SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Chloramphenicol Sodium Succinate for Injection, USP**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive 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:	January 08, 2009
SDS Revision Date:	June 01, 2015
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

Signal Word:	Not applicable.
Hazard Statements:	Not applicable.
Precautionary Statements:	Not applicable.
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:	Adverse reactions from therapeutic doses include: bone marrow suppression, aplastic anemia, hypoplastic anemia, thrombocytopenia, and granulocytopenia are the most serious adverse events. Nausea, vomiting, glossitis, stomatitis, diarrhea, enterocolitis, headache, mild depression, mental confusion, delirium, fever, macular and vesicular rashes, angioedema, urticaria, and anaphylaxis have been reported. Occupational exposure has not been fully investigated.
Aggravation of Pre-Existing Conditions:	Individuals with a history of previous hypersensitivity and/or toxic reactions to chloramphenicol.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Chloramphenicol Sodium Succinate	982-57-0	1 gm vials	

SECTION 4 : FIRST AID MEASURES

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

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. 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

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 : HANDLING and STORAGE

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 dust, vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

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.
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

Physical State:	Lyophilized powder.
Color:	White to yellow
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	151°C
Solubility:	slightly soluble. in water. (2.5 mg/ml)
Vapor Density:	Not established.
Vapor Pressure:	Not established.

Percent Volatile:	Not established.
pH:	6.4 - 7.0
Molecular Formula:	Mixture
Molecular Weight:	445.21
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Excessive heat may cause decomposition.

SECTION 11 : TOXICOLOGICAL INFORMATION

Chloramphenicol Sodium Succinate :

Acute Toxicity:	LD50 IV Rat: 1500 mg/kg IMMEDIATE EFFECTS: Eye, skin, and respiratory irritation may occur.

Chloramphenicol Sodium Succinate :

OSHA:	Not listed
IARC:	Not listed
NTP:	Not listed

Chloramphenicol Sodium Succinate :

RTECS Number:	AB6905000
Acute Effects:	> Eye, skin, and respiratory irritation may occur.
Chronic Effects:	DELAYED EFFECTS: Hypersensitivity reactions ranging from mild to life-threatening may occur.
Other Toxicological Information:	Intravenous. - Rat LD50 : 1500 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50 : 1530 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit TDLo : 1200 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)] Subcutaneous - Rat TDLo : 60 gm/kg/5W-I [Liver - other changes Blood - normocytic anemia Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases] Subcutaneous - Rat TDLo : 156 gm/kg/26W-I [Liver - other changes Kidney, Ureter, Bladder - other changes Blood - normocytic anemia] Subcutaneous - Rat TDLo : 6 gm/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)] Subcutaneous - Rat TDLo : 35 gm/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct] Intraperitoneal. - Rat LD50 : 1400 mg/kg [Details of toxic effects not reported other than lethal dose value]
Chronic Effects:	DELAYED EFFECTS: Hypersensitivity reactions ranging from mild to life-threatening may occur.

SECTION 12 : ECOLOGICAL INFORMATION

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

SECTION 13 : DISPOSAL CONSIDERATIONS

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

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Chloramphenicol Sodium Succinate :

EINECS Number:	213-568-1
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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Disclaimer:	The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.