

SAFETY DATA SHEET

Zoetis New Zealand Limited



Section 1: Identification of the Substance and Supplier

Trade Name:	RIMADYL® Tablets 50mg
ACVM Registration No.:	A0070845
Classification:	Restricted Veterinary Medicine (RVM)
Recommended Use:	Oral anti-inflammatory and analgesic for relief of chronic and acute pain and inflammation in dogs.
Company Details:	Zoetis New Zealand Limited
Address:	Level 5, 8 Mahuhu Crescent Auckland Central Auckland 1010 New Zealand
Telephone No.:	0800 963 847 (Business Hours)
Emergency Telephone No.:	National Poisons Centre: 0800 POISON (0800 764 766) Emergency Services: In an emergency dial 111
Date of Preparation:	30 June 2014

Section 2: Hazards Identification

Hazard Classification:	6.1D, 6.9B, 9.3C
Priority Identifier(s):	WARNING – KEEP OUT OF REACH OF CHILDREN
Secondary Identifier(s):	6.1D May be harmful if swallowed, inhaled or absorbed through the skin. 6.9B May cause target organ damage from repeated oral exposure at high doses. 9.3C Harmful to terrestrial vertebrates.

Section 3: Composition / Information on Ingredients

Chemical Identity of Ingredients

Ingredient	CAS No.	Concentration
Carprofen	53716-49-7	333.0 g/kg
Other ingredients determined not to be hazardous.	-	-

This is a commercial product whose exact ratio of components may vary.
Trace quantities of impurities are also likely.

Section 4: First Aid Measures

Necessary First Aid Measures:	<p>For advice contact the National Poisons Centre at 0800 POISON (0800 764 766) or a doctor immediately. If the patient is not breathing begin artificial respiration and seek medical advice immediately. Never give fluids or induce vomiting if a patient is unconscious or convulsing, regardless of injury.</p> <p>Ingestion: DO NOT induce vomiting. If the patient is conscious wash mouth out with water. Do not give anything by mouth to an unconscious person. Seek medical advice immediately.</p> <p>Eye Contact: Flush the eye(s) out with running water for at least 15 minutes. Removal of contact lenses should be done with caution within 5 minutes of exposure. If symptoms develop seek medical advice immediately.</p> <p>Skin Contact: Remove any contaminated clothing and wash the affected area immediately with soap and water. If symptoms develop seek medical advice immediately.</p> <p>Inhalation: Move the patient to fresh air. If symptoms develop seek medical advice immediately.</p>
Poisoning Symptoms:	The most common symptoms include headache, tinnitus, drowsiness, nausea, vomiting, and abdominal pain.
Workplace Facilities:	No specific facilities required. Standard emergency equipment must be available.
Hygiene Practices:	Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while using this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Notes for Medical Personnel:	Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient. Note the nature of this product.

Section 5: Fire-Fighting Measures

Type of hazard:	This product is not explosive or flammable, however, irritating and possibly toxic gases may be generated by thermal decomposition or combustion.
Fire Hazard Properties:	May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.
Regulatory Requirements:	Not applicable.
Extinguishing Media & Methods:	Use carbon dioxide, dry chemical, or foam to extinguish fires involving this product.
Hazchem Code:	Not allocated.
Recommended Protective Clothing:	During large-scale fire fighting operations wear approved positive pressure, self-contained breathing apparatus and full protective turn-out gear.

Section 6: Accidental Release Measures

Personal Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment to minimise exposure. This may include eye protection, chemically resistant gloves, boots and overalls.
Environmental Precautions:	Prevent material from entering surface water drains or waterways. If a significant quantity of material enters drains, advise emergency services.
Procedure for Spills:	<ol style="list-style-type: none">1. Non-essential personnel should be evacuated from the affected area.2. Stop leak and contain the source of spill if it is safe to do so. Reposition any leaking containers to minimise further leakage.3. Absorb the spill with an absorbent material (e.g. sand).4. Collect the spilled material into labelled containers for disposal, minimising dust generation.5. Decontaminate the spill area thoroughly with detergent and water, preventing runoff from entering drains.
Procedure for Disposal:	Contaminated material must be disposed of at an approved landfill or other approved facility in accordance with local, regional and national requirements. Avoid contamination of any water supply with product or empty container.

