

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Water

Product Name: Sterile Water for Injection, USP

Product Code: 0517-3005-01, 0517-3005-25, 0517-3010-01, 0517-3010-25, 0517-3020-01, 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

American Regent, Inc.

5 Ramsey Road

P.O. Box 9001

Shirley, NY

1-800-645-1706

www.americanregent.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	(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 advice (show the label where possible). In the event of accidental injection, immediately call a poison center or seek medical advice.

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

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.

Sterile Water for Injection, USP

Safety Data Sheet

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

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 at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

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 : No data available

Sterile Water for Injection, USP

Safety Data Sheet

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

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.

Sterile Water for Injection, USP

Safety Data Sheet

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

Revision Date : 03/25/2019

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 American Regent prescribing information for further information at: <http://www.americanregent.com/AllProducts.aspx>

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