Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

TEVA Pharmaceuticals
650 Cathill Rd
PO Box 904
Sellersville, PA 18960
Date Approved:
Date Last Revision:

Telephone Number: 215-591-3000
Emergency Number: 1-888-838-2872

Amoxicillin for Oral Suspension

125 mg amoxicillin as the trihydrate per 5 mL in bottles of 80 mL, 100 mL, 150 mL
250 mg amoxicillin as the trihydrate per 5 mL in bottles of 80 mL, 100 mL, 150 mL

Chemical Name: (2*S*,5*R*,6*R*)-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

Intended Use: Semi-synthetic derivative of penicillin, an analog of ampicillin, with a broadspectrum of bactericidal activity against many gram-positive and gram-negative microorganisms, administered orally

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number
Amoxicillin Trihydrate	61336-70-7
Sugar (Fruit Granulated)	N/A

See Section 8 for exposure limits.

According to 29 CFR 1910.1200, no other hazardous ingredients are present at ≥ 1%. No carcinogens are present at ≥ 0.1%.

3. HAZARDS IDENTIFICATION

Emergency Overview: Serious and occasional fatal hypersensitivity (anaphylactic) reactions have been reported in patents on penicillin therapy and other antibiotics. Serious anaphylactic reactions require immediate emergency treatment with epinephrine. Oxygen, intravenous steroids, and airway management, including intubation, should also be administered as indicated.

The health hazards associated with this mixture have not been thoroughly investigated. The signs and symptoms of exposure listed below are based upon potential health effects from the active pharmaceutical ingredient contained in this formula unless otherwise noted.

Routes of Exposure:

Eyes:
Possible mild to moderate irritant

Skin:
Possible moderate irritant

Ingestion:
Clinical Route

Inhalation:
Not expected

Signs and Symptoms of Over Exposure:
None expected from incidental contact. Allergic and hypersensitivity reactions, including serum sickness, erythematous, maculopapular rashes, erthema multiforme, Stevens-Johnson Syndrome, exfoliative dermatitis, toxic epidermal necrolysis. Following overdosage, patients have experienced primarily gastrointestinal symptoms, including stomach and abdominal pain, vomiting, and diarrhea. Rash, hyperactivity, or drowsiness have also been observed in a small number of patients.

Carcinogenicity:

Not known. Refer to Section 11, Toxicological Information.

NTP:	Not Listed	IARC:	Not Listed
OSHA:	Not Listed	ACGIH:	Not Listed

Teratogenicity/Reproductive Effects:
Some reproductive effects have been observed in animal studies. However, the significance of these studies in humans is not known. Refer to Section 11, Toxicological Information.

Medical Conditions Aggravated By Exposure:
Hypersensitivity to final formulation or any of its ingredients.

4. FIRST AID MEASURES

Eyes:
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.

Skin:
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention.

Ingestion:
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation:
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Note to Physicians:
Before initiating therapy with amoxicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, amoxicillin should be discontinued and appropriate therapy instituted. Amoxicillin may be removed from circulation by hemodialysis.

5. FIRE-FIGHTING MEASURES

Flashpoint: N/D

Flash point Method: N/D

Fire and explosion hazards: Not expected under normal conditions.

Extinguishing media: Use foam, carbon dioxide, or dry chemical. Use water spray to cool fire-exposed containers and to protect personnel.

Hazardous combustion products: May produce carbon dioxide, carbon monoxide, and other toxic thermal decomposition products.

Fire-fighting instructions: Because fire may produce toxic thermal decomposition products, wear self-contained breathing apparatus and protective clothing. Do not release runoff from fire control methods to sewers or waterways.

6. ACCIDENTAL RELEASE MEASURES

Spills: Absorb with inert dry material and dispose of as pharmaceutical waste. Keep spills and runoff from entering drains or surface water. In the event of a spill, contact the appropriate authorities as required by Federal, State, and Local regulations.

7. HANDLING AND STORAGE

Handling: Avoid contact with eyes, skin or clothing. Use only with appropriate personal protective equipment, safe work practices, and good hygiene practices. Wash thoroughly after handling and before eating, drinking, smoking, and/or applying cosmetics.

Storage: Store at controlled room temperature: 59°-86°F (15°-30°C). Exposure to light may affect the potency of the active pharmaceutical ingredient.

