

**SAFETY DATA SHEET****Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY**

<b>Product Name:</b>	<b>Reliven Injection</b>
<b>Product Identifier:</b>	5 mg/mL meloxicam, an anti-inflammatory injection for dogs and cats.
<b>Product Code:</b>	504210 (20 mL)
<b>Recommended Use:</b>	<u>Dogs:</u> For alleviation of inflammation and pain in both acute and chronic musculoskeletal disorders. For reduction of post-operative pain and inflammation following orthopaedic and soft tissue surgery in dogs. <u>Cats:</u> For reduction of pain after surgery. For management of febrile conditions in combination with appropriate antibiotics.
<b>Restrictions on Use:</b>	For animal treatment only.
<b>Company Identification:</b>	Jurox Pty Limited
<b>Address:</b>	85 Gardiner Street Rutherford, NSW 2320, Australia
<b>Customer Centre:</b>	1800 023 312
<b>Email:</b>	customerservice@jurox.com.au
<b>National Poisons Information Centre:</b>	13 1126 (24 hours)
<b>Emergency Telephone Number:</b>	1800 023 312 (9a.m. – 5p.m, Monday to Friday)

**Section 2: HAZARDS IDENTIFICATION**

**GHS Hazard Classifications:** This product has been assessed according to GHS and is classified as follows:

GHS Category	Hazard code	Hazard Statement
Flammable Liquid Category 3	H226	Flammable liquid and vapour
Eye Irritant Category 2A	H319	Causes serious eye irritation

**GHS Label Elements:**

Signal Word:

**WARNING**

Pictograms:



Flame



Exclamation mark

Precautionary Statements:Prevention

P210 Keep away from heat / sparks / open flames / hot surfaces – No smoking.

P233 Keep container tightly closed.

P241 Use explosion-proof electrical/ventilating/lighting/intrinsically safe equipment.

P242 Use only non-sparking tools.

P243 Take precautionary measures against static discharge.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves / eye protection / face protection.

Response

P370 + P378 In case of fire: Use water spray / fog for extinction.

P303 + P361 + P353 IF ON SKIN (or hair): Remove / Take off immediately all contaminated clothing. Rinse skin with water / shower.

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.

Storage

P403 + 235 Store in a well-ventilated place. Keep cool.

Disposal

P501 Dispose of unused product in accordance with local regulations.

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

**Other hazards:** Accidental self-injection may give rise to pain. People with known hypersensitivity to NSAIDs should avoid contact with the veterinary medicinal product. Typical adverse reactions of NSAIDs such as loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure have occasionally been reported. In very rare cases elevated liver enzymes have been reported.

N.B.: These statements are determined by Work Health and Safety regulations and may not reflect Signal Headings and First Aid and Safety statements on product labelling, which are determined by a competent authority during assessment for registration.

**Section 3: COMPOSITION / INFORMATION on INGREDIENTS**

INGREDIENT	CAS No.	CONTENT
Ethanol	64-17-5	15%
Meloxicam	71125-38-7	0.5%
Ingredients not contributing to the hazards		>60%

**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:** Loss of appetite, vomiting, diarrhoea, faecal occult blood, lethargy and renal failure.

**Inhalation:** If respiratory symptoms occur, remove patient to fresh air. Lay patient down and keep warm and rested. If breathing is shallow or has stopped, ensure airway is clear and apply resuscitation. If breathing is difficult, give oxygen. Seek medical assistance immediately.

**Ingestion:** If swallowed, DO NOT induce vomiting. Rinse mouth. Keep subject warm and at rest. For advice, contact a doctor or the National Poisons Centre on 13 1126.

**Skin:** If skin contact occurs, wash affected area thoroughly with plenty of soap and water for at least 20 minutes. If skin irritation or rash occurs, get medical advice/attention.

**Eye:** If eye contact occurs, rinse cautiously with water for at least 20 minutes. Continue rinsing. If eye irritation persists, get medical advice/attention.

**Injection:** Possible swelling at injection site. Treat as for needle stick injury. Wash the wound thoroughly with soap and water or use a waterless cleanser or antiseptic if water is unavailable. Apply a dressing as necessary, and apply pressure through the dressing if bleeding is still occurring. Do not squeeze or rub the injury site. Dispose of the needle in a suitable sharps container and seek medical advice/attention immediately.

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

**Advice to Doctor:** Meloxicam is a non-steroidal anti-inflammatory (NSAID). The usual symptoms of overdose include lethargy, drowsiness, nausea, vomiting and epigastric pain. Treat symptomatically. Gastrointestinal bleeding may occur. Anaphylactoid reactions are possible. Hypertension, acute renal failure, respiratory depression and coma occasionally occur.

## Section 5: FIRE FIGHTING MEASURES

**Flash Point:** 36-49°C.

**Hazardous Combustion Products:** Flammable liquid. Moderate fire hazard when exposed to heat or flame. Combustion products include carbon monoxide, carbon dioxide and other pyrolysis products typical of burning organic material.

