SAFETY DATA SHEET

Prednisolone / Chloramphenicol Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Prednisolone / Chloramphenicol Formulation

Supplier’s company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd.
Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Carcinogenicity : Category 2
Reproductive toxicity : Category 1B

GHS label elements
Hazard pictograms
Signal word : Danger
Hazard statements : H351 Suspected of causing cancer.
H360 May damage fertility or the unborn child.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed:
- Dust contact with the eyes can lead to mechanical irritation.
- Contact with dust can cause mechanical irritation or drying of the skin.
- May form combustible dust concentrations in air during processing, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>56-75-7</td>
</tr>
<tr>
<td>Sulfuric acid, mono-C16-18-alkyl esters, sodium salts</td>
<td>68955-20-4</td>
</tr>
<tr>
<td>Prednisolone</td>
<td>50-24-8</td>
</tr>
<tr>
<td>Tetradecanol</td>
<td>112-72-1</td>
</tr>
<tr>
<td>Dodecan-1-ol</td>
<td>112-53-8</td>
</tr>
<tr>
<td>Basic phenylmercury nitrate</td>
<td>8003-05-2</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.
- 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:
- If in eyes, rinse well with water.
- Get medical attention if irritation develops and persists.

If swallowed:
- If swallowed, DO NOT induce vomiting.
- Get medical attention.
- Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed:
- Suspected of causing cancer.
- May damage fertility or the unborn child.
- Contact with dust can cause mechanical irritation or drying of...
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Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides

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. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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

Handling
Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not breathe vapours.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

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.
- 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.

Storage
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

Packaging material:
- Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Reference concentration / Basis |
|------------|---------|-------------------------------|----------------------------------------------------|---------------------------------------------------|
|            |         |                               |                                                    |                                                   |


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<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Target substance</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic phenylmercury nitrate</td>
<td>8003-05-2</td>
<td>total inorganic mercury (Mercury)</td>
<td>Urine</td>
<td>Not specified</td>
<td>35 µg/g creatinine</td>
<td>JSOH</td>
</tr>
</tbody>
</table>

Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapour type

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: cream

Colour: No data available
### Prednisolone / Chloramphenicol Formulation

**Version**: 2.0  
**Revision Date**: 2021/08/27  
**SDS Number**: 5710731-00004  
**Date of last issue**: 2021/04/09  
**Date of first issue**: 2020/04/23

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form combustible dust concentrations in air during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Lower explosion limit and upper explosion limit / flammability limit</td>
<td>No data available</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>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</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>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Density and / or relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reac-
tions: May form combustible dust concentrations in air during pro-
cessing, handling or other means. 
Can react with strong oxidizing agents.

Conditions to avoid: Heat, flames and sparks. 
Avoid dust formation.

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 
Not classified based on available information.

Components:

Propylene glycol: 
Acute oral toxicity: LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 44.9 mg/l 
Exposure time: 4 h 
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg 
Assessment: The substance or mixture has no acute dermal toxicity

Chloramphenicol: 
Acute oral toxicity: LD50 Oral (Rat): 2,500 mg/kg

Sulfuric acid, mono-C16-18-alkyl esters, sodium salts: 
Acute oral toxicity: LD50 (Rat): 4,010 mg/kg 
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg 
Method: OECD Test Guideline 402 
Remarks: Based on data from similar materials
### Prednisolone / Chloramphenicol Formulation

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**Date of last issue:** 2021/04/09  
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#### Prednisolone:

<table>
<thead>
<tr>
<th>Route</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
<th>Acute toxicity (other routes of administration)</th>
</tr>
</thead>
</table>
|       | LD50 (Mouse): 1,680 mg/kg | Remarks: No data available | Remarks: No data available | LD50 (Rat): 147 mg/kg  
Application Route: Subcutaneous  
LD50 (Mouse): 767 mg/kg  
Application Route: Intraperitoneal |

#### Tetradecanol:

<table>
<thead>
<tr>
<th>Route</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
</tr>
</thead>
</table>
|       | LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 401  
Assessment: The substance or mixture has no acute oral toxicity | LC50 (Rat): > 1.5 mg/l  
Exposure time: 1 h  
Test atmosphere: vapour  
Assessment: The substance or mixture has no acute inhalation toxicity | LD50 (Rabbit): > 5,000 mg/kg |

