Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Florfenicol (45\%) Injection Formulation

## Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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 |
| :--- | :--- |
| Restrictions on use | $:$ Not applicable |

## SECTION 2. HAZARDS IDENTIFICATION

## GHS Classification

Acute toxicity (Oral) : Category 5
Skin corrosion/irritation : Category 2
Serious eye damage/eye : Category 2A irritation

Reproductive toxicity : Category 1B
Specific target organ toxicity

- single exposure

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

- repeated exposure


## GHS label elements

Hazard pictograms


| Signal Word | $:$ Danger |
| :--- | :--- |
| Hazard Statements | H303 May be harmful if swallowed. |
|  | H315 Causes skin irritation. |
|  | H319 Causes serious eye irritation. |
|  | H335 May cause respiratory irritation. |
|  | H360Df May damage the unborn child. Suspected of damaging |
|  | fertility. |
|  | H372 Causes damage to organs (Liver, Brain, Testis, Spinal |
|  | cord, Blood, gallbladder) through prolonged or repeated expo- |
|  | sure. |

Public

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

Precautionary Statements


#### Abstract

Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe mist or vapors. P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.


## Response:

P302 + P352 IF ON SKIN: Wash with plenty of water. P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312 Call a POISON CENTER or doctor/ physician if you feel unwell.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

## Storage:

P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

## Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (\% w/w) |
| :--- | :--- | :---: |
| Florfenicol | $73231-34-2$ | $>=30-<50$ |
| N-Methyl-2-pyrrolidone | $872-50-4$ | $>=30-<50$ |

## 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.

Public

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |


| If inhaled | $:$If inhaled, remove to fresh air. <br> Get medical attention. |
| :--- | :--- | :--- |
| In case of skin contact | $:$In case of contact, immediately flush skin with plenty of water <br> for at least 15 minutes while removing contaminated clothing <br> and shoes. |
| Get medical attention. |  |
| Wash clothing before reuse. |  |
| Thoroughly clean shoes before reuse. |  |

## SECTION 5. FIRE-FIGHTING MEASURES

| Suitable extinguishing media | $:$Water spray <br> Alcohol-resistant foam <br> Carbon dioxide (CO2) |  |
| :--- | :--- | :--- |
|  |  | Dry chemical |
| Unsuitable extinguishing <br> media | $:$ | Ene known. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Use personal protective equipment. tive equipment and emerFollow safe handling advice (see section 7 ) and personal

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

gency procedures
Environmental precautions

Methods and materials for containment and cleaning up
protective equipment recommendations (see section 8).
Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
: Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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 : See Engineering measures under EXPOSURE
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 mist or vapors.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.
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,

## SAFETY DATA SHEET

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

Conditions for safe storage : Keep in properly labeled containers.

Materials to avoid
industrial hygiene monitoring, medical surveillance and the use of administrative controls.

Store locked up.
Keep tightly closed.
Keep in a cool, well-ventilated place.
Store in accordance with the particular national regulations.

Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

| Components | CAS-No. | Value type <br> (Form of <br> exposure $)$ | Control parame- <br> ters / Permissible <br> concentration | Basis |
| :--- | :--- | :--- | :--- | :--- |
| Florfenicol | $73231-34-2$ | TWA | $100 \mu \mathrm{~g} / \mathrm{m3}$ (OEB <br> $2)$ | Internal |

Biological occupational exposure limits

| Components | CAS-No. | Control <br> parameters | Biological <br> specimen | Sam- <br> pling <br> time | Permissible <br> concentra- <br> tion | Basis |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| N-Methyl-2-pyrrolidone | $872-50-4$ | 5-Hydroxy- <br> N-methyl-2- <br> pyrrolidone | Urine | End of <br> shift | $100 \mathrm{mg} / \mathrm{l}$ | MX BEI |
|  |  | 5-Hydroxy- <br> N-methyl-2- <br> pyrrolidone | Urine | End of <br> shift (As <br> soon as <br> possible <br> after <br> exposure <br> ceases) | $100 \mathrm{mg} / \mathrm{l}$ | ACGIH <br> BEI |

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Laboratory operations do not require special containment.

