

Material Safety Data Sheet

Ampicare 250 mg Capsules

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s): Ampicare 250 mg Capsules
Product code(s): XVD 682 (500 capsules)

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

Relevant identified uses: Veterinary medicinal product
Uses advised against: Not for human use. Refer to the product information leaflet
Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name: Animalcare Limited
Address: 10 Great Northway
York Business Park
Nether Poppleton
York
YO26 6RB
United Kingdom

1.4 Emergency telephone number

Daytime: +44 (0) 1904 487687

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008 This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms: Not applicable

Signal word: Not applicable

Hazard statements: Not applicable

Precautionary statements: Not applicable

Supplemental information: Treat symptomatically; provide support to maintain life functions. Accidental ingestion should require no special treatment, only observation.
For specialist advice doctors should contact the nearest poison information centre.

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC) None known

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

| <i>Substance name in the mixture</i> | <i>CAS No</i> | <i>Quantity</i> |
|--------------------------------------|---------------|-----------------|
| Ampicillin trihydrate | [7177-48-2] | 250 mg/capsule |
| Magnesium stearate | [557-04-0] | Proprietary |
| Other non-dangerous ingredients | NA | Proprietary |

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

| | |
|--------------------|--|
| Eyes: | Remove any contact lenses before rinsing. Flush with water for at least 15 minutes. Make sure that no solid particles remain in the eye. Obtain medical attention. |
| Skin: | Wash immediately with soap and water. Obtain medical attention in cases of persistent irritation |
| Ingestion: | If swallowed, obtain immediate medical attention. Do not induce vomiting unless directed by medical personnel. Rinse mouth thoroughly with water |
| Inhalation: | Remove to fresh air. If difficulty breathing administer oxygen or artificial respiration |

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more information on health effects and symptoms

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically; provide support to maintain life functions. Accidental ingestion should require no special treatment, only observation. For specialist advice doctors should contact the nearest Poisons Information Centre

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

| | |
|--|--|
| Suitable extinguishing media: | Use carbon dioxide, dry chemical or alcohol-resistant foam spray extinguishers. Use water spray to cool fire-exposed containers. A fine water mist may be used to smother or to disperse vapours |
| Unsuitable extinguishing media: | None known |

5.2 Special hazards arising from the substance or mixture

| | |
|--|--|
| Specific hazards during firefighting: | Not flammable or combustible |
| Hazardous combustion products: | Decomposition products may include the following materials: Carbon oxides (CO _x), nitrogen oxides (NO _x) |

5.3 Advice for fire-fighters

| | |
|---|--|
| Special protective equipment for firefighters: | Use personal protective equipment |
| Further information: | Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations |

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

| | |
|--|--|
| Advice for non-emergency personnel: | Provide good ventilation. Prevent skin and eye contact |
|--|--|

Advice 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

6.2 Environmental precautions

Spillages or uncontrolled discharges into watercourses, drains or sewers must be immediately alerted to the Environment Agency or other equivalent body.

6.3 Methods and material for containment and cleaning up

Small spills: For small spillages absorb with cloth or suitable absorbent and dispose of as contaminated waste. Prevent skin contact

Large spills: For large spillages, evacuate area. Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves

6.4 Reference to other sections

See Section 1 for emergency contact information

See section 8 for personal protection

See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling: Wear dust mask, goggles and gloves when handling powder. Ensure adequate ventilation in dusty atmosphere. Avoid exposure to dust

Hygiene measures: None identified

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep out of reach of children. Keep in the original packaging.

Storage temperature: Store below 25 °C

Further information on storage conditions: Keep in a dry place. Protect from direct incidence of light

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. At this time, none of the constituents have known exposure limits

8.2 Exposure controls

Engineering measures: Good general ventilation should be sufficient to control worker exposure to airborne contaminants

Individual protection measures:

Hygiene measures: No specific measures identified

Eye/face protection: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent)

Skin/body protection: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent)

Hand protection: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent)

Respiratory protection: Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent)

Environmental exposure controls: Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| | |
|-----------------------------------|---|
| Appearance | Powder |
| Colour: | White |
| Odour: | None |
| Odour threshold: | No data available |
| pH: | No data available |
| Density: | No data available |
| Melting point: | No data available |
| Boiling point: | No data available |
| Flash point: | No data available |
| Evaporation rate: | No data available |
| Flammability: | No data available |
| Water solubility: | Slightly soluble |
| Partition coefficient: | No data available |
| Auto-ignition temperature: | No data available |
| Thermal decomposition: | No data available |
| Viscosity: | No data available |
| Vapour pressure: | No data available |
| Vapour density: | No data available |
| Explosive properties: | No data available |
| Oxidizing properties: | The substance or mixture is not classified as oxidizing |

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

Strong oxidants

10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

| | |
|---------------------------------------|---|
| Acute toxicity: | Ampicillin trihydrate LD ₅₀ >10000 mg/kg (Rat, oral) |
| Chronic toxicity: | Ampicillin trihydrate may affect genetic material. May cause adverse reproductive effects based on animal data. Passes through the placental barrier in humans. |
| Skin irritation/sensitization: | No data available |
| Reproductive toxicity: | No data available |
| Carcinogenicity: | Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related carcinogenic/tumorigenic effects based on animal data |
| Mutagenicity: | No data available |

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15: REGULATORY INFORMATION

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

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

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