

# SAFETY DATA SHEET

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### Contact information

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#### General

##### Manufacturer:

Parnell Technologies Pty Ltd  
 Unit 4, Century Estate  
 476 Gardeners Road, NSW 2015  
 Australia

##### Distributor:

Parnell U.S.1, Inc.  
 7015 College Blvd, Level 6  
 Overland Park, KS 66211  
 USA

##### Emergency telephone number

+61 2 9667 4411 (business hours)

+1-800-887-2763 (24 hours)

### Product identifier

### Contrased Sterile Injectable Solution

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

Active pharmaceutical ingredient; indicated for the reversal of the sedative and analgesic effects of dexmedetomidine hydrochloride and medetomidine hydrochloride in dogs

#### Note

The pharmacological, toxicological, and ecological properties of this material and/ or its ingredients have not been fully characterized and it should only be handled by technically qualified individuals. Exposure by any route should be minimized. Exercise due care: wear suitable protective clothing, gloves, and eye/face protections.

## SECTION 2 - HAZARDS IDENTIFICATION

### Classification of the substance or mixture

Not Classified.

#### Globally Harmonized System [GHS]

Not a hazardous substance or mixture.

#### Label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) re-quired

#### GHS hazard pictogram

Not Applicable

#### GHS signal word

Not Applicable

#### GHS hazard statements

Not Applicable

#### GHS precautionary statements

Not Applicable

#### Other hazards

No known hazards

**SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS**

**Substance / Mixture:** Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Atipamezole HCL	104075-48-1	$\geq 3$ - $< 10$
Methyl hydroxybenzoate	99-76-3	$\geq 1$ - $\leq 3$
Sodium chloride	7647-14-5	$\geq 3$ - $< 10$

**SECTION 4 - FIRST AID MEASURES**
**Description of first aid measures**
**Immediate Medical Attention Needed**

If you feel unwell, seek medical advice.

**Eye Contact**

If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

**Skin Contact**

Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

**Inhalation**

Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

**Ingestion**

Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

**Protection of first aid responders**

Avoid contact with skin, eyes, and clothing. See Section 8 for Exposure Controls/Personal Protection recommendations.

**Most important symptoms and effects, both acute and delayed**

Skin contact may provoke the following symptoms:  
 Skin irritation  
 Eye contact may provoke the following symptoms:  
 Eye irritation  
 Inhalation may provoke the following symptoms:  
 Respiratory tract irritation  
 Cough

**Indication of immediate medical attention and special treatment needed, if necessary**

Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively.

## SECTION 5 - FIREFIGHTING MEASURES

<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for local circumstances and the surrounding environment.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit carbon monoxide, carbon dioxide, and oxides of sulfur and/or nitrogen, and/or other fluorine-, sulfur-, or nitrogen-containing compounds. Exposure to combustion products may be a hazard to health.
<b>Flammability/Explosivity</b>	No information identified. High concentrations of finely divided organic particles can explode if ignited.
<b>Unsuitable extinguishing media</b>	None known.
<b>Special protective equipment for fire-fighters</b>	Wear full protective clothing and a NIOSH-approved (or equivalent) self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

<b>Personal precautions, protective equipment, and emergency procedures</b>	If substance is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated.
<b>Environmental precautions</b>	Avoid emptying into drains and release to the environment, prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water (see Section 12).
<b>Methods and material for containment and cleaning up</b>	Surround spill with absorbents and place a damp cloth. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spilled materials into a leak-proof container suitable for disposal in Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in. Keep in suitable, closed containers for disposal. Wipe up with absorbent material (e.g. cloth, fleece). (see section 13). Decontaminate the area.

## SECTION 7 - HANDLING AND STORAGE

<b>Precautions for safe handling</b>	Follow recommendations for handling pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid contact with skin, eyes, and clothing. Avoid breathing dust. Wash thoroughly after handling.
<b>Conditions for safe storage including any incompatibilities</b>	Store in a closed container. Keep in properly labeled containers. Store in accordance with the particular national regulations.
<b>Materials to avoid</b>	None Known
<b>Packaging material</b>	Unsuitable material: None known
<b>Specific end use(s)</b>	No information identified.

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION**

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<b>Note</b>	Wash hands, face, and other potentially exposed areas immediately in the event of physical contact.
<b>Control Parameters/Occupational Exposure Limit Values</b>	This mixture has no ingredients that have PEL, TLV, or other recommended exposure limit.
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Exposure/Engineering controls</b>	Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential.
<b>Respiratory protection</b>	None Known.
<b>Hand protection</b>	Wear nitrile or other impervious gloves if skin contact is possible.
<b>Skin protection</b>	Wear disposable coveralls appropriate to the task, booties, and safety glasses with side shields. Ensure gloves are protective against solvents in use. Protective garments (coveralls, disposable coveralls, lab coats) are not to be worn in common areas (e.g., cafeterias) or out-of-doors. Employees must be trained in proper gowning and de-gowning practices.
<b>Eye/face protection</b>	Wear safety glasses with side shields, chemical splash goggles, or full-face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
<b>Environmental Exposure Controls</b>	Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.
<b>Other protective measures</b>	Wash hands in the event of contact with this substance, especially before eating, drinking, or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors). Decontaminate all protective equipment following use.