Section 7: Handling and Storage

Handling

Precautions for Safe Handling:	No special technical protective measures required. No special handling advice required.
Regulatory Requirements:	Not required.
Handling Practices:	Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.
Approved Handlers:	Approved handlers are not required for this product.

Storage

Conditions for Safe Storage:	Store below 25°C (Air Conditioning). Protect from direct sunlight. Keep out of reach of children. Store in a well ventilated area in the original container, tightly closed, away from foodstuffs.
Store Site Requirements:	No additional requirements.
Packaging:	Store in the original container, away from foodstuffs.

Section 8: Exposure Control / Personal Protection

Always Read and Follow the Label Instructions and Warnings

Workplace Exposure Guidelines

Workplace Exposure Standards:	A time weighted average (TWA) concentration for an 8-hour day, and 5-day week has not been established by NOHS Australia for any of the major ingredients in this product. There is a blanket limit of 10 mg/m ³ for dusts or mists when limits have not otherwise been established. The ADI (Acceptable Daily Intake) for Carprofen is set at 0.005 mg/kg/day. The corresponding NOEL (No Observable Effect Level) is set at 1 mg/kg/day. Values taken from Australian ADI List, December 2005.
Application in the Workplace:	The nature of this product makes it unlikely that this level will be approached during normal handling.
Exposure Standards Outside the Workplace:	None set.
Engineering Controls:	Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.
Personal Protection:	<p>The following instructions are for those coming into frequent and / or lengthy contact with this product. For occasional handling employ precautions suitable for the conditions under which the product is being handled.</p> <p>Hands: Impervious gloves are recommended if skin contact is possible and for bulk processing operations.</p> <p>Eyes: It is always prudent to utilise protective eyewear.</p> <p>Skin: When prolonged or frequently repeated contact could occur, utilise chemically protective clothing. Selection of specific items such as a face shield, gloves, boots, or overalls will depend on the situation.</p> <p>Respiratory: Respiratory protection is not normally required; however, if necessary utilise an air-purifying respirator that complies with NZ standards.</p>
General Hygiene:	Change work clothes regularly. Avoid ingestion, contact with skin and eyes, and inhalation of dusts, mists or vapours. Do not eat, drink or smoke while handling this product. Wash hands and exposed skin before eating, drinking or smoking and after work. Wash any protective clothing after use.

Section 9: Physical and Chemical Properties

Appearance:	Off-white tablets
Odour:	Characteristic odour
Specific Gravity / Density:	No data available
Melting Point:	No specific data. Solid at normal temperatures
Boiling Point:	No data available
pH:	No data available
Solubility in Water:	No data available
Flashpoint:	Not applicable. This product is not flammable
Oxidising Properties:	Not applicable. This product is not an oxidiser
Corrosive Properties:	Not applicable. This product is not corrosive
Vapour Pressure:	Not applicable

Section 10: Stability and Reactivity

Stability of the Substance:	This product is stable under normal conditions of use.
Conditions to Avoid:	None known.
Material to Avoid:	Keep away from strong oxidisers.
Hazardous Decomposition Products:	Carbon dioxide, and if combustion is incomplete, carbon monoxide and smoke. Nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Water.
Hazardous Polymerisation:	This product is unlikely to spontaneously polymerise.
Specific Data:	No specific data available.

Section 11: Toxicological Information

HSNO Classifications

- 6.1D** May be harmful if swallowed, inhaled or absorbed through the skin.
- 6.9B** May cause target organ damage from repeated oral exposure to high doses.

