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Section 1 - Identification

- (a) **Product Identifier:** Penicillin G Potassium, USP for Injection
- (b) **Product Code:** 70860-126
70860-127
- Common/Trade Name:** Penicillin G
- Chemical Name(s):** 4-Thia-1-azabicyclo [3.2.0]heptane-2-carboxylic acid,3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-, monopotassium salt, [2S-(2 α , 5 α , 6 β)]
- Chemical Family:** Antibiotic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Single Dose Vial
- (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
- OSHA:**
Physical Hazard: Combustible dust

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
Signal Word:	Danger
Symbol:	

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Hazard Statements:	<p>H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled</p> <p>H317 - May cause an allergic skin reaction may form combustible dust concentrations in air</p>
Precautionary Statements:	<p>P261 - Avoid breathing dust/fume/gas/mist/vapors/spray</p> <p>P272 - Contaminated work clothing must not be allowed out of the workplace</p> <p>P280 - Wear protective gloves/protective clothing/eye protection/face protection</p> <p>P285 - In case of inadequate ventilation wear respiratory protection</p> <p>P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing</p> <p>P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician</p> <p>P302+ P352 - IF ON SKIN: Wash with plenty of soap and water</p> <p>P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention</p> <p>P363 - Wash contaminated clothing before reuse</p>

(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
4-Thia-1-azabicyclo [3.2.0]heptane-2-carboxylic acid,3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-, monopotassium salt, [2 <i>S</i> -(2 <i>α</i> , 5 <i>α</i> , 6 <i>β</i>)]	Penicillin G	5,000,000 (5 million) units/vial And 20,000,000 (20 million) units/vial	113-98-4	N/A
Sodium Citrate 4.0-5.0%	Sodium Citrate	q.s.	68-04-2	N/A

Note: Finished product also contains antioxidant and preservative components as required. Sodium Citrate used as a buffering agent to adjust pH.


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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.
- 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:** None.

Section 5 – Fire-fighting Measures

- (a) **Extinguishing Media** Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO₂.
- (b) **Hazardous Combustion Products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.
Fine particles (such as dust and mists) may fuel fires/explosions.
- (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.

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Section 6 – Accidental Release Measures

Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Spill: 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.

For large spills, non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Environmental Precautions: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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. 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: Store at 20° to 25°C (68° to 77° F) [see USP Controlled Room Temperature] and protect from light.


Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Penicillin G Potassium	OSHA	TLV	NE
	ACGIH	PEL	NE

(b) 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.


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(c) Individual Protection Measures

Respiratory Protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eye Protection:	Wear safety glasses or goggles if eye contact is possible. Approved eye protection (e.g., bearing the ANSI Z87 stamp) is preferred.
Skin Protection:	<p>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 ANSI 103 or international equivalent.)</p> <p>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.)</p>
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 lyophilized cake or powder
(b) Odor	Not available
(c) Odor Threshold	Not available
(d) pH	6.0-8.5
(e) Melting Point:	Not available
(f) Initial Boiling Point:	Not available
(g) Flash Point	Not available
(h) Evaporation Rate:	Not available

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(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Not available
(o)	Partition Coefficient: (Method, pH, Endpoint, Value)	1.83
(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	No dangerous reaction known under conditions of normal use.
(d)	Conditions to Avoid	None known.
(e)	Incompatible Materials	As a precautionary measure, keep away from strong oxidizers
(f)	Hazardous Decomposition Products	No data available

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Ingestion, skin, eyes.
(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.

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(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
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(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Penicillin G Potassium	LD ₅₀	Oral	Mouse	6257 mg/kg
Penicillin G Potassium	LD ₅₀	Oral	Rat	8900 mg/kg
Penicillin G Potassium	LD ₅₀	Oral	Rabbit	5848 mg/kg

(e) Hazardous Chemical Listings


NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information

		<u>Aquatic Toxicity:</u>			
(a) Ecotoxicity		Species	Method, Endpoint	Duration	Result
		<i>Daphnia magna</i> (Water Flea)	LC ₅₀	48 Hours	> 1000 mg/L
		<i>Nitzschia fonticola</i> (Diatom)	LC ₅₀	630 Days	2000 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		No data available			

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Section 13 - Disposal Considerations

Waste Disposal: 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.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a)	UN Number	N/A
(b)	UN Proper Shipping Name	N/A
(c)	Transport Hazard Class(es)	N/A
(d)	Packing Group	N/A
(e)	Environmental Hazards	N/A
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	N/A
(g)	Special Precautions	N/A

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: Exempt
 CERCLA – N/A
 SARA 302 - N/A
 SARA 313 - N/A

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

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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
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

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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: SDS033

Revision: 01

Title: SDS033-Penicillin G Potassium, USP for Inj

All dates and times are in Eastern Standard Time.

Penicillin G Potassium, USP for Inj SDS

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	Director of Corporate Quality		
Michael Spengler (MSPENGLER)	QC Applications Specialist		
Christopher Martensen (CMARTENSEN)	Quality Engineer-CSV		
Emily Means (EMEANS)	QA Document Specialist	01 Aug 2019, 04:37:03 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	07 Aug 2019, 11:45:47 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	07 Aug 2019, 11:46:26 AM	Approved