1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dihydrostreptomycin Sulfate 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 : No data available
Colour : No data available
Odour : No data available
Causes serious eye irritation. Causes damage to organs through prolonged or repeated exposure.

GHS Classification
Serious eye damage/eye irritation : Category 2A
Specific target organ toxicity - repeated exposure : Category 1

GHS label elements
Hazard pictograms : 

Signal word : Danger
Hazard statements : H319 Causes serious eye irritation.
H372 Causes damage to organs through prolonged or repeated exposure.
Precautionary statements : Prevention:
P260 Do not breathe mist or vapours.
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P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear eye protection/ face protection.

Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 Get medical advice/ attention if you feel unwell.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

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

Physical and chemical hazards
Not classified based on available information.

Health hazards
Causes serious eye irritation. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards
Not classified based on available information.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>Sodium metabisulphite</td>
<td>7681-57-4</td>
<td>&gt;= 1 - &lt; 2.5</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.
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

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

Most important symptoms and effects, both acute and delayed:

- Causes serious eye irritation.
- Causes damage to organs through prolonged or repeated exposure.

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
- Sulphur 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 dis-
posal 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

Handling
Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation : Use only with adequate ventilation.
Advice on safe handling : Avoid inhalation of vapour or mist.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
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.
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>dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>TWA</td>
<td>0.4 mg/m3 (OEB 2)</td>
<td></td>
</tr>
</tbody>
</table>

Further information: OTO

<table>
<thead>
<tr>
<th></th>
<th>Wipe limit</th>
<th>Not required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium metabisulphite</td>
<td>7681-57-4</td>
<td>TWA</td>
</tr>
</tbody>
</table>

Occupational exposure limits of decomposition products

<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>Sulphur dioxide</td>
<td>7446-09-5</td>
<td>PC-TWA</td>
<td>5 mg/m3</td>
<td>GBZ 2.1-2007</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PC-STEL</td>
<td>10 mg/m3</td>
<td>GBZ 2.1-2007</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>STEL</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. No open handling permitted. Totally enclosed processes and materials transport systems are required. Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0.25 ppm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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: Combined particulates and inorganic gas/vapour 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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hand protection: Chemical-resistant gloves

Remarks: Consider double gloving.

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: No data available

Colour: No data available

Odour: No data available
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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) : No data available
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 : No data available
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 reactions:
- Can react with strong oxidizing agents.
- Hazardous decomposition products will be formed at elevated temperatures.

Conditions to avoid: None known.
Incompatible materials: Oxidizing agents

Hazardous decomposition products:
- Thermal decomposition: Sulphur dioxide

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity:
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
dihydrostreptomycin sulphate:
Acute oral toxicity: LD50 (Rat): 9,000 - 25,000 mg/kg
LD50 Oral (Mouse): 30,000 mg/kg

Sodium metabisulphite:
Acute oral toxicity: LD50 (Rat): 1,540 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity: LC50 (Rat): > 5.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Skin corrosion/irritation:
Not classified based on available information.
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Components:
Sodium metabisulphite:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:
Sodium metabisulphite:
Species: Rabbit
Result: Irreversible effects on the eye
Method: OECD Test Guideline 405

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:
Sodium metabisulphite:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
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

Sodium metabisulphite:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo
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Cytogenetic assay:
Species: Mouse
Application Route: Subcutaneous
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

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

Sodium metabisulphite:
Species: Mouse
Application Route: Ingestion
Exposure time: 24 Months
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
Not classified based on available information.

Components:
dihydrostreptomycin sulphate:
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 5 mg/kg body weight
Test Type: Embryo-foetal 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.

Sodium metabisulphite:
Species: Rat
Application Route: Ingestion
Result: negative
Effects on foetal development:

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs through prolonged or repeated exposure.

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
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 metabisulphite:
Species: Rat
NOAEL: 110 mg/kg
LOAEL: 220 mg/kg
Application Route: Ingestion
Exposure time: 104 Weeks

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

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Sodium metabisulphite:**

**Toxicity to fish**

| LC50 (Oncorhynchus mykiss (rainbow trout)) | 178 mg/l |
| Exposure time: 96 h |

**Toxicity to daphnia and other aquatic invertebrates**

| EC50 (Daphnia magna (Water flea)) | 89 mg/l |
| Exposure time: 48 h |

**Toxicity to algae/aquatic plants**

| ErC50 (Desmodesmus subspicatus (green algae)) | 43.8 mg/l |
| Exposure time: 72 h |

| EC10 (Desmodesmus subspicatus (green algae)) | 33.3 mg/l |
| Exposure time: 72 h |

**Toxicity to fish (Chronic toxicity)**

| NOEC (Danio rerio (zebra fish)) | >= 316 mg/l |
| Exposure time: 34 d |
| Method: OECD Test Guideline 210 |
| Remarks: Based on data from similar materials |

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

| NOEC (Daphnia magna (Water flea)) | >= 10 mg/l |
| Exposure time: 21 d |

**Toxicity to microorganisms**

| EC10 (Pseudomonas putida) | 30.8 mg/l |
| Exposure time: 17 h |

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**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
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.

National Regulations

GB 6944/12268
Not regulated as a dangerous good

Special precautions for user
Not applicable

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

16. OTHER INFORMATION

Further information
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Full text of other abbreviations:
ACGIH: USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
GBZ 2.1-2007 / PC-TWA: Permissible concentration - time weighted average

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, storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.
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