SAFETY DATA SHEET

AmpTabs Ampicillin Tablets, Part Number 300021

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

1.1 Product identifier

Product name: AmpTabs Ampicillin Tablets, Part Number 300021
EC number: 200-708-1
CAS number: 69-52-3
Part no.: 300021
Chemical formula: Na.C_{16}H_{18}N_{3}O_{4}S

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

Material uses: Pharmaceutical product. Mono-constituent substance
Acute toxicity category: Not classified
Material uses: Analytical reagent.
200 tablets 25 mg/Tab Amp Tabs Ampicillin Tablets 300021-61

1.3 Details of the supplier of the safety data sheet

Agilent Technologies LDA UK Ltd.
5500 Lakeside Cheadle Royal Business Park,
Cheadle, Cheshire, SK8 3GR
United Kingdom
Tel: +44 (0) 345 712 5292
E-mail address of person responsible for this SDS: pdl-msds_author@agilent.com

1.4 Emergency telephone number

Emergency telephone number (with hours of operation): CHEMTREC®: +(44)-870-8200418

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition: Mono-constituent substance
Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]
H317 SKIN SENSITISATION Category 1
H334 RESPIRATORY SENSITISATION Category 1

See Section 16 for the full text of the H statements declared above.
See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms: 

Signal word: Danger
Hazard statements: H317 - May cause an allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements
SECTION 2: Hazards identification


Response: P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

Storage: Not applicable.

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

Supplemental label elements: Not applicable.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles: Not applicable.

Special packaging requirements: Not applicable.

SECTION 3: Composition/information on ingredients

3.1 Substances: Mono-constituent substance

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Identifiers</th>
<th>%</th>
<th>Regulation (EC) No. 1272/2008 [CLP]</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2S-[2S-(\alpha,5\alpha,6\beta(S*))]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate]</td>
<td>EC: 200-708-1 CAS: 69-52-3</td>
<td>100</td>
<td>Resp. Sens. 1, H334 Skin Sens. 1, H317</td>
<td>[A]</td>
</tr>
</tbody>
</table>

See Section 16 for the full text of the H statements declared above.

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

Type
[A] Constituent
[B] Impurity
[C] Stabilising additive
4.1 Description of 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 10 minutes. Get medical attention if irritation occurs.

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. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 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. 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.

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.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact: No known significant effects or critical hazards.
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

Eye contact: No specific data.
Inhalation: Adverse symptoms may include the following: wheezing and breathing difficulties asthma
Skin contact: Adverse symptoms may include the following: irritation redness
Ingestion: No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

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.
SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Hazard from the substance or mixture: No specific fire or explosion hazard.

Hazardous combustion products: Decomposition products may include the following materials: carbon dioxide, carbon monoxide, nitrogen oxides, sulfur oxides, metal oxide/oxides.

5.3 Advice for firefighters

Special precautions for fire-fighters: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

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. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilt material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders: If specialised 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".

6.2 Environmental precautions: Avoid dispersal of spilt 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).

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: 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.

6.4 Reference to other sections: See Section 1 for emergency contact information. See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures: Put on appropriate personal protective equipment (see Section 8). Persons with a history of skin sensitisation 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. 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. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Storage: 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 unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations: Industrial applications, Professional applications.

Industrial sector specific solutions: Not available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits: No exposure limit value known.

Recommended monitoring procedures: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs: No DNELs/DMELs available.

PNECs: No PNECs available

8.2 Exposure controls
SECTION 8: Exposure controls/personal protection

**Appropriate engineering controls**
Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapour 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.

**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: safety glasses with side-shields.

**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.

**Environmental exposure controls**
Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties

**Appearance**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Solid.</td>
</tr>
<tr>
<td>Colour</td>
<td>White to yellowish.</td>
</tr>
<tr>
<td>Odour</td>
<td>Not available.</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>Not available.</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>202°C</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>Not available.</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not available.</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits</td>
<td>Not applicable.</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable.</td>
</tr>
</tbody>
</table>

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SECTION 9: Physical and chemical properties

- Auto-ignition temperature: Not applicable.
- Decomposition temperature: 215°C
- pH: Not available.
- Viscosity: Not applicable.
- Solubility(ies): Easily soluble in the following materials: cold water and hot water.
- Miscible with water: Yes.
- Partition coefficient: n-octanol/water: Not available.
- Vapour pressure: Not available.
- Evaporation rate: Not available.
- Relative density: Not available.
- Vapour density: Not applicable.
- Oxidising properties: Not available.
- Partition coefficient: water/octanol: Not available.
- Miscible with water: Yes.

9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

- 10.1 Reactivity: No specific test data related to reactivity available for this product or its ingredients.
- 10.2 Chemical stability: The product is stable.
- 10.3 Possibility of hazardous reactions: Under normal conditions of storage and use, hazardous reactions will not occur.
- 10.4 Conditions to avoid: No specific data.
- 10.5 Incompatible materials: May react or be incompatible with oxidising materials.
- 10.6 Hazardous decomposition products: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Dose</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2S-[2α,5α,6β(S*)]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate]</td>
<td>LD50 Oral</td>
<td>Rat</td>
<td>&gt;5314 mg/kg</td>
<td>-</td>
</tr>
</tbody>
</table>

Acute toxicity estimates

N/A

Irritation/Corrosion

Conclusion/Summary: Not available.

