SAFETY DATA SHEET

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 1.3  Revision Date: 27.08.2021  SDS Number: 5491617-00004  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: Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India  412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTeward@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Acute toxicity (Oral): Category 4
Serious eye damage/eye irritation: Category 2A
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:

- Danger symbol
- Exclamation mark
- Plant symbol

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.
- H361a Suspected of damaging the unborn child.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

**Prevention:**
- P203 Obtain, read and follow all safety instructions before use.
- 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:**
- 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.
- P318 IF exposed or concerned, get medical advice.
- P333 + P317 If skin irritation or rash occurs: Get medical help.
- P337 + P317 If eye irritation persists: Get medical help.
- P342 + P316 If experiencing respiratory symptoms: Get emergency medical help immediately.
- 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.
SAFETY DATA SHEET

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

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>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
</tbody>
</table>

<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; 5</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
### 5. FIREFIGHTING MEASURES

**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.

#### 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/PERSOAL 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/PERSOAL 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., 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Respiratory protection</strong></td>
<td>If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.</td>
</tr>
<tr>
<td>Filter type</td>
<td>Particulates type</td>
</tr>
<tr>
<td>Hand protection</td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td>Chemical-resistant gloves</td>
</tr>
<tr>
<td><strong>Eye protection</strong></td>
<td></td>
</tr>
<tr>
<td>Remarks</td>
<td>Consider double gloving.</td>
</tr>
<tr>
<td>Eye protection</td>
<td>Wear safety glasses with side shields or goggles.</td>
</tr>
<tr>
<td></td>
<td>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.</td>
</tr>
<tr>
<td></td>
<td>Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>Work uniform or laboratory coat.</td>
</tr>
<tr>
<td></td>
<td>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.</td>
</tr>
<tr>
<td></td>
<td>Use appropriate degowning techniques to remove potentially contaminated clothing.</td>
</tr>
<tr>
<td>Hygiene measures</td>
<td>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</td>
</tr>
<tr>
<td></td>
<td>When using do not eat, drink or smoke.</td>
</tr>
<tr>
<td></td>
<td>Contaminated work clothing should not be allowed out of the workplace.</td>
</tr>
<tr>
<td></td>
<td>Wash contaminated clothing before re-use.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
</tbody>
</table>

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>suspension</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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Odour Threshold : No data available
pH : 5.0 - 6.0
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
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: > 5,000 mg/kg
  Method: Calculation method

Components:

Dihydrostreptomycin sulphate:
- Acute oral toxicity: LD50 (Rat): 430 mg/kg
  Remarks: Based on data from similar materials

2-(4-Aminobenzoyloxy)ethylidihydroxyethylammonium (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
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Acute toxicity (other routes of administration):
- **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-Aminobenzoxyloxy)ethyl diethyl ammonium (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-Aminobenzoxyloxy)ethyl diethyl ammonium (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)
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
Assessment : Probability of respiratory sensitisation in humans based on animal testing

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
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:  
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:  
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: >= 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
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:
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
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
### Toxicty to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(4-Aminobenzoyloxy)ethylidethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(4-Aminobenzoyloxy)ethylidethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate</td>
<td>&gt; 0.01 - 0.1 mg/l</td>
<td></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### M-Factor (Acute aquatic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>M-Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(4-Aminobenzoyloxy)ethylidethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate</td>
<td>10</td>
</tr>
</tbody>
</table>

### M-Factor (Chronic aquatic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>M-Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(4-Aminobenzoyloxy)ethylidethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate</td>
<td>10</td>
</tr>
</tbody>
</table>

### Ecotoxicology Assessment

**Procaine hydrochloride:**

**Ecotoxicology Assessment**

<table>
<thead>
<tr>
<th>Summer</th>
<th>Toxic effects cannot be excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute aquatic toxicity</td>
<td>Toxic effects cannot be excluded</td>
</tr>
<tr>
<td>Chronic aquatic toxicity</td>
<td>Toxic effects cannot be excluded</td>
</tr>
</tbody>
</table>

**Dexamethasone:**

**Ecotoxicology Assessment**

<table>
<thead>
<tr>
<th>Summer</th>
<th>Toxic effects cannot be excluded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute aquatic toxicity</td>
<td>Toxic effects cannot be excluded</td>
</tr>
<tr>
<td>Chronic aquatic toxicity</td>
<td>Toxic effects cannot be excluded</td>
</tr>
</tbody>
</table>

#### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>&gt; 56 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

#### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>&gt; 9.2 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>NOEC</td>
<td>9.2 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

#### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>&gt; 1,000 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>NOEC</td>
<td>1,000 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
</tbody>
</table>
Toxicity to fish (Chronic toxicity):

- NOEC: 0.033 mg/l
- Exposure time: 32 d
- Species: Pimephales promelas (fathead minnow)
- Method: OECD Test Guideline 210

M-Factor (Chronic aquatic toxicity):

- 1

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:**

- 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
- **Labels**: 9

**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 IMO instruments**
- 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**

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

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 1.3
Revision Date: 27.08.2021
SDS Number: 5491617-00004
Date of last issue: 10.10.2020
Date of first issue: 10.03.2020

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

16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations

AICS - 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; LD50 - Lethal Dose to 50% of a test population; LC50 - Lethal Concentration to 50% of a test population; 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; UNR/MG - 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-
rial 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 ap-
propriateness of the SDS material in the user’s end product, if applicable.

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