

SECTION 1 - IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Ausrichter Pty Ltd
2/21 Chester St
Camperdown NSW 2050

Phone: 02 9517 1166
Fax: 02 9516 5810
ausrichter@bigpond.com

Chemical nature: Butorphanol is a morphinan-type synthetic opioid. It is presented here in water solution.

Trade Name: **Butomidor Injection**

Product Use: Analgesic and sedative for use in horses, dogs and cats; for use as described on the product label.

Creation Date: **September, 2008**

This version issued: **August, 2013** and is valid for 5 years from this date.

SECTION 2 - HAZARDS IDENTIFICATION**Statement of Hazardous Nature**

This product is classified as: Xi, Irritating. Hazardous according to the criteria of SWA.

Not a Dangerous Good according to the Australian Dangerous Goods (ADG) Code.

Risk Phrases: R36. Irritating to eyes.

Safety Phrases: S36, S45, S24/25. Wear suitable protective clothing. In case of accident or if you feel unwell, contact a doctor or Poisons Information Centre immediately (show this SDS where possible). Avoid contact with skin and eyes.

SUSMP Classification: S8

ADG Classification: None allocated. Not a Dangerous Good under the ADG Code.

UN Number: None allocated

**GHS Signal word: WARNING.****HAZARD STATEMENT:**

H227: Combustible liquid.

H320: Causes eye irritation.

PREVENTION

P102: Keep out of reach of children.

P264: Wash contacted areas thoroughly after handling.

P280: Wear protective gloves, protective clothing and eye or face protection.

RESPONSE

P337: If eye irritation persists: seek medical attention.

P353: Rinse skin or shower with water.

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P332+P313: If skin irritation occurs: Get medical advice.

P337+P313: If eye irritation persists: Get medical advice.

P370+P378: In case of fire, use carbon dioxide, dry chemical, foam, water fog.

STORAGE

P411+P235: Store at temperatures not exceeding 30°C. Keep cool.

DISPOSAL

P501: Dispose of contents and containers as specified on the registered label.

Emergency Overview

Physical Description & Colour: Clear, colourless liquid.

Odour: No odour.

Major Health Hazards: eye irritant.

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Potential Health Effects

Acute Effects:

Rats: The acute intravenous LD₅₀ 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 LD₅₀ 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.

Inhalation:

Short Term Exposure: Significant inhalation exposure is considered to be unlikely.

Long Term Exposure: No data for health effects associated with long term inhalation.

Skin Contact:

Short Term Exposure: There is no data available for this product, nor for its ingredients.

Long Term Exposure: No data for health effects associated with long term skin exposure.

Eye Contact:

Short Term Exposure: This product is an eye irritant. Symptoms may include stinging and reddening of eyes and watering which may become copious. Other symptoms may also become evident. If exposure is brief, symptoms should disappear once exposure has ceased. However, lengthy exposure or delayed treatment may cause permanent damage.

Long Term Exposure: No data for health effects associated with long term eye exposure.

Ingestion:

Short Term Exposure: There is no data available for this product. See section 11 for data on ingredients.

Long Term Exposure: No data for health effects associated with long term ingestion.

Carcinogen Status:

SWA: No significant ingredient is classified as carcinogenic by SWA.

NTP: No significant ingredient is classified as carcinogenic by NTP.

IARC: No significant ingredient is classified as carcinogenic by IARC.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS No	Conc,%	TWA (mg/m ³)	STEL (mg/m ³)
Butorphanol tartrate	58786-99-5	10g/L	not set	not set
Benzethonium chloride	121-54-0	0.1g/L	not set	not set
Other non hazardous ingredients	various	<3	not set	not set
Water	7732-18-5	to 100	not set	not set

This is a commercial product whose exact ratio of components may vary slightly. Minor quantities of other non hazardous ingredients are also possible.

The SWA TWA exposure value is the average airborne concentration of a particular substance when calculated over a normal 8 hour working day for a 5 day working week. The STEL (Short Term Exposure Limit) is an exposure value that may be equalled (but should not be exceeded) for no longer than 15 minutes and should not be repeated more than 4 times per day. There should be at least 60 minutes between successive exposures at the STEL. The term "peak" is used when the TWA limit, because of the rapid action of the substance, should never be exceeded, even briefly.

