



# METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)

Novachem Pty Ltd

Chemwatch Hazard Alert Code: 3

Version No: 1.1

Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Issue Date: 25/05/2023

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S.GHS.AUS.EN

## SECTION 1 Identification of the substance / mixture and of the company / undertaking

### Product Identifier

Product name	METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)
Chemical Name	methadone hydrochloride
Synonyms	C21-H27-N-O.HCl; (+/-)-6-dimethylamino-4,4-diphenyl-3-heptanone hydrochloride; (+/-)-4,4-diphenyl-6-dimethylamino-4,4-diphenyl-3-heptanonehydrochloride; 1,1-diphenyl-1-(2-dimethylaminopropyl)-2-butanone hydrochloride; dl-methadone hydrochloride; racemic methadonehydrochloride; (R)-methadone hydrochloride CAS RN: 125-58-6; 5967-73-7; (S)-methadone hydrochloride CAS RN: 15284-15-8; Adanonhydrochloride; Algidon; Algolsin; Amidon hydrochloride; dl-Amidone hydrochloride; AN-148; Biodone; Butalgin; Depridol; Diaminonhydrochloride; Dolophine hydrochloride; Dolophin hydrochloride; Fenadone; Heptadon hydrochloride; Hoechst 10,820; Ketalgin hydrochloride; Macodin; Mephanon; Miadone; Moheptan; Phenadone hydrochloride; Physeptone hydrochloride; Physeptone; Tussal
Proper shipping name	ALKALOIDS, SOLID, N.O.S. or ALKALOID SALTS, SOLID, N.O.S. * (contains METHADONE HYDROCHLORIDE B.P. Cert. (methadone hydrochloride))
Chemical formula	C21H28ClNO
Other means of identification	D425b
CAS number	125-56-4*

### Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Used for treatment of narcotic addiction. Warning: Abuse can lead to habituation. Methadone is used as an analgesic in chronic pain, often in rotation with other opioids Due to its activity at the NMDA receptor, it may be more effective against neuropathic pain; for the same reason, tolerance to the analgesic effects may be less than that of other opioids. [-Regeant -] Therapeutic or pharmacologically-active agent.Opioid analgesic agents are used for the management and treatment of moderate to severe pain,.
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### Details of the manufacturer or supplier of the safety data sheet

Registered company name	Novachem Pty Ltd	Novachem Pty Ltd
Address	25 Crissane Road, Heidelberg West Victoria 3081 Australia	25 Crissane Road, Heidelberg West Victoria 3081 Australia
Telephone	+61384151255	+61384151255
Fax	+61386250088	+61386250088
Website	<a href="http://www.novachem.com.au">www.novachem.com.au</a>	<a href="http://www.novachem.com.au">www.novachem.com.au</a>
Email	novachem@novachem.com.au	novachem@novachem.com.au

### Emergency telephone number

Association / Organisation	Victorian Poisons Information Centre	Victorian Poisons Information Centre
Emergency telephone numbers	13 11 26	13 11 26
Other emergency telephone numbers	Not Available	Not Available

## SECTION 2 Hazards identification

### Classification of the substance or mixture

Poisons Schedule	Not Applicable
Classification [1]	Serious Eye Damage/Eye Irritation Category 2A, Sensitisation (Respiratory) Category 1, Specific Target Organ Toxicity - Repeated Exposure Category 2, Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Germ Cell Mutagenicity Category 2, Hazardous to the Aquatic Environment Long-Term Hazard Category 1, Acute Toxicity (Oral) Category 3, Reproductive Toxicity Category 1B
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

### Label elements

## METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)

Hazard pictogram(s)	
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Signal word	<b>Danger</b>
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### Hazard statement(s)

H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H341	Suspected of causing genetic defects.
H410	Very toxic to aquatic life with long lasting effects.
H301	Toxic if swallowed.
H360Fd	May damage fertility. Suspected of damaging the unborn child.

### Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P260	Do not breathe dust/fume.
P264	Wash all exposed external body areas thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.

