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

· 1.1 Product identifier
· Product name: (4S)-2-[[[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]amino]carboxymethyl]-5,5-dimethylthiazolidine-4-carboxylic Acid Sodium Salt (Penicilloic Acids of Amoxicillin Sodium Salt)

· Part number: MM0232.04
· CAS Number: 68728-47-2
· 1.2 Relevant identified uses of the substance or mixture and uses advised against
No further relevant information available.
· Application of the substance / the mixture Reference material for laboratory use only
· 1.3 Details of the supplier of the safety data sheet
· Manufacturer/Supplier:
  LGC Limited
  Queens Road
  Teddington
  Middlesex TW11 0LY
  UNITED KINGDOM

· Further information obtainable from:
  Product safety department
eMail : sds-request@lgcgroup.com
· 1.4 Emergency telephone number: +44 (0) 20 8943 7000 (Monday - Friday : 8am - 5pm)

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture
· Classification according to Regulation (EC) No 1272/2008

GHS08 health hazard
Resp. Sens. 1  H334  May cause allergy or asthma symptoms or breathing difficulties if inhaled.

GHS07
Acute Tox. 4  H302  Harmful if swallowed.
Skin Sens. 1  H317  May cause an allergic skin reaction.

· 2.2 Label elements
· Labelling according to Regulation (EC) No 1272/2008
The substance is classified and labelled according to the CLP regulation.
Product name: (4S)-2-[[[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]amino]carboxymethyl]-5,5-dimethylthiazolidine-4-carboxylic Acid Sodium Salt (Penicilloic Acids of Amoxicillin Sodium Salt)

- Hazard pictograms
  GHS07  GHS08

- Signal word Danger
- Hazard statements
  H302 Harmful if swallowed.
  H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  H317 May cause an allergic skin reaction.
- Precautionary statements
  P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  P280 Wear protective gloves.
  P284 [In case of inadequate ventilation] wear respiratory protection.
  P321 Specific treatment (see on this label).
  P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- 2.3 Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

 SECTION 3: Composition/information on ingredients

- 3.1 Chemical characterisation: Substances
  - CAS No. Description
  68728-47-2 (4S)-2-[[[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]amino]carboxymethyl]-5,5-dimethylthiazolidine-4-carboxylic Acid Sodium Salt (Penicilloic Acids of Amoxicillin Sodium Salt)
  - Identification number(s) None
  - RTECS: -
  - Additional information: For the wording of the listed hazard phrases refer to section 16.

 SECTION 4: First aid measures

- 4.1 Description of first aid measures
  - General information:
    Immediately remove any clothing soiled by the product.
    Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.
  - After inhalation:
    Supply fresh air and call a doctor.
**Product name:** (4S)-2-[[((2R)-2-Amino-2-(4-hydroxyphenyl)acetyl)amino]carboxymethyl]-5,5-dimethylthiazolidine-4-carboxylic Acid Sodium Salt (Penicilloic Acids of Amoxicillin Sodium Salt)

(Contd. from page 2)

- After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing:
  - Rinse mouth. Do not induce vomiting.
  - Seek medical treatment.

**4.2 Most important symptoms and effects, both acute and delayed**
No further relevant information available.

**4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

---

**SECTION 5: Firefighting measures**

- **5.1 Extinguishing media**
  - Suitable extinguishing agents: Use fire extinguishing methods suitable for surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture**
  - Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
  - Protective equipment: Wear self-contained respiratory protective device.

---

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures**
  - Avoid formation of dust.
- **6.2 Environmental precautions:**
  - Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
  - Dispose of contaminated material as waste according to item 13.
  - Ensure adequate ventilation.
- **6.4 Reference to other sections**
  - See Section 7 for information on safe handling.
  - See Section 8 for information on personal protection equipment.
  - See Section 13 for disposal information.

---

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**
  - Ensure good ventilation/extraction at the workplace.
  - Store in cool, dry place in tightly closed receptacles.
- **Information about fire - and explosion protection:**
  - No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
  - Storage:
    - Requirements to be met by storerooms and receptacles:
      - Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.
      - Store only in the original receptacle unless other advice is given on the CoA.

