

SAFETY DATA SHEET

1. Identification

Product identifier Norepinephrine Bitartrate

Other means of identification

Catalog number 1468501 108341-18-0 **CAS** number

Synonyms Noradrenaline bitartrate monohydrate * Levarterenol bitartrate monohydrate

Chemical name 1,2-Benzenediol, 4-(2-amino-1-hydroxyethyl)-, (R)-[R-(R*,R*)]-2,3-dihydroxybutanedioate (1:1)

(salt), monohydrate

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

U. S. Pharmacopeia Company name **Address** 12601 Twinbrook Parkway

> Rockville MD 20852-1790

United States

Telephone **RS Technical Services** 301-816-8129

Website www.usp.org E-mail RSTECH@usp.org

CHEMTREC within US & 1-800-424-9300 **Emergency phone number**

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Not classified. Physical hazards

Health hazards Acute toxicity, oral Category 2

> Specific target organ toxicity, single exposure Category 1 (cardiovascular system, central

nervous system)

Environmental hazards Not classified. **OSHA** defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Fatal if swallowed. Causes damage to organs (cardiovascular system, central nervous system).

Precautionary statement

Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Prevention

Response If swallowed: Immediately call a poison center/doctor. Rinse mouth. If exposed: Call a poison

center/doctor.

Store locked up. **Storage**

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

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Potent pharmacologically active material.

Material name: Norepinephrine Bitartrate USP SDS US 1468501 Version #: 05 Revision date: 09-21-2018 Issue date: 09-22-2005

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%	
Norepinephrine Bitartrate	Noradrenaline bitartrate monohydrate Levarterenol bitartrate monohydrate	108341-18-0	100	

4. First-aid measures

Move to fresh air. Call a physician if symptoms develop or persist. Inhalation Rinse skin with water/shower. Get medical attention if irritation develops and persists. Skin contact

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Rinse mouth thoroughly. Call a physician or poison control center immediately. Do not induce Ingestion vomiting without advice from poison control center. If vomiting occurs, keep head low so that

stomach content doesn't get into the lungs.

Most important

symptoms/effects, acute and delayed

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. If blood pressure fails to lower, a short-acting alpha adrenergic blocking agent may be administered.

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding Suitable extinguishing media

materials.

Unsuitable extinguishing media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting

equipment/instructions

Specific methods General fire hazards Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Use standard firefighting procedures and consider the hazards of other involved materials.

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

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8. Exposure controls/personal protection

Occupational exposure limits No exposure limits noted for ingredient(s).

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering

controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary.

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Hand protection Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When

the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Other Train employees in proper gowning and degowning practices. Wear disposable lab coat,

disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head

cover for spill cleanup. Chose respiratory protection appropriate to the task and the level of

existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or

quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.

Form Crystalline powder.
Color White. Light grey.

Odor Odorless.

Odor threshold Not available.

pH Not available.

Melting point/freezing point 208.4 - 219.2 °F (98 - 104 °C)

Initial boiling point and boiling

range

Not available.

Flash point

Evaporation rate

Flammability (solid, gas)

Not available.

Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

(%

Flammability limit - upper

Not available.

(%)

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density Not available.

Relative density Not available.

Solubility(ies)

Solubility (water) Freely soluble.

Solubility (other) Ether: Practically insoluble.
Chloroform: Practically insoluble.

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Alcohol: Slightly soluble.

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical familySympathomimetic amine.Molecular formulaC8H11NO3.C4H6O6.H2O

Molecular weight 337.28 pH in aqueous solution 3.5

10. Stability and reactivity

ReactivityThe product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Oxidizing agents. Acids. Bases.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological information

Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.

Ingestion Fatal if swallowed.

Symptoms related to the

physical, chemical, and toxicological

Headache. Confusion. Tremor. Nervousness. Palpitations. Chest pain. Gastrointestinal

disturbances. Respiratory difficulties. Urinary retention.

Information on toxicological effects

Acute toxicity Fatal if swallowed

Product Species Test Results

Norepinephrine Bitartrate (CAS 108341-18-0)

Oral

characteristics

LD50 Rat 20 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete.

Norepinephrine administered intravenously late in pregnancy may cause uterine contractions

which could lead to fetal anoxia.

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Specific target organ toxicity -

single exposure

Causes damage to organs (cardiovascular system, central nervous system).

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information

Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this product. No data available.

Bioaccumulative potential Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN2811 **UN number**

UN proper shipping name Transport hazard class(es)

Toxic solid, organic, n.o.s. (Norepinephrine Bitartrate)

6.1 Class Subsidiary risk Ш Packing group

IATA

UN2811 **UN** number

UN proper shipping name Transport hazard class(es) Toxic solid, organic, n.o.s. (Norepinephrine Bitartrate)

Class 6.1 Subsidiary risk П Packing group Other information

Passenger and cargo

aircraft

Allowed with restrictions.

Allowed with restrictions.

Cargo aircraft only Transport in bulk according to Annex II of MARPOL 73/78 and

Not applicable.

the IBC Code

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General information

It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material

is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No

Country(s) or region Inventory name On inventory (yes/no)*

New Zealand New Zealand Inventory No.

Philippines Philippine Inventory of Chemicals and Chemical Substances No

(PICCS)

United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory

No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

 Issue date
 09-22-2005

 Revision date
 09-21-2018

Version # 05

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