Safety Data Sheet (SDS)

MATERIAL: NIPRIDE RTU	SUPPLIER(S): Exela Pharma Sciences, LLC	SDS NO.: SDS-FP-006-00	ISSUE DATE: 02/07/2017

Section 1 – Chemical Product and Company

Distributor:		**Emergency Telephone:**	(828) 758-5474, ext. 119
Exela Pharma Sciences, LLC 1245 Blowing Rock Blvd Lenoir, NC 28645 (828) 758-5474		**Product Identifier:**	NIPRIDE RTU
		Product Code:	51754-1006-1
		Common/Trade Name:	Sodium Nitroprusside Injection
Chemical Formula:	$Na_2[Fe(CN)_5NO] \cdot 2H_2O$	**Chemical Family:**	Vasodilator
Product Use:	Pharmaceutical	**Product Type:**	Regulated Prescription Drug
Container Information:	Vials		

Section 2 – Hazards Identification

U.S. OSHA Classification:	Target Organ Toxin; Possible Irritant
Precautionary Statements:	Pre-existing hypotension or pre-existing skin, eye, nervous system, blood, or cardiovascular ailments may be aggrevated by exposure. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Do not breathe dust/fume/gas/mist/vapors/spray. If exposed or concerned, get medical advice/attention.
Primary Physical and Health Hazards:	This material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include skin, eyes, blood, central nervous system and cardiovascular system.
Routes of Entry:	Inhalation, eye/skin contact, or ingestion.
Medical Conditions Generally Aggravated by Exposure:	Pre-existing hypotension or pre-existing skin, eye, nervous system, blood, or cardiovascular ailments.

Section 3 – Composition / Information on Ingredients

Ingredient	Weight	CAS No.
Sodium Nitroprusside Dihydrate	0.5 mg/mL, 50 mg / 100 mL	13755-38-9
Sodium Chloride	9 mg/mL, 900 mg / 100 mL	7440-23-5
Water for Injection	N/A	7732-18-5

Section 4 – First Aid Measures

Eye Exposure:	Immediately flush with plenty of water. Seek medical attention.
Skin Exposure:	Immediately remove from skin with dry cloth followed by flushing with plenty of water for at least 15 minutes.
Ingestion:	Flush mouth out with water. Obtain medical attention immediately if ingested.
Inhalation:	Move exposed subject to fresh air immediately. Obtain medical attention if ill effects occur.
Injection:	See patient package insert in shipping carton for complete information. Antidotal treatment of cyanide toxicity consists of • providing a buffer for cyanide by using sodium nitrite to convert as much hemoglobin into methemoglobin as the person can safely tolerate; and then • infusing sodium thiosulfate in sufficient quantity to convert the cyanide into thiocyanate. The necessary medications for treating cyanide toxicity are contained in commercially available Cyanide Antidote Kits. Cyanide Antidote Kits contain both amyl nitrite and sodium nitrite for induction of methemoglobinemia. The amyl nitrite is supplied in the form of inhalant ampules, for administration in environments where intravenous administration of sodium nitrite may be delayed. In a patient who already has a patient intravenous line, use of amyl nitrite confers no benefit that is not provided by infusion of sodium nitrite. Sodium nitrite is available in a 3% solution, and 4-6 mg/kg (about 0.2 mL/kg) should be injected over 2-4 minutes. This dose can be expected to convert about 10% of the patient's hemoglobin into methemoglobin; this level of methemoglobinemia is not associated with any important hazard of its own. The nitrite infusion may cause transient vasodilatation and hypotension, and this hypotension must, if it occurs, be routinely managed. Immediately after infusion of the sodium nitrite, sodium thiosulfate should be infused. This agent is available in 10% and 25% solutions, and the recommended dose is 150-200 mg/kg; a typical adult dose is 50 mL of the 25% solution. Thiosulfate treatment of an acutely cyanide-toxic patient will raise thiocyanate levels, but not to a dangerous degree. The nitrite/thiosulfate regimen may be repeated, at half the original doses, after two hours. Hemodialysis is ineffective in removal of cyanide, but it will eliminate most thiocyanate.
Notes to Physician:	See patient package insert in shipping carton for complete information.

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:	Use water or an ABC multi-purpose extinguisher for surrounding materials.
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.

Section 7 – Handling and Storage

General Handling:	Protect from light by retaining in carton until contents have been used. As a general rule, when handling pharmaceutical products, avoid all contact and inhalation of mists or vapors associated with the product. Avoid contact with skin, eyes or clothing. Use in well ventilated area.
Storage Conditions:	Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature]. Follow instructions provided in packaging.
Waste Disposal Method:	Dispose of in accordance with federal, state, and local regulations.