Acute Effects

Ingestion:	Single dose oral toxicity is considered to be low. No hazards are anticipated from swallowing small amounts incidental to normal handling conditions. <ul style="list-style-type: none">• Oral LD₅₀ (Mouse) 282 mg/kg• Oral LD₅₀ (Rat) 149 mg/kg
Skin Contact:	Exposure to this product is not likely to cause significant irritation, nor is it likely to be absorbed through the skin in harmful amounts. <ul style="list-style-type: none">• Dermal Irritation (Rabbit) Non-irritating
Eye Contact:	Eye contact with this product is considered unlikely to cause any significant irritation or pain. <ul style="list-style-type: none">• Ocular Irritation (Rabbit) Non-irritating
Inhalation:	No inhalation hazards incidental to normal handling operations are anticipated from this product when used at room temperatures.
Sensitisation:	Not a sensitiser in experimental animals. However, workers handling this material have developed red and blotchy patches on their hands and faces.

Chronic / Long Term Effects

Subchronic Effects:	Subchronic oral toxicity studies for carprofen were conducted in rats and dogs for 13 weeks. In rats, daily administration of this material at dose of 5 mg/kg was well-tolerated. In dogs, daily administration of this material at dose levels of 5 and 25 mg/kg showed a slight change in serum enzyme values at the high dose (25 mg/kg); no signs of toxicity were seen at 5 mg/kg.
Chronic Toxicity:	Chronic oral toxicity studies for carprofen were conducted in rats and dogs. In rats, oral administration of daily doses of 1, 3, and 10 mg/kg for 2 years showed increased mortality rate, intestinal lesions, and changes in blood enzyme levels. In dogs, daily oral doses of 2 and 7 mg/kg for 1 year were well-tolerated.
Carcinogenicity:	No carcinogenic potential was detected in mice and rats at doses up to 10 mg/kg/day or in dogs given up to 25 mg/kg/day.
Mutagenicity:	No evidence of mutagenic or clastogenic activity in <i>in vitro</i> or <i>in vivo</i> tests.

Reproductive Effects: Carprofen was administered to pregnant rats, mice and rabbits. No impairment of reproduction was seen in rats or mice at doses up to 20 mg/kg/day or 40 mg/kg/day respectively. In rabbits, reduced litter size and a significantly increased percentage of early and late resorptions were seen at 20 mg/kg/day. Other non-steroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late foetal development, and lactation. Therefore, it is recommended that exposure late in pregnancy be avoided.

Teratogenicity: No evidence of teratogenicity was observed in rats for carprofen when administered at daily oral doses of 2, 6, and 20 mg/kg. However, slightly prolonged gestation, which was associated with an increased number of dead pups at birth, was observed (this is a common finding among non-steroidal, anti-inflammatory drugs). No evidence of teratogenicity was seen in studies with mice or rabbits.

At Increased Risk from Exposure: Individuals who have shown hypersensitivity to this material and individuals with heart conditions and impaired kidney and/or liver functions may be more susceptible to toxicity in cases of overexposure.

Section 12: Ecotoxicity Information

HSNO Classifications

9.3C Harmful to terrestrial vertebrates.

The environmental characteristics of this material have not been fully evaluated.
Avoid contamination of any water supply with product or empty container.

Ecotoxicity Effects

Toxicity to Birds:	No information available
Acute Toxicity to Fish:	Not applicable
Toxicity to Algae:	Not applicable
Toxicity to Aquatic Invertebrates:	Not applicable
Toxicity to Soil Dwelling Organisms:	Not applicable
Acute Toxicity to Bees:	Not applicable

Environmental Fate

No information available.

Section 13: Disposal Considerations

Product Disposal: Preferably dispose of product by use in accordance with label directions. Otherwise dispose of product at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with product.

Container Disposal: Dispose of empty containers by wrapping in paper and putting in garbage for disposal at an approved landfill, or other approved facility in accordance with local, regional and national regulations. Avoid contamination of any water supply with empty container.

