

SAFETY DATA SHEET

Amoxicillin for Oral Suspension USP, 125 mg/5ml, 200 mg/5ml, 250 mg/5ml & 400 mg/5ml



Section 1. Identification

- GHS product identifier** : Amoxicillin for Oral Suspension USP, 125 mg/5ml, 200 mg/5ml, 250 mg/5ml & 400 mg/5ml
- Chemical name** : 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[amino(4-hydroxyphenyl)acetyl]amino-3,3-dimethyl-7-oxo-, trihydrate 2S-[2 α , [5 α , 6 β (S*)]]-(2S,5R,6R)-6-[(R)-(-)-2-Amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate
- Other means of identification** : Not available.
- Product code** : **Amoxicillin for Oral Suspension USP, 125 mg/5ml**
 Pack of 80 ml: 0143-9888-80
 Pack of 100 ml: 0143-9888-01
 Pack of 150 ml: 0143-9888-15
- Amoxicillin for Oral Suspension USP, 250 mg/5ml**
 Pack of 80 ml: 0143-9889-80
 Pack of 100 ml: 0143-9889-01
 Pack of 150 ml: 0143-9889-15
- Amoxicillin for Oral Suspension USP, 200 mg/5ml**
 Pack of 50 ml: 0143-9886-50
 Pack of 75 ml: 0143-9886-75
 Pack of 100 ml: 0143-9886-01
- Amoxicillin for Oral Suspension USP, 400 mg/5ml**
 Pack of 50 ml: 0143-9887-50
 Pack of 75 ml: 0143-9887-75
 Pack of 100 ml: 0143-9887-01
- Product type** : Solid.
- Container information** : **Amoxicillin for Oral Suspension USP, 200 mg/5ml, 400 mg/5ml**
Pack of 50 ml :
 50ml HDPE angled bottle
 33 mm CRC White Cap
Pack of 75 ml :
 75ml HDPE angled bottle
 33 mm CRC White Cap
Pack of 100 ml :
 125ml HDPE angled bottle
 33 mm CRC White Cap
- Amoxicillin for Oral Suspension USP, 125 mg/5ml, 250 mg/5ml**
Pack of 80 ml :
 100ml HDPE angled bottle
 33 mm CRC White Cap
Pack of 100 ml :
 125ml HDPE angled bottle
 33 mm CRC White Cap
Pack of 150 ml :
 175ml White HDPE angled bottle
 33 mm CRC White Cap



Section 1. Identification

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

Identified uses : Indicated for the treatment of infections caused by susceptible strains of microorganisms.

Manufacturer : Hikma Pharmaceuticals
Bayadar Wadi Seer , P.O Box 182400, Amman, Jordan
Tel: +96265802900
Fax: +962 6 581 7102
www.Hikma.com
Email: Ljaloukh@hikma.com

Supplier : West-Ward Pharmaceuticals Corp
401 Industrial Way West Eatontown
New Jersey (NJ) 07724
Tel: 732-542-1191, ext. 2722
Fax: 732-542-6150
Email: ctrotta@west-ward.com

Emergency telephone number (with hours of operation) : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887 24/7

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : RESPIRATORY SENSITIZATION - Category 1
SKIN SENSITIZATION - Category 1

GHS label elements

Hazard pictograms :



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

Prevention : P280 - Wear protective gloves.
P284 - Wear respiratory protection.
P261 - Avoid breathing dust.
P272 (OSHA) - Contaminated work clothing must not be allowed out of the workplace.

Response : P304 + P341 (OSHA) - IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or physician.
P302 + P352 + P363 - IF ON SKIN: Wash with plenty of soap and water. Wash contaminated clothing before reuse.
P333 + P313 - If skin irritation or rash occurs: Get medical attention.

Storage : Not applicable.

Section 2. Hazards identification

Disposal : P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture
Chemical name : 4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 6-[[amino(4-hydroxyphenyl)acetyl]amino-3,3-dimethyl-7-oxo-, trihydrate 2S-[2α, [5α, 6β(S*)]]-(2S,5R,6R)-6-[(R)-(-)-2-Amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate

Other means of identification : Not available.

CAS number/other identifiers

CAS number : Not applicable.

