SAFETY DATA SHEET
according to the Hazardous Products Regulations

Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

SECTION 1. IDENTIFICATION

Product name: Benzy1penicillin / Dihydrostreptomycin Sulphate Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Respiratory sensitization: Sub-category 1A
Skin sensitization: Sub-category 1B
Reproductive toxicity: Category 2
Specific target organ toxicity - repeated exposure (Oral): Category 1 (ear, Kidney, inner ear)

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.
H361d Suspected of damaging the unborn child.
H372 Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
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.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P342 + P311 If experiencing respiratory symptoms: Call a doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents and 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>Mixture</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dihydrostreptomycin sulphate</td>
<td>No data available</td>
<td>5490-27-7</td>
<td>27.89</td>
</tr>
<tr>
<td></td>
<td>Benzylpenicillin</td>
<td>No data available</td>
<td>61-33-6</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxymethanesulphonate</td>
<td>Methanesulfinic acid, 1-hydroxy-, sodium salt (1:1)</td>
<td>149-44-0</td>
<td>0.25</td>
</tr>
</tbody>
</table>

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 | | | |
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.
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.
Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.
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 (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
- Avoid release to the environment.
- 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.
- Do not breathe mist or vapors.
- Do not swallow.
- Avoid contact with eyes.
- Wash skin thoroughly after handling.
- 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, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

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

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives
  - Gases

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>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: OTO</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Not required</td>
</tr>
<tr>
<td>Benzylpenicillin</td>
<td>61-33-6</td>
<td>TWA</td>
<td>600 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: RSEN, DSEN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
</tr>
</tbody>
</table>

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

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.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: suspension
Color: off-white, white
Odor: No data available
Odor Threshold: No data available
pH: 5.0 - 7.2
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): No data available
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: 1.14 - 1.18 g/cm³
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: 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:
Dihydrostreptomycin sulphate:
Acute oral toxicity: LD50 (Rat): 9,000 - 25,000 mg/kg
LD50 Oral (Mouse): 30,000 mg/kg

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

Sodium hydroxymethanesulphinate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation
Not classified based on available information.

Components:
Sodium hydroxymethanesulphinate:
Species: Rat
Result: No skin irritation

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

Components:
Sodium hydroxymethanesulphinate:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

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:**

**Benzylpenicillin:**
- **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.

**Sodium hydroxymethanesulphinate:**
- **Test Type:** Maximization Test
- **Routes of exposure:** Skin contact
- **Species:** Guinea pig
- **Method:** OECD Test Guideline 406
- **Result:** negative

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

**Components:**

**Dihydrostreptomycin sulphate:**
- **Genotoxicity in vitro:** Test Type: Chromosome aberration test in vitro
  - **Test system:** Human lymphocytes
  - **Result:** negative

**Benzylpenicillin:**
- **Germ cell mutagenicity - Assessment:** Weight of evidence does not support classification as a germ cell mutagen.

**Sodium hydroxymethanesulphinate:**
- **Genotoxicity in vitro:**
  - **Test Type:** Bacterial reverse mutation assay (AMES)
    - **Method:** OECD Test Guideline 471
    - **Result:** negative
  - **Test Type:** In vitro mammalian cell gene mutation test
    - **Method:** OECD Test Guideline 476
    - **Result:** positive
- **Genotoxicity in vivo:**
  - **Test Type:** Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
    - **Species:** Mouse
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Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: positive

Germ cell mutagenicity -
Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Carcinogenicity
Not classified based on available information.

Components:

Dihydrostreptomycin sulphate:
Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 5 mg/kg body weight
Result : negative

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Dihydrostreptomycin sulphate:
Effects on fetal development : Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 5 mg/kg body weight

Test Type: Embryo-fetal development
Species: Guinea pig
Application Route: Intramuscular
General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body weight
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: Maternal toxicity observed., Embryotoxic effects and adverse effects on the offspring were detected.

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.

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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.

Sodium hydroxymethanesulphinate:
Effects on fertility:  
Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative

Effects on fetal development:  
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: positive

Reproductive toxicity - Assessment:  
Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Components:
Dihydrostreptomycin sulphate:
Assessment:  
Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
Dihydrostreptomycin sulphate:
Species:  
Guinea pig
LOAEL:  
40 mg/kg
Application Route:  
Oral
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Exposure time: 90 d
Target Organs: ear
Symptoms: hearing loss

Species: Cat
LOAEL: 100 mg/kg
Application Route: Oral
Exposure time: 60 d
Target Organs: ear
Symptoms: ataxia, hearing loss, Reduced body weight

Species: Cat
LOAEL: 300 mg/kg
Application Route: Oral
Exposure time: 21 d
Target Organs: ear
Symptoms: ataxia, hearing loss, Reduced body weight

Sodium hydroxymethanesulphinate:
Species: Rat
NOAEL: 600 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Method: OECD Test Guideline 408

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Dihydrostreptomycin sulphate:
General Information: Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting, Headache, hypotension

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

SECTION 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

Toxicity to daphnia and other: EC50 (Daphnia magna (Water flea)): 3.6 mg/l
aquatic invertebrates

Toxicity to algae/aquatic plants:

- EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l
  Exposure time: 72 hrs
  Method: OECD Test Guideline 201
- NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l
  Exposure time: 72 hrs
  Method: OECD Test Guideline 201
- EC50 (blue-green algae): 0.74 mg/l
  Exposure time: 72 hrs
  Method: OECD Test Guideline 201
- NOEC (blue-green algae): 0.14 mg/l
  Exposure time: 72 hrs
  Method: OECD Test Guideline 201

Toxicity to microorganisms:

- EC50: > 500 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209
- NOEC: 5 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

Sodium hydroxymethanesulphinate:

Toxicity to fish:

- LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:

- ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):

- NOEC (Danio rerio (zebra fish)): 13.5 mg/l
  Exposure time: 35 d
  Method: OECD Test Guideline 210

Toxicity to daphnia and other:

- EC10 (Daphnia magna (Water flea)): 8 mg/l
aquatic invertebrates (Chron- ic toxicity) Exposition time: 21 d Method: OECD Test Guideline 211

Toxicity to microorganisms: NOEC: 10 mg/l Exposure time: 4 h

Persistence and degradability
Components:
Benzylpenicillin:
Biodegradability: Result: Readily biodegradable. Biodegradation: 70.10 % Exposure time: 28 d Method: OECD Test Guideline 301B

Sodium hydroxymethanesulphinate:

Bioaccumulative potential
Components:
Sodium hydroxymethanesulphinate:
Partition coefficient: n- octanol/water log Pow: < 0.3

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Do not dispose of waste into sewer. 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
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

Domestic regulation

TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

The ingredients of this product are reported in the following inventories:
AICS   :  not determined
DSL    :  not determined
IECSC  :  not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIC - 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 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 Loading Rate; 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 Develop-
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