

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078945687

N/A

## Safety Data Sheet

According to OSHA Hazard Communication Standard, 29 CFR 1910.1200

Initial Preparation Date: 08.17.2022

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### Umbrellin<sup>™</sup> (amoxicillin and clavulanate potassium) Oral Drops

#### SECTION 1: Identification

##### Product Identifier

**Product Name:** Umbrellin<sup>™</sup> (amoxicillin and clavulanate potassium) Oral Drops

**Synonyms:** Amoxicillin trihydrate and clavulanate potassium suspension

**Product code:** 21307540

**Additional information:** Individuals who are allergic to penicillin antibiotics might exhibit allergic reactions, possibly severe. May cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

##### Recommended Use of the Product and Restriction on Use

**Relevant Identified Uses:** Veterinary product used as antibiotic agent.

**Uses Advised Against:** Not for human use.

**Reasons Why Uses Advised Against:** Not determined or not applicable.

##### Manufacturer or Supplier Details

###### Supplier:

###### United States

Aspen Veterinary Resources, LTD.  
3155 W. Heartland Drive  
Liberty, MO 64068  
1-800-792-1238

##### Emergency Telephone Number:

###### United States

CHEMTREC

Within USA and Canada: 1-800-424-9300 (24 hours)

Outside USA and Canada: +1-703-527-3887 (24 hours)

#### SECTION 2: Hazard(s) Identification

##### GHS Classification:

Respiratory sensitization, category 1

Skin sensitization, category 1

##### Label elements

###### Hazard Pictograms:



**Signal Word:** Danger

##### Hazard statements:

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

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H317 May cause an allergic skin reaction

#### Precautionary Statements:

P261 Avoid breathing dust, fumes, gas, mist, vapors or spray.

P284 In case of inadequate ventilation wear respiratory protection.

P272 Contaminated work clothing must not be allowed out of the workplace

P280 Wear protective gloves, protective clothing, eye protection and face protection.

P304+P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or physician.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P333+P313 If skin irritation or rash occurs: Get medical advice or attention.

P321 Specific treatment (see Sections 4-8 of this SDS and any supplemental information on the product label).

P363 Wash contaminated clothing before reuse

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

**Hazards Not Otherwise Classified:** None

### SECTION 3: Composition/Information on Ingredients

Identification	Name	Weight %
CAS Number: 61336-70-7	Amoxicillin trihydrate	5
CAS Number: 61177-45-5	Potassium Clavulanate (Clavulanic acid)	1.25
CAS Number: 7631-86-9	Silicon dioxide (amorphous)	<1

#### Additional Information:

The specific chemical identity and/or exact percentages (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200)

### SECTION 4: First Aid Measures

#### Description of First Aid Measures

##### General Notes:

For personal protection, see section 8 of the SDS. IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

##### After Inhalation:

If inhaled, remove person to fresh air and place in a position comfortable for breathing. Keep person at rest. If breathing is difficult, administer oxygen. If breathing has stopped, provide artificial respiration. If exposed, seek medical advice/attention.

##### After Skin Contact:

Remove contaminated clothing and shoes. Rinse skin with copious amounts of water [shower] for several minutes. Launder contaminated clothing before reuse. If symptoms develop or persist, seek medical advice/attention.

##### After Eye Contact:

Rinse eyes with plenty of water for several minutes. Remove contact lenses if present and easy to do so.

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Protect unexposed eye. If symptoms develop or persist, seek medical advice/attention.

#### After Swallowing:

If swallowed, DO NOT induce vomiting unless told to do so by a physician or poison control center. Rinse mouth with water. Never give anything by mouth to an unconscious person. If spontaneous vomiting occurs, place on the left side with head down to prevent aspiration of liquid into the lungs. If symptoms develop or persist, seek medical advice/attention.

#### Most Important Symptoms and Effects, Both Acute and Delayed

##### Acute Symptoms and Effects:

Inhalation exposure may cause allergy, asthma symptoms or breathing difficulties. Symptoms may include cough, chronic phlegm, shortness of breath, wheezing and chest tightness. Symptoms may be delayed.

