

Section 7: HANDLING AND STORAGE

Handling: This is a Schedule 8 (Controlled Drug) product and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Possession without authority is illegal. Handle this product with care to avoid exposure, taking all recommended precautions. Avoid contact with skin, eyes and inhalation of vapours. Take care to avoid accidental self-injection. Use personal protective equipment as required. Do not eat, drink or smoke while handling product.

Storage: Buprelieve Injection is a Controlled Drug (S8) and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Possession without authority is illegal. Keep out of reach of children. Store below 25ºC (air conditioning). Protect from light. Store away from foodstuffs.

Other Information: Avoid contact with incompatible substances as listed in Section 10. Always read the label before use.

Section 8: EXPOSURE CONTROLS and PERSONAL PROTECTION

This SDS describes personal protective measures relating to long term industrial and manufacturing exposure and emergency situations, such as accidents and spills. See product label for personal protective measures during normal use of the marketed product.

Exposure Limits: An exposure limit for the mixture has not been established. No exposure standards for the ingredients are available.

Engineering Controls: Use only in a well-ventilated area. Make sure that the work environment remains clean and that vapours and mists are minimised.

Personal Protective Equipment (PPE):

Eye protection: Protective glasses or goggles are recommended when bulk quantities of this product are being handled.

Skin protection: When handling bulk quanitites, prevent skin contact by wearing chemical protective gloves e.g. PVC.

Respiratory protection: Not required for the normal use of this product.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	A clear, colourless solution
Odour:	Not available
Odour Threshold:	Not available
pH:	3.5 – 5.5
Melting Point / Freezing point:	Not available
Initial Boiling Point and Boiling Range:	Not available
Flashpoint:	Not available
Evaporation Rate:	Not available

Upper / Lower Flammability or Explosive Limits:	Not available
Vapour Pressure:	Not available
Vapour Density:	Not available
Relative Density:	1.003 – 1.033
Solubility:	Soluble in water
Partition Coefficient:	Not available
Auto-Ignition Temperature:	Not available
Decomposition Temperature:	Not applicable
Viscosity:	Not available

Section 10: STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or polymerise under normal storage conditions.

Stability: When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

Conditions to Avoid: Protect this product from light.

Incompatible Materials: Oxidising agents.

Hazardous Decomposition Products: No data available.

Section 11: TOXICOLOGICAL INFORMATION

Signs & Symptoms of Exposure: Exposure may cause nausea and vomiting may occur. May cause tiredness, numbness, weakness of limbs, irritability, hallucinations, and rapid or shortened breathing. May also cause nausea, vomiting, headache, and sweating.

Medical Conditions Generally Aggravated by Exposure: Persons sensitive to buprenorphine hydrochloride may experience allergic reaction. Buprenorphine exposure may also aggravate liver, kidneys, and pulmonary disease conditions, pre-existing central nervous system, ocular, gastrointestinal ailments, hypothyroidism, and adrenocortical insufficiency. Exposure is not recommended for pregnant women since buprenorphine can cross the placental barrier.

Acute Toxicity:
Ingestion: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the oral route. However, buprenorphine is readily absorbed sublingually and through the lining of the mouth. Acute effects may include nausea, dizziness/vertigo, hypoventilation, sweating, hypotension, vomiting, miosis and headache.

Buprenorphine hydrochloride: Oral LD_{50}: > 1000 mg/kg (rat); 800 mg/kg (mouse).

Inhalation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the inhalation route. Due to the nature of the product, exposure by inhalation is unlikely.

Dermal: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be acutely toxic by the dermal route.

Injection : Buprenorphine hydrochloride:
Subcutaneous LD_{50}: > 1000 mg/kg (rat, mouse) ;
Intramuscular LD_{50} : <600 mg/kg (rat, mouse) ;
Intravenous LD50 : 62 mg/kg (rat), 72 mg/kg (mouse).

Skin Corrosion / Irritation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be skin corrosive or irritant.

Serious Eye Damage / Irritation: Not data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be eye corrosive or irritant.

Respiratory or Skin Sensitisation: No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as a skin sensitiser or a respiratory sensitiser.

Germ Cell Mutagenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.

Carcinogenicity: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.

Reproductive Toxicity: Buprenorphine is listed as a TGA Pregnancy Category C chemical (Drugs which, owing to their pharmacological effects, have caused or may be suspected of causing, harmful effects on the human foetus or neonate without causing malformation. These effects may be reversible). Buprenorphine readily crosses the placental barrier and may cause respiratory depression in neonates. During the last three months of pregnancy, chronic use of buprenorphine may be responsible for a withdrawal syndrome in neonates.

STOT: Single exposure: No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a specific target organ toxicant after single exposure. As with other potent opioids, clinically significant respiratory depression may occur after single exposure.

STOT: Repeat exposure: No data for the mixture is available. Prolonged continuous use of buprenorphine may result in physical dependence or tolerance (a decrease in response to a given dose). May cause damage to organs through prolonged or repeated exposure. Possible target organs include the central nervous system, cardiovascular system, respiratory system and the gastrointestinal system.

Aspiration hazard: No data available.

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Information on the environmental toxicity of buprenorphine hydrochloride is not currently available.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation potential	Mobility
Buprenorphine hydrochloride	No data available	No data available	No data available	No data available

Section 13: DISPOSAL INFORMATION

Product Disposal: Dispose of product only by using according to label or at an approved landfill.

Container Disposal: Crush or puncture and bury in an approved landfill if an approved recycling system is not available.

Section 14: TRANSPORT INFORMATION

Not considered a Dangerous Good for land, sea and air transport.

Section 15: REGULATORY INFORMATION

Poison Schedule (SUSMP): S8

APVMA No.: 69057

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations.

Section 16: OTHER INFORMATION

Legend:

ADG	Australian Code for the Transport of Dangerous Goods by Road & Rail, 7th Edition.
AICS	Australian Inventory of Chemical Substances.
BCF	Bioconcentration Factor. The ratio of a chemical's concentration in an organism or biota to the chemical's concentration in water.
CAS No.	Chemical Abstracts Service Registry Number.
EC_{50}	The median effect concentration, being a statistically derived concentration of a substance that can be expected to cause an adverse reaction in 50% of organisms a 50% reduction in growth or in the growth rate of organisms.
GHS	Globally Harmonized System of Classification and Labelling of Chemicals.
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
HSIS	Hazardous Substances Information System.
LD_{50}	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme.
PPE	Personal Protective Equipment.
PVC	Polyvinyl Chloride.
SDS	Safety Data Sheet.
STOT	Specific Target Organ Toxicity.
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons.
SWA	Safe Work Australia.

References:

ChemID Plus

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

This version issued: 27 November 2018 and is valid for 5 years from this date.

Supercedes: This version supercedes the version created on 12 July 2018.

Revision History:

Date of Revision	Reason
12 July 2018	Change of product name from 'Bupredyne Injection' to 'Buprelieve Injection'
27 November 2018	Minor updates to Section 1

END OF SDS