

# Ilium Medetomidine injection

## Troy Laboratories Pty Ltd

Chemwatch Hazard Alert Code: 2

Chemwatch: 5394-78

Issue Date: 10/12/2021

Version No: 4.1

Print Date: 31/03/2025

Safety Data Sheet according to Work Health and Safety Regulations (Hazardous Chemicals) 2023 and ADG requirements

L.GHS.AUS.EN.E

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

#### Product Identifier

Product name	Ilium Medetomidine injection
Chemical Name	Not Applicable
Synonyms	APVMA number 64251; ACVM number A10488
Chemical formula	Not Applicable
Other means of identification	Not Available

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

Relevant identified uses	For use as a sedative and analgesic in the restraint of cats and dogs. To be used as directed on product label.
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#### Details of the manufacturer or supplier of the safety data sheet

Registered company name	Troy Laboratories Pty Ltd
Address	37 Glendenning Road Glendenning NSW 2761 Australia
Telephone	02 8808 3600
Fax	02 9677 9300
Website	<a href="http://www.Troylab.com.au">www.Troylab.com.au</a>
Email	admin@troylab.com.au

#### Emergency telephone number

Association / Organisation	Ixom Emergency Response Service
Emergency telephone number(s)	1800 033 111 (24 hours)
Other emergency telephone number(s)	Not Available

### SECTION 2 Hazards identification

#### Classification of the substance or mixture

Poisons Schedule	S4
Classification <sup>[1]</sup>	Non hazardous
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

#### Label elements

Hazard pictogram(s)	Not Applicable
Signal word	<b>Not Applicable</b>

#### Hazard statement(s)

Not Applicable

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**Precautionary statement(s) Prevention**

Not Applicable

**Precautionary statement(s) Response**

Not Applicable

**Precautionary statement(s) Storage**

Not Applicable

**Precautionary statement(s) Disposal**

Not Applicable

**SECTION 3 Composition / information on ingredients****Substances**

See section below for composition of Mixtures

**Mixtures**

CAS No	%[weight]	Name
86347-15-1	<1	<u>medetomidine hydrochloride</u>
Not Available	balance	Ingredients determined not to be hazardous

**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

**SECTION 4 First aid measures****Description of first aid measures**

<b>Eye Contact</b>	<p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> <li>▶ Wash out immediately with water.</li> <li>▶ If irritation continues, seek medical attention.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<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>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ For advice, contact a Poisons Information Centre or a doctor at once.</li> <li>▶ Urgent hospital treatment is likely to be needed.</li> <li>▶ <b>If swallowed do NOT induce vomiting.</b></li> <li>▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> <li>▶ Observe the patient carefully.</li> <li>▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.</li> <li>▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.</li> <li>▶ Transport to hospital or doctor without delay.</li> </ul>

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

Treat symptomatically.

Following recent ingestion or overdose of anxiolytic sedatives, hypnotics and neuroleptics, the stomach may be emptied by gastric lavage and aspiration. Patients should be managed with intensive symptomatic and supportive therapy with particular attention being paid to the maintenance of cardiovascular, respiratory and renal functions and to the maintenance of electrolyte balance.

MARTINDALE: The Extra Pharmacopoeia, 29th Edition

**SECTION 5 Firefighting measures****Extinguishing media**

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.

Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.

In such an event consider:

- ▶ foam.
- ▶ dry chemical powder.
- ▶ carbon dioxide.

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## Special hazards arising from the substrate or mixture

<b>Fire Incompatibility</b>	None known.
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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> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ The material is not readily combustible under normal conditions.</li> <li>▶ However, it will break down under fire conditions and the organic component may burn.</li> <li>▶ Not considered to be a significant fire risk.</li> <li>▶ Heat may cause expansion or decomposition with violent rupture of containers.</li> <li>▶ Decomposes on heating and may produce toxic fumes of carbon monoxide (CO).</li> <li>▶ May emit acrid smoke.</li> </ul> <p>Decomposes on heating and produces toxic fumes of: carbon dioxide (CO<sub>2</sub>) nitrogen oxides (NO<sub>x</sub>) other pyrolysis products typical of burning organic material. May emit corrosive fumes.</p>
<b>HAZCHEM</b>	Not Applicable