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Information on basic physical and chemical properties**

<b>Appearance</b>	Clear liquid.
<b>Color</b>	Colorless
<b>Odor</b>	No information identified.
<b>Odor threshold</b>	No information identified.
<b>pH</b>	4 - 5.5
<b>Melting point/freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	No information identified.
<b>Upper/lower flammability or explosive limits</b>	No information identified.
<b>Vapor pressure</b>	No information identified.
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	No information identified.
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (<i>n</i>-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular formula</b>	No information identified.
<b>Molecular weight</b>	No information identified.
<b>Density</b>	1.005 g/cm <sup>3</sup>

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Uncontrolled

## SECTION 10 - STABILITY AND REACTIVITY

<b>Reactivity</b>	Not classified as a reactivity hazard.
<b>Chemical stability</b>	No decomposition if stored and applied as directed. Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Stable under recommended storage conditions. No hazards to be specially mentioned. None known.
<b>Conditions to avoid</b>	No information identified.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	No information identified.

## SECTION 11 - TOXICOLOGICAL INFORMATION

### Information on toxicological effects

**Route of entry** May be exposed *via* ingestion, inhalation, or skin contact.

**Acute toxicity**

**Product:** No data available

**Components:**

**Atipamezole HCL:**

**Acute oral toxicity** Acute toxicity estimate: 300 - 2,000 mg/kg  
Assessment: The component/mixture is moderately toxic after single ingestion.

**Acute inhalation toxicity** Acute toxicity estimate: 1 - 5 mg/l  
Test atmosphere: dust/mist  
Assessment: The component/mixture is moderately toxic after short term inhalation.

**Acute dermal toxicity** Acute toxicity estimate: 1,000 - 2,000 mg/kg  
Assessment: The component/mixture is moderately toxic after single contact with skin.

**Methyl hydroxybenzoate:**

**Acute oral toxicity** LD<sub>50</sub> (Rat): > 5000 mg/kg

**Acute inhalation toxicity** No data available

**Acute dermal toxicity** No data available

**Sodium chloride:**

**Acute oral toxicity** LD<sub>50</sub> (Rat): > 3,550 mg/kg  
Remarks: Excessive exposure may cause:  
Nausea and/or vomiting.

**SECTION 11 - TOXICOLOGICAL INFORMATION ...continued**

**Acute inhalation toxicity** LC<sub>50</sub> (Rat): > 42 mg/l  
 Exposure time: 1 h  
 Test atmosphere: dust/mist

**Acute dermal toxicity** LD<sub>50</sub> (Rabbit): 10,000 mg/kg

**Skin corrosion/irritation** Uncontrolled

**Serious eye damage/eye irritation**

**Product:** No data available

**Components:**

**Methyl hydroxybenzoate**

**Species** Rabbit

**Result** Not irritating to skin

**Species** Rabbit

**Result** Slightly irritating to eyes

**Sodium chloride:**

**Species** Rabbit

**Result** No eye irritation

**Germ cell mutagenicity**

**Product:** No data available

**STOT-single exposure**

**Product:** No data available

**Components:**

**Sodium chloride:**

**Assessment** Evaluation of available data suggests that this material is not an STOT-SE toxicant.

**Repeated dose toxicity**

**Product:** No data available

**Components:**

**Methyl hydroxybenzoate**

**Species** Rat

**Result** NOAEL (28 days, OECD 422, gavage): 1000 mg/kg

NOEL (90 days, OECD 408, gavage): 1000 mg/kg

**Sodium chloride:**

**Remarks** Medical experience with sodium chloride has shown a strong association between elevated blood pressure and prolonged dietary overuse. Related effects could occur in the kidneys

**Aspiration toxicity**

**Product:** No data available

**Components:** No data available

**SECTION 12 - ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Product:** No data available

**Components:**

**SECTION 12 - ECOLOGICAL INFORMATION...continued**
**Methyl hydroxybenzoate:**

**Toxicity to fish** LC<sub>50</sub>: 59.5 mg/l  
 Exposure time: 96 h  
 Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates** EC<sub>50</sub>: 11.2 mg/l  
 Exposure time: 48 h  
 Method: ISO 6341

**Toxicity to algae/aquatic plants** (*Scenedesmus capricornutum* (freshwater algae)): 31 mg/l  
 Exposure time: 72 h  
 Method: ISO 8692

