

Pfizer Ltd

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### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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**Material Name: Ceftazidime for Injection** 

Trade Name: Not applicable

Chemical Family: Cephalosporin antibiotic

Intended Use: Pharmaceutical product used as antibiotic agent

### 2. HAZARDS IDENTIFICATION

**Appearance:** White to off-white powder

Signal Word: DANGER

Statement of Hazard: May cause allergic skin reaction.

May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

**Additional Hazard Information:** 

**Known Clinical Effects:** 

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. 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. 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.

EU Indication of danger: Harmful

Irritant

**EU Hazard Symbols:** 

**EU Risk Phrases:** 

R42 - May cause sensitization by inhalation. R43 - May cause sensitization by skin contact.

PZ01117

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### 2. HAZARDS IDENTIFICATION

Australian Hazard Classification (NOHSC):

Non-Dangerous Goods. Hazardous Substance.

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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	<b>EU EINECS/ELINCS List</b>	<b>EU Classification</b>	%		
Ceftazidime	78439-06-2	Not Listed	Xn;R42/43	88-90		

Ingredient	CAS Number	<b>EU EINECS/ELINCS List</b>	<b>EU Classification</b>	%
Sodium carbonate monohydrate	5968-11-6	Not Listed	Not Listed	*

Additional Information: Ingredient(s) indicated as hazardous have been assessed under standards for workplace

safety.

For the full text of the R phrases mentioned in this Section, see Section 16

#### 4. 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.

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.

# 5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other

sulfur-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn

out gear.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

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## 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that

controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of

dry solids. Clean spill area thoroughly.

Measures for Environmental

**Protections:** 

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to

avoid environmental release.

**Additional Consideration for Large** 

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

**General Handling:** Minimize dust generation and accumulation. Avoid breathing dust. When handling, use

> appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

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

# 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium carbonate monohydrate

Czech Republic OEL - TWA Listed Romania OEL - TWA Listed

Ceftazidime

Pfizer Occupational Exposure OEB 1 - Sensitizer (control exposure to the range of >1000ug/m³ to < 3000ug/m³)

Band (OEB):

**Engineering Controls:** 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.

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

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental

legislation.

Refer to applicable national standards and regulations in the selection and use of personal **Personal Protective Equipment:** 

protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk

processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and

for bulk processing operations.

Respiratory protection: If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear

an appropriate respirator with a protection factor sufficient to control exposures to the bottom of

the OEB range.

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Powder Color: White to off-white

Molecular Formula: Mixture **Molecular Weight:** Mixture

Will not occur Polymerization:

### 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions. **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

#### 11. TOXICOLOGICAL INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual

ingredients.

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

Ceftazidime

Rat Intravenous LD50 6100 mg/kg Rat Subcutaneous LD50 20 g/kg Rat Oral LD50 > 20,000 mg/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)

Ceftazidime

Skin Irritation Rabbit Non-irritating Eye Irritation Rabbit Slight

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

common among the cephalosporins.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Ceftazidime

Fertility and Embryonic Development Rat No route specified 40 x human dose NOAEL No effects at maximum dose

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

Ceftazidime

Bacterial Mutagenicity (Ames) Salmonella Negative

Micronucleus Mouse Negative

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. **Carcinogen Status:** 

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### 12. ECOLOGICAL INFORMATION

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

the environment should be avoided.

# 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.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

EU Symbol: Xn EU Indication of danger: Harmful

Irritant

**EU Risk Phrases:** 

R42 - May cause sensitization by inhalation. R43 - May cause sensitization by skin contact.

**EU Safety Phrases:** 

S22 - Do not breathe dust. S24 - Avoid contact with skin.

S36/37 - Wear suitable protective clothing and gloves.

#### **OSHA Label:**

**DANGER** 

May cause allergic skin reaction.

May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

#### Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A Class D, Division 2, Subdivision B

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# 15. REGULATORY INFORMATION



Sodium carbonate monohydrate

Australia (AICS): Listed

# **16. OTHER INFORMATION**

### Text of R phrases mentioned in Section 3

R42 - May cause sensitization by inhalation. R43 - May cause sensitization by skin contact.

**Data Sources:** Publicly available toxicity information.

Updated Section 8 - Exposure Controls / Personal Protection. Reasons for Revision:

Prepared by: Product Stewardship Hazard Communications

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**