

# Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Issue date: 11/17/2023 Version: 3.0

#### **SECTION 1: Identification**

#### 1.1. Identification

Product form : Mixture

Product name : Norepinephrine in 0.9% Sodium Chloride Injection

#### 1.2. Recommended use and restrictions on use

Use of the substance/mixture : Pharmaceuticals

## 1.3. Supplier

Long Grove Pharmaceuticals, LLC 9450 W. Bryn Mar Ave., Suite 200 Rosemont, IL 60018 - USA

T 847-999-0600

#### 1.4. Emergency telephone number

Emergency number : CHEMTREC +1 (800) 424-9300 (North America) 24/7

#### SECTION 2: Hazard(s) identification

#### 2.1. Classification of the substance or mixture

#### **GHS-US** classification

This product does not meet the criteria for classification as a hazardous mixture under the OSHA Hazard Communication Standard (29 CFR 1910.1200). However, it contains a potent pharmacologically active material. Occupational exposure may cause physiological effects.

#### 2.2. GHS Label elements, including precautionary statements

## **GHS US labelling**

No labelling applicable

## 2.3. Other hazards which do not result in classification

No additional information available

## 2.4. Unknown acute toxicity (GHS US)

Not applicable

#### **SECTION 3: Composition/information on ingredients**

## 3.1. Substances

Not applicable

## 3.2. Mixtures

Name	Product identifier	%
Contains no hazardous ingredients at levels requiring disclosure by the OSHA Hazard Communication Standard (29 CFR 1910.1200)		

## **SECTION 4: First-aid measures**

### 4.1. Description of first aid measures

First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an

unconscious person.

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a comfortable position for breathing.

First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at

least 15 minutes.

First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact

lenses if present and easy to do so. Continue rinsing.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison

control center or medical professional. Get medical attention immediately.

## 4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : May cause skin irritation.

# Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Symptoms/effects after eye contact

: Direct contact with eyes is likely to be irritating.

Symptoms/effects after ingestion

: May cause gastrointestinal irritation.

Symptoms/effects upon intravenous administration

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, and weakness. If product is injected into any part of the body, seek medical attention immediately.

#### Immediate medical attention and special treatment, if necessary

No additional information available

### **SECTION 5: Fire-fighting measures**

#### 5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media

: Use extingushing media appropriate for surrounding fire (e.g, carbon dioxide (CO2), dry

powder, foam, water spray).

#### 5.2. Specific hazards arising from the chemical

: The product is not flammable. Fire hazard Product is not explosive. Explosion hazard Reactivity : No data available.

#### 5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any

chemical fire. Do not dispose of fire-fighting water in the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

#### **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained cleaning

personnel properly equipped with respiratory and eye protection.

#### 6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8. : Evacuate unnecessary personnel. Keep upwind. **Emergency procedures** 

#### 6.1.2. For emergency responders

Protective equipment : For further information refer to section 8: "Exposure controls/personal protection".

#### 6.2. **Environmental precautions**

Avoid release to the environment. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

# Methods and material for containment and cleaning up

: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or For containment

streams. Prevent entry to sewers and public waters.

Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Clean Methods for cleaning up

surface thoroughly to remove residual contamination. Keep in properly labeled containers. This material and its container must be disposed of in a safe way, and as per local legislation.

#### Reference to other sections

No additional information available

# **SECTION 7: Handling and storage**

# Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Handle in

accordance with good industrial hygiene and safety procedures. Wear recommended personal protective equipment. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not breathe mist, vapors. Avoid accidental injection.

#### 7.2. Conditions for safe storage, including any incompatibilities

: Keep container tightly closed. Store in a dry, cool and well-ventilated place. Protect from light. Storage conditions

Storage temperature  $20 - 25 \,^{\circ}\text{C}$  (68°  $- 77 \,^{\circ}\text{F}$ ). Excursions permitted to  $15^{\circ} - 30^{\circ}\text{C}$  (59°  $- 86^{\circ}\text{F}$ ).

## **SECTION 8: Exposure controls/personal protection**

#### 8.1. Control parameters

# Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

No additional information available

#### 8.2. Appropriate engineering controls

Appropriate engineering controls

: Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Ensure adequate ventilation, especially in confined areas.

## 8.3. Individual protection measures/Personal protective equipment

## Personal protective equipment symbol(s):





## Personal protective equipment:

Safety glasses. Gloves.

### Hand protection:

For bulk processing operations and if skin contact with the product is possible, wear impermeable protective gloves. Gloves should be classified under Standard EN 374 or ASTM F1296. Suitable gloves for this specific application can be recommended by the glove supplier.