Dermal exposure may cause an allergic skin reaction. Symptoms may include irritation, redness, pain, rash, inflammation, itching, burning and dermatitis.

Direct contact with eyes may cause temporary irritation. Symptoms include tearing, redness, and discomfort.

Prolonged skin contact may result in mild irritation.

##### Delayed Symptoms and Effects:

Symptoms of exposure may be delayed.

#### Immediate Medical Attention and Special Treatment

##### Specific Treatment:

In case of an allergic reaction, seek immediate medical attention.

##### Notes for the Doctor:

Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.

### SECTION 5: Firefighting Measures

#### Extinguishing Media

##### Suitable Extinguishing Media:

Use extinguishing media appropriate for surrounding fire.

##### Unsuitable Extinguishing Media:

Do not use water jet.

#### Specific Hazards During Fire-Fighting:

Thermal decomposition may produce irritating and toxic fumes including carbon oxides, nitrogen oxides and sulfur oxides.

#### Special Protective Equipment for Firefighters:

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

#### Special precautions:

Avoid contact with skin, eyes, hair and clothing. Do not breathe fumes/gas/mists/aerosols/vapors/dusts. Move containers from fire area if safe to do so. Use water spray/fog for cooling fire exposed containers. Avoid unnecessary run-off of extinguishing media which may cause pollution.

### SECTION 6: Accidental Release Measures

#### Personal Precautions, Protective Equipment, and Emergency Procedures:

Evacuate unnecessary personnel. Ventilate area. Extinguish any sources of ignition. Wear recommended personal protective equipment (see Section 8). Do not touch damaged containers or spilled material unless

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wearing appropriate protective clothing. Avoid the generation of dusts during clean-up. Avoid contact with skin, eyes and clothing. Avoid breathing mist, vapor, dust, fume and spray. Do not walk through spilled material. Wash thoroughly after handling.

#### Environmental Precautions:

Prevent further leakage or spillage if safe to do so. Prevent from reaching drains, sewers and waterways. Discharge into the environment must be avoided.

#### Methods and Material for Containment and Cleaning Up:

Contain and collect spillage and place in suitable container for future disposal. Following product recovery, flush area with water. Never return spills to original containers for re-use. Dispose of in accordance with all applicable regulations (see Section 13).

#### Reference to Other Sections:

For personal protective equipment see Section 8. For disposal see Section 13.

### SECTION 7: Handling and Storage

#### Precautions for Safe Handling:

Use appropriate personal protective equipment (see Section 8). Use only with adequate ventilation. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid dust generation. Do not breathe mist/vapor/spray/dust. Do not eat, drink, smoke, or use personal products when handling chemical substances. Avoid contact with skin, eyes and clothing. Wash affected areas thoroughly after handling. Wash contaminated clothing before reuse. Avoid release to the environment. Keep away from incompatible materials (See Section 10). Keep containers tightly closed when not in use.

#### Conditions for Safe Storage, Including Any Incompatibilities:

Store in cool, dry, well-ventilated location out of direct sunlight. Store away from heat, open flames and other sources of ignition. Before reconstitution: Store at temperature of 15 - 25°C (59 - 77°F). Keep away from food, drink and animal feeding stuffs. Keep out of the reach of children. Keep container tightly sealed. Store away from incompatible materials (See Section 10).

### SECTION 8: Exposure Controls/Personal Protection

Only those substances with limit values have been included below.

