

SAFETY DATA SHEET

PRODUCT: Sodium Nitroprusside Injection; 50 mg/2 mL (25 mg/mL)

Section 1: PRODUCT AND COMPANY INFORMATION

54/1, Boodhihal village, Nelamangala, Bangalore, India-562123. PRODUCT NAME: Sodium Nitroprusside Injection; 50 mg/2 mL (25 mg/mL)

Section 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance	Clear, reddish brown solution, filled in 2mL USP type I amber tubular glass vial.
Classification of the substance or Mixture	
U.S. OSHA Classification	Target Organ Toxin; Possible Irritant
GHS - Classification	*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Name	CAS Number
Sodium Nitroprusside USP	13755-38-9
Water for injection*	7732-18-5

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. * Proprietary

Section 4: FIRST AID MEASURES

Eye Contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin Contact:	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. 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 patent 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.

Section 5: FIRE FIGHTING MEASURES

Flammability	None anticipated for this aqueous product.
Fire & Explosion Hazard	None anticipated for this aqueous product.
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal firefighting equipment. As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous-based and is not expected to present a fire hazard concern.

Section 6: ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
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Section 7: HANDLING AND STORAGE

Handling	No special handling required for hazard control under conditions of normal product use.
Storage	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits	Compound	Issuer	Type	Exposure Limit
	Sodium Nitroprusside	OSHA	PEL	N/A
		ACGI	TLV	N/A
Respiratory Protection	Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or 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 (N95 or equivalent) is recommended under conditions where airborne dust or 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. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.			
Skin Protection	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.			

Eye Protection	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Engineering Controls	Engineering controls are normally not needed during the normal use of this product.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

<p>Appearance Clear reddish brown solution</p> <p>Decomposition Temperature (°C): No data available.</p> <p>Evaporation Rate (Gram/s): No data available</p> <p>Vapour Pressure (kPa): No data available</p> <p>Vapour Density (g/ml): No data available</p> <p>Relative Density: No data available</p> <p>Viscosity: No data available</p> <p>Flammability: Auto ignition Temperature (Solid) (°C): No data available</p> <p>Flammability (Solids): No data available</p> <p>Flash Point (Liquid) (°C): No data available</p> <p>Upper Explosive Limits (Liquid) (% by Vol.): No data available</p> <p>Lower Explosive Limits (Liquid) (% by Vol.): No data available</p>
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Section 10: STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions. However, product is sensitive to certain wavelengths of light. Protect from light.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (CO _x), nitrogen oxides (NO _x), and hydrogen cyanide.

Section 11: TOXICOLOGY INFORMATION

Likely Routes of Exposure	Ingestion, Inhalation, skin, eye
Signs and Symptoms	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) 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

Delayed and immediate effects and also chronic effects from short and long term exposure	Target organ effects: Based on clinical use, possible target organs include the skin, eyes, blood, central nervous system, and cardiovascular system. Sodium nitroprusside has not been tested for effects on fertility.
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Section 12: ECOLOGICAL INFORMATION

Ecotoxicity

(a)	Ecotoxicity	N/A
(b)	Persistence and degradability	Not determined for product.
(c)	Bioaccumulative potential	Not determined for product.
(d)	Mobility in soil	Not determined for product.
(e)	Other Adverse Effects	N/A

Section 13: DISPOSAL CONDITIONS

Waste Disposal: All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal: Dispose of container and unused contents in accordance with federal, state and local regulations

Section 14: TRANSPORTATION INFORMATION

UN Number None allocated
DG Class None allocated
Subsidiary Risk None allocated
Packing Group None allocated
Hazchem Code None allocated
The following refers to all modes of transportation unless specified below. Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	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.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program

OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System