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|  Pharmaceutical Division | Dexmedetomidine Hydrochloride Injection | | Safety Data Sheet (SDS) | |
| | Effective Date: 17NOV2017 | SDS No : SDS021 | Revision No: 01 | Page 1 of 8 |


Section 1 - Identification

- (a) **Product Identifier:** Dexmedetomidine Hydrochloride Injection
- (b) **Product Code:** 70860-605
- Common/Trade Name:** Precedex
- Chemical Name:** (+)-4-(S)-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole monohydrochloride
- Chemical Family:** Sedative
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

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. |

| | | | | |
|--|--|--------------------|--------------------------------|----------------|
|  Pharmaceutical Division | Dexmedetomidine Hydrochloride Injection | | Safety Data Sheet (SDS) | |
| | Effective Date: 17NOV2017 | SDS No : SDS021 | Revision No: 01 | Page 2 of 8 |


Section 3 – Composition / Information on Ingredients

| (a) Chemical Name | (b) Common Name / Synonym | % Composition or other measure | (c) CAS No. | (d) Impurities / Stabilizing Additives |
|--|-------------------------------|---|-------------|---|
| (+)-4-(S)-[1-(2,3-dimethylphenyl)ethyl]-1H-imidazole monohydrochloride | Dexmedetomidine Hydrochloride | 236 mcg/ 2 mL* | 145108-58-3 | N/A |
| NaCl | Sodium Chloride | 18 mg/ 2 mL | 7440-23-5 | N/A |
| H ₂ O | Water for Injection | q.s. to 2mL | 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.

| | | | | |
|--|--|--------------------|--------------------------------|----------------|
|  Pharmaceutical Division | Dexmedetomidine Hydrochloride Injection | | Safety Data Sheet (SDS) | |
| | Effective Date: 17NOV2017 | SDS No : SDS021 | Revision No: 01 | Page 3 of 8 |

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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|--|--|--------------------|--------------------------------|----------------|
|  Pharmaceutical Division | Dexmedetomidine Hydrochloride Injection | | Safety Data Sheet (SDS) | |
| | Effective Date: 17NOV2017 | SDS No : SDS021 | Revision No: 01 | Page 4 of 8 |

(c) Individual Protection Measures

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|----------------------------------|---|
| 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 |

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|--|--|--------------------|--------------------------------|----------------|
|  Pharmaceutical Division | Dexmedetomidine Hydrochloride Injection | | Safety Data Sheet (SDS) | |
| | Effective Date: 17NOV2017 | SDS No : SDS021 | Revision No: 01 | Page 5 of 8 |

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|-----|---|--------------------------|
| (n) | Solubility(ies) | Freely soluble in water |
| (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

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|-----|---|---|
| (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

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|-----|--|---|
| (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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|--|--|--------------------|--------------------------------|----------------|
|  Pharmaceutical Division | Dexmedetomidine Hydrochloride Injection | | Safety Data Sheet (SDS) | |
| | Effective Date: 17NOV2017 | SDS No : SDS021 | Revision No: 01 | Page 6 of 8 |

(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 |

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|--|--|---------------------------|--------------------------------|-----------------------|
|  Pharmaceutical Division | Dexmedetomidine Hydrochloride Injection | | Safety Data Sheet (SDS) | |
| | Effective Date: 17NOV2017 | SDS No : SDS021 | Revision No: 01 | Page 7 of 8 |

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division 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
- 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:

Athenex Pharmaceutical Division
 10 N. Martingale Road, Suite 230
 Schaumburg, IL 60173
 847-886-9515

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 |

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|--|--|--------------------|--------------------------------|----------------|
|  Pharmaceutical Division | Dexmedetomidine Hydrochloride Injection | | Safety Data Sheet (SDS) | |
| | Effective Date: 17NOV2017 | SDS No : SDS021 | Revision No: 01 | Page 8 of 8 |

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|-----------|---|
| 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 |
| 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 |

Signature Manifest

Document Number: SDS021

Revision: 01

Title: Dexmedetomidine HCl Injection

All dates and times are in Eastern Standard Time.

Dexmedetomidine HCl SDS

Change Request

| Name/Signature | Title | Date | Meaning/Reason |
|---------------------------------------|----------------------|--------------------------|----------------|
| Christopher Martensen (CMARTENSEN) | Quality Engineer-CSV | | |
| Michael Scribner (MSCRIBNER) | Director of Quality | 13 Nov 2017, 10:50:00 AM | Approved |

Dept Approval

| Name/Signature | Title | Date | Meaning/Reason |
|---------------------|-------------------------------|--------------------------|----------------|
| John Andre (JANDRE) | Regulatory Affairs Consultant | 21 Nov 2017, 03:09:27 PM | Approved |

Final QA Approval/Set Effective Date

| Name/Signature | Title | Date | Meaning/Reason |
|-----------------------|-------------------------|--------------------------|----------------|
| Sheila Moran (SMORAN) | VP of Quality Assurance | 28 Nov 2017, 08:46:57 AM | Approved |