Sensitiser

Skin: May cause skin sensitisation.
AmpTabs Ampicillin Tablets, Part Number 300021


SECTION 11: Toxicological information

Respiratory

Mutagenicity

Conclusion/Summary

Carcinogenicity

Conclusion/Summary

Reproductive toxicity

Conclusion/Summary

Teratogenicity

Conclusion/Summary

Specific target organ toxicity (single exposure)

Conclusion/Summary: Not available.

Specific target organ toxicity (repeated exposure)

Conclusion/Summary: Not available.

Aspiration hazard

Conclusion/Summary: Not available.

Information on likely routes of exposure: Routes of entry anticipated: Oral, Dermal, Inhalation.

Potential acute health effects

Inhalation: May cause sensitisation by inhalation.

Ingestion: Not available.

Skin contact: Not available.

Eye contact: Not available.

Potential chronic health effects

General: Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.

Carcinogenicity: Not available.

Mutagenicity: Not available.

Reproductive toxicity: Not available.

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SECTION 12: Ecological information

12.1 Toxicity

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>Result</th>
<th>Species</th>
<th>Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2S-[2α,5α,6β(S*)]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate</td>
<td>Acute EC50 &gt;1000 mg/l Fresh water</td>
<td>Algae - Chlorella vulgaris</td>
<td>72 hours</td>
</tr>
<tr>
<td></td>
<td>Chronic NOEC &gt;1000 mg/l Fresh water</td>
<td>Algae - Chlorella vulgaris</td>
<td>72 hours</td>
</tr>
</tbody>
</table>

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

- Soil/water partition coefficient ($K_{OC}$): Not available.
- Mobility: Not available.

12.5 Results of PBT and vPvB assessment

<table>
<thead>
<tr>
<th>Product/ingredient name</th>
<th>PBT</th>
<th>P</th>
<th>B</th>
<th>T</th>
<th>vPvB</th>
<th>vP</th>
<th>vB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium [2S-[2α,5α,6β(S*)]-6-(aminophenylacetamido)-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>No</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

12.6 Other adverse effects

No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- **Product**
  - **Methods of disposal**: The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times 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.

- **Hazardous waste**: The classification of the product may meet the criteria for a hazardous waste.

- **Packaging**
  - **Methods of disposal**: The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

- **Special precautions**: This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.
SECTION 14: Transport information

<table>
<thead>
<tr>
<th>14.1 UN number</th>
<th>ADR/RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>14.2 UN proper shipping name</th>
<th>-</th>
<th>-</th>
<th>-</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.3 Transport hazard class(es)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>14.4 Packing group</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>14.5 Environmental hazards</td>
<td>No.</td>
<td>No.</td>
<td>No.</td>
</tr>
</tbody>
</table>

Additional information

14.6 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.

14.7 Transport in bulk according to IMO instruments: Not available.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV
None of the components are listed.

Substances of very high concern
None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Label: Not applicable.

Other EU regulations

Ozone depleting substances (1005/2009/EU)
Not listed.

Prior Informed Consent (PIC) (649/2012/EU)
Not listed.

Persistent Organic Pollutants
Not listed.

Seveso Directive
This product is not controlled under the Seveso Directive.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals
Not listed.

Montreal Protocol
SECTION 15: Regulatory information

Not listed.

Stockholm Convention on Persistent Organic Pollutants
Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)
Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals
Not listed.

Inventory list
Australia : Not determined.
Canada : Not determined.
China : This material is listed or exempted.
Europe : This material is listed or exempted.
Japan : Japan inventory (CSCL): This material is listed or exempted.
Japan inventory (ISHL): This material is listed or exempted.
New Zealand : This material is listed or exempted.
Philippines : Not determined.
Republic of Korea : This material is listed or exempted.
Taiwan : This material is listed or exempted.
Thailand : Not determined.
Turkey : This material is listed or exempted.
United States : Not determined.
Viet Nam : This material is listed or exempted.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments might still be required.

SECTION 16: Other information

Indicates information that has changed from previously issued version.

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

<table>
<thead>
<tr>
<th>Classification</th>
<th>Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resp. Sens. 1, H334&lt;br&gt;Skin Sens. 1, H317</td>
<td>Expert judgment&lt;br&gt;Expert judgment</td>
</tr>
</tbody>
</table>

Full text of abbreviated H statements

| H317 | May cause an allergic skin reaction. |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |

Full text of classifications [CLP/GHS]

| Resp. Sens. 1<br>Skin Sens. 1 | RESPIRATORY SENSITISATION - Category 1<br>SKIN SENSITISATION - Category 1 |

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SECTION 16: Other information

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