## 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
Hand protection Material
: Combined particulates and organic vapor type
: Chemical-resistant gloves

Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |


| Eye protection | Wear safety glasses with side shields or goggles. <br> If the work environment or activity involves dusty conditions, <br>  <br> mists or aerosols, wear the appropriate goggles. <br>  <br> Wear a faceshield or other full face protection if there is a <br> potential for direct contact to the face with dusts, mists, or <br> aerosols. |
| :--- | :--- |
| Skin and body protection $\quad:$Work uniform or laboratory coat. |  |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution
Color : clear

Odor : No data available
Odor Threshold : No data available
$\mathrm{pH} \quad:$ No data available
Melting point/freezing point : No data available
Initial boiling point and boiling : No data available range

Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Upper explosion limit / Upper : No data available flammability limit

Lower explosion limit / Lower : No data available
flammability limit
Vapor pressure : No data available
Relative vapor density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n - : Not applicable
octanol/water
Autoignition temperature : No data available

Public

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : Not applicable

## SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.
tions
Conditions to avoid : None known.
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 $\quad:$ Acute toxicity estimate: $3,784 \mathrm{mg} / \mathrm{kg}$ 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): $>0.28 \mathrm{mg} / \mathrm{l}$
Exposure time: 4 h

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

Acute dermal toxicity $\quad:$ Remarks: No data available
Acute toxicity (other routes of : LD50 (Rat): 1,913-2,253 mg/kg
administration)
Application Route: Intraperitoneal
LD50 (Mouse): $100 \mathrm{mg} / \mathrm{kg}$
Application Route: Intravenous

N-Methyl-2-pyrrolidone:
Acute oral toxicity $\quad$ : LD50 (Rat): $4,150 \mathrm{mg} / \mathrm{kg}$
Acute inhalation toxicity : LC50 (Rat): $>5.1 \mathrm{mg} / \mathrm{l}$
Exposure time: 4 h
Test atmosphere: dust/mist Method: OECD Test Guideline 403

Acute dermal toxicity $\quad: \quad$ LD50 (Rat) $:>5,000 \mathrm{mg} / \mathrm{kg}$

## Skin corrosion/irritation

Causes skin irritation.

## Components:

Florfenicol:

| Species | $:$ Rabbit |
| :--- | :--- |
| Result | $:$ No skin irritation |

## N-Methyl-2-pyrrolidone:

Result : Skin irritation

## Serious eye damage/eye irritation

Causes serious eye irritation.

## Components:

Florfenicol:

| Species | $:$ Rabbit |
| :--- | :--- |
| Result | $:$ Mild eye irritation |

N-Methyl-2-pyrrolidone:

| Species | $:$ Rabbit |
| :--- | :--- | :--- |
| Result | $:$ Irritation to eyes, reversing within 21 days |

Respiratory or skin sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Public

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

## Components:

## Florfenicol:

| Test Type | $:$ Maximization Test |
| :--- | :---: | :--- |
| Species | $:$ Guinea pig |
| Result | $:$ negative |

## N-Methyl-2-pyrrolidone:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

## Germ cell mutagenicity

Not classified based on available information.

## Components:

## Florfenicol:

Genotoxicity in vitro

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

## N -Methyl-2-pyrrolidone:

Genotoxicity in vitro
: Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Test Type: DNA damage and repair, unscheduled DNA syn-

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |


|  | thesis in mammalian cells (in vitro) <br> Result: negative |
| :--- | :--- |
| Genotoxicity in vivo $\quad:$ | Test Type: Mammalian erythrocyte micronucleus test (in vivo <br> cytogenetic assay) <br> Species: Mouse |
|  | Application Route: Ingestion |
| Method: OECD Test Guideline 474 |  |
| Result: negative |  |$\quad$| Test Type: Mutagenicity (in vivo mammalian bone-marrow |
| :--- |
| cytogenetic test, chromosomal analysis) |
| Species: Hamster |
| Application Route: Ingestion |
| Method: OECD Test Guideline 475 |
| 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 |
|  | $:$ | Mouse |
| Species | $:$ | oral (gavage) |
| Application Route | $:$ | negative |
| Exposure time | $:$ | Testes, Blood |
| Result |  |  |

## N-Methyl-2-pyrrolidone:

| Species | $:$ Rat |  |
| :--- | :--- | :--- |
| Application Route | $:$ Ingestion |  |
| Exposure time | $:$ | 2 Years |
| Result | $:$ negative |  |
| Species | $:$ Rat |  |
| Application Route | $:$ inhalation (vapor) |  |
| Exposure time | $:$ 2 Years |  |
| Result | $:$ negative |  |

## Reproductive toxicity

May damage the unborn child. Suspected of damaging fertility.

