SAFETY DATA SHEET

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 1.3  Revision Date: 27.08.2021  SDS Number: 5491642-00004  Date of last issue: 10.10.2020  Date of first issue: 10.03.2020

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Manufacturer or supplier's details
Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : +1-908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary medicine

2. HAZARDS IDENTIFICATION

GHS Classification
Acute toxicity (Oral) : Category 4
Serious eye damage/eye irritation : Category 2
Respiratory sensitisation : Category 1
Skin sensitisation : Category 1
Reproductive toxicity : Category 2
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

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.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P261 Avoid breathing mist or vapours.
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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P284 Wear respiratory protection.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ 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 advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.
P391 Collect spillage.

Storage:
P405 Store locked up.

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

Additional Labelling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 33.36 %

Other hazards which do not result in classification
None known.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>&gt;= 50 -&lt; 70</td>
</tr>
<tr>
<td>2-(4-Aminobenzoyloxy)ethyl(diethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate</td>
<td>6130-64-9</td>
<td>&gt;= 30 -&lt; 50</td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>51-05-8</td>
<td>&gt;= 1 -&lt; 10</td>
</tr>
<tr>
<td>Chlorphenamine hydrogen maleate</td>
<td>113-92-8</td>
<td>&gt;= 1 -&lt; 3</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>&gt;= 0.025 -&lt; 0.1</td>
</tr>
</tbody>
</table>

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.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
May cause an allergic skin reaction.
Causes serious eye irritation.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of damaging the unborn child.
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.
5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides
Chlorine compounds
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.

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 vapours.
- 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 sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.
- 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 labelled 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>TWA</td>
<td>OEB 2 (&gt;= 100 &lt; 1000 µg/m3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>0.4 mg/m3</td>
<td>Customer derived OEL</td>
</tr>
<tr>
<td>Chlorphenamine hydrogen maleate</td>
<td>113-92-8</td>
<td>TWA</td>
<td>10 µg/m3</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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., dripless 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 con-
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**: 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: suspension

**Colour**: white

**Odour**: No data available

**Odour Threshold**: No data available

**pH**: 5.0 - 6.0

**Melting point/freezing point**: No data available

**Initial boiling point and boiling**: No data available
SAFETY DATA SHEET

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 1.3
Revision Date: 27.08.2021
SDS Number: 5491642-00004
Date of last issue: 10.10.2020
Date of first issue: 10.03.2020

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
Vapour pressure: No data available
Relative vapour density: No data available
Relative density: No data available
Density: 1.17 - 1.21 g/cm³
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition 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

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.

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: 662.58 mg/kg
- Method: Calculation method

Acute dermal toxicity:
- Acute toxicity estimate: > 2,000 mg/kg
- Method: Calculation method

Components:

Dihydrostrepotomycin sulphate:
- Acute oral toxicity: LD50 (Rat): 430 mg/kg
- 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 oral toxicity: LD50 (Rat): 118 - 306 mg/kg
- LD50 (Mouse): 130 mg/kg
- Acute inhalation toxicity: LC50 (Rat): 0.61 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rat): 365 mg/kg
- 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
**SAFETY DATA SHEET**

**Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation**

**Version**: 1.3  
**Revision Date**: 27.08.2021  
**SDS Number**: 5491642-00004  
**Date of last issue**: 10.10.2020  
**Date of first issue**: 10.03.2020

---

**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)ethyl-diethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**

- Result: No skin irritation

**Chlorphenamine hydrogen maleate:**

- Species: Rabbit  
- Result: No skin irritation

**Dexamethasone:**

- Species: Rabbit  
- Result: No skin irritation

**Serious eye damage/eye irritation**

Causes serious eye irritation.

**Components:**

**2-(4-Aminobenzoyloxy)ethyl-diethylammonium (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 sensitisation**

**Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

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

**Components:**

**Dihydrostreptomycin sulphate:**

- Test Type: Human repeat insult patch test (HRIPT)
Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Exposure routes: Skin contact
Species: Humans
Result: positive
Remarks: Based on data from similar materials

Assessment: Probability or evidence of skin sensitisation in humans

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

Test Type: Maximisation Test
Exposure routes: 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 sensitisation in humans

**Chlorphenamine hydrogen maleate:**

Exposure routes: 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 assay  
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  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 20 mg/kg body weight  
Result: No effects on fertility, No effects on foetal development

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 20 mg/kg body weight
Result: Reduced embryonic survival, No malformations were observed.
Remarks: The significance of these findings for humans is not certain.

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 15 mg/kg body weight
Result: No significant adverse effects were reported

**Dexamethasone:**

**Effects on foetal development**

- Test Type: Development
  - Species: Mouse
    - Application Route: Subcutaneous
    - 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: \( \geq 0.062 \) mg/kg body weight
      - Result: Specific developmental abnormalities

- Species: Rat
  - Application Route: Subcutaneous
    - Developmental Toxicity: LOAEL: \( \geq 0.02 \) 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**

Not classified based on available information.

**Components:**

**Chlorphenamine hydrogen maleate:**

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

**Dexamethasone:**

- **Exposure routes:** 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:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>10 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Weeks</td>
</tr>
<tr>
<td>Remarks</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Monkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>15 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>105 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Heart</td>
</tr>
</tbody>
</table>

**Dexamethasone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.0015 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>7 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.003 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Adrenal gland, thymus gland</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.125 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.4 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

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
Symptoms: hearing loss

Chlorphenamine hydrogen maleate:
Inhalation: Symptoms: central nervous system effects
Remarks: May cause respiratory tract irritation.
Skin contact: Remarks: May irritate skin.
Eye contact: Symptoms: Eye irritation
Remarks: May cause irreversible eye damage.
Ingestion: Symptoms: central nervous system effects
Remarks: Based on Human Evidence

Dexamethasone:
Ingestion: Target Organs: Immune system
Target Organs: Adrenal gland
Target Organs: Bone
Symptoms: muscle weakness

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Dihydrostreptomycin sulphate:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50: > 0.01 - 0.1 mg/l
Remarks: Based on data from similar materials
M-Factor (Acute aquatic toxicity) : 10
M-Factor (Chronic aquatic toxicity) : 10

2-(4-Aminobenzoyloxy)ethyl-diethylammonium (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
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.033 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Persistence and degradability

Components:

Dexamethasone:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 3.54 d
Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

Dihydrostreptomycin sulphate:
Bioaccumulation: Species: Fish
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

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: 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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Dihydrostreptomycin sulphate)
Class: 9
Packing group: III
SAFETY DATA SHEET

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 1.3  Revision Date: 27.08.2021  SDS Number: 5491642-00004  Date of last issue: 10.10.2020
Date of first issue: 10.03.2020

Labels:

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

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.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable
Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

The components of this product are reported in the following inventories:
AICS: not determined
SAFETY DATA SHEET

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version: 1.3  Revision Date: 27.08.2021  SDS Number: 5491642-00004  Date of last issue: 10.10.2020

Date of first issue: 10.03.2020

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

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 Standardisation; 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 mate-

18 / 19
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.

SG / EN