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

Product Identifier
- Material Name: Argatroban Injection (Hospira, Inc.)
- Trade Name: Not established
- 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
- Poisons Information Centre: 13 1126

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
- GHS - Classification
  Flammable liquids- Category 2

Label Elements
- Signal Word: Danger
- Hazard Statements: H225 - Highly flammable liquid and vapor

Precautionary Statements:
- P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
- P233 - Keep container tightly closed
- P280 - Wear protective gloves/protective clothing/eye protection/face protection
- P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
- P403 + P235 - Store in a well-ventilated place. Keep cool
- P501 - Dispose of contents/container in accordance with all local and national regulations
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

<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>Ethyl alcohol (ethanol)</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>Flam. Liq. 2 (H225)</td>
<td>40-50</td>
</tr>
<tr>
<td>Argatroban</td>
<td>74863-84-6</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>10</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>Water for Injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sorbitol crystalline - NF</td>
<td>50-70-4</td>
<td>200-061-5</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. For information on potential delayed effects, see Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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
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: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: Flammable liquid and vapor Fine particles (such as 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 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
Flammable liquid and vapor- keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after 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. Wash hands and any exposed skin after removal of PPE. 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
Refer to available public information for specific member state Occupational Exposure Limits.
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Ethyl alcohol (ethanol)**

<table>
<thead>
<tr>
<th>Country/Region</th>
<th>Exposure Limit</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH STEL</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>1000 ppm</td>
<td>1880 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAK</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>1000 ppm</td>
<td>1907 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>500 ppm</td>
<td></td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>500 ppm</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Netherlands OEL - TWA</td>
<td>260 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
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</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>500 ppm</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

**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.
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Solution</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>Mixture</td>
</tr>
<tr>
<td>Solvent Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting/Freezing Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling Point (°C)</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition Coefficient (Method, pH, Endpoint, Value)</td>
<td>No data available</td>
</tr>
<tr>
<td>Argatroban</td>
<td>No data available</td>
</tr>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water for Injection</td>
<td>No data available</td>
</tr>
<tr>
<td>Sorbitol crystalline - NF</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation Rate (Gram/s)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Pressure (kPa)</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor Density (g/ml)</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition Temperature (Solid) (°C):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (Solids):</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash Point (Liquid) (°C):</td>
<td>&lt;23 (Calculated)</td>
</tr>
<tr>
<td>Upper Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower Explosive Limits (Liquid) (% by Vol.):</td>
<td>No data available</td>
</tr>
</tbody>
</table>

Material Name: Argatroban Injection (Hospira, Inc.)
Revision date: 15-Dec-2016
Version: 1.0

PZ03263
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: As a precautionary measure, keep away from heat sources and electrostatic discharge. Fine particles (such as 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: Adverse effects associated with therapeutic use include decrease in blood pressure (hypotension), shortness of breath (dyspnea), vomiting, fever, diarrhea, chest pain, back pain, headache.

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

Argatroban
Rat Oral LD50 > 15,000 mg/kg

Ethyl alcohol (ethanol)
Mouse Oral LD50 3450 mg/kg
Rat Oral LD50 7060 mg/kg
Rat Inhalation LC50 10h 20,000ppm

Sorbitol crystalline - NF
Mouse Oral LD50 17,800 mg/kg
Rat Para-periosteal LD50 7100mg/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)

Argatroban
Skin Irritation Rabbit Negative
Skin Sensitization - LLNA Mouse Negative

Ethyl alcohol (ethanol)
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

Argatroban
11. TOXICOLOGICAL INFORMATION

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

Argatroban
- Bacterial Mutagenicity (Ames) Not specified Negative
- HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative
- Chromosome Aberration Hamster Lung Cells Negative
- Micronucleus Mouse Negative

Carcinogen Status: 
Carcinogenicity of the mixture has not been determined. Alcohol is listed as a carcinogen by IARC. The IARC monograph examining the carcinogenic potential of ethanol examined only alcoholic beverages. No other components are listed as carcinogens by IARC, US OSHA or NTP.

Ethyl alcohol (ethanol)
- IARC: Group 1 (Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

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

Toxicity:
- Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
  - Ethyl alcohol (ethanol) *Onchorhynchus mykiss* (Rainbow Trout) LC50/96h 12,900-15,300 mg/L

Persistence and Degradability:
- Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
  - Argatroban Activated sludge Ready 8-10% After 28 Day(s)
  - Ethyl alcohol (ethanol) Not Ready

Bio-accumulative Potential:
- Partition Coefficient: (Method, pH, Endpoint, Value)
  - 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.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 1170
UN proper shipping name: Ethanol solution
Transport hazard class(es): 3
Packing group: II

15. REGULATORY INFORMATION

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

Ethyl alcohol (ethanol)
   CERCLA/SARA 313 Emission reporting Not Listed
   California Proposition 65 carcinogen 4/29/2011 in alcoholic beverages
carcinogen 4/29/2011 in alcoholic beverages
developmental toxicity 10/1/1987 in alcoholic beverages
   Inventory - United States TSCA - Sect. 8(b) Present
   Australia (AICS): Present
   EU EINECS/ELINCS List 200-578-6

Argatroban
   CERCLA/SARA 313 Emission reporting Not Listed
   California Proposition 65 Not Listed
   EU EINECS/ELINCS List Not Listed

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

Sorbitol crystalline - NF
   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 200-061-5
16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

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

Reasons for Revision: New data sheet.

Revision date: 15-Dec-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