

SAFETY DATA SHEET

Zoetis New Zealand Limited



Section 1: Identification of the Substance and Supplier

Trade Name: TORBUGESIC®

ACVM Registration No.: A007730

Classification: Restricted Veterinary Medicine (RVM)

Recommended Use: Injectable analgesic and sedative for use in horses, dogs and cats.

Company Details: Zoetis New Zealand Limited

Address: Level 4, 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: 01 July 2019

Section 2: Hazards Identification

Hazard Classification: 6.9B

Priority Identifier(s): WARNING - KEEP OUT OF REACH OF CHILDREN

Secondary Identifier(s): 6.9B May cause organ damage from repeated oral exposure at high doses.

Section 3: Composition / Information on Ingredients

Chemical Identity of Ingredients

| Ingredient | CAS No. | Concentration |
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| Butorphanol tartrate | 58786-99-5 | 0.2% |
| 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

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| 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>Self-Injection: Immediate medical advice should be sought on the management of all instances of accidental self-injection, particularly those near a joint or associated with bruising. Allow the wound to bleed freely and avoid squeezing the injection site to avoid spread of the product. Clean the wound thoroughly with soap and water, then keep it clean and dry.</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: | No specific information available. |
| Workplace Facilities: | No specific facilities required. Standard emergency equipment must be available. |
| Hygiene Practices: | Avoid self-injection, 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: | Butorphanol has opioid-like activity. Accidental self-injection may lead to an inflammatory response and deep injections, particularly those near a joint or associated with bruising should be treated medically or surgically. |

Section 5: Fire-Fighting Measures

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| Type of hazard: | This product is non-flammable, non-combustible and non-explosive. |
| Fire Hazard Properties: | This product is unlikely to decompose at temperatures normally achieved in a fire. This product is likely to decompose only after heating to dryness followed by further strong heating. |
| Regulatory Requirements: | Not applicable. |
| Extinguishing Media & Methods: | Use dry chemical, foam, carbon dioxide or water 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

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| 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

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| Precautions for Safe Handling: | No special technical protective measures required. No special handling advice required. |
| Regulatory Requirements: | Not required. |
| Handling Practices: | Avoid self-injection, 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

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| Conditions for Safe Storage: | Store below 25°C (Air Conditioning). Protect from light. 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 | |
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| Workplace Exposure Standards: | A time weighted average (TWA) concentration for an 8-hour day and a 5-day week has not been established by NOHSC 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. |
| 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 self-injection, 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

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| Appearance: | Clear, colourless liquid. |
| Odour: | No odour. |
| Specific Gravity / Density: | Not data available. Expected to be approximately 1.0. |
| Melting Point: | Approximately 0°C |
| Boiling Point: | Approximately 100°C at 100 kPa |
| pH: | No data available |
| Solubility in Water: | Completely soluble in water. |
| 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: | No data available |

Section 10: Stability and Reactivity

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| Stability of the Substance: | This product is stable under normal conditions of use. |
| Conditions to Avoid: | Store as recommended. No special conditions to avoid. |
| Material to Avoid: | No particular materials to avoid. |
| Hazardous Decomposition Products: | This product is unlikely to spontaneously decompose. No significant quantities of decomposition products are expected at temperatures normally achieved in a fire. |
| Hazardous Polymerisation: | This product is unlikely to spontaneously polymerise. |
| Specific Data: | No specific data available. |

Section 11: Toxicological Information

HSNO Classifications

6.9B May cause organ damage from repeated oral exposure at high doses.

Acute Effects

Principle routes of exposure are expected to be by skin contact, accidental self-injection, ingestion and/or inhalation of syringe-expressed aerosols. As with any chemical product contact with unprotected bare skin; inhalation of vapour, mist or dust in the workplace atmosphere; or ingestion in any form should be avoided by observing good occupational work practices.

Butorphanol tartrate is an acute oral toxin [LD₅₀ (rat) 315 mg/kg]; NOAEL 0.3 mg/kg/day.

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| Rats: | The acute intravenous LD ₅₀ in rats is 20 mg/kg. Test animals showed either muscle tenseness or flaccidity within 30 seconds after dosing. Convulsions and death followed. |
| Mice: | The acute intravenous LD ₅₀ in mice is 32 mg/kg. Ataxia, extreme nervousness, convulsions and death occurred within 1 minute after dosing. Surviving rats at this dose level appeared clinically normal 30 minutes after receiving the test material. |
| Horses: | Rapid intravenous administration of butorphanol at a dosage of 2.0 mg/kg bw (20 times the recommended dosage) to a previously unmedicated horse resulted in a brief episode of inability to stand, muscle fasciculation, a convulsive seizure of 6 seconds duration and recovery within 3 minutes. The same dosage administered after 10 successive daily 1.0 mg/kg dosages of butorphanol resulted only in transient sedative effects. In two horses, the only detectable drug effects were transient behavioural changes typical of narcotic agonist activity. These included muscle fasciculation about the head and neck, dysphoria, lateral nystagmus, ataxia and salivation. Repeated administration of butorphanol at 1.0 mg/kg (10 times the recommended dose) every four hours for 48 hours caused constipation in one of the two horses. Following intravenous injection of normal doses of butorphanol, butorphanol is largely eliminated from the blood within 3 to 4 hours. The drug is extensively metabolised in the liver and excreted in the urine. |
| Humans: | At therapeutic doses, butorphanol is completely absorbed, rapidly distributed in the tissues, has a plasma half life of about 3 hours and is extensively metabolised prior to elimination, the major route of elimination being renal. |

Chronic / Long Term Effects

No data is available relating to the effects of chronic / long-term exposure to this product.

Section 12: Ecotoxicity Information

HSNO Classifications

Not applicable. This product is not classified as ecotoxic.

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

Ecotoxicity Effects

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| Toxicity to Birds: | Not applicable |
| 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

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| 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. Used needles and syringes should immediately be placed in a designated and appropriately labelled "sharps" container. |

Section 14: Transport Information

Dangerous Goods Classification

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| UN No.: | Not applicable. This product is not a dangerous good. |
| Class: | Not applicable. This product is not a dangerous good. |
| Packing Group: | Not applicable. This product is not a dangerous good. |
| Proper Shipping Name: | Not applicable. This product is not a dangerous good. |

Section 15: Regulatory Information

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| HSNO Approval No.: | HSR001963 |
| HSNO Controls: | See www.epa.govt.nz for controls |
| ACVM Registration No.: | A007730 |
| ACVM Controls: | See www.foodsafety.govt.nz for registration conditions |

Section 16: Other Information

Note: This product is a veterinary medicine and must therefore be used in accordance with the container label directions. A comprehensive package of toxicological and environmental data for the active ingredients of this product has been submitted to the Government health and environment authorities and has been evaluated by expert toxicologists and environmental scientists.

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| CONTACT POINT: | Zoetis New Zealand Limited: | 0800 963 847 (Business Hours) |
| | National Poisons Centre: | 0800 POISON (0800 764 766) |
| | Emergency Services: | Dial 111 |

This Safety Data Sheet summarises our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products.

PLEASE READ ALL LABELS CAREFULLY BEFORE USING PRODUCT.

If clarification of further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company.

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