## 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>	<ul style="list-style-type: none"> <li>▶ Clean up all spills immediately.</li> <li>▶ Avoid breathing vapours and contact with skin and eyes.</li> <li>▶ Control personal contact with the substance, by using protective equipment.</li> <li>▶ Contain and absorb spill with sand, earth, inert material or vermiculite.</li> <li>▶ Wipe up.</li> <li>▶ Place in a suitable, labelled container for waste disposal.</li> </ul>
<b>Major Spills</b>	<p>Moderate hazard.</p> <ul style="list-style-type: none"> <li>▶ Clear area of personnel and move upwind.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water course.</li> <li>▶ Stop leak if safe to do so.</li> <li>▶ Contain spill with sand, earth or vermiculite.</li> <li>▶ Collect recoverable product into labelled containers for recycling.</li> <li>▶ Neutralise/decontaminate residue (see Section 13 for specific agent).</li> <li>▶ Collect solid residues and seal in labelled drums for disposal.</li> <li>▶ Wash area and prevent runoff into drains.</li> <li>▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using.</li> <li>▶ If contamination of drains or waterways occurs, advise emergency services.</li> </ul>

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>	<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>▶ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>▶ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ <b>When handling, DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> </ul>
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Continued...

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	<ul style="list-style-type: none"> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> <li>▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>▶ Use good occupational work practice.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>

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

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul>
<b>Storage incompatibility</b>	None known

**SECTION 8 Exposure controls / personal protection**

**Control parameters**

**Occupational Exposure Limits (OEL)**

**INGREDIENT DATA**

Not Available


Ingredient	Original IDLH	Revised IDLH
medetomidine hydrochloride	Not Available	Not Available

**MATERIAL DATA**

**Exposure controls**

<b>Appropriate engineering controls</b>	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Type of Contaminant:</th> <th style="text-align: left;">Air Speed:</th> </tr> </thead> <tbody> <tr> <td>solvent, vapours, degreasing etc., evaporating from tank (in still air)</td> <td>0.25-0.5 m/s (50-100 f/min)</td> </tr> <tr> <td>aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)</td> <td>0.5-1 m/s (100-200 f/min.)</td> </tr> <tr> <td>direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td> <td>1-2.5 m/s (200-500 f/min)</td> </tr> <tr> <td>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).</td> <td>2.5-10 m/s (500-2000 f/min.)</td> </tr> </tbody> </table> <p>Within each range the appropriate value depends on:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Lower end of the range</th> <th style="text-align: left;">Upper end of the range</th> </tr> </thead> <tbody> <tr> <td>1: Room air currents minimal or favourable to capture</td> <td>1: Disturbing room air currents</td> </tr> <tr> <td>2: Contaminants of low toxicity or of nuisance value only</td> <td>2: Contaminants of high toxicity</td> </tr> <tr> <td>3: Intermittent, low production.</td> <td>3: High production, heavy use</td> </tr> <tr> <td>4: Large hood or large air mass in motion</td> <td>4: Small hood - local control only</td> </tr> </tbody> </table> <p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the</p>	Type of Contaminant:	Air Speed:	solvent, vapours, degreasing etc., evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min)	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min)	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)	Lower end of the range	Upper end of the range	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents	2: Contaminants of low toxicity or of nuisance value only	2: Contaminants of high toxicity	3: Intermittent, low production.	3: High production, heavy use	4: Large hood or large air mass in motion	4: Small hood - local control only
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	extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye and face protection</b>	<ul style="list-style-type: none"> <li>▶ Safety glasses with side shields.</li> <li>▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]</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 lenses 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. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	<ul style="list-style-type: none"> <li>▶ Wear chemical protective gloves, e.g. PVC.</li> <li>▶ Wear safety footwear or safety gumboots, e.g. Rubber</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ P.V.C apron.</li> <li>▶ Barrier cream.</li> <li>▶ Skin cleansing cream.</li> <li>▶ Eye wash unit.</li> </ul>

## Recommended material(s)

## GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the

**computer-generated** selection:

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Material	CPI
BUTYL	C
NAT+NEOPR+NITRILE	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NEOPRENE/NATURAL	C
NITRILE	C
NITRILE+PVC	C
PE	C
PE/EVAL/PE	C
PVA	C
PVC	C
SARANEX-23	C
SARANEX-23 2-PLY	C
TEFLON	C
VITON	C
VITON/CHLOROBUTYL	C

\* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

**NOTE:** As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

\* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice

## Respiratory protection

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

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant.

Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	A-AUS / Class1	-
up to 50	1000	-	A-AUS / Class 1
up to 50	5000	Airline *	-
up to 100	5000	-	A-2
up to 100	10000	-	A-3
100+			Airline**

\* - Continuous Flow \*\* - Continuous-flow or positive pressure demand

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)

- ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- ▶ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

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of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

## Ansell Glove Selection

Glove — In order of recommendation
AlphaTec 02-100
AlphaTec® 15-554
AlphaTec® Solvex® 37-185
TouchNTuff® DermaShield™ 73-701
AlphaTec® 38-612
AlphaTec® 53-001
AlphaTec® 58-005
AlphaTec® 58-008
AlphaTec® 58-530B
AlphaTec® 58-530W

The suggested gloves for use should be confirmed with the glove supplier.

## SECTION 9 Physical and chemical properties

## Information on basic physical and chemical properties

<b>Appearance</b>	Clear colourless liquid with no odour; mixes with water.		
<b>Physical state</b>	Liquid	<b>Relative density (Water = 1)</b>	1.004
<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 Applicable
<b>pH (as supplied)</b>	5-6	<b>Decomposition temperature (°C)</b>	Not Available
<b>Melting point / freezing point (°C)</b>	~0	<b>Viscosity (cSt)</b>	Not Available
<b>Initial boiling point and boiling range (°C)</b>	~100	<b>Molecular weight (g/mol)</b>	Not Applicable
<b>Flash point (°C)</b>	Not Applicable	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Available	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Applicable	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Applicable	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Available
<b>Lower Explosive Limit (%)</b>	Not Applicable	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	2.37 @20C	<b>Gas group</b>	Not Available
<b>Solubility in water</b>	Miscible	<b>pH as a solution (1%)</b>	Not Available
<b>Vapour density (Air = 1)</b>	Not Available	<b>VOC g/L</b>	Not Available
<b>Heat of Combustion (kJ/g)</b>	Not Available	<b>Ignition Distance (cm)</b>	Not Available
<b>Flame Height (cm)</b>	Not Available	<b>Flame Duration (s)</b>	Not Available
<b>Enclosed Space Ignition Time Equivalent (s/m3)</b>	Not Available	<b>Enclosed Space Ignition Deflagration Density (g/m3)</b>	Not Available

## SECTION 10 Stability and reactivity

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	Product is considered stable and hazardous polymerisation will not occur.
<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>a) Acute Toxicity</b>	Based on available data, the classification criteria are not met.
<b>b) Skin Irritation/Corrosion</b>	Based on available data, the classification criteria are not met.
<b>c) Serious Eye Damage/Irritation</b>	Based on available data, the classification criteria are not met.
<b>d) Respiratory or Skin sensitisation</b>	Based on available data, the classification criteria are not met.
<b>e) Mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>f) Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>g) Reproductivity</b>	Based on available data, the classification criteria are not met.
<b>h) STOT - Single Exposure</b>	Based on available data, the classification criteria are not met.
<b>i) STOT - Repeated Exposure</b>	Based on available data, the classification criteria are not met.
<b>j) Aspiration Hazard</b>	Based on available data, the classification criteria are not met.

<b>Inhaled</b>	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Not normally a hazard due to non-volatile nature of product
<b>Ingestion</b>	The material has <b>NOT</b> been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
<b>Skin Contact</b>	Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.
<b>Eye</b>	Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
<b>Chronic</b>	Exposure to the material may cause concerns for human fertility, generally on the basis that results in animal studies provide sufficient evidence to cause a strong suspicion of impaired fertility in the absence of toxic effects, or evidence of impaired fertility occurring at around the same dose levels as other toxic effects, but which are not a secondary non-specific consequence of other toxic effects.  Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, generally on the basis that results in appropriate animal studies provide strong suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of other toxic effects.

