SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Benzylpenicillin Formulation

Version 2.5  Revision Date: 2021/08/27  SDS Number: 3928977-00011  Date of last issue: 2020/10/10
Date of first issue: 2019/01/02

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Benzylpenicillin Formulation

Manufacturer or supplier's details
Company: MSD
Address: No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone: +1-908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: suspension
Colour: white
Odour: No data available

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.

GHS Classification
Respiratory sensitisation: Category 1
Skin sensitisation: Category 1
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 3

GHS 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.
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H400 Very toxic to aquatic life.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

**Prevention:**
- P261 Avoid breathing mist or vapours.
- P272 Contaminated work clothing should not be allowed out of the workplace.
- P273 Avoid release to the environment.
- P280 Wear protective gloves.
- P284 Wear respiratory protection.

**Response:**
- P302 + P352 IF ON SKIN: Wash with plenty of water.
- 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.
- P362 + P364 Take off contaminated clothing and wash it before reuse.
- P391 Collect spillage.

**Disposal:**
- P501 Dispose of contents/container to an approved waste disposal plant.

**Physical and chemical hazards**
Not classified based on available information.

**Health hazards**
May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

**Environmental hazards**
Very toxic to aquatic life. Harmful to aquatic life with long lasting effects.

**Other hazards which do not result in classification**
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Benzy1penicillin</td>
<td>61-33-6</td>
</tr>
</tbody>
</table>

4. 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.

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.

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.

Most important symptoms and effects, both acute and delayed : 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).

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).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

Specific hazards during firefighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Metal oxides

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.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal pro-
7. HANDLING AND STORAGE

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 breathing mist or vapours.
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.

Avoidance of contact : Oxidizing agents

Storage

Conditions for safe storage : Keep in properly labelled containers.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Packaging material : Unsuitable material: None known.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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

Further information: RSEN, DSEN

Wipe limit

100 µg/100 cm2

Internal

Engineering measures:
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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

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
Eye/face 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.

Skin and body protection:
Work uniform or laboratory coat.

Hand protection:
Material:
Chemical-resistant gloves

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.
Contaminated work clothing should not be allowed out of the workplace.
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: suspension

Colour: white
# Benzylpenicillin Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit/Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit/Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
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</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:

Benzylpenicillin:
Acute oral toxicity: LD50 (Rat): 8,000 mg/kg
   LD50 (Mouse): > 5,000 mg/kg
Acute toxicity (other routes of administration): LD50 (Mouse): 3,500 mg/kg
   Application Route: Intraperitoneal
   LD50 (Mouse): 329 mg/kg
   Application Route: Intravenous

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:

Benzylpenicillin:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Dermal
Species: Mouse
Result: Weak sensitizer
Maximisation Test
  : Dermal
  : Guinea pig
  : positive

Remarks
  : Based on data from similar materials

Remarks
  : Strong sensitizer
  : Based on human experience.

Germ cell mutagenicity
Not classified based on available information.

Components:

Benzylpenicillin:
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:

Benzylpenicillin:
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
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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:

Benzylpenicillin:
Inhalation: Symptoms: Allergic reactions, Abdominal pain, bronchospasm, skin rash

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Benzylpenicillin:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 hrs
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 3.6 mg/l
Exposure time: 48 hrs
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC50 (blue-green algae): 0.74 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (blue-green algae): 0.14 mg/l
Exposure time: 72 hrs
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials
## Benzylpenicillin Formulation

**M-Factor (Acute aquatic toxicity):** 1

**Toxicity to microorganisms:**
- EC50: > 500 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209
- Remarks: Based on data from similar materials

**NOEC:** 5 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209
- Remarks: Based on data from similar materials

### Persistence and degradability

**Components:**

**Benzylpenicillin:**

**Biodegradability:**
- Result: Readily biodegradable.
- Biodegradation: 70.10 %
- Exposure time: 28 d
- Method: OECD Test Guideline 301B
- Remarks: Based on data from similar materials

**Bioaccumulative potential

**Components:**

**Benzylpenicillin:**

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

**Mobility in soil:**
No data available

**Other adverse effects:**
No data available

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- Waste from residues: Dispose of in accordance with local regulations.
- 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.

### 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Benzylpenicillin Formulation

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin)

Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Benzylpenicillin)

Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

GB 6944/12268
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Benzylpenicillin)

Class : 9
Packing group : III
Labels : 9

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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases
The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet:

Date format: yyyy/mm/dd

Full text of other abbreviations:

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TGD - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
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Benzylpenicillin Formulation

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<tr>
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<td>2021/08/27</td>
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<td>2020/10/10</td>
<td>2019/01/02</td>
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</tbody>
</table>

Disclaimer
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.

CN / EN