

STERILE WATER FOR INJECTION, USP

Safety Data Sheet



According to 29 CFR 1910.1200 (g) [Federal Register Vol. 77, No. 58 Dated March 26, 2012]

Date of Issue: 03/12/2020

Revision: 000

1. IDENTIFICATION

(a) **Product Identifier:**

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

(b) **Intended Use of the Product:** Sterile Water for Injection, USP is indicated for diluting or dissolving drugs for intravenous, intramuscular or subcutaneous injection, according to instructions of the manufacturer of the drug to be administered.

(c) **Name, Address, Telephone of the Manufacturer:**

Medefil, Inc.
405 Windy Point Drive
Glendale Heights, IL. 60139
(630) 682 – 4600
www.medefilinc.com

(d) **Emergency Telephone Number:** 1-630-682-4600

2. HAZARDS IDENTIFICATION

(a) **Classification of the Substance of Mixture**

GHS-US Classification: Not classified as hazardous

(b) **Label Elements**

Signal Word (GHS-US): Not applicable
Hazard Statements (GHS-US): Not applicable
Precautionary Statements (GHS-US): Not applicable

(c) **Other Hazards:** No data available

(d) **Unknown Acute Toxicity (GHS-US):** No data available

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 **Substance**

Name	CAS Number	%	GHS-US Classification
Water for Injection	7732-18-5	100	Not classified

3.2 **Mixture** Not applicable

4. FIRST AID MEASURES

4.1 **Description of First-aid Measures**

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General: This product is intended for therapeutic use only when prescribed by a physician. In the event of accidental injection, immediately call a poison center and seek medical help. Potential adverse reactions from prescribed doses and overdoses are described in package insert.

Skin Contact: Obtain medical help if irritation develops or persists.

Eye Contact: Obtain medical help if irritation develops or persists.

Ingestion: obtain medical help.

Inhalation: Obtain medical help if breathing difficulty.

4.2 Most Important Symptoms and Effects Both Acute and Delayed

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

Chronic Symptoms: None expected under normal conditions of use.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

5. FIRE-FIGHTING MEASURES

5.1. **Extinguishing Media:** Use extinguishing media as for primary cause of fire.

5.2. **Special Hazards Arising From the Substance or Mixture:**

Fire Hazard: Not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. **Advice for Firefighters:** Not applicable.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Not applicable.

6.2. Environmental Precautions

None.

6.3. Methods and Materials for Containment and Cleaning Up

Wipe with a damp cloth and place in container for disposal.

7. HANDLING AND STORAGE

7.1. Precautions for Safe Handling

No special handling requirements for normal use of this material.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Storage Conditions: Store as directed by product packaging.

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Incompatible Products: None Known.

7.3 **Specific End Use(s):**
No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 **Control Parameters:** No Occupational Exposure Limit (OEL) or short term exposure limit (STEL) has been identified.

8.2 **Exposure Controls:**

Appropriate Engineering Controls: Engineering controls should be used as the primary means to control exposure.

Personal Protective Equipment: Not generally required. Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hand Protection: Not required for normal use of this product.

Eye Protection: Not required under normal conditions of use.

Skin and Body Protection: Not required for the normal use of this product.

Respiratory Protection: Not required under normal conditions of use.

Other Information: Not applicable.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 **Information on Basic Physical and Chemical Properties**

Physical State:	Liquid
Appearance:	Clear, colorless solution
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
Specific Gravity:	1.0
Solubility:	Aqueous
Partition Coefficient:	No data available
Viscosity:	No data available

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

10. STABILITY AND REACTIVITY

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| 10.1. Reactivity: | No data available. |
| 10.2. Chemical Stability: | Stable under recommended handling and storage conditions. |
| 10.3. Possibility of Hazardous Reactions: | None. |
| 10.4. Conditions to Avoid: | None. |
| 10.5. Incompatible Materials: | None. |
| 10.6. Hazardous Decomposition Products: | No data available. |

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.	

12 ECOLOGICAL INFORMATION

Environmental Overview: No harmful effects to aquatic organisms are expected.

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|--|---------------------|
| 12.1 Toxicity: | No data available. |
| 12.2 Persistence and Degradability: | No data available. |
| 12.3 Bio-accumulative Potential: | No data available . |
| 12.4 Mobility in Soil: | No data available. |

13 DISPOSAL CONSIDERATIONS

- | | |
|--------------------------------------|--|
| 13.1 Waste Treatment Methods: | Dispose of contents/container in accordance with local, regional, national, and international regulations. |
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14 TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below

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|--------------------------------------|------------------------------|
| 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. |

15 REGULATORY INFORMATION

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CERCLA/SARA313 Emission reporting

Not listed

California Proposition 65

Not listed

Inventory – United States TSCA – Sec. 8(b)

Present

16 OTHER INFORMATION

Date of Preparation of Latest Information:

March 12, 2020

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 Prescribing Information for further information at www.medefilinc.com

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