

Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dihydrostreptomycin Sulfate Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
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@msd.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**

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 vapors.
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:

Dihydrostreptomycin Sulfate Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 5918686-00011 Date of last issue: 11.02.2025
Date of first issue: 20.05.2020

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Dihydrostreptomycin sulphate	5490-27-7	>= 30 -< 50
Sodium metabisulphite	7681-57-4	>= 1 -< 3

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 prod- : Carbon oxides

Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

ucts	Sulfur 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 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

Dihydrostreptomycin Sulfate Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 5918686-00011 Date of last issue: 11.02.2025
 Date of first issue: 20.05.2020

- 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.
 Do not breathe decomposition products.
- 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.
- 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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Dihydrostreptomycin sulphate	5490-27-7	TWA	4 mg/m ³ (OEB 1)	
Further information: OTO				
Sodium metabisulphite	7681-57-4	VLE-PPT	5 mg/m ³	NOM-010-STPS-2014
		TWA	5 mg/m ³	ACGIH

Occupational exposure limits of decomposition products

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sulphur dioxide	7446-09-5	VLE-CT	0.25 ppm	NOM-010-STPS-2014
		STEL	0.25 ppm	ACGIH

- 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.

Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

Personal protective equipment

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|--------------------------|---|--|
| 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/vapor 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. |

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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|--|---|-------------------|
| 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 |
| 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 |

Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

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 characteristics	
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
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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
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Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

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

Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

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

Reproductive toxicity

Not classified based on available information.

Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

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.
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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
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Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

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
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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

Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

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	: 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**NOM-002-SCT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

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

SECTION 16. OTHER INFORMATION

Revision Date	: 14.04.2025
Date format	: dd.mm.yyyy

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014	: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA	: 8-hour, time-weighted average
ACGIH / STEL	: Short-term exposure limit
NOM-010-STPS-2014 / VLE-	: Time weighted average limit value
PPT	
NOM-010-STPS-2014 / VLE-	: Short term exposure limit value
CT	

AIIC - 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 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, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Tempera-

Dihydrostreptomycin Sulfate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 11.02.2025
4.0	14.04.2025	5918686-00011	Date of first issue: 20.05.2020

ture; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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