**Extinguishing Media:** Foam, dry chemical powder, BCF (where regulations permit), carbon dioxide, water spray or fog (large fires only).

**Protective Equipment:** For bulk product: Safety glasses with side shields / chemical goggles. Chemical protective gloves e.g. PVC. Safety footwear or safety gumboots e.g. rubber. Overalls / PVC apron – PVC protective suit may be required if exposure severe. Respiratory protection – Type A filter of sufficient capacity. Eyewash unit. Ready access to a safety shower.

**Hazchem Code:** •3Y

## Section 6: ACCIDENTAL RELEASE MEASURES

**Spills and Disposal:** Wear appropriate protective clothing. For small spills (i.e. those associated with normal use of the product), wipe up spill with paper towels or other suitable materials. Rinse area with 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 contamination of drains and waterways occurs, advise local authority.

## Section 7: HANDLING AND STORAGE

**Handling:** The product should be handled with care to avoid exposure. 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:** Store in original container, away from foodstuffs. Store below 30°C (room temperature). Keep out of reach of children.

**Other Information:** Always read the label before use. See label for further information on handling and storage.

## Section 8: EXPOSURE CONTROLS/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:** No exposure limits have been assigned for this product. Known exposure limits for ingredients are as follows:

Occupational Exposure Limits (OEL)

Australian Exposure Standards

INGREDIENT	TWA	STEL
Ethanol	1880 mg / m <sup>3</sup> / 1000 ppm	Not available

Emergency Limits

INGREDIENT	TEEL-1	TEEL-2	TEEL-3
Ethanol	Not available	Not available	15000 ppm

**Engineering Controls:** Use only in a well ventilated area. Ensure that the work environment remains clean.

**Personal Protective Equipment (PPE):**

Eye Protection: Protective glasses or goggles are recommended when handling bulk quantities of this product.

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

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

Other: For the bulk product, overalls, PVC apron or protective suit. Have eyewash unit at hand. Ensure there is ready access to a safety shower.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, yellow solution.	<b>Upper / Lower Flammability Limits:</b>	Not available.
<b>Odour:</b>	Not available.	<b>Vapour Pressure:</b>	Not available.
<b>Odour Threshold:</b>	Not available.	<b>Vapour Density:</b>	Not available.
<b>pH:</b>	6.5-7.5	<b>Relative Density / Specific Gravity:</b>	Not available.
<b>Melting Point / Freezing Point:</b>	Not available.	<b>Solubility:</b>	Miscible in water.
<b>Boiling Point and Boiling Range:</b>	Not available.	<b>Partition Coefficient (n-octanol/water):</b>	Not available.
<b>Flash Point:</b>	36-49°C	<b>Auto-Ignition Temperature:</b>	Not available.
<b>Evaporation Rate:</b>	Not available.	<b>Decomposition Temperature:</b>	Not available.
<b>Flammability:</b>	Flammable	<b>Viscosity:</b>	Not available.

## Section 10: STABILITY AND REACTIVITY

**Reactivity:** May react with oxidizing agents.

**Chemical Stability:** When stored appropriately this product should show no significant degradation within the expiry period shown on the label. Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur.

**Conditions to Avoid:** Extreme temperatures.

**Incompatible Materials:** Oxidising agents.

**Hazardous Decomposition Products:** Heating may cause expansion or decomposition leading to violent rupture of containers. Combustion products include carbon monoxide, carbon dioxide, other pyrolysis products typical of burning organic material.

## Section 11: TOXICOLOGICAL INFORMATION

### **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, exposure to meloxicam may cause gastrointestinal tract discomfort and produce nausea and vomiting. In an occupational setting, ingestion of insignificant quantities is not thought to be cause for concern.

Ethanol: Oral (rat) LD<sub>50</sub>: 7060 mg/kg

Meloxicam: Oral (mouse) LD<sub>50</sub>: 470 mg/kg

**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.

Ethanol: Inhalation (rat) LC<sub>50</sub>: 63926.976 mg/l/4h

**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.

Ethanol: Dermal (rabbit) LD<sub>50</sub>: 17100 mg/kg

**Injection:** Avoid needle stick injury. Accidental self-injection may give rise to pain.

**Aspiration Hazard:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an aspiration hazard.

**Respiratory Irritation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a respiratory irritant.

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

**Serious Eye Damage / Irritation:** Based on available data for the ingredients, the mixture is considered to be an Eye Irritant Category 2A.

Ethanol: Eye (rabbit): 500 mg - Severe irritation, 100 mg / 24 hr - Moderate irritation

**Respiratory or Skin Sensitisation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a skin sensitiser or 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:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be a reproductive toxicant. However, animal studies have shown meloxicam caused a reduction in birth index, live births, and neonatal survival at oral doses greater than or equal to 0.125 mg/kg/day when treated during the late gestation and lactation period.