<b>Ilium Medetomidine injection</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available
<b>medetomidine hydrochloride</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Oral (Rat) LD50: 31 mg/kg <sup>[2]</sup>	Not Available

**Legend:** 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>MEDETOMIDINE HYDROCHLORIDE</b>	*Pfizer MSDS for sterile injectable solution. Carcinogenesis, Mutagenesis, Impairment of Fertility Animal carcinogenicity studies have not been performed with the S-isomer, dexmedetomidine. Dexmedetomidine was not mutagenic in vitro, in either the bacterial reverse mutation assay (E. coli and Salmonella typhimurium) or the mammalian cell forward mutation assay (mouse lymphoma). Dexmedetomidine was clastogenic in the in vitro human lymphocyte chromosome aberration test with, but not without, rat S9 metabolic activation. In contrast, dexmedetomidine was not clastogenic in the in vitro human lymphocyte chromosome aberration test with or without human S9 metabolic activation. Although dexmedetomidine was clastogenic in an in vivo mouse micronucleus test in NMRI mice, there was no evidence of clastogenicity in CD-1 mice. Fertility in male or female rats was not affected after daily subcutaneous injections of dexmedetomidine at doses up to 54 mcg/kg (less than the maximum recommended human intravenous dose on a mcg/m <sup>2</sup> basis) administered from 10 weeks prior to mating in males, and 3 weeks prior to mating and during mating in females. In an in-vitro human placenta study, placental transfer of dexmedetomidine occurred. In a study in the pregnant rat, placental transfer of dexmedetomidine was observed when radiolabeled dexmedetomidine was administered subcutaneously. Thus, foetal exposure should be expected in humans. Teratogenic effects were not observed in rats following subcutaneous administration of dexmedetomidine during the period of fetal organogenesis (from gestation day 5 to 16) with doses up to 200 mcg/kg (representing a dose approximately equal to the maximum recommended human intravenous dose based on body surface area) or in rabbits following intravenous administration of
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Continued...



## Ilium Medetomidine injection

dexmedetomidine during the period of fetal organogenesis (from gestation day 6 to 18) with doses up to 96 mcg/kg (representing approximately half the human exposure at the maximum recommended dose based on plasma area under the time-curve comparison). However, foetal toxicity, as evidenced by increased post-implantation losses and reduced live pups, was observed in rats at a subcutaneous dose of 200 mcg/kg. The no-effect dose in rats was 20 mcg/kg (representing a dose less than the maximum recommended human intravenous dose based on a body surface area comparison). In another reproductive toxicity study when dexmedetomidine was administered subcutaneously to pregnant rats at 8 and 32 mcg/kg (representing a dose less than the maximum recommended human intravenous dose based on a body surface area comparison) from gestation day 16 through weaning, lower offspring weights were observed. Additionally, when offspring of the 32 mcg/kg group were allowed to mate, elevated foetal and embryocidal toxicity and delayed motor development was observed in second generation offspring. 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. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.

alpha-Adrenergic receptors have actions in common, but also individual effects. Common (or still receptor unspecified) actions include:

- vasoconstriction
- decreased motility of smooth muscle in gastrointestinal tract

Subtype unspecific alpha agonists can be used to treat rhinitis (they decrease mucus secretion). Subtype unspecific alpha antagonists can be used to treat pheochromocytoma (they decrease vasoconstriction caused by norepinephrine).

Alpha-agonist toxicity may occur accidentally or intentionally. Toxicity is often due to intentional overdose and accidental pediatric ingestion. Overdoses can occur after ingestion of pills, skin patches, or via self-administered medication pumps that may be misused or malfunctioning. Chronic and accidental overdose can occur in situations involving chronic pain, with use of oral extended-release and transdermal formulations. Pharmacy dosing and compounding errors have also occurred, which is of particular concern for pediatric toxicity. In addition, drug-drug interactions may occur.

Alpha-adrenergic agonist toxicity is due to a broad group of pharmaceutical agents known as alpha agonists, which can be further broken down into central alpha-2 agonists and peripheral alpha-1 agonists. Stimulation of central alpha-2 receptors causes decreased secretion of catecholamines through a negative feedback mechanism. Stimulation of peripheral alpha-1 receptors primarily increases blood pressure via induced vasoconstriction. Alpha-adrenergic agonist toxicity is of primary concern with alpha-2 adrenergic agonist xenobiotics through the resulting depletion of catecholamines associated with these agents; however, there are many topical alpha-1 agonists that when misused cause similar toxicity.

