



Water for Injection (WFI), USP

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations
Issue date: 1/30/2025 Version: 1.0

SECTION 1 Identification

1.1. Product identifier

Product form : Substance
Trade name : Water for Injection (WFI), USP

1.2. Other means of identification

No additional information available

1.3. Recommended use of the chemical and restrictions on use

Use of the substance/mixture : Pharmaceuticals
Restrictions on use : All other uses not recommended above

1.4. Supplier's details

GMP Liquid Ingredients (GMPLI)
210 Riveredge Road
Tinton Falls, NJ 07724
T 732-856-7690
cbritt@eoiconsultinggroup.com, hgannamani@eoiconsultinggroup.com

1.5. Emergency phone number

Emergency number : 732-856-7690 Mon-Fri, 8am-5pm

SECTION 2 Hazard 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. Hazards associated with known or reasonably anticipated uses

No additional information available

2.4. Hazards not otherwise classified

No additional information available

2.5. Unknown acute toxicity

No additional information available

SECTION 3 Composition/information on ingredients

3.1. Substances

Trade name : Water for Injection (WFI), USP

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Name	Product identifier	%	GHS US classification
Water	CAS-No.: 7732-18-5	100	Not classified

Full text of hazard classes and H-statements : see section 16

3.2. Mixtures

Not applicable

SECTION 4 First aid measures

4.1. Description of necessary first-aid measures

First-aid measures general	: No hazards which require special first aid measures.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: No hazards which require special first aid measures.
First-aid measures after eye contact	: Rinse eyes with water as a precaution. Remove contact lenses, if present and easy to do. Continue rinsing.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms/effects, acute and delayed

Symptoms/effects after inhalation	: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact	: Not expected to present a significant skin hazard under anticipated conditions of normal use.
Symptoms/effects after eye contact	: Not expected to present a significant eye contact hazard under anticipated conditions of normal use.
Symptoms/effects after ingestion	: Not expected to present a significant ingestion hazard under anticipated conditions of normal use.

4.3. Indication of immediate medical attention and special treatment needed, if necessary

Other medical advice or treatment	: Treat symptomatically.
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SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Specific hazards arising from the chemical

Fire hazard	: No fire hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Special protective equipment and precautions for fire-fighters

Firefighting instructions	: Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection. Move containers from fire area if it can be done without personal risk. Use water spray or fog for cooling exposed containers. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Do not take actions involving personal risks. Absorb spillage to prevent material-damage. Stop leak if safe to do so.

For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.
Emergency procedures : Evacuate the danger area. If outdoors, move to an area upwind of the danger area. If possible without taking personal risks, remove ignition sources, ventilate area. Prevent other non-emergency personnel from entering the danger area.

For emergency responders

Protective equipment : Wear the recommended personal protective equipment. Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
Emergency procedures : Evacuate unnecessary personnel. Stop leak if safe to do so.

Environmental precautions : Avoid release to the environment.

6.2. Methods and materials for containment and cleaning up

For containment : Contain with non-combustible inert absorbent. Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Stop leak, if possible without risk.
Methods for cleaning up : Take up liquid spill into absorbent material. Dispose of collected material as soon as possible in accordance with applicable local/regional/national/international regulations.

For further information refer to section 8: "Exposure controls/personal protection", For further information refer to section 13

SECTION 7 Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Take precautionary measures against static discharge.
Hygiene measures : Do not eat, drink or smoke when using this product.
Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.

7.2. Conditions for safe storage, including incompatibilities

Storage conditions : Store in a cool, dry place.

SECTION 8 Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Appropriate engineering controls

Appropriate engineering controls : Handle in accordance with good industrial hygiene and safety procedures.
Environmental exposure controls : Avoid release to the environment. Take measures to reduce or limit air emissions and releases to soil and the aquatic environment.

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8.3. Individual protection measures, such as personal protective equipment

Personal protective equipment:

Personal protective equipment should be chosen according to national standards and in discussion with the supplier of the protective equipment. Wear recommended personal protective equipment.

Hand protection:
Select hand protection according to the other used substances
Eye protection:
Wear safety glasses which protect from splashes
Skin and body protection:
Body protection should be chosen depending on activity and possible exposure
Respiratory protection:
No respiratory protection needed under normal use conditions

SECTION 9 Physical and chemical properties

9.1. Basic physical and chemical properties

Physical state	: Liquid
Color	: Colorless
Odor	: No data available
Odor threshold	: No data available
pH	: 7
Melting point	: Not applicable
Freezing point	: 0 °C / 32 °F
Boiling point	: 100 °C / 212 °F
Flash point	: No data available
Flammability (solid, gas)	: Not applicable.
Vapor pressure	: No data available
Relative vapor density at 20°C	: No data available
Relative density	: No data available
Solubility	: No data available
Partition coefficient n-octanol/water (Log Pow)	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Explosion limits	: No data available
Particle characteristics	: No data available

Water

Particle characteristics	No data available
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9.2. Data relevant with regard to physical hazard classes (supplemental)

No additional information available

SECTION 10 Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

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10.2. Chemical stability

Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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

Water

LD50 oral rat	> 10000 mg/kg body weight
LD50 dermal rat	> 10000 mg/kg body weight
LD50 dermal rabbit	> 10000 mg/kg body weight
LC50 Inhalation - Rat	> 100 mg/l/4h

Skin corrosion/irritation : Not classified
pH: 7

Serious eye damage/irritation : Not classified
pH: 7

Respiratory or skin sensitization : 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

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Viscosity, kinematic	No data available
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Water

Viscosity, kinematic	No data available
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Symptoms/effects after inhalation : Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact : Not expected to present a significant skin hazard under anticipated conditions of normal use.

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

SECTION 12 Ecological information

12.1. Ecotoxicity

Ecology - general	: The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

12.2. Persistence and degradability

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Persistence and degradability	Not rapidly degradable
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Water

Persistence and degradability	Rapidly degradable
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12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Ozone	: Not classified
Fluorinated greenhouse gases	: No

SECTION 13 Disposal considerations

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Disposal must be done according to official regulations. Refer to all applicable national, international and local regulations or provisions.
Additional information	: Do not re-use empty containers.
Ecological waste information	: Avoid release to the environment.

SECTION 14 Transport information

In accordance with DOT / IMDG / IATA

DOT	IMDG	IATA
14.1. UN number		
Not regulated for transport		

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DOT	IMDG	IATA
14.2. Proper Shipping Name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
	Not regulated	
No supplementary information available		

14.6. Transport in bulk

Not applicable

14.7. Special precautions for user

DOT

Not regulated

IMDG

Not regulated

IATA

Not regulated

SECTION 15 Regulatory information

15.1. Federal regulations

All components of this product are present and listed as Active on the United States Environmental Protection Agency Toxic Substances Control Act (TSCA) inventory.

This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.

15.2. International regulations

CANADA

Water (7732-18-5)

Listed on the Canadian DSL (Domestic Substances List)

EU-Regulations

No additional information available

National regulations

Water (7732-18-5)

Listed on INSQ (Mexican National Inventory of Chemical Substances)

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15.3. State regulations

California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm

SECTION 16 Other information

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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.