SAFETY DATA SHEET

Prednisolone / Chloramphenicol Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Prednisolone / Chloramphenicol Formulation

Manufacturer or supplier's details

Company name of supplier: MSD
Address: 2000 Galloping Hill Road
Kenilworth - New Jersey - U.S.A. 07033
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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 dis-
posal plant.
SAFETY DATA SHEET
Prednisolone / Chloramphenicol Formulation

Other hazards
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

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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloramphenicol</td>
<td>56-75-7</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>prednisolone</td>
<td>50-24-8</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

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. 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.

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 the skin. Dust contact with the eyes can lead to mechanical irritation.

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
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 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. 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.

SECTION 7. HANDLING AND STORAGE

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 vapors. 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 use of administrative controls.

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
Organic peroxides
Explosives

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloramphenicol</td>
<td>56-75-7</td>
<td>TWA</td>
<td>0.2 mg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Not required</td>
<td></td>
</tr>
<tr>
<td>prednisolone</td>
<td>50-24-8</td>
<td>TWA</td>
<td>10 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td></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 vapor type
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: cream
Color: No data available
Odor: No data available
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form combustible dust concentrations in air during processing, handling or other means.
Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor density: Not applicable
Relative density: No data available
Density: No data available
Solubility(ies)
Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Autoignition temperature: No data available
Decomposition temperature: No data available
Viscosity
Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form combustible dust concentrations in air during processing, 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.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
Chloramphenicol:
Acute oral toxicity
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

Skin corrosion/irritation
Not classified based on available information.
Components:
prednisolone:
Remarks : No data available

Serious eye damage/eye irritation
Not classified based on available information.
Components:
Chloramphenicol:
Remarks : Mild eye irritation

prednisolone:
Remarks : No data available

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
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 fetal development: Species: Monkey, female
Result: No significant adverse effects were reported

Species: Mouse
Developmental Toxicity: LOAEL: 500 mg/kg body weight
Result: Embryo-fetal toxicity, Fetal growth retardation

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

Species: Rabbit
Developmental Toxicity: LOAEL: 1,000 mg/kg body weight
Result: Embryo-fetal 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 fetal development: Test Type: Embryo-fetal development
Species: Mouse
Application Route: Oral
Developmental Toxicity: LOAEL: 0.5 mg/kg body weight
Result: Malformations were observed., Cleft palate
Test Type: Embryo-fetal 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 fetal development.

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

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

**Components:**

**Chloramphenicol:**
Routes of exposure: Oral
Target Organs: Blood, Bone marrow

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

**Components:**

**Chloramphenicol:**
Routes of exposure: 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.

**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

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>2.5 mg/kg</td>
<td>Oral</td>
<td>6 Weeks</td>
<td>Adrenal gland</td>
</tr>
</tbody>
</table>

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

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

**Experience with human exposure**

**Components:**

**Chloramphenicol:**

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

**prednisolone:**

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

### SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**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 (Ceriodaphnia dubia (water flea)): 0.23 mg/l  
Exposure time: 7 d
Persistence and degradability
No data available

Bioaccumulative potential

Components:
prednisolone:
Partition coefficient: n-octanol/water : log Pow: 1.46

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

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

Domestic regulation

NOM-002-SCT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

NOM-165-SEMARNAT-2013, Norm establishing a list of substances subject to report for the Registry of Emissions and Pollutant Transfer

Components | CAS-No. | MPU (kg/year) | Transfer/Release (kg/year)
--- | --- | --- | ---

Basic phenylmercury nitrate: 8003-05-2
   MPU: Applicable reporting threshold when the substance, pure or in mixture in a composition
   of more than 1% by weight, is used for industrial activities at facilities that are subject to report
   or are produced by them
   Federal Law for the control of chemical precursors, essential chemical products and machinery for
   producing capsules, tablets and pills.

The ingredients of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AIIC - 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 Sys-
tem; 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 con-
centration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemi-
cal Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International
Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Or-
ganisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-
centration 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; OECD - Organization for Economic Co-operation and Develop-
ment; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumu-
lative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substanc-
es; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No
1907/2006 of the European Parliament and of the Council concerning the Registration, Evalua-
tion, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Tempera-
ture; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transpor-
tation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Na-
tions; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB -
Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Infor-
mation System
SAFETY DATA SHEET

Prednisolone / Chloramphenicol Formulation

Version 1.2  Revision Date: 09.04.2021  SDS Number: 5710732-00003  Date of last issue: 25.08.2020
Date of first issue: 23.04.2020

Sources of key data used to compile the Material Safety Data Sheet:
- Internal technical data
- Data from raw material SDSs
- OECD eChem Portal search results

Revision Date: 09.04.2021

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8