

# SAFETY DATA SHEET

**zoetis**

Title: METHADYNE INJECTION

Document: SDS-AU128

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Status: Current

Issue Date: 21-Jun-2024

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## Section 1: IDENTIFICATION of CHEMICAL PRODUCT and COMPANY

**Product Name:** Methadyne Injection

**Product Identifier:** 10 mg/mL methadone hydrochloride

**Recommended Use:** For analgesia and restraint in horses, and analgesia and anaesthetic premedication in dogs and cats.

**Restrictions on Use:** For animal treatment only.

**Company Identification:** Zoetis Australia Pty Ltd  
ABN: 94 156 476 425

**Address:** Level 6, 5 Rider Boulevard  
Rhodes NSW 2138  
Australia

**Telephone:** 1800 814 883

**Fax:** (02) 8876 0444

**Email:** productsupport.au@zoetis.com

**National Poisons Information Centre:** 13 11 26 (24 hours)

**Police, Fire Brigade, Ambulance:** Dial 000

**Emergency Telephone Number:** 1800 814 883 (all hours)

## Section 2: HAZARDS IDENTIFICATION

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

GHS Category	Hazard code	Hazard Statement
STOT – RE Category 2	H373	May cause damage to organs through prolonged or repeated exposure
Chronic aquatic hazard Category 3	H412	Harmful to aquatic life with long lasting effects

**Signal word:** WARNING

**GHS Pictograms:**



Health hazard

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## Precautionary statements:

### Prevention

P260 Do not breathe vapours.

P273 Avoid release to the environment.

### Response

P314 Get medical advice/attention if you feel unwell.

### Storage

None

### Disposal

P501 Dispose of empty container by wrapping with paper and putting in garbage. Return unused expired product to pharmacy or pharmacy inspector.

N.B.: The above 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
Methadone hydrochloride	125-56-4	1%
Ingredients not contributing to the hazards		> 90%

## Section 4: FIRST AID MEASURES

**General Information:** Respiratory depression, systemic hypotension, respiratory arrest, shock, cardiac arrest and death may occur. Consult the National Poisons Centre on 13 11 26 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:** Methadone side effects generally encompass a broad range of symptoms that may commonly include constipation, drowsiness, dry mouth, euphoria, lightheadedness, slowed breathing, and weakness. Additional side effects of methadone that are not as common often include palpitations, hives, impaired concentration, nausea, skin rash, sweating, vomiting, muscle twitching, and disorientation.

**Inhalation:** If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary. 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 and seek medical assistance immediately.

**Ingestion:** If swallowed do NOT induce vomiting. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. **Contact a doctor or the National Poisons Centre on 13 11 26 immediately.**

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**Skin:** If skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.

**Eye:** If eye contact occurs: Immediately flush the eye continuously with running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Continue flushing for at least 20 minutes. If eye irritation persists, get medical advice/attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

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

**Advice to Doctor:** Treat symptomatically for a narcotic analgesic.

## Section 5: FIRE FIGHTING MEASURES

**Flash Point:** No data.

**Hazardous Combustion Products:** If involved in a fire, may emit poisonous and irritant fumes.

**Extinguishing Media:** There is no restriction on the type of extinguisher which may be used. Use extinguishing media suitable for surrounding area.

**Protective Equipment:** Protective gloves and breathing apparatus.

**HAZCHEM Code:** None specified.

## Section 6: ACCIDENTAL RELEASE MEASURES

**Spills and Disposal:** Exclude non-essential people from the area. Wear gloves and appropriate protective clothing. 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. In the event of a major spill, prevent spillage from entering drains or water courses and call emergency services.

**Protective Clothing:** For appropriate personal protective equipment see section 8.

**Environmental Precautions:** Prevent from entering drains, waterways or sewers. If spill does enter waterways contact local authority.

## Section 7: HANDLING AND STORAGE

**Handling:** This is a Schedule 8 (Controlled Drug) product and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Possession without authority is illegal. Handle this product with care to avoid exposure, taking all recommended precautions. 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:** Methadyne Injection is a Controlled Drug (S8) and therefore must be stored and maintained in accordance with the relevant State Poisons Act. Possession without authority is illegal. Keep out of reach of children. Store below 30°C (room temperature). Protect from light.

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**Other Information:** Avoid contact with incompatible substances as listed in Section 10. Always read the label before use.

## 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 or its ingredients.

**Engineering Controls:** Use only in a well-ventilated area. Make sure that the work environment remains clean and that vapours and mists are minimised.

