

## Section 1 - Identification of The Material and Supplier

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**Chemical nature:** Atipamezole injection.  
**Trade Name:** **Mobitor Injection**  
**Product Use:** Veterinary reversing Agent for Medetomidine.  
**Creation Date:** **February, 2015**  
**This version issued:** **April, 2023** and is valid for 5 years from this date.  
**Poisons Information Centre: Phone 13 1126 from anywhere in Australia**

## Section 2 - Hazards Identification

### Statement of Hazardous Nature

This product is classified as: Not classified as hazardous according to the criteria of SWA.

Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA and IMDG/IMSBC criteria.

**SUSMP Classification:** S4

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

**UN Number:** None allocated

**GHS Signal word: NONE. Not hazardous.**

### PREVENTION

P102: Keep out of reach of children.

### RESPONSE

P353: Rinse skin or shower with water.

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

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

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

P370+P378: Not combustible. Use extinguishing media suited to burning materials.

### STORAGE

P402+P404: Store in a dry place. Store in a closed container.

### DISPOSAL

P501: Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

## Emergency Overview

**Physical Description & Colour:** Clear colourless liquid.

**Odour:** No odour.

**Major Health Hazards:** no significant risk factors have been found for this product. This is a physiologically active product and so contact should be minimised, especially if the user is taking a form of medication, as interactions can sometimes give unexpected and undesired results.

## Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m <sup>3</sup> )	STEL (mg/m <sup>3</sup> )
Atipamezole hydrochloride	104075-48-1	5.0g/L	not set	not set
Other non hazardous ingredients	various	<5g/L	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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Issued by: Headway Animal Health Pty Ltd

Phone: (61-2) 98960856

**Poisons Information Centre: 13 1126 from anywhere in Australia, (0800 764 766 in New Zealand)**

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## Section 4 - First Aid Measures

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### 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.

**Inhalation:** First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

**Skin Contact:** Wash gently and thoroughly with water (use non-abrasive soap if necessary) for 5 minutes or until chemical is removed.

**Eye Contact:** No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the product is removed. Obtain medical advice if irritation becomes painful or lasts more than a few minutes. Take special care if exposed person is wearing contact lenses.

**Ingestion:** If product is swallowed or gets in mouth, do NOT induce vomiting; wash mouth with water and give some water to drink. If symptoms develop, or if in doubt contact a Poisons Information Centre or a doctor.

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## Section 5 - Fire Fighting Measures

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**Fire and Explosion Hazards:** The major hazard in fires is usually inhalation of heated and toxic or oxygen deficient (or both), fire gases. 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 product 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.

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## Section 6 - Accidental Release Measures

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**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.

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## Section 7 - Handling and Storage

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**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 Scheduled Poison. Observe all relevant regulations regarding sale, transport and storage of this schedule of poison. Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight. Make sure that the product does not come into contact with substances listed under "Incompatibilities" in Section 10. Some liquid preparations settle or separate on standing and may require stirring before use. Check packaging - there may be further storage instructions on the label.

## SAFETY DATA SHEET

## 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/m<sup>3</sup>)**                      **STEL (mg/m<sup>3</sup>)**

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.

**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:** You should avoid contact even with mild skin irritants. Therefore you should wear suitable impervious elbow-length gloves and facial protection when handling this product. See below for suitable material types.

**Protective Material Types:** We suggest that protective clothing be made from the following materials: rubber, PVC.

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

Safety deluge showers should, if practical, be provided near to where this product is being handled commercially.

## Section 9 - Physical and Chemical Properties:

<b>Physical Description &amp; colour:</b>	Clear colourless liquid.
<b>Odour:</b>	No odour.
<b>Boiling Point:</b>	Approximately 100°C at 100kPa.
<b>Freezing/Melting Point:</b>	Approximately 0°C.
<b>Volatiles:</b>	Water component.
<b>Vapour Pressure:</b>	2.37 kPa at 20°C (water vapour pressure).
<b>Vapour Density:</b>	As for water.
<b>Specific Gravity:</b>	1.005
<b>Water Solubility:</b>	Completely soluble in water.
<b>pH:</b>	4.0-6.0
<b>Volatility:</b>	No data.
<b>Odour Threshold:</b>	No data.
<b>Evaporation Rate:</b>	As for water.
<b>Coeff Oil/water Distribution:</b>	No data
<b>Autoignition temp:</b>	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:** Protect this product from light. Store in the closed original container in a dry, cool, well-ventilated area out of direct sunlight.