## Components:

## Florfenicol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study Species: Rat

Public

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |


|  | Application Route: Oral <br> Fertility: LOAEL: $12 \mathrm{mg} / \mathrm{kg}$ body weight <br> Result: decreased pup survival, reduced lactation |
| :---: | :---: |
| Effects on fetal development | Test Type: Embryo-fetal development Species: Rat <br> General Toxicity Maternal: NOAEL: $4 \mathrm{mg} / \mathrm{kg}$ body weight <br> Embryo-fetal toxicity.: LOAEL: $40 \mathrm{mg} / \mathrm{kg}$ body weight <br> Result: No teratogenic effects., Fetotoxicity. <br> 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: $120 \mathrm{mg} / \mathrm{kg}$ body weight Embryo-fetal toxicity.: LOAEL: $40 \mathrm{mg} / \mathrm{kg}$ 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. |
| N-Methyl-2-pyrrolidone: |  |
| Effects on fertility | Test Type: Two-generation reproduction toxicity study Species: Rat <br> Application Route: Ingestion <br> Method: OECD Test Guideline 416 <br> Result: negative |
| Effects on fetal development | Test Type: Embryo-fetal development Species: Rat <br> Application Route: Ingestion <br> Method: OECD Test Guideline 414 <br> Result: positive |
|  | Test Type: Fertility/early embryonic development Species: Rat <br> Application Route: inhalation (vapor) <br> Result: positive |
|  | Test Type: Embryo-fetal development Species: Rabbit Application Route: Ingestion Result: positive |
| Reproductive toxicity - Assessment | Clear evidence of adverse effects on development, based on animal experiments. |

## STOT-single exposure

May cause respiratory irritation.

P Public

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

## Components:

N-Methyl-2-pyrrolidone:
Assessment : May cause respiratory irritation.

## STOT-repeated exposure

Causes 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:
Florfenicol:
Species : Dog
NOAEL : $3 \mathrm{mg} / \mathrm{kg}$
Exposure time : 13 Weeks
Target Organs : Liver, Testis, Brain, Spinal cord
Species : Mouse
NOAEL : $200 \mathrm{mg} / \mathrm{kg}$
Exposure time : 13 Weeks
Target Organs: Liver, Testis
Species : Rat
NOAEL : $30 \mathrm{mg} / \mathrm{kg}$
Exposure time : 13 Weeks
Target Organs : Liver, Testis

| Species | $:$ Dog |
| :--- | :--- |
| NOAEL | $: 3 \mathrm{mg} / \mathrm{kg}$ |
| LOAEL | $: 12 \mathrm{mg} / \mathrm{kg}$ |
| Exposure time | $: 52 \mathrm{Weeks}$ |
| Target Organs | $:$ Liver, gallbladder |
| Species | $: 1 \mathrm{mg} / \mathrm{kg}$ |
| NOAEL | $: 3 \mathrm{mg} / \mathrm{kg}$ |
| LOAEL | $: 52 \mathrm{Weeeks}$ |
| Exposure time | $:$ Testis |

N-Methyl-2-pyrrolidone:

| Species | $:$ Rat, male |
| :--- | :---: | :--- |
| NOAEL | $: 169 \mathrm{mg} / \mathrm{kg}$ |
| LOAEL | $: 433 \mathrm{mg} / \mathrm{kg}$ |
| Application Route | $:$ Ingestion |

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |


| Exposure time | 90 Days |
| :---: | :---: |
| Method | OECD Test Guideline 408 |
| Species | Rat |
| NOAEL | $0.5 \mathrm{mg} / \mathrm{l}$ |
| LOAEL | $1 \mathrm{mg} / \mathrm{l}$ |
| Application Route | inhalation (dust/mist/fume) |
| Exposure time | 96 Days |
| Method | OECD Test Guideline 413 |
| Species | Rabbit |
| NOAEL | 826 mg/kg |
| LOAEL | 1,653 mg/kg |
| Application Route | Skin contact |
| Exposure time | 20 Days |
| Aspiration toxicity |  |
| Not classified based on available information. |  |
| Experience with human exposure |  |
| Components: |  |
| N-Methyl-2-pyrrolidone: |  |
| Skin contact | Symptoms: Skin irritation |

## 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)): > $780 \mathrm{mg} / \mathrm{l}$
Exposure time: 96 h
Method: FDA 4.11
Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > $330 \mathrm{mg} / \mathrm{l}$ aquatic invertebrates

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 <br> Exposure time: 14 d <br> Method: FDA 4.01 |

