SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Prednisolone / Chloramphenicol Formulation

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

1.1 Product identifier
   Trade name : Prednisolone / Chloramphenicol Formulation

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

1.3 Details of the supplier of the safety data sheet
   Company : MSD
             Kilshel gain
             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)
   Carcinogenicity, Category 2 : H351: Suspected of causing cancer.
   Reproductive toxicity, Category 1B : H360: May damage fertility or the unborn child.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   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.
   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.

Hazardous components which must be listed on the label:
Chloramphenicol

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.

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloramphenicol</td>
<td>56-75-7</td>
<td>200-287-4</td>
<td></td>
<td>Carc. 2; H351 Repr. 1B; H360</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>prednisolone</td>
<td>50-24-8</td>
<td>200-021-7</td>
<td></td>
<td>Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Bone marrow, Adrenal gland, Liver) Aquatic Chronic 2; H411</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
<tr>
<td>Basic phenylmercury nitrate</td>
<td>8003-05-2</td>
<td>060-008-00-9</td>
<td></td>
<td>Acute Tox. 3; H301 Skin Corr. 1; H314 Eye Dam. 1; H318 Repr. 1B; H360D STOT RE 1; H372 (Kidney) Aquatic Acute 1;</td>
<td>&gt;= 0,0002 - &lt; 0,0025</td>
</tr>
</tbody>
</table>
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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. 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.

4.2 Most important symptoms and effects, both acute and delayed
Risks: Suspected of causing cancer. May damage fertility or the unborn child.

For explanation of abbreviations see section 16.
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

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. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages
6.3 Methods and material for containment and cleaning up

Methods for 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.

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:
- 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.

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
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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 Organic peroxides Explosives

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<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>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>25 ppm 79 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>56-75-7</td>
<td>TWA</td>
<td>0.2 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Eye Wipe limit Not required

<table>
<thead>
<tr>
<th>Substance name</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Sampling time</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic phenylmercury nitrate</td>
<td>8003-05-2</td>
<td>Mercury (Mercury): 30 µg/g creatinine (Urine)</td>
<td></td>
<td>AN 361</td>
</tr>
</tbody>
</table>

Further information: Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Substances</th>
<th>Environmental Compartment</th>
<th>Value Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Freshwater - intermittent</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Hexadecan-1-ol</td>
<td>Fresh water sediment</td>
<td>30 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>3 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>5.8 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Octadecan-1-ol</td>
<td>Fresh water sediment</td>
<td>56.6 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>5.66 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

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

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
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 14387

Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: cream
Colour: No data available
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): May form combustible dust concentrations in air during processing, handling or other means.
Flammability (liquids): Not applicable
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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>Auto-ignition temperature</td>
<td>No data available</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>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>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>Particle characteristics</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9.2 **Other information**

- **Explosives**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Evaporation rate**: Not applicable
- **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: May form combustible dust concentrations in air during pro-
10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

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
Not classified based on available information.

Components:

Chloramphenicol:
Acute oral toxicity: LD50 Oral (Rat): 2.500 mg/kg

Prednisolone:
Acute oral toxicity: LD50 (Mouse): 1.680 mg/kg
LD50 (Rat): > 3.857 mg/kg
Acute inhalation toxicity: Remarks: No data available
Acute dermal toxicity: Remarks: No data available
Acute toxicity (other routes of administration): LD50 (Rat): 147 mg/kg
Application Route: Subcutaneous
LD50 (Mouse): 767 mg/kg
Application Route: Intraperitoneal

Basic phenylmercury nitrate:
Acute oral toxicity: LD50 (Mouse): > 50 - 300 mg/kg
Remarks: Based on data from similar materials
Acute toxicity estimate: 50,005 mg/kg
Method: Calculation method
Acute inhalation toxicity: Assessment: Corrosive to the respiratory tract.

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

**Components:**

**prednisolone:**
Remarks: No data available

**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:**

**Chloramphenicol:**
Remarks: Mild eye irritation

**prednisolone:**
Remarks: No data available

**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:**

**prednisolone:**
Remarks: No data available

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**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
Cell type: Bone marrow
Result: negative

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

Test Type: Mouse Lymphoma
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Rat
Application Route: Oral
Result: negative

Test Type: sister chromatid exchange assay
Species: Humans
Result: negative

Carcinogenicity
Suspected of causing cancer.
Components:

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:

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

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
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Reproductive toxicity - Assessment:
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:
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

Basic phenylmercury nitrate:
Effects on foetal development:
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive
Remarks: Based on data from similar materials

Reproductive toxicity - Assessment:
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

STOT - single exposure
Not classified based on available information.

Components:
Chloramphenicol:
Exposure routes: Oral
Target Organs: Blood, Bone marrow

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-
Repeated dose toxicity

Components:

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

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

Basic phenylmercury nitrate:
Species : Rat
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.

