SECTION 1. IDENTIFICATION

Product name : Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

Manufacturer or supplier's details
Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary medicine
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Acute toxicity (Oral) : Category 4
Eye irritation : Category 2A
Respiratory sensitization : Category 1
Skin sensitization : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Cardio-vascular system)

GHS label elements
Hazard pictograms :

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

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe mist or vapors.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P272 Contaminated work clothing must not be allowed out of the workplace.
- P280 Wear protective gloves, protective clothing, eye protection and face protection.
- P285 In case of inadequate ventilation wear respiratory protection.

**Response:**
- P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel unwell. Rinse mouth.
- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P304 + P341 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308 + P313 IF exposed or concerned: Get medical attention.
- P333 + P313 If skin irritation or rash occurs: Get medical attention.
- P337 + P313 If eye irritation persists: Get medical attention.
- P342 + P311 If experiencing respiratory symptoms: Call a doctor.
- P363 Wash contaminated clothing before reuse.

**Storage:**
- P405 Store locked up.

**Disposal:**
- P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards:
None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

**Components**

<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- Aminobenzoxyloxy)ethyldiethylammonium (6R)-6-</td>
<td>6130-64-9</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>
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| (2-phenylacetamido)penicillanate monohydrate |  |
| Procaaine hydrochloride | 51-05-8 | >= 1 - < 5 |
| Chlorphenamine hydrogen maleate | 113-92-8 | >= 1 - < 5 |
| Dexamethasone | 50-02-2 | < 0.1 |

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention.

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

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
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.
May cause damage to organs through prolonged or repeated exposure if swallowed.
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.
Specific hazards during fire fighting:
Exposure to combustion products may be a hazard to health.
Hazardous combustion products:
Carbon oxides
Nitrogen oxides (NOx)
Sulfur 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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 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 diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures:
See Engineering measures under EXPOSURE
CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.
Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe mist or vapors.
- Do not swallow.
- Do not get in eyes.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensizers.
- Do not eat, drink or smoke when using this product.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</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 (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
- Wipe limit 100 µg/100 cm² Internal

Further information: Dexamethasone
- 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 containment devices). Minimize open handling.

**Personal protective equipment**

**Respiratory protection**: General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Hygiene measures**: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: suspension
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
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<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
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<tr>
<td>pH</td>
<td>5.0 - 6.0</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
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<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
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</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1.17 - 1.21 g/cm³</td>
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<tr>
<td>Solubility(ies)</td>
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</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
</tbody>
</table>

No data available:  Not applicable
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Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 709.59 mg/kg Method: Calculation method

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

2-(4-Aminobenzoyloxy)ethylidihydrostreptomycin (6R)-6-(2-phenylacetamido)penicillanate monohydrate:
Acute oral toxicity: LD50 (Mouse): > 2,000 mg/kg

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

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

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

**Dexamethasone:**
- Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
- LD50 (Mouse): > 6,500 mg/kg

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

Application Route: Subcutaneous

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**2-(4-Aminobenzoxyloxy)ethylidiethylammonium (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)ethylidiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:**
Result: No eye irritation

**Chlorphenamine hydrogen maleate:**
- Species: Rabbit
- Result: Severe irritation

**Dexamethasone:**
- Species: Rabbit
- Result: Mild eye irritation
Respiratory or skin sensitization

Skin sensitization
May cause an allergic skin reaction.

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

Components:

Dihydrostreptomycin sulphate:
Test Type: Human repeat insult patch test (HRIPT)
Routes of exposure: Skin contact
Species: Humans
Result: positive
Remarks: Based on data from similar materials
Assessment: Probability or evidence of skin sensitization in humans

2-(4-Aminobenzoyloxy)ethyldiethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: positive
Remarks: Based on data from similar materials
Assessment: Probability or evidence of skin sensitization in humans
Assessment: Probability of respiratory sensitization in humans based on animal testing

Chlorphenamine hydrogen maleate:
Routes of exposure: Dermal
Remarks: No data available

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Chlorphenamine hydrogen maleate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
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<table>
<thead>
<tr>
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</tbody>
</table>

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

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:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>30 - 60 mg/kg body weight</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>2 Years</td>
<td>20 - 50 mg/kg body weight</td>
<td>negative</td>
</tr>
</tbody>
</table>

**IARC**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is
NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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,

Effects on fetal development: Test Type: Embryo-fetal development

Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 20 mg/kg body weight
Result: Reduced embryonic survival,

Remarks: The significance of these findings for humans is not certain.

