1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol Premix Formulation

**Manufacturer or supplier’s details**

Company : MSD
Address : JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

**Recommended use of the chemical and restrictions on use**

Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

**GHS Classification**

Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

**GHS label elements**

Hazard pictograms : ![Warning]

Signal word : Warning

Hazard statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H373 May cause damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

**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 explosive dust-air mixture during processing, handling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Substance / Mixture:** Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium carbonate</td>
<td>471-34-1</td>
<td>&gt;= 60 -&lt; 100</td>
</tr>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>&gt;= 3 -&lt; 10</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 damaging fertility. Suspected of damaging the unborn child.
- May cause damage to organs through prolonged or repeated exposure.
- 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

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

Unsuitable extinguishing media:
- None known.

Specific hazards during firefighting:
- Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides
- Metal oxides

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

Special protective equipment for 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 re-
leased 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: Use only with adequate ventilation.

Advice on safe handling: Do not breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage: Keep in properly labelled containers. Store locked up. 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>Calcium carbonate</td>
<td>471-34-1</td>
<td>NAB (Inhalable)</td>
<td>10 mg/m³ (Calcium carbonate)</td>
<td>ID OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Total inhalable particulates, containing no asbestos and with a crystalline silica content of &lt; 1%.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Engineering measures: Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### 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: Particulates type

**Hand protection**
- Material: Chemical-resistant gloves

**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.

**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**
- powder

**Colour**
- white

**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 explosive dust-air mixture during processing, handling or other means.

**Flammability (liquids)**
- No data available
SAFETY DATA SHEET

Florfenicol Premix Formulation

Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure: No data available
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.
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 explosive dust-air mixture 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.

Components:

Calcium carbonate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 420
   Assessment: The substance or mixture has no acute oral toxicity

Acute inhalation toxicity: LC50 (Rat): > 3 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Method: OECD Test Guideline 403
   Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 402
   Assessment: The substance or mixture has no acute dermal toxicity

Florfenicol:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
   LD50 (Mouse): > 2,000 mg/kg
   LD50 (Dog): > 1,280 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 0.28 mg/l
   Exposure time: 4 h

Acute dermal toxicity: Remarks: No data available

Acute toxicity (other routes of administration):
LD50 (Rat): 1,913 - 2,253 mg/kg
   Application Route: Intraperitoneal

LD50 (Mouse): 100 mg/kg
   Application Route: Intravenous

Skin corrosion/irritation
Not classified based on available information.

Components:

Calcium carbonate:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Florfenicol:
Species: Rabbit
Result : No skin irritation

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

**Components:**

**Calcium carbonate:**
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

**Florfenicol:**
Species : Rabbit
Result : Mild eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Calcium carbonate:**
Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

**Florfenicol:**
Test Type : Maximisation Test
Species : Guinea pig
Result : negative

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

**Components:**

**Calcium carbonate:**
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

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

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

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

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

Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: positive

Genotoxicity in vivo:
Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Florfenicol:
Species: Rat
Application Route: oral (gavage)
Exposure time: 2 Years
Result: negative
Target Organs: Liver, Testes

Species: Mouse
Application Route: oral (gavage)
Exposure time: 2 Years
Result: negative
Target Organs: Testes, Blood

Reproductive toxicity
Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

Calcium carbonate:
Effects on fertility:
Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422  
Result: negative

**Effects on foetal development**:  
- Test Type: Embryo-foetal development  
- Species: Rat  
- Application Route: Ingestion  
- Method: OECD Test Guideline 414  
- Result: negative

**Florfenicol**:  
**Effects on fertility**:  
- Test Type: Two-generation reproduction toxicity study  
- Species: Rat  
- Application Route: Oral  
- Fertility: LOAEL: 12 mg/kg body weight  
- Result: decreased pup survival, reduced lactation

**Effects on foetal development**:  
- Test Type: Embryo-foetal development  
- Species: Rat  
- General Toxicity Maternal: NOAEL: 4 mg/kg body weight  
- Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight  
- Result: No teratogenic effects, Fetotoxicity  
- Remarks: The effects were seen only at maternally toxic doses.