### Precautionary statement(s) Response

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician/first aider.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308+P313	IF exposed or concerned: Get medical advice/ attention.
P330	Rinse mouth.

### Precautionary statement(s) Storage

P405	Store locked up.
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### Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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## SECTION 3 Composition / information on ingredients

### Substances

CAS No	%[weight]	Name
125-56-4	>98	methadone hydrochloride

**Legend:** 1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; \* EU IOELVs available

### Mixtures

See section above for composition of Substances

## SECTION 4 First aid measures

### Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>▶ Immediately hold eyelids apart and flush the eye continuously with running water.</li> <li>▶ 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.</li> <li>▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.</li> <li>▶ Transport to hospital or doctor without delay.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Immediately remove all contaminated clothing, including footwear.</li> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
Inhalation	<ul style="list-style-type: none"> <li>▶ If fumes or combustion products are inhaled remove from contaminated area.</li> <li>▶ Lay patient down. Keep warm and rested.</li> <li>▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.</li> <li>▶ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.</li> </ul>

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	<ul style="list-style-type: none"> <li>▶ Transport to hospital, or doctor, without delay.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ <b>IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.</b></li> <li>▶ For advice, contact a Poisons Information Centre or a doctor.</li> <li>▶ Urgent hospital treatment is likely to be needed.</li> <li>▶ In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.</li> <li>▶ If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist.</li> <li>▶ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS.</li> </ul> <p><b>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</b></p> <ul style="list-style-type: none"> <li>▶ <b>INDUCE</b> vomiting with fingers down the back of the throat, <b>ONLY IF CONSCIOUS</b>. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> </ul> <p><b>NOTE:</b> Wear a protective glove when inducing vomiting by mechanical means.</p>

### Indication of any immediate medical attention and special treatment needed

Many drugs have been found that lessen the risk of neurotoxicity from NMDA receptor antagonists. Centrally acting alpha 2 agonists such as clonidine and guanfacine are thought to most directly target the etiology of NMDA neurotoxicity. Other drugs acting on various neurotransmitter systems known to inhibit NMDA antagonist neurotoxicity include: anticholinergics, diazepam, barbiturates, ethanol 5-HT2A serotonin receptor agonists, anticonvulsants and muscimol.

Treat symptomatically for a narcotic analgesic.

A vigorous program of symptomatic and supportive therapy has saved many victims of poisoning. The single most important element in therapy is the correction of anoxia by all available means: the maintenance of a patent airway, the administration of oxygen, the use of artificial respiration, and the injection of specific narcotic antagonists such as nalorphine, levallorphan or naloxone promptly antagonises the respiratory depression, coma and hypotension from overdoses of morphine, codeine, all semi-synthetics and almost all synthetic narcotics.

GOSELIN et al: Clinical Toxicology of Commercial Products.

In fully conscious patients, remove swallowed poison by thorough gastric lavage and emesis. The chances of removing a significant amount of the drug are better if treatment is started within the first two hours. If the patient is unconscious or depressed, emesis is contraindicated and the dangers of gastric lavage are not justified.

DREISBACH AND ROBERTSON: Handbook of Poisoning, Appleton & Lange

## SECTION 5 Firefighting measures

### Extinguishing media

- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

### Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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### Advice for firefighters

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding area.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.</li> <li>▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions).</li> <li>▶ Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust (420 micron or less) may burn rapidly and fiercely if ignited - particles exceeding this limit will generally not form flammable dust clouds; once initiated, however, larger particles up to 1400 microns diameter will contribute to the propagation of an explosion.</li> </ul> <p>Combustion products include:  carbon monoxide (CO)  carbon dioxide (CO<sub>2</sub>)  hydrogen chloride  phosgene  nitrogen oxides (NO<sub>x</sub>)  other pyrolysis products typical of burning organic material.</p>
<b>HAZCHEM</b>	2X

## SECTION 6 Accidental release measures

### Personal precautions, protective equipment and emergency procedures

See section 8

### Environmental precautions

See section 12

### Methods and material for containment and cleaning up

<b>Minor Spills</b>	▶ Clean up waste regularly and abnormal spills immediately.
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## METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)

	<ul style="list-style-type: none"> <li>▶ Avoid breathing dust and contact with skin and eyes.</li> <li>▶ Wear protective clothing, gloves, safety glasses and dust respirator.</li> <li>▶ Use dry clean up procedures and avoid generating dust.</li> </ul>
<b>Major Spills</b>	

Personal Protective Equipment advice is contained in Section 8 of the SDS.

