



# SAFETY DATA SHEET

Revision date 11-Dec-2023

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

### 1.1. Product identifier

**Product Name** Zosyn Galaxy (Piperacillin and Tazobactam Injection) in Galaxy® Containers (PL 2040 Plastic)

**Product Code(s)** WP00020

**Synonyms** (Piperacillin and Tazobactam Injection) in Galaxy® Containers (PL 2040 Plastic)

**Trade Name:** ZOSYN

**Chemical Family:** Penicillin

### 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

Pfizer Inc  
66 Hudson Boulevard East  
New York, New York 10001  
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

GHS - Classification: Regulated according to Regulation (EC) 1272/2008 and/or other applicable regulations.

**Respiratory sensitization** Category 1 - (H334)

**Skin sensitization** Category 1 - (H317)

### 2.2. Label elements

**Signal word** Danger

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

**Precautionary Statements** P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P285 - In case of inadequate ventilation wear respiratory protection  
P271 - Use only outdoors or in a well-ventilated area  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing  
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician

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P302+ P352 - IF ON SKIN: Wash with plenty of soap and water  
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
P321 - Specific treatment (see supplemental first aid instructions on this label)  
P363 - Wash contaminated clothing before reuse



## 2.3. 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)
Piperacillin sodium (CAS #: 59703-84-3)	85		261-868-6	Resp. Sens.1 (H334) Skin Sens.1 (H317)	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)
Tazobactam Sodium (CAS #: 89785-84-2)	10		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Sodium citrate (CAS #: 68-04-2)	*	-	200-675-3	Not classified as hazardous	Not Listed	No data available	No data available
Disodium EDTA (dihydrate) (CAS #: 6381-92-6)	*	-	Not Listed	Not classified as hazardous	Not Listed	No data available	No data available
Water	*	-	231-791-2	Not classified	Not Listed	No data	No data

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(CAS #: 7732-18-5)				as hazardous		available	available
Dextrose (CAS #: 14431-43-7)	*		Not Listed	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

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
Piperacillin sodium 59703-84-3	10000	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

## Additional information

\* Proprietary

Non-hazardous ingredients provided for completeness. 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.

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>Inhalation</b>	Remove to fresh air. Seek immediate medical attention/advice.
<b>Eye contact</b>	Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.
<b>Skin contact</b>	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.
<b>Ingestion</b>	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

<b>Most important symptoms and effects</b>	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

<b>Note to physicians</b>	None.
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## Section 5: FIRE-FIGHTING MEASURES

### 5.1. Extinguishing media

<b>Suitable Extinguishing Media</b>	Use carbon dioxide, dry chemical, or water spray.
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## 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.

## 5.3. Advice for firefighters

### Special protective equipment for fire-fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

## Section 6: ACCIDENTAL RELEASE MEASURES

### 6.1. Personal precautions, protective equipment and emergency procedures

#### Personal precautions

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 spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

#### 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

Minimize generating airborne mists and vapors. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). 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 drug product.

## Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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## 8.1. Control parameters

### 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.

#### Piperacillin sodium

Pfizer Occupational Exposure Band (OEB):

OEB 1 - Sensitizer (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### Tazobactam Sodium

Pfizer Occupational Exposure Band (OEB):

OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

## 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

Frozen Solution

#### Color

No information available

#### Odor

No information available.

#### Odor threshold

No information available

#### Molecular formula

Mixture

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## Molecular weight

Mixture

### Property

### Values

pH

No data available

Melting point / freezing point

No data available

Boiling point / boiling range

Flash point

No information available

Evaporation rate

No data available

Flammability (solid, gas)

No data available

Flammability Limit in Air

Upper flammability limit:

No data available

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

## 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

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

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**Hazardous decomposition products** No data available.