**Specific Target Organ Toxicity (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.

**Specific Target Organ Toxicity (STOT): Repeated 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 repeat exposure. However, substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure:

**Ethanol:** Prolonged exposure to ethanol may cause damage to the liver and cause scarring. It may also worsen damage caused by other agents.

**Meloxicam:** Prolonged use of non-steroidal analgesics damages the lining of the gastrointestinal tract, causing ulcers and bleeding. There may be diarrhoea or constipation, perforations causing serious infection, and blood in the vomit or stools.

### Section 12: ECOLOGICAL INFORMATION

**Ecotoxicity:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as ecotoxic by GHS criteria.

**Ethanol:**

LC<sub>50</sub> (96 hr) (fish): 42 mg/L  
EC<sub>50</sub> (48 hr) (crustacea): 2 mg/L  
EC<sub>50</sub> (96 hr) (algae / aquatic plants): 17.921 mg/L  
NOEC (2016 hr) (fish): 0.000375 mg/L

**Meloxicam:** Daphnia EC<sub>50</sub> (48 h): > 1 mg/L

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Ethanol	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)	LOW (LogKOW = -0.31)	HIGH (KOC = 1)
Meloxicam	No data available	No data available	LOW	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:** Dispose of empty container by wrapping with paper and putting in garbage.

### Section 14: TRANSPORT INFORMATION

**Dangerous Goods Classification:** Under special provisions 144 of the Australian Dangerous Goods Code, an aqueous solution containing not more than 24% alcohol by volume is not subject to this Code. Therefore not considered a Dangerous Good for land, sea and air transport.

**HAZCHEM Code:** •3Y

### Section 15: REGULATORY INFORMATION

**Poisons Schedule:** S4

**APVMA Registration No:** 65707

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

**SUSMP:** Meloxicam is listed in the SUSMP.

**Section 16: OTHER INFORMATION****Legend:**

<b>AICS</b>	Australian Inventory of Chemical Substances.
<b>APVMA</b>	Australian Pesticides and Veterinary Medicines Authority.
<b>BCF</b>	Bromochlorodifluoromethane.
<b>CAS No.</b>	Chemical Abstracts Service Registry Number.
<b>CNS</b>	Central nervous system.
<b>EC<sub>50</sub></b>	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 or a 50% reduction in growth or in the growth rate of organisms.
<b>GHS</b>	Globally Harmonized System of Classification and Labelling of Chemicals.
<b>Hazchem Code</b>	Emergency action code of numbers and letters that provide information to emergency services especially firefighters.
<b>KOC</b>	Soil-Water Partition Coefficient. The ratio of a chemical's concentration that is adsorbed in the soil to the concentration of chemical in solution.
<b>KOW</b>	Octanol Water Partition Coefficient. The ratio of a compound's concentration in a known volume of n-octanol to its concentration in a known volume of water after the octanol and water have reached equilibrium.
<b>LC<sub>50</sub></b>	The median lethal concentration, being a statistically derived concentration of a substance that can be expected to cause death in 50% of animals.
<b>LD<sub>50</sub></b>	The median lethal dose, being a statistically derived single dose of a substance that can be expected to cause death in 50% of animals.
<b>NICNAS</b>	National Industrial Chemicals Notification and Assessment Scheme.
<b>NSAID</b>	Non-steroidal anti-inflammatory drug.
<b>OEL</b>	Occupational Exposure Limits.
<b>PPE</b>	Personal Protective Equipment.
<b>PVC</b>	Polyvinyl chloride.
<b>STEL</b>	Short term exposure limit.
<b>STOT</b>	Specific Target Organ Toxicity.
<b>SUSMP</b>	Standard for the Uniform Scheduling of Medicines and Poisons.
<b>TEELs</b>	Temporary Emergency Exposure Limits. Guidelines designed to predict the response of members of the general public to different concentrations of a chemical during an emergency response incident.
<b>TEEL-1</b>	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience notable discomfort, irritation, or certain asymptomatic, nonsensory effects. However, these effects are not disabling and are transient and reversible upon cessation of exposure.
<b>TEEL-2</b>	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience irreversible or other serious, long-lasting, adverse health effects or an impaired ability to escape.
<b>TEEL-3</b>	The airborne concentration of a substance above which it is predicted that the general population, including susceptible individuals, could experience life-threatening adverse health effects or death.
<b>TWA</b>	Time-Weighted Average. The average exposure over a specified period, usually a nominal eight hours.

**References:**

ChemIDPLusLite, <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp> entries for Meloxicam (RN: 71125-38-7).

Hazardous Substances Data Bank (HSDB), <http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB> entry for Meloxicam (CASRN: 71125-38-7).

VSDB (Veterinary Substances Database, <http://sitem.herts.ac.uk/aeru/vsdb/>), entry for meloxicam.



**This version issued:** 12 March 2018 and is valid for 5 years from this date.

**Supercedes:** This version supercedes the version issued on 18 March 2013.

**Revision History:**

Date of Revision	Reason
12 March 2018	Minor updates to all the sections of SDS. Addition of Revision History in Section 16.

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**END OF SDS**