#### Dodecan-1-ol:

<table>
<thead>
<tr>
<th>Route</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
</tr>
</thead>
</table>
|       | LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401 | LC50 (Rat): > 12 mg/l  
Exposure time: 6 h  
Test atmosphere: vapour  
Assessment: The substance or mixture has no acute inhalation toxicity  
Remarks: Based on data from similar materials | LD50 (Rabbit): > 5,000 mg/kg |

#### Basic phenylmercury nitrate:

<table>
<thead>
<tr>
<th>Route</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
</tr>
</thead>
</table>
|       | LD50 (Mouse): > 50 - 300 mg/kg  
Remarks: Based on data from similar materials | Assessment: Corrosive to the respiratory tract. |

#### Skin corrosion/irritation

Not classified based on available information.
## Components:

### Propylene glycol:
- **Species**: Rabbit
- **Method**: OECD Test Guideline 404
- **Result**: No skin irritation

### Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:
- **Species**: Rabbit
- **Method**: OECD Test Guideline 404
- **Result**: Skin irritation
- **Remarks**: Based on data from similar materials

### Prednisolone:
- **Remarks**: No data available

### Tetradecanol:
- **Species**: Human
- **Result**: No skin irritation

### Dodecan-1-ol:
- **Species**: Human
- **Result**: No skin irritation

### Basic phenylmercury nitrate:
- **Result**: Corrosive after 4 hours or less of exposure
- **Remarks**: Based on data from similar materials

### Serious eye damage/eye irritation
Not classified based on available information.

## Components:

### Propylene glycol:
- **Species**: Rabbit
- **Result**: No eye irritation
- **Method**: OECD Test Guideline 405

### Chloramphenicol:
- **Remarks**: Mild eye irritation

### Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:
- **Species**: Rabbit
- **Result**: Irreversible effects on the eye
- **Method**: OECD Test Guideline 405
- **Remarks**: Based on data from similar materials

### Prednisolone:
- **Remarks**: No data available
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Tetradecanol:
- Species: Rabbit
- Result: Irritation to eyes, reversing within 21 days
- Method: OECD Test Guideline 405

Dodecan-1-ol:
- Species: Rabbit
- Result: Irritation to eyes, reversing within 21 days
- Method: OECD Test Guideline 405

Basic phenylmercury nitrate:
- Result: Irreversible effects on the eye
- Remarks: Based on skin corrosivity.

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Propylene glycol:
- Test Type: Maximisation Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Result: negative

Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:
- Test Type: Maximisation Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Method: OECD Test Guideline 406
- Result: negative

Prednisolone:
- Remarks: No data available

Tetradecanol:
- Test Type: Maximisation Test
- Exposure routes: Skin contact
- Species: Guinea pig
- Method: OECD Test Guideline 406
- Result: negative

Dodecan-1-ol:
- Test Type: Maximisation Test
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Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Chloramphenicol:
Genotoxicity in vitro:
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Test system: human diploid fibroblasts
Result: positive

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

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

Test Type: Chromosome aberration test in vitro
Test system: mammalian cells
Result: positive

Genotoxicity in vivo:
Test Type: Chromosomal aberration
Species: Mouse
Cell type: Bone marrow
Result: positive

Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Result: negative

Test Type: Micronucleus test
Species: Rat
<table>
<thead>
<tr>
<th>Compounds</th>
<th>Genotoxicity in vitro</th>
<th>Genotoxicity in vivo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 471</td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test Type: sister chromatid exchange assay</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td>Prednisolone:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: sister chromatid exchange assay</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Species: Humans</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tetradecanol:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: In vitro mammalian cell gene mutation test</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 471</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dodecan-1-ol:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Chromosome aberration test in vitro</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 471</td>
<td>Method: OECD Test Guideline 473</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>
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Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo
Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative

Carcinogenicity
Suspected of causing cancer.

Components:

Propylene glycol:
- Species: Rat
- Application Route: Ingestion
- Exposure time: 2 Years
- Result: negative

Chloramphenicol:
- Remarks: IARC: (International Agency for Research on Cancer)
- Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

Prednisolone:
- Species: Rat
- Application Route: Oral
- Exposure time: 18 Months
- Result: negative

Reproductive toxicity
May damage fertility or the unborn child.