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:**

**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

### SECTION 12: Ecological information

#### 12.1 Toxicity

**Components:**

**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: 0,23 mg/l
Exposure time: 7 d
Species: Ceriodaphnia dubia (water flea)

**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
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**Revision Date**: 27.08.2021  
**SDS Number**: 5723174-00004  
**Date of last issue**: 09.04.2021  
**Date of first issue**: 23.04.2020

- 0,1 mg/l  
  Exposure time: 72 h  
  Remarks: Based on data from similar materials

**M-Factor (Acute aquatic toxicity)**: 100

**Toxicity to microorganisms**: NOEC (Bacteria): > 0,001 - 0,01 mg/l  
  Exposure time: 18 h  
  Remarks: Based on data from similar materials

**Toxicity to fish (Chronic toxicity)**: NOEC: > 0,0001 - 0,001 mg/l  
  Exposure time: 32 d  
  Species: Pimephales promelas (fathead minnow)  
  Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC: > 0,001 - 0,01 mg/l  
  Exposure time: 35 d  
  Species: Mysidopsis bahia (opossum shrimp)  
  Remarks: Based on data from similar materials

**M-Factor (Chronic aquatic toxicity)**: 10

### 12.2 Persistence and degradability

**Components:**

**Basic phenylmercury nitrate:**
- Biodegradability: Result: Readily biodegradable.  
  Remarks: Based on data from similar materials

### 12.3 Bioaccumulative potential

**Components:**

- **prednisolone:**
  - Partition coefficient: n-octanol/water: \( \log \text{Pow} = 1.46 \)

- **Basic phenylmercury nitrate:**
  - Partition coefficient: n-octanol/water: \( \log \text{Pow} = 1.27 \)

### 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

Not regulated as a dangerous good

#### 14.2 UN proper shipping name

Not regulated as a dangerous good

#### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

#### 14.4 Packing group

Not regulated as a dangerous good

#### 14.5 Environmental hazards

Not regulated as a dangerous good

#### 14.6 Special precautions for user

Not applicable

#### 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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Prednisolone / Chloramphenicol Formulation

Version 1.3
Revision Date: 27.08.2021
SDS Number: 5723174-00004
Date of last issue: 09.04.2021
Date of first issue: 23.04.2020

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII):
- Conditions of restriction for the following entries should be considered:
  - Basic phenylmercury nitrate (Number on list 18)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
- Not applicable

REACH - List of substances subject to authorisation (Annex XIV):
- Not applicable

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

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

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.
- H314: Causes severe skin burns and eye damage.
- H318: Causes serious eye damage.
- H351: Suspected of causing cancer.
- H360: May damage fertility or the unborn child.
- H360D: May damage the unborn child.
- H361d: Suspected of damaging the unborn child.
- H372: Causes damage to organs through prolonged or repeated...
**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**Prednisolone / Chloramphenicol Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<td>00004</td>
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</table>

**Full text of other abbreviations**

- H400 : Very toxic to aquatic life.
- H410 : Very toxic to aquatic life with long lasting effects.
- H411 : Toxic to aquatic life with long lasting effects.
- EUH071 : Corrosive to the respiratory tract.

**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; **AIIC** - Australian Inventory of Industrial Chemicals; **ASTM** - American Society for the Testing of Materials; **bw** - Body weight; **CLP** - Classification Labelling Packaging Regulation; **EC No 1272/2008** - 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; **EL** - Loading rate associated with x% response; **EMS** - Emergency Schedule; **ENCS** - Existing and New Chemical Substances (Japan); **ER** - 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; **MARPOL** - International Convention for the Prevention of Pollution from Ships; **NO** - 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, 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; **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; **TECI** - Taiwan Chemical Substance 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

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<table>
<thead>
<tr>
<th>Full text of other abbreviations</th>
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<tbody>
<tr>
<td><strong>Acute Tox.</strong></td>
<td>Acute toxicity</td>
</tr>
<tr>
<td><strong>Aquatic Acute</strong></td>
<td>Short-term (acute) aquatic hazard</td>
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<tr>
<td><strong>Aquatic Chronic</strong></td>
<td>Long-term (chronic) aquatic hazard</td>
</tr>
<tr>
<td><strong>Carc.</strong></td>
<td>Carcinogenicity</td>
</tr>
<tr>
<td><strong>Eye Dam.</strong></td>
<td>Serious eye damage</td>
</tr>
<tr>
<td><strong>Repr.</strong></td>
<td>Reproductive toxicity</td>
</tr>
<tr>
<td><strong>Skin Corr.</strong></td>
<td>Skin corrosion</td>
</tr>
<tr>
<td><strong>STOT RE</strong></td>
<td>Specific target organ toxicity - repeated exposure</td>
</tr>
<tr>
<td><strong>AN 361</strong></td>
<td>Norway. Directive on measures and limit values for physical and chemical factors in the work environment (biological limit values).</td>
</tr>
<tr>
<td><strong>FOR-2011-12-06-1358</strong></td>
<td>Norway. Occupational Exposure limits</td>
</tr>
<tr>
<td><strong>FOR-2011-12-06-1358 / TWA</strong></td>
<td>Long term exposure limit</td>
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Further information

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

Classification of the mixture:

<table>
<thead>
<tr>
<th>Carc.</th>
<th>Repr.</th>
<th>Classification procedure</th>
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<tbody>
<tr>
<td>2</td>
<td>1B</td>
<td>H351, H360</td>
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Calculation method

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