Test Type: Embryo-fetal development

Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 15 mg/kg body weight
Result: No significant adverse effects were reported

Dexamethasone:

Effects on fetal development: Test Type: Development

Species: Mouse
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 6 mg/kg body weight
Result: Specific developmental abnormalities,

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
### Reproductive toxicity - Assessment
- May damage the unborn child.

**STOT-single exposure**
Not classified based on available information.

**Components:**

**Chlorphenamine hydrogen maleate:**
- Assessment: May cause drowsiness or dizziness.

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

**Components:**

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

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

**Repeated dose toxicity**

**Components:**

**Chlorphenamine hydrogen maleate:**
- Species: Rat
- NOAEL: 10 mg/kg
- Application Route: Oral
- Exposure time: 6 Weeks
- Remarks: No significant adverse effects were reported

- Species: Monkey
- LOAEL: 15 mg/kg
- Application Route: Oral
- Exposure time: 105 Weeks
- Target Organs: Heart
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<tr>
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</thead>
<tbody>
<tr>
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<td>04/04/2023</td>
<td>03/10/2020</td>
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</table>

### Dexamethasone:

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

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.4 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Immune system</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>8 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Immune system</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

**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 |
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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

SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Dihydrostreptomycin sulphate:**
Toxicity to fish: LC50 (Onchorhynchus 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

2-(4-Aminobenzoyloxy)ethylidenammonium (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

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
SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Do not dispose of waste into sewer.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 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
Environmentally hazardous: yes

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.
**SAFETY DATA SHEET**

**Dexamethasone / Chlorphenamine Hydrogen Maleate Formulation**

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**Version** 2.6  
**Revision Date:** 09/30/2023  
**SDS Number:** 5491621-00011  
**Date of last issue:** 04/04/2023  
**Date of first issue:** 03/10/2020

<table>
<thead>
<tr>
<th><strong>Domestic regulation</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>49 CFR</strong></td>
<td></td>
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<tr>
<td><strong>UN/ID/NA number</strong></td>
<td>UN 3082</td>
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<tr>
<td><strong>Proper shipping name</strong></td>
<td>Environmentally hazardous substance, liquid, n.o.s. (Dihydrostreptomycin sulphate)</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>9</td>
</tr>
<tr>
<td><strong>Packing group</strong></td>
<td>III</td>
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<tr>
<td><strong>Labels</strong></td>
<td>CLASS 9</td>
</tr>
<tr>
<td><strong>ERG Code</strong></td>
<td>171</td>
</tr>
<tr>
<td><strong>Marine pollutant</strong></td>
<td>yes (Dihydrostreptomycin sulphate)</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.</td>
</tr>
</tbody>
</table>

**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.

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**SECTION 15. REGULATORY INFORMATION**

**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards**

- Acute toxicity (any route of exposure)
- Respiratory or skin sensitization
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)
- Serious eye damage or eye irritation

**SARA 313**

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations**

**Pennsylvania Right To Know**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
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<tbody>
<tr>
<td>Dihydrostreptomycin sulphate</td>
<td>5490-27-7</td>
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<tr>
<td>2-(4-Aminobenzoyloxy)ethyl diethylammonium (6R)-6-(2-phenylacetamido)penicillanate monohydrate</td>
<td>6130-64-9</td>
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<tr>
<td>Water</td>
<td>7732-18-5</td>
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</table>

The ingredients of this product are reported in the following inventories:
SECTION 16. OTHER INFORMATION

Further information

NFPA 704:  

<table>
<thead>
<tr>
<th>Flammability</th>
<th>Health</th>
<th>Instability</th>
<th>Special hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>0</td>
<td>*</td>
</tr>
</tbody>
</table>

HMIS® IV:

- HEALTH: 2
- FLAMMABILITY: 1
- PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-
Sources of key data used to compile the Material Safety Data Sheet:


Revision Date: 09/30/2023

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.