



SAFETY DATA SHEET

Revision date 26-Dec-2021

Version 1.01

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Argatroban Injection (Hospira, Inc.)
Product Code(s) PZ03263
Trade Name: Not applicable
Chemical Family: Not determined

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product

1.3. 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

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Emergency Telephone - Poisons Information Centre: 13 1126

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Physical Hazards Flammable liquids Category 2

2.2. 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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2.3. Other hazards

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 require 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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Ethyl alcohol (ethanol) (CAS #: 64-17-5)	40-50	-	200-578-6	Flam. Liq. 2 (H225)	Not Listed	No data available	No data available
Argatroban (CAS #: 74863-84-6)	10		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified as hazardous	Not Listed	No data available	No data available
Sorbitol solution (CAS #: 50-70-4)	*		200-061-5	Not classified as hazardous	Not Listed	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Ethyl alcohol (ethanol) 64-17-5	7060	No data available	116.9 133.8	No data available	No data available
Argatroban 74863-84-6	>15,000	No data available	No data available	No data available	No data available
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Sorbitol solution 50-70-4	15900	No data available	No data available	No data available	No data available

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. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
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.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media Dry chemical, CO2, alcohol-resistant foam or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Flammable liquid and vapor. Fine particles (such as mists) may fuel fires/explosions.

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

5.3. Advice for firefighters

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Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Eliminate all sources of ignition and ventilate area using explosion-proof equipment. Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

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

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up 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.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on 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.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

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

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Ethyl alcohol (ethanol)

ACGIH TLV	STEL: 1000 ppm
Austria	1000 ppm 1900 mg/m ³ STEL 2000 ppm STEL 3800 mg/m ³
Bulgaria	1000 mg/m ³
Czech Republic	1000 mg/m ³ Ceiling: 3000 mg/m ³
Denmark	1000 ppm 1900 mg/m ³
Estonia	500 ppm 1000 mg/m ³ STEL: 1000 ppm STEL: 1900 mg/m ³
Finland	1000 ppm 1900 mg/m ³ STEL: 1300 ppm STEL: 2500 mg/m ³
France	1900 mg/m ³
Germany	200 ppm 380 mg/m ³ Ceiling / Peak: 800 ppm Ceiling / Peak: 1520 mg/m ³
Germany	200 ppm 380 mg/m ³
Hungary	1900 mg/m ³ STEL: 3800 mg/m ³
Ireland	STEL: 1000 ppm
Latvia	1000 mg/m ³
Netherlands	260 mg/m ³ STEL: 1900 mg/m ³ H*
Poland	1900 mg/m ³
Romania	1000 ppm 1900 mg/m ³ STEL: 5000 ppm STEL: 9500 mg/m ³
Russia	TWA: 1000 mg/m ³ MAC: 2000 mg/m ³
Slovakia	500 ppm 960 mg/m ³
Spain	STEL: 1000 ppm STEL: 1910 mg/m ³
Switzerland	500 ppm 960 mg/m ³ STEL: 1000 ppm STEL: 1920 mg/m ³
OSHA PEL	1000 ppm 1900 mg/m ³ (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m ³
United Kingdom	TWA: 1000 ppm TWA: 1920 mg/m ³ STEL: 3000 ppm STEL: 5760 mg/m ³

Sorbitol solution

Russia MAC: 10 mg/m³

Pfizer Occupational Exposure Band

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(OEB) Statement: The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

8.2. 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.

Environmental exposure controls No information available.

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.

Eye/face protection 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.).

Hand protection 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.).

Skin and body protection 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.)

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solution
Color	Clear
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

<u>Property</u>	<u>Values</u>
pH	No data available
Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	<23 °C
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available

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Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	No data available
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

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

9.2. Other information

No information available

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No data available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact No data available.

Sensitivity to Static Discharge No data available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid As a precautionary measure, keep away from heat sources and electrostatic discharge. Fine particles (such as mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

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(hypotension), shortness of breath (dyspnea), vomiting, fever, diarrhea, chest pain, back pain, headache.

Acute toxicity Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation Based on available data, the classification criteria are not met.
Skin corrosion/irritation Based on available data, the classification criteria are not met.
Respiratory or skin sensitization Based on available data, the classification criteria are not met.
STOT - single exposure Based on available data, the classification criteria are not met.
STOT - repeated exposure Based on available data, the classification criteria are not met.
Reproductive toxicity Based on available data, the classification criteria are not met.
Germ cell mutagenicity Based on available data, the classification criteria are not met.
Carcinogenicity Based on available data, the classification criteria are not met.
Aspiration hazard Based on available data, the classification criteria are not met.

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

Ethyl alcohol (ethanol)

Mouse Oral LD50 3450 mg/kg
Rat Oral LD50 7060 mg/kg
Rat Inhalation LC50 10h 20,000 ppm

Argatroban

Rat Oral LD50 > 15,000 mg/kg

Sorbitol solution

Rat Oral LD50 15,900 mg/kg
Mouse Oral LD50 17,800 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ethyl alcohol (ethanol)	= 7060 mg/kg (Rat)	-	= 116.9 mg/L (Rat) 4 h = 133.8 mg/L (Rat) 4 h
Water	> 90 mL/kg (Rat)	-	-
Sorbitol solution	= 15900 mg/kg (Rat)	-	-

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)

Ethyl alcohol (ethanol)

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Argatroban

Skin irritation Rabbit Negative
Skin Sensitization - LLNA Mouse Negative

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

Argatroban

Reproductive & Fertility Rat Intravenous 27 mg/kg/day NOAEL Negative
Embryo / Fetal Development Rat Intravenous 27 mg/kg/day NOAEL 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

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. Ethanol has been shown to be carcinogenic in long-term studies only when consumed as alcoholic beverage

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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

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

12.1. Toxicity

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

Ethyl alcohol (ethanol)

Oncorhynchus mykiss (Rainbow Trout) NPDES LC50 96 Hours 12,900 mg/L

Fingerling Trout NPDES LC50 24 Hours 11200 mg/L

Pimephales promelas (Fathead Minnow) NPDES LC50 96 Hours 14200 mg/L

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Argatroban

Activated sludge Ready 8-10 % After 28 Day(s)

12.3. Bioaccumulative potential

Bioaccumulation

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

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
Ethyl alcohol (ethanol)	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

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Section 13: DISPOSAL CONSIDERATIONS

13.1. 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 wastewater 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.

Section 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
Environmental Hazard(s): Not applicable

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Ethyl alcohol (ethanol)

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	carcinogen 7/1/1988 when associated with alcohol abuse carcinogen 4/29/2011 developmental toxicity 10/1/1987
TSCA	Present
EINECS	200-578-6
AICS	Present

Argatroban

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	231-791-2
AICS	Present

Sorbitol solution

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
EINECS	200-061-5
AICS	Present

Chemical name	French RG number	Title
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Ethyl alcohol (ethanol) 64-17-5	RG 84	-
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European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

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

Reason for revision Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 11 - Toxicology Information.

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Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this 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.