Safety Data Sheet (SDS)

MATERIAL: Cupric Chloride Injection, USP 0.4 mg /mL	SUPPLIER(S): Exela Pharma Sciences, LLC	SDS NO.: SDS-FP-33-00	ISSUE DATE: 11AUG2023

Section 1 – Chemical Product and Company

Distributor:		**Emergency Telephone:**	ChemTrec 1-800-424-9300
Exela Pharma Sciences, LLC 1245 Blowing Rock Blvd Lenoir, NC 28645 (828) 758-5474		**Product Identifier:**	Cupric Chloride Dihydrate, USP
		Product Code:	51754-0103-1
		Common/Trade Name:	Copper (II) Chloride Injection
		Chemical Family:	Nonpyrogenic solution
Chemical Formula: **Chemical Name:**	Mixture containing $CuCl_2 \cdot 2H_2O$	**Product Type:**	Regulated Prescription Drug
Intended Use:	An additive to intravenous solutions for total parenteral nutrition (TPN). Refer to drug product package insert for instructions and restrictions on use.		
Container Information:	Plastic Vial		

Section 2 – Hazards Identification

GHS Pictograms:	Not Classified	**Signal Word:**	Not Classified
GHS Class:	This drug product is not classified as per the OSHA Hazard communication Standard 2012 (29 CFR 1910.1200(b)(5)(iii)).		
Precautionary Statements:	The product should be used as per the package insert included with the product. As a general rule, when handling pharmaceutical products, use appropriate personal protective equipment.		
Routes of Entry:	Inhalation, eye/skin contact, or ingestion.		
Target Organs:	Refer to package insert.		

Section 3 – Composition / Information on Ingredients

Ingredient	Quantity	%	CAS No.	GHS Classification
Cupric Chloride, USP	1.07 mg/mL (10 mL) [0.4 mg Cu^{++}/mL]	0.107	10125-13-0	H302: Harmful if swallowed [Warning Acute toxicity, oral] H319: Causes serious eye irritation; Skin corrosion/irritation H314: Causes severe skin burns and eye damage [Danger Skin corrosion/irritation] H315: Causes skin irritation H400: Very toxic to aquatic life [Warning Hazardous to the aquatic environment, acute hazard] H410: Very toxic to aquatic life with long lasting effects [Warning Hazardous to the aquatic environment, long-term hazard] H290: May be corrosive to metals
Sodium Chloride, USP	9 mg/mL	0.9	7647-14-5	Not Classified
Hydrochloric Acid, NF	N/A	*	7647-01-0	H314: Causes severe skin burns and eye damage [Danger Skin corrosion/irritation]
Sodium Hydroxide, NF	N/A	*	1310-73-2	H314: Causes severe skin burns and eye damage [Danger Skin corrosion/irritation]

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Section 3 – Composition / Information on Ingredients

				H335: May cause respiratory irritation
Water for Injection	q.s. to 1 mL	q.s. to 100	7732-18-5	Not Classified
* To adjust pH				

Section 4 – First Aid Measures

Eye Exposure:	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
Skin Exposure:	Immediately remove contaminated clothing. Flush area with large amounts of water for at least 15 minutes. Use soap. Seek medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Move exposed subject to fresh air and keep patient at rest. Seek medical attention immediately.
Notes to Physician:	Refer to package insert for warnings and precautions, symptoms related to overdosage, anticipated adverse reactions, and contraindications. Treat symptomatically.

Section 5 – Fire Fighting Measures

Flash Point:	Not established
Auto-ignition Temperature:	Not established
Flammable Limits in Air:	**Lower %:** Not established **Upper %:** Not established
Flammable Limits:	Not established
Extinguishing Media:	Extinguish fires with dry chemical, CO_2, water spray or alcohol-resistant foam.
Products of Combustion:	Formation of toxic gases is possible during heating or fire.
Special Fire Fighting Procedures:	No special provisions required beyond normal fire-fighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Section 6 – Accidental Release Measures

Spill:	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.
Release to Air:	If aerosolized, reduce exposures by ventilating the area; clean up spill immediately to prevent further evaporation/aerosolization.
Release to Water:	Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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Section 7 – Handling and Storage

General Handling:	As a general rule, when handling pharmaceutical products, use appropriate personal protective equipment. Avoid contact with skin, eyes, or clothing. Avoid inhalation of mists or vapors associated with the product. Release to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store as directed by product packaging.
Waste Disposal Method:	Dispose of in accordance with federal, state, and local regulations.

Section 8 – Exposure Controls / Personal Protection

Engineering Controls:	Engineering controls such as showers, eyewash stations, ventilation systems should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed below in this section.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Respiratory Protection:	Under normal conditions of product use, respiratory protection is not required. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N99 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.
Hands:	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. Protective gloves must meet the standard in accordance with EN374, ASTM F1001 or international equivalent. Use most conservative level of protection based on band or limit. Individuals with known sensitivity should wear protective gloves to avoid skin contact.
Eye Protection:	Safety glasses or goggles recommended. Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.
Ventilation:	Local exhaust or general ventilation is recommended.
Skin Protection:	Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas or if direct skin contact is anticipated. Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.
Other Protective Equipment:	Not required.
Additional Exposure Precautions:	Not required.