**Incompatibilities:** No particular Incompatibilities.

**Fire Decomposition:** Only small quantities of decomposition products are expected from this product at temperatures normally achieved in a fire. This will only occur after heating to dryness. Combustion forms carbon dioxide, and if incomplete, carbon monoxide and possibly smoke. Water is also formed. May form nitrogen and its compounds, and under some circumstances, oxides of nitrogen. Occasionally hydrogen cyanide gas in reducing atmospheres. May form hydrogen chloride gas, other compounds of chlorine. 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.

## SAFETY DATA SHEET

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## Section 11 - Toxicological Information

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### Local Effects:

**Target Organs:** There is no data to hand indicating any particular target organs.

### Acute:

**Swallowed:** LD<sub>50</sub> (oral, rat) Atipamezole = 80 mg/kg.

While the MEDASED Injection formulation has not been tested *per se*, the finished product is not expected to be toxic orally based on the amount of active ingredient in the mixture (0.5 %). A 60 kg human would need to consume more than 90 X 10 mL vials to ingest enough active to approach the (oral, rat) LD<sub>50</sub> of 80 mg/kg.

**Eye:** May irritate eyes on contact. Avoid contact with eyes.

**Skin:** May irritate skin. Absorption via intact skin is unlikely.

**Inhaled:** Not considered to be a significant route of exposure during normal use.

### Chronic:

No long-term toxicity studies have been conducted to evaluate the chronic toxicity of this material. Atipamezole has not been found to be teratogenic, mutagenic or carcinogenic.

**Reproductive Effects:** No data available.

**Teratogenic and mutagenic effects:** Atipamezole is not teratogenic or mutagenic.

**Carcinogenic Effects:** No carcinogenic effects known.

**Toxicity to Other Domestic Species:** No data.

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## Classification of Hazardous Ingredients

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### Ingredient

### Risk Phrases

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

Any acute health effects are expected to be related to the pharmacological action of atipamezole as an  $\alpha$ -2-adrenoreceptor antagonist. Ingestion of this material may cause effects similar to those seen in animal studies including effects on nervous system and respiratory system. High doses may result in a heightened state of alertness and excitation. Potential side effects include vomiting, hypersalivation, diarrhoea, and tremors.

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## Potential Health Effects

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### Inhalation:

**Short Term Exposure:** Significant inhalation exposure is considered to be unlikely. Available data indicates that this product is not harmful. However product may be mildly irritating, although unlikely to cause anything more than mild transient discomfort.

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

### Skin Contact:

**Short Term Exposure:** Available data indicates that this product is not harmful. It should present no hazards in normal use. However product may be irritating, but is unlikely to cause anything more than mild transient discomfort.

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

### Eye Contact:

**Short Term Exposure:** This product may be irritating to eyes, but is unlikely to cause anything more than mild transient discomfort.

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

### Ingestion:

**Short Term Exposure:** Significant oral exposure is considered to be unlikely. However, this product may be irritating to mucous membranes but is unlikely to cause anything more than transient discomfort.

**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.

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## Section 12 - Ecological Information

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No data. Not expected to accumulate in the soil or water or cause long term problems.

## SAFETY DATA SHEET

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### Section 13 - Disposal Considerations

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**Disposal:** Dispose of small quantities and empty containers by wrapping with paper and putting in garbage. Discarded needles should immediately be placed in a designated and appropriately labelled sharps container. For larger quantities, if recycling or reclaiming is not possible, use a commercial waste disposal service.

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### Section 14 - Transport Information

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**UN Number:** This product is not classified as a Dangerous Good by ADG, IATA or IMDG/IMSBC criteria. No special transport conditions are necessary unless required by other regulations.

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### Section 15 - Regulatory Information

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

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### Section 16 - Other Information

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

**Acronyms:**

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

THIS SDS SUMMARISES OUR BEST KNOWLEDGE OF THE HEALTH AND SAFETY HAZARD STATEMENT: 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" (Feb 2016)

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