SAFETY DATA SHEETS

This SDS packet was issued with item:

078940506

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078940505

SAFETY DATA SHEET

Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 200 mg/ 28.5 mg per 5 mL

Section 1. Identification

GHS product identifier : Amoxicillin and Clavulanate Potassium for Oral Suspension USP, 200 mg/ 28.5 mg per 5 mL

Other means of identification : Amoxicillin is (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
Clavulanate Potassium is potassium (Z)-(2R,5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylate

Product type : Solid.

Product code : Pack of 50 ml: 0143-9981-50
Pack of 75 ml: 0143-9981-75
Pack of 100 ml: 0143-9981-01

Chemical family : Not available.

Product type : Not available.

Container information : 75ml PE Angled bottles for 50 ml (after reconstitution)
100ml PE Angled bottles for 75 ml (after reconstitution)
125ml PE Angled bottles for 100 ml (after reconstitution)
33 mm CRC White with Liner C
33 mm CRC White Caps(AMC)

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

Identified uses : Amoxicillin and Clavulanate Potassium Powder for Oral Suspension, USP is a combination penicillin-class antibacterial and beta-lactamase inhibitor indicated for treatment of the following:
- Lower respiratory tract infections
- Acute bacterial otitis media
- Sinusitis
- Skin and skin structure infections
- Urinary tracy infections

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

Supplier's details : Hikma Pharmaceuticals USA Inc.
246 Industrial Way West
Eatontown, New Jersey (NJ) 07724

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 : EYE IRRITATION - Category 2B
RESPIRATORY SENSITIZATION - Category 1
SKIN SENSITIZATION - Category 1
AQUATIC HAZARD (ACUTE) - Category 3
AQUATIC HAZARD (LONG-TERM) - Category 3

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H320 - Causes eye irritation.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 - May cause an allergic skin reaction.
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements

Prevention : P280 - Wear protective gloves.
P284 - Wear respiratory protection.
P273 - Avoid release to the environment.
P261 - Avoid breathing dust.
P264 - Wash hands thoroughly after handling.
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.
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 - If eye irritation persists: Get medical attention.

Storage : Not applicable.

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

Other means of identification : Amoxicillin is (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
Clavulanate Potassium is potassium (Z)-(2R,5R)-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]-heptane-2-carboxylate

CAS number/other identifiers

CAS number : Not applicable.

Section 3. Composition/information on ingredients

Product code : Pack of 50 ml: 0143-9981-50
Pack of 75 ml: 0143-9981-75
Pack of 100 ml: 0143-9981-01

Ingredient name	%	CAS number
Amoxicillin	≥25 - ≤50	26787-78-0
Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate	≥10 - ≤25	61177-45-5
Silicon dioxide	≥10 - ≤25	7631-86-9
Dipentene	≥0.3 - <1	138-86-3

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. If irritation persists, get medical attention.

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 : Causes eye irritation.

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

Section 4. First aid measures

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

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.

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 : This material is harmful to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
metal oxide/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). Water polluting material. May be harmful to the environment if released in large quantities.

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.

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. Avoid release to the environment. 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.
Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate	None.
Silicon dioxide	**NIOSH REL (United States, 10/2013).** TWA: 6 mg/m³ 10 hours.
Dipentene	**AIHA WEEL (United States, 10/2011).** TWA: 30 ppm 8 hours.

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.

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: chemical splash goggles.

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. After reconstitution, it is a creamy suspension.]

Color : White to off white.

Odor : Not available.

Odor threshold : Not available.

pH : 3.8 to 6.6 [Conc. (% w/w): 1%]

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 : 1.04 to 1.1

Solubility : Not available.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : NMT 500

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 : Reactive or incompatible with the following materials: oxidizing materials.

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

Section 11. Toxicological information

Product/ingredient name	Result	Species	Dose	Exposure
Amoxicillin	LD50 Oral	Rat	>15 g/kg	-
Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate	LD50 Oral	Rat	7936 mg/kg	-
Dipentene	LD50 Oral	Rat	5300 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Silicon dioxide	Eyes - Mild irritant	Rabbit	-	24 hours 25 mg	-

Sensitization

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

Classification

Product/ingredient name	OSHA	IARC	NTP	ACGIH	EPA	NIOSH
Silicon dioxide	-	3	-	-	-	-

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

Eye contact : Causes eye irritation.

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 : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : Adverse symptoms may include the following:
wheezing and breathing difficulties
asthma

Section 11. Toxicological information

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
Dipentene	Acute EC50 28.2 mg/L Fresh water	Daphnia - Daphnia magna	48 hours
	Acute EC50 20.2 mg/L Fresh water	Fish - Pimephales promelas - Juvenile (Fledgling, Hatchling, Weanling)	96 hours
	Acute IC50 13.798 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata	96 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Section 12. Ecological information

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Amoxicillin	0.87	-	low
Dipentene	4.57	-	high

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	-	-	-
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) 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	≥25 - ≤50	No.	No.	No.	Yes.	No.
Potassium [2R-(2α,3Z,5α)]-3-(2-hydroxyethylidene)-7-oxo-4-oxa-1-azabicyclo[3.2.0]heptane-2-carboxylate	≥10 - ≤25	Yes.	No.	Yes.	Yes.	No.
Silicon dioxide	≥10 - ≤25	No.	No.	No.	Yes.	No.
Dipentene	≥0.3 - <1	Yes.	No.	No.	Yes.	No.

SARA 313

There is no data available.

State regulations

Massachusetts : The following components are listed: Silicon dioxide

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : The following components are listed: Silicon dioxide

California Prop. 65

No products were found.

Section 16. Other information

Procedure used to derive the classification

Classification	Justification
EYE IRRITATION - Category 2B	Calculation method
RESPIRATORY SENSITIZATION - Category 1	Calculation method
SKIN SENSITIZATION - Category 1	Calculation method
AQUATIC HAZARD (ACUTE) - Category 3	Calculation method
AQUATIC HAZARD (LONG-TERM) - Category 3	Calculation method

History

Revision date mm/dd/yyyy : 09/15/2018

Version : 2

Prepared by : KMK Regulatory Services Inc.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.