SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Rifampin for Injection, USP**
Product Use/Restriction:	Anti-Infective
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:	October 27, 2014
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(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

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.
Skin:	May cause skin irritation.
Inhalation:	May cause irritation of respiratory tract.
Ingestion:	May cause irritation.
Signs/Symptoms:	Possible adverse reactions include: nausea, vomiting, abdominal pain, pruritus, headache, unconsciousness, increased liver enzymes, increased bilirubin, hypotension, tachycardia, ventricular arrhythmias, seizures, and cardiac arrest. Brownish-red or orange discoloration of the skin, urine, sweat, saliva, tears, and feces has have been reported. Facial or periorbital edema has also been reported in pediatric patients
Aggravation of Pre-Existing Conditions:	Individuals with a history of sensitivity to any of the rifamycins.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Sodium Formaldehyde Sulfoxylate	149-44-0	10 mg/vial	
Sodium Hydroxide	1310-73-2	as needed to adjust pH	
Rifampin	13292-46-1	600 mg/vial	

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:	Avoid excessive heat. Temperatures above 100 °F. Protect from light.
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

Sodium Hydroxide :

Guideline ACGIH:	TLV-STEL: C 2 mg/m3

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Crystalline powder.
Color:	red brown.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	VERY SLIGHTLY SOLUBLE IN WATER. FREELY SOLUBLE IN CHLOROFORM, SOLUBLE IN ETHYL ACETATE,

	AND IN METHANOL
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	7.8 - 8.8 after reconstitution
Molecular Formula:	Mixture
Molecular Weight:	822.95
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:	Avoid direct sunlight, conditions that might generate heat, and sources of ignition. Avoid contact with incompatible materials.
Incompatible Materials:	Avoid storage near oxidizers.

SECTION 11 : TOXICOLOGICAL INFORMATION

Teratogenicity:	Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. Since colistimethate sodium is transferred across the placental barrier in humans, it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Sodium Formaldehyde Sulfoxylate :

Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: >2 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Sodium Hydroxide :

Eye:	Administration into the eye - Rabbit Standard Draize test: 400 ug [Mild] Administration into the eye - Rabbit Standard Draize test: 1 % [Severe] Administration into the eye - Rabbit Standard Draize test: 50 ug/24H [Severe] Administration into the eye - Rabbit Standard Draize test: 1 mg/24H [Severe] Administration into the eye - Rabbit Rinsed with water: 1 mg/30S [Severe] (RTECS)

Rifampin :

Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 1570 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Reproductive Toxicity:	Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. May cross the placenta. When administered during the last few weeks of pregnancy, rifampin can cause post-natal hemorrhages in the mother and infant. Rifampin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

Sodium Formaldehyde Sulfoxylate :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

Sodium Hydroxide :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

Rifampin :

California PROP 65:	Listed: developmental.
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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

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