

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

<b>Product Name:</b>	<b>PROLET 20 MG TABLETS FOR SMALL DOGS PROLET 50 MG TABLETS FOR DOGS</b>
<b>Product Code:</b>	502680 (100 x 20 mg); 502675 (500 x 20 mg); 502485 (100 x 50 mg); 502490 (500 x 50 mg)
<b>Recommended Use:</b>	A non-steroidal anti-inflammatory drug for the relief of pain and inflammation in dogs.
<b>Company Identification:</b>	Jurox Pty Limited
<b>Address:</b>	85 Gardiner Street Rutherford NSW 2320 Australia
<b>Email:</b>	customerservice@jurox.com.au
<b>Customer Centre:</b>	1800 023 312
<b>National Poisons Information Centre:</b>	131126 (Australia-wide)
<b>Emergency Telephone Number:</b>	1800 023 312 (Monday- Friday, 9a.m. – 5p.m.)

**Section 2: HAZARDS IDENTIFICATION**

<b>Hazard Classifications:</b>	<b>Considered a Hazardous Substance according to the criteria of GHS.</b>  <b>Not considered a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.</b>
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**GHS Hazard Classification:\***

GHS Category	Hazard code	Hazard Statement
Acute Toxicity (Oral) Category 3	H301	Toxic if swallowed.
Skin Sensitizer Category 1	H317	May cause an allergic skin reaction.
Reproductive Toxicity Category 1B*	H360	May damage fertility or the unborn child.*
Acute Aquatic Hazard Category 2	H401	Toxic to aquatic life.
Chronic Aquatic Hazard Category 2	H411	Toxic to aquatic life with long lasting effects.

\*LIMITED EVIDENCE

**GHS Pictograms\*:****Skull and crossbones****Health hazard****Aquatic pollutant****Signal Word\*:****DANGER****Precautionary Statements\*:****Prevention**

- P201 Obtain special instructions before use.
- P270 Do not eat, drink or smoke when using this product.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P281 Use personal protective equipment as required.
- P261 Avoid breathing dust/fumes.
- P273 Avoid release to the environment.

**Response**

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P308+P313	IF exposed or concerned: Get medical advice.
P330	Rinse mouth.
P333+P313	If skin irritation or rash occurs: Get medical advice.
P363	Wash contaminated clothing before reuse.

**Storage**

P405 Store locked up.

**Disposal**

P501 Dispose of contents / container in accordance with local / national regulations.

\* 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
Carprofen	53716-49-7	33.3 %
Other non-hazardous ingredients		>60%

**Section 4: FIRST AID MEASURES**

<b>General information:</b>	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 product container or label at hand.
<b>Inhalation:</b>	Unlikely to present an inhalation problem.
<b>Ingestion:</b>	If swallowed, DO NOT induce vomiting. Rinse mouth with water. If vomiting occurs, maintain a clear and open airway. For advice, contact the National Poisons Centre on 13 1126. Seek medical assistance immediately. Show this SDS to a medical practitioner.
<b>Skin:</b>	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.
<b>Eye:</b>	If eye contact occurs, rinse cautiously with water for at least 20 minutes. Remove contact lenses, if present and easy to do. If eye irritation persists, get medical advice.
<b>Advice to Doctor:</b>	Contains carprofen, which is a non-steroidal anti-inflammatory agent. Treat symptomatically.

**Section 5: FIRE FIGHTING MEASURES**

<b>Flash Point:</b>	Not Applicable.
<b>Hazardous Combustion Products:</b>	If involved in a fire, may emit toxic and corrosive fumes.
<b>Extinguishing Media:</b>	There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.
<b>Protective Equipment:</b>	Protective gloves and boots and breathing apparatus.
<b>Special Hazards:</b>	Avoid contamination with oxidising agents as ignition may result.
<b>HAZCHEM Code:</b>	None specified

**Section 6: ACCIDENTAL RELEASE MEASURES**

<b>Spills and Disposal:</b>	Due to the nature of the packaging, large spills are unlikely to occur. In the event of a large spill, wear appropriate protective clothing. Exclude non-essential people from the area. Use dry
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clean up procedures and avoid generating dust. Ventilate area and wash spill site after pick-up complete. Dispose of waste safely.

**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 Emergency Services.

### Section 7: HANDLING AND STORAGE

**Handling:** This is a Schedule 4 (Prescription Animal Remedy) product, available only to or through a veterinarian. Handle this product with care to avoid exposure, taking all recommended precautions. Avoid contact with skin and eyes. Wash hands after use.

**Storage:** Keep out of reach of children. Store below 30°C (room temperature) in a dry place. Protect from light. Store away from foodstuffs.

**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. Do not handle until all safety precautions have been read and understood.

**Engineering Controls:** Do not handle until all safety precautions have been read and understood. Make sure that the work environment remains clean.

**Personal Protective Equipment (PPE):** Eye protection: Safety glasses with eye side shields or chemical 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. Safety footwear or safety gumboots, e.g. rubber.

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

**Hygiene Precautions:** Do not drink, eat or smoke when handling this product. Wash hands after use.

### Section 9: PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** White, half-scored tablets.

**Odour:** Not available.

**Odour threshold:** Not available.

**pH:** Not applicable.

**Melting Point:** Not available.

**Boiling Point:** Not available.

**Flash Point:** Not flammable.

**Evaporation Rate:** Not available.

**Flammability:** Not applicable.

**Upper flammability limits:** Not applicable.

**Lower flammability limits:** Not applicable.

**Vapour Pressure:** Not applicable.

**Vapour density:** Not applicable.

**Relative density:** Not applicable.

**Specific Gravity:** Not applicable.

**Solubility in Water:** Disintegrates in water.

**Partition coefficient:** Not applicable.

**Auto-ignition temperature:** Not available.

**Decomposition temperature:** Not available.

**Viscosity:** Not applicable.

**Section 10: STABILITY AND REACTIVITY**

<b>Reactivity:</b>	This product is unlikely to react or polymerise under normal storage conditions.
<b>Stability:</b>	When stored appropriately this product should show no significant degradation within the expiry period shown on the labelling.
<b>Conditions to Avoid:</b>	Extreme temperatures.
<b>Incompatible Materials:</b>	Avoid oxidising agents.
<b>Hazardous Decomposition Products:</b>	Decomposes on heating and produces carbon dioxide (CO <sub>2</sub> ), hydrogen chloride, phosgene, nitrogen oxides. May emit poisonous fumes.

