Safety Data Sheet (SDS)

Norepinephrine Bitartrate in Sodium Chloride Injection

1 PRODUCT AND COMPANY INFORMATION

Product Identifier(s):

Product Name:	**Norepinephrine Bitartrate in Sodium Chloride Injection**
Chemical Name:	(-)-α-(aminomethyl)-3,4-dihydroxybenzyl alcohol tartrate (1:1) (salt) monohydrate
Chemical Family:	Sympathomimetic Amine
Distributed By:	WG Critical Care, LLC. 120 Route 17 North Suite 115 Paramus, NJ 07652 USA
Recommended Use:	Pharmaceuticals product used as cardiovascular drug, peripheral vasoconstrictor (alpha-adrenergic action) for blood pressure control in acute hypotensive states and as an inotropic stimulator of the heart and dilator of coronary arteries for treatment of cardiac arrest and profound hypotension (beta-adrenergic action).
Uses Advised Against:	This is a pharmaceutical product designed to be administered by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.
Product Type:	Pharmaceutical
Container Information:	Plastic Container
Customer Service Phone Number:	+1-888-493-0861
Emergency Phone Number:	+1-866-562-4708 (ProPharma)

2 HAZARDS INDENTIFICATION

Product Form: Mixture

Classification

Health Hazards Not classified as hazardous

Physical hazards	Hazard Class	Hazard Category
U.S. OSHA GHS EU	Not classified Not classified	Not classified Not classified

OSHA Regulatory Status
This product is safe for consumers when used according to the label directions. Potential hazards that may occur if product is not used according to the consumer label are as follows in this Safety Data Sheet (SDS).

Label elements Not Applicable

Emergency Overview

Signal Word
Not Classified

Hazard statements
Not classified in accordance with internal standards for workplace safety

Precautionary Statements - Prevention
Do not breath vapor or spay
Wash hands thoroughly after handling

Precautionary Statements - Response
Get medical attention if you feel unwell
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

Precautionary Statements - Storage
Storage as directed by product packaging

Precautionary Statements - Disposal
Dispose of waste in accordance with all applicable laws and regulations

Hazards not otherwise classified (HNOC)
Not Applicable

Other Information
An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8)

Unknown Acute Toxicity
None know

3 COMPOSITION / INFORMATION ON INGREDIENTS

Common name Norepinephrine Bitartrate in Sodium Chloride Injection

Synonyms (-)-α-(aminomethyl)-3,4-dihydroxybenzyl alcohol tartrate (1:1) (salt) monohydrate

Chemical Formula Mixture

Chemical Name of Components	CAS No.	Amount %	Amount mg/mL
Norepinephrine Bitartrate	108341-18-0	0.0032	*
Sodium Chloride	7647-14-5	0.9	*
Hydrochloric Acid	1310-73-2	q.s. to pH	*
Sodium Hydroxide	7647-01-0	q.s. to pH	*
Water for Injection	7732-18-5	> 98	*

Chemical Name of Components	CAS No.	Amount %	Amount mg/mL
Norepinephrine Bitartrate	108341-18-0	0.0064	*
Sodium Chloride	7647-14-5	0.9	*
Hydrochloric Acid	1310-73-2	q.s. to pH	*
Sodium Hydroxide	7647-01-0	q.s. to pH	*
Water for Injection	7732-18-5	> 98	*

Chemical Name of Components	CAS No.	Amount %	Amount mg/mL
Norepinephrine Bitartrate	108341-18-0	0.0128	*
Sodium Chloride	7647-14-5	0.9	*
Hydrochloric Acid	1310-73-2	q.s. to pH	*
Sodium Hydroxide	7647-01-0	q.s. to pH	*
Water for Injection	7732-18-5	> 98	*

*In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

4 FIRST AID MEASURES

Description of first aid measures

GENERAL: Consult a physician. Show this safety data sheet to the doctor in attendance.

