MATERIAL SAFETY DATA SHEET

SODIUM NITROPRUSSIDE INJECTION 50MG/2ML (25MG/ML)

1. IDENTIFICATION					
Material Identification	:	Sodium Nitroprusside Injection 50mg/2ml (25mg/ml)			
Active ingredient	:	Sodium Nitroprusside			
Molecular Formula	:	$Na_2[Fe(CN)_5NO]$	**Molecular Weight**	:	297.95 g/mol
CAS Number	:	13755-38-9			
Product Use	:	Antihypertension, Vasodilator			
Manufactured by	:	**Micro Labs Limited** Plot no. 113-116, KIADB, Bommasandra Industrial Area, Bommasandra-Jigani Link Road, Anekal taluk, Bangalore-560099, Karnataka, India	**Manufactured for**	:	**Armas Pharmaceuticals Inc. ("Distributor")** 151 Route 33 East, Suite 203, Manalapan, NJ 07726
Emergency Contact	:	+91-80-27839033			

2. HAZARDS IDENTIFICATION		
Label Elements		
Signal	:	Warning 
Physical hazards	:	Not classified
Hazard statements	:	H301: Toxic if swallowed
Precautionary statements	:	P264: Wash {hands} thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P301+310: IF SWALLOWED: Call a POISON CENTER or doctor / physician if you feel unwell. P330: Rinse mouth. P405: Store locked up. P501:Dispose of contents/container in accordance with all local and national regulations
Hazard(s) not otherwise classified (HNOC)	:	None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS	
Material	%
Sodium Nitroprusside	2.5

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES		
Eyes 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.
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.
Inhalation	:	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
General information	:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

5. FIRE FIGHTING MEASURES		
Extinguishing media	:	Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Firefighting instructions	:	Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	:	Do not enter fire area without proper protective equipment, including respiratory protection.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	For non-emergency personnel: Protective equipment: Safety glasses. Gloves. Dust mask. Emergency procedures: Evacuate unnecessary personnel. For emergency responders: Protective equipment: Equip cleanup crew with proper protection. Emergency procedures: Ventilate area.
Environmental precautions	:	Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.
Methods and material for containment and cleaning up	:	On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

7. HANDLING AND STORAGE

Precautions for safe handling	:	Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
Hygiene measures	:	Do not eat, drink or smoke when using this product. Wash exposed skin thoroughly after handling.
Conditions for safe storage, including any incompatibilities		
Storage conditions	:	Keep container closed when not in use.
Incompatible products	:	Strong oxidizers. Strong acids.
Incompatible materials	:	Sources of ignition. Direct sunlight.
Specific end use(s)	:	No additional information available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Controls	:	Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation.
Personal Protective Equipment	:	Avoid all unnecessary exposure.
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.

Hands	:	Wear protective gloves.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES		
Physical State	:	Injection
Color	:	Reddish brown color solution
Appearance	:	Sodium Nitroprusside Injection 50mg/2ml: Reddish brown color solution, free of visible particulate matter.
Molecular Formula	:	$Na_2[Fe(CN)_5NO]$
Molecular Weight	:	297.95 g/mol
10. STABILITY AND REACTIVITY		
Reactivity	:	No additional information available.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Contact with acids liberates toxic gas.
Conditions to Avoid	:	Direct sunlight. Extremely high or low temperatures.
Incompatible Materials	:	Strong acids. Strong oxidizers.
Hazardous decomposition products	:	Hydrogen cyanide. Carbon monoxide. Carbon dioxide.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity :

Toxic if swallowed.

Ingredient	Percent	Test type	Route of Administration	Value	Units	Species
Sodium nitroprusside	100	LD50	Oral	99 61 34	mg/kg mg/kg mg/kg	Rat Mouse Rabbit
Sodium nitroprusside dihydrate	100	LD50	Intravenous	1.8 5.0 6.0 9.3	mg/kg mg/kg mg/kg mg/kg	Rabbit Dog Mouse Rat

Occupational Exposure Potential	:	Information on the absorption of this material via inhalation or skin contact is not available. Avoid aerosol generation and skin contact.

Signs and Symptoms	:	None anticipated from normal handling of this product. 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.
Aspiration Hazard	:	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	:	None anticipated from normal handling of this product.
Ocular Irritation/ Corrosion	:	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
Dermal or Respiratory Sensitization	:	None anticipated from normal handling of this product.
Germ cell mutagenicity	:	The mutagenic potential has not been evaluated.
Carcinogenicity	:	The carcinogenic potential has not been evaluated.
IARC:	:	No data available
NTP:	:	No data available
Reproductive toxicity:	:	None anticipated from normal handling of this product. 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.

12. ECOLOGICAL INFORMATION		
Aquatic Toxicity:	:	Not determined 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 concentration.
Persistence and degradability	:	No data available
Bioaccumulative potential	:	No data available
Mobility in soil	:	No data available
Effect on ozone layer	:	No data available
Other information	:	Avoid release to the environment.

13. DISPOSAL CONSIDERATIONS		
Waste Treatment Methods	:	**A) Waste disposal recommendations:** Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to comply with local, state and federal regulations. **B) Ecology-waste materials:** Avoid release to the environment. Hazardous waste due to toxicity.

14. TRANSPORTATION INFORMATION		
Environmental hazards	:	No data available
Special precautions for user	:	No data available
Transport hazard class(es)	:	No data available
Packing group	:	No data available
IATA UN number	:	No data available
Environmental hazards	:	No data available
Special precautions for user	:	No data available

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY / STATUTORY INFORMATION

This safety data sheet complies with the requirements of WHMIS (Canada), OSHA 1910.1200 (US), and EU Regulation EC No. 1907/2006 (European Union).

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

A) Canada - DSL/NDSL Status: This product is not listed on the Canadian DSL/NDSL.
B) United States - TSCA Status: This product is not listed on the US EPA TSCA
C) European Union - ECHA Status: This product is not registered with the EU ECHA.

15.2 Chemical Safety Assessment
No data available

16. OTHER INFORMATION

Date of preparation: 09/05/20

Other information: None.
NFPA health hazard: 2 - Intense or continued exposure could cause temporary incapacitation or possible residual injury unless prompt medical attention is given.
NFPA fire hazard: 0 - Materials that will not burn.
NFPA reactivity: 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.

HMIS III Rating
Health: 2 Moderate Hazard - Temporary or minor injury may occur
Flammability: 0 Minimal Hazard
Physical: 0 Minimal Hazard
Personal Protection: F

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End of Safety Data Sheet