1. Identification

Product identifier: Amoxicillin Related Compound D

Catalog number: 1031547

Chemical name: (4S)-2-[(R)-2-amino-2-(4-hydroxyphenyl)acetamido](carboxy)methyl]-5,5-dimethylthiazolidine-4-carboxylic acid, monosodium salt

Synonym(s): Amoxicillin penicilloic acid sodium salt

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Company name: U. S. Pharmacopeia

Address: 12601 Twinbrook Parkway

Rockville

MD

20852-1790

US

Emergency phone number

RS Technical Services 301-816-8129

CHEMTREC within US & Canada 1-800-424-9300

CHEMTREC outside US & Canada +1 703-527-3887

Website: www.usp.org

E-mail: RSTECH@usp.org

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Sensitization, respiratory Category 1

Sensitization, skin Category 1

OSHA hazard(s): Not classified.

Label elements

Signal word: Danger

Hazard statement: May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention: Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves. In case of inadequate ventilation wear respiratory protection.

Response: If on skin: Wash with plenty of water/soap. If skin irritation or rash occurs: Get medical advice/attention. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. Wash contaminated clothing before reuse.

Storage: Not available.

Disposal: Dispose of contents/container to an approved disposal site.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

Substance: Amoxicillin Related Compound D

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amoxicillin Related Compound D</td>
<td>Amoxicillin penicilloic acid sodium salt</td>
<td>68728-47-2</td>
<td>100</td>
</tr>
</tbody>
</table>
4. First-aid measures

**Inhalation**
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

**Skin contact**
Rinse skin with water/shower. For minor skin contact, avoid spreading material on unaffected skin. Get medical attention if irritation develops and persists.

**Eye contact**
Rinse with water. Get medical attention if irritation develops and persists.

**Ingestion**
Rinse mouth. Get medical attention if symptoms occur.

**Most important symptoms/effects, acute and delayed**
May cause allergic skin reaction. May cause allergic respiratory reaction.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically. Treatment of penicillin overdose may include the following: Perform gastric decontamination in cases of severe ingestion. Administer activated charcoal as a slurry. Manage anaphylaxis with establishment of patent airway, epinephrine, and diphenhydramine. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. Treat dysrhythmias with standard antiarrhythmic drugs, if necessary. Monitor fluid and electrolyte status and patients with severe vomiting and/or diarrhea. Monitor for renal and hematologic abnormalities. For coagulopathies, administer vitamin K. For moderate to severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis. Hemodialysis may aid in the removal of penicillins from the blood. [Meditext 2007 and PDR 2007]

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

**Suitable extinguishing media**
Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
No unusual fire or explosion hazards noted.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire-fighting equipment/instructions**
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate personal protective equipment.

**Methods and materials for containment and cleaning up**
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

**Precautions for safe handling**
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

**Biological limit values**
No biological exposure limits noted for the ingredient(s).

**Exposure guidelines**
No exposure standards allocated.
Appropriate engineering controls

Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

Individual protection measures, such as personal protective equipment

Eye/face protection

Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other

For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

Respiratory protection

Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards

Not available.

General hygiene considerations

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance

White powder.

Physical state

Solid.

Form

Powder.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate

Not available.

Flammability (solid, gas)

Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)

Not available.

Flammability limit - upper (%)

Not available.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor density

Not available.

Relative density

Not available.

Solubility in water

Not available.

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.
Molecular formula: C16H20NaN3O6S
Molecular weight: 405.4

10. Stability and reactivity
Reactivity: No reactivity hazards known.
Chemical stability: Stable at normal conditions.
Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.
Conditions to avoid: None known.
Incompatible materials: None known.
Hazardous decomposition products: NOx, SOx, NaOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure:
- **Ingestion**: Due to lack of data the classification is not possible.
- **Inhalation**: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- **Skin contact**: May cause an allergic skin reaction.
- **Eye contact**: Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics:

Delayed and immediate effects of exposure:
- **Penicillins**: Drop in blood pressure. Superinfections.

Cross sensitivity:
Persons sensitive to penicillin or cephalosporins, cephemycins, griseofulvin, or penicillamine may be sensitive to this material also.

Medical conditions aggravated by exposure:
- **Penicillins**: Bleeding disorders. Gastrointestinal disease. Kidney impairment. Therapeutic use of this material can reduce effectiveness of estrogen-containing contraceptives.

Acute toxicity: Due to lack of data the classification is not possible.
Skin corrosion/irritation: Due to lack of data the classification is not possible.
Serious eye damage/eye irritation: Due to lack of data the classification is not possible.

Respiratory sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitization: May cause an allergic skin reaction.
Germ cell mutagenicity: Due to lack of data the classification is not possible.
Carcinogenicity: Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity: Due to lack of data the classification is not possible.
Specific target organ toxicity - single exposure: Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure: Due to lack of data the classification is not possible.

Aspiration hazard: Based on available data, the classification criteria are not met.

12. Ecological information
Ecotoxicity: No ecotoxicity data noted for the ingredient(s).
Persistence and degradability: No data is available on the degradability of this product.
Bioaccumulative potential: Not available.
Mobility in soil: Not available.
Other adverse effects: Not available.

13. Disposal considerations
Disposal instructions: This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.
Local disposal regulations: Not available.
Hazardous waste code: Not regulated.
Waste from residues / unused products
Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging
Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT
Not regulated as a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.

15. Regulatory information

US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
No

SARA 311/312 Hazardous chemical
No

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
Not regulated.

US state regulations
This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 02-04-2010
Revision date 04-11-2013
Version # 02
Further information Not available.
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**Revision Information**

This document has undergone significant changes and should be reviewed in its entirety.