SECTION 1. IDENTIFICATION

Product name: Dihydrostreptomycin Sulfate Formulation

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)

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 vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear eye protection and 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 attention if you feel unwell.
P337 + P313 If eye irritation persists: Get medical attention.

Disposal:
SAFETY DATA SHEET

Dihydrostreptomycin Sulfate Formulation

Version: 1.7  Revision Date: 04/04/2023
SDS Number: 5918690-00008  Date of last issue: 10/01/2022
Date of first issue: 05/20/2020

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Sodium metabisulphite</td>
<td>7681-57-4</td>
<td>&gt;= 1 - &lt; 5</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. 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. Causes damage to organs through prolonged or repeated exposure if swallowed.
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 fire fighting: Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides
                                 Sulfur 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 Advice on safe handling:
- Use only with adequate ventilation.
- Do not breathe decomposition products.
- Do not breathe mist or vapors.
- Do not swallow.
- Do not get in eyes.
- Avoid prolonged or repeated contact with skin.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- 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.  
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>
</tbody>
</table>

Further information: OTO  
Wipe limit Not required

Sodium metabisulphite 7681-57-4  
TWA 5 mg/m³ ACGIH

TWA 5 mg/m³ NIOSH REL

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>STEL</td>
<td>0.25 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>2 ppm</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ST</td>
<td>5 ppm</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>5 ppm</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>13 mg/m³</td>
<td></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:  
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
- **Remarks:** Consider double gloving.

**Eye protection**

- **Remarks:** 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**

- **Remarks:** 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**

- **Remarks:** 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:** No data available
- **Color:** No data available
- **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
SAFETY DATA SHEET

Dihydrostreptomycin Sulfate Formulation

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 : No data available
Solubility(ies)
   Water solubility : No data available
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.
      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
SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

- 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.

**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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Sodium metabisulphite:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: 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 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

**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:

**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.

**Sodium metabisulphite:**
- Effects on fertility:
  - Test Type: Three-generation study
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

- Effects on fetal development:
  - Test Type: Embryo-fetal 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: 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

SECTION 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

SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
Waste from residues: Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.

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

49 CFR
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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
Specific target organ toxicity (single or repeated exposure)
Serious eye damage or eye irritation

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
Dihydrostreptomycin sulphate 5490-27-7
Sodium metabisulphite 7681-57-4

California List of Hazardous Substances

Sodium metabisulphite 7681-57-4
California Permissible Exposure Limits for Chemical Contaminants

Sodium metabisulphite  7681-57-4

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

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

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

HMIS® IV:

- HEALTH: *
- FLAMMABILITY: 1
- PHYSICAL HAZARD: 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

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL: USA. NIOSH Recommended Exposure Limits
- OSHA Z-1: USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- NIOSH REL / ST: STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
- OSHA Z-1 / TWA: 8-hour time weighted average

AICL - Australian Inventory of Industrial Chemicals; 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 Haz-

Revision Date: 04/04/2023

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.

US / Z8