INHALATION: Move to fresh air if discomfort occurs, get medical attention.

EYES:	Rinse thoroughly with plenty of water. If skin irritation persists, call a physician.
SKIN:	Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
INGESTION:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Most important symptoms and effects; both acute and delayed

OVERVIEW:	For information on potential signs and symptoms of exposure, See Section 2 - Hazards
Indication of any immediate medical attention and special treatment needed:	None.

5 FIRE FIGHTING MEASURES

Extinguishing Media:	As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical
Unsuitable Extinguishing Media:	None Known
Special hazards arising from the substance or mixture:	None Known
Fire and Explosion Hazard:	Product is not explosive
Advice for Fire-Fighters:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6 ACCIDENTAL RELEASE MEASURE

Personal precautions, protective equipment and emergency procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Methods and material for containment and cleaning up	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7 HANDLING AND STORAGE

Precautions for safe handling	Avoid breathing vapor or mist. Avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Release to the environment should be avoided. Review and implement appropriate technical and procedural waste and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emission of this material to the atmosphere should be controlled with dust collectors, HEPA filtration system or other equivalent controls.
Conditions for safe storage, including any incompatibilities	
Storage Conditions	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 (Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F). [See USP Controlled Room Temperature.]
Special Precautions:	No special precautions required for hazard control
Incompatible Materials:	Not known. Storage as directed by product packaging.
Specific end use(s)	Pharmaceutical Drug Product. Human prescription drug. For intravenous infusion only

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Exposure Guidelines

Chemical Name	ACGIH TLV	OSHA PEL	AIHA WEEL
Norepinephrine Bitartrate	8hr TWA: Not Established	8hr TWA: not established	8hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value. AIHA WEEL: Workplace Environmental Exposure Level

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include Sodium Chloride, Sodium Hydroxide and Hydrochloric Acid.

Appropriate engineering controls

Engineering Controls Engineering controls should be used as primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Eye/face protection Wear safety glasses or goggles if eye contact is possible.

Skin and body protection Impervious disposable protective clothing is recommended if skin contact with Drug Product is possible and for bulk processing operations.

Respiratory protection Under normal condition of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask).

General Considerations Refer to applicable national standards and regulations in the selection and use of personal protective equipment.

9 PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE:	Liquid	**APPEARANCE:**	Clear Colorless
UPPER FLAMMABILITY LIMIT:	Not Applicable	**LOWER FLAMMABILITY LIMIT:**	Not Applicable
EXPLOSIVE LIMITS:	Not Applicable	**ODOR:**	No data available
VAPOR PRESSURE:	Not Applicable	**ODOR THRESHOLD:**	No data available
VAPOR DENSITY:	Not Applicable	**pH:**	3.0-4.5
RELATIVE DENSITY:	Not Applicable	**MELTING POINT:**	Not Applicable
FREEZING POINT:	Not Applicable	**SOLUBILITY:**	micsible
INITIAL BOILING POINT:	Not Applicable	**BOILING RANGE:**	Not Applicable
FLASH POINT:	Not Applicable	**EVAPORATION RATE:**	Not Applicable
FLAMMABILITY:	Not Applicable	**PARTITION COEFFICIENT (N-OCTANOL / WATER)**	Not Applicable
AUTO-IGNITION TEMPERATURE:	Not Applicable	**DECOMPOSITION TEMPERATURE:**	Not Applicable
VISCOSITY:	Not Applicable		

10 STABILITY AND REACTIVITY

Reactivity:	No data available
Chemical Stability	Stable under standard use and storage conditions
Possibility of Hazardous reactions:	Hazardous polymerization not anticipated to occur with this product
Conditions to avoid:	Fine particles (dust / mist) may fuel fires / explosions
Incompatible Materials:	As a precautionary procedure keep away from strong oxidizers
Hazardous decomposition products:	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx), and sulfur.

11 TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information	Not determined for the product formulation. Information for the active ingredient is as follows:

Known Clinical Effects The most common adverse effect seen during clinical use of this drug include headache, increase in blood pressure (hypertension), decreased heart rate (bradycardia), palpitations, restlessness, tremors, weakness.

Chemical Name	Test Type	Route of Administration	Value	Units	Species
l-Norepinephrine Bitartrate Monohydrate	LD50	Intravenous	210	mcg/kg	Rat
l-Norepinephrine Bitartrate Monohydrate	LD50	Intravenous	1.03	mg/kg	Mouse
l-Norepinephrine Bitartrate Monohydrate	LD50	Intraperitoneal	26.8	mg/kg	Mouse
Norepinephrine	LD50	Oral	20	mg/kg	Rat
Norepinephrine	LD50	Intravenous	550 250 100	mcg/kg mcg/kg mcg/kg	Mouse Rabbit Rat
Norepinephrine	LD50	Intraperitoneal	6	mg/kg	Mouse
Norepinephrine	LD50	Intravenous	550	mcg/kg	Mouse
Sodium Chloride	LC50	Sub-tenon Injection (eye)	> 42	g/m^3	Rat
Sodium Chloride	LD50	Oral	3	g/Kg	Rat
Sodium Chloride	LD50	Oral	4	g/Kg	Mouse
Sodium Chloride	LD50	Dermal	10	g/Kg	Rabbit

Information on toxicological effects

Occupational Exposure Potential Some literature reports indicate that Norepinephrine may be absorbed by inhalation.
Information on the absorption of this product via skin contact is not available. Avoid liquid aerosol generation and skin contact.

Symptoms None anticipated from normal handling of this product. In clinical use, adverse effects may include hypertension, bradycardia, restlessness, palpitations, tremor, weakness, headache and elevated blood pressure. Overdosage can result in severe hypertension, bradycardia, increased peripheral resistance, decreased cardiac output and potentially fatal arrhythmias including ventricular tachycardia and fibrillation. Prolonged administration can result in depletion of plasma volume and electrolyte imbalance.
Administration to pregnant women can cause fetal anoxia by provoking uterine contractions; therefore, the drug should not be used during pregnancy.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	None anticipated from normal handling of this product. However, inadvertent contact with this product may be irritating to mucous membranes.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product.
Germ cell mutagenicity	The genotoxic potential of norepinephrine bitartrate has not been evaluated.
Carcinogenicity	None of the components of this formulation are listed as carcinogen by IARC, NTP, or OSHA. IARC: Not listed NTP: Not listed OSHA: Not listed

Reproductive toxicity

Repeated dose	None anticipated from normal handling of this product. Animal reproduction studies have not been conducted with norepinephrine bitartrate. Therefore, the drug should not be used during pregnancy.
STOT - single exposure	NA
STOT - repeated exposure	Based on clinical use, possible target organs include the nervous system, cardio-vascular system, reproductive system, and fetus.
Aspiration hazard	None anticipated for normal handling of this product

12 ECOLOGICAL INFORMATION

Environmental Overview	Environmental properties have not been investigated. Releases to the environment should be avoided.
Aquatic toxicity	Not determined for product.
Persistence and degradability	Not determined for product
Bioaccumulation	Not determined for product
Other adverse effects	Not available

13 DISPOSAL CONSIDERATIONS

Waste treatment methods	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
Contaminated Packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations.
US EPA Waste Number	Not Applicable
California Hazardous Waste Codes:	Not Applicable

14 TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

DOT: Not Regulated

IMDG: Not Regulated

ICAO / IATA: Not Regulated

EU ADR: Not Regulated

IMO: Not Regulated

ADG: Not Regulated

15 REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations
TSCA – No
CERCLA-No
SARA 302 – No
SARA 313 – No
OSHA Substance Specific - No
California Proposition 65: 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 MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PUROPOSE). 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.