Components:

Propylene glycol:
- Effects on fertility: Test Type: Two-generation reproduction toxicity study
  Species: Mouse
  Application Route: Ingestion
  Result: negative

- Effects on foetal development: Test Type: Embryo-foetal development
  Species: Mouse
  Application Route: Ingestion
  Result: negative

Chloramphenicol:
- Effects on foetal development: Species: Monkey, female
  Result: No significant adverse effects were reported
Species: Mouse
Developmental Toxicity: LOAEL: 500 mg/kg body weight
Result: Embryo-foetal toxicity, Fetal growth retardation

Species: Rat
Developmental Toxicity: LOAEL: 500 - 2,000 mg/kg body weight
Result: Embryo-foetal toxicity, Fetal growth retardation, Teratogenic effects

Species: Rabbit
Developmental Toxicity: LOAEL: 1,000 mg/kg body weight
Result: Embryo-foetal toxicity, Fetal growth retardation

Reproductive toxicity - Assessment: Clear evidence of adverse effects on sexual function and fertility, and/or on development, based on animal experiments

Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Prednisolone:

Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 1 mg/kg body weight
Result: No effects on fertility

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 0.5 mg/kg body weight
Result: Malformations were observed., Cleft palate

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 30 mg/kg body weight
Result: decreased blood formation

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: NOAEL: 25 mg/kg body weight
Result: No effects on foetal development

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

Dodecan-1-ol:

Effects on fertility: Test Type: Combined repeated dose toxicity study with the
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**Prednisolone / Chloramphenicol Formulation**

<table>
<thead>
<tr>
<th>Version</th>
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<tr>
<td>2.0</td>
<td>2021/08/27</td>
<td>5710731-00004</td>
<td>2021/04/09</td>
<td>2020/04/23</td>
</tr>
</tbody>
</table>

- **Reproduction/developmental toxicity screening test**
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

- **Effects on foetal development**
  - Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

**Basic phenylmercury nitrate:**

- **Effects on foetal development**
  - Test Type: Embryo-foetal development
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Result: positive
  - Remarks: Based on data from similar materials

- **Reproductive toxicity - Assessment**
  - Clear evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

**Components:**

**Chloramphenicol:**

- **Exposure routes**
  - Oral

- **Target Organs**
  - Blood, Bone marrow

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**

- **Assessment**
  - May cause respiratory irritation.

**STOT - repeated exposure**

Not classified based on available information.

**Components:**

**Chloramphenicol:**

- **Exposure routes**
  - Oral, Inhalation

- **Target Organs**
  - Blood, Bone marrow, Liver

**Prednisolone:**

- **Target Organs**
  - Bone marrow, Adrenal gland, Liver

- **Assessment**
  - Causes damage to organs through prolonged or repeated exposure.

**Basic phenylmercury nitrate:**

- **Exposure routes**
  - Oral

- **Target Organs**
  - Kidney

- **Assessment**
  - Shown to produce significant health effects in animals at con-
centrations of 10 mg/kg bw or less.

**Repeated dose toxicity**

**Components:**

**Propylene glycol:**
- **Species:** Rat, male
- **NOAEL:** >= 1,700 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 2 yr

**Chloramphenicol:**
- **Species:** Dog
- **Target Organs:** Blood, Bone marrow
- **Symptoms:** decrease in appetite, Reduced body weight

**Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:**
- **Species:** Rat
- **NOAEL:** 428 mg/kg
- **LOAEL:** 970 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

**Prednisolone:**
- **Species:** Rat
- **LOAEL:** 0.6 mg/kg
- **Application Route:** Oral
- **Exposure time:** 63 Days
- **Target Organs:** Bone marrow

- **Species:** Dog
  - **LOAEL:** 2.5 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 6 Weeks
  - **Target Organs:** Adrenal gland

- **Species:** Rabbit
  - **LOAEL:** 1 mg/kg
  - **Application Route:** Oral
  - **Exposure time:** 24 Weeks
  - **Target Organs:** Liver

**Dodecan-1-ol:**
- **Species:** Rat
  - **NOAEL:** > 2,000 mg/kg
  - **Application Route:** Ingestion
  - **Exposure time:** 41 - 45 Days

