
	Piperacillin And Tazobactam for Injection		Safety Data Sheet (SDS)	
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Section 1 - Identification

- (a) **Product Identifier:** Piperacillin And Tazobactam for Injection
- (b) **Product Code:** 70860-120
70860-121
70860-122
70860-123
- Common/Trade Name:** Zosyn
- Chemical Name(s):** **Piperacillin Sodium:** sodium (2S,5R,6R)-6-[(R)-2-(4-ethyl-2,3-dioxo-1-piperazine-carboxamido)-2-phenylacetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate
- Tazobactam Sodium:** sodium (2S,3S,5R)-3-methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate-4,4-dioxide
- Chemical Family:** Penicillin/Antibiotic Agent
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials (Single dose, Pharmacy Bulk Package)
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **Classification:** **GHS:**
Respiratory Sensitization: Category 1
Skin Sensitization: Category 1
- US OSHA:**
Physical Hazard: Combustible Dust

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	Danger
Symbol:	
Hazard Statements:	H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled H317 - May cause an allergic skin reaction May form combustible dust concentrations in air
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 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

(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

Single-dose Vials

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
sodium (2S,3S,5R)-3-methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate-4,4-dioxide	Piperacillin sodium	2g/20 mL vial 3g/30 mL vial 4g/50 mL vial	59703-84-3	N/A*

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sodium (2S,3S,5R)-3-methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate-4,4-dioxide	Tazobactam Sodium	250mg/20 mL vial 375mg/30 mL vial 500mg/50 mL vial	89785-84-2	N/A*
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Pharmacy Bulk Pack


(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
sodium (2S,3S,5R)-3-methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate-4,4-dioxide	Piperacillin sodium	36 g/250 mL vial	59703-84-3	N/A*
sodium (2S,3S,5R)-3-methyl-7-oxo-3-(1H-1,2,3-triazol-1-ylmethyl)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate-4,4-dioxide	Tazobactam Sodium	4.5 g/250 mL vial	89785-84-2	N/A*

*Piperacillin and tazobactam for injection is a monosodium salt of piperacillin and a monosodium salt of tazobactam containing a total of 2.35 mEq (54 mg) of sodium (Na⁺) per gram of piperacillin in the combination product.

Section 4 – First Aid Measures

Eye Exposure: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

Skin Exposure: 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.

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- 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.
- Injection:** See patient package insert in shipping carton for complete information.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.
- Notes to physician** Treat symptomatically. See patient package insert in shipping carton for complete information.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Use carbon dioxide, dry chemical, or water spray.
- (b) **Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
- (c) **Special Protective Equipment / Precautions:** 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

- Spill:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.
- 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.
- Release to Air:** Not available.
- Release to Water:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental

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Section 7 - Handling and Storage

General Handling: Minimize dust generation and accumulation. 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.

Storage Conditions: Prior to Reconstitution: Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits


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 OEB:** OEB 1 – Sensitizer (control exposure to the range of 1000ug/m³ to 3000ug/m³)
- **Tazobactam Sodium OEB:** OEB 1 – Sensitizer (control exposure to the range of 1000ug/m³ to 3000ug/m³)

Compound	Issuer	Type	Exposure Limit
Piperacillin Sodium	OSHA	TLV	NE
	ACGIH	PEL	NE
	----	STEL	NE
Tazobactam Sodium	OSHA	TLV	NE
	ACGIH	PEL	NE
	----	STEL	NE

(b) Engineering Controls

Ventilation: Mechanical exhaust. 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.


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(c) Individual Protection Measures

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.)
Eye 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.)
Skin 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.)
Other 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.
Additional Exposure Precautions:	None available

Section 9 - Physical and Chemical Properties

(a) Appearance	White to off-white sterile, powder
(b) Odor	Not available
(c) Odor Threshold	Not available
(d) pH	Not available
(e) Melting Point:	Not available
(f) Initial Boiling Point:	Not available
(g) Flash Point	Not available
(h) Evaporation Rate:	Not available
(i) Flammability	Not available
(j) Upper Lower Flammability or Explosion	Not available
(k) Vapor Pressure:	Not available

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(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Not available
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	No data available.
(b)	Chemical Stability	The product is stable under normal conditions of use.
(c)	Possibility of Hazardous Reactions	None known.
(d)	Conditions to Avoid	Fine particles (such as dust and mists) may fuel fires/explosions.
(e)	Incompatible Materials	As a precautionary measure, keep away from strong oxidizers.
(f)	Hazardous Decomposition Products	None known.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Not available.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	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.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	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.

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(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Tazobactam Sodium	LD ₅₀	Oral	Mouse	> 5000 mg/kg
Piperacillin sodium	LD ₅₀	Oral	Rat	> 10 g/kg

(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

(a) Ecotoxicity	<p>The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.</p> <p><u>Aquatic Toxicity:</u> (Species, Method, End Point, Duration, Result)</p> <p>Tazobactam Sodium</p> <table border="1" style="width: 100%;"> <tr> <td><i>Daphnia magna</i> (Water Flea)</td> <td>LC50</td> <td>48 Hours</td> <td>> 8.5 mg/L</td> </tr> </table>	<i>Daphnia magna</i> (Water Flea)	LC50	48 Hours	> 8.5 mg/L
<i>Daphnia magna</i> (Water Flea)	LC50	48 Hours	> 8.5 mg/L		
(b) Persistence and degradability	No data available				
(c) Bioaccumulative potential	No data available				
(d) Mobility in soil	No data available				
(e) Other Adverse Effects	No data available				


Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

DOT: Not regulated for transport.
IATA: Not regulated for transport.
IMDG: Not regulated for transport.

(a) UN Number	Not Available
(b) UN Proper Shipping Name	Not Available

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(c)	Transport Hazard Class(es)	Not Available
(d)	Packing Group	Not Available
(e)	Environmental Hazards	Not Available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g)	Special Precautions	Not Available

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA: Not listed
 CERCLA - Not on this list
 SARA 302 - Not on this list
 SARA 304: Not regulated
 SARA 313 - Not on this list

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division
 10 N. Martingale Road, Suite 230
 Schaumburg, IL 60173
 847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number

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CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS031

Revision: 01

Title: Piperacillin And Tazobactam for Injection

All dates and times are in Eastern Standard Time.

PipTaz SDS

Change Request

Name/Signature	Title	Date	Meaning/Reason
Emily Means (EMEANS)	QA Document Specialist		
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Michael Scribner (MSCRIBNER)	Director of Corporate Quality	18 Feb 2019, 03:07:32 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
John Andre (JANDRE)	Regulatory Affairs Consultant	18 Feb 2019, 03:53:04 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	19 Feb 2019, 02:21:03 PM	Approved