# SAFETY DATA SHEET

## SECTION 1 : IDENTIFICATION

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| Product Name: | **Morphine Sulfate Injection, USP Simplist®** |
| Manufacturer Name: | Fresenius Kabi Simplist™ |
| Address: | Three Corporate Drive<br>Lake Zurich, Illinois 60047 |
| General Phone Number: | (847) 550-2300 |
| SDS Creation Date: | February 13, 2019 |
| SDS Revision Date: | March 19, 2020 |

## SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. category 1.
Germ cell mutagenicity. Category 2.
Reproductive toxicity. Category 2.
Skin Sensitization. category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of causing genetic defects.
Suspected of damaging fertility or the unborn child.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Store locked up.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Potential Health Effects:
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.

Target Organs:
In clinical use, target organ effects include the central nervous system, eyes, respiratory system, gastrointestinal tract, cardiovascular system and female reproductive system.

## SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS# | Ingredient Percent | EC Num. |
|---|---|---|---|
| Citric acid monohydrate | 7647-01-0 | 0.74-1.11 mg/mL by weight | |
| Sodium citrate dihydrate | 6132-04-3 | 2.3-3.45 mg/mL by weight | |
| Edetate disodium dihydrate | 6381-92-6 | 0.111 mg/mL by weight | |
| Calcium chloride dihydrate | 10035-04-8 | 0.053 mg/mL by weight | |
| Morphine Sulfate | 64-31-3 | 2 , 4, 5, 8, or 10 mg/mL by weight | |
| Sodium Chloride | 7647-14-5 | 7.5-8.4 mg/mL by weight | |
| Water for Injection | 7732-18-5 | Quantity Sufficient | |

## 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. 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: | Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Protect from light. Do not freeze. Retain vial in carton until time of use. Do not use if the color is darker than pale yellow, discolored or if it contains a precipitate. |
| 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. 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 solution. |
| Color: | Colorless. |
| Odor: | Odorless. |
| Odor Threshold: | No information. |
| Boiling Point: | Approximately that of water, 100°C (212°F) |
| Melting Point: | Approximately that of water, 0°C (32°F) |
| Specific Gravity: | Approximately 1.0 |
| Solubility: | Not established. |
| Vapor Density: | Not established. |
| Vapor Pressure: | Not established. |
| Percent Volatile: | Not established. |
| pH: | 2.5 - 6.5 |
| 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: | No conditions contributing to instability are known to exist for normal handling of this product. |

## SECTION 11 : TOXICOLOGICAL INFORMATION

**Morphine Sulfate :**

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| Acute Toxicity: | The lethal human dose has been identified as 0.3 to 0.4 g (4.3 to 5.7 mg/kg in a 70 kg adult). |

**Morphine Sulfate :**

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| RTECS Number: | QC8750000 |
| Ingestion: | Oral - Rat LD50: 461 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Oral - Mouse LD50: 600 mg/kg [Behavioral - Analgesia] |
| Mutagenicity: | Mutagenic in micronucleus assay. Mutagenic in one or more mutagenicity assays |
| Teratogenicity: | Pregnancy Category C:<br>Morphine sulfate is not teratogenic in rats at 35 mg/kg/day (thirty-five times the usual human dose) but does result in increased pup mortality and growth retardation at doses that narcotize the animal (> 10 mg/kg/day, ten times the usual human dose). Astramorph/PF should only be given to pregnant women when no other method of controlling pain is available and means are at hand to manage the delivery and perinatal care of the opiate-dependent infant. |

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| Other Toxicological Information: | Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes]<br>Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]<br>Intravenous. - Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]<br>Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability]<br>Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]<br>Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)]<br>Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death]<br>Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]<br>Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]<br>Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion]<br>Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold]<br>Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system]<br>Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral]<br>Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg |

**Sodium Chloride :**

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| RTECS Number: | VZ4725000 |
| Eye: | Eye - Rabbit Standard Draize test.: 10 mg [Moderate] |
| 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] |

## 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. |

## SECTION 15 : REGULATORY INFORMATION

**Morphine Sulfate :**

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| EINECS Number: | 200-582-8 |
| Canada DSL: | Listed |

**Sodium Chloride :**

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| TSCA Inventory Status: | Listed |
| EINECS Number: | 231-598-3 |
| Canada DSL: | 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: | X |

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| SDS Creation Date: | February 13, 2019 |
| SDS Revision Date: | March 19, 2020 |
| SDS Revision Notes: | Update - Changed product name from Trademarked Product (TM) to Registered Product (®). Added HMIS ratings. |