### SECTION 7 Handling and storage

#### Precautions for safe handling

<b>Safe handling</b>	<p><b>NOTE :</b> Do NOT pipette by mouth. Only trained personnel should be allowed to handle or use this product.</p> <ul style="list-style-type: none"> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> <li>▶ Organic powders when finely divided over a range of concentrations regardless of particulate size or shape and suspended in air or some other oxidizing medium may form explosive dust-air mixtures and result in a fire or dust explosion (including secondary explosions)</li> <li>▶ Minimise airborne dust and eliminate all ignition sources. Keep away from heat, hot surfaces, sparks, and flame.</li> <li>▶ Establish good housekeeping practices.</li> <li>▶ Remove dust accumulations on a regular basis by vacuuming or gentle sweeping to avoid creating dust clouds.</li> </ul>
<b>Other information</b>	<p><b>NOTE:</b> Special security requirements may be mandated under Federal/State Regulation(s).</p> <ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Store in vault fitted with warning devices or detectors recommended by various Federal/State authorities.</li> <li>▶ Store in vault used only for the purpose of storage of drugs of addiction.</li> </ul>

#### Conditions for safe storage, including any incompatibilities

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Packaging as recommended by manufacturer.</li> <li>▶ Check that containers are clearly labelled.</li> <li>▶ Tamper-proof containers.</li> <li>▶ Polyethylene or polypropylene containers.</li> <li>▶ Glass container is suitable for laboratory quantities</li> </ul> <p>For low viscosity materials</p> <ul style="list-style-type: none"> <li>▶ Drums and jerricans must be of the non-removable head type.</li> <li>▶ Where a can is to be used as an inner package, the can must have a screwed enclosure.</li> </ul> <p>For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.):</p> <ul style="list-style-type: none"> <li>▶ Removable head packaging;</li> <li>▶ Cans with friction closures and</li> <li>▶ low pressure tubes and cartridges</li> </ul> <p>may be used.</p>
<b>Storage incompatibility</b>	<ul style="list-style-type: none"> <li>▶ Avoid strong acids, bases.</li> <li>▶ Avoid reaction with oxidising agents</li> </ul>

### SECTION 8 Exposure controls / personal protection

#### Control parameters

##### Occupational Exposure Limits (OEL)

##### INGREDIENT DATA

Not Available

##### Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
methadone hydrochloride	Not Available	Not Available

##### Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
methadone hydrochloride	E	≤ 0.01 mg/m <sup>3</sup>


**Notes:** Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

#### Exposure controls

<b>Appropriate engineering controls</b>	<p><b>For potent pharmacological agents:</b></p> <p><b>Powders</b></p> <p>To prevent contamination and overexposure, no open handling of powder should be allowed.</p> <ul style="list-style-type: none"> <li>▶ Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.</li> <li>▶ In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.</li> </ul>
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## METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)

	<ul style="list-style-type: none"> <li>Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.</li> </ul> <p>Air should be supplied by an independent system. Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg.</p>
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye and face protection</b>	<p>For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:</p> <ul style="list-style-type: none"> <li>Chemical goggles</li> <li>Face shield. Full face shield may be required for supplementary but never for primary protection of eyes</li> <li>Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience.</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	<p><b>NOTE:</b></p> <ul style="list-style-type: none"> <li>The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.</li> <li>Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.</li> </ul> <p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care.</p> <ul style="list-style-type: none"> <li>Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference.</li> <li>Double gloving should be considered.</li> <li>PVC gloves.</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>Handle extremely poisonous natural toxins in closed systems such as glove bags or other enclosures, to avoid accidental contact. Workers should wear complete disposable clothing including shoe covers, gloves and mask with an independent air supply.</li> <li>For quantities up to 500 grams a laboratory coat may be suitable.</li> <li>For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.</li> <li>For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.</li> </ul>

