

| Version | Revision Date: | SDS Number:   | Date of last issue: 06.04.2024  |
|---------|----------------|---------------|---------------------------------|
| 3.4     | 28.09.2024     | 9374229-00008 | Date of first issue: 27.08.2021 |

#### **SECTION 1:** Identification of the substance/mixture and of the company/undertaking

| 1.1 | <b>Product identifier</b><br>Trade name              | :    | Florfenicol (2%) Liquid Formulation                                   |  |  |  |
|-----|--|------|---|--|--|--|
| 1.2 | Relevant identified uses of th                       | ne s | ubstance or mixture and uses advised against                          |  |  |  |
|     | Use of the Sub-<br>stance/Mixture                    |      | Veterinary product  |  |  |  |
|     | Recommended restrictions on use                      | :    | Not applicable  |  |  |  |
| 1.3 | 1.3 Details of the supplier of the safety data sheet |      |   |  |  |  |
|     | Company  | :    | MSD<br>Walton Manor, Walton<br>MK7 7AJ Milton Keynes - United Kingdom |  |  |  |
|     | Telephone  | :    | +1-908-740-4000   |  |  |  |
|     | E-mail address of person responsible for the SDS     | :    | EHSDATASTEWARD@msd.com  |  |  |  |

#### **1.4 Emergency telephone number**

+1-908-423-6000

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

# Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Specific target organ toxicity - repeated exposure, Category 2 Long-term (chronic) aquatic hazard, Category 2 H373: May cause damage to organs through prolonged or repeated exposure. H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms



UK REACH Regulations SI 2019/758



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|----------------|---------------------------|---|---------------------------|--|
| Signal         | word                      | : | Warning                   |  |
| Hazaro         | d statements              | : | H373                      | May cause damage to organs through prolonged or repeated exposure.     |
|                |                           |   | H411                      | Toxic to aquatic life with long lasting effects.                       |
| Precau         | utionary statements       | : | Prevention                | :  |
|                |                           |   | P273                      | Avoid release to the environment.                                      |
|                |                           |   | Response:                 |  |
|                |                           |   | P314<br>P391              | Get medical advice/ attention if you feel unwell.<br>Collect spillage. |

Hazardous components which must be listed on the label: Florfenicol

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form combustible dust concentrations in air during processing, handling or other means.

### **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

#### Components

| Chemical name                        | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification  | Concentration<br>(% w/w) |
|--------------------------------------|---|---|--------------------------|
| Florfenicol                          | 73231-34-2  | Repr. 2; H361fd<br>STOT RE 1; H372<br>(Liver, Brain, Tes-<br>tis, Spinal cord,<br>Blood, gallbladder)<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br>M-Factor (Acute<br>aquatic toxicity): 10<br>M-Factor (Chronic<br>aquatic toxicity): 10 | 2                        |
| Substances with a workplace exposure | e limit :   |   |                          |
| Propylene glycol                     | 57-55-6<br>200-338-0                                  |   | 98                       |



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For explanation of abbreviations see section 16.

## **SECTION 4: First aid measures**

| 4.1 Description of first aid measu | ures  |
|------------------------------------|---|
| General advice                     | <ul> <li>In the case of accident or if you feel unwell, seek medical advice immediately.</li> <li>When symptoms persist or in all cases of doubt seek medical advice.</li> </ul>  |
| Protection of first-aiders         | : First Aid responders should pay attention to self-protection,<br>and use the recommended personal protective equipment<br>when the potential for exposure exists (see section 8).   |
| If inhaled                         | : If inhaled, remove to fresh air.<br>Get medical attention.  |
| In case of skin contact            | <ul> <li>In case of contact, immediately flush skin with soap and plenty<br/>of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul> |
| In case of eye contact             | : If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.  |
| If swallowed                       | : If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |
| 4.2 Most important symptoms ar     | nd effects, both acute and delayed  |
| Risks                              | : May cause damage to organs through prolonged or repeated exposure.  |
|                                    | Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation.   |
| 4.3 Indication of any immediate r  | medical attention and special treatment needed  |
| Treatment                          | : Treat symptomatically and supportively.   |
| SECTION 5: Firefighting meas       | sures   |
| 5.1 Extinguishing media            | Water eprov   |

