SAFETY DATA SHEET

Florfenicol Solid Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol Solid Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
          Cruzeiro - Sao Paulo - Brazil  CEP 12730-340

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 in accordance with ABNT NBR 14725 Standard

Acute toxicity (Oral) : Category 5

Reproductive toxicity : Category 2

Specific target organ toxicity - repeated exposure : Category 1 (Liver, Brain, Testis, Spinal cord, Blood, gallbladder)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.
                   H361fd Suspected of damaging fertility. Suspected of
damaging the unborn child.
                   H372 Causes 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.
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Precautionary Statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P260 Do not breathe dust.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P312 Call a POISON CENTER/ doctor if you feel unwell.
- P391 Collect spillage.

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Florfenicol</td>
<td>73231-34-2</td>
<td>Acute toxicity (Oral), Reproductive toxicity, Specific target organ toxicity - repeated exposure (Liver, Brain, Testis, Spinal cord, Blood, gallbladder), Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 50 &lt;= 70</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.

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: May be harmful if swallowed. Suspected of damaging fertility. Suspected of damaging the unborn child. Causes 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.

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 fire fighting: 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
Nitrogen oxides (NOx)

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: 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.

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. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents.
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Organic peroxides
Explosives
Gases

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>Florfenicol</td>
<td>73231-34-2</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Color: white
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
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Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

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.

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 reac-
tions : 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.
SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
May be harmful if swallowed.

Product:
Acute oral toxicity:
- Acute toxicity estimate: 5.000 mg/kg
  Method: Calculation method

Components:
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:
Florfenicol:
Species: Rabbit
Result: No skin irritation

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

Components:
Florfenicol:
Species: Rabbit
Result: Mild eye irritation
Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Florfenicol:
- Test Type: Maximization Test
- Species: Guinea pig
- Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:

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
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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:

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 fetal development:
Test Type: Embryo-fetal development
Species: Rat
General Toxicity Maternal: NOAEL: 4 mg/kg body weight
Embryo-fetal 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-fetal development
Species: Mouse
Application Route: oral (gavage)
General Toxicity Maternal: NOAEL: 120 mg/kg body weight
Embryo-fetal 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
Causes damage to organs (Liver, Brain, Testis, Spinal cord, Blood, gallbladder) through prolonged or repeated exposure.

Components:

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

**Components:**

**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.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:**

**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

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
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)
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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.

Domestic regulation

ANTT
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Florfenicol)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable
Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

SECTION 16. OTHER INFORMATION

Further information
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.

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