# SAFETY DATA SHEET
according to the Hazardous Products Regulations

# Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04/04/2023 |
|---|---|---|---|
| 2.6 | 09/30/2023 | 5491648-00012 | Date of first issue: 03/10/2020 |

## SECTION 1. IDENTIFICATION

Product name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation
Other means of identification : No data available

**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 medicine
Restrictions on use : Not applicable

## SECTION 2. HAZARDS IDENTIFICATION

**GHS classification in accordance with the Hazardous Products Regulations**

Acute toxicity (Oral) : Category 4

Eye irritation : Category 2A

Respiratory sensitization : Category 1

Skin sensitization : Category 1

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Cardio-vascular system)

**GHS label elements**

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Cardio-vascular system)

through prolonged or repeated exposure if swallowed.

Precautionary Statements :

**Prevention:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
P284 Wear respiratory protection.

**Response:**

P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical attention.
P333 + P313 If skin irritation or rash occurs: Get medical attention.
P337 + P313 If eye irritation persists: Get medical attention.
P342 + P311 If experiencing respiratory symptoms: Call a doctor.
P362 + P364 Take off contaminated clothing and wash it before reuse.

**Storage:**

P405 Store locked up.

**Disposal:**

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**

| Chemical name | Common Name/Synonym | CAS-No. | Concentration (% w/w) |
|---|---|---|---|
| Dihydrostreptomycin sulphate | D-Streptamine, O-2-deoxy-2- | 5490-27-7 | >= 30 - < 60 * |

| | | | |
|---|---|---|---|
| | (methylamino)-.alpha.-L-glucopyranosyl-(1->2)-O-5-deoxy-3-C-(hydroxymethyl)-.alpha.-L-lyxofuranosyl-(1->4 | | |
| 2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate | No data available | 6130-64-9 | >= 30 - < 60 * |
| Procaine hydrochloride | Benzoic acid, 4-amino-, 2-(diethylamino)ethyl ester, hydrochloride (1:1) | 51-05-8 | >= 1 - < 5 * |
| Chlorphenamine hydrogen maleate | No data available | 113-92-8 | >= 1 - < 5 * |
| Dexamethasone | No data available | 50-02-2 | >= 0 - < 0.1 * |

* Actual concentration or concentration range 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.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

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.

| | | |
|---|---|---|
| | | Rinse mouth thoroughly with water.<br>Never give anything by mouth to an unconscious person. |
| Most important symptoms and effects, both acute and delayed | : | Harmful if swallowed.<br>May cause an allergic skin reaction.<br>Causes serious eye irritation.<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled.<br>Suspected of damaging the unborn child.<br>May cause damage to organs through prolonged or repeated exposure if swallowed.<br>Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). |
| 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>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<br>Nitrogen oxides (NOx)<br>Sulfur oxides<br>Chlorine compounds<br>Metal oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>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 get on skin or clothing.
Do not breathe mist or vapors.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
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 locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parame-ters / Permissible concentration | Basis |
|---|---|---|---|---|
| Dihydrostreptomycin sulphate | 5490-27-7 | TWA | OEB 2 (>= 100 < 1000 µg/m3) | Internal |
| | | TWA | 0.4 mg/m³ | Customer derived OEL |
| Chlorphenamine hydrogen maleate | 113-92-8 | TWA | 10 µg/m3 (OEB 3) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 100 µg/100 cm2 | Internal |
| Dexamethasone | 50-02-2 | TWA | 10 µg/m3 (OEB 3) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 100 µg/100 cm² | Internal |

**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.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

**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 : Particulates 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.

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.
Contaminated work clothing should not be allowed out of the workplace.
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 | : | suspension |
| Color | : | white |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| pH | : | 5.0 - 6.0<br>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) | : | Not applicable |
| 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 | : | 1.17 - 1.21 g/cm³<br>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. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## SECTION 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity**

Harmful if swallowed.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: 709.59 mg/kg<br>Method: Calculation method |

**Components:**

**Dihydrostreptomycin sulphate:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 430 mg/kg<br>Remarks: Based on data from similar materials |

**2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**

Acute oral toxicity : LD50 (Mouse): > 2,000 mg/kg

**Procaine hydrochloride:**

Acute oral toxicity : LD50 (Rat): 200 mg/kg

**Chlorphenamine hydrogen maleate:**

Acute inhalation toxicity : LC50 (Rat): 0.61 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 89 mg/kg

