


SAFETY DATA SHEET

Sodium Nitroprusside Injection

1. IDENTIFICATION

Product Identifier:	Sodium Nitroprusside Injection	
Synonyms:	Sodium nitroferricyanide dihydrate * Disodium pentacyanonitrosylferrate(2-) dihydrate	
National Drug Code (NDC):	17478-014-02	
Recommended Use:	Pharmaceutical. Sodium Nitroprusside is indicated for the immediate reduction of blood pressure of adult and pediatric patients in hypertensive crises. Concomitant longer-acting antihypertensive medication should be administered so that the duration of treatment with sodium Nitroprusside can be minimized. Sodium Nitroprusside is also indicated for producing controlled hypotension in order to reduce bleeding during surgery and treatment of acute congestive heart failure.	
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045	
Contact Telephone:	1-800-932-5676	
E mail:	customer.service@akorn.com	
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)	

2. HAZARD(S) IDENTIFICATION

Physical Hazards:	Not classifiable.	
Health Hazards:	Acute Toxicity, Oral	Category 5
	Specific Target Organ Toxicity- Repeated Exposure	Category 2
Symbol(s):		
Signal Word:	Warning.	
Hazard Statement(s):	H303 May be harmful if swallowed.	
	H373 May cause damage to organs through prolonged or repeated exposure.	
Precautionary Statement(s):	P260 Do not breathe vapors or spray.	
	P264 Wash hands and other exposed areas thoroughly after handling.	

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P314 Get medical advice/attention if you feel unwell.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified:
Supplementary Information:

Not classifiable.
None.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Sodium Nitroprusside	Sodium nitroferricyanide dihydrate * Disodium pentacyanonitrosylferrate (2-) dihydrate	13755-38-9	$\text{Na}_2[\text{Fe}(\text{CN})_5\text{NO}] \cdot 2\text{H}_2\text{O}$	297.95	2.5%

The formula also contains Water for Injection.

4. FIRST AID MEASURES

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

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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.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

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) 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.

Medical Conditions Aggravated by Exposure:

Pre-existing hypotension or pre-existing skin, eye, nervous system, blood, or cardiovascular ailments.

Notes to Physician:

Treat supportively and symptomatically.

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5. FIREFIGHTING MEASURES

Suitable Extinguishing Media: Use water, carbon dioxide, dry chemical or water spray.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical

Hazardous Combustion Products: No data available.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions: Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up: Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations. Wipe working area surfaces to dryness, and then wash with soap and water.

Environmental Precautions: Contain material and prevent release to basements, confined spaces, waterways or soil.

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. HANDLING AND STORAGE

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light. Store away from oxidizing agents and acids.

Specific End Use: Pharmaceutical drug product.

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guidelines:

Ingredient	Type	Value
Sodium Nitroprusside	OSHA PEL	5 mg/m ³
	ACGIH STEL	100 mcg/m ³
	ACGIH TWA	50 mcg/m ³

OSHA: Occupational Safety and Health Administration; PEL: Permissible Exposure Limit; ACGIH: American Conference of Governmental Industrial Hygienists; STEL: Short Time Exposure Limit; TWA: Time Weighted Average.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

Respiratory Protection:

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection:

Avoid contact with eyes. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection:

Wear chemically compatible gloves for handling solutions and ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection:

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

General Hygiene Considerations:

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State/Color:

Reddish-brown liquid.

Odor:

No data available.

Odor Threshold:

No data available.

pH:

No data available.

Melting Point:

No data available.

Freezing Point:

No data available.

Boiling Point:

No data available.

Flash Point:

No data available.

Evaporation Rate:

No data available.

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Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Soluble in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.

10. STABILITY AND REACTIVITY

Reactivity:	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability:	Stable under recommended storage conditions. However, product is sensitive to certain wavelengths of light. Protect from light.
Possibility of Hazardous Reactions:	Not determined.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Not determined.
Incompatible Materials:	In the presence of strong acid, the active ingredient can degrade to release hydrogen cyanide.
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

Information on the Likely Routes of Exposure

Inhalation:	No data available.
Ingestion:	Toxic if swallowed.
Skin Contact:	No data available.
Eye Contact:	No data available.
Symptoms Related to the Physical, Chemical and Toxicological Characteristics:	See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

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Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Sodium Nitroprusside	Rat	Oral	LD ₅₀	99 mg/kg (anhydrous)
	Mouse	Oral	LD ₅₀	61 mg/kg (anhydrous)
	Rabbit	Oral	LD ₅₀	34 mg/kg (anhydrous)

Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

Repeated Doses Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
Sodium Nitroprusside	Reproductivity Study	Sheep	Intravenous	1-25 mcg/kg/min /infusion for 60 minutes	Not specified	Fetus cyanide levels were dose-related to maternal levels of nitroprusside; the high dose resulted in fetal death
Sodium Nitroprusside	Reproductivity and Development Study	Rat	Intravenous	7.4 mg/kg	Not specified	No adverse fetal effects

Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

Aspiration Hazard:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

Based on clinical use, possible target organs include the skin, eyes, blood, central nervous system, and cardiovascular system.

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Systemic Effects:	No data available.
Reproductive Effects:	Pregnancy Category C. There are no adequate, well-controlled studies of Sodium Nitroprusside in either laboratory animals or pregnant women.
Carcinogenicity:	Carcinogenicity studies in laboratory animals have not been conducted with Sodium Nitroprusside.
National Toxicology Program (NTP):	Not considered to be a carcinogen.
International Agency for Research on Cancer (IARC):	Not considered to be a carcinogen.
Occupational Safety and Health Administration (OSHA):	Not considered to be a carcinogen.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
Sodium Nitroprusside	Bluegill (Lepomis macrochirus)	LC ₅₀	0.12 mg/l	96 hours

Terrestrial Toxicity:	No data available.
Persistence and Degradability:	No data available.
Bioaccumulative Potential:	No data available.
Mobility in Soil:	No data available.
Mobility in Environment:	No data available.
Other Adverse Effects:	No data available.

13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

14. TRANSPORT INFORMATION

Department of Transportation (DOT): Not regulated as a hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

International Air Transport Association (IATA): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

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International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not applicable	Not applicable

15. REGULATORY INFORMATION

US FEDERAL REGULATIONS

Toxic Substance Control Act (TSCA):

Ingredient	Inventory
Sodium Nitroprusside	Yes

CERCLA Hazardous Substance:

Ingredient	Reportable Quantity
Not applicable	Not applicable

EPCRA Extremely Hazardous Substances and Toxic Chemicals:

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Sodium Nitroprusside	Listed	Listed	Listed

California Proposition 65:

Sodium Nitroprusside is known to State of California to cause cancer, birth defects, or other reproductive harm.

16. OTHER INFORMATION

See footer of this document for Revision Date and Revision Number.

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