8. EXPOSURE CONTROL/ PERSONAL PROTECTION

Exposure Limits:

Ingredient	OSHA PEL	ACGIH TLV	Other
Amoxicillin Trihydrate	Not Established	Not Established	None Identified
Sugar (Fruit Granulated)	Not Established	Not Established	None Identified

Eye/Skin Protection: Avoid contact with eyes and skin. Wear eye protection and appropriate gloves while handling.

Respiratory Protection: Not required unless misting or aerosolization could occur. Respiratory equipment must be NIOSH-approved and comply with OSHA's Respiratory Protection Standard, 29 CFR 1910.134.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Off white to pinkish colored mixed berry flavored suspension with a fruity odor.

Vapor Pressure: N/D

Vapor Density: N/D

Specific Gravity: N/D

Solubility: N/D

Boiling Point: N/D

pH: N/D

10. STABILITY AND REACTIVITY

Stability: Under normal circumstances, believed to be stable.

Conditions to Avoid: None known

Incompatibility: None known

Hazardous Polymerization: None known

Hazardous Decomposition Products: None known

11. TOXICOLOGICAL INFORMATION

Unless otherwise noted the following pertains to the active pharmaceutical ingredient.

Oral Toxicity:
LD_{50} = > 15,000 mg/kg (oral, rat)
LD_{50} = > 25,000 mg/kg (oral, rat)

Acute Effects: Gastrointestinal signs include nausea, vomiting, and diarrhea. Interstitial nephritis resulting in oliguric renal failure has been reported in small number of patients after overdosage with amoxicillin. Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of amoxicillin. Skin rashes and urticaria have been reported frequently. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or history of sensitivity to multiple allergens.

Effects of Repeated Doses: Amoxicillin may produce rashes, hypersensitivity, and gastrointestinal effects such as diarrhea or loose stools.

Skin Irritation: Amoxicillin may produce moderate skin rashes and urticaria. Contact dermatitis and severe allergic reactions have occurred.

Reproductive and Developmental Effects: FDA Pregnancy Category B (Animal studies have failed to show a risk to the fetus, but there are no adequate studies in pregnant women: or animal studies have shown an adverse effect, but human studies have not shown a risk to the fetus in the first trimester, and there is no evidence of risk in later trimesters.)

Reproductive studies have been performed in mice and rats at doses up to ten times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to amoxicillin. There are, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Sensitization: Amoxicillin is a potential sensitizer by all exposure routes. The literature supports the conclusion that amoxicillin is a potent sensitizer capable of inducing allergic reactions in those that are not known to be allergic to pencillins as well as those that are. Severe allergic reactions have occurred in those predisposed by allergies of any kind. Hypersensitivity can develop through contact with dusts and liquids containing amoxicillin by all exposure routes.

Mutagenicity: Not known

Carcinogenicity: Not known

National Toxicology Program: Not listed
I.A.R.C. Monographs: Not listed
OSHA: Not listed

12. ECOLOGICAL INFORMATION

Not Determined

13. DISPOSAL CONSIDERATIONS

This product should be disposed of as pharmaceutical waste in accordance with all Federal, State, and Local regulations.

14. TRANSPORTATION INFORMATION

Proper Shipping Name: Amoxicillin for Oral Suspension, USP is typically supplied as 125 mg amoxicillin as the trihydrate per 5 mL in bottles of 80 mL, 100 mL, and 150 mL or 250 mg amoxicillin as the trihydrate per 5 mL in bottles of 80 mL, 100 mL, and 150 mL. All packaging and transportation must meet the applicable Federal, State, and Local regulations.

15. REGULATORY INFORMATION

The following regulations apply to storage and/or handling. It is the responsibility of the end users to determine the applicability of these regulations at their specific locations.

This product is regulated under the Food, Drug, and Cosmetic Act.

TSCA Status: FDA-regulated material is exempt from TSCA.

EPCRA Section 313 (SARA Title III): Not listed

EPCRA Section 302: Not listed

CERCLA: Not listed

RCRA: Not a RCRA hazardous waste

DOT: Not applicable

16. OTHER INFORMATION

N/A = Not Applicable N/D = Not Determined ~ = Approximately Equal To

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