1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Prednisolone / Chloramphenicol Formulation

Manufacturer or supplier's details

Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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:
P203 Obtain, read and follow all safety instructions before use.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P318 IF exposed or concerned, get medical advice.
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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
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>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; 0.25</td>
</tr>
<tr>
<td>Basic phenylmercury nitrate</td>
<td>8003-05-2</td>
<td>&gt;= 0.0002 - &lt; 0.0025</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 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.

5. FIREFIGHTING MEASURES
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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

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.
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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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components 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></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>Not required</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></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
</tr>
<tr>
<td>Basic phenylmercury nitrate</td>
<td>8003-05-2</td>
<td>TWA</td>
<td>0.1 mg/m³ (Mercury)</td>
<td>IN OEL</td>
</tr>
</tbody>
</table>

Further information: Potential contribution to the overall exposure by the cutaneous route including mucous membranes and eye.

<table>
<thead>
<tr>
<th>Components</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TWA</td>
<td>0.1 mg/m³ (Mercury)</td>
<td>ACGIH</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.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : cream

Colour : No data available

Odour : No data available

Odour 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 : No data available
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flammability limit

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: Not applicable

Relative vapour 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

Auto-ignition 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

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.

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 : 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 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
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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)

**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

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.

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

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 concentrations of 10 mg/kg bw or less.

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
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**Prednisolone / Chloramphenicol Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>09.04.2021</td>
<td>5710730-00003</td>
<td>25.08.2020</td>
<td>23.04.2020</td>
</tr>
</tbody>
</table>

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

**Basic phenylmercury nitrate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&lt; 1.25 mg/kg</td>
<td>Ingestion</td>
<td>2 yr</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Chloramphenicol:**

<table>
<thead>
<tr>
<th>General Information</th>
<th>Target Organs: Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Target Organs: Bone marrow</td>
</tr>
<tr>
<td></td>
<td>Symptoms: aplastic anemia, confusion, Diarrhoea, Fever, Headache, Nausea, Vomiting</td>
</tr>
</tbody>
</table>

**prednisolone:**

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

**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: 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

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

Persistence and degradability

Components:

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

Bioaccumulative potential

Components:
prednisolone:
Partition coefficient: n-octanol/water
: log Pow: 1.46
Basic phenylmercury nitrate:
Partition coefficient: n-octanol/water: log Pow: 1.27

Mobility in soil
No data available

Other adverse effects
No data available

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.

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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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: Internal technical data, data from raw material SDSs, OECD
SAFETY DATA SHEET

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date of last issue: 25.08.2020
date of first issue: 23.04.2020

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.

IN / EN