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: oral (gavage)  
General Toxicity Maternal: NOAEL: 120 mg/kg body weight  
Embryo-foetal toxicity: LOAEL: 40 mg/kg body weight  
Result: Fetotoxicity

**Reproductive toxicity - Assessment**:  
- Some evidence of adverse effects on sexual function and fertility, based on animal experiments. Some evidence of adverse effects on development, based on animal experiments.

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

**STOT - repeated exposure**  
May cause damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.

**Components**:  
**Florfenicol**:  
- Target Organs  
- Assessment: Liver, Brain, Testis, Spinal cord, Blood, gallbladder  
- Causes damage to organs through prolonged or repeated exposure.
Repeated dose toxicity

Components:

Calcium carbonate:
Species : Rat
NOAEL : > 1,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days
Method : OECD Test Guideline 422

Florfenicol:
Species : Dog
NOAEL : 3 mg/kg
Exposure time : 13 Weeks
Target Organs : Liver, Testis, Brain, Spinal cord
Species : Mouse
NOAEL : 200 mg/kg
Exposure time : 13 Weeks
Target Organs : Liver, Testis
Species : Rat
NOAEL : 30 mg/kg
Exposure time : 13 Weeks
Target Organs : Liver, Testis
Species : Dog
NOAEL : 3 mg/kg
LOAEL : 12 mg/kg
Exposure time : 52 Weeks
Target Organs : Liver, gallbladder
Species : Rat
NOAEL : 1 mg/kg
LOAEL : 3 mg/kg
Exposure time : 52 Weeks
Target Organs : Testis

Aspiration toxicity
Not classified based on available information.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Calcium carbonate:
Toxicity to fish : LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates:
- EL50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
  Test substance: Water Accommodated Fraction
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- NOELR (Pseudokirchneriella subcapitata (green algae)): 50 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Method: OECD Test Guideline 201
- EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  Exposure time: 72 h
  Test substance: Water Accommodated Fraction
  Method: OECD Test Guideline 201

Toxicity to microorganisms:
- NOEC: 1,000 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209
- EC50: > 1,000 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209

Florfenicol:
Toxicity to fish:
- LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l
  Exposure time: 96 h
  Method: FDA 4.11
- LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l
  Exposure time: 96 h
  Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 330 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): > 2.9 mg/l
  Exposure time: 14 d
  Method: FDA 4.01
- NOEC (Pseudokirchneriella subcapitata (green algae)): 2.9 mg/l
  Exposure time: 14 d
  Method: FDA 4.01
- IC50 (Skeletonema costatum (marine diatom)): 0.0336 mg/l
  Exposure time: 72 h
  Method: ISO 10253
- NOEC (Skeletonema costatum (marine diatom)): 0.00423 mg/l
  Exposure time: 72 h
Method: ISO 10253

EC50 (Lemna gibba (gibbous duckweed)): 0.76 mg/l
Exposure time: 7 d
Method: OECD Test Guideline 221

NOEC (Lemna gibba (gibbous duckweed)): 0.39 mg/l
Exposure time: 7 d
Method: OECD Test Guideline 221

EC50 (Navicula pelliculosa (Freshwater diatom)): 61 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae): 0.066 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 0.051 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 10
Toxicity to fish (Chronic toxicity):
    NOEC (Pimephales promelas (fathead minnow)): 5.5 mg/l
    Exposure time: 32 d
    Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
    NOEC (Daphnia magna (Water flea)): 1.5 mg/l
    Exposure time: 21 d
    Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 10

Persistence and degradability
No data available

Bioaccumulative potential

Components:

Florfenicol:
Partition coefficient: n-octanol/water: log Pow: 0.373

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
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Florfenicol)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (Florfenicol)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Florfenicol)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.
SAFETY DATA SHEET

Florfenicol Premix Formulation

Version: 3.8
Revision Date: 2020/10/10
SDS Number: 437405-00012
Date of last issue: 2020/03/23
Date of first issue: 2016/01/06

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use: Not applicable
Prohibited substances: Not applicable
Restricted substances: Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

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:

Date format: yyyy/mm/dd

Full text of other abbreviations
ID OEL: Indonesia. Occupational Exposure Limits
ID OEL / NAB: Long term exposure limit

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 -
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.