**Respiratory protection**

Type -P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	- -	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3 Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

\* - Negative pressure demand \*\* - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

Class P2 particulate filters are used for protection against mechanically and thermally generated particulates or both.  
P2 is a respiratory filter rating under various international standards, Filters at least 94% of airborne particles

Suitable for:

- Relatively small particles generated by mechanical processes eg. grinding, cutting, sanding, drilling, sawing.
- Sub-micron thermally generated particles e.g. welding fumes, fertilizer and bushfire smoke.
- Biologically active airborne particles under specified infection control applications e.g. viruses, bacteria, COVID-19, SARS
  - The use of a disposable filtering facepiece respirator is required when working with toxins in solution if there is a concern for aerosol generation.

**SECTION 9 Physical and chemical properties**

## METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)

### Information on basic physical and chemical properties

<b>Appearance</b>	colourless crystals or white crystalline powder		
<b>Physical state</b>	Divided Solid Crystalline	<b>Relative density (Water = 1)</b>	Not Available
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	2.5-4.5	<b>Decomposition temperature (°C)</b>	Not Available
<b>Melting point / freezing point (°C)</b>	233-236; 245	<b>Viscosity (cSt)</b>	Not Available
<b>Initial boiling point and boiling range (°C)</b>	Not Available	<b>Molecular weight (g/mol)</b>	345.95
<b>Flash point (°C)</b>	Not Available	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Available	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Available	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Available	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Applicable
<b>Lower Explosive Limit (%)</b>	Not Available	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	Not Available	<b>Gas group</b>	Not Available
<b>Solubility in water</b>	Partly miscible	<b>pH as a solution (1%)</b>	4.5-6.5
<b>Vapour density (Air = 1)</b>	Not Available	<b>VOC g/L</b>	Not Available

### SECTION 10 Stability and reactivity

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	<ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul>
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

### SECTION 11 Toxicological information

#### Information on toxicological effects

<b>Inhaled</b>	<p>The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.</p> <p>If prior damage to the circulatory or nervous systems has occurred or if kidney damage has been sustained, proper screenings should be conducted on individuals who may be exposed to further risk if handling and use of the material result in excessive exposures.</p> <p>Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual.</p>
<b>Ingestion</b>	<p><b>Toxic effects</b> may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual.</p> <p>NMDA antagonists may cause irreversible damage to the nervous system akin to those caused by PCP (angel dust). Certain NMDA antagonists (notably those used to produce anaesthesia) induce arousal, seizures and a psychosis resembling schizophrenia.</p> <p>Morphine and other analgesics cause nausea, vomiting, constipation, drowsiness and confusion. Urination can be difficult, and the bowel and bile ducts can spasm.</p> <p>Adverse effects associated with opioids include constipation, nausea, vomiting, urinary retention, sedation, impaired cognition, behavioral restlessness, pruritus, miosis, respiratory depression, and postural hypotension. The most common of these adverse effects include constipation, sedation, nausea, vomiting, and pruritus.</p> <p>Because of the distribution of opioid receptors both within and outside the nervous system, opioid analgesics produce a broad spectrum of adverse effects including dysphoria, euphoria, respiratory depression, suppression of endocrine systems, cardiovascular disorders (e.g., bradycardia), convulsion, pruritus, and miosis.</p> <p>Opioids can cause fatal overdose through respiratory depression, especially when combined with other sedatives such as alcohol and benzodiazepines.</p>

## METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)

<b>Skin Contact</b>	<p>This material can cause inflammation of the skin on contact in some persons.</p> <p>The material may accentuate any pre-existing dermatitis condition</p> <p>Contact dermatitis has been reported with morphine and other narcotic analgesics.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>
<b>Eye</b>	This material can cause eye irritation and damage in some persons.
<b>Chronic</b>	<p>Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems.</p> <p>Strong evidence exists that this substance may cause irreversible mutations (though not lethal) even following a single exposure.</p> <p>Inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.</p> <p>Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population.</p> <p>Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.</p> <p>This material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects.</p> <p>Ample evidence exists from experimentation that reduced human fertility is directly caused by exposure to the material.</p> <p>Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.</p> <p>Constipation is considered the most common adverse effect associated with chronic opioid use, because opioids have various GI effects such as decrease in motility, secretions, and blood flow. In addition to these, long-term use of opioid analgesia can produce tolerance and in some cases opioid-induced hyperalgesia and/or allodynia.</p> <p>Neuroactive agents may produce tachyphylaxis whereby a high-intensity prolonged stimulus or often-repeated stimulus may bring about a diminished response (also known as desensitization).</p> <p>Chronic morphine poisoning or addiction causes pin-point pupils, rapid mood changes and poor social adaptation. As dependence and tolerance occurs, there is an overwhelming need to continue taking the drug or similar drugs and to increase the dose.</p> <p>Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis, caused by particles less than 0.5 micron penetrating and remaining in the lung.</p>

<b>METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (Rat) LD50: 95 mg/kg <sup>[2]</sup>	Not Available
<b>Legend:</b>	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

<b>METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)</b>	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia.
<b>METHADONE HYDROCHLORIDE</b>	Equivocal tumourigen by RTECS criteria. Neoplastic by RTECS criteria Depressed general activity, cardiac changes, lowered blood pressure, analgesia, liver, testicular and endocrine tumors, effects on newborn, effects on fertility, specific developmental abnormalities (central nervous system, blood and lymphatic systems, including spleen and marrow), foetotoxicity recorded.
<b>METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE) &amp; METHADONE HYDROCHLORIDE</b>	<p>Laboratory (in vitro) and animal studies show, exposure to the material may result in a possible risk of irreversible effects, with the possibility of producing mutation.</p> <p>Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins.</p> <p>Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema.</p> <p>Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure.</p> <p>The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions.</p> <p>NMDA receptor antagonists induce a state called dissociative anesthesia, marked by catalepsy, amnesia, and analgesia.</p> <p>Depressed NMDA receptor function is associated with an array of negative symptoms. For example, NMDA receptor hypofunction that occurs as the brain ages may be partially responsible for memory deficits associated with aging. Schizophrenia may also have to do with irregular NMDA receptor function (the glutamate hypothesis of schizophrenia). Increased levels of another NMDA antagonist, kynurenic acid, may aggravate the symptoms of schizophrenia, according to the "kynurenic hypothesis".</p> <p>Cytochrome P450 enzymes are essential for the metabolism of many medications. Although this class has more than 50 enzymes, six of them metabolize 90 percent of drugs, with the two most significant enzymes being CYP3A4 and CYP2D6. Genetic variability (polymorphism) in these enzymes may influence a patient's response to commonly prescribed drug classes, including beta blockers and antidepressants. Cytochrome P450 enzymes can be inhibited or induced by drugs, resulting in clinically significant drug-drug interactions that can cause unanticipated adverse reactions or therapeutic failures.</p>

<b>Acute Toxicity</b>	✓	<b>Carcinogenicity</b>	✗
<b>Skin Irritation/Corrosion</b>	✓	<b>Reproductivity</b>	✓
<b>Serious Eye Damage/Irritation</b>	✓	<b>STOT - Single Exposure</b>	✗
<b>Respiratory or Skin sensitisation</b>	✓	<b>STOT - Repeated Exposure</b>	✓
<b>Mutagenicity</b>	✓	<b>Aspiration Hazard</b>	✗

**Legend:** ✗ – Data either not available or does not fill the criteria for classification  
 ✓ – Data available to make classification

## SECTION 12 Ecological information

## Toxicity

Continued...

## METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)

METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
<b>Legend:</b>	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.

Wastes resulting from use of the product must be disposed of on site or at approved waste sites.

**DO NOT discharge into sewer or waterways.**

### Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
methadone hydrochloride	HIGH	HIGH

### Bioaccumulative potential

Ingredient	Bioaccumulation
methadone hydrochloride	MEDIUM (LogKOW = 4.1665)

### Mobility in soil

Ingredient	Mobility
methadone hydrochloride	LOW (KOC = 72790)


## SECTION 13 Disposal considerations

### Waste treatment methods

<b>Product / Packaging disposal</b>	<p>Valuable substance, hold all residues for recovery. Disposal of the material must be carried out in accordance with the requirements of the relevant Federal/State Act(s) or Code(s) regulating the disposal of Drugs of Addiction.</p> <ul style="list-style-type: none"> <li>▶ Consult manufacturer/supplier for recycling options.</li> <li>▶ Decontaminate empty containers with water; incinerate plastic bags.</li> </ul> <p>There is conflicting evidence as to which methods are most effective for the inactivation of non-proteinaceous biotoxins. The following disposal instructions have been developed to ensure all the non-proteinaceous biotoxin wastes are disposed in a manner that is consistent and safe for all personnel involved.</p> <p>Note: Additional instructions may apply to biotoxins regulated as "select agents"..A biotoxin is regulated as a select agent only if the aggregate amount of the biotoxin under the control of a principal investigator exceeds a certain predefined amount.</p> <p><b>For biotoxins containing non-proteinaceous biotoxins (includes biotoxin contaminated debris)</b></p> <p><b>Solid waste:</b> (Debris includes disposable items such as gloves, labcoats, absorbent paper, plastic pipette tips and empty containers)</p> <ul style="list-style-type: none"> <li>▶ Do NOT add bleach or any other chemical to deactivate.</li> </ul> <p>Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> <li>▶ Reduction</li> <li>▶ Reuse</li> <li>▶ Recycling</li> <li>▶ Disposal (if all else fails)</li> </ul> <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.</p> <ul style="list-style-type: none"> <li>▶ <b>DO NOT allow wash water from cleaning or process equipment to enter drains.</b></li> <li>▶ It may be necessary to collect all wash water for treatment before disposal.</li> <li>▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</li> <li>▶ Where in doubt contact the responsible authority.</li> </ul>
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## SECTION 14 Transport information

### Labels Required

<b>Marine Pollutant</b>	
<b>HAZCHEM</b>	2X

### Land transport (ADG)

<b>UN number or ID number</b>	1544
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## METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)

<b>UN proper shipping name</b>	ALKALOIDS, SOLID, N.O.S. or ALKALOID SALTS, SOLID, N.O.S. * (contains METHADONE HYDROCHLORIDE B.P. Cert. (methadone hydrochloride))	
<b>Transport hazard class(es)</b>	Class	6.1
	Subsidiary risk	Not Applicable
<b>Packing group</b>	III	
<b>Environmental hazard</b>	Environmentally hazardous	
<b>Special precautions for user</b>	Special provisions	43 223 274
	Limited quantity	5 kg

### Air transport (ICAO-IATA / DGR)

<b>UN number</b>	1544	
<b>UN proper shipping name</b>	Alkaloids, solid, n.o.s. ** (contains METHADONE HYDROCHLORIDE B.P. Cert. (methadone hydrochloride)); Alkaloid salts, solid, n.o.s. ** (contains METHADONE HYDROCHLORIDE B.P. Cert. (methadone hydrochloride))	
<b>Transport hazard class(es)</b>	ICAO/IATA Class	6.1
	ICAO / IATA Subrisk	Not Applicable
	ERG Code	6L
<b>Packing group</b>	III	
<b>Environmental hazard</b>	Environmentally hazardous	
<b>Special precautions for user</b>	Special provisions	A3 A5 A6 A801
	Cargo Only Packing Instructions	677
	Cargo Only Maximum Qty / Pack	200 kg
	Passenger and Cargo Packing Instructions	670
	Passenger and Cargo Maximum Qty / Pack	100 kg
	Passenger and Cargo Limited Quantity Packing Instructions	Y645
	Passenger and Cargo Limited Maximum Qty / Pack	10 kg