### Personal Protective Equipment (PPE):

Eye protection: Protective glasses or goggles are recommended when this product is being used.

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.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, colourless solution	<b>limits</b>
<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>	4.5 – 6.5	<b>Relative density:</b> Not available
<b>Melting Point:</b>	Not available	<b>Specific Gravity:</b> Approx. 1.0
<b>Boiling Point:</b>	Not available	<b>Solubility in Water:</b> Miscible
<b>Flash Point:</b>	Not available	<b>Partition coefficient:</b> Not available
<b>Evaporation Rate:</b>	Not available	<b>Auto-ignition temperature:</b> Not available
<b>Flammability:</b>	Not flammable	<b>Decomposition temperature:</b> Not available
<b>Upper flammability limits:</b>	Not applicable	<b>Viscosity:</b> Not available
<b>Lower flammability</b>	Not available	

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## Section 10: STABILITY AND REACTIVITY

**Reactivity:** This product is unlikely to react or polymerise under normal storage conditions.

**Stability:** When stored appropriately this product should show no significant degradation within the expiry period shown on the label.

**Conditions to Avoid:** Protect this product from light.

**Incompatible Materials:** Oxidising agents.

**Hazardous Decomposition Products:** No data available.

## 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. Adverse effects may occur following ingestion of methadone. May result in rapid shallow breathing, temporary paralysis or weakness of muscles, reduced urine output, drowsiness, nausea, vomiting, flushed face, irregular heartbeat, constipation, loss of appetite, general feeling of discomfort, false sense of well-being, dry mouth, stomach cramps, confusion, headache, visual disturbances and symptoms of shock (cold clammy skin, rapid weak pulse, dizziness, weakness and fainting). Doses of 50 mg or less have been known to be lethal to nontolerant adults. The fatal dose in children is 10-20 mg.

Methadone hydrochloride: Oral LD<sub>50</sub>: 95mg/kg (rat).

Methadone: Oral LD<sub>50</sub>: 70mg/kg (mouse).

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.

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. Adverse effects may occur following skin absorption (see ingestion).

**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:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not considered to be an eye irritant.

**Respiratory or Skin Sensitisation:** No data for the mixture is available. Based on available data for the ingredients, the mixture is not thought to cause respiratory or skin sensitisation.

**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:** Methadone readily crosses the placental barrier and may cause respiratory depression in neonates and withdrawal syndrome in neonates. Cases of intra-uterine death have been

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reported during methadone usage in the late mid-trimester or last trimester of pregnancy. Methadone is secreted in breast milk in concentration approaching plasma levels.

**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. As with other potent opioids, clinically significant respiratory depression may occur after single exposure.

**STOT: Repeat exposure:** Repeated exposure to opioid analgesics may result in physical dependence. Prolonged exposure to methadone can cause cardiac abnormalities (Q-T interval prolongation) in some patients.

**Aspiration Hazard:** No data available.

## Section 12: ECOLOGICAL INFORMATION

**Ecotoxicity:** Methadone hydrochloride is harmful in the aquatic environment.

Methadone hydrochloride:  
Algae EC<sub>50</sub> (96 h) 1.358 mg/L;  
Fish EC<sub>50</sub> (96 h) 3.482 mg/L.

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Methadone hydrochloride	HIGH	HIGH	MED (logKOW = 4.1665)	LOW (KOC = 72790)

## Section 13: DISPOSAL INFORMATION

**Product Disposal:** Dispose of product only by using according to label or at an approved landfill.

**Container Disposal:** Crush or puncture and bury in an approved landfill if an approved recycling system is not available.

## Section 14: TRANSPORT INFORMATION

**Dangerous Goods Classification:** Not classified as a Dangerous Good for land, sea or air transport.

## Section 15: REGULATORY INFORMATION

**Poison Schedule (Product):** Schedule 8

**APVMA No.:** 89036

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

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## Section 16: OTHER INFORMATION

This information is based on data believed by Zoetis 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 Zoetis 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>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>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>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>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:

ChemID Plus

EPA New Zealand Chemical Classification and Information Database (CCID)

HSDB (Hazardous Substances Data Bank)

### Revision History:

Date of Revision	Reason
01 March 2023	Updates to Customer Service and emergency contact telephone numbers to Zoetis numbers.
21 June 2024	Minor revision to update the company details to Zoetis Australia. Minor formatting changes.

END OF SDS