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Section 1 - Identification

- (a) **Product Identifier:** Dexmedetomidine Injection, USP
- (b) **Product Code:** 83634-600
- Common/Trade Name:** Precedex
- Chemical Name:** 1H-Imidazole, 4-[1-(2,3-dimethylphenyl)ethyl]-, monohydrochloride, (S)
- Chemical Family:** Sedative
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** **US OSHA:**
Target Organ Toxin
Possible Reproductive Toxin
Possible Irritant

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
GHS Signal Word:	Not applicable
GHS Hazard Statement:	Not applicable
GHS Symbols:	Not applicable
GHS Precautionary Statements:	P260 - Do not breathe dust/fume/gas/mist/vapors/spray
Other Hazards	Dexmedetomidine hydrochloride should be considered a potent drug, a potential occupational reproductive hazard, and possibly irritating to the eyes. Evaluation of potential occupational exposures should include consideration of the dermal route. Possible target organs include the central nervous system, the cardiovascular system, and possibly the fetus.

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(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
1H-Imidazole, 4-[1-(2,3-dimethylphenyl)ethyl]-, monohydrochloride, (S)	Dexmedetomidine Hydrochloride	236 mcg/ 2 mL*	145108-58-3	N/A
NaCl	Sodium Chloride	18 mg/ 2 mL	7647-14-5	N/A
H ₂ O	Water for Injection	q.s. to 2 mL	7732-18-5	N/A
Nitrogen	Nitrogen	A.R.	7727-37-9	N/A

*236 mcg of Dexmedetomidine Hydrochloride is equivalent to 200 mcg of Dexmedetomidine base
q.s. – Quantity Sufficient
A.R. – As Required

Section 4 – First Aid Measures

Eye Exposure: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.


Skin Exposure: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Injection: In cases of accidental injection, wash and disinfect area, seek emergency medical attention.

Inhalation: If inhaled, remove to fresh air. Get medical attention. Provide symptomatic/supportive care as necessary.

Notes to Physician: Treat symptomatically and supportively. See patient package insert in shipping carton for complete information.

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Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** As with any fire, use extinguishing media appropriate for primary cause of fire.
- (b) **Hazardous Combustion Products:** None determined for this aqueous product
- (c) **Special Protective Equipment / Precautions:** No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Section 6 - Accidental Release Measures

- Spill:** Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
- Release to Air:** Not available.
- Release to Water:** Not available. Refer to the local, state, and federal guidelines; drain disposal is not recommended.

Section 7 - Handling and Storage

- General Handling:** No special handling required under conditions of normal product use.
- Storage Conditions:** Store at 25°C (77°F), excursions permitted between 15° to 30°C (59° to 86°F).


Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Dexmedetomidine	OSHA	PEL	NE
Hydrochloride	ACGIH	TLV	NE

(b) Engineering Controls

Ventilation: Engineering controls are normally not needed during the normal use of this product.


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(c) Individual Protection Measures

Respiratory Protection:	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air purifying respirator with a HEPA cartridge (N99 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Eye Protection:	Chemical resistant goggles must be worn.
Skin Protection:	Use of Latex or Nitrile gloves recommended.
Other Protective Equipment:	Protective Latex or Nitrile gloves
Additional Exposure Precautions:	Wash hands following use. No eating, drinking, or smoking while handling this product.

Section 9 - Physical and Chemical Properties

(a)	Appearance	clear, colorless solution
(b)	Odor	No odor
(c)	Odor Threshold	Not available
(d)	pH	4.5 to 7.0
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Freely soluble in water

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(o)	Partition Coefficient: n-octanol/water	water at pH 7.4 is 2.89.
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not determined
(b)	Chemical Stability	Stable under standard use and storage conditions.
(c)	Possibility of Hazardous Reactions	Not determined
(d)	Conditions to Avoid	Not determined
(e)	Incompatible Materials	Dexmedetomidine reported to produce violent reactions with BrF ₃ , H ₂ SO ₄ and KMnO ₄ .
(f)	Hazardous Decomposition Products	During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x), nitrogen oxides (NO _x), and hydrogen chloride.


Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Possibly skin, eyes, mouth
(b)	Symptoms related to the physical, chemical and toxicological characteristics	None known from occupational exposure. In clinical use, adverse effects have included hypotension, hypertension, nausea, bradycardia, fever, vomiting, hypoxia, tachycardia and anemia.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	Based on clinical use, possible target organs include the central nervous system, the cardiovascular system, and possibly the fetus.

(d) Acute Toxicity

Not determined for the product formulation or active ingredient dexmedetomidine. By analogy, information for the racemic medetomidine hydrochloride mixture is as follows:

Component	Type	Route	Species	Dosage
Medetomidine	LD ₅₀	Oral	Rat	31 mg/kg

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(e) Hazardous Chemical Listings

NTP: Not Listed **IARC:** Not Listed **OSHA:** Not Listed

Section 12 - Ecological Information

(a)	Ecotoxicity	N/A
(b)	Persistence and degradability	N/A
(c)	Bioaccumulative potential	N/A
(d)	Mobility in soil	N/A
(e)	Other Adverse Effects	N/A

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.


(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA – Not regulated
 CERCLA - Not on this list

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SARA 302 - Not on this list
SARA 311/312: Not on this list
SARA 313 - Not on this list
OSHA – Not on this list

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Avenacy
10 N. Martingale Road, Suite 225
Schaumburg, IL 60173
847-773-4901

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit

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MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System