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

Product Identifier

Material Name: Hydroxyethyl Starch in Sodium Chloride Injection (Hospira, Inc.)

Trade Name: VOLUMEN

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

Emergency telephone number:
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 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
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>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</td>
<td>**</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>
</tbody>
</table>

<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>Hydroxyethyl starch</td>
<td>9005-27-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>6</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</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 CLP/GHS abbreviations 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: None data available

Medical Conditions: None known

Aggravated by Exposure: None

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.
SAFETY DATA SHEET

Material Name: Hydroxyethyl Starch in Sodium Chloride Injection (Hospira, Inc.)
Revision date: 07-Oct-2016

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

Methods for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal.

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 product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Sodium chloride

- Latvia OEL - TWA: 5 mg/m³
- Lithuania OEL - TWA: 5 mg/m³

Sodium hydroxide

- ACGIH Ceiling Threshold Limit: 2 mg/m³
- Australia PEAK: 2 mg/m³
- Austria OEL - MAKs: 2 mg/m³
- Bulgaria OEL - TWA: 2.0 mg/m³
- Czech Republic OEL - TWA: 1 mg/m³
- Estonia OEL - TWA: 1 mg/m³
- France OEL - TWA: 2 mg/m³
- Greece OEL - TWA: 2 mg/m³
- Hungary OEL - TWA: 2 mg/m³
- Japan - OELs - Ceilings: 2 mg/m³
- Latvia OEL - TWA: 0.5 mg/m³
- OSHA - Final PELS - TWAs: 2 mg/m³
- Poland OEL - TWA: 0.5 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Exposure Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slovakia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>2 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

### HYDROCHLORIC ACID

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

**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 gloves (e.g. Nitrile, etc.) are 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:** 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

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**pH:** 3.5-7.0

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

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

**Partition Coefficient:** No data available

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

**Evaporation Rate (Gram/s):** No data available
SAFETY DATA SHEET

Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
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.
Known Clinical Effects: Serious allergic reactions, including anaphylaxis, have been reported. Adverse effects associated with therapeutic use include effects on cardiovascular system, blood clotting irregularities, bleeding, decreased red blood cell count (anemia), vomiting, headache, flu-like syndrome, swelling, muscle pain.

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

Hydroxyethyl starch
   Rat Oral LD50 > 50 g/kg

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

Sodium hydroxide
   Mouse IP LD50 40 mg/kg

HYDROCHLORIC ACID
   Rat Oral LD 50 238-277 mg/kg
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)
11. TOXICOLOGICAL INFORMATION

**Sodium chloride**
Eye Irritation  Rabbit  Moderate
Skin Irritation  Rabbit  Mild

**Sodium hydroxide**
Eye Irritation  Rabbit  Severe
Skin Irritation  Rabbit  Severe

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

**Hydroxyethyl starch**
Embryo / Fetal Development  Mouse  Intravenous  60 mL/kg  NOAEL  Not teratogenic
Embryo / Fetal Development  Rabbit  Intravenous  75 mL/kg  NOAEL  Not Teratogenic
Embryo / Fetal Development  Mouse Rat  Intraperitoneal  50 g/kg  NOAEL  Not Teratogenic

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

**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.

**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.

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

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

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

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

Sodium hydroxide
SAFETY DATA SHEET

Material Name: Hydroxyethyl Starch in Sodium Chloride
Injection (Hospira, Inc.)
Revision date: 07-Oct-2016

15. REGULATORY INFORMATION

| CERCLA/SARA 313 Emission reporting | Not Listed |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 1000 lb 454 kg |
| 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 5 Schedule 6 |
| EU EINECS/ELINCS List | 215-185-5 |

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 |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | |
| 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 5 Schedule 6 |
| EU EINECS/ELINCS List | 231-595-7 |

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H373 - May cause damage to organs through prolonged or repeated exposure

Data Sources: Safety data sheets for individual ingredients. Publicly available toxicity information.
Revision date: 07-Oct-2016

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