# Sterile Water for Injection, USP

Safety Data Sheet

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Revision Date: 11/10/2015 Date of issue: 11/10/2015 Version: 1.0

## SECTION 1: IDENTIFICATION

### 1.1. Product Identifier

**Product Form:** Water

**Product Name:** Sterile Water for Injection, USP

**Product Code:** 0517-3005-25; 0517-3010-25; 0517-3020-25; 0517-3050-25

### 1.2. Intended Use of the Product

**Use of the substance/mixture:** Used as a diluent.

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

**Company**

Luitpold Pharmaceuticals, Inc.
One Luitpold Drive
P.O. Box 9001
Shirley, NY 11967
1-800-645-1706
www.luitpold.com

### 1.4. Emergency Telephone Number

**Emergency Number** : CHEMTREC 1-800-424-9300

## SECTION 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the Substance or Mixture

**GHS-US classification**

Not classified

### 2.2. Label Elements

**GHS-US Labeling**

No labeling applicable

### 2.3. Other Hazards

No data available

### 2.4. Unknown Acute Toxicity (GHS-US)

No data available

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. Substance

| Name | Product Identifier | % | GHS-US classification |
|---|---|---|---|
| Water for Injection | (CAS No) 7732-18-5 | 100 | Not classified |

### 3.2. Mixture

Not applicable

## SECTION 4: FIRST AID MEASURES

### 4.1. Description of First Aid Measures

**First-aid Measures General**: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical attention (show the label where possible). In the event of accidental injection, immediately call a poison center and seek medical attention.

**First-aid Measures After Inhalation**: Obtain medical attention if breathing difficulty.

**First-aid Measures After Skin Contact**: Obtain medical attention if irritation develops or persists.

**First-aid Measures After Eye Contact**: Obtain medical attention if irritation develops or persists.

**First-aid Measures After Ingestion**: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

### 4.2. Most important symptoms and effects, both acute and delayed

**Symptoms/Injuries:** None expected under normal conditions of use.

**Chronic Symptoms:** None known.

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

If exposed or concerned, get medical advice and attention.

## SECTION 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing Media

**Suitable Extinguishing Media:** Use extinguishing media appropriate for surrounding fire.

**Unsuitable Extinguishing Media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

### 5.2. Special Hazards Arising From the Substance or Mixture

**Fire Hazard:** Product is not flammable.

**Explosion Hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

### 5.3. Advice for Firefighters

**Precautionary Measures Fire:** Exercise caution when fighting any fire.

**Firefighting Instructions:** Use water spray or fog for cooling exposed containers.

**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

#### 6.1.1. For Non-emergency Personnel

**Protective Equipment:** Use appropriate personal protection equipment (PPE).

**Emergency Procedures:** Evacuate unnecessary personnel.

#### 6.1.2. For Emergency Responders

**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.

### 6.2. Environmental Precautions

No additional information available

### 6.3. Methods and Material for Containment and Cleaning Up

No additional information available

### 6.4. Reference to Other Sections

See Section 8, Exposure Controls and Personal Protection. See Section 13, Disposal Considerations.

## SECTION 7: HANDLING AND STORAGE

### 7.1. Precautions for Safe Handling

**Additional Hazards When Processed:** Use only as directed by the information identified in the package insert.

**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for Safe Storage, Including Any Incompatibilities

**Technical Measures:** Comply with applicable regulations.

**Storage Conditions:** Store in a dry, well-ventilated place at 20° - 25°C (68° - 77°F) away from direct sunlight and incompatible materials.

**Incompatible Products:** None known.

### 7.3. Specific End Use(s)

Pharmaceutical

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. Control Parameters

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), or OSHA (PEL).

### 8.2. 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 chemically resistant protective gloves. |
| **Eye Protection** | : Chemical safety goggles. |
| **Skin and Body Protection** | : Wear suitable protective clothing. Wash contaminated clothing before reuse. |
| **Respiratory Protection** | : In case of inadequate ventilation wear respiratory protection. |
| **Other Information** | : When using, do not eat, drink or smoke. |

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on Basic Physical and Chemical Properties

| | |
|---|---|
| **Physical State** | : Liquid |
| **Appearance** | : Clear, colorless |
| **Odor** | : Odorless |
| **Odor Threshold** | : No data available |
| **pH** | : 5.0 - 7.0 |
| **Evaporation Rate** | : No data available |
| **Melting Point** | : No data available |

| | |
|---|---|
| **Freezing Point** | : 32 °F (0°C) |
| **Boiling Point** | : 212 °F (100 °C) |
| **Flash Point** | : No data available |
| **Auto-ignition Temperature** | : No data available |
| **Decomposition Temperature** | : No data available |
| **Flammability (solid, gas)** | : No data available |
| **Vapor Pressure** | : No data available |
| **Relative Vapor Density at 20 °C** | : No data available |
| **Relative Density** | : No data available |
| **Specific Gravity** | : 1.0 |
| **Solubility** | : Aqueous |
| **Partition Coefficient: N-Octanol/Water** | : No data available |
| **Viscosity** | : No data available |

**9.2. Other Information** No additional information available

## SECTION 10: STABILITY AND REACTIVITY

**10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.

**10.2. Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).

**10.3. Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.

**10.4. Conditions to Avoid:** Do not mix with other drugs. Avoid heat, light and humidity. Keep away from flames; thermally decomposes to form toxic vapors.

**10.5. Incompatible Materials:** None known.

**10.6. Hazardous Decomposition Products:** None known.

## SECTION 11: TOXICOLOGICAL INFORMATION

**11.1. Information On Toxicological Effects**

**Acute Toxicity:** Not classified

**Skin Corrosion/Irritation:** Not classified (**pH:** 5.0 - 7.0)

**Serious Eye Damage/Irritation:** Not classified (**pH:** 5.0 - 7.0)

**Respiratory or Skin Sensitization:** Not classified

**Germ Cell Mutagenicity:** Not classified

**Carcinogenicity:** Not classified

**Reproductive Toxicity:** Not classified

**Specific Target Organ Toxicity (Single Exposure):** Not classified

**Specific Target Organ Toxicity (Repeated Exposure):** Not classified

**Aspiration Hazard:** Not classified

**Chronic Symptoms:** None known.

## SECTION 12: ECOLOGICAL INFORMATION

**12.1. Toxicity**

**Ecology - General** : Not classified.

**12.2. Persistence and Degradability** Not established

**12.3. Bioaccumulative Potential** Not established

**12.4. Mobility in Soil** No additional information available

**12.5. Other Adverse Effects** No additional information available

## SECTION 13: DISPOSAL CONSIDERATIONS

**13.1. Waste treatment methods**

**Waste Disposal Recommendations:** Dispose of contents/container in accordance with local, regional, national, and international regulations.

## SECTION 14: TRANSPORT INFORMATION

**14.1. In Accordance with DOT** Not regulated for transport

**14.2. In Accordance with IMDG** Not regulated for transport

**14.3. In Accordance with IATA** Not regulated for transport

## SECTION 15: REGULATORY INFORMATION

**15.1 US Federal Regulations**

| **Water (7732-18-5)** |
|---|
| Listed on the United States TSCA (Toxic Substances Control Act) inventory |

**15.2 US State Regulations** Neither this product nor its chemical components appear on any US state lists.

## SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

**Revision Date** : 11/10/2015

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

*Refer to Luitpold/American Regent prescribing information for further information at: http://www.americanregent.com/AllProducts.aspx*

*The information above is believed to be accurate and represents the best information currently available to American Regent. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.*

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