(Contd. on page 4)
Product name: (4S)-2-[[[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]amino]carboxymethyl]-5,5-dimethylthiazolidine-4-carboxylic Acid Sodium Salt (Penicilloic Acids of Amoxicillin Sodium Salt)

Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions: None.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- 8.1 Control parameters
  - Ingredients with limit values that require monitoring at the workplace: Not required.
  - Additional information: Lists used were valid at the time of SDS preparation.
- 8.2 Exposure controls
  - Personal protective equipment:
    - General protective and hygienic measures:
      Keep away from foodstuffs, beverages and feed.
      Immediately remove all soiled and contaminated clothing.
      Wash hands before breaks and at the end of work.
    - Respiratory protection:
      In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
      Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.
    - Protection of hands:
      The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
      Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.
      The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374.

  - Material of gloves
    Butyl rubber, BR
    Nitrile rubber, NBR
  - Penetration time of glove material
    The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
  - Eye protection: Safety glasses
## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- **General Information**
  - Appearance:
    - **Form:** Solid
    - **Colour:** White
  - Odour:
    - **Odour:** Odourless
    - **Odour threshold:** Not determined.
  - **pH-value:** Not applicable.

- **Change in condition**
  - **Melting point/freezing point:** 242 °C
  - **Initial boiling point and boiling range:** Not determined.

- **Flash point:** Not applicable.

- **Flammability (solid, gas):** Not determined.

- **Ignition temperature:** Not determined.

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Not determined.

- **Explosive properties:** Not determined.

- **Explosion limits:**
  - **Lower:** Not determined.
  - **Upper:** Not determined.

- **Vapour pressure:** Not applicable.

- **Density:** Not determined.
  - **Relative density**
  - **Vapour density**
  - **Evaporation rate**

- **Solubility in / Miscibility with water:** Not determined.

- **Partition coefficient: n-octanol/water:** Not determined.

- **Viscosity:**
  - **Dynamic:** Not applicable.
  - **Kinematic:** Not applicable.

### 9.2 Other information
No further relevant information available.
SECTION 10: Stability and reactivity

- 10.1 Reactivity Stable under normal conditions.
- 10.2 Chemical stability Stable under normal conditions.
- Thermal decomposition / conditions to be avoided: Formation of toxic gases is possible during heating or in case of fire.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid Heat.
- 10.5 Incompatible materials: Strong oxidizing agents.
- 10.6 Hazardous decomposition products: Formation of toxic gases is possible during heating or in case of fire.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
  - Acute toxicity Harmful if swallowed.
  - Primary irritant effect: Skin corrosion/irritation Based on available data, the classification criteria are not met.
  - Serious eye damage/irritation Based on available data, the classification criteria are not met.
  - Respiratory or skin sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.
  - May cause an allergic skin reaction.
  - CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
    - Germ cell mutagenicity Based on available data, the classification criteria are not met.
    - Carcinogenicity Based on available data, the classification criteria are not met.
    - Reproductive toxicity Based on available data, the classification criteria are not met.
    - STOT-single exposure Based on available data, the classification criteria are not met.
    - STOT-repeated exposure Based on available data, the classification criteria are not met.
    - Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity: No further relevant information available.
  - 12.2 Persistence and degradability No further relevant information available.
  - 12.3 Bioaccumulative potential No further relevant information available.
  - 12.4 Mobility in soil No further relevant information available.
  - Additional ecological information:
    - General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water Do not allow undiluted product to reach ground water, water course or sewage system.
Product name: (4S)-2-[[[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]amino]carboxymethyl]-5,5-dimethylthiazolidine-4-carboxylic Acid Sodium Salt (Penicilloic Acids of Amoxicillin Sodium Salt)

- 12.5 Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.
- 12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations
- 13.1 Waste treatment methods
  - Recommendation: Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
  - European waste catalogue: Waste disposal key numbers from EWC have to be assigned depending on origin and processing.
  - Uncleaned packaging: Recommendation: Dispose of in accordance with national regulations.

SECTION 14: Transport information
- 14.1 UN-Number
  - ADR, ADN, IMDG, IATA: Not applicable
  - ADR, ADN, IMDG, IATA: Not applicable
- 14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA
    - Class: Not applicable
- 14.4 Packing group
  - ADR, IMDG, IATA: Not applicable
- 14.5 Environmental hazards: Not applicable.
- 14.6 Special precautions for user: Not applicable.
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Not applicable.
- UN "Model Regulation": Not applicable

SECTION 15: Regulatory information
- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU: Named dangerous substances - ANNEX I Substance is not listed.
Product name: (4S)-2-([(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]amino)carboxymethyl]-5,5-dimethylthiazolidine-4-carboxylic Acid Sodium Salt (Penicilloic Acids of Amoxicillin Sodium Salt)

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user’s intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

Abbreviations and acronyms:
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1

Sources

Data compared to the previous version altered. All sections have been updated.