**Section 11: TOXICOLOGICAL INFORMATION**

<b>Acute Toxicity:</b>	<p><b>Inhalation:</b> Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual.</p> <p><b>Ingestion:</b> Based on available data for the ingredients, the mixture is considered to be toxic if swallowed - Acute Toxicity (Oral) Category 3. Non-steroidal anti-inflammatory drug (NSAID) overdose may produce nausea, vomiting, indigestion and upper abdominal pain. Other effects may include drowsiness, dizziness, confusion, disorientation, lethargy, "pins and needles", intense headache, blurred vision, ringing in the ears, muscle twitching, convulsions, stupor and coma.</p> <p>Carprofen: Oral LD<sub>50</sub>: 282 mg/kg (mice); 149 mg/kg (rats)</p> <p><b>Dermal:</b> 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.</p>
<b>Skin Corrosion / Irritation:</b>	No data for the mixture is available. Based on available data for the ingredients, the mixture is not classified as Skin corrosive / Irritant. However, Skin contact with the material may damage the health of the individual.
<b>Serious Eye Damage / Irritation:</b>	No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant. Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
<b>Respiratory or Skin Sensitisation:</b>	Based on available data for the ingredients, the mixture is classified as Skin Sensitizer Category 1 - May cause an allergic skin reaction.
<b>Chronic Effects:</b>	Oral toxicity studies in rats have shown that repeated exposure may cause intestinal ulceration, peritonitis and mortality, especially at doses > 10 mg / kg body weight / day.
<b>Mutagenicity:</b>	No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be mutagenic.
<b>Carcinogenicity:</b>	No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be carcinogenic.
<b>Reproductive Toxicity:</b>	Based on available data for the ingredients, the mixture is classified as Reproductive Toxicity Category 1B - May damage fertility or the unborn child. Exposure to carprofen for prolonged periods may cause physical defects in the developing embryo.
<b>STOT – Single Exposure:</b>	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.
<b>STOT - Repeat exposure:</b>	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 repeated exposure. However, prolonged use of non-steroidal analgesics damages the lining of the gastrointestinal tract and may damage the kidneys.
<b>Aspiration hazard:</b>	Unlikely to present an aspiration hazard.

**Section 12: ECOLOGICAL INFORMATION**

**Ecotoxicity:** Based on available data for the ingredients, the mixture is classified as Acute Aquatic Hazard Category 2 & Chronic Aquatic Hazard Category 2 - Toxic to aquatic life with long lasting effects. The active ingredient carprofen is very toxic in the aquatic environment.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Carprofen	HIGH	HIGH	LOW	LOW

**Section 13: DISPOSAL INFORMATION**

**Product Disposal:** Dispose of product only by using according to APVMA approved label or by approved waste collection.

**Container Disposal:** Wrap with paper and place in garbage.

**Section 14: TRANSPORT INFORMATION**

**Dangerous Goods Classification:** Not classified as a Dangerous Good according to the criteria of the Australian Dangerous Goods (ADG) Code.

**Section 15: REGULATORY INFORMATION**

**Poisons Schedule:** S4

**APVMA Registration Nos:** 61915 (20 mg); 55976 (50mg)

**ACIS:** All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Carprofen is mentioned in SUSMP.

**Section 16: OTHER INFORMATION**

This information is based on data believed by Jurox Pty Limited to be accurate at the time of writing but is subject to change without notice. It is given in good faith, but no warranty expressed or implied is made as to its accuracy, completeness otherwise and no assumption of liability from howsoever arising is made by Jurox Pty Limited by reason of the provision of this information. Every person dealing with the materials referred to herein does so at his/her own risk absolutely and must make independent determinations of suitability and completeness of information from all sources to ensure their proper use.

**Legend:**

<b>ADG</b>	Australian Code for the Transport of Dangerous Goods by Road & Rail, 7 <sup>th</sup> Edition.
<b>AICS</b>	Australian Inventory of Chemical Substances.
<b>APVMA</b>	Australian Pesticides and Veterinary Medicines Authority.
<b>CAS No.</b>	Chemical Abstracts Service Registry Number.
<b>CO<sub>2</sub></b>	Carbon dioxide.
<b>EC</b>	European Commission.
<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>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>PPE</b>	Personal Protective Equipment.
<b>PVC</b>	Polyvinyl Chloride.
<b>SDS</b>	Safety Data Sheet.
<b>STOT</b>	Specific Target Organ Toxicity.
<b>SUSMP</b>	Standard for the Uniform Scheduling of Medicines and Poisons.

**References**

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

ChemID PlusLite, <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>, entry for Carprofen (RN: 53716-49-7).

**This version issued:** 08 August 2017 and is valid for 5 years from this date.

**Supersedes:** This SDS supersedes the version issued on 05 November 2012.

**Revision History:**

Date of Revision	Reason
08 August 2017	Updates to section 1, 2, 3, 4, 5, 8, 10, 11, 12, 13 & 15; Updates to Legend and addition of Revision History in Section 16.

END OF SDS