**Basic phenylmercury nitrate:**
- **Species:** Rat


**SAFETY DATA SHEET**

**Prednisolone / Chloramphenicol Formulation**

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- **NOAEL**: < 1.25 mg/kg
- **Application Route**: Ingestion
- **Exposure time**: 2 yr
- **Remarks**: Based on data from similar materials

**Aspiration toxicity**
Not classified based on available information.

**Components:**

**Dodecan-1-ol:**
The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

**Experience with human exposure**

**Components:**

**Chloramphenicol:**

**General Information**
Target Organs: Blood
Target Organs: Bone marrow
Symptoms: aplastic anemia, confusion, Diarrhoea, Fever, Headache, Nausea, Vomiting

**prednisolone:**
Ingestion
Symptoms: sodium retention, Headache, Vertigo, fluid retention, subcutaneous bleeding, striae, skin atrophy, menstrual irregularities

12. **ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Propylene glycol:**

- **Toxicity to fish**
  - LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
  - Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  - Exposure time: 48 h

- **Toxicity to algae/aquatic plants**
  - ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
  - NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  - Exposure time: 7 d

- **Toxicity to microorganisms**
  - NOEC (Pseudomonas putida): > 20,000 mg/l
Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:

Toxicity to fish:
- LC50 (Danio rerio (zebra fish)): 5.2 mg/l
  Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 2.8 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
  Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
- ErC50 (Desmodesmus subspicatus (green algae)): 34 mg/l
  Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Ceriodaphnia dubia (water flea)): 0.204 mg/l
  Exposure time: 7 d
  Remarks: Based on data from similar materials

Toxicity to microorganisms:
- NOEC (Pseudomonas putida): 550 mg/l
  Exposure time: 18 h

Prednisolone:

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 85 mg/l
  Exposure time: 48 h

Toxicity to algae/aquatic plants:
- NOEC (Pseudokirchneriella subcapitata (green algae)): 160 mg/l
  Exposure time: 72 h
  EC50 (Pseudokirchneriella subcapitata (green algae)): > 160 mg/l
  Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Ceriodaphnia dubia (water flea)): 0.23 mg/l
  Exposure time: 7 d

Tetradecanol:

Toxicity to fish:
- LC50 (Oncorhynchus mykiss (rainbow trout)): > 1 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
  Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): 3.2 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- EL50 (Desmodesmus subspicatus (green algae)): > 10 mg/l
  Exposure time: 96 h
  Test substance: Water Accommodated Fraction
  EL10 (Desmodesmus subspicatus (green algae)): 2.9 mg/l
  Exposure time: 96 h
  Test substance: Water Accommodated Fraction
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): EC10 (Daphnia magna (Water flea)): 0.0063 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 1

### Dodecan-1-ol:

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 1.01 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.765 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: ErC50 (Desmodesmus subspicatus (green algae)): 0.66 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (green algae)): 0.085 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1

Toxicity to microorganisms: EC0 (Pseudomonas putida): > 10,000 mg/l
Exposure time: 30 min

### Basic phenylmercury nitrate:

Toxicity to fish: EC50 (Oncorhynchus mykiss (rainbow trout)): > 0.001 - 0.01 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)): > 0.001 - 0.01 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 0.01 - 0.1 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity): 100
### Toxicity to fish (Chronic toxicity)

| NOEC (Pimephales promelas (fathead minnow)) | > 0.0001 - 0.001 mg/l |
| Exposure time: | 32 d |
| Remarks: | Based on data from similar materials |

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

| NOEC (Mysidopsis bahia (opossum shrimp)) | > 0.001 - 0.01 mg/l |
| Exposure time: | 35 d |
| Remarks: | Based on data from similar materials |

### M-Factor (Chronic aquatic toxicity)

| NOEC (Bacteria) | > 0.001 - 0.01 mg/l |
| Exposure time: | 18 h |
| Remarks: | Based on data from similar materials |

### Persistence and degradability

#### Components:

#### Propylene glycol:

**Biodegradability**

| Result: | Readily biodegradable. |
| Biodegradation: | 98.3 % |
| Exposure time: | 28 d |
| Method: | OECD Test Guideline 301F |

#### Sulfuric acid, mono-C16-18-alkyl esters, sodium salts:

**Biodegradability**

| Result: | Readily biodegradable. |
| Biodegradation: | 77 % |
| Exposure time: | 30 d |
| Method: | OECD Test Guideline 301D |

