



SAFETY DATA SHEET

United States

Section 1. Identification

Product name

Water for Injection, EP/USP Sterile Grade, 200L

Catalogue Number

WFI-EPZ-2XL



9 0 W F I E P Z 2 X L

Other means of identification

Not available.

Product type

Liquid.

Relevant identified uses of the substance or mixture and uses advised against

For further manufacturing.

Supplier / Manufacturer

Cytiva Austria
Kremsplstr. 5
4061 Pasching
AUSTRIA
Tel. (+43) 7229 64865
Fax (+43) 7229 64866

HyClone Laboratories
925 West 1800 South
Logan, Utah 84321
Phone: (435) 792-8000

Cytiva Singapore
1 Maritime Square #13-01
Harbourfront Centre
Singapore 099253

Cytiva Singapore
25 Tuas South Street 1
Singapore 638034

Cytiva
Amersham Place
Little Chalfont
Buckinghamshire
HP7 9NA United Kingdom
+44 1494 508000

Cytiva USA
100 Results Way
Marlborough, MA 01752
1-800-526-3593

In case of emergency

INFOTRAC - 24 Hour number: 1-800-535-5053
Outside of the United States, call 24 Hour number: 001-352-323-3500 (Call Collect)

Section 2. Hazards identification

OSHA/HCS status

While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture

Not classified.

GHS label elements

Signal word

No signal word.

Hazard statements

No known significant effects or critical hazards.

Precautionary statements

Prevention

Not applicable.

Response

Not applicable.



9 5 W F I E P Z 2 X L

Storage	Not applicable.
Disposal	Not applicable.
Hazards not otherwise classified	None known.
Hazards identified when used	No known significant effects or critical hazards.

Section 3. Composition/information on ingredients

Substance/mixture	Substance		
Other means of identification	Not available.		
Ingredient name	Synonyms	%	Identifiers
water	AQUA; water, distilled, conductivity or of similar purity; R718; Water (purified water); CRAON 17-502; water, distilled; DEIONIZED WATER; Hydrogen Oxide; water (moisture); soft water	100	CAS: 7732-18-5

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
Skin contact	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Ingestion	Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact	No known significant effects or critical hazards.
Inhalation	No known significant effects or critical hazards.
Skin contact	No known significant effects or critical hazards.
Ingestion	No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact	No specific data.
Inhalation	No specific data.
Skin contact	No specific data.
Ingestion	No specific data.

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

Notes to physician	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	No specific treatment.
Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	In a fire or if heated, a pressure increase will occur and the container may burst.
Hazardous thermal decomposition products	No specific data.
Special protective actions for fire-fighters	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.



Special protective equipment for fire-fighters	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.
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Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
For emergency responders	If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
Environmental precautions	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill	Stop leak if without risk. Move containers from spill area. Absorb with an inert material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
Large spill	Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Section 7. Handling and storage

Precautions for safe handling

Protective measures	Put on appropriate personal protective equipment (see Section 8).
Advice on general occupational hygiene	Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.
Conditions for safe storage, including any incompatibilities	Store between the following temperatures: 2 to 30°C (35.6 to 86°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
water	None.

Biological exposure indices

No exposure indices known.

Appropriate engineering controls	Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
Environmental exposure controls	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
Eye/face protection	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
Skin protection	
Hand protection	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
Body protection	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.



Other skin protection	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

Physical state	Liquid.
Color	Clear. Colorless.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Boiling point or initial boiling point and boiling range	Not available.
Flash point	Not available.
Burning time	Not applicable.
Burning rate	Not applicable.
Evaporation rate	Not available.
Flammability	Not available.
Lower and upper explosive (flammable) limits	Not available.
Vapor pressure	Not available.
Relative vapor density	Not available.
Relative density	Not available.
Solubility in water	Not available.
Partition coefficient: n-octanol/water	Not applicable.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
SADT	Not available.
Viscosity	Dynamic (room temperature): Not available. Kinematic (room temperature): Not available. Kinematic (40°C (104°F)): Not available.
Flow time (ISO 2431)	Not available.

Particle characteristics

Median particle size	Not applicable.
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Section 10. Stability and reactivity

Reactivity	No specific test data related to reactivity available for this product or its ingredients.
Chemical stability	The product is stable.
Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
Conditions to avoid	No specific data.
Incompatible materials	No specific data.
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Not available.

Conclusion/Summary [Product]	Not available.
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Skin corrosion/irritation

Not available.



Conclusion/Summary [Product]	Not available.
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Serious eye damage/eye irritation

Not available.

Conclusion/Summary [Product]	Not available.
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Respiratory corrosion/irritation

Not available.

