1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Dihydrostreptomycin Sulfate Formulation

Manufacturer or supplier’s details

Company: MSD
Address: Briahnager - Off Pune Nagar Road, Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Serious eye damage/eye irritation: Category 2A

Specific target organ toxicity - repeated exposure (Oral): Category 1 (ear, Kidney, inner ear)

GHS label elements

Hazard pictograms:

Signal word: Danger

Hazard statements:
H319 Causes serious eye irritation.
H372 Causes damage to organs (ear, Kidney, inner ear) through prolonged or repeated exposure if swallowed.

Precautionary statements:

Prevention:
P260 Do not breathe mist or vapours.
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.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>dihydrostreptomycin sulphate</td>
</tr>
<tr>
<td>Chemical name</td>
<td>5490-27-7</td>
</tr>
<tr>
<td>CAS-No.</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Concentration (%) w/w</td>
<td></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. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Causes serious eye irritation.

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
## 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**: 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.

**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

### 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>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>Sodium metabisulphite</td>
<td>7681-57-4</td>
<td>TWA</td>
<td>5 mg/m³</td>
<td>ACGIH</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>TWA</td>
<td>2 ppm 5 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>5 ppm 10 mg/m³</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>0.25 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**Engineering measures:**
- 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.

**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

**Hand protection:**
**SAFETY DATA SHEET**

**Dihydrostreptomycin Sulfate Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>05.06.2020</td>
<td>5918684-00002</td>
<td>20.05.2020</td>
<td>20.05.2020</td>
</tr>
</tbody>
</table>

**Material**

Chemical-resistant gloves

**Remarks**

Consider double gloving.

**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. 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.

**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
- **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
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:
- Sulphur dioxide

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact
SAFETY DATA SHEET

Dihydrostreptomycin Sulfate Formulation

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.

**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
Method : OECD Test Guideline 405
Result : Irreversible effects on the eye

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo 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
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Revision Date: 05.06.2020
SDS Number: 5918684-00002
Date of last issue: 20.05.2020
Date of first issue: 20.05.2020

Exposure time: 24 Months
Result: negative
Remarks: Based on data from similar materials

Reproductive toxicity
Not classified based on available information.

Components:

dihydrostreptomycin sulphate:
Effects on foetal development:
Test Type: Embryo-foetal development
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:
Effects on fertility:
Test Type: Three-generation study
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 (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 and LOAEL Data

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guinea pig</td>
<td>40 mg/kg</td>
<td>Oral</td>
<td>90 d</td>
<td>ear</td>
<td>hearing loss</td>
</tr>
<tr>
<td>Cat</td>
<td>100 mg/kg</td>
<td>Oral</td>
<td>60 d</td>
<td>ear</td>
<td>ataxia, hearing loss, Reduced body weight</td>
</tr>
<tr>
<td>Cat</td>
<td>300 mg/kg</td>
<td>Oral</td>
<td>21 d</td>
<td>ear</td>
<td>ataxia, hearing loss, Reduced body weight</td>
</tr>
</tbody>
</table>

### Sodium Metabisulphite

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>110 mg/kg</td>
<td>220 mg/kg</td>
<td>Ingestion</td>
<td>104 Weeks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**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

### Ecotoxicity

**Components**: Sodium metabisulphite

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): 178 mg/l&lt;br&gt;Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): 89 mg/l&lt;br&gt;Exposure time: 48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Desmodesmus subspicatus (green algae)): 43.8 mg/l&lt;br&gt;Exposure time: 72 h</td>
</tr>
</tbody>
</table>
EC10 (Desmodesmus subspicatus (green algae)): 33.3 mg/l
Exposure time: 72 h

Toxicity to microorganisms: EC10 (Pseudomonas putida): 30.8 mg/l
Exposure time: 17 h

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: >= 10 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

**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 IMO instruments**
Not applicable for product as supplied.
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15. REGULATORY INFORMATION

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

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

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL : Short-term exposure Limit STEL (15 min)

ACGIH - USA. ACGIH Threshold Limit Values (TLV)
IN OEL - India. Permissible levels of certain chemical substances in work environment.

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, Bioaccumu-
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.