



# SAFETY DATA SHEET

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Bacteriostatic Water for Injection, USP (Hospira Inc.)

**Trade Name:** Bacteriostatic Water for Injection, USP

**Chemical Family:** Not determined

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product

### Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company  
275 North Field Drive  
Lake Forest, Illinois 60045  
1-800-879-3477

Hospira UK Limited

Horizon

Honey Lane

Hurley

Maidenhead, SL6 6RJ

United Kingdom

**Emergency telephone number:**

CHEMTREC (24 hours): 1-800-424-9300

**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**

International CHEMTREC (24 hours): +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### Label Elements

**Signal Word:** Not Classified

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

### Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

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### 3. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredient     | CAS Number | EU<br>EINECS/ELINCS<br>List | GHS Classification                         | %   |
|----------------|------------|-----------------------------|--------------------------------------------|-----|
| BENZYL ALCOHOL | 100-51-6   | 202-859-9                   | Acute Tox. 4 (H302)<br>Acute Tox. 4 (H332) | 0.9 |

| Ingredient          | CAS Number | EU<br>EINECS/ELINCS<br>List | GHS Classification | % |
|---------------------|------------|-----------------------------|--------------------|---|
| Water for Injection | 7732-18-5  | 231-791-2                   | Not Listed         | * |

**Additional Information:**

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Flush eye(s) immediately with plenty of water. If irritation occurs or persists, get medical attention.

**Skin Contact:** Rinse with plenty of water. If skin irritation persists, call a physician.

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Move to fresh air. If discomfort occurs, get medical attention.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

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

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Not applicable

**Advice for Fire-Fighters**

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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### 6. ACCIDENTAL RELEASE MEASURES

#### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

#### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

#### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

#### Precautions for Safe Handling

Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

#### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging. Do not refrigerate.

**Specific end use(s):** Pharmaceutical product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Control Parameters

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

#### BENZYL ALCOHOL

|                          |                       |
|--------------------------|-----------------------|
| Pfizer OEL TWA-8 Hr:     | 10 ppm                |
| Bulgaria OEL - TWA       | 5.0 mg/m <sup>3</sup> |
| Czech Republic OEL - TWA | 40 mg/m <sup>3</sup>  |
| Finland OEL - TWA        | 10 ppm                |
|                          | 45 mg/m <sup>3</sup>  |
| Latvia OEL - TWA         | 5 mg/m <sup>3</sup>   |
| Lithuania OEL - TWA      | 5 mg/m <sup>3</sup>   |
| Poland OEL - TWA         | 240 mg/m <sup>3</sup> |

#### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Wear impervious gloves (e.g. Nitrile, etc.) if skin contact is possible. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

|                           |                    |                          |                    |
|---------------------------|--------------------|--------------------------|--------------------|
| <b>Physical State:</b>    | Liquid             | <b>Color:</b>            | Colourless         |
| <b>Odor:</b>              | No data available. | <b>Odor Threshold:</b>   | No data available. |
| <b>Molecular Formula:</b> | Mixture            | <b>Molecular Weight:</b> | Mixture            |

**Solvent Solubility:** No data available  
**Water Solubility:** Soluble  
**pH:** 4.5-7.0  
**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available  
**Partition Coefficient: (Method, pH, Endpoint, Value)**

#### Water for Injection

No data available

#### BENZYL ALCOHOL

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available  
**Vapor Pressure (kPa):** No data available  
**Vapor Density (g/ml):** No data available  
**Relative Density:** No data available  
**Viscosity:** No data available

#### Flammability:

|                                                     |                   |
|-----------------------------------------------------|-------------------|
| <b>Autoignition Temperature (Solid) (°C):</b>       | No data available |
| <b>Flammability (Solids):</b>                       | No data available |
| <b>Flash Point (Liquid) (°C):</b>                   | No data available |
| <b>Upper Explosive Limits (Liquid) (% by Vol.):</b> | No data available |
| <b>Lower Explosive Limits (Liquid) (% by Vol.):</b> | No data available |

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

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### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

**Short Term:** May cause eye irritation (based on components) .

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

##### BENZYL ALCOHOL

|        |        |       |            |
|--------|--------|-------|------------|
| Rat    | Oral   | LD 50 | 1230 mg/kg |
| Mouse  | Oral   | LD 50 | 1360mg/kg  |
| Rabbit | Dermal | LD 50 | 2gm/kg     |

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

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

#### Toxicity:

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

##### BENZYL ALCOHOL

|                                   |           |       |          |                |
|-----------------------------------|-----------|-------|----------|----------------|
| Fathead Minnow                    | NPDES     | LC-50 | 96 Hours | 460 - 770 mg/L |
| Bluegill                          | NPDES     | LC-50 | 96 Hours | 10 mg/L        |
| <i>Daphnia Magna</i> (Water Flea) | Surrogate | ErC50 | 48 Hours | 23 - 400 mg/L  |

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

### 13. DISPOSAL CONSIDERATIONS

**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 waste water 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.

### 14. TRANSPORT INFORMATION

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

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

### 15. REGULATORY INFORMATION

#### Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

##### BENZYL ALCOHOL

|                                             |            |
|---------------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting          | Not Listed |
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| EU EINECS/ELINCS List                       | 202-859-9  |

##### Water for Injection

|                                                                 |            |
|-----------------------------------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting                              | Not Listed |
| California Proposition 65                                       | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                     | Present    |
| Australia (AICS):                                               | Present    |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present    |
| EU EINECS/ELINCS List                                           | 231-791-2  |

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed  
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 10 - Stability and Reactivity.

**Revision date:** 06-Nov-2018

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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End of Safety Data Sheet