Conclusion/Summary [Product]	Not available.
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Respiratory or skin sensitization

Not available.

Skin

Conclusion/Summary [Product]	Not available.
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Respiratory

Conclusion/Summary [Product]	Not available.
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Germ cell mutagenicity

Not available.

Conclusion/Summary [Product]	Not available.
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Carcinogenicity

Not available.

Conclusion/Summary [Product]	Not available.
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Reproductive toxicity

Not available.

Conclusion/Summary [Product]	Not available.
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Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure	Routes of entry anticipated: Oral, Dermal, Eyes.
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Potential acute health effects

Eye contact	No known significant effects or critical hazards.
Inhalation	No known significant effects or critical hazards.



Skin contact	No known significant effects or critical hazards.
Ingestion	No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	No specific data.
Inhalation	No specific data.
Skin contact	No specific data.
Ingestion	No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure**Short term exposure**

Potential immediate effects	Not available.
Potential delayed effects	Not available.

Long term exposure

Potential immediate effects	Not available.
Potential delayed effects	Not available.

Potential chronic health effects

Not available.

Conclusion/Summary [Product]	Not available.
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General	No known significant effects or critical hazards.
Carcinogenicity	No known significant effects or critical hazards.
Mutagenicity	No known significant effects or critical hazards.
Reproductive toxicity	No known significant effects or critical hazards.

Numerical measures of toxicity**Acute toxicity estimates**

N/A

Section 12. Ecological information**Toxicity**

Not available.

Conclusion/Summary [Product]	Not available.
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Ingredient name	Conclusion/Summary
water	Not applicable.

Persistence and degradability

Not available.

Ingredient name	Conclusion/Summary
water	Not applicable

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
water	-	-	Readily

Bioaccumulative potential

Product/ingredient name	LogP_{ow}	BCF	Potential
water	-1.38	-	Low

Mobility in soil

Soil/Water partition coefficient	Not available.
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Other adverse effects	No known significant effects or critical hazards.
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Section 13. Disposal considerations

Disposal methods

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	TDG Classification	Mexico Classification
UN number	Not available.	Not available.	Not available.
UN proper shipping name	Not available.	Not available.	Not available.
Transport hazard class(es)	Not available.	Not available.	Not available.
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-
	ADR/RID	IMDG	IATA
UN number	Not available.	Not available.	Not available.
UN proper shipping name	Not available.	Not available.	Not available.
Transport hazard class(es)	Not available.	Not available.	Not available.
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-
Special precautions for user	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.		
Transport in bulk according to IMO instruments	Not available.		
Proper shipping name	Not available.		

Section 15. Regulatory information

U.S. Federal regulations TSCA 8(a) CDR Exempt/Partial exemption: Not determined

TSCA 12(b) - Chemical export notification

Not applicable.

Clean Air Act Section 112(b) Hazardous Air Pollutants (HAPs)	Not listed
Clean Air Act Section 602 Class I Substances	Not listed
Clean Air Act Section 602 Class II Substances	Not listed
DEA List I Chemicals (Precursor Chemicals)	Not listed
DEA List II Chemicals (Essential Chemicals)	Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ Not applicable.

SARA 311/312

Classification Not applicable.

Composition/information on ingredients

No products were found.



State regulations

Massachusetts	None of the components are listed.
New York	None of the components are listed.
New Jersey	None of the components are listed.
Pennsylvania	None of the components are listed.

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations**Chemical Weapon Convention List Schedules I, II & III Chemicals**

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

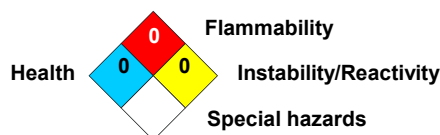
Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

United States	All components are active or exempted.
Canada inventory	All components are listed or exempted.

Section 16. Other information**National Fire Protection Association (U.S.A.)****Procedure used to derive the classification**

Classification	Justification
Not classified.	

History

Date of printing	9/6/2025
Date of issue/Date of revision	9/6/2025
Date of previous issue	9/6/2022
Version	0.02

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Key to abbreviations

ATE = Acute Toxicity Estimate
 BCF = Bioconcentration Factor
 GHS = Globally Harmonized System of Classification and Labelling of Chemicals
 IATA = International Air Transport Association
 IBC = Intermediate Bulk Container
 IMDG = International Maritime Dangerous Goods
 LogPow = logarithm of the octanol/water partition coefficient
 MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
 N/A = Not available
 UN = United Nations

References

Not available.

Indicates information that has changed from previously issued version.

Notice to reader

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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.