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



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|------------------------------------|---|-----|-----------------------------------|--|
|                                    |   |     | Dry chemical                      |  |
| Unsuitable extinguishing media     |   | :   | None known.                       |  |
| 5.2 Specia                         | I hazards arising from                        | the | e substance or mi                 | xture  |
| •                                  | Specific hazards during fire-<br>fighting     |     | Exposure to com                   | pustion products may be a hazard to health.  |
| Hazardous combustion prod-<br>ucts |   | :   | Carbon oxides                     |  |
| 5.3 Advice                         | for firefighters                              |     |                                   |  |
| •                                  | Special protective equipment for firefighters |     |                                   | e, wear self-contained breathing apparatus.<br>tective equipment.  |
| Specif<br>ods                      | Specific extinguishing meth-<br>ods           |     | cumstances and<br>Use water spray | g measures that are appropriate to local cir-<br>the surrounding environment.<br>to cool unopened containers.<br>ged containers from fire area if it is safe to do |

## **SECTION 6:** Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

| Personal precautions | • | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal pro-<br>tective equipment recommendations (see section 8). |
|----------------------|---|---|
|                      |   |   |

#### 6.2 Environmental precautions

| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil<br>barriers).<br>Retain and dispose of contaminated wash water. |
|---------------------------|---|--|
|                           |   | If spillage enters rivers or watercourses, inform the Environ-<br>ment Agency (emergency telephone number 0800 807060).  |

### 6.3 Methods and material for containment and cleaning up

| Methods for cleaning up | <ul> <li>Soak up with inert absorbent material.<br/>Avoid dispersal of dust in the air (i.e., clearing dust surfaces<br/>with compressed air).</li> <li>Dust deposits should not be allowed to accumulate on surfac-<br/>es, as these may form an explosive mixture if they are re-<br/>leased into the atmosphere in sufficient concentration.</li> <li>For large spills, provide dyking or other appropriate contain-<br/>ment to keep material from spreading. If dyked material can<br/>be pumped, store recovered material in appropriate container.</li> </ul> |
|-------------------------|--|
|-------------------------|--|



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|         |                           | bent.<br>Local or nationa<br>posal of this ma<br>employed in the<br>mine which regu<br>Sections 13 and | ning materials from spill with suitable absor-<br>al regulations may apply to releases and dis-<br>aterial, as well as those materials and items<br>a cleanup of releases. You will need to deter-<br>ulations are applicable.<br>d 15 of this SDS provide information regarding<br>national requirements. |

## 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

|                                 | 5   |
|---------------------------------|---|
| 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 mist or vapours.   |
|                                 | 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 as-                        |
|                                 | sessment  |
|                                 | 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 contami-                         |
|                                 | nated 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.   |
| 7.2 Conditions for safe storage | e, including any incompatibilities  |
|                                 |   |

| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store in accordance with the particular national regulations.                |
|---|---|--|
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures |



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|----------------|---------------------------------|---|---|
|                |                                 | Organic peroxide<br>Explosives<br>Gases | S   |
| -              | <b>c end use(s)</b><br>c use(s) | : No data available                     | ı   |

## **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

#### **Occupational Exposure Limits**

| Components       | CAS-No.    | Value type (Form of exposure)              | Control parameters   | Basis    |
|------------------|------------|--|----------------------|----------|
| Propylene glycol | 57-55-6    | TWA (Total va-<br>pour and parti-<br>cles) | 150 ppm<br>474 mg/m3 | GB EH40  |
|                  |            | TWA (particles)                            | 10 mg/m3             | GB EH40  |
| Florfenicol      | 73231-34-2 | TWA  | 100 µg/m3 (OEB 2)    | Internal |

#### Derived No Effect Level (DNEL)

| Substance name   | End Use   | Exposure routes | Potential health ef-<br>fects | Value     |
|------------------|-----------|-----------------|-------------------------------|-----------|
| Propylene glycol | Workers   | Inhalation      | Long-term local ef-<br>fects  | 10 mg/m3  |
|                  | Workers   | Inhalation      | Long-term systemic<br>effects | 168 mg/m3 |
|                  | Consumers | Inhalation      | Long-term local ef-<br>fects  | 10 mg/m3  |
|                  | Consumers | Inhalation      | Long-term systemic<br>effects | 50 mg/m3  |

