SAFETY DATA SHEET

Benzylpenicillin Formulation

SECTION 1. IDENTIFICATION

Product name : Benzylpenicillin Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
          Kenilworth - New Jersey - U.S.A. 07033
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASEWARD@merck.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Respiratory sensitization : Category 1
Skin sensitization : 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.

Precautionary Statements : Prevention:
P261 Avoid breathing mist or vapors.
P272 Contaminated work clothing must not be allowed out of the workplace.
P280 Wear protective gloves.
P285 In case of inadequate ventilation wear respiratory protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, 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.
P363 Wash contaminated clothing before reuse.
**SAFETY DATA SHEET**

**Benzylpenicillin Formulation**

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

**Other hazards**
None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mixtures</strong></td>
<td>6-(2-Phenylacetamido)penicillanic acid</td>
<td>61-33-6</td>
<td>&gt;= 20 - &lt; 30</td>
<td></td>
</tr>
</tbody>
</table>

Actual concentration is withheld as a trade secret

**SECTION 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.

**SECTION 5. FIRE-FIGHTING 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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 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 vapor 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 sensitized individuals should consult their physician regarding working with respiratory irritants or sensitizers. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labeled 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

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients 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**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: suspension

Color: white

Odor: No data available

Odor 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

Vapor pressure: No data available

Relative vapor density: No data available

Relative density: No data available

Density: No data available
SAFETY DATA SHEET

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Solubility(ies)
  Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Autoignition 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

SECTION 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.

SECTION 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 administration) : LD50 (Mouse): 3,500 mg/kg
Application Route: Intraperitoneal
LD50 (Mouse): 329 mg/kg
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Benzylpenicillin Formulation

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 sensitization

Skin sensitization
May cause an allergic skin reaction.

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

Components:

6-(2-Phenylacetamido)penicillanic acid:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Dermal
Species : Mouse
Result : Weak sensitizer

Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Result : positive
Remarks : Based on data from similar materials

Result : Strong sensitizer
Remarks : Based on human experience.

Germ cell mutagenicity
Not classified based on available information.

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.

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP
No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
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 fetal development:
  - Test Type: Development
  - Species: Mouse
  - Result: No effects on fetal development.
  - Test Type: Development
  - Species: Rat
  - Result: No effects on fetal development.
  - Test Type: Development
  - Species: Rabbit
  - Result: No effects on fetal 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

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

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

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
SAFETY DATA SHEET

Benzylpenicillin Formulation

Version: 1.4  Revision Date: 03/23/2020  SDS Number: 3928958-00005  Date of last issue: 09/13/2019
Date of first issue: 01/02/2019

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

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

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.

Domestic regulation

49 CFR
UN/ID/NA number: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (6-(2-Phenylacetamido)penicillanic acid)

Class: 9
Packing group: III
Labels: CLASS 9
ERG Code: 171
Marine pollutant: yes (6-(2-Phenylacetamido)penicillanic acid)
Remarks: Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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.
SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Respiratory or skin sensitization

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

Water 7732-18-5
6-(2-Phenylacetamido)penicillanic acid 61-33-6

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information
SAFETY DATA SHEET

Benzylpenicillin Formulation

Version 1.4
Revision Date: 03/23/2020
SDS Number: 3928958-00005
Date of last issue: 09/13/2019
Date of first issue: 01/02/2019

NFPA 704:

Flammability

Health 2
Instability 0

PHYSICAL HAZARD

Special hazard

HMIS® IV:

HEALTH

2

FLAMMABILITY

* 2

PHYSICAL HAZARD

1 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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
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.