Public

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

IC50 (Skeletonema costatum (marine diatom)): $0.0336 \mathrm{mg} / \mathrm{l}$
Exposure time: 72 h
Method: ISO 10253
NOEC (Skeletonema costatum (marine diatom)): $0.00423 \mathrm{mg} / \mathrm{l}$
Exposure time: 72 h
Method: ISO 10253
EC50 (Lemna gibba (gibbous duckweed)): $0.76 \mathrm{mg} / \mathrm{l}$
Exposure time: 7 d
Method: OECD Test Guideline 221
NOEC (Lemna gibba (gibbous duckweed)): $0.39 \mathrm{mg} / \mathrm{l}$
Exposure time: 7 d
Method: OECD Test Guideline 221
EC50 (Navicula pelliculosa (Freshwater diatom)): $61 \mathrm{mg} / \mathrm{l}$
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Navicula pelliculosa (Freshwater diatom)): $19 \mathrm{mg} / \mathrm{l}$
Exposure time: 72 h
Method: OECD Test Guideline 201
EC50 (Anabaena flos-aquae): $0.066 \mathrm{mg} / \mathrm{l}$
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Anabaena flos-aquae): $0.051 \mathrm{mg} / \mathrm{l}$
Exposure time: 72 h
Method: OECD Test Guideline 201
Toxicity to fish (Chronic tox- : NOEC (Pimephales promelas (fathead minnow)): $5.5 \mathrm{mg} / \mathrm{l}$ icity)

Exposure time: 32 d
Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC (Daphnia magna (Water flea)): $1.5 \mathrm{mg} / \mathrm{l}$
Exposure time: 21 d
Method: OECD Test Guideline 211

## N-Methyl-2-pyrrolidone:

| Toxicity to fish | LC50 (Oncorhynchus mykiss (rainbow trout)): > $500 \mathrm{mg} / \mathrm{l}$ Exposure time: 96 h |
| :---: | :---: |
| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): > 1,000 mg/l Exposure time: 24 h Method: DIN 38412 |
| Toxicity to algae/aquatic plants | ErC50 (Desmodesmus subspicatus (green algae)): $600.5 \mathrm{mg} / \mathrm{l}$ Exposure time: 72 h |
|  | EC10 (Desmodesmus subspicatus (green algae)): $92.6 \mathrm{mg} / \mathrm{l}$ Exposure time: 72 h |

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): $12.5 \mathrm{mg} / \mathrm{l}$ aquatic invertebrates (Chronic toxicity)

Toxicity to microorganisms

Exposure time: 21 d
Method: OECD Test Guideline 211
EC50: > $600 \mathrm{mg} / \mathrm{l}$
Exposure time: 30 min
Method: ISO 8192

## Persistence and degradability

## Components:

N-Methyl-2-pyrrolidone:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 73 \%
Exposure time: 28 d
Method: OECD Test Guideline 301C

## Bioaccumulative potential

## Components:

## Florfenicol:

Partition coefficient: n- : log Pow: 0.373 octanol/water
$\mathrm{pH}: 7$

## N-Methyl-2-pyrrolidone:

Partition coefficient: n- : log Pow: -0.46
octanol/water

Mobility in soil
Components:

## Florfenicol:

Distribution among environmental compartments

Other adverse effects
No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

## Disposal methods

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

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

## SECTION 14. TRANSPORT INFORMATION

```
International Regulations
UNRTDG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
    N.O.S.
    (Florfenicol)
Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes
IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
    (Florfenicol)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo : 964
aircraft)
Packing instruction (passen- : }96
ger aircraft)
Environmentally hazardous : yes
IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
    N.O.S.
    (Florfenicol)
Class
: 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant
```

: UN 3082
: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Florfenicol)
9
III
9
F-A, S-F
yes

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

| UN number | $:$ | UN 3082 |
| :--- | :--- | :--- |
| Proper shipping name | $:$ | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, |
|  |  | N.O.S. |
|  |  | (Florfenicol) |
| Class | $:$ | 9 |
| Packing group | $:$ | III |
| Labels | $:$ | 9 |

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

Public

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.

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

| AICS | $:$ not determined |
| :--- | :--- |
| DSL | $:$ not determined |
| IECSC | $:$ not determined |

## SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

## Full text of other abbreviations

ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
MX BEI : Official Mexican Norm NOM-047-SSA1-2011, Environmental Health - Biological exposure indices for workers occupationally exposed to chemical agents

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 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 (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; NZloC - 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

## Florfenicol (45\%) Injection Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| :--- | :--- | :--- | :--- |
| 2.1 | 30.09 .2023 | $10843841-00003$ | Date of first issue: 31.08.2022 |

1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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 and European Chemicals Agency, http://echa.europa.eu/

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

