SAFETY DATA SHEET

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

Product Identifier

Material Name: Epinephrine Injection (Hospira, Inc.)

Trade Name: Not applicable
Chemical Family: Not determined

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
International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail: pfizer-MSDS@pfizer.com

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 warnings 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

PZ03223
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epinephrine</td>
<td>51-43-4</td>
<td>200-098-7</td>
<td>Acute Tox. 2 (H300)</td>
<td>1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 2 (H310)</td>
<td></td>
</tr>
<tr>
<td>Sodium bisulfite</td>
<td>7631-90-5</td>
<td>231-548-0</td>
<td>Acute Tox. 4 (H302)</td>
<td>&lt;2.0</td>
</tr>
<tr>
<td>HYDROCHLORIC ACID</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Skin Corr. 1B (H314)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3 (H335)</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
** to adjust pH
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 R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

**Eye Contact:**
Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:**
Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

**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:**
Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**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:**
Extinguish fires with CO2, extinguishing powder, foam, or water.

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

**Hazardous Combustion Products:**
Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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 spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up 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.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium bisulfite
ACGIH Threshold Limit Value (TWA) 5 mg/m³
Australia TWA 5 mg/m³
Belgium OEL - TWA 5 mg/m³
Denmark OEL - TWA 5 mg/m³
France OEL - TWA 5 mg/m³
Greece OEL - TWA 5 mg/m³
Ireland OEL - TWAs 5 mg/m³
Portugal OEL - TWA 5 mg/m³
Spain OEL - TWA 5 mg/m³
Switzerland OEL - TWAs 5 mg/m³
Vietnam OEL - TWAs 5 mg/m³

HYDROCHLORIC ACID
ACGIH Ceiling Threshold Limit: 2 ppm
## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia - PEAK</td>
<td>5 ppm 7.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>5 ppm 8.0 mg/m³</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm 3 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm 3.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 ppm 7 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>2 ppm 3.0 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Luxembourg OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Malta OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>8 mg/m³</td>
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<tr>
<td>Poland OEL - TWA</td>
<td>5 mg/m³</td>
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<tr>
<td>Portugal OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>5 ppm 8.0 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>5 ppm 8 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>5 ppm 7.6 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 ppm 3.0 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Epinephrine**

**Pfizer Occupational Exposure Band (OEB):** OEB 4 - Skin (control exposure to the range of 1ug/m³ to <10ug/m³, provide additional precautions to protect from skin contact)

**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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (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 full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Liquid

**Odor:** No data available.

**Molecular Formula:** Mixture

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**Solubility:** Soluble: Water

**pH:** 2.2-5.0

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Epinephrine**
No data available

**Sodium bisulfite**
No data available

**Water for Injection**
No data available

**Sodium chloride**
No data available

**Sodium citrate**
No data available

**HYDROCHLORIC ACID**
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
Specific Gravity: ~1
Viscosity: No data available

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

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 be absorbed through the skin and cause systemic effects. May be absorbed through mucous membranes and cause systemic effects.
Known Clinical Effects: Adverse effects associated with therapeutic use include increased heart rate (tachycardia), palpitations, sweating, nausea, vomiting, difficulty breathing, dizziness, weakness, headache, anxiety, nervousness.

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

Epinephrine
- Rat Dermal LD50 62 mg/kg
- Rat Oral LD50 30 mg/kg

Sodium chloride
- Rat Oral LD50 3000 mg/kg
- Mouse Oral LD50 4000 mg/kg

HYDROCHLORIC ACID
- Rat Oral LD50 238-277 mg/kg

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

Sodium chloride
11. TOXICOLOGICAL INFORMATION

Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Epinephrine
Embryo / Fetal Development  Rat  Intravenous  Dose not specified  Not teratogenic
Embryo / Fetal Development  Rabbit  Subcutaneous  30 times human dose  LOAEL  Developmental toxicity
Embryo / Fetal Development  Mouse  Subcutaneous  7 times human dose  LOAEL  Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Epinephrine
Bacterial Mutagenicity (Ames)  *Salmonella*  Negative
Sister Chromatid Exchange  Negative with activation
Sister Chromatid Exchange  Chinese Hamster Ovary (CHO) cells  Equivocal without activation

HYDROCHLORIC ACID
Bacterial Mutagenicity (Ames)  *Salmonella*  Negative
In Vivo Micronucleus  Rat  Negative

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

Sodium bisulfite
IARC:  Group 3 (Not Classifiable)

HYDROCHLORIC ACID
IARC:  Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

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

Toxicity:  No data available

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.

Additional Information: The US Federal EPA waste listing for epinephrine does not include epinephrine salts. Disposal should be performed in accordance with all federal, state, and local regulatory requirements.

Epinephrine
- RCRA - P Series Wastes: Listed

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.

15. REGULATORY INFORMATION

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

Epinephrine
- CERCLA/SARA 313 Emission reporting: Not Listed
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - California Proposition 65: Not Listed
  - Inventory - United States TSCA - Sect. 8(b): Present
  - Australia (AICS): Present
  - Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 3
  - EU EINECS/ELINCS List: 200-098-7

Sodium bisulfite
- CERCLA/SARA 313 Emission reporting: Not Listed
- CERCLA/SARA Hazardous Substances and their Reportable Quantities:
  - California Proposition 65: Not Listed
  - Inventory - United States TSCA - Sect. 8(b): Present
  - Australia (AICS): Present
  - EU EINECS/ELINCS List: 231-548-0
### 15. REGULATORY INFORMATION

**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

**HYDROCHLORIC ACID**
- CERCLA/SARA 313 Emission reporting: 1.0 %
- CERCLA/SARA Hazardous Substances and their Reportable Quantities: 5000 lb, 2270 kg
- CERCLA/SARA - Section 302 Extremely Hazardous TPQs: 500 lb
- EU EINECS/ELINCS List: 231-791-2

**Sodium chloride**
- 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: 231-598-3

**Sodium citrate**
- 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: 200-675-3

### 16. OTHER INFORMATION

**Text of CLP/GHS Classification abbreviations mentioned in Section 3**
- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Acute toxicity, oral-Cat.2; H300 - Fatal if swallowed
- Acute toxicity, dermal-Cat.2; H310 - Fatal in contact with skin
- Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
- Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

**Data Sources:** Safety data sheets for individual ingredients. Publicly available toxicity information.

**Reasons for Revision:** New data sheet.
Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet