

Section 1 - Identification of The Material and Supplier

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Chemical nature: Active ingredient is a synthetic alpha-2-adrenoreceptor agonist with sedative and analgesic properties.

Trade Name: **Stilator Injection**

Other Names: Medetomidine hydrochloride sterile injectable solution

Product Use: Sedative/analgesic; alpha-2-adrenergic agonist agent.

Creation Date: **March, 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: Xn, Harmful. 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: **WARNING.**

HAZARD STATEMENT:

H302: Harmful if swallowed.

PREVENTION

P102: Keep out of reach of children.

P262: Do not get in eyes, on skin, or on clothing.

P264: Wash contacted areas thoroughly after handling.

P270: Do not eat, drink or smoke when using this product.

RESPONSE

P337: If eye irritation persists: seek medical attention.

P353: Rinse skin or shower with water.

P301+P312: IF SWALLOWED: Call a POISON CENTRE or doctor if you feel unwell.

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

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

STORAGE

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

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

DISPOSAL

P501: If product can not be recycled, consider controlled incineration, or contact a specialist waste disposal company (see Section 13 of this SDS).

Emergency Overview

Physical Description & colour: Clear, colourless liquid.

Odour: No odour.

Major Health Hazards: harmful if swallowed.

SAFETY DATA SHEET

Section 3 - Composition/Information on Ingredients

Ingredients	CAS No	Conc,%	TWA (mg/m ³)	STEL (mg/m ³)
Medetomidine hydrochloride	86347-15-1	1mg/mL	not set	not set
Other non hazardous ingredients	various	proprietary	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.

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 material. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied.

Inhalation: No first aid measures normally required. However, if inhalation has occurred, and irritation has developed, remove to fresh air and observe until recovered. If irritation becomes painful or persists more than about 30 minutes, seek medical advice.

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 swallowed, do NOT induce vomiting. Wash mouth with water and contact a Poisons Information Centre, or call 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 vaccines. 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.

SAFETY DATA SHEET

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. 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.

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.

Ventilation: This product should only be used in a well ventilated area. If natural ventilation is inadequate, use of a fan is suggested.

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. Otherwise, not normally necessary.

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. Expected to be about 1.0
Water Solubility:	Completely soluble in water.
pH:	No data. Expected to be neutral.
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 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 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.

SAFETY DATA SHEET

Polymerisation: This product will not undergo polymerisation reactions.

Section 11 - Toxicological Information

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

Medetomidine is a potent non-narcotic α_2 -adrenoreceptor agonist which produces sedation and analgesia. These effects are dose dependent in depth and duration. Profound sedation and recumbency, with reduced sensitivity to environmental stimuli (sounds, etc.), are seen with medetomidine. The pharmacological restraint and pain relief provided by medetomidine facilitates handling dogs and aids in the conduct of diagnostic or therapeutic procedures. It also facilitates minor surgical procedures (with or without local anaesthesia) and dental care where intubation is not required. Spontaneous muscle contractions (twitching) can be expected in some dogs sedated with medetomidine.

ADVERSE REACTIONS: As with all α_2 -agonists, the potential for isolated cases of hypersensitivity, including paradoxical response (excitation), exists. Incidents of prolonged sedation, bradycardia, cyanosis, vomiting, apnea, death from circulatory failure with severe congestion of lungs, liver, kidney and recurrence of sedation after initial recovery have been reported.

SIDE EFFECTS: Bradycardia with occasional atrioventricular blocks will occur together with decreased respiratory rates. Body temperature is slightly or moderately decreased. Urination typically occurs during recovery at about 90 to 120 minutes posttreatment. In approximately 10% of treated dogs, occasional episodes of vomiting occur between 5 to 15 minutes posttreatment. An increase in blood glucose concentration is seen due to α_2 -adrenoreceptor-mediated inhibition of insulin secretion.

Classification of Hazardous Ingredients

Ingredient	Risk Phrases
Medetomidine Hydrochloride:	LD ₅₀ Oral, Rat 31mg/kg

Potential Health Effects

Inhalation:

Short term exposure: 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. Available data shows that this product is a Central Nervous System depressor, but symptoms are not available. This product is unlikely to cause any irritation problems in the short or long term.

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 12 - Ecological Information

The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment.

Section 13 - Disposal Considerations

Disposal: Dispose of 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.

SAFETY DATA SHEET

Section 14 - Transport Information

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.

Section 15 - Regulatory Information

AICS: All of the significant ingredients in this formulation are compliant with NICNAS regulations. The following ingredient: Medetomidine, 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)
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" (Feb 2016)
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