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Exposure Limits			
Compound	**Issuer**	**Type**	**Exposure Limit**
Cupric Chloride Dihydrate	OSHA	PEL - TWA	1 mg/m^3 (as CU)
	ACGIH	TLV - TWA	1 mg/m^3 (as CU)
	NIOSH	REL - TWA	1 mg/m^3 (as CU)
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
Sodium Hydroxide	OSHA	PEL - TWA	2 mg/m^3
	ACGIH	TLV - TWA	2 mg/m^3
Hydrochloric Acid	OSHA	PEL - C	5 ppm or 7 mg/m^3
	ACGIH	TLV - C	2 ppm
	CAL/OSHA	PEL - TWA	0.3 ppm or 0.45 mg/m^3
OSHA – Occupational Safety and Health Administration; PEL – Permissible Exposure Level; TWA – Time-Weighted Average; NIOSH - National Institute for Occupational Safety and Health; ACGIH – American Conference of Governmental Industrial Hygenists; TLV – Threshold Limit Value; STEL – Short Term Exposure Level; C – Ceiling; CAL/OSHA – California Division of Occupational Safety and Health; NE – Not evaluated;			

Section 9 – Physical and Chemical Properties

Physical State:	Liquid	**Auto-ignition Temperature:**	No data available
Appearance:	Clear colorless solution	**Flammability (solid, gas):**	No data available
Odor:	None	**Flammability/Explosive Limits**	No data available
Odor Threshold:	No data available	**Vapor Pressure:**	No data available
pH:	2 (1.5 – 2.5)	**Vapor Density:**	2.54 g/cm^3.
Melting Point:	No data available	**Specific Gravity:**	No data available
Boiling Point/Range:	No data available	**Solubility in Water:**	Soluble
Evaporation Rate:	No data available	**Partition coefficient: n-octanol/water:**	No data available
Decomposition Temperature:	No data available	**Viscosity:**	No data available

Section 10 – Stability and Reactivity

Chemical Stability:	Stable under standard storage and use conditions as specified in the package insert.
Reactivity/Incompatibility (Materials to Avoid):	Evolves flammable hydrogen gas on contact with metals. Contact with acids or acid fumes may evolve highly toxic hydrogen chloride fumes. Water loss occurs with heating.
Hazardous Decomposition:	No data available
Hazardous Polymerization:	Hazardous polymerization does not occur.
Conditions to Avoid:	Exposure to moisture. Exposure to moist air.

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Section 11 – Toxicological Information

Acute Toxicity				
Component	**Type**	**Route**	**Species**	**Dosage**
Cupric Chloride	LD_{50}	Oral	Mouse	110 mg/kg
Sodium chloride	LD_{50}	Oral	Mouse	4000 mg/kg
	LD_{50}	Oral	Rat	3000 mg/kg
Hydrochloric acid	LD_{50}	Oral	Rat	238-277 mg/kg
Dermal Irritation/Corrosion:	Causes severe skin irritation and burns with itching, erythema, and burning pain.			
Ocular Irritation/Corrosion:	Severe eye irritation. Causes eye burns. May cause corneal damage. Symptoms can include redness, pain, blurred vision, discoloration, loss of vision, eye damage such as permanent corneal opacification, chemical conjunctivitis, and ulceration.			
Signs and Symptoms of Exposure:	None known from workplace exposure.			
Chemical Listed as Carcinogen:	**NTP:** No **IARC:** No **OSHA:** No			
Reproductive Toxicity:	No data available.			
Mutagenicity:	No information available			
Carcinogenicity:	None of the components of this formulation are listed as a carcinogen by IARC, NTP, or OSHA.			
Target Organ Effects:	This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired.			

Section 12 – Ecological Information

Environmental properties have not been thoroughly investigated. Release to the environment should be avoided.	
Aquatic Toxicity:	No data available.
Persistence/Biodegradability:	No data available.
Bioaccumulation:	No data available
Mobility in Soil:	No data available.

Section 13 – Disposal Considerations

Waste Disposal:	Dispose of any cleanup materials and waste residue according to all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14 – Transport Information

Regulatory Organizations:	**USDOT:** Not Regulated
	EUDAR: Not Regulated
	ICAO: Not Regulated
	IATA: Not Regulated

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	IMO: Not Regulated

Section 15 – Regulatory Information

Below is selected regulatory information chosen primarily for possible Exela Pharma Sciences usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations	
TSCA	Yes –Sodium Chloride, Hydrochloric Acid, Sodium Hydroxide, and Water for Injection
CERCLA	Yes – Cupric Chloride, Hydrochloric Acid
SARA 302	Yes- Hydrochloric Acid, Threshold Planning Quantity (TPQ) 500 (gas only)
SARA 313	Yes- Cupric Chloride, Hydrochloric Acid
OSHA Substance Specific	Not Listed
California PROP 65	Not Listed.
RCRA Status	Not Listed
RTECS Number:	GL7030000 – Cupric Chloride, VZ4725000 – Sodium Chloride, MW4025000 – Hydrochloric Acid, WB4900000-Sodium Hydroxide

Section 16 – Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
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