# SAFETY DATA SHEET

## SECTION 1 : IDENTIFICATION

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| Product Name: | **Dexmedetomidine Hydrochloride Injection in 0.9% Sodium Chloride** |
| Product Use/Restriction: | This material is for use as an adjunct to general anesthesia producing sedation, stabilizing heart rate and blood pressure, and producing analgesia. |
| Manufacturer Name: | Fresenius Kabi USA, LLC |
| Address: | Three Corporate Drive<br>Lake Zurich, Illinois 60047 |
| General Phone Number: | (847) 550-2300 |
| Customer Service Phone Number: | (888) 386-1300 |
| Health Issues Information: | (800) 551-7176 |
| SDS Creation Date: | September 24, 2018 |

## SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

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| Signal Word: | WARNING. |
| GHS Class: | Reproductive toxicity. Category 2.<br>Reproductive toxicity. Effects on or via lactation. |
| Hazard Statements: | Suspected of damaging fertility or the unborn child.<br>May cause harm to breast-fed children. |
| Precautionary Statements: | Obtain special instructions before use.<br>Do not handle until all safety precautions have been read and understood.<br>Do not breathe dust/fume/gas/mist/vapours/spray.<br>Avoid contact during pregnancy and while nursing.<br>Wash hands thoroughly after handling.<br>Do not eat, drink or smoke when using this product.<br>Wear protective gloves/protective clothing/eye protection/face protection.<br>IF exposed or concerned: Get medical advice/attention.<br>Store locked up.<br>Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations. |
| Emergency Overview: | Potent drug, toxic by absorption through the skin and ingestion and highly toxic by inhalation. This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. |
| Route of Exposure: | Inhalation Ingestion Eye contact Skin Absorption. Injection. |
| Potential Health Effects: | |
| Eye: | Highly toxic. |
| Skin: | Very toxic in contact with skin. |
| Inhalation: | Highly toxic. |
| Ingestion: | Toxic if swallowed. |
| Target Organs: | Target organs include the nervous system, cardiovascular system, eyes, thymus, reproductive system, lungs, liver, endocrine system and hematopoletic system. |
| Aggravation of Pre-Existing Conditions: | Not determined. |

## SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS# | Ingredient Percent | EC Num. |
|---|---|---|---|
| Glacial acetic acid | 64-19-7 | 119.4 mcg/mL by weight | |
| Dexmedetomidine Hydrochloride | 145108-58-3 | 4.72 mcg/mL by weight | |
| Sodium Chloride | 7647-14-5 | 9 mg/mL by weight | |
| Water for Injection | 7732-18-5 | Quantity Sufficient 1 mL | |
| Sodium acetate trihydrate | 127-09-3 | 5.4 mcg/mL by weight | |

## SECTION 4 : FIRST AID MEASURES

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| Eye Contact: | Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention. |
| Skin Contact: | Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists. |
| Inhalation: | If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention. |
| Ingestion: | If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. |
| Other First Aid: | For Adverse Event Information, please call (800) 551-7176. |

## SECTION 5 : FIRE FIGHTING MEASURES

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| Flash Point: | Not established. |
| Flash Point Method: | Not established. |
| Auto Ignition Temperature: | Not established. |
| Lower Flammable/Explosive Limit: | Not established. |
| Upper Flammable/Explosive Limit: | Not established. |
| Fire Fighting Instructions: | Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water. |
| Extinguishing Media: | Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.<br>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Protective Equipment: | As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear. |
| Hazardous Combustion Byproducts: | Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion. |

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

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| Personal Precautions: | Evacuate area and keep unnecessary and unprotected personnel from entering the spill area.<br>Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8. |
| Environmental Precautions: | Avoid runoff into storm sewers, ditches, and waterways. |
| Methods for containment: | Contain spills with an inert absorbent material such as soil, sand or oil dry. |
| Methods for cleanup: | Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue. |

## SECTION 7 : HANDLING and STORAGE

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| Handling: | When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions. |
| Storage: | Keep tightly closed in a dry and cool place. Store at controlled room temperature 15 to 30°C (59 to 86°F). |
| Work Practices: | Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. |
| Hygiene Practices: | Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist. |

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

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| Engineering Controls: | General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits. |
| Eye/Face Protection: | Chemical splash goggles. Wear a face shield also when splash hazard exist. |
| Skin Protection Description: | Protective laboratory coat, apron, or disposable garment recommended. |
| Hand Protection Description: | Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data.<br>Nitrile rubber or natural rubber gloves are recommended. |

