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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Water for injection

Product Code(s) EX02902

Synonyms Sterile Water for Injection, USP; Water for Injection, BP

Trade Name: Not established Chemical Family: Not applicable

Water

CAS No. 7732-18-5

REACH registration number -

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

Recommended Use Pharmaceutical product

1.3. Details of the supplier of the safety data sheet

Pfizer Inc Pfizer Ireland Pharmaceuticals

66 Hudson Boulevard East OSG Building

New York, New York 10001 Ringaskiddy, Co. Cork.

1-800-879-3477 Ireland

+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification: This substance is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

Signal word Not classified

Hazard statements Not classified in accordance with international standards for workplace safety.

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2.3. Other hazards

Other hazards No information available.

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor InformationThis product does not contain any known or suspected endocrine disruptors.

Note: This document has been prepared in accordance with standards for workplace safety, which

require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

NonHazardous

Noniriazaradas							
Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	100	-	231-791-2	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Γ	Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4	
L			mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm	
	Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available	

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Not an expected route of exposure.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contact Due to the nature of this material first aid is not normally required.

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Ingestion Due to the nature of this material first aid is not normally required.

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

Most important symptoms and

No data available

effects

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

Not applicable.

Hazardous combustion products

Not applicable

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

precautions for fire-fightersUse personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Not applicable.

6.2. Environmental precautions

Environmental precautions No special precautions are needed in handling this material.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

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

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections

See section 8 for more information. See section 13 for more information.

Additional Information: No special measures are required.

Section 7: HANDLING AND STORAGE

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7.1. Precautions for safe handling

Advice on safe handling None under normal use conditions.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

No Occupational Exposure Limit (OEL) or Short Term Exposure Limit (STEL) has been identified.

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE).

Eye/face protection Not required under normal conditions of use.

Hand protection Not required for the normal use of this product.

Skin and body protection Not required for the normal use of this product.

Respiratory protection None required under normal conditions of use.

Thermal hazards No information available.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical stateLiquidColorColorlessOdorNone.

Odor threshold No information available

 Property
 Values

 Melting point / freezing point
 0

 Boiling point or initial boiling point and boiling range
 100

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Flammability (solid, gas) No data available

Lower and upper explosion limit/flammability limit

Lower explosion limit
Upper explosion limit
No data available
Autoignition temperature
No data available
Decomposition temperature

SADT (°C) No data available

oH T

pH (as aqueous solution) No data available Kinematic viscosity No data available Dynamic viscosity No data available Solubility No data available No data available Vapor pressure Density and/or relative density No data available **Bulk density** No data available **Liquid Density** No data available Vapor density No data available

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information available

9.2. Other information

Molecular formula H2O Molecular weight 18.02

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable.

Explosion data

Sensitivity to mechanical impact No information available. **Sensitivity to static discharge** No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid None known.

10.5. Incompatible materials

Incompatible materials None.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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Acute toxicity Based on available data, the classification criteria are not met. Serious eye damage/eye irritation Based on available data, the classification criteria are not met. Skin corrosion/irritation Based on available data, the classification criteria are not met. Respiratory or skin sensitization Based on available data, the classification criteria are not met. STOT - single exposure Based on available data, the classification criteria are not met. STOT - repeated exposure Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Reproductive toxicity Based on available data, the classification criteria are not met. Germ cell mutagenicity Based on available data, the classification criteria are not met. Carcinogenicity **Aspiration hazard** Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

Addic Toxiony. (Openics, Rodic, End Folin, Dose)					
Chemical name	Oral LD50	Dermal LD50	Inhalation LC50		
Water	> 90 mL/kg (Rat)	-	-		

Carcinogenicity Not listed as a carcinogen by IARC, NTP or US OSHA.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

No information available

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

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12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM properties Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Water

CERCLA/SARA Section 313 de minimus % Not Listed California Proposition 65 Not Listed TSCA Present EINECS 231-791-2 AICS Present

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National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018

Storage of Hazardous Material

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Major Accidents Ordinance SR 814.012

Not applicable

Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

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Key or legend to abbreviations and acronyms used in the safety data sheet

Data Sources: Publicly available toxicity information.

Reason for revision Updated Section 1 - Identification of the Substance/Preparation and the

Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

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Prepared By Pfizer Global Environment, Health, and Safety

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