#### Occupational Exposure Limit Values:

Country (Legal Basis)	Substance	Identifier	Permissible concentration
NIOSH	Silicon dioxide (amorphous)	7631-86-9	REL-TWA: 6 mg/m <sup>3</sup> (up to 10 hrs.)
	Silicon dioxide (amorphous)	7631-86-9	IDLH: 3000 mg/m <sup>3</sup>
OSHA	Silicon dioxide (amorphous)	7631-86-9	8-Hour TWA-PEL: 0.8 mg/m <sup>3</sup> (Amorphous, including natural diatomaceous earth)
	Silicon dioxide (amorphous)	7631-86-9	TWA: 5 mg/m <sup>3</sup> (Particulates not otherwise regulated, Respirable fraction)
	Silicon dioxide (amorphous)	7631-86-9	TWA: 15 mg/m <sup>3</sup> (Particulates not otherwise regulated, Total dust)
United States(California)	Silicon dioxide (amorphous)	7631-86-9	8-Hour TWA-PEL: 6 mg/m <sup>3</sup> (precipitated and gel)
	Silicon dioxide (amorphous)	7631-86-9	8-Hour TWA-PEL: 6 mg/m <sup>3</sup> (total dust)
	Silicon dioxide (amorphous)	7631-86-9	8-Hour TWA-PEL: 3 mg/m <sup>3</sup> (respirable dust)

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Country (Legal Basis)	Substance	Identifier	Permissible concentration
ACGIH	Silicon dioxide (amorphous)	7631-86-9	8-Hour TWA: 10 mg/m <sup>3</sup> (Particulates not otherwise regulated, Total dust)
	Silicon dioxide (amorphous)	7631-86-9	8-Hour TWA: 3 mg/m <sup>3</sup> (Particulates not otherwise regulated, Respirable fraction)
	Silicon dioxide (amorphous)	7631-86-9	8-Hour TWA: 10 mg/m <sup>3</sup> ([TLA-TWA] Particles (insoluble or poorly soluble) not otherwise specified, inhalable particles)
	Silicon dioxide (amorphous)	7631-86-9	8-Hour TWA: 3 mg/m <sup>3</sup> ([TLA-TWA] Particles (insoluble or poorly soluble) not otherwise specified, respirable particles)

#### Biological Limit Values:

No biological exposure limits noted for the ingredient(s).

#### Information on Monitoring Procedures:

Not determined or not applicable.

#### Appropriate Engineering Controls:

Emergency eye wash stations and safety showers should be available in the immediate vicinity of use or handling. Provide adequate ventilation to maintain the airborne concentrations of vapor, mists, and/or dusts below the applicable workplace exposure limits, while observing recognized national standards (or equivalent).

#### Personal Protection Equipment

##### Eye and Face Protection:

If exposure is likely, wear safety glasses with side shields or goggles. Use eye protection equipment that has been tested and approved by recognized national standards (or equivalent).

##### Skin and Body Protection:

Wear protective gloves. If skin contact is possible or for bulk processing operations, wear chemical resistant, impervious gloves approved by the appropriate standards. Gloves must be inspected prior to use. Avoid skin contact with used gloves. Appropriate techniques should be used to remove used gloves and contaminated clothing.

If exposure is likely or for bulk processing operations, wear suitable protective clothing. 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. Ensure that all personal protective equipment is approved by recognized national standards (or equivalent).

##### Respiratory Protection:

If engineering controls do not maintain airborne concentrations below the applicable workplace exposure limits, or to an acceptable level (if exposure limits have not been established), a respirator approved by recognized national standards (or equivalent) must be worn.

#### General Hygienic Measures:

When handling chemical products, do not eat, drink or smoke. Wash hands after handling, before breaks, and at the end of the workday. Avoid contact with skin, eyes and clothing. Wash contaminated clothing before reuse. Perform routine housekeeping.

### SECTION 9: Physical and Chemical Properties

#### Information on Basic Physical and Chemical Properties

Appearance	Powder. Reconstitute with water for use. Off-white color.
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Odor	Not determined or not available.
Odor threshold	Not determined or not available.
pH	Not determined or not available.
Melting point/freezing point	Not determined or not available.
Initial boiling point/range	Not determined or not available.
Flash point (closed cup)	Not determined or not available.
Evaporation rate	Not determined or not available.
Flammability (solid, gas)	Not determined or not available.
Upper flammability/explosive limit	Not determined or not available.
Lower flammability/explosive limit	Not determined or not available.
Vapor pressure	Not determined or not available.
Vapor density	Not determined or not available.
Density	Not determined or not available.
Relative density	Not determined or not available.
Solubilities	Not determined or not available.
Partition coefficient (n-octanol/water)	Not determined or not available.
Auto/Self-ignition temperature	Not determined or not available.
Decomposition temperature	Not determined or not available.
Dynamic viscosity	Not determined or not available.
Kinematic viscosity	Not determined or not available.
Explosive properties	Not determined or not available.
Oxidizing properties	Not determined or not available.

