

Section 1 - Identification of The Material and Supplier

Headway Animal Health Pty Ltd

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Chemical nature: Injection containing Methadone hydrochloride
Trade Name: **Methaway 10mg/mL Injection**
APVMA Code: 89038 / 135600
Product Use: Analgesic and anaesthetic product for use as described on the product label.
Creation Date: **March, 2020**
This version issued: **March, 2020 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 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 or IMDG/IMSBC criteria.

SUSMP Classification: S8

CONTROLLED DRUG – Possession without authority illegal.

ADG Classification: None allocated. Not a Dangerous Good according to Australian Dangerous Goods (ADG) Code, IATA or IMDG/IMSBC criteria.

UN Number: None allocated.

GHS Signal word: NONE. Not hazardous.

PREVENTION

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

P264: Wash contacted areas thoroughly after handling. P281: Use personal protective equipment as required.

RESPONSE

P301+P330+P331: IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P307+P311: If exposed: Call a POISON CENTRE or doctor.

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

STORAGE

P410: Protect from sunlight.

P411: Store at temperatures not exceeding 30°C.

DISPOSAL:

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

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Section 3 - Composition/Information on Ingredients

| Ingredients | CAS No | Conc, mg/mL | TWA (mg/m ³) | STEL (mg/m ³) |
|---------------------------------|-----------|-------------|--------------------------|---------------------------|
| Methadone hydrochloride | 1095-90-5 | 10 | not set | not set |
| Other non hazardous ingredients | secret | to 1 mL | 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 liquid. 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: Irritation is unlikely. However, if irritation does occur, flush with lukewarm, gently flowing water 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.

Section 5 - Fire Fighting Measures

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.

Fire decomposition products from this product may be toxic if inhaled. Take appropriate protective measures.

Extinguishing Media: In case of fire, use carbon dioxide, dry chemical, foam or water fog. Fire

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

Flash point: No data

Upper Flammability Limit: No data.

Lower Flammability Limit: No data.

Autoignition temperature: No data.

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Flammability Class: No data.

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 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.

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: The information at hand indicates that this product is not harmful and that normally no special skin protection is necessary. However, we suggest that you routinely avoid contact with all chemical products and that you wear suitable gloves (preferably elbow-length) when lengthy skin contact is likely.

Protective Material Types: There is no data that enables us to recommend any type except that it should be impermeable.

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

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Section 9 - Physical and Chemical Properties:

| | |
|---|--|
| Physical Description & colour: | Liquid, no data regarding colour. |
| Odour: | No data. |
| Boiling Point: | Not available. |
| Freezing/Melting Point: | No specific data. Liquid at normal temperatures. |
| Volatiles: | No data. |
| Vapour Pressure: | No data. |
| Vapour Density: | No data. |
| Specific Gravity: | No data. |
| Water Solubility: | No data. |
| pH: | No data. |
| Volatility: | No data. |
| Odour Threshold: | No data. |
| Evaporation Rate: | No data. |
| Coeff Oil/water Distribution: | No data. |
| Autoignition temp: | No data. |

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: 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.

Section 11 - Toxicological Information

Local Effects:

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

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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Potential Health Effects

Inhalation:

Short Term Exposure: Available data indicates that this product is not harmful. In addition product is unlikely to cause any discomfort or irritation.

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. In addition product is unlikely to cause any discomfort in normal use.

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 not harmful. 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

Insufficient data to be sure of status.

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. Unused expired product should be returned to a pharmacy or pharmacy inspector.

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. This product is a controlled drug. Possession without authority is illegal.

Section 15 - Regulatory Information

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

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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 (7th 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.

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