**Dexamethasone:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (Mouse): > 6,500 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 14 mg/kg
Application Route: Subcutaneous

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**

Result : No skin irritation

**Chlorphenamine hydrogen maleate:**

Species : Rabbit
Result : No skin irritation

**Dexamethasone:**

Species : Rabbit
Result : Mild skin irritation

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:**

**2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**

Result : No eye irritation

**Chlorphenamine hydrogen maleate:**

Species : Rabbit
Result : Severe irritation

**Dexamethasone:**

Species : Rabbit
Result : Mild eye irritation

**Respiratory or skin sensitization**

**Skin sensitization**

May cause an allergic skin reaction.

**Respiratory sensitization**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:**

**Dihydrostreptomycin sulphate:**

Test Type : Human repeat insult patch test (HRIPT)
Routes of exposure : Skin contact
Species : Humans
Result : positive
Remarks : Based on data from similar materials

Assessment : Probability or evidence of skin sensitization in humans

**2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : positive
Remarks : Based on data from similar materials

Assessment : Probability or evidence of skin sensitization in humans

Assessment : Probability of respiratory sensitization in humans based on animal testing

**Chlorphenamine hydrogen maleate:**

Routes of exposure : Dermal

Remarks : No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**Procaine hydrochloride:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

**Chlorphenamine hydrogen maleate:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Test Type: sister chromatid exchange assay
Test system: Chinese hamster ovary cells
Result: positive

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: rat hepatocytes
Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**Dexamethasone:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: in vitro test
Test system: mouse lymphoma cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:**

**Chlorphenamine hydrogen maleate:**

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| NOAEL | : | 30 - 60 mg/kg body weight |
| Result | : | negative |

| | | |
|---|---|---|
| Species | : | Mouse |
| Application Route | : | Oral |
| Exposure time | : | 2 Years |
| NOAEL | : | 20 - 50 mg/kg body weight |
| Result | : | negative |

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:**

**Dihydrostreptomycin sulphate:**

| | | |
|---|---|---|
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on development, based on animal experiments. |

**Chlorphenamine hydrogen maleate:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Oral<br>Fertility: LOAEL: 20 mg/kg body weight<br>Result: No effects on fertility., No effects on fetal development. |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Mouse<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 20 mg/kg body weight<br>Result: Reduced embryonic survival, No malformations were observed.<br>Remarks: The significance of these findings for humans is not certain.<br><br>Test Type: Embryo-fetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 15 mg/kg body weight<br>Result: No significant adverse effects were reported |

**Dexamethasone:**

| | | |
|---|---|---|
| Effects on fetal development | : | Test Type: Development<br>Species: Mouse<br>Application Route: Subcutaneous<br>Developmental Toxicity: LOAEL: 6 mg/kg body weight |

Result: Specific developmental abnormalities., Cleft palate

Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: NOAEL: 0.025 mg/kg body weight
Result: Specific developmental abnormalities.

Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: >= 0.062 mg/kg body weight
Result: Specific developmental abnormalities.

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: >= 0.02 mg/kg body weight
Result: Skeletal and visceral variations ., Retardations.

Reproductive toxicity - Assessment : May damage the unborn child.

**STOT-single exposure**

Not classified based on available information.

**Components:**

**Chlorphenamine hydrogen maleate:**

Assessment : May cause drowsiness or dizziness.

**STOT-repeated exposure**

May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

**Components:**

**Chlorphenamine hydrogen maleate:**

Target Organs : Cardio-vascular system
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Dexamethasone:**

Routes of exposure : Oral
Target Organs : Adrenal gland, Immune system, thymus gland
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity**

**Components:**

**Chlorphenamine hydrogen maleate:**

Species : Rat
NOAEL : 10 mg/kg

| | | |
|---|---|---|
| Application Route | : | Oral |
| Exposure time | : | 6 Weeks |
| Remarks | : | No significant adverse effects were reported |

| | | |
|---|---|---|
| Species | : | Monkey |
| LOAEL | : | 15 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 105 Weeks |
| Target Organs | : | Heart |