### Sea transport (IMDG-Code / GGVSee)

<b>UN number</b>	1544	
<b>UN proper shipping name</b>	ALKALOIDS, SOLID, N.O.S. or ALKALOIDS SALTS, SOLID, N.O.S. * (contains METHADONE HYDROCHLORIDE B.P. Cert. (methadone hydrochloride))	
<b>Transport hazard class(es)</b>	IMDG Class	6.1
	IMDG Subrisk	Not Applicable
<b>Packing group</b>	III	
<b>Environmental hazard</b>	Marine Pollutant	
<b>Special precautions for user</b>	EMS Number	F-A, S-A
	Special provisions	43 223 274
	Limited Quantities	5 kg

### Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

### Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
methadone hydrochloride	Not Available

### Transport in bulk in accordance with the IGC Code

Product name	Ship Type
methadone hydrochloride	Not Available

## SECTION 15 Regulatory information

### Safety, health and environmental regulations / legislation specific for the substance or mixture

methadone hydrochloride is found on the following regulatory lists

Australia Chemicals with non-industrial uses removed from the Australian Inventory of Chemical Substances (old Inventory)

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 8

FEI Equine Prohibited Substances List - Controlled Medication

FEI Equine Prohibited Substances List (EPSL)

### National Inventory Status

Continued...

## METHADONE HYDROCHLORIDE B.P. CERT. (METHADONE HYDROCHLORIDE)

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	No (methadone hydrochloride)
Canada - NDSL	No (methadone hydrochloride)
China - IECSC	No (methadone hydrochloride)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (methadone hydrochloride)
Korea - KECI	No (methadone hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (methadone hydrochloride)
USA - TSCA	No (methadone hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	No (methadone hydrochloride)
Russia - FBEPH	No (methadone hydrochloride)
<b>Legend:</b>	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

### SECTION 16 Other information

<b>Revision Date</b>	25/05/2023
<b>Initial Date</b>	25/05/2023

#### Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

#### Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average  
 PC—STEL: Permissible Concentration-Short Term Exposure Limit  
 IARC: International Agency for Research on Cancer  
 ACGIH: American Conference of Governmental Industrial Hygienists  
 STEL: Short Term Exposure Limit  
 TEEL: Temporary Emergency Exposure Limit.  
 IDLH: Immediately Dangerous to Life or Health Concentrations  
 ES: Exposure Standard  
 OSF: Odour Safety Factor  
 NOAEL :No Observed Adverse Effect Level  
 LOAEL: Lowest Observed Adverse Effect Level  
 TLV: Threshold Limit Value  
 LOD: Limit Of Detection  
 OTV: Odour Threshold Value  
 BCF: BioConcentration Factors  
 BEI: Biological Exposure Index  
 AIIC: Australian Inventory of Industrial Chemicals  
 DSL: Domestic Substances List  
 NDSL: Non-Domestic Substances List  
 IECSC: Inventory of Existing Chemical Substance in China  
 EINECS: European INventory of Existing Commercial chemical Substances  
 ELINCS: European List of Notified Chemical Substances  
 NLP: No-Longer Polymers  
 ENCS: Existing and New Chemical Substances Inventory  
 KECI: Korea Existing Chemicals Inventory  
 NZIoC: New Zealand Inventory of Chemicals  
 PICCS: Philippine Inventory of Chemicals and Chemical Substances  
 TSCA: Toxic Substances Control Act  
 TCSI: Taiwan Chemical Substance Inventory  
 INSQ: Inventario Nacional de Sustancias Químicas  
 NCI: National Chemical Inventory  
 FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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