

Dihydrostreptomycin Sulfate Formulation

Version 3.0 Revision Date: 2023/09/30 SDS Number: 5918685-00008 Date of last issue: 2023/04/04
Date of first issue: 2020/05/20

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Dihydrostreptomycin Sulfate Formulation

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Serious eye damage/eye irritation : Category 2

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.

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

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

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) | ENCS No. |
|------------------------------|-----------|-----------------------|----------|
| Dihydrostreptomycin sulphate | 5490-27-7 | >= 30 - < 40 | |
| Sodium metabisulphite | 7681-57-4 | >= 1 - < 2.5 | |

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.

5. FIREFIGHTING MEASURES

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

- 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
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 (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 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.
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7. HANDLING AND STORAGE**Handling**

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

- 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 vapours.
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.
Do not breathe decomposition products.
- Avoidance of contact : Oxidizing agents
- 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.

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

Threshold limit value and permissible exposure limits for each component in the work environment

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Reference concentration / Permissible concentration | Basis |
|------------------------------|-----------|----------------------------------|--|-------|
| Dihydrostreptomycin sulphate | 5490-27-7 | TWA | 0.4 mg/m ³ (OEB 2) | |
| Further information: OTO | | | | |
| | | Wipe limit | Not required | |
| Sodium metabisulphite | 7681-57-4 | TWA | 5 mg/m ³ | ACGIH |

Dihydrostreptomycin Sulfate Formulation

Version 3.0 Revision Date: 2023/09/30 SDS Number: 5918685-00008 Date of last issue: 2023/04/04
 Date of first issue: 2020/05/20

Occupational exposure limits of decomposition products

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|-----------------|-----------|----------------------------------|--|-------|
| Sulphur dioxide | 7446-09-5 | 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 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

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : No data available

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Dihydrostreptomycin Sulfate Formulation

Version 3.0 Revision Date: 2023/09/30 SDS Number: 5918685-00008 Date of last issue: 2023/04/04
Date of first issue: 2020/05/20

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : 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

Dihydrostreptomycin Sulfate Formulation

Version 3.0 Revision Date: 2023/09/30 SDS Number: 5918685-00008 Date of last issue: 2023/04/04
Date of first issue: 2020/05/20

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

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: > 2,000 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

Dihydrostreptomycin Sulfate Formulation

Version 3.0 Revision Date: 2023/09/30 SDS Number: 5918685-00008 Date of last issue: 2023/04/04
Date of first issue: 2020/05/20

II**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 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 |
|-----------------------|---|--|

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

| | |
|----------------------|---|
| | 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.

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. |

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

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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 | : | 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 |

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

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

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

Bioaccumulative potential

No data available

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

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. |

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

| | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |

IATA-DGR

| | | |
|--|---|----------------|
| UN/ID No. | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| Packing instruction (cargo aircraft) | : | Not applicable |
| Packing instruction (passenger aircraft) | : | Not applicable |

IMDG-Code

| | | |
|----------------------|---|----------------|
| UN number | : | Not applicable |
| Proper shipping name | : | Not applicable |
| Class | : | Not applicable |
| Subsidiary risk | : | Not applicable |
| Packing group | : | Not applicable |
| Labels | : | Not applicable |
| EmS Code | : | Not applicable |

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

Marine pollutant : Not applicable

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

Not applicable for product as supplied.

National Regulations

Refer to section 15 for specific national regulation.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

| Chemical name | Concentration (%) | Remarks |
|----------------------|-------------------|---------|
| Disodium pyrosulfite | >=1 - <10 | - |

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

| Chemical name | Remarks |
|----------------------|---------|
| Disodium pyrosulfite | - |

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Dihydrostreptomycin Sulfate Formulation

Version 3.0 Revision Date: 2023/09/30 SDS Number: 5918685-00008 Date of last issue: 2023/04/04
Date of first issue: 2020/05/20

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

|| Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Not regulated as a dangerous good

Aviation Law

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

DSL : not determined

AICS : not determined

IECSC : not determined

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

16. OTHER INFORMATION

Further information

Sources of key data used to compile the 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.

Date format : yyyy/mm/dd

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

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 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

Dihydrostreptomycin Sulfate Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2023/04/04 |
| 3.0 | 2023/09/30 | 5918685-00008 | Date of first issue: 2020/05/20 |

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JP / EN