## SECTION 1 : PRODUCT AND COMPANY IDENTIFICATION

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|---|---|
| Product Name: | **Caffeine Citrate Injection, USP** |
| 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 |

**HMIS**

| | |
|---|---|
| Health Hazard | 1 |
| Fire Hazard | 1 |
| Reactivity | 0 |
| Personal Protection | X |

## SECTION 2 : COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS# | Ingredient Percent | EC Num. |
|---|---|---|---|
| Caffeine Citrate | 69-22-7 | 20 mg/mL | |
| Sodium Citrate Dihydrate | 6132-04-3 | 8.3 mg/mL | |
| Citric Acid Monohydrate | 5949-29-1 | 5 mg/mL | |
| Water for Injection | 7732-18-5 | Quantity Sufficient | |

## SECTION 3 : HAZARDS IDENTIFICATION

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| Emergency Overview: | 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: | Contact with eyes may cause irritation. |
| Signs/Symptoms: | Possible adverse reactions include: fever, tachypnea, tachycardia, increased left ventricular output, jitterness, fine tremor of the extremities, hypertonia, opisthotonos, tonic-clonic movements, nonpurposeful jaw and lip movements, vomiting, gastrointestinal effects, renal effects, hyperglycemia, elevated blood urea nitrogen, and elevated total leukocyte concentration. Occupational exposure has not been fully investigated. |

## 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 |

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| | 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: | Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. |
| 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 - EXPOSURE GUIDELINES

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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. |
| 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: | No information. |
| Odor Threshold: | No information. |
| Boiling Point: | Not established. |
| Melting Point: | Not established. |
| Density: | No information. |
| Specific Gravity: | No information. |
| Specific Volume: | No information. |
| Solubility: | Soluble. in water. |
| Vapor Density: | Not established. |
| Vapor Pressure: | Not established. |
| Percent Volatile: | Not established. |

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| Evaporation Point: | No information. |
| pH: | 4.7 |
| Molecular Formula: | Mixture |
| Molecular Weight: | 386.31 |
| Viscosity: | No information. |
| Coefficient of Water/Oil Distribution: | No information. |
| Flash Point: | Not established. |
| Flash Point Method: | Not established. |
| Auto Ignition Temperature: | Not established. |
| VOC Content: | No information. |

## 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

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| Reproductive Toxicity: | Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. |
| **Sodium Citrate Dihydrate :** | |
| Eye: | No or moderate irritation in rabbits. |
| Skin: | Dermal - Rat LD50: >2000mg/kg (OECD Guideline 402, GLP) (TS : Citric acid) (ECHA)<br>No irritation in rabbits. |
| Ingestion: | Oral - Rat LD50: >8000 mg/kg (TS : Sodium Citrate) (CHEMINFO) |
| **Citric Acid Monohydrate :** | |
| RTECS Number: | GE7810000 |
| Eye: | Administration into the eye - Rabbit Rinsed with water: 5 mg/30S [Mild] (RTECS) |
| Skin: | Irritating to human skin. |
| Ingestion: | Oral - Rat LD50: 3000 mg/kg (CHEMINFO) |
| Other Toxicological Information: | Intraperitoneal. - Rat LD50 : 375 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. |
| **Sodium Citrate Dihydrate :** | |
| Ecotoxicity: | Golden orfe (Leuciscus idus melanotus) LC50 (48 h) 440 mg/L (TS : Citric acid)<br>Water flea (Ceriodaphnia sp.) EC50 (48hr) 736 mg/L (TS : Sodium Citrate)<br>Green algae (Scenedesmus quadricauda) Toxicity Threshold (8d) 640 mg/L, NOEC (8d) 425 mg/L (ECHA) |
| **Citric Acid Monohydrate :** | |
| Ecotoxicity: | Golden orfe (Leuciscus idus) LC50 (96hr) = 440–760 mg/l .(TS : Citric Acid) (OECD SIDS)<br>Water flea (Daphnia magna) LC50 (24hr) 1535 mg/L .(TS : Citric Acid) (ECHA)<br>Green algae (Scenedesmus quadricauda) EC0 (7d) = 640 mg/l .(TS : Citric Acid) (OECD SIDS) |
| Bioaccumulation: | Readily biodegradable (90%). |

## 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

**Caffeine Citrate :**

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| Canada DSL: | Listed |

**Citric Acid Monohydrate :**

| | |
|---|---|
| Canada DSL: | Listed |

## SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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|---|---|
| HMIS Health Hazard: | 1 |
| HMIS Fire Hazard: | 1 |
| HMIS Reactivity: | 0 |
| HMIS Personal Protection: | X |

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|---|---|
| SDS Creation Date: | September 25, 2014 |
| SDS Revision Date: | September 25, 2014 |

Disclaimer:

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