#### Eye protection:

Use eye protection suitable to the environment. Avoid direct contact with eyes.

#### Skin and body protection:

Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

#### Respiratory protection:

Use NIOSH (or other equivalent national standard) -approved dust/particulate respirator. Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

## **SECTION 9: Physical and chemical properties**

## 9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Solution
Color : Colorless

Odor No data available Odor threshold No data available рH No data available No data available Melting point Freezing point No data available Boiling point : No data available Flash point No data available Relative evaporation rate (butylacetate=1) : No data available : No data available Flammability (solid, gas) Vapor pressure No data available Relative vapor density at 20°C : No data available Relative density No data available Solubility : Soluble in water Partition coefficient n-octanol/water (Log Pow) : No data available : No data available Auto-ignition temperature Decomposition temperature : No data available Viscosity, kinematic No data available Viscosity, dynamic : No data available **Explosive limits** : No data available

Explosive properties

: No data available

# Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Oxidising properties : No data available

#### 9.2. Other information

No additional information available

## **SECTION 10: Stability and reactivity**

## 10.1. Reactivity

No data available.

#### 10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

#### 10.3. Possibility of hazardous reactions

No data available.

#### 10.4. Conditions to avoid

Heat, high temperature, and open flame.

#### 10.5. Incompatible materials

No data available.

## 10.6. Hazardous decomposition products

None under normal use.

## **SECTION 11: Toxicological information**

#### 11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified Acute toxicity (dermal) : Not classified Acute toxicity (inhalation) Not classified Skin corrosion/irritation : Not classified Serious eye damage/irritation : Not classified Respiratory or skin sensitisation : Not classified Germ cell mutagenicity : Not classified Carcinogenicity : Not classified Reproductive toxicity Not classified STOT-single exposure : Not classified STOT-repeated exposure : Not classified Aspiration hazard : Not classified Viscosity, kinematic : No data available

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : May cause skin irritation.

Symptoms/effects after eye contact : Direct contact with eyes is likely to be irritating.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

Symptoms/effects upon intravenous : The most common adverse effect seen during clinical use of this drug include headache, administration increase in blood pressure (hypertension), decreased heart rate (bradycardia), palpitations,

restlessness, tremors, and weakness. If product is injected into any part of the body, seek

medical attention immediately.

## **SECTION 12: Ecological information**

## 12.1. Toxicity

Ecology - general : No data available.

### 12.2. Persistence and degradability

No data available.

### 12.3. Bioaccumulative potential

No data available.

## 12.4. Mobility in soil

No data available.

# Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

#### 12.5. Other adverse effects

No data available.

## **SECTION 13: Disposal considerations**

#### 13.1. Disposal methods

Waste treatment methods

: Do not discharge to public wastewater systems without permit of pollution control authorities. No discharge to surface waters is allowed without an NPDES permit. Incinerator may be used.

Product/Packaging disposal recommendations

Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

### **SECTION 14: Transport information**

## Department of Transportation (DOT)

Not regulated for transport

### Transport by sea (IMDG)

Not regulated for transport

#### Air transport (IATA)

Not regulated for transport

## **SECTION 15: Regulatory information**

#### 15.1. US Federal regulations

## Norepinephrine in 0.9% Sodium Chloride Injection

This product is regulated under the United States Federal Food, Drug, and Cosmetic Act (FFDCA) and is exempt from listing on TSCA

#### 15.2. International regulations

No additional information available

## 15.3. US State regulations

This product does not contain any substances known to the state of California to cause cancer and/or reproductive harm

Component	State or local regulations
Sodium hydroxide (1310-73-2)	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
Hydrogen chloride (7647-01-0)	U.S Massachusetts - Right To Know List; U.S New Jersey - Right to Know Hazardous Substance List; U.S Pennsylvania - RTK (Right to Know) - Environmental Hazard List

## **SECTION 16: Other information**

: Author: EMA. Other information

NFPA health hazard : 0 - Materials that, under emergency conditions, would offer no hazard beyond that of ordinary combustible materials.

NFPA fire hazard : 0 - Materials that will not burn under typical fire conditions,

including intrinsically noncombustible materials such as

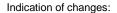
concrete, stone, and sand.

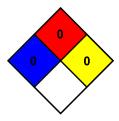
NFPA reactivity : 0 - Material that in themselves are normally stable, even

under fire conditions.



Health : 0 Flammability : 0 Physical : 0





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Revision 1.0: New SDS Created.

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.