### SECTION 10: Stability and Reactivity

#### Reactivity:

Not reactive under recommended handling and storage conditions.

#### Chemical Stability:

Stable under recommended handling and storage conditions.

#### Possibility of Hazardous Reactions:

Hazardous reactions are not anticipated under recommended conditions of handling and storage.

#### Conditions to Avoid:

Direct sources of heat; Exposure to sunlight; Incompatible materials; Generation and dispersal of dust

#### Incompatible Materials:

Strong oxidizing agents; Acids; Bases.

#### Hazardous Decomposition Products:

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

### SECTION 11: Toxicological Information

#### Acute Toxicity

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:** No data available.

**Substance Data:**

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Name	Route	Result
Silicon dioxide (amorphous)	oral	LD50 Rat: > 1000 mg/kg
	dermal	LD50 Rabbit: > 2000 mg/kg
	inhalation	LC50 Rat: > 5.01 mg/L (4 hr [dust])
Amoxicillin trihydrate	oral	LD50 Rabbit: 12,500 mg/kg
Potassium Clavulanate (Clavulanic acid)	oral	LD50 Rat: 7936 mg/kg

#### Skin Corrosion/Irritation

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:**

No data available.

**Substance Data:** No data available.

#### Serious Eye Damage/Irritation

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:**

No data available.

**Substance Data:** No data available.

#### Respiratory or Skin Sensitization

**Assessment:**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

May cause an allergic skin reaction.

**Product Data:**

No data available.

**Substance Data:**

Name	Result
Potassium Clavulanate (Clavulanic acid)	May cause an allergic skin reaction.
	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

#### Carcinogenicity

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:** No data available.

**Substance Data:** No data available.

#### International Agency for Research on Cancer (IARC):

Name	Classification
Silicon dioxide (amorphous)	Group 3

**National Toxicology Program (NTP):** None of the ingredients are listed.

**OSHA Carcinogens:** Not applicable

#### Germ Cell Mutagenicity

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:**

No data available.

**Substance Data:** No data available.

#### Reproductive Toxicity

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:**

No data available.



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**Substance Data:** No data available.

#### Specific Target Organ Toxicity (Single Exposure)

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:**

No data available.

**Substance Data:** No data available.

#### Specific Target Organ Toxicity (Repeated Exposure)

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:**

No data available.

**Substance Data:** No data available.

#### Aspiration toxicity

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:**

No data available.

**Substance Data:** No data available.

#### Information on Likely Routes of Exposure:

Inhalation; Ingestion; Skin contact; Eye contact

#### Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:

Refer to Section 4 of this SDS.

#### Other Information:

No data available.

### SECTION 12: Ecological Information

#### Acute (Short-Term) Toxicity

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:** No data available.

**Substance Data:**

Name	Result
Silicon dioxide (amorphous)	Fish LC50 Pimephales promelas: > 5000 mg/L (96 hr [mortality])
	Aquatic Invertebrates EC50 Daphnia magna: > 100 mg/L (48 hr [mobility])
	Aquatic Plants EC50 Desmodium subspicatus: 15 mg/L (72 hr [yield])

#### Chronic (Long-Term) Toxicity

**Assessment:** Based on available data, the classification criteria are not met.

**Product Data:** No data available.

**Substance Data:**

Name	Result
Silicon dioxide (amorphous)	Aquatic Invertebrates NOEC Daphnia magna: 68 mg/L (21 d [mortality])
	Aquatic Plants NOEC Desmodium subspicatus: 4 mg/L (21 d [growth rate])

#### Persistence and Degradability

**Product Data:** No data available.

**Substance Data:**

Name	Result
Silicon dioxide (amorphous)	Persistence assessment based on biodegradability is not relevant for metals and their inorganic compounds such as this substance.
Amoxicillin trihydrate	Accumulation in organisms is not to be expected.

