SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Veterinary medicine

1.3 Details of the supplier of the safety data sheet
   Company : MSD
             Kilsheelan
             Clonmel Tipperary, IE
   Telephone : 353-51-601000
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Acute toxicity, Category 4 : H302: Harmful if swallowed.
   Eye irritation, Category 2 : H319: Causes serious eye irritation.
   Respiratory sensitisation, Category 1 : H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
   Skin sensitisation, Category 1 : H317: May cause an allergic skin reaction.
   Reproductive toxicity, Category 2 : H361d: Suspected of damaging the unborn child.
   Short-term (acute) aquatic hazard, Category 1 : H400: Very toxic to aquatic life.
   Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   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.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
- P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P308 + P313 IF exposed or concerned: Get medical advice/ attention.
- P391 Collect spillage.

Hazardous components which must be listed on the label:
- Dihydrostreptomycin sulphate
- 2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate
- Procaine hydrochloride
- Chlorphenamine hydrogen maleate

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

2.3 Other hazards:
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
## Chemical name

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
<td>226-823-7</td>
</tr>
<tr>
<td>2-(4-Aminobenzo-yloxy)ethylhexylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate</td>
<td>6130-64-9</td>
<td></td>
</tr>
<tr>
<td>Procaine hydrochloride</td>
<td>51-05-8</td>
<td>200-077-2</td>
</tr>
<tr>
<td>Chlorphenamine hydrogen maleate</td>
<td>113-92-8</td>
<td>204-037-5</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>200-003-9</td>
</tr>
</tbody>
</table>

## Classification

<table>
<thead>
<tr>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Tox. 4; H302 Skin Sens. 1; H317 Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Resp. Sens. 1; H334 Skin Sens. 1; H317</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>Acute Tox. 3; H301</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Acute Tox. 3; H301 Acute Tox. 3; H311 Eye Dam. 1; H318 STOT SE 3; H336 STOT RE 2; H373 (Cardio-vascular system)</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td>Acute Tox. 3; H301</td>
<td></td>
</tr>
<tr>
<td>Acute toxicity estimate</td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity: 365 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Repr. 1B; H360D STOT RE 2; H373 (Adrenal gland, Immune system, thymus gland)</td>
<td>&gt;= 0,025 - &lt; 0,1</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Version 1.4
Revision Date: 27.08.2021
SDS Number: 5500083-00005
Date of last issue: 09.04.2021
Date of first issue: 10.03.2020

Aquatic Chronic 1; H410
M-Factor (Chronic aquatic toxicity): 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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).

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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
**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.

**Hand protection**

- **Material**: Chemical-resistant gloves
- **Remarks**: Consider double gloving.

**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.

**Respiratory protection**

- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Equipment should conform to NS EN 143

**Filter type**: Particulates type (P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

- **Physical state**: suspension
- **Colour**: white
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: 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
- **Flash point**: No data available
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **pH**: 5.0 - 6.0
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Viscosity
- Viscosity, kinematic: No data available

Solubility(ies)
- Water solubility: No data available
- Partition coefficient: n-octanol/water: Not applicable
- Vapour pressure: No data available

Relative density: No data available
Density: 1.17 - 1.21 g/cm³
Relative vapour density: No data available
Particle characteristics
- Particle size: Not applicable

9.2 Other information
- Explosives: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.
- Evaporation rate: No data available
- Molecular weight: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
- Not classified as a reactivity hazard.

10.2 Chemical stability
- Stable under normal conditions.

10.3 Possibility of hazardous reactions
- Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
- Conditions to avoid: None known.

10.5 Incompatible materials
- Materials to avoid: Oxidizing agents
10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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:

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

  - Acute toxicity estimate: 430 mg/kg
  - Method: Calculation method

2-(4-Aminobenzoyloxy)ethyl diethylammonium (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
  - Acute toxicity estimate: 200 mg/kg
  - Method: Calculation method

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
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Acute dermal toxicity: LD50 (Rat): 365 mg/kg
   Acute toxicity estimate: 365 mg/kg
   Method: Calculation method

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 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:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Human repeat insult patch test (HRIPT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Humans</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Assessment: Probability or evidence of skin sensitisation in humans

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Assessment: Probability or evidence of skin sensitisation in humans

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

Chlorphenamine hydrogen maleate:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**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: >= 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.
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assessment

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
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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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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.
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Skin contact: Remarks: May irritate skin.
Eye contact: Symptoms: Eye irritation
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

SECTION 12: Ecological information

**12.1 Toxicity**

**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 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

### 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

### 12.2 Persistence and degradability

**Components:**

**Dexamethasone:**

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

### 12.3 Bioaccumulative potential

**Components:**

**Dihydrostreptomycin sulphate:**

**Bioaccumulation:**  
- Species: Fish  
- Bioconcentration factor (BCF): 3.16

**Partition coefficient: n-octanol/water:**  
- log Pow: -7.51

**Procaine hydrochloride:**
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12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment

**Product:**
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects
No data available

**SECTION 13: Disposal considerations**

13.1 Waste treatment methods

**Product** : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

**Contaminated packaging** : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

**SECTION 14: Transport information**

14.1 UN number or ID number

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ADN</strong></td>
<td>UN 3082</td>
</tr>
<tr>
<td><strong>ADR</strong></td>
<td>UN 3082</td>
</tr>
<tr>
<td><strong>RID</strong></td>
<td>UN 3082</td>
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</tbody>
</table>
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Date of first issue: 10.03.2020

IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Dihydrostreptomycin sulphate)
IATA : Environmentally hazardous substance, liquid, n.o.s. (Dihydrostreptomycin sulphate)

14.3 Transport hazard class(es)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
### Labels:
- 9

### EmS Code:
- F-A, S-F

#### IATA (Cargo)
- Packing instruction (cargo aircraft): 964
- Packing instruction (LQ): Y964
- Packing group: III
- Labels: Miscellaneous

#### IATA (Passenger)
- Packing instruction (passenger aircraft): 964
- Packing instruction (LQ): Y964
- Packing group: III
- Labels: Miscellaneous

### 14.5 Environmental hazards

<table>
<thead>
<tr>
<th>ADN</th>
<th>Environmentally hazardous: yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>Environmentally hazardous: yes</td>
</tr>
<tr>
<td>RID</td>
<td>Environmentally hazardous: yes</td>
</tr>
<tr>
<td>IMDG</td>
<td>Marine pollutant: yes</td>
</tr>
</tbody>
</table>

#### IATA (Passenger)
- Environmentally hazardous: yes

#### IATA (Cargo)
- Environmentally hazardous: yes

### 14.6 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.

### 14.7 Maritime transport in bulk according to IMO instruments

- Remarks: Not applicable for product as supplied.

### SECTION 15: Regulatory information

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

- REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)

- REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

- REACH - List of substances subject to authorisation

- Conditions of restriction for the following entries should be considered:
  - Number on list 3
  - Not applicable

- Not applicable
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(Annex XIV)
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quantity 1</td>
</tr>
<tr>
<td></td>
<td>100 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H301: Toxic if swallowed.
H302: Harmful if swallowed.
H311: Toxic in contact with skin.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H336: May cause drowsiness or dizziness.
H360D: May damage the unborn child.
H361d: Suspected of damaging the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure if swallowed.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
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Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity
Resp. Sens. : Respiratory sensitisation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICL - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulate 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information
Sources of key data used to compile the Safety Data Sheet:

Classification of the mixture:
Acute Tox. 4 H302

Classification procedure:
Calculation method
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<table>
<thead>
<tr>
<th>Property</th>
<th>UN Number</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>H334</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>H317</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>H361d</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

NO / EN