#### Predicted No Effect Concentration (PNEC)

| Substance name   | Environmental Compartment | Value          |
|------------------|---------------------------|----------------|
| Propylene glycol | Fresh water               | 260 mg/l       |
|                  | Freshwater - intermittent | 183 mg/l       |
|                  | Marine water              | 26 mg/l        |
|                  | Sewage treatment plant    | 20000 mg/l     |
|                  | Fresh water sediment      | 572 mg/kg dry  |
|                  |                           | weight (d.w.)  |
|                  | Marine sediment           | 57.2 mg/kg dry |
|                  |                           | weight (d.w.)  |
|                  | Soil                      | 50 mg/kg dry   |
|                  |                           | weight (d.w.)  |

#### 8.2 Exposure controls

#### Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).



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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

| Eye/face protection                                | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions,<br>mists or aerosols, wear the appropriate goggles.<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. |
|--|---|---|
| Hand protection<br>Material                        | : | Chemical-resistant gloves   |
| Skin and body protection<br>Respiratory protection | : | Work uniform or laboratory coat.<br>If adequate local exhaust ventilation is not available or expo-<br>sure assessment demonstrates exposures outside the rec-<br>ommended guidelines, use respiratory protection.<br>Equipment should conform to BS EN 143   |
| Filter type  | : | Particulates type (P)   |

## **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

| Appearance<br>Colour<br>Odour<br>Odour Threshold    | : | liquid<br>Colorless to pale yellow<br>odourless, characteristic, very faint<br>No data available |
|---|---|--|
| рН  | : | No data available  |
| Melting point/freezing point                        | : | No data available  |
| Initial boiling point and boiling                   | : | No data available  |
| range<br>Flash point                                | : | No data available  |
| Evaporation rate                                    | : | No data available  |
| Flammability (solid, gas)                           | : | May form combustible dust concentrations in air during pro-<br>cessing, handling or other means. |
| Upper explosion limit / Upper<br>flammability limit | : | No data available  |
| Lower explosion limit / Lower<br>flammability limit | : | No data available  |
| Vapour pressure                                     | : | No data available  |
| Relative vapour density                             | : | No data available  |
| Relative density                                    |   | No data available  |
| I CHAINE DENSILY                                    | • | NU Uala avaliable  |



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|---------------------------|---|---|---|
| Der                       | sity  | : No data avail   | able  |
| ا<br>Pari<br>octa<br>Auto | ubility(ies)<br>Water solubility<br>ition coefficient: n-<br>inol/water<br>p-ignition temperature | <ul> <li>No data avail</li> <li>Not applicabl</li> <li>No data avail</li> </ul> | able  |
| Viso                      | omposition temperature<br>cosity<br>/iscosity, kinematic  | : No data avail<br>: No data avail  |   |
|                           | losive properties<br>dizing properties  | : Not explosive   | e or mixture is not classified as oxidizing.                      |
| Flar                      | r information<br>nmability (liquids)<br>ecular weight   | : No data avail<br>: No data avail  |   |
|                           | icle size   | : Not applicabl   |   |

## **SECTION 10: Stability and reactivity**

| 10.1 Reactivity   |   |
|---|---|
| Not classified as a reactivity hazar                              | d.  |
| <b>10.2 Chemical stability</b><br>Stable under normal conditions. |   |
| 10.3 Possibility of hazardous reactio                             | ns  |
| Hazardous reactions :   | May form combustible dust concentrations in air during pro-<br>cessing, handling or other means.<br>Can react with strong oxidizing agents. |
| 10.4 Conditions to avoid  |   |
| Conditions to avoid :   | Heat, flames and sparks.<br>Avoid dust formation.   |
| 10.5 Incompatible materials                                       |   |
| Materials to avoid  | Oxidizing agents  |
| 10.6 Hazardous decomposition prod                                 | ucts  |

No hazardous decomposition products are known.



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### **SECTION 11: Toxicological information**

## 11.1 Information on toxicological effects

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

#### Acute toxicity

Not classified based on available information.

