



# SAFETY DATA SHEET

Issuing Date 27-Feb-2017

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Revision Number 1

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**Product Name** Amoxicillin Capsules; Amoxicillin Chewable Tablets; Amoxicillin Granules for Oral Suspension  
**Active Ingredient** Amoxicillin Trihydrate

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Identified Use** Pharmaceutical  
**Uses advised against** Other than Relevant Use

### 1.3. Details of the supplier of the safety data sheet

**Manufacturer, Supplier** Teva Canada Limited  
30 Novopharm Court  
Scarborough, Ontario, Canada M1B 2K9  
Telephone 1-866-470-6886

For further information, please contact

**E-mail Address** TevaSDSRequest@tevapharm.com

### 1.4. Emergency Telephone Number

**Emergency Telephone Number** United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]  
International: 01-703-527-3887 (Chemtrec) [24-hours]

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Exempt from requirements - regulated as a medicinal product.

### 2.2. Label Elements

Exempt from requirements - regulated as a medicinal product

### 2.3. Other hazards

None known

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

N.A.

### 3.2. Mixtures

Chemical Name	EC No	REACH Reg. No	CAS-No	Weight %
6-{ [Amino(4-hydroxy phenyl)acetyl]amino-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo [3,2,0]heptane-2-carboxylic acid trihydrate	-	Not available	61336-70-7	Proprietary
Excipients	-	Not available	-	Remainder

**SECTION 4: First aid measures****4.1. Description of first aid measures**

<b>Eye Contact</b>	Flush eyes with water for at least 15 minutes. Get medical attention if eye irritation develops or persists.
<b>Skin Contact</b>	Wash off immediately with plenty of water. Get medical advice/attention if you feel unwell.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Get medical advice/attention if you feel unwell.
<b>Inhalation</b>	Remove person to fresh air. If signs/symptoms continue, get medical attention.

**4.2. Most important symptoms and effects, both acute and delayed**

See product insert.

**4.3. Indication of immediate medical attention and special treatment needed**

**Notes to Physician** Treat symptomatically.

**SECTION 5: Fire-fighting measures****5.1. Extinguishing media****Suitable Extinguishing Media**

Water spray. Carbon dioxide (CO<sub>2</sub>). Foam. Dry powder. Halons.

**Unsuitable extinguishing media**

No information available.

**5.2. Special hazards arising from the substance or mixture**

Thermal decomposition can lead to release of irritating gases and vapors.

**5.3. Advice for firefighters****Special protective equipment for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Avoid all unnecessary contact.

**6.1.1. For non-emergency personnel**

**Protective equipment** See section 8

**Emergency procedures** Evacuate the danger area and alert emergency team

**6.1.2. For emergency responders**

See section 8

**6.2. Environmental Precautions**

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

**6.3. Methods and materials for containment and cleaning up****6.3.1. Methods for Containment**

No information available.

**6.3.2. For cleaning up**

Take up mechanically and collect in suitable container for disposal.

**6.3.3. Other information**

No information available

**6.4. Reference to other sections**

See Sections 8 & 13 for additional information.

## SECTION 7: Handling and storage

### 7.1. Precautions for Safe Handling

#### **Handling**

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

#### **Hygiene Measures**

Handle in accordance with good industrial hygiene and safety practice.

### 7.2. Conditions for safe storage, including any incompatibilities

Store in accordance with: label.

### 7.3. Specific end use(s)

#### **Exposure Scenario**

No information available.

#### **Other Guidelines**

No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### **Exposure Limits**

No occupational exposure limit values have been defined by authorities in production Country.

#### **Biological occupational exposure limits**

No information available.

#### **Derived No Effect Level (DNEL)**

No information available.

#### **Predicted No Effect Concentration (PNEC)**

No information available.

### 8.2. Exposure controls

#### **Engineering Measures**

Provide engineering control.

#### **Personal protective equipment**

##### **Eye/face protection**

Use eye protection appropriate for the task.

##### **Skin protection:**

- Body protection

Use protective clothing appropriate for the task.

- Hand protection

Use appropriate protective gloves.

##### **Respiratory Protection**

Use appropriate respiratory protection.

#### **Environmental exposure controls**

No information available.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

#### **Appearance**

##### **Physical State**

Capsules, Chewable Tablets, and Granules for Oral Solution

#### **Flash Point**

No information available

### 9.2. Other information

No information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No information available.

### 10.2. Chemical Stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

None known.

### 10.4. Conditions to avoid

Heat, flames and sparks.

### 10.5. Incompatible materials.

None in particular.

### 10.6. Hazardous decomposition products

None under normal use.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

<b>acute toxicity</b>	No hazard expected under normal handling conditions.
<b>skin corrosion/irritation</b>	No hazard expected under normal handling conditions.
<b>serious eye damage/irritation</b>	No hazard expected under normal handling conditions.
<b>respiratory or skin sensitization</b>	No hazard expected under normal handling conditions.
<b>germ cell mutagenicity</b>	No hazard expected under normal handling conditions.
<b>carcinogenicity</b>	No hazard expected under normal handling conditions.
<b>reproductive toxicity</b>	No hazard expected under normal handling conditions.
<b>STOT - single exposure</b>	No hazard expected under normal handling conditions.
<b>STOT - repeated exposures</b>	No hazard expected under normal handling conditions.
<b>aspiration hazard</b>	No hazard expected under normal handling conditions.

### Other Information

No hazard expected under normal handling conditions. .

## SECTION 12: Ecological information

### 12.1. Toxicity

#### **Ecotoxicity effects**

No information available.

### 12.2. Persistence and degradability

No information available.

### 12.3. Bioaccumulative potential

No information available.

### 12.4. Mobility in soil

No information available.

### 12.5. Results of PBT and vPvB assessment

No information available.

### 12.6. Other adverse effects

None known

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

<b>Waste from Residues/Unused Products</b>	Dispose of in accordance with local regulations.
<b>Contaminated Packaging</b>	Empty containers should be taken for local recycling, recovery or waste disposal.

### SECTION 14: Transport information

#### 14.1.

**UN-No** -

#### 14.2.

**Proper Shipping Name** -

#### 14.3. Transport hazard class(es)

**ADR / RID / ADN (land transport)** -  
**IMDG (sea transport)** -  
**IATA / ICAO (air transport)** -

#### 14.4.

**Packing Group** -

#### 14.5. Environmental hazards

**Marine Pollutant** -

#### 14.6. Special precautions for user

**Emergency No.** -  
**ADR/RID-Labels** -

#### 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

**Technical name** -  
**Ship type** -  
**Annex II** -

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of: GHS

#### 15.2. Chemical Safety Assessment

No information available

**SECTION 16: Other information****CLP/GHS - Regulation****Hazard Statements**

Training appropriate for workers is required to ensure protection of human health and environment.

**Source of data**

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES  
A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS  
H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK  
N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH  
N.T.P. - NATIONAL TOXICOLOGY PROGRAM  
I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER  
ECHA (European chemicals agency) databases  
FDA (Food & Drug administration) database  
EMA (European Medicines agency) documents  
ChemAdvisor  
Chemspider database

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**Revision Note**

Not applicable

**Disclaimer**

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**End of Safety Data Sheet**