The primary mechanism of toxicity of alpha agonists is through central alpha-2 agonism. Central alpha-2 agonist toxicity may occur from an acute or nonacute overdose of central alpha-2 agonists or misuse of topical alpha-1 agonists, which when ingested, stimulate alpha-2 receptors. In overdose, an overall depletion of catecholamines occurs, leading to central nervous system depression, along with bradycardia and hypotension. Other clinical findings can include miosis, hypothermia, and possible respiratory depression. Paradoxically, in overdose, there is also transient stimulation of peripheral alpha-1 receptors and post-synaptic alpha-2 receptors, causing brief catecholamine release, which leads to an early, transient hypertension. Symptomatology is not necessarily dose-dependent.

The primary mechanism of action of alpha-2 agonists is stimulation of presynaptic alpha-2 receptors in the central nervous system, activating inhibitory neurons which lead to a reduction in sympathetic output via a negative feedback mechanism. This causes an overall decrease in the secretion of the catecholamine, norepinephrine, which is beneficial for the desired therapeutic effects of decreased blood pressure and heart rate

The substance exhibits effects on the adrenergic receptors

The adverse effects seen with adrenergic drugs are broad. The most common side effects are changes in heart rate and blood pressure.

Non-selective binding to the adrenergic receptors can cause different side effects that vary based on the specific agent as well as the dosage. The common non-selective agonists are norepinephrine, epinephrine, and isoproterenol (isoprenaline). Common side effects are tachycardia, hypertension, arrhythmias, palpitations, and anxiety. Norepinephrine is less likely to cause arrhythmias than some of the other pressor medications, probably because it is more alpha-1 receptor-selective as compared with the beta-1 receptor. [

Adrenergic receptors all have drug antagonists. Alpha-blockers are not generally indicated for the treatment of alpha-agonist overdoses. Beta-blockers may be used to treat adverse effects arising from adrenergic receptor agonists acutely. Beta-blockers can treat tachycardia and hypertension that may occur from vasopressors. Toxicity should be monitored in the pediatric population when using beta-2 agonists as they can increase concentrations of liver aminotransferase

Many cells have these receptors, and the binding of a catecholamine to the receptor will generally stimulate the sympathetic nervous system (SNS). SNS is responsible for the fight-or-flight response, which is triggered for example by exercise or fear causing situations. This response dilates pupils, increases heart rate, mobilizes energy, and diverts blood flow from non-essential organs to skeletal muscle. These effects together tend to increase physical performance momentarily.

High catecholamine levels in blood are associated with stress, which can be induced from psychological reactions or environmental stressors such as elevated sound levels, intense light, or low blood sugar levels.

Extremely high levels of catecholamines (also known as catecholamine toxicity) can occur in central nervous system trauma due to stimulation and/or damage of nuclei in the brainstem, in particular those nuclei affecting the sympathetic nervous system. In emergency medicine, this occurrence is widely known as catecholamine dump.

Extremely high levels of catecholamine can also be caused by neuroendocrine tumours in the adrenal medulla, a treatable condition known as pheochromocytoma.

High levels of catecholamines can also be caused by monoamine oxidase A (MAO-A) deficiency. As MAO-A is one of the enzymes responsible for degradation of these neurotransmitters, its deficiency increases the bioavailability of these neurotransmitters considerably. It occurs in the absence of pheochromocytoma, neuroendocrine tumours, and carcinoid syndrome, but it looks similar to carcinoid syndrome such as facial flushing and aggression.

The acute porphyria's can cause elevated catecholamines

Epinephrine (adrenaline) reacts with both alpha- and beta-adrenoreceptors, causing vasoconstriction and vasodilation, respectively. Although alpha receptors are less sensitive to epinephrine, when activated at pharmacologic doses, they override



## Ilium Medetomidine injection

the vasodilation mediated by beta-adrenoreceptors because there are more peripheral alpha1 receptors than beta-adrenoreceptors. The result is that high levels of circulating epinephrine cause vasoconstriction. However, the opposite is true in the coronary arteries, where beta2 response is greater than that of alpha1, resulting in overall dilation with increased sympathetic stimulation. At lower levels of circulating epinephrine (physiologic epinephrine secretion), beta-adrenoreceptor stimulation dominates since epinephrine has a higher affinity for the beta2 adrenoreceptor than the alpha1 adrenoreceptor, producing vasodilation followed by decrease of peripheral vascular resistance.