#### 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<br>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<br>Application Route: Intraperitoneal                                |
|   |   | LD50 (Mouse): 100 mg/kg<br>Application Route: Intravenous  |
| Propylene glycol:                               |   |  |
| Acute oral toxicity                             | : | LD50 (Rat): 22,000 mg/kg   |
| Acute inhalation toxicity                       | : | LC50 (Rat): > 44.9 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist                          |
| Acute dermal toxicity                           | : | LD50 (Rabbit): > 2,000 mg/kg<br>Assessment: The substance or mixture has no acute dermal<br>toxicity |
|   |   |  |

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

#### Florfenicol:

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

## SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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|---------------|--|---|------|--|--|--|--|--|
| S<br>N<br>F   | Species<br>Method<br>Result  |   | :    | Rabbit<br>OECD Test Guide<br>No skin irritation            | eline 404  |  |  |  |
|               |  | s eye damage/eye irr<br>ssified based on availa |      |  |  |  |  |  |
| <u>c</u>      | Compo  | nents:  |      |  |  |  |  |  |
| S             | Florfen<br>Species<br>Result   |   | :    | Rabbit<br>Mild eye irritation                              |  |  |  |  |
| S             | Propyle<br>Species<br>Method<br>Result   |   | :    | Rabbit<br>OECD Test Guide<br>No eye irritation             | eline 405  |  |  |  |
| F             | Respira  | atory or skin sensitis                          | atic | n  |  |  |  |  |
| -             |  | nsitisation<br>sified based on availa           | able | information.   |  |  |  |  |
|               | <b>Respiratory sensitisation</b><br>Not classified based on available information. |   |      |  |  |  |  |  |
| <u>c</u>      | Components:  |   |      |  |  |  |  |  |
| T             | F <b>lorfen</b><br>Fest Ty<br>Species<br>Result                                    | ре  | :    | Maximisation Tes<br>Guinea pig<br>negative                 | t  |  |  |  |
| T<br>E<br>S   | Test Ty  | re routes                                       | :    | Maximisation Tes<br>Skin contact<br>Guinea pig<br>negative | t  |  |  |  |
|               |  | ell mutagenicity<br>ssified based on availa     | able | information.   |  |  |  |  |
| <u>c</u>      | Compo  | nents:  |      |  |  |  |  |  |
| -             | Florfen<br>Genoto:   | icol:<br>xicity in vitro                        | :    | Result: negative   | ial reverse mutation assay (AMES)<br>lamage and repair, unscheduled DNA syn-<br>ian cells (in vitro) |  |  |  |



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|----------------|--|------|---|---|
|                |  |      | Test system: rat h<br>Result: negative  | nepatocytes   |
|                |  |      |   | o mammalian cell gene mutation test<br>use lymphoma cells                           |
|                |  |      |   | nosome aberration test in vitro<br>nese hamster ovary cells                         |
| Gen            | otoxicity in vivo                                | :    | Test Type: Micror<br>Species: Mouse<br>Cell type: Bone m<br>Application Route<br>Result: negative | narrow  |
| Pror           | oylene glycol:                                   |      |   |   |
| -              | otoxicity in vitro                               | :    | Test Type: Bacte<br>Result: negative  | rial reverse mutation assay (AMES)  |
|                |  |      |   | nosome aberration test in vitro<br>est Guideline 473                                |
| Gen            | otoxicity in vivo                                | :    | cytogenetic assay<br>Species: Mouse   | nalian erythrocyte micronucleus test (in vivo<br>/)<br>e: Intraperitoneal injection |
| Corr           | sinogonioit <i>u</i>                             |      |   |   |
|                | <b>cinogenicity</b><br>classified based on avail | ahle | information   |   |
|                | ponents:   | abic | information.  |   |
|                |  |      |   |   |
|                | fenicol:   |      | Det   |   |
| Spe            | lication Route                                   | :    | Rat<br>oral (gavage)  |   |
|                | osure time                                       | ÷    | 2 Years   |   |
| Res            | ult  | :    | negative  |   |
| Targ           | jet Organs                                       | :    | Liver, Testes   |   |
| Spe            | cies   | :    | Mouse   |   |
|                | lication Route                                   | :    | oral (gavage)   |   |
|                | osure time                                       | :    | 2 Years   |   |
| Res<br>Targ    | uit<br>jet Organs                                | :    | negative<br>Testes, Blood   |   |
|                |  |      |   |   |
| -              | oylene glycol:                                   | _    | Det   |   |
| Spe            | CIES   | :    | Rat   |   |
|                |  |      | 44/04   |   |