#### Tetradecanol:

**Biodegradability**

| Result: | Readily biodegradable. |
| Biodegradation: | 92 % |
| Exposure time: | 28 d |

#### Dodecan-1-ol:

**Biodegradability**

| Result: | Readily biodegradable. |
| Biodegradation: | 79 % |
| Exposure time: | 28 d |
| Method: | OECD Test Guideline 301D |

#### Basic phenylmercury nitrate:

**Biodegradability**

| Result: | Readily biodegradable. |
| Remarks: | Based on data from similar materials |

### Bioaccumulative potential

#### Components:

#### Propylene glycol:
Partition coefficient: n-octanol/water

**prednisolone:**
- log Pow: -1.07

**Tetradecanol:**
- log Pow: 5.5

**Dodecan-1-ol:**
- log Pow: ≥ 4
  - Remarks: Based on data from similar materials

**Basic phenylmercury nitrate:**
- log Pow: 1.27

**Mobility in soil**
- No data available

**Hazardous to the ozone layer**
- Not applicable

**Other adverse effects**
- No data available

### 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
- Waste from residues: Dispose 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: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable

**IATA-DGR**
- UN/ID No.: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
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</tr>
</tbody>
</table>

Labels: Not applicable
Packing instruction (cargo aircraft): Not applicable
Packing instruction (passenger aircraft): Not applicable

**IMDG-Code**
- UN number: Not applicable
- Proper shipping name: Not applicable
- Class: Not applicable
- Subsidiary risk: Not applicable
- Packing group: Not applicable
- Labels: Not applicable
- EmS Code: Not applicable
- Marine pollutant: Not applicable

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
Not applicable for product as supplied.

**National Regulations**
Refer to section 15 for specific national regulation.

**Special precautions for user**
Not applicable

**15. REGULATORY INFORMATION**

**Related Regulations**

**Fire Service Law**
Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

**Priority Assessment Chemical Substance**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
<tr>
<td>Sodium alkyl(C=8-18) sulfate</td>
<td>214</td>
</tr>
<tr>
<td>Alkanol(C=10-16) (only the substances that contain any of C=11-14 components)</td>
<td>171</td>
</tr>
</tbody>
</table>

**Industrial Safety and Health Law**

**Harmful Substances Prohibited from Manufacture**
Not applicable

**Harmful Substances Required Permission for Manufacture**
Not applicable

**Substances Prevented From Impairment of Health**
Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**
Not applicable
Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Poisonous substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Cabinet Order Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mercury compounds and preparations containing them</td>
<td>17</td>
</tr>
</tbody>
</table>

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Class II Designated Chemical Substances

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,2-dichloro-N-[2-hydroxy-1-(hydroxymethyl)-2-(4-nitrophenyl)ethyl]acetamide</td>
<td>30</td>
<td>4.0</td>
</tr>
</tbody>
</table>

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Not regulated as a dangerous good

Aviation Law
Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

<table>
<thead>
<tr>
<th>Bulk transportation</th>
<th>Not classified as noxious liquid substance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marine Pollution and Sea Disaster Prevention etc Law</td>
<td></td>
</tr>
</tbody>
</table>
Pack transportation : Not classified as marine pollutant
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Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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

16. OTHER INFORMATION

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

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

Date format: yyyy/mm/dd

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- JSOH: Occupational exposure limits based on biological monitoring (JSOH).
- ACGIH / TWA: 8-hour, time-weighted average

ALIC - 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; KEGI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; PCA - Proposed Classification and Labelling of Chemicals; REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals; RLD - Recommended Limiting Dose; RLD50 - Recommended Limiting Dose (50%); RLD100 - Recommended Limiting Dose (100%); RTECS - Registry of Toxic Effects of Chemical Substances; RzC - Recommended Use Code; ScVEG - Life Cycle Assessment; Sch - Austrian Norm; SCL - Scottish Chemicals Register; SLS - Standard Log Scale; SMD - Standard Magnitude of Difference; SMR - Standard of the German Institute for Standardisation; SNF - Statement of the Netherlands Food and Consumer Product Safety Authority; SSCL - South African Standard for Chemicals; TWA - Time Weighted Average; V - Volatile Substance; W/L - Water, Liquid
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Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS 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.

JP / EN