SAFETY DATA SHEET

Benzylpenicillin Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Benzylpenicillin Formulation

Manufacturer or supplier's details

Company : MSD
Address : JL Raya Pandaan KM. 48
           Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification

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

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.
H410 Very toxic 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.

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>
</table>

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6-(2-Phenylacetamido)penicillanic acid</td>
<td>61-33-6</td>
<td>&gt;= 25 -&lt; 30</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.
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.
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 and personal protective equipment recommendations.

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.

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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.

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

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>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: RSEN

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
Hand protection
Material: Chemical-resistant gloves

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.

Skin and body protection: Work uniform or laboratory coat.

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.

9. 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

Flammability (liquids): 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.
Molecular weight : No data available
Particle size : Not applicable

10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac-
tions : 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
Information on likely routes of exposure : Inhalation
                                           Skin contact
                                           Ingestion
                                           Eye contact

Acute toxicity
Not classified based on available information.

Components:
6-(2-Phenylacetamido)penicillanic acid:
Acute oral toxicity : LD50 (Rat): 8,000 mg/kg
                     : LD50 (Mouse): > 5,000 mg/kg
Acute toxicity (other routes of : LD50 (Mouse): 3,500 mg/kg
SAFETY DATA SHEET

Benzylpenicillin Formulation

Administration

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:

6-(2-Phenylacetamido)penicillanic acid:

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

Germ cell mutagenicity
Not classified based on available information.

Components:

6-(2-Phenylacetamido)penicillanic acid:

Germ cell mutagenicity: 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

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**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

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

Bioaccumulative potential

Components:

6-(2-Phenylacetamido)penicillanic acid:
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
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
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Version  1.4  Revision Date:  2020/03/23  SDS Number:  3928975-00005  Date of last issue:  2019/09/13  Date of first issue:  2019/01/02

Class  :  9
Packing group  :  III
Labels  :  9

IATA-DGR
UN/ID No.  :  UN 3082
Proper shipping name  :  Environmentally hazardous substance, liquid, n.o.s. (6-(2-Phenylacetamido)penicillanic acid)
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. (6-(2-Phenylacetamido)penicillanic acid)
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.

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

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered  :  Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use  :  Not applicable
## 16. OTHER INFORMATION

### Further information

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Date format</td>
<td>yyyy/mm/dd</td>
</tr>
</tbody>
</table>

### Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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 Organisation 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
SAFETY DATA SHEET

Benzylpenicillin Formulation

Version 1.4  Revision Date: 2020/03/23  SDS Number: 3928975-00005  Date of last issue: 2019/09/13

Date of first issue: 2019/01/02

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; TDG - Transportation of Dangerous Goods; 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

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.

ID / EN