**Dexamethasone:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 0.0015 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 7 d |
| Target Organs | : | Liver |
| Remarks | : | Significant toxicity observed in testing |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 0.003 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 90 d |
| Target Organs | : | Blood, Adrenal gland, thymus gland |
| Remarks | : | Significant toxicity observed in testing |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 0.125 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 6 Weeks |
| Target Organs | : | Adrenal gland |
| Remarks | : | Significant toxicity observed in testing |

| | | |
|---|---|---|
| Species | : | Rat |
| LOAEL | : | 0.4 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 3 Months |
| Target Organs | : | Immune system |
| Remarks | : | Significant toxicity observed in testing |

| | | |
|---|---|---|
| Species | : | Dog |
| LOAEL | : | 8 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 3 Months |
| Target Organs | : | Immune system |
| Remarks | : | Significant toxicity observed in testing |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Dihydrostreptomycin sulphate:**

| | | |
|---|---|---|
| General Information | : | Target Organs: ear<br>Symptoms: hearing loss |

**Chlorphenamine hydrogen maleate:**

| | | |
|---|---|---|
| Inhalation | : | Symptoms: central nervous system effects<br>Remarks: May cause respiratory tract irritation. |
| Skin contact | : | Remarks: May irritate skin. |
| Eye contact | : | Symptoms: Eye irritation<br>Remarks: May cause irreversible eye damage. |
| Ingestion | : | Symptoms: central nervous system effects<br>Remarks: Based on Human Evidence |

**Dexamethasone:**

| | | |
|---|---|---|
| Ingestion | : | Target Organs: Immune system<br>Target Organs: Adrenal gland<br>Target Organs: Bone<br>Symptoms: muscle weakness |

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Dihydrostreptomycin sulphate:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l<br>Exposure time: 96 h<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : | EC50: > 0.01 - 0.1 mg/l<br>Remarks: Based on data from similar materials |

**2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**

**Ecotoxicology Assessment**

| | | |
|---|---|---|
| Acute aquatic toxicity | : | Toxic effects cannot be excluded |
| Chronic aquatic toxicity | : | Toxic effects cannot be excluded |

**Procaine hydrochloride:**

**Ecotoxicology Assessment**

| | | |
|---|---|---|
| Acute aquatic toxicity | : | Toxic effects cannot be excluded |
| Chronic aquatic toxicity | : | Toxic effects cannot be excluded |

**Dexamethasone:**

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 56 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l<br>Exposure time: 32 d<br>Method: OECD Test Guideline 210 |
| Toxicity to microorganisms | : | EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br><br>NOEC: 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209 |

**Persistence and degradability**

**Components:**

**Dexamethasone:**

| | | |
|---|---|---|
| Biodegradability | : | Result: Not readily biodegradable.<br>Biodegradation: 50 %<br>Exposure time: 3.54 d<br>Method: OECD Test Guideline 314 |

**Bioaccumulative potential**

**Components:**

**Dihydrostreptomycin sulphate:**

| | | |
|---|---|---|
| Bioaccumulation | : | Species: Fish<br>Bioconcentration factor (BCF): 3.16 |
| Partition coefficient: n-octanol/water | : | log Pow: -7.51 |

**Procaine hydrochloride:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: 1.389 |

**Dexamethasone:**

| | | |
|---|---|---|
| Partition coefficient: n-octanol/water | : | log Pow: 1.83 |

**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.<br>Dispose of in accordance with local regulations. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

| | | |
|---|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.<br>(Dihydrostreptomycin sulphate) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| Environmentally hazardous | : | yes |

**IATA-DGR**

| | | |
|---|---|---|
| UN/ID No. | : | UN 3082 |
| Proper shipping name | : | Environmentally hazardous substance, liquid, n.o.s.<br>(Dihydrostreptomycin sulphate) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | Miscellaneous |
| Packing instruction (cargo aircraft) | : | 964 |
| Packing instruction (passen- | : | 964 |

ger aircraft)
Environmentally hazardous : yes

**IMDG-Code**

| | | |
|---|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| EmS Code | : | F-A, S-F |
| Marine pollutant | : | yes |

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

Not applicable for product as supplied.

**Domestic regulation**

**TDG**

| | | |
|---|---|---|
| UN number | : | UN 3082 |
| Proper shipping name | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | 9 |
| ERG Code | : | 171 |
| Marine pollutant | : | yes(Dihydrostreptomycin sulphate) |

**Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

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

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

## SECTION 16. OTHER INFORMATION

**Full text of other abbreviations**

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

| | | |
|---|---|---|
| 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/ |
| Revision Date | : | 09/30/2023 |
| Date format | : | mm/dd/yyyy |

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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