The adrenergic receptors or adrenoreceptors are a class of G protein-coupled receptors that are targets of many catecholamines like norepinephrine (noradrenaline) and epinephrine (adrenaline) produced by the body, but also many medications like beta blockers, beta2 agonists and alpha2 agonists, which are used to treat high blood pressure and asthma for example.

There are two main groups of adrenoreceptors, alpha and beta, with 9 subtypes in total:

alpha types comprise the alpha1 (a Gq coupled receptor) and alpha2 (a Gi coupled receptor)[

alpha1 has 3 subtypes; alpha1A, alpha1B and alpha1D

alpha2 has 3 subtypes; alpha2A, alpha2B and alpha2C

beta types comprise the beta1, beta2 and beta3. All 3 are coupled to Gs proteins, but beta2 and beta3 also couple to Gi

Gi and Gs are linked to adenylyl cyclase. Agonist binding thus causes a rise in the intracellular concentration of the second messenger (Gi inhibits the production of cAMP) cAMP. Downstream effectors of cAMP include cAMP-dependent protein kinase (PKA), which mediates some of the intracellular events following hormone binding.

alpha-Receptors are excitatory mainly to receptors of the eye, gastrointestinal tract and vascular smooth muscle. alpha-Receptors can be further subdivided into two types. alpha-1 Receptors are primarily located in postjunctional positions and initiate postsynaptic excitatory smooth muscle and exocrine gland events. alpha-2 Receptors are primarily presynaptic inhibitors that mediate negative feedback of noradrenaline release and oppose alpha-1 stimulation. alpha-1 Receptors dominate the peripheral nervous system whilst alpha-2 receptors dominate the central nervous system. Central nervous system sympathomimetic effects result from stimulation of central adrenergic neurons. Selective agonists include phenylephrine (alpha-1,2), isoproterenol (beta-1,2), dobutamine (beta-1) and terbutaline (beta-2). Antagonists include phenoxybenzamine, a selective alpha-1 (post-synaptic) blocker and yohimbine, a selective alpha-2 (pre-synaptic) blocker.

CLINICAL EFFECTS of ADRENORECEPTOR BLOCKAGE and STIMULATION.

alpha	beta-1	beta-2
	STIMULATION	
Mydriasis Vasoconstriction Coronary dilation Decreased GI Motility Bladder contraction	Miosis Tachycardia Increased cardiac contractility Accelerated AV conduction Renin Stimulation	Miosis Vasodilation Bronchodilation Hyperglycaemia Decreased GI motility Bladder relaxation Renin release
	BLOCKADE	
Miosis Postural hypotension Reflex tachycardia Angina (uncommon) Gastric hyperacidity	Hypotension Cardiac arrhythmias Bradycardia Pulmonary oedema Hyperkalaemia (uncommon)	Hypoglycaemia with hypertension Bronchospasm Raynaud's phenomenon Hyperkalaemia (uncommon)

Actions of the alpha2 adrenergic receptor agonists include:

decreased insulin release from the pancreas, increased glucagon release from the pancreas, contraction of sphincters of the GI-tract, negative feedback in the neuronal synapses - presynaptic inhibition of norepinephrine release in CNS, increased platelet aggregation (increased blood clotting tendency), decreases peripheral vascular resistance

alpha2 Agonists can be used to treat: hypertension – decrease blood pressure raising actions of the sympathetic nervous system  
alpha2 Antagonists can be used to treat: impotence – relax penile smooth muscles and ease blood flow, depression – enhance mood by increasing norepinephrine secretion.

The alpha2 receptor couples to the Gi/o protein. It is a presynaptic receptor, causing negative feedback on, for example, norepinephrine (NE). When NE is released into the synapse, it feeds back on the alpha2 receptor, causing less NE release from the presynaptic neuron. This decreases the effect of NE. There are also alpha2 receptors on the nerve terminal membrane of the post-synaptic adrenergic neuron.

For G-protein inhibitors:/ antagonists/ modulators.