## Section 11: TOXICOLOGICAL INFORMATION

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

<b>General Information:</b>	The information included in this section describes the potential hazards of the individual ingredients
<b>Short term</b>	Individuals who are allergic to penicillin antibiotics could have allergic reaction, possibly severe (anaphylactic). If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.
<b>Known Clinical Effects:</b>	May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. 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.
<b>Acute toxicity</b>	Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>	Based on available data, the classification criteria are not met.
<b>Skin corrosion/irritation</b>	Based on available data, the classification criteria are not met.
<b>Respiratory or skin sensitization</b>	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction. Classification is based on mixture calculation methods based on component data.
<b>STOT - single exposure</b>	Based on available data, the classification criteria are not met.
<b>STOT - repeated exposure</b>	Based on available data, the classification criteria are not met.
<b>Reproductive toxicity</b>	Based on available data, the classification criteria are not met.
<b>Germ cell mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.

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

##### **Piperacillin sodium**

Rat Oral LD50 > 10 g/kg

##### **Tazobactam Sodium**

Mouse Oral LD50 > 5000 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Piperacillin sodium	> 10 g/kg ( Rat )	-	-
Water	> 90 mL/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.

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

##### **Piperacillin sodium**

Reproductive & Fertility Rat Oral 0.5 times human dose NOAEL No effects at maximum dose

Reproductive & Fertility Mouse Oral 0.5 times human dose NOAEL No effects at maximum dose

Embryo / Fetal Development Rat No route specified Dose not specified Not Teratogenic

Embryo / Fetal Development Mouse No route specified Not Teratogenic

##### **Tazobactam Sodium**

Reproductive & Fertility Rat Oral 3 times human dose NOAEL No effects at maximum dose

Embryo / Fetal Development Rat Oral 14 times human dose NOAEL Not Teratogenic, No effects at maximum dose

Embryo / Fetal Development Mouse Oral 6 times human dose NOAEL Not Teratogenic, No effects at maximum dose

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

##### **Piperacillin sodium**

Bacterial Mutagenicity (Ames) *Salmonella* Negative

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*In Vivo* Chromosome Aberration Mouse Bone Marrow Negative

## **Tazobactam Sodium**

Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative

Mammalian Cell Mutagenicity Chinese Hamster Ovary (CHO) cells Negative

*In Vitro* Cytogenetics Hamster Lung Cells Negative

*In Vivo* Chromosome Aberration Mouse Negative

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

## **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:** The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

### **12.1. Toxicity**

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

##### **Tazobactam Sodium**

*Daphnia magna* (Water Flea) LC50 48 hours > 8.5 mg/L

### **12.2. Persistence and degradability**

**Persistence and degradability** No information available.

### **12.3. Bioaccumulative potential**

**Bioaccumulation** No information available.

### **12.4. Mobility in soil**

**Mobility in soil** No information available.

### **12.5. Results of PBT and vPvB assessment**

#### **PBT and vPvB assessment**

Chemical name	PBT and vPvB assessment
Piperacillin sodium	The substance is not PBT / vPvB
Sodium citrate	The substance is not PBT / vPvB PBT assessment does not apply
Disodium EDTA (dihydrate)	The substance is not PBT / vPvB

### **12.6. Endocrine disrupting properties**



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**Endocrine disrupting properties** No information available.

## **12.7. Other adverse effects**

No information available.

## **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.

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

<b>UN number:</b>	Not applicable
<b>UN proper shipping name:</b>	Not applicable
<b>Transport hazard class(es):</b>	Not applicable
<b>Packing group:</b>	Not applicable
<b>Environmental Hazard(s):</b>	Not applicable
<b>Special precautions for user:</b>	Not applicable

## **Section 15: REGULATORY INFORMATION**

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

Piperacillin sodium

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>EINECS</b>	261-868-6

Tazobactam Sodium

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

Sodium citrate

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed
<b>TSCA</b>	Present
<b>EINECS</b>	200-675-3
<b>AICS</b>	Present
<b>Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)</b>	Schedule 5

Disodium EDTA (dihydrate)

<b>CERCLA/SARA Section 313 de minimus %</b>	Not Listed
<b>California Proposition 65</b>	Not Listed

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

## 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

Sensitization, skin-Cat.1; H317 - May cause an allergic skin reaction. Sensitization, respiratory-Cat.1; H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Data Sources:

Pfizer proprietary drug development information. Publicly available toxicity information.

### Reason for revision

Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory Information.

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Updated Section 16 - Other Information.

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**Prepared By** Pfizer Global Environment, Health, and Safety

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