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#### Bioaccumulative Potential

**Product Data:** No data available.

**Substance Data:**

Name	Result
Silicon dioxide (amorphous)	Accumulation in organisms is not to be expected (BCF: 3.162 L/kg).
Amoxicillin trihydrate	Accumulation in organisms is not to be expected (BCF: 1.75).
Potassium Clavulanate (Clavulanic acid)	Accumulation in organisms is not to be expected (BCF: 1.23).

#### Mobility in Soil

**Product Data:** No data available.

**Substance Data:**

Name	Result
Silicon dioxide (amorphous)	This substance is mobile; therefore, adsorption to soil is not expected (QSAR log Koc: 1.337).
Amoxicillin trihydrate	This substance is mobile; therefore, adsorption to soil is not expected (Koc: 88.8 L/kg).
Potassium Clavulanate (Clavulanic acid)	This substance is mobile; therefore, adsorption to soil is not expected (Koc: 56.5 L/kg).

#### Results of PBT and vPvB assessment

**Product Data:**

**PBT assessment:** This product does not contain any substances that are assessed to be a PBT.

**vPvB assessment:** This product does not contain any substances that are assessed to be a vPvB.

**Substance Data:**

**PBT assessment:**

Silicon dioxide (amorphous)	This substance is not PBT.
Amoxicillin trihydrate	This substance is not PBT.

**vPvB assessment:**

Silicon dioxide (amorphous)	This substance is not vPvB.
Amoxicillin trihydrate	This substance is not vPvB.

**Other Adverse Effects:** No data available.

### SECTION 13: Disposal Considerations

**Disposal Methods:**

It is the responsibility of the waste generator to properly characterize all waste materials according to applicable regulatory agencies. Dispose of in accordance with all applicable local, regional, state and federal regulations.

**Contaminated packages:**

Not determined or not applicable.

### SECTION 14: Transport Information

#### United States Transportation of Dangerous Goods (49 CFR DOT)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None

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Environmental Hazards	None
Special Precautions for User	None

#### International Maritime Dangerous Goods (IMDG)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

#### International Air Transport Association Dangerous Goods Regulations (IATA-DGR)

UN Number	Not regulated
UN Proper Shipping Name	Not regulated
UN Transport Hazard Class(es)	None
Packing Group	None
Environmental Hazards	None
Special Precautions for User	None

### SECTION 15: Regulatory Information

#### United States Regulations

**Inventory Listing (TSCA):** All ingredients are listed-active or exempt.

**Significant New Use Rule (TSCA Section 5):** None of the ingredients are listed.

**Export Notification under TSCA Section 12(b):** None of the ingredients are listed.

**SARA Section 302 Extremely Hazardous Substances:** None of the ingredients are listed.

**SARA Section 313 Toxic Chemicals:** None of the ingredients are listed.

**CERCLA:** None of the ingredients are listed.

**RCRA:** None of the ingredients are listed.

**Section 112(r) of the Clean Air Act (CAA):** None of the ingredients are listed.

#### Massachusetts Right to Know:

7631-86-9	Silicon dioxide (amorphous)	Listed
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**New Jersey Right to Know:** None of the ingredients are listed.

#### New York Right to Know:

7631-86-9	Silicon dioxide (amorphous)	Listed
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#### Pennsylvania Right to Know:

7631-86-9	Silicon dioxide (amorphous)	Listed
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#### California Proposition 65:

**⚠️WARNING:** This product can expose you to Silica, crystalline (airborne particles of respirable size); which is known to the State of California to cause cancer. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov)

**Additional information:** Not determined.

### SECTION 16: Other Information

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**Abbreviations and Acronyms:** None

**Disclaimer:**

This product has been classified in accordance with OSHA HCS 2012 guidelines. The information provided in this SDS is correct, to the best of our knowledge, based on information available. The information given is designed only as a guidance for safe handling, use, storage, transportation and disposal and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials, unless specified in the text. The responsibility to provide a safe workplace remains with the user.

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**End of Safety Data Sheet**