SAFETY DATA SHEET

Benzylpenicillin Formulation

Version 1.4
Revision Date: 23.03.2020
SDS Number: 3928957-00005
Date of last issue: 13.09.2019
Date of first issue: 02.01.2019

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

1.1 Product identifier
Trade name: Benzylpenicillin Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary product

1.3 Details of the supplier of the safety data sheet
Company: MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone: +27119239300
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Respiratory sensitisation, Category 1
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin sensitisation, Category 1
H317: May cause an allergic skin reaction.
Short-term (acute) aquatic hazard, Category 1
H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
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.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
P273 Avoid release to the environment.
P280 Wear protective gloves.

**Response:**
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
P391 Collect spillage.

Hazardous components which must be listed on the label:
6-(2-Phenylacetamido)penicillanic acid

### 2.3 Other hazards
None known.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-(2-Phenylacetamido)penicillanic acid</td>
<td>61-33-6</td>
<td>200-506-3</td>
<td></td>
<td>Resp. Sens.1A; H334 Skin Sens.1B; H317 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt;= 25 - &lt; 30</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

General advice:
In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
### Protection of first-aiders

First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

### If inhaled

- If inhaled, remove to fresh air.
- If not breathing, give artificial respiration.
- If breathing is difficult, give oxygen.
- Get medical attention.

### In case of skin contact

- In case of contact, immediately flush skin with soap and plenty of water.
- Remove contaminated clothing and shoes.
- Get medical attention.
- Wash clothing before reuse.
- Thoroughly clean shoes before reuse.

### In case of eye contact

- Flush eyes with water as a precaution.
- Get medical attention if irritation develops and persists.

### If swallowed

- If swallowed, DO NOT induce vomiting.
- Get medical attention if symptoms occur.
- Rinse mouth thoroughly with water.

### 4.2 Most important symptoms and effects, both acute and delayed

Risks:

- May cause an allergic skin reaction.
- May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media: Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical

- Unsuitable extinguishing media: None known.

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.
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Hazardous combustion products: Carbon oxides  
Metal oxides

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions: Discharge into the environment must be avoided.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE
CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Do not get on skin or clothing.
Avoid inhalation of vapour or mist.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Keep tightly closed.
Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-(2-Phenylacetamido)penicillanic acid</td>
<td>61-33-6</td>
<td>TWA</td>
<td>2000 µg/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN
Further information: RSEN
8.2 Exposure controls

**Engineering measures**
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

**Personal protective equipment**
- **Eye protection**: Wear safety glasses with side shields or goggles.
  If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
  Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

- **Hand protection**: Material - Chemical-resistant gloves

- **Skin and body protection**: Work uniform or laboratory coat.

- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - **Filter type**: Particulates type (P)

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**
- **Appearance**: suspension
- **Colour**: white
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
Relative density : No data available
Density : No data available
Solubility(ies)
   Water solubility : soluble
   Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
   Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
   Flammability (liquids) : Not applicable
   Molecular weight : No data available
   Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
   Not classified as a reactivity hazard.

10.2 Chemical stability
   Stable under normal conditions.

10.3 Possibility of hazardous reactions
   Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
   Conditions to avoid : None known.

10.5 Incompatible materials
   Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
   No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
   Information on likely routes of : Inhalation
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<table>
<thead>
<tr>
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</tbody>
</table>

exposure
Skin contact
Ingestion
Eye contact

**Acute toxicity**
Not classified based on available information.

**Components:**

6-(2-Phenylacetamido)penicillanic acid:

<table>
<thead>
<tr>
<th>Application Route</th>
<th>LD50 (Rat):</th>
<th>LD50 (Mouse):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraperitoneal</td>
<td>8.000 mg/kg</td>
<td>&gt; 5.000 mg/kg</td>
</tr>
<tr>
<td>Intravenous</td>
<td>3.500 mg/kg</td>
<td>329 mg/kg</td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**
Not classified based on available information.