**Toxicity to fish (Chronic toxicity)** NOEC: 50 mg/l  
 Exposure time: 48 d

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)** NOEC (*Daphnia magna*): 0.2 mg/l  
 Exposure time: 21 d  
 Method: OECD Test Guideline 211  
 EC<sub>50</sub> (*Daphnia magna*): 0.89 mg/l  
 Exposure time: 21 d  
 Method: OECD Test Guideline 211

**Sodium chloride:**

**Toxicity to fish** LC<sub>50</sub> (*Lepomis macrochirus* (Bluegill sunfish)): 5,840 mg/l  
 Exposure time: 96 h  
 Test Type: flow-through test  
 Method: OECD Test Guideline 203  
 LC<sub>50</sub> (*Pimephales promelas* (fathead minnow)): 10,610 mg/l  
 Exposure time: 96 h  
 Test Type: static test  
 Method: OECD Test Guideline 203

**Toxicity to daphnia and other aquatic invertebrates** EC<sub>50</sub> (*Daphnia magna* (Water flea)): 1,900 mg/l  
 Exposure time: 48 h  
 Test Type: static test

**Toxicity to algae/aquatic plants** EC<sub>50</sub> (Other): 2,430 mg/l  
 End point: Growth inhibition (cell density reduction)  
 Exposure time: 120 h  
 Test Type: static test  
 Method: OECD Test Guideline 201

**Toxicity to microorganisms** IC<sub>50</sub> (activated sludge): > 1,000 mg/l  
 Method: OECD 209 Test

**Persistence and degradability** No data available

**Bioaccumulative potential**

**Product:** No data available

**Components:**
**Sodium chloride:**

**Partition coefficient: n-octanol/water** Remarks: No bioconcentration is expected because of the relatively high-water solubility.

**Mobility in soil**

**Components:** No data available

**Other adverse effects**

**SECTION 12 - ECOLOGICAL INFORMATION...continued**

**Results of PBT and vPvB assessment** No additional information available.

**Note** Releases to the environment should be avoided.

**SECTION 13 - DISPOSAL CONSIDERATIONS**

**Waste treatment methods** Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not let down the drain or flush down the toilet. All waste containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility. Follow all applicable regional, national, and local laws.

**SECTION 14 - TRANSPORT INFORMATION**
**International Regulations**
**UNRTDG**

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable

**IATA-DGR**

UN/ID No. : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 Packing instruction (cargo aircraft) : Not applicable  
 Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 EmS Code : Not applicable  
 Marine pollutant : Not applicable

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

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**SECTION 14 - TRANSPORT INFORMATION...continued**

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**Domestic regulation****NZS 5433**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

**49 CFR Road**

Not regulated as a dangerous good

**ADG**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

**TDG**

Not regulated as a dangerous good

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**SECTION 15 - REGULATORY INFORMATION**

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**Safety, health, and environmental regulations/legislation specific for the substance or mixture** This SDS generally complies with the requirements listed under current guidelines in the USA, Australia, New Zealand, and Canada.

**Chemical safety assessment** Not conducted.

**The ingredients of this product are reported in the following inventories:**

**TSCA** : Product contains substance(s) not listed on TSCA inventory.

**TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

**SARA 311/312 Hazards:**

No Hazards category to report.

**Massachusetts Right to Know Components:**

No components are subject to the Massachusetts Right to Know Act.

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## SECTION 15 - REGULATORY INFORMATION...continued

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### Pennsylvania Right to Know Components:

No components are subject to the Pennsylvania Right to Know Act.

### New Jersey Right to Know Components:

No components are subject to the New Jersey Right to Know Act.

### California Prop. 65 Components:

Not listed.

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

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated (Please use the original publication of the SUSMP to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

**Prohibition/Licensing Requirements** : There is no applicable prohibition, authorisation, and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

**DSL** : This product contains components that are not listed on the Canadian DSL nor NDSL.

#### HSNO Approval Number

Not applicable

#### HSW Controls

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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## SECTION 16 - OTHER INFORMATION

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**Full text of H phrases and GHS classifications** No information identified.

**Sources of data** Information from published literature and internal company data.

**Abbreviations**

ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**Revision Date**

12/29/2023

**Disclaimer**

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.

	<b>Category:</b> Safety Data Sheets (SDS) <b>Title:</b> Contrasted Sterile Injectable Solution US ANZ CA SDS		
<b>Version</b> 01	<b>State</b> Effective	<b>Effective Date</b> 02-FEB-2024	<b>Document ID</b> 992343

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**REVISION HISTORY**

**Version 01 Effective on 02-Feb-2024**

Ver 1

**DOCUMENT ELECTRONIC SIGNATURES**

**DOCUMENT APPROVAL WORKFLOW**

**Author Approval**

Con Benikos  
Vice President Quality  
con.benikos@parnell.com

I am the author of this document.  
*Signed 2:41:21 AM UTC 02-Feb-2024*