

Dihydrostreptomycin Sulfate Formulation

Version **Revision Date:** SDS Number: Date of last issue: 04.04.2023 30.09.2023 5918682-00009 Date of first issue: 20.05.2020 2.1

SECTION 1. IDENTIFICATION

Product name Dihydrostreptomycin Sulfate Formulation

Manufacturer or supplier's details

MSD Company

Address Talcahuano 750, 6th floor, Ciudad Autonoma

Buenos Aires, Argentina C1013AAP

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

repeated exposure (Oral)

Specific target organ toxicity - : 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:



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> 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/ at-

tention.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

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 -< 2,5

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 contact, immediately flush eyes with plenty of water In case of eye contact

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).

Treat symptomatically and supportively. Notes to physician

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)



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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-

ucts

Carbon oxides

Sulfur oxides Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec-:

tive 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.

Use only with adequate ventilation.

SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

Advice on safe handling : Do not breathe mist or vapors.

Do not swallow.

Do not get in eyes.



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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.

Do not breathe decomposition products.

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	0.4 mg/m3 (OEB 2)		
	Further information: OTO				
		Wipe limit	Not required		
Sodium metabisulphite	7681-57-4	CMP	5 mg/m³	AR OEL	
	Further information: A4 - Not classifiable as a human carcinogen				
		TWA	5 mg/m ³	ACGIH	

Occupational exposure limits of decomposition products

Components	CAS-No.	Value type	Control parame-	Basis		
		(Form of	ters / Permissible			
		exposure)	concentration			
Sulphur dioxide	7446-09-5	CMP	2 ppm	AR OEL		
	Further inform	Further information: A4 - Not classifiable as a human carcinogen				
		CMP - CPT	5 ppm	AR OEL		
	Further inform	Further information: A4 - Not classifiable as a human carcinogen				
		STEL	0.25 ppm	ACGIH		

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



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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
Hand protection

Combined particulates and inorganic gas/vapor type

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.

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



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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

No data available Density

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

No data available Viscosity, kinematic

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 reac-

Can react with strong oxidizing agents.

tions 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 : Inhalation

exposure 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



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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



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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:

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
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



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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 tox-

icity)

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 (Chron-

ic 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



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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Not applicable

Registry.

Control of precursors and essential chemicals for the

preparation of drugs.

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

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Further information

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, http://echa.europa.eu/

Full text of other abbreviations

ACGIH USA. ACGIH Threshold Limit Values (TLV) AR OEL Argentina. Occupational Exposure Limits

ACGIH / TWA 8-hour, time-weighted average ACGIH / STEL Short-term exposure limit AR OEL / CMP TLV (Threshold Limit Value) AR OEL / CMP - CPT STEL (Short Term Limit Value)

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



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- 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 Temperature; 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

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.

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