**Serious eye damage/eye irritation**
Not classified based on available information.

**Respiratory or skin sensitisation**

**Skin sensitisation**
May cause an allergic skin reaction.

**Respiratory sensitisation**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:**

6-(2-Phenylacetamido)penicillanic acid:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local lymph node assay (LLNA)</td>
<td>Dermal</td>
<td>Mouse</td>
<td>Weak sensitizer</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Maximisation Test</td>
<td>Dermal</td>
<td>Guinea pig</td>
<td>positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Based on human experience.</td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity**
Not classified based on available information.
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Components:

6-(2-Phenylacetamido)penicillanic acid:
Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

Components:

6-(2-Phenylacetamido)penicillanic acid:
Effects on fertility:
Test Type: Fertility
Species: Mouse
Result: No effects on fertility
Test Type: Fertility
Species: Rat
Result: No effects on fertility
Test Type: Fertility
Species: Rabbit
Result: No effects on fertility

Effects on foetal development:
Test Type: Development
Species: Mouse
Result: No effects on foetal development
Test Type: Development
Species: Rat
Result: No effects on foetal development
Test Type: Development
Species: Rabbit
Result: No effects on foetal development

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

6-(2-Phenylacetamido)penicillanic acid:
Inhalation: Symptoms: Allergic reactions, Abdominal pain, bronchospasm, skin rash
SECTION 12: Ecological information

12.1 Toxicity

Components:

6-(2-Phenylacetamido)penicillanic acid:

Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): 1.000 mg/l
Exposure time: 96 hrs
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 1.000 mg/l
Exposure time: 48 hrs
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50 (Anabaena flos-aquae): 0,006 mg/l
Exposure time: 96 hrs
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 hrs
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity): 100

M-Factor (Chronic aquatic toxicity): 100

12.2 Persistence and degradability

Components:

6-(2-Phenylacetamido)penicillanic acid:

Biodegradability: Biodegradation: 27 %
Exposure time: 28 d
Method: OECD Test Guideline 301D
Remarks: Not inherently biodegradable.
Based on data from similar materials

12.3 Bioaccumulative potential

Components:

6-(2-Phenylacetamido)penicillanic acid:

Partition coefficient: n-octanol/water: log Pow: 1.83

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant
SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

| ADN | UN 3082 |
| ADR | UN 3082 |
| RID | UN 3082 |
| IMDG | UN 3082 |
| IATA | UN 3082 |

14.2 UN proper shipping name

| ADN | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid) |
| ADR | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid) |
| RID | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid) |
| IMDG | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (6-(2-Phenylacetamido)penicillanic acid) |
| IATA | Environmentally hazardous substance, liquid, n.o.s. (6-(2-Phenylacetamido)penicillanic acid) |

14.3 Transport hazard class(es)

| ADN | 9 |
| ADR | 9 |
| RID | 9 |
| IMDG | 9 |
| IATA | 9 |
14.4 Packing group

**ADN**
Packing group: III  
Classification Code: M6  
Hazard Identification Number: 90  
Labels: 9

**ADR**
Packing group: III  
Classification Code: M6  
Hazard Identification Number: 90  
Labels: 9  
Tunnel restriction code: (-)

**RID**
Packing group: III  
Classification Code: M6  
Hazard Identification Number: 90  
Labels: 9

**IMDG**
Packing group: III  
Labels: 9  
EmS Code: F-A, S-F

**IATA (Cargo)**
Packing instruction (cargo aircraft): 964  
Packing instruction (LQ): Y964  
Packing group: III  
Labels: Miscellaneous

**IATA (Passenger)**
Packing instruction (passenger aircraft): 964  
Packing instruction (LQ): Y964  
Packing group: III  
Labels: Miscellaneous

14.5 Environmental hazards

**ADN**
Environmentally hazardous: yes

**ADR**
Environmentally hazardous: yes

**RID**
Environmentally hazardous: yes

**IMDG**
Marine pollutant: yes

**IATA (Passenger)**
Environmentally hazardous: yes

**IATA (Cargo)**
Environmentally hazardous: yes
14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

- H317: May cause an allergic skin reaction.
- H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- H400: Very toxic to aquatic life.
- H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- Aquatic Acute: Short-term (acute) aquatic hazard
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Resp. Sens.: Respiratory sensitisation
- Skin Sens.: Skin sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - In-
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**Further information**


**Classification of the mixture:**

<table>
<thead>
<tr>
<th></th>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resp. Sens. 1</td>
<td>H334 Calculation method</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>H317 Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400 Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410 Calculation method</td>
</tr>
</tbody>
</table>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

ZA / EN