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|-------------|------------------|--|------|---|---|
|             |                  | ition Route<br>are time                            | :    | Ingestion<br>2 Years<br>negative  |   |
|             | -                | <b>Juctive toxicity</b><br>ssified based on availa | able | information.  |   |
|             | Compo            | onents:  |      |   |   |
|             | Florfer          | nicol:   |      |   |   |
|             | Effects          | on fertility                                       | :    | Species: Rat<br>Application Route<br>Fertility: LOAEL: 1                      | eneration reproduction toxicity study<br>: Oral<br>I2 mg/kg body weight<br>I pup survival, reduced lactation  |
|             | Effects<br>ment  | on foetal develop-                                 | :    | Species: Rat<br>General Toxicity M<br>Embryo-foetal tox<br>Result: No teratog | o-foetal development<br>Maternal: NOAEL: 4 mg/kg body weight<br>icity: LOAEL: 40 mg/kg body weight<br>genic effects, Fetotoxicity<br>ects were seen only at maternally toxic dos- |
|             |                  |  |      | Species: Mouse<br>Application Route<br>General Toxicity M                     | Maternal: NOAEL: 120 mg/kg body weight<br>icity: LOAEL: 40 mg/kg body weight  |
|             | Reprod<br>sessme | luctive toxicity - As-<br>ent                      | :    | fertility, based on   | f adverse effects on sexual function and<br>animal experiments., Some evidence of<br>n development, based on animal experi-   |
|             | Propyl           | ene glycol:  |      |   |   |
|             | •••              | on fertility                                       | :    | Test Type: Two-g<br>Species: Mouse<br>Application Route<br>Result: negative   | eneration reproduction toxicity study<br>: Ingestion  |
|             | Effects<br>ment  | on foetal develop-                                 | :    | Test Type: Embry<br>Species: Mouse<br>Application Route<br>Result: negative   | o-foetal development<br>: Ingestion   |

## STOT - single exposure

Not classified based on available information.

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# Florfenicol (2%) Liquid Formulation

| /ersion<br>8.4    | Revision Date:<br>28.09.2024 | SDS Number:<br>9374229-00008 | Date of last issue: 06.04.2024<br>Date of first issue: 27.08.2021                  |
|-------------------|------------------------------|------------------------------|--|
| STOT              | - repeated exposu            | e                            |  |
|                   | • •                          | ans through prolonged o      | or repeated exposure.  |
| Comr              | oonents:                     |                              |  |
|                   |                              |                              |  |
|                   | enicol:                      |                              |  |
|                   | t Organs<br>ssment           |                              | stis, Spinal cord, Blood, gallbladder<br>e to organs through prolonged or repeated |
| Repe              | ated dose toxicity           |                              |  |
| <u>Comp</u>       | oonents:                     |                              |  |
| Florfe            | enicol:                      |                              |  |
| Specie            | es                           | : Dog                        |  |
| NOAE              |                              | : 3 mg/kg                    |  |
|                   | sure time                    | : 13 Weeks                   |  |
| large             | t Organs                     | : Liver, Testis, Bi          | ain, Spinal cord   |
| Speci             | es                           | : Mouse                      |  |
| NOAE              | EL                           | : 200 mg/kg                  |  |
|                   | sure time                    | : 13 Weeks                   |  |
| Targe             | t Organs                     | : Liver, Testis              |  |
| Specie            | es                           | : Rat                        |  |
| NOAE              | EL                           | : 30 mg/kg                   |  |
|                   | sure time                    | : 13 Weeks                   |  |
| Targe             | t Organs                     | : Liver, Testis              |  |
| Specie            | es                           | : Dog                        |  |
| NOAE              |                              | : 3 mg/kg                    |  |
| LOAE              |                              | : 12 mg/kg                   |  |
|                   | sure time                    | : 52 Weeks                   |  |
| Targe             | t Organs                     | : Liver, gallbladd           | er   |
| Specie            | es                           | : Rat                        |  |
| NOAE              |                              | : 1 mg/kg                    |  |
| LOAE              |                              | : 3 mg/kg                    |  |
|                   | sure time                    | : 52 Weeks                   |  |
| Targe             | t Organs                     | : Testis                     |  |
| Prop <sub>3</sub> | /lene glycol:                |                              |  |
| Specie            | es                           | : Rat, male                  |  |
| NOAE              |                              | : >= 1,700 mg/kg             | I  |
|                   | ation Route                  | : Ingestion                  |  |
|                   | