



# SAFETY DATA SHEET

Revision date 22-Sep-2022

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

### 1.1. Product identifier

**Product Name** Bacteriostatic 0.9% Sodium Chloride Injection, USP  
**Product Code(s)** PZ02897  
**Trade Name:** Not applicable  
**Chemical Family:** Mixture

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

**Recommended Use** Pharmaceutical product used as diluent

### 1.3. Details of the supplier of the safety data sheet

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
1-800-879-3477

Pfizer Ireland Pharmaceuticals  
OSG Building  
Ringaskiddy, Co. Cork.  
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: Not classified as hazardous according to Regulation (EC) 1272/2008 and/or other applicable regulations.

### 2.2. Label elements

**Signal word** Not Classified

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

### 2.3. Other hazards

**Other hazards**

**Note:**

No data available

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

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## 3.1 Substances

### Substances

Not applicable

## 3.2 Mixtures

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC 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)	99.1	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
SODIUM CHLORIDE (CAS #: 7647-14-5)	0.9	-	231-598-3	Not classified as hazardous	Not Listed	No data available	No data available

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

### Acute Toxicity Estimate

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
SODIUM CHLORIDE 7647-14-5	3000	10000	No data available	No data available	No data available

### Additional information

Non-hazardous ingredients provided for completeness. 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

<b>Inhalation</b>	Not an expected route of exposure.
<b>Eye contact</b>	Due to the nature of this material first aid is not normally required.
<b>Skin contact</b>	Due to the nature of this material first aid is not normally required.
<b>Ingestion</b>	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 effects** No data available

### 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

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**Suitable Extinguishing Media** As for primary cause of fire.

## **5.2. Special hazards arising from the substance or mixture**

**Specific hazards arising from the chemical** Not applicable.

**Hazardous combustion products** Not applicable

## **5.3. Advice for firefighters**

**Special protective equipment for fire-fighters** Not applicable.

## **Section 6: ACCIDENTAL RELEASE MEASURES**

### **6.1. Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Not applicable.  
**For emergency responders** Use personal protection recommended in Section 8.

### **6.2. Environmental precautions**

**Environmental precautions** None.

### **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** None.

### **6.4. Reference to other sections**

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## **Section 7: HANDLING AND STORAGE**

### **7.1. Precautions for safe handling**

**Advice on safe handling**  
No special handling requirements for normal use of this material.  
**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)**

## **Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### **8.1. Control parameters**

**Exposure Limits**  
Refer to available public information for specific member state Occupational Exposure Limits.

#### **SODIUM CHLORIDE**

Latvia

5 mg/m<sup>3</sup>

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Russia

MAC: 5 mg/m<sup>3</sup>

## Pfizer Occupational Exposure Band (OEB) Statement:

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

## SODIUM CHLORIDE

Pfizer Occupational Exposure Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

## 8.2. Exposure controls

### Engineering controls

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

### Environmental exposure controls

No information available.

### 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.

### General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. Information on basic physical and chemical properties

Physical state	Liquid
Color	Colorless
Odor	None.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

### Property

### Values

pH	4.5-7.0
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available

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Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

## 9.2. Other information

No information available

### 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 data available.

### 10.2. Chemical stability

Stability Stable.

### Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

### 10.4. Conditions to avoid

Conditions to avoid None.

### 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

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	Mild eye irritant in experimental animals (based on components)
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	Based on available data, the classification criteria are not met.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

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

### SODIUM CHLORIDE

Rat Sub-tenon injection (eye) LC50/1hr > 42 g/m<sup>3</sup>

Rat Oral LD 50 3 g/kg

Mouse Oral LD 50 4 g/kg

Rabbit Dermal LD 50 > 10 g/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg ( Rat )	-	-
SODIUM CHLORIDE	= 3 g/kg ( Rat )	> 10000 mg/kg ( Rabbit )	> 42 mg/L ( Rat ) 1 h

**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

## Irritation / Sensitization: (Study Type, Species, Severity)

### SODIUM CHLORIDE

Skin irritation Rabbit Mild

Eye irritation Rabbit Mild

**Carcinogenicity** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

## 11.2. Information on other hazards

### 11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

### 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

Chemical name	PBT and vPvB assessment
SODIUM CHLORIDE	The substance is not PBT / vPvB PBT assessment does not apply

## 12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

## 12.7. Other adverse effects

No information available.

## Section 13: DISPOSAL CONSIDERATIONS

### 13.1. Waste treatment methods

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: Not applicable  
UN proper shipping name: Not applicable  
Transport hazard class(es): Not applicable  
Packing group: Not applicable  
Environmental Hazard(s): Not applicable  
  
Special precautions for user: 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

SODIUM CHLORIDE

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed

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**TSCA** Present  
**EINECS** 231-598-3  
**AICS** Present

## France

### Occupational Illnesses (R-463-3, France)

Chemical name	French RG number	Title
SODIUM CHLORIDE 7647-14-5	RG 78	-

## 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 (EC) 1005/2009

Not applicable

### Plant protection products directive (91/414/EEC)

Chemical name	Plant protection products directive (91/414/EEC)
SODIUM CHLORIDE - 7647-14-5	Plant protection agent

### Legend:

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

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

**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### 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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**is no known information at this time.**