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

1.1. Product identifier

Product Name Cefazolin for Injection (Hospira, Inc.)

Product Code(s) PZ03062
Trade Name: Not applicable

Chemical Family: Cephalosporin antibiotic

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

Recommended Use Pharmaceutical product used as antibiotic agent

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

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Respiratory sensitizationCategory 1Skin sensitizationCategory 1

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 H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H317 - May cause an allergic skin reaction

Precautionary Statements - EU (§28 1272/2008)

Precautionary Statements - EU (§28, P272 - Contaminated work clothing should not be allowed out of the workplace

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray

P280 - Wear protective gloves/protective clothing/eye protection/face protection P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position

comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or

doctor/physician

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention P362 + P364 - Take off contaminated clothing and wash it before reuse

P501 - Dispose of contents/container in accordance with local, regional, national, and

international regulations as applicable

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for this substance (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 active substance or its intermediates 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

Hazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Cefazolin (CAS #: 25953-19-9)	100		247-362-8	[CLP] Resp. Sens. 1 (H334) Skin Sens. 1 (H317)	Not classified	No data available	No data available

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

Acute Toxicity Estimate No information available

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Chemical name	Oral LD50 mg/kg	Dermal LD50	Inhalation LC50 - 4	Inhalation LC50 - 4	Inhalation LC50 - 4
		mg/kg	hour - dust/mist - mg/L	hour - vapor - mg/L	hour - gas - ppm
Cefazolin	11000	No data available	No data available	No data available	No data available
25953-19-9					

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

Additional information

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

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. 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.

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 or water spray.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

Fine particles (such as dust and mists) may fuel fires/explosions.

Hazardous combustion products Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and

other sulfur-containing compounds.

Explosion data

Sensitivity to mechanical impact No information available. **Sensitivity to static discharge** No information available.

5.3. Advice for firefighters

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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

Personnel involved in clean-up should wear appropriate personal protective equipment (see Personal precautions

Section 8). Minimize exposure.

Use personal protection recommended in Section 8. For emergency responders

6.2. Environmental precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be **Environmental precautions**

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 or leak. Collect spilled material by a method that controls dust

generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated

surface thoroughly.

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

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 Minimize dust generation and accumulation. Avoid breathing

> dust/fume/gas/mist/vapors/spray. 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.

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

7.2. Conditions for safe storage, including any incompatibilities

Store as directed by product packaging. **Storage Conditions**

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Cefazolin

Germany TRGS DS

RS

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Russia MAC: 0.3 mg/m³

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 controlsGeneral room ventilation is adequate unless the process generates dust, mist or fumes.

Engineering controls should be used as the primary means to control exposures. 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

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

Physical state Powder Color White

OdorNo information available.Odor thresholdNo information available

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Values **Property**

No data available Melting point / freezing point No data available Boiling point or initial boiling point and boiling range No data available Flammability (solid, gas)

Lower and upper explosion limit/flammability limit

Lower explosion limit No data available No data available **Upper explosion limit** No data available Flash point

No data available **Autoignition temperature**

Decomposition temperature

No data available SADT (°C) No data available pН 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

9.2. Other information

Molecular formula C14H14N8O4S3

Molecular weight 454.5

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.

Hazardous polymerization Will not occur.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and 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

Short term Inhalation of significant quantities of this substance could result in the health effects

> described in 'Known clinical effects'. Ingestion of this material can cause effects similar to those seen in clinical use including cholinergic crisis, characterized by severe nausea, vomiting, salivation, sweating, slow heart rate, low blood pressure, muscle weakness,

respiratory depression.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea

> and abdominal pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Pseudomembranous colitis (manifested by watery diarrhea, urge to defecate, abdominal cramps, low-grade fever, bloody stools, and abdominal pain) may also occur. Concomitant administration of aminoglycosides and cephalosporins has caused nephrotoxicity. Individuals who are sensitive to beta lactam antibiotics, both penicillins and cephalosporins, may experience contact or systemic

hypersensitivity and anaphylaxis upon exposure to this drug.

Acute toxicity

Serious eye damage/eye irritation

Skin corrosion/irritation Respiratory or skin sensitization

STOT - single exposure STOT - repeated exposure Reproductive toxicity Germ cell mutagenicity

Carcinogenicity **Aspiration hazard** Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.

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

Rat Oral LD50 > 11000 mg/kg

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Chemical name	Oral LD50	Dermal LD50	Inhalation LC50			
Cefazolin	> 11000 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)

Cefazolin

Skin Sensitization - GPMT Guinea Pig Negative

Skin Irritation / Sensitization Hypersensitivity reactions, including cross reactions (with penicillins) and anaphylaxis, are

common among the cephalosporins.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Cefazolin

90 Day(s) Rat Oral 20 mg/kg/day NOEL Gastrointestinal System

3 Month(s) Dog Subcutaneous 250 mg/kg/day NOAEL No effects at maximum dose

6 Month(s) Dog Subcutaneous 125 mg/kg/day NOAEL No effects at maximum dose

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

Embryo / Fetal Development Rat Oral 10 mg/kg/day NOEL Maternal toxicity, Not teratogenic

2 Generation Reproductive Toxicity Rat Subcutaneous Dose not specified No effects at maximum dose

Embryo / Fetal Development Rabbit Subcutaneous Dose not specified Not Teratogenic

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

Cefazolin

In Vitro Bacterial Mutagenicity (Ames) Salmonella, E. coli Negative

In Vitro Micronucleus Mouse Negative

In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative

Not listed as a carcinogen by IARC, NTP or US OSHA. Carcinogenicity

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

The environmental characteristics of this material have not been fully evaluated. Releases **Environmental Overview:**

to the environment should be avoided.

12.1. Toxicity

12.2. Persistence and degradability

No information available. Persistence and degradability

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

No information available. Mobility in soil

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment Based on available data, the classification criteria are not met.

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

No information available. Other adverse effects

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.

Section 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.

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Not applicable
Not applicable
Not applicable
Not applicable
Not applicable

Section 15: REGULATORY INFORMATION

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

Cefazolin

CERCLA/SARA Section 313 de minimus % Not Listed
California Proposition 65 Not Listed
EINECS 247-362-8
Standard for Uniform Scheduling of Medicines and Schedule 4

Poisons (SUSMP)

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018

Storage of Hazardous Material

WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20

Not applicable
Not applicable

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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.

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

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

DSL/NDSL - 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

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

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled H317 - May cause an allergic skin reaction

Data Sources: Publicly available toxicity information.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on

Ingredients. Updated Section 7 - Handling and Storage. Updated Section 11 - Toxicology

Information. Updated Section 12 - Ecological Information.

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