Product code : **Amoxicillin for Oral Suspension USP, 125 mg/5ml**
 Pack of 80 ml: 0143-9888-80
 Pack of 100 ml: 0143-9888-01
 Pack of 150 ml: 0143-9888-15

Amoxicillin for Oral Suspension USP, 250 mg/5ml
 Pack of 80 ml: 0143-9889-80
 Pack of 100 ml: 0143-9889-01
 Pack of 150 ml: 0143-9889-15

Amoxicillin for Oral Suspension USP, 200 mg/5ml
 Pack of 50 ml: 0143-9886-50
 Pack of 75 ml: 0143-9886-75
 Pack of 100 ml: 0143-9886-01

Amoxicillin for Oral Suspension USP, 400 mg/5ml
 Pack of 50 ml: 0143-9887-50
 Pack of 75 ml: 0143-9887-75
 Pack of 100 ml: 0143-9887-01

Ingredient name	%	CAS number
Amoxicillin	≥5 - ≤25	26787-78-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours. In the event of any complaints or symptoms, avoid further exposure.
- Skin contact** : Wash with plenty of soap and water. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 20 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.
- Ingestion** : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Skin contact** : May cause an allergic skin reaction.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Adverse symptoms may include the following:
wheezing and breathing difficulties
asthma
- Skin contact** : Adverse symptoms may include the following:
irritation
redness
- Ingestion** : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- Specific treatments** : No specific treatment.

Section 4. First aid measures

- Protection of first-aiders** : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- Suitable extinguishing media** : Use an extinguishing agent suitable for the surrounding fire.

- Unsuitable extinguishing media** : None known.

- Specific hazards arising from the chemical** : No specific fire or explosion hazard.

- Hazardous thermal decomposition products** : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides

- Special protective actions for fire-fighters** : No special measures are required.

- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Move containers from spill area. Avoid dust generation. Using a vacuum with HEPA filter will reduce dust dispersal. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Section 6. Accidental release measures

- Large spill** : Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitization problems or asthma, allergies or chronic or recurrent respiratory disease should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Amoxicillin	None.

- Appropriate engineering controls** : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Section 8. Exposure controls/personal protection

- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Appearance

- Physical state** : Solid. Powder.
- Color** : White to off-white powder with fruity flavour. After reconstitution, it is white to off-white suspension with fruity flavour.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : Not available.
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- Vapor density** : Not available.
- Relative density** : Not available.
- Solubility** : Not available.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- Viscosity** : Not available.

Section 10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- Conditions to avoid** : No specific data.
- Incompatible materials** : Not available.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Amoxicillin	LD50 Oral	Rat	>15 g/kg	-

Irritation/Corrosion

There is no data available.

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

Classification

Product/ingredient name	OSHA	IARC	NTP	ACGIH	EPA	NIOSH
Sucrose	-	-	-	A4	-	-

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)

There is no data available.

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Eye contact. Inhalation. Ingestion.

Potential acute health effects

Section 11. Toxicological information

Eye contact	: No known significant effects or critical hazards.
Inhalation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	: May cause an allergic skin reaction.
Ingestion	: No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact	: No known significant effects or critical hazards.
Inhalation	: Adverse symptoms may include the following: wheezing and breathing difficulties asthma
Skin contact	: Adverse symptoms may include the following: irritation redness
Ingestion	: No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects	: No known significant effects or critical hazards.
Potential delayed effects	: No known significant effects or critical hazards.

Long term exposure

Potential immediate effects	: No known significant effects or critical hazards.
Potential delayed effects	: No known significant effects or critical hazards.

Potential chronic health effects

General	: Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

There is no data available.

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Amoxicillin	Acute EC50 >1500 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata	72 hours
	Acute EC50 >1000 mg/L Fresh water	Crustaceans - Moina macrocopa	48 hours
	Acute EC50 >1000 mg/L Fresh water	Daphnia - Daphnia magna - Juvenile (Fledgling, Hatchling, Weanling)	48 hours
	Acute LC50 >1000 mg/L Fresh water	Fish - Oryzias latipes - Juvenile (Fledgling, Hatchling, Weanling)	96 hours
	Chronic NOEC 250 mg/L Marine water	Algae - Phaeodactylum tricornutum - Exponential growth phase	96 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
Amoxicillin	0.87	-	low

Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-

Section 14. Transport information

Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) PAIR: Vanillin
TSCA 8(a) CDR Exempt/Partial exemption: Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Immediate (acute) health hazard

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Amoxicillin	≥5 - ≤25	No.	No.	No.	Yes.	No.

SARA 313

There is no data available.

State regulations

Massachusetts : The following components are listed: Sucrose

New York : None of the components are listed.

Section 15. Regulatory information

New Jersey : None of the components are listed.
Pennsylvania : The following components are listed: Sucrose
California Prop. 65

No products were found.

Section 16. Other information

Procedure used to derive the classification

Classification	Justification
RESPIRATORY SENSITIZATION - Category 1 SKIN SENSITIZATION - Category 1	Calculation method Calculation method

History

Date of issue mm/dd/yyyy : 06/15/2016
Version : 1
Prepared by : KMK Regulatory Services Inc.

Notice to reader

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