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| Respiratory Protection: | No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers. |
| Other Protective: | Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment. |

EXPOSURE GUIDELINES

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

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| Physical State: | Liquid. |
| Color: | Colorless. |
| Odor: | No detectable odor. |
| Boiling Point: | Not established. |
| Melting Point: | 156.5-157.5 °C (Dexmedetomidine Hydrochloride powder - API) |
| Specific Gravity: | Not established. |
| Solubility: | Not established. |
| Vapor Density: | Not established. |
| Vapor Pressure: | Not established. |
| Percent Volatile: | Not established. |
| pH: | 4.3 (1% solution in water) |
| Molecular Weight: | Anhydrous Molecular Weight: 236.75 amu |
| Flash Point: | Not established. |
| Flash Point Method: | Not established. |
| Auto Ignition Temperature: | Not established. |

## SECTION 10 : STABILITY and REACTIVITY

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| Chemical Stability: | Stable under normal temperatures and pressures. |
| Hazardous Polymerization: | Not reported. |
| Conditions to Avoid: | Fine particles (such as dust and mists) may fuel fires/explosions. |
| Incompatible Materials: | Strong oxidizing agents. |

## SECTION 11 : TOXICOLOGICAL INFORMATION

**Dexmedetomidine Hydrochloride :**

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| ACGIH: | Not listed |
| OSHA: | Not listed |
| IARC: | Not listed |
| NTP: | Not listed |

**Glacial acetic acid :**

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| RTECS Number: | AF1225000 |

**Dexmedetomidine Hydrochloride :**

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|---|---|
| RTECS Number: | NI5156750 |
| Skin: | Application of 975 mcg of dexmedetomidine to the skin of human volunteers produced sedation and reduced blood pressure with sedation appearing within 1-2 hours after application of dexmedetomidine. |
| Inhalation: | Reported to be highly toxic by inhalation. |
| Ingestion: | Reported to be a toxic by ingestion. LD50(iv) = 2 mg/kg in dogs. |
| Other Toxicological Information: | Intraperitoneal. - Mouse TDLo: 100 ug/kg [Behavioral - analgesia]<br>Subcutaneous - Mouse TDLo: 3 ug/kg [Behavioral - changes in psychophysiological tests Biochemical - Neurotransmitters or modulators (putative) - catecholamine levels in CNS]<br>Intravenous. - Rat TDLo: 40 ug/kg [Sense Organs and Special Senses (Eye) - mydriasis (pupillary dilation)] [RTECS} |

**Sodium Chloride :**

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| RTECS Number: | VZ4725000 |

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| Skin: | Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]<br>Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild]<br>Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild] |
| Inhalation: | Inhalation - Rat LC50: >42 gm/m3/1H [Details of toxic effects not reported other than lethal dose value] |
| Ingestion: | Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value]<br>Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value] |

**Sodium acetate trihydrate :**

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| RTECS Number: | AJA4300010 |

## SECTION 12 : ECOLOGICAL INFORMATION

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| Ecotoxicity: | No ecotoxicity data was found for the product. |
| Environmental Stability: | No environmental information found for this product. |

## SECTION 13 : DISPOSAL CONSIDERATIONS

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| Waste Disposal: | Dispose of in accordance with Local, State, Federal and Provincial regulations. |

## SECTION 14 : TRANSPORT INFORMATION

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| DOT Shipping Name: | Not Regulated. |
| DOT UN Number: | Not Regulated. |
| DOT Hazard Class: | Not Regulated. |
| DOT Packing Group: | Not Regulated. |

## SECTION 15 : REGULATORY INFORMATION

**Glacial acetic acid :**

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| TSCA Inventory Status: | Listed |

**Dexmedetomidine Hydrochloride :**

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|---|---|
| TSCA Inventory Status: | Not listed |

**Sodium Chloride :**

| | |
|---|---|
| TSCA Inventory Status: | Listed |

**Sodium acetate trihydrate :**

| | |
|---|---|
| TSCA Inventory Status: | Listed |

## SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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| HMIS Health Hazard: | 3 |
| HMIS Fire Hazard: | 0 |
| HMIS Reactivity: | 0 |
| HMIS Personal Protection: | 1 |

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| SDS Creation Date: | September 24, 2018 |
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