



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 15-Dec-2016

Version: 1.0

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## 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

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

### Emergency telephone number:

Poisons Information Centre: 13 1126

## 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

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**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**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Ethyl alcohol (ethanol)	64-17-5	200-578-6	Flam. Liq. 2 (H225)	40-50
Argatroban	74863-84-6	Not Listed	Not Listed	10

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Water for Injection	7732-18-5	231-791-2	Not Listed	*
Sorbitol crystalline - NF	50-70-4	200-061-5	Not Listed	*

**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**

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**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:** 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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Ethyl alcohol (ethanol)

ACGIH Threshold Limit Value (STEL)	1000 ppm
Australia TWA	1000 ppm
	1880 mg/m <sup>3</sup>
Austria OEL - MAKs	1000 ppm
	1900 mg/m <sup>3</sup>
Belgium OEL - TWA	1000 ppm
	1907 mg/m <sup>3</sup>
Bulgaria OEL - TWA	1000 mg/m <sup>3</sup>
Czech Republic OEL - TWA	1000 mg/m <sup>3</sup>
Denmark OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Estonia OEL - TWA	500 ppm
	1000 mg/m <sup>3</sup>
Finland OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
France OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	500 ppm
	960 mg/m <sup>3</sup>
Germany (DFG) - MAK	500 ppm
	960 mg/m <sup>3</sup>
Greece OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Hungary OEL - TWA	1900 mg/m <sup>3</sup>
Latvia OEL - TWA	1000 mg/m <sup>3</sup>
Lithuania OEL - TWA	500 ppm
	1000 mg/m <sup>3</sup>
Netherlands OEL - TWA	260 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	1000 ppm
	1900 mg/m <sup>3</sup>
Poland OEL - TWA	1900 mg/m <sup>3</sup>
Portugal OEL - TWA	1000 ppm
Romania OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Russia OEL - TWA	1000 mg/m <sup>3</sup>
Slovakia OEL - TWA	500 ppm
	960 mg/m <sup>3</sup>
Slovenia OEL - TWA	1000 ppm
	1900 mg/m <sup>3</sup>
Sweden OEL - TWAs	500 ppm
	1000 mg/m <sup>3</sup>
Switzerland OEL - TWAs	500 ppm
	960 mg/m <sup>3</sup>
Vietnam OEL - TWAs	1000 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.

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Personal Protective Equipment:</b>	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.
<b>Hands:</b>	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.)
<b>Eyes:</b>	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.)
<b>Skin:</b>	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.)
<b>Respiratory protection:</b>	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>	Solution	<b>Color:</b>	Clear
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		
<b>Melting/Freezing Point (°C):</b>	No data available		
<b>Boiling Point (°C):</b>	No data available.		
<b>Partition Coefficient: (Method, pH, Endpoint, Value)</b>			
<b>Argatroban</b>			
No data available			
<b>Ethyl alcohol (ethanol)</b>			
No data available			
<b>Water for Injection</b>			
No data available			
<b>Sorbitol crystalline - NF</b>			
No data available			
<b>Decomposition Temperature (°C):</b>	No data available.		
<b>Evaporation Rate (Gram/s):</b>	No data available		
<b>Vapor Pressure (kPa):</b>	No data available		
<b>Vapor Density (g/ml):</b>	No data available		
<b>Relative Density:</b>	No data available		
<b>Viscosity:</b>	No data available		
<b>Flammability:</b>			
<b>Autoignition Temperature (Solid) (°C):</b>		No data available	
<b>Flammability (Solids):</b>		No data available	
<b>Flash Point (Liquid) (°C):</b>		<23 (Calculated)	
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>		No data available	
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>		No data available	

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### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available
<b>Conditions to Avoid:</b>	As a precautionary measure, keep away from heat sources and electrostatic discharge. Fine particles (such as mists) may fuel fires/explosions.
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers
<b>Hazardous Decomposition Products:</b>	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 7060mg/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

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### 11. TOXICOLOGICAL INFORMATION

Reproductive & Fertility Rat Intravenous 27 mg/kg/day NOEL Negative  
Embryo / Fetal Development Rat Intravenous 27 mg/kg/day NOEL Not Teratogenic

#### 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)

*Oncorhynchus 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.

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### 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 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

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### 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  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

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**