

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 1 of 10

Section 1 - Identification

- (a) **Product Identifier:** Norepinephrine Bitartrate Injection, USP
- (b) **Product Code:** 83634-307-04 and 83634-307-41
- Common/Trade Name:** Levophed, Norepinephrine
- Chemical Name:** (-)- α -(aminomethyl)-3,4-dihydroxybenzyl alcohol tartrate (1:1) (salt) monohydrate
- Chemical Family:** Vasoconstrictor
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Avenacy 10 N. Martingale Road, Suite 225, Schaumburg, IL 60173, 847-773-4901
- (e) **Emergency Telephone:** 855-283-6229

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** Not classified.

(b) Signal Word, Hazard statement(s), Symbol(s), and/ or Precautionary	(c) Description of Hazards:
GHS Signal Word:	Not classified.
GHS Hazard Statement:	Not applicable.
GHS Symbols:	Not applicable.
GHS Precautionary Statements:	Not applicable.
Additional Information:	No labeling applicable according to 29 CFR 1910.1200 and the Hazardous Products Regulations (HPR) SOR/2015-17. Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 2 of 10

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
(-)- α -(aminomethyl)-3,4-dihydroxybenzyl alcohol tartrate (1:1) (salt) monohydrate	Norepinephrine bitartrate	4 mg	51-40-1	N/A
Sodium chloride	Sodium chloride	32 mg	7647-14-5	NA
Sodium metabisulfite	Sodium metabisulfite	0.8 mg	7681-57-4	NA
Water	Water	q.s. to 4 mL	7732-18-5	NA

q.s. – quantity sufficient

Section 4 – First Aid Measures

Eye Exposure:	Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists. May cause slight irritation to eyes.
Skin Exposure:	Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists. Prolonged exposure may cause skin irritation.
Ingestion:	Rinse mouth. Do NOT induce vomiting. Obtain medical attention. Ingestion may cause adverse effects.
Inhalation:	When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists. Prolonged exposure may cause irritation.
General:	Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). Not expected to present a significant hazard under anticipated conditions of normal use. If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 3 of 10

Section 5 – Fire-fighting Measures

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| (a) Extinguishing Media: | Water spray, fog, carbon dioxide (CO ₂), alcohol-resistant foam, or dry chemical. Do not use a heavy water stream. Use of heavy stream of water may spread fire. |
| (b) Hazardous Combustion Products: | Not flammable. Product is not explosive. Hazardous reactions will not occur under normal conditions. |
| (c) Special Protective Equipment / Precautions: | Exercise caution when fighting any chemical fire.
Use water spray or fog for cooling exposed containers.
Do not enter fire area without proper protective equipment, including respiratory protection.
Refer to Section 9 for flammability properties. |

Section 6 - Accidental Release Measures

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| Health and Safety Precautions: | Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray). Use appropriate personal protective equipment (PPE). Evacuate unnecessary personnel.
Protective Equipment: Equip cleanup crew with proper protection.
Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area. |
| Measures for Environmental Protections: | Prevent entry to sewers and public waters.
Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.
Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.
See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations. |

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 4 of 10

Section 7 - Handling and Storage

General Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Handle in accordance with good industrial hygiene and safety procedures.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F). [See USP Controlled Room Temperature.] Protect from light. Retain in carton until time of use. Incompatible Materials: Strong acids, strong bases, strong oxidizers. Water reactive materials.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), OSHA (PEL), or Canadian provincial governments.

Sodium Metabisulfite (7681-57-4)		
USA ACGIH	ACGIH OEL TWA	5 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA)	5 mg/m ³
Alberta	OEL TWA	5 mg/m ³
British Columbia	OEL TWA	5 mg/m ³
Manitoba	OEL TWA	5 mg/m ³
New Brunswick	OEL TWA	5 mg/m ³
Newfoundland & Labrador	OEL TWA	5 mg/m ³
Nova Scotia	OEL TWA	5 mg/m ³
Nunavut	OEL STEL	10 mg/m ³
Nunavut	OEL TWA	5 mg/m ³
Northwest Territories	OEL STEL	10 mg/m ³
Northwest Territories	OEL TWA	5 mg/m ³
Ontario	OEL TWA	5 mg/m ³
Prince Edward Island	OEL TWA	5 mg/m ³
Quebec	VEMP (OEL TWA)	5 mg/m ³
Saskatchewan	OEL STEL	10 mg/m ³
Saskatchewan	OEL TWA	5 mg/m ³

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 5 of 10

(b) Engineering Controls

Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

(c) Individual Protection Measures

Eye Protection:	Chemical safety goggles.
Skin Protection:	Wear protective gloves and clothing.
Respiratory Protection:	If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Additional Information:	Materials for Protective Clothing: Chemically resistant materials and fabrics. When using, do not eat, drink or smoke.

Section 9 - Physical and Chemical Properties

(a)	Appearance	Colorless solution, liquid
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	3.0 – 4.5
(e)	Melting Point:	Not available
(f)	Initial Boiling Point:	Not available
(g)	Boiling Point:	Not available
(h)	Flash Point (Liquid) (°C)	Not available
(i)	Evaporation Rate:	Not available
(j)	Flammability	Not available
(k)	Upper Lower Flammability or Explosion Limits	Not available
(l)	Vapor Pressure (kPa):	Not available
(m)	Vapor Density:	Not available
(n)	Relative Density	Not available
(o)	Solubility(ies)	Freely soluble in water; slightly soluble in alcohol; practically insoluble in chloroform or ether
(p)	Partition Coefficient: n-octanol/water	Not available
(q)	Auto-ignition Temperature	Not available
(r)	Decomposition Temperature	Not available

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 6 of 10

(s)	Viscosity	Not available
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Section 10 - Stability and Reactivity

(a)	Reactivity	Hazardous reactions will not occur under normal conditions.
(b)	Chemical Stability	Stable under recommended handling and storage conditions (see section 7).
(c)	Possibility of Hazardous Reactions	Hazardous polymerization does not occur.
(d)	Conditions to Avoid	Direct sunlight, extremely high or low temperatures, and incompatible materials.
(e)	Incompatible Materials	Strong acids, strong bases, strong oxidizers. Water reactive materials.
(f)	Hazardous Decomposition Products	None expected under normal conditions of use.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Eye, skin, ingestion, skin contact, inhalation
(b)	Symptoms related to the physical, chemical and toxicological characteristics	Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation. Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation. Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes. Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects. Chronic Symptoms: None expected under normal conditions of use.

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 7 of 10

(c)	Delayed and immediate effects and chronic effects from short and long term exposure	LD50 and LC50 Data: Not available Skin Corrosion/Irritation: Not classified Eye Damage/Irritation: Not classified Respiratory or Skin Sensitization: Not classified Germ Cell Mutagenicity: Not classified Carcinogenicity: Not classified Specific Target Organ Toxicity (Repeated Exposure): Not classified Reproductive Toxicity: Not classified Specific Target Organ Toxicity (Single Exposure): Not classified Aspiration Hazard: Not classified
(d)	Other Toxicological Information	Not applicable.

(d) Acute Toxicity:

Norepinephrine Bitartrate (51-40-1):

Acute Toxicity (Oral): Not classified

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

Sodium Chloride (7647-14-5)	
LD50 Oral Rat	3550 mg/kg (Species: Wistar)
LD50 Dermal Rabbit	> 10000 mg/kg (Species: New Zealand White)
LC50 Inhalation Rat	> 42 g/m ³ (Exposure time: 1 h)
LC50 Fish 1	5560 (5560 – 6080) mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [flowthrough])
EC50 - Crustacea [1]	1000 mg/l (Exposure time: 48 h - Species: Daphnia magna)
LC50 Fish 2	12946 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
EC50 - Crustacea [2]	340.7 (340.7 – 469.2) mg/l (Exposure time: 48 h - Species: Daphnia magna [Static])
NOEC Chronic Fish	252 mg/l (Species: Pimephales promelas)
Sodium Metabisulfite (7681-57-4)	
LD50 Oral Rat	1131 mg/kg
LD50 Dermal Rat	> 2000 mg/kg

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 8 of 10

IARC Group	3
LC50 Fish 1	32 mg/l (Exposure time: 96 h - Species: <i>Lepomis macrochirus</i> [static])
ErC50 algae	48.1 mg/l

Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

(a)	Ecotoxicity	No Data Available
(b)	Persistence and degradability	No Data Available
(c)	Bioaccumulative potential	No Data Available
(d)	Mobility in soil	Avoid release to the environment.
(e)	Other Adverse Effects	No Data Available

Section 13 - Disposal Considerations

Waste Disposal: 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 waste water.

Section 14 - Transport Information

In Accordance with DOT Not regulated for transport
 In Accordance with IMDG Not regulated for transport
 In Accordance with IATA Not regulated for transport
 In Accordance with TDG Not regulated for transport

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Avenacy 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.

Sodium chloride (7647-14-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Sodium metabisulfite (7681-57-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 9 of 10

US State Regulations

Sodium metabisulfite (7681-57-4)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

Canadian Regulations

Sodium chloride (7647-14-5)

Listed on the Canadian DSL (Domestic Substances List)

Sodium metabisulfite (7681-57-4)

Listed on the Canadian DSL (Domestic Substances List)

Section 16 - Other Information

As of the date of effectiveness, 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.

For additional information
contact:

Avenacy
10 N. Martingale Road, Suite 225
Schaumburg, IL 60173
847-773-4901

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
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

	Document Type: Safety Data Sheet	Norepinephrine Bitartrate Injection, USP		
	Effective Date: 14 MAY 2026	SDS No.: SDS035	Revision No: 01	Page 10 of 10

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