Section 8 – Exposure Controls / Personal Protection

Respiratory Protection:	Under normal conditions of product use, respiratory protection is not required.
Eye Protection:	Eye protection is not required during expected product use conditions but may be warranted should a splash potential exist.
Ventilation:	Local exhaust or general ventilation is recommended.
Skin Protection:	If solution contact with unprotected skin is likely, use of impervious gloves is a prudent practice.
Other Protective Equipment:	Not required.
Additional Exposure Precautions:	Not required.

Exposure Limits

Compound	Issuer	Type	TWA
Sodium Nitroprusside Dihydrate	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Sodium Chloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

NE = Not Established

Section 9 – Physical and Chemical Properties

Physical State:	Aqueous Solution	**Specific Gravity:**	Approximately 1.0
Appearance and Odor:	Reddish brown solution, odorless	**Evaporation Rate:**	Not available
Odor Threshold:	Not applicable	**Flammability (solid, gas):**	Not available
Boiling Point:	Above 212°F	**Melting Point:**	Not available
Vapor Pressure:	Not applicable	**Solubility in Water:**	Soluble
Vapor Density:	Not applicable	**pH:**	4.9
		Partition coefficient: n-octanol/water:	Not applicable
Auto-ignition Temperature:	Not applicable	**Decomposition Temperature:**	Not applicable

Section 10 – Stability and Reactivity

Stability:	Normally stable under standard storage and use conditions. Product sensitive to certain wavelengths of light. Protect from light.
Incompatibility (Materials to Avoid):	Not determined. May degrade in the presence of acid.
Hazardous Decomposition:	Toxic fumes of cyanides and oxides of nitrogen.
Hazardous Polymerization:	Not determined.
Conditions to Avoid:	Avoid light exposure.

Section 11 – Toxicological Information

Acute Toxicity				
Component	**Type**	**Route**	**Species**	**Dosage**
Sodium Nitroprusside	LD_{50}	Oral	Rat	99 mg/kg
Sodium Nitroprusside	LD_{50}	Oral	Mouse	61 mg/kg
Sodium Nitroprusside	LD_{50}	Oral	Rabbit	34 mg/kg
Sodium Nitroprusside Dihydrate	LD_{50}	Intravenous	Rabbit	1.8, 2.8 mg/kg
Sodium Nitroprusside Dihydrate	LD_{50}	Intravenous	Dog	5.0 mg/kg
Sodium Nitroprusside Dihydrate	LD_{50}	Intravenous	Mouse	6.0, 8.4 mg/kg
Sodium Nitroprusside Dihydrate	LD_{50}	Intravenous	Rat	9.3, 11.2 mg/kg

Dermal Irritation/Corrosion:	None anticipated from normal handling of this product.
Ocular Irritation/Corrosion:	None anticipated from normal handling of this product. Inadvertent contact of this product with eyes may produce irritation with redness and tearing.
Signs and Symptoms of Exposure:	None known from workplace exposure. In clinical use, adverse effects are generally an extension of the pharmacologic actions of sodium nitroprusside (e.g. excessive vasodilation and hypotension) and may include nausea, vomiting, sweating, dizziness, restlessness, headache, palpitation and substernal distress. In clinical use, deaths attributable to sodium nitroprusside have resulted in patients following administration.
Carcinogenicity:	None known.
Chemical Listed as Carcinogen:	**NTP:** No **IARC:** No **OSHA:** No
Reproductive Toxicity:	Sodium nitroprusside has not been tested for effects on fertility. Studies to assess the potential for developmental toxicity in animals have not been conducted. However, the infusion of 25 mcg/kg/min of sodium nitroprusside for one hour to pregnant ewes resulted in the death of all fetuses; pregnant ewes infused with 1 mcg/kg/min of sodium nitroprusside for one hour delivered normal lambs.
Target Organ Effects:	Based on clinical use, possible target organs include, skin, eyes, blood, central nervous system and cardiovascular system.

Section 12 – Ecological Information

Aquatic Toxicity:	Not available for product. Information for sodium nitroprusside (14402-89-2) is as follows: Lethal Threshold Concentration (LETC, 48 hr) < 210 mg/l in Daphnia magna. LC50 (24 hr) = 350 mg/L in Poecilia reticulate (guppy). LT50 = 48 hours in Polycelis nigra (a planarian) when applied at a 0.0008 M

Section 13 – Disposal Considerations

Waste Disposal:	Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 – Transport Information

Regulatory Organizations:	**DOT:** Not Regulated
	ICAO/IATA: Not Regulated
	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	Not on this list
CERCLA	Not on this list
SARA 302	Not on this list
SARA 313	Not on this list
OSHA Substance Specific	No
RCRA Status	Not Listed

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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SDS creation Date: February 2017