G protein-coupled receptors (GPCRs) are essential cell membrane signaling molecules and represent the most important class of drug targets. Some signaling pathways downstream of a GPCR may be responsible for drug adverse effects, while others mediate therapeutic efficacy. Biased ligands preferentially activate only a subset of all GPCR signaling pathways. They hold great potential to become next-generation GPCR drugs with less side effects due to their potential to exclusively activate desired signaling pathways.

GPCR ligands include odorants, tastants, and neurotransmitters, and vary in size and properties. Dramatic chemical diversity may occur even among ligands of the same receptor. Chemical variability of antagonists significantly correlates with the binding site hydrophobicity and anti-correlates with the number of hydrogen bond donors in the binding site. The number of disulfide bridges in the extracellular region of a receptor anti-correlates with the range of molecular weights of its antagonists, highlighting the role of the entrance pathway in determining the size selectivity for GPCR antagonists.

The number of protein targets included in the cross-pharmacology profile of the different GPCRs changes significantly upon varying the ligand similarity and binding affinity criteria. However, with the exception of muscarinic receptors, aminergic GPCRs distinguish themselves from the rest of the members in the family by their remarkably high levels of pharmacological similarity among them.

GPCRs are classified under the GRAFS system (Metabotropic Glutamate, Rhodopsin, Adhesion, Frizzled/taste2/Smoothed and Secretin), with therapies having been developed for about 30 GPCRs from the glutamate, rhodopsin and secretin families. GPCR signaling requires significant conformational changes within the trans-membrane TM domain, triggered by agonist binding, and is often coupled to interactions from the extracellular domains or loops. It is becoming clear that many binding sites and mechanisms exist for positive and negative allosteric regulation, and for biased signaling pathways, likely in greater numbers than seen in most other protein systems.

When GPCRs are exposed to a neutral agonist, such as morphine on mu-opioid receptor, an occupied receptor can generate several signal waves (non-biased agonist). In GPCR signaling, the ability of a molecule to selectively activate one pathway without affecting another pathway is called biased agonism. Biased signaling occurs at different signaling proteins, including G proteins, GRKs, beta-arrestins, and even at levels of the allosteric binding site. Since GPCR activation-induced two distinct signal waves, G protein-dependent signaling followed by beta-arrestin-dependent signaling opens a new promising therapeutic future in the world of GPCRs. This is true since discovering such molecules dramatically lowers the adverse effects by turning off unwanted signals. For example, the analgesic effect of morphine (neutral agonist) through the activation of u-receptors is accompanied by several side effects, including constipation, respiratory depression, tolerance, nausea, and sedation. Despite the long history and obvious desirability of developing drugs targeting GPCRs, there are several problems associated with their development. For example, the muscarinic M1 receptor is a well-validated target for agonists that could alleviate cognitive decline during neurodegeneration.

Muscarinic acetylcholine receptors (MRs, or mAChRs), which are more sensitive to muscarine than to nicotine, are a group of class A GPCRs comprising five distinct subtypes, named as muscarinic M1, M2, M3, M4, and M5 receptors (M1R-M5R). M1R, M3R, and M5R are coupled to the Gq/11 family of G proteins, whereas M2R and M4R are coupled to the Gi/o family of G proteins.

However, the orthosteric binding site of M1 is virtually identical to those of the related receptors M2, M3, M4, and M5 as they all bind the native ligand acetylcholine, and activation of M2 and M3 in particular gives rise to dose-limiting side effects (gastrointestinal [GI] disturbances, cardiovascular effects).

Atropine and other anticholinergic agents exert their bronchodilator effects through the blockade of MRs in the airways. As a tertiary ammonium derivative, atropine is a nonselective antagonist with similar affinity for all of the MR subtypes. The half-life of atropine for M3R residence is 3.5 hours. Although extensively used in the past, atropine is rarely used at the present time because it is well absorbed into the systemic circulation and penetrates the blood-brain barrier, leading to multiple systemic side effects, including tachycardia.

Several long-acting muscarinic antagonists (LAMAs) are under investigation or are available for the treatment of obstructive airway diseases. LAMAs are considered to be safe drugs at recommended dosages. However, because MRs are expressed not only in the lungs, but also in the heart and the digestive and urinary tracts, the blockade of different MR subtypes in these organs by LAMA treatment can cause diverse, unwanted physiologic effects. For example, these agents can initially block prejunctional M2R on cholinergic airway nerves that normally reduce the release of the bronchoconstricting neurotransmitter acetylcholine, thus resulting in cough and paradoxical bronchoconstriction. Side effects including cardiovascular morbidity and mortality of inhaled LAMA agents in asthma need to be further studied and defined.

