# ASCORBIC ACID INJECTION USP 500MG/ML

## SAFETY DATA SHEET

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

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

### Product Identifier

**Product name:** Ascorbic Acid Injection USP 500mg/mL

### Intended Use of the Product

**Use of the substance/mixture:** Pharmaceutical. For injection, intravenous, intramuscular or subcutaneous use for the prevention and treatment of scurvy. Use only as directed. Refer to product insert for usage instructions and product information.

### Name, Address, and Telephone of the Responsible Party

**Supplier:**
Mylan Institutional LLC
1718 Northrock Court
Rockford, IL 61103 USA
1-888-258-4199
www.mylan.com

**Manufacturer:**
Mylan Teoranta
Galway, Ireland

### Emergency Telephone Number

**Emergency number** : +1 877-446-3679

## 2. HAZARDS IDENTIFICATION

**Patients/Consumers:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

### Classification of the Substance or Mixture

**Classification (GHS-US)**
Not classified

### Label Elements

**GHS-US labeling** No labeling applicable

### Other Hazards

**Other hazards not contributing to the classification**: Overexposure of to large amounts of ascorbic acid may cause hemolytic anemia in predisposed individuals.

**Unknown acute toxicity (GHS-US)** Not available

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Mixture

| Name | Product identifier | % (w/w) | Classification (GHS-US) |
|---|---|---|---|
| L-Ascorbic acid | (CAS No) 50-81-7 | - | Not classified |

Sodium Bicarbonate and Sodium Hydroxide are added to adjust the pH of the solution.
Full text of H-phrases: see section 16

## 4. FIRST AID MEASURES

### Description of First Aid Measures

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

**Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

**Skin Contact:** Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

**Eye Contact:** The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.
**Ingestion:** Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

### Most Important Symptoms and Effects Both Acute and Delayed

**Inhalation:** Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
**Skin Contact:** Contact during a long period may cause light irritation.
**Eye Contact:** May cause slight irritation.
**Ingestion:** If a large quantity has been ingested: abdominal pain, diarrhea, nausea.
**Injection:** Mild soreness may occur at the site of injection. May cause temporary dizziness or faintness.

### Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

## 5. FIREFIGHTING MEASURES

### Extinguishing Media

**Suitable extinguishing media:** Use extinguishing media appropriate for surrounding fire.
**Unsuitable extinguishing media:** None known.

### Special Hazards Arising From the Substance or Mixture

**Fire hazard:** Not considered flammable but may burn at high temperatures.
**Explosion hazard:** Product is not explosive.
**Reactivity:** Hazardous reactions will not occur under normal conditions.

### Advice for Firefighters

**Precautionary measures fire:** Exercise caution when fighting any chemical fire.
**Firefighting instructions:** Use water spray or fog for cooling exposed containers. Do not allow run-off from fire fighting to enter drains or water courses.
**Protection during firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.
**Hazardous Combustion Products:** Not available
**Other information:** Refer to Section 9 for flammability properties.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

#### For Non-Emergency Personnel

**Protective equipment:** Use appropriate personal protection equipment (PPE).
**Emergency procedures:** Evacuate unnecessary personnel.

#### For Emergency Personnel

**Protective equipment:** Equip cleanup crew with proper protection.
**Emergency procedures:** Ventilate area.

### Environmental Precautions

Prevent entry to sewers and public waters.

### Methods and Material for Containment and Cleaning Up

**Methods for cleaning up:** For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

### Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection.

## 7. HANDLING AND STORAGE

### Precautions for Safe Handling

**Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
**Hygiene measures:** This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

### Conditions for Safe Storage, Including Any Incompatibilities

**Storage conditions:** Keep container closed when not in use. Keep away from heat and direct sunlight.
**Storage temperature:** 2 - 8 °C (35.6°-46.4°F)
**Special rules on packaging:** Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use. Pressure may develop within vial; relieve pressure with a sterile syringe allowing vial to equilibrate.

### Specific End Use(s)

Pharmaceutical. Refer to product insert for usage instructions and product information.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control Parameters

| Sodium hydroxide (1310-73-2) | | |
|---|---|---|
| USA ACGIH | ACGIH Ceiling (mg/m³) | 2 mg/m³ |
| USA OSHA | OSHA PEL (TWA) (mg/m³) | 2 mg/m³ |
| USA NIOSH | NIOSH REL (ceiling) (mg/m³) | 2 mg/m³ |
| USA IDLH | US IDLH (mg/m³) | 10 mg/m³ |
| Alberta | OEL Ceiling (mg/m³) | 2 mg/m³ |
| British Columbia | OEL Ceiling (mg/m³) | 2 mg/m³ |
| Manitoba | OEL Ceiling (mg/m³) | 2 mg/m³ |
| New Brunswick | OEL Ceiling (mg/m³) | 2 mg/m³ |
| New Foundland & Labrador | OEL Ceiling (mg/m³) | 2 mg/m³ |
| Nova Scotia | OEL Ceiling (mg/m³) | 2 mg/m³ |
| Nunavut | OEL Ceiling (mg/m³) | 2 mg/m³ |
| Northwest Territories | OEL Ceiling (mg/m³) | 2 mg/m³ |
| Ontario | OEL Ceiling (mg/m³) | 2 mg/m³ |
| Prince Edward Island | OEL Ceiling (mg/m³) | 2 mg/m³ |
| Québec | PLAFOND (mg/m³) | 2 mg/m³ |
| Saskatchewan | OEL Ceiling (mg/m³) | 2 mg/m³ |
| Yukon | OEL Ceiling (mg/m³) | 2 mg/m³ |

