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

Safety Data Sheet (SDS)

1. IDENTIFICATION

(a)	**Product Identifier:**	Sodium Nitroprusside Injection
(b)	**Product Code:**	NDC 14789-012-02
	Common/Trade Name:	NITROPRESS®
	Chemical Name:	Disodium pentacyanonitrosylferrate(2-) dihydrate
	Chemical Family:	Vasodilator
(c)	**Product Use:**	Relaxes both arterial and venous smooth muscle. Clinically, it is used as a hypotensive agent for short-term, rapid reduction of blood pressure in hypertensive emergencies
	Product Type:	Regulated Prescription Drug
	Container Information:	Vial
(d)	**Distributor:**	Nexus Pharmaceuticals, Inc., 175 E. Hawthorn Parkway, Suite 155, Vernon Hills, IL 60061, 847-996-3790
(e)	**Emergency Telephone:**	800-913-2720

2. HAZARDS IDENTIFICATION

(a)	**Classification:**	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.
(b)	**Signal Word**	N/A
	Hazard statement(s), Symbol(s)	This material should be considered a potent drug, and potentially irritating to the skin, eyes, and respiratory tract. Based on clinical use, possible target organs include the skin, eyes, blood, central nervous system, and cardiovascular system; Avoid aerosol generation and skin contact.
	Precautionary statement(s):	Pre-existing hypotension or pre-existing skin, eye, nervous system, blood, or cardiovascular ailments may be aggravated by exposure. P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

(c) Description of Hazards: N/A

(d) Unknown Acute Toxicity: N/A

3. COMPOSITION / INFORMATION ON INGREDIENTS

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Sodium Nitroprusside Dihydrate	N/A	2.5% by weight	13755-38-9	N/A

4. FIRST AID MEASURES

Eye Exposure: 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 Exposure: 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.

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

Injection: N/A

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Notes to Physician: See patient package insert in shipping carton for complete information.

5. FIRE-FIGHTING MEASURES

(a) Extinguishing Media As with any fire, use extinguishing media appropriate for primary cause of fire.

(b) Hazardous Combustion Products: None anticipated for this aqueous product.

(c) Special Protective Equipment / Precautions: 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.

6. ACCIDENTAL RELEASE MEASURES

Spill: Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill 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.

Release to Air: N/A

Release to Water: N/A

7. HANDLING AND STORAGE

General Handling: No special handling required for hazard control under conditions of normal product use.

Storage Conditions: No special storage required for hazard control. Protect from light. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Sodium Nitroprusside	OSHA	PEL	N/A
	ACGIH	TLV	N/A

(b) Engineering Controls

Ventilation: N/A

(c) Individual Protection Measures

Respiratory Protection:	Respiratory protection is normally not needed during intended product use. 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 (N95 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. 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.

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.
Skin Protection:	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Other Protective Equipment:	N/A
Additional Exposure Precautions:	N/A

9. PHYSICAL AND CHEMICAL PROPERTIES

(a)	**Appearance**	Liquid; Reddish brown
(b)	**Odor**	N/A
(c)	**Odor Threshold**	N/A
(d)	**pH**	5 for a 5% aqueous solution
(e)	**Melting Point:**	N/A
(f)	**Initial Boiling Point:**	N/A
(g)	**Flash Point**	N/A
(h)	**Evaporation Rate:**	N/A
(i)	**Flammability**	N/A
(j)	**Upper Lower Flammability or Explosion Limits**	N/A
(k)	**Vapor Pressure:**	N/A
(l)	**Vapor Density:**	N/A
(m)	**Relative Density**	N/A
(n)	**Solubility(ies)**	Slightly soluble in alcohol. Soluble in water
(o)	**Partition Coefficient: n-octanol/water**	N/A
(p)	**Auto-ignition Temperature**	N/A
(q)	**Decomposition Temperature**	N/A
(r)	**Viscosity**	N/A

10. STABILITY AND REACTIVITY

(a)	**Reactivity**	Not determined.
(b)	**Chemical Stability**	Stable under standard use and storage conditions. However, product is sensitive to certain wavelengths of light. Protect from light.
(c)	**Possibility of Hazardous Reactions**	Not determined.
(d)	**Conditions to Avoid**	Not determined.
(e)	**Incompatible Materials**	Not determined. May degrade in presence of acid.
(f)	**Hazardous Decomposition Products**	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/ or toxic fumes of carbon oxides (Cox), nitrogen oxides (NOx), and hydrogen cyanide.

11. TOXICOLOGICAL INFORMATION

(a)	**Likely Routes of Exposure**	Ingestion, Inhalation, skin, eye
(b)	**Symptoms related to the physical, chemical and toxicological characteristics**	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 sedum nitroprusside have resulted in patients following administration.
(c)	**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.

(d) Acute Toxicity

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

(e) Hazardous Chemical Listings

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

12. ECOLOGICAL INFORMATION

(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

13. DISPOSAL CONSIDERATIONS

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.

14. TRANSPORT INFORMATION

(a)	**UN Number**	N/A
(b)	**UN Proper Shipping Name**	N/A
(c)	**Transport Hazard Class(es)**	N/A
(d)	**Packing Group**	N/A
(e)	**Environmental Hazards**	N/A

(f)	**Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)**	N/A
(g)	**Special Precautions**	N/A

DOT status: Not regulated IMDG
Status: Not regulated ICAO/IATA
Status: Not Regulated

15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Nexus 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 listed
CERCLA: Not listed
SARA 302: Not listed
SARA 313: Not listed
RCRA Status: Not Listed

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.

NEXUS PHARMACEUTICALS

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Safety Data Sheet (SDS)

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

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 Association
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