Another potential source of side effects when targeting other receptors could arise due to signaling through multiple different pathways.

There are multiple signaling pathways for GPCRs, and it is sometimes possible to bias the signaling of a given GPCR through either a specific G protein or through beta arrestin which could reduce the side effects of some drugs.

Targeting G protein alpha-subunits has the potential for pleiotropic effects and could result in multiple side effects.

Particular targets of concern include ion channels such as the G protein-activated inward rectifier K<sup>+</sup> channel (GIRK) and the N-type voltage-gated calcium channels. Gbeta-gamma activates GIRK channels in neurons and in atria, leading to a hyperpolarization-induced decrease in action potential firing. Therefore, when considering the use of Gbeta-gamma inhibitors in cardiac or immune therapy, interfering with the regulation of action potentials would have highly undesirable side effects, such as arrhythmias. However, empirical data using prototypical Gbeta-gamma blockers indicate that these pathways are unaffected by Gbeta-gamma inhibitors, and animals treated with gallein show no signs of arrhythmias or alterations in heart rate.

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

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

## SECTION 12 Ecological information

### Toxicity

Ilium Medetomidine injection	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

medetomidine hydrochloride	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

**Legend:** 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

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

### Persistence and degradability

Continued...

## Ilium Medetomidine injection

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

**Bioaccumulative potential**

Ingredient	Bioaccumulation
	No Data available for all ingredients

**Mobility in soil**

Ingredient	Mobility
	No Data available for all ingredients

**SECTION 13 Disposal considerations****Waste treatment methods**

<b>Product / Packaging disposal</b>	<ul style="list-style-type: none"> <li>▶ Containers may still present a chemical hazard/ danger when empty.</li> <li>▶ Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> <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> <li>▶ Recycle wherever possible.</li> <li>▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.</li> <li>▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material).</li> <li>▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.</li> </ul>
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**SECTION 14 Transport information****Labels Required**

<b>Marine Pollutant</b>	NO
<b>HAZCHEM</b>	Not Applicable

**Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS****Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS****Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS****14.7. Maritime transport in bulk according to IMO instruments****14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code**

Not Applicable

**14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code**

Product name	Group
medetomidine hydrochloride	Not Available

**14.7.3. Transport in bulk in accordance with the IGC Code**

Product name	Ship Type
medetomidine hydrochloride	Not Available

**SECTION 15 Regulatory information****Safety, health and environmental regulations / legislation specific for the substance or mixture**

medetomidine hydrochloride is found on the following regulatory lists

Continued...

## Ilium Medetomidine injection

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 4

**Additional Regulatory Information**

Not Applicable

**National Inventory Status**

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (medetomidine hydrochloride)
Canada - DSL	No (medetomidine hydrochloride)
Canada - NDSL	No (medetomidine hydrochloride)
China - IECSC	No (medetomidine hydrochloride)
Europe - EINEC / ELINCS / NLP	No (medetomidine hydrochloride)
Japan - ENCS	No (medetomidine hydrochloride)
Korea - KECI	No (medetomidine hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (medetomidine hydrochloride)
USA - TSCA	No (medetomidine hydrochloride)
Taiwan - TCSI	No (medetomidine hydrochloride)
Mexico - INSQ	No (medetomidine hydrochloride)
Vietnam - NCI	No (medetomidine hydrochloride)
Russia - FBEPH	No (medetomidine 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>	10/12/2021
<b>Initial Date</b>	30/04/2020

**SDS Version Summary**

Version	Date of Update	Sections Updated
3.1	06/05/2020	Composition / information on ingredients - Ingredients, Identification of the substance / mixture and of the company / undertaking - Supplier Information
4.1	10/12/2021	Classification change due to full database hazard calculation/update.

**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

Continued...

**Ilium Medetomidine injection**

- BEI: Biological Exposure Index
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration
- MARPOL: International Convention for the Prevention of Pollution from Ships
- IMSBC: International Maritime Solid Bulk Cargoes Code
- IGC: International Gas Carrier Code
- IBC: International Bulk Chemical Code
  
- 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
- KECl: 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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