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SECTION 4 - FIRST AID MEASURES

General Information:

You should call The Poisons Information Centre if you feel that you may have been poisoned, burned or irritated by this product. The number is 13 1126 from anywhere in Australia (0800 764 766 in New Zealand) and is available at all times. Have this SDS with you when you call.

Self Injection: Accidental self injection may lead to an inflammatory response. Medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed vaccine. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied. Check your tetanus immunisation status. If a significant quantity of the product is injected, seek immediate medical attention. **Do not attempt to drive.**

Contact or Poisoning: From the available evidence, this product would appear to offer no significant health hazard by any exposure route, apart from injection and the unlikely event of eye contact. Consequently, First Aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

SECTION 5 - FIRE FIGHTING MEASURES

Fire and Explosion Hazards: There is no risk of an explosion from this product under normal circumstances if it is involved in a fire.

Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a fire. This will only occur after heating to dryness.

Fire decomposition products from this product are not expected to be hazardous or harmful.

Extinguishing Media: Not Combustible. Use extinguishing media suited to burning materials.

Fire Fighting: If a significant quantity of this product is involved in a fire, call the fire brigade.

Flash point: Does not burn.

Upper Flammability Limit: Does not burn.

Lower Flammability Limit: Does not burn.

Autoignition temperature: Not applicable - does not burn.

Flammability Class: Does not burn.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Accidental release: This product is sold in small packages, and the accidental release from one of these is not usually a cause for concern. For minor spills, refer to product label for specific instructions. No special protective clothing is normally necessary because of this product. However it is good practice to wear latex gloves when handling injectables. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

SECTION 7 - HANDLING AND STORAGE

Handling: Keep exposure to this product to a minimum, and minimise the quantities kept in work areas. Check Section 8 of this SDS for details of personal protective measures, and make sure that those measures are followed. The measures detailed below under "Storage" should be followed during handling in order to minimise risks to persons using the product in the workplace. Also, avoid contact or contamination of product with incompatible materials listed in Section 10.

Storage: This product is a Schedule 8 Poison; **possession without authority is illegal.** Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Store packages of this product in a cool place. Avoid freezing. Make sure that containers of this product are kept tightly closed. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Check packaging - there may be further storage instructions on the label.

SECTION 8 - EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following Australian Standards will provide general advice regarding safety clothing and equipment:

Respiratory equipment: **AS/NZS 1715**, Protective Gloves: **AS 2161**, Occupational Protective Clothing: AS/NZS 4501 set 2008, Industrial Eye Protection: **AS1336** and **AS/NZS 1337**, Occupational Protective Footwear: **AS/NZS2210**.

SWA Exposure Limits **TWA (mg/m³)** **STEL (mg/m³)**

Exposure limits have not been established by SWA for any of the significant ingredients in this product.

No special equipment is usually needed when occasionally handling small quantities. The following instructions are for bulk handling or where regular exposure in an occupational setting occurs without proper containment systems.

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Ventilation: No special ventilation requirements are normally necessary for this product. However make sure that the work environment remains clean and that vapours and mists are minimised.

Eye Protection: Eye protection such as protective glasses or goggles is recommended when this product is being used.

Skin Protection: Since there is no reliable skin contact toxicology data for this product, our advice is to treat it cautiously. Wear latex gloves when preparing for injections. Your experience with this product may show these measures to be excessive, but caution is warranted at least initially.

Protective Material Types: We suggest that protective clothing be made from the following material: latex.

Respirator: Usually, no respirator is necessary when using this product. However, if you have any doubts consult the Australian Standard mentioned above.

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES:

Physical Description & colour:	Clear, colourless liquid.
Odour:	No odour.
Boiling Point:	Approximately 100°C at 100kPa.
Freezing/Melting Point:	Approximately 0°C.
Volatiles:	Water component.
Vapour Pressure:	2.37 kPa at 20°C (water vapour pressure).
Vapour Density:	No data.
Specific Gravity:	No data.
Water Solubility:	Completely soluble in water.
pH:	No data.
Volatility:	No data.
Odour Threshold:	No data.
Evaporation Rate:	No data.
Coeff Oil/water Distribution:	No data
Autoignition temp:	Not applicable - does not burn.

