



SAFETY DATA SHEET

Revision date 13-Jun-2025

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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

Pfizer Ireland Pharmaceuticals
OSG Building
Ringaskiddy, Co. Cork.
Ireland
+353 21 4378701

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

OSHA Classification

Hazards not otherwise classified (HNOC)
Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200
Not applicable

2.2. Label elements



Signal word Danger

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Hazard statements

H225 - Highly flammable liquid and vapor

Precautionary Statements - EU (§28, 1272/2008)

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
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 local, regional, national, and international regulations as applicable

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

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 (EU Index 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 (603-002-00-5)	Flam. Liq. 2 (H225)	Not classified	No data available	No data available
Argatroban (CAS #: 74863-84-6)	10		Not Listed	Not classified	Not classified	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index 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	Not classified	No data available	No data available

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Sorbitol solution (CAS #: 50-70-4)	*		200-061-5	Not classified	Not classified	No data available	No data available
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Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	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

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

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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.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

5.3. Advice for firefighters

Special protective equipment and precautions 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 dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or 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

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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.

Ethyl alcohol (ethanol)

ACGIH TLV
Austria

STEL: 1000 ppm
TWA-TMW: 1000 ppm;
TWA-TMW: 1900 mg/m³;
STEL-KZGW: 2000 ppm (3 X 60 min);
STEL-KZGW: 3800 mg/m³ (3 X 60 min);

Bulgaria
Czech Republic

TWA: 1000 mg/m³;
1000 mg/m³
Ceiling: 3000 mg/m³

Denmark

TWA: 1000 ppm;
TWA: 1900 mg/m³;
STEL: 2000 ppm;
STEL: 3800 mg/m³;

Estonia

TWA: 500 ppm;
TWA: 1000 mg/m³;
STEL: 1000 ppm;
STEL: 1900 mg/m³;

Finland

TWA: 1000 ppm;
TWA: 1900 mg/m³;
STEL: 1300 ppm;
STEL: 2500 mg/m³;

France

Germany DFG

1900 mg/m³
TWA-MAK: 200 ppm; II(4);
TWA-MAK: 380 mg/m³; II(4);
Peak: 800 ppm;
Peak: 1520 mg/m³;

Germany TRGS

TWA-AGW; 200 ppm (exposure factor 4);
TWA-AGW; 380 mg/m³ (exposure factor 4);

Hungary

TWA-AK: 1000 ppm;
TWA-AK: 1900 mg/m³;
STEL-CK: 2000 ppm;
STEL-CK: 3800 mg/m³;

Ireland

Latvia

Netherlands

STEL: 1000 ppm;
TWA: 1000 mg/m³;
TWA: 137 ppm;
TWA: 260 mg/m³;
STEL: 1000 ppm;
STEL: 1900 mg/m³;

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Poland	Sk
Romania	TWA-NDS: 1900 mg/m ³ ; TWA: 1000 ppm; TWA: 1900 mg/m ³ ; STEL: 5000 ppm; STEL: 9500 mg/m ³ ; TWA: 1000 mg/m ³ MAC: 2000 mg/m ³
Russia	TWA: 500 ppm; TWA: 960 mg/m ³ ; Ceiling: 1920 mg/m ³ ; STEL (VLA-EC): 1000 ppm; STEL (VLA-EC): 1910 mg/m ³ ; TWA-MAK: 500 ppm; TWA-MAK: 960 mg/m ³ ; STEL-KZGW: 1000 ppm; STEL-KZGW: 1920 mg/m ³ ; TWA: 1000 ppm TWA: 1900 mg/m ³ (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m ³
Slovakia	TWA: 1000 ppm; TWA: 1920 mg/m ³ ; STEL: 3000 ppm; STEL: 5760 mg/m ³ ;
Spain	
Switzerland	
OSHA PEL	
United Kingdom	MAC: 10 mg/m ³
Sorbitol solution	
Russia	

Pfizer Occupational Exposure Band (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.

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

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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.).

Thermal hazards

No information available.

Environmental exposure controls

No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	Solution
Physical state	Liquid
Color	Clear
Odor	No information available.
Odor threshold	No information available

Property

Values

Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	<23 °C (Calculated)
Autoignition temperature	No data available
Decomposition temperature	
SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

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

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

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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 information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information 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 (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

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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

Ethyl alcohol (ethanol)

IARC

NTP

Group 1

Known

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects

No information available.

Section 12: ECOLOGICAL INFORMATION

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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 Based on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment
Ethyl alcohol (ethanol)	Not PBT/vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects

No information available.

PMT or vPvM properties

Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

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.

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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

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
	Developmental
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

National regulations

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

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

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TRGS 905

Not applicable

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Mutagens	Netherlands - List of Reproductive Toxins
Ethyl alcohol (ethanol) 64-17-5	Present	-	Fertility Category 1A Development Category 1A Can be harmful via breastfeeding

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable

Storage of Hazardous Material Not applicable

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable

Major Accidents Ordinance SR 814.012 Not applicable

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 (EU) 2024/590

Not applicable.

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Ethyl alcohol (ethanol) 64-17-5	Product-type 1: Human hygiene Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals Product-type 4: Food and feed area

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

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

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

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

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

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TCSI - Taiwan Chemical Substance Inventory

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 any hazard and/or precautionary statements referred to under Sections 2-15

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.