### Exposure Controls

**Appropriate engineering controls:** Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Personal protective equipment:** Not generally required. The use of personal protective equipment may be necessary as conditions warrant.

**Hand protection:** Wear protective gloves.

**Eye protection:** In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

**Skin and body protection:** In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

**Respiratory protection:** When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on Basic Physical and Chemical Properties

| | | |
|---|---|---|
| **Physical state** | : | Liquid |
| **Appearance** | : | Clear, colorless to pale yellow liquid |
| **Odor** | : | Not available |
| **Odor threshold** | : | Not available |
| **pH** | : | 5.5 - 7 |
| **Relative evaporation rate (butyl acetate=1)** | : | Not available |
| **Melting point** | : | Not available |
| **Freezing point** | : | Not available |
| **Boiling point** | : | Not available |
| **Flash point** | : | Not available |
| **Auto-ignition temperature** | : | Not available |
| **Decomposition Temperature** | : | Not available |
| **Flammability (solid, gas)** | : | Not available |
| **Upper/Lower flammable limit** | : | Not available |
| **Vapor pressure** | : | Not available |
| **Relative vapor density at 20 °C** | : | Not available |
| **Relative density** | : | Not available |
| **Specific gravity** | : | Not available |
| **Solubility** | : | Slightly soluble. |
| **Log Pow/Kow** | : | Not available |
| **Viscosity (kinematic, dynamic)** | : | Not available |

**Explosion data - sensitivity to mechanical impact** : Not available
**Explosion data - sensitivity to static discharge** : Not available

## 10. STABILITY AND REACTIVITY

**Reactivity** Hazardous reactions will not occur under normal conditions.
**Chemical Stability** Stable under normal conditions.
**Possibility of Hazardous Reactions** Hazardous polymerization will not occur.
**Conditions to Avoid** Direct sunlight. Extremely high or low temperatures.
**Incompatible Materials** strong acids. Strong bases.
**Hazardous Decomposition Products** Carbon oxides (CO, $CO_2$).

## 11. TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects - Product

**Acute toxicity:** Not classified
**LD50 and LC50 Data:** Not available
**Skin Corrosion/Irritation:** Not classified (pH: 5.5 – 7)
**Serious Eye Damage/Irritation:** Not classified (pH: 5.5 – 7)
**Respiratory or Skin Sensitization:** Not classified
**Germ Cell Mutagenicity:** Not classified
**Teratogenicity:** Not available
**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

### Information on Toxicological Effects - Ingredient(s)

**LD50 and LC50 Data:**

| **L-Ascorbic acid (50-81-7)** | |
|---|---|
| ATE (oral) | 11900.000 mg/kg |

## 12. ECOLOGICAL INFORMATION

### Toxicity

Not available

### Persistence and Degradability

| **Ascorbic Acid Injection USP 500mg/mL** | |
|---|---|
| Persistence and degradability | Not established. |

### Bioaccumulative Potential

| **Ascorbic Acid Injection USP 500mg/mL** | |
|---|---|
| Bioaccumulative potential | Not established. |

## 13. DISPOSAL CONSIDERATIONS

**Waste disposal recommendations:** Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not empty into drains or sewers.
**Additional information:** Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

## 14. TRANSPORT INFORMATION

**In Accordance With ICAO/IATA/DOT/TDG**
**UN Number** Not regulated for transport
**UN Proper Shipping Name** Not regulated for transport

## 15. REGULATORY INFORMATION

### US Federal Regulations

| **L-Ascorbic acid (50-81-7)** |
|---|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

### US State Regulations

Not available

### Canadian Regulations

| **Ascorbic Acid Injection USP 500mg/mL** | |
|---|---|
| WHMIS Classification | Uncontrolled product according to WHMIS classification criteria |

| **L-Ascorbic acid (50-81-7)** |
|---|
| Listed on the Canadian DSL (Domestic Substances List) inventory. |

| WHMIS Classification | Uncontrolled product according to WHMIS classification criteria |
|---|---|

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

## 16. OTHER INFORMATION

**Revision date** : 02/11/2014

**Data sources** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

**Other information** : This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

**Party Responsible For The Preparation Of This Document:**
Mylan Global Environmental, Health, and Safety Department
Phone Number: 304-599-2595

*This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.*
*To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*

North America Mylan Pharmaceuticals