SECTION 10 - STABILITY AND REACTIVITY

Reactivity: This product is unlikely to react or decompose under normal storage conditions. However, if you have any doubts, contact the supplier for advice on shelf life properties.

Conditions to Avoid: Store in a cool place, preferably below 30°C. Avoid freezing. Keep containers tightly closed.

Incompatibilities: No particular Incompatibilities.

Fire Decomposition: Only small quantities of decomposition products are expected from this products at temperatures normally achieved in a fire. This will only occur after heating to dryness. Carbon dioxide, and if combustion is incomplete, carbon monoxide. Nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. Hydrogen chloride gas, other compounds of chlorine. Water. Carbon monoxide poisoning produces headache, weakness, nausea, dizziness, confusion, dimness of vision, disturbance of judgment, and unconsciousness followed by coma and death.

Polymerisation: This product will not undergo polymerisation reactions.

SECTION 11 - TOXICOLOGICAL INFORMATION

Local Effects:

Target Organs: Central nervous system.

Adverse effects may include dizziness, light-headedness, headache, nausea and blurred vision.

Significant adverse effects are associated with chronic high level exposures.

Butorphanol tartrate:

LD₅₀ (Oral), Rat 315mg/kg

LD₅₀ (Oral), Mouse 395mg/kg

LD₅₀ (Oral), Dog >50mg/kg

Classification Of Hazardous Ingredients

Ingredient

Risk Phrases

No ingredient mentioned in the HSIS Database is present in this product at hazardous concentrations.

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SECTION 12 - ECOLOGICAL INFORMATION

Insufficient data to be sure of status. Expected to not be an environmental hazard.

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of small quantities and empty containers by wrapping with paper and putting with domestic garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service. Discarded needles or sharps should be immediately placed in a designated and appropriately labelled container. Unused or expired product should be recorded and destroyed in accordance with State and Territory legislative requirements.

SECTION 14 - TRANSPORT INFORMATION

ADG Code: This product is not classified as a Dangerous Good. No special transport conditions are necessary unless required by other regulations.

SECTION 15 - REGULATORY INFORMATION

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Butorphanol, is mentioned in the SUSMP.

SECTION 16 - OTHER INFORMATION

This SDS contains only safety-related information. For other data see product literature.

Acronyms:

ADG Code	Australian Code for the Transport of Dangerous Goods by Road and Rail (7 th edition)
AICS	Australian Inventory of Chemical Substances
SWA	Safe Work Australia, formerly ASCC and NOHSC
CAS number	Chemical Abstracts Service Registry Number
Hazchem Code	Emergency action code of numbers and letters that provide information to emergency services especially firefighters
IARC	International Agency for Research on Cancer
NOS	Not otherwise specified
NTP	National Toxicology Program (USA)
R-Phrase	Risk Phrase
SUSMP	Standard for the Uniform Scheduling of Medicines & Poisons
UN Number	United Nations Number

THIS SDS 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 MUST REVIEW THIS SDS IN THE CONTEXT OF HOW THE PRODUCT WILL BE HANDLED AND USED IN THE WORKPLACE.

IF CLARIFICATION OR FURTHER INFORMATION IS NEEDED TO ENSURE THAT AN APPROPRIATE RISK ASSESSMENT CAN BE MADE, THE USER SHOULD CONTACT THIS COMPANY SO WE CAN ATTEMPT TO OBTAIN ADDITIONAL INFORMATION FROM OUR SUPPLIERS. OUR RESPONSIBILITY FOR PRODUCTS SOLD IS SUBJECT TO OUR STANDARD TERMS AND CONDITIONS, A COPY OF WHICH IS SENT TO OUR CUSTOMERS AND IS ALSO AVAILABLE ON REQUEST.

Please read all labels carefully before using product.

This SDS is prepared in accord with the SWA document "Preparation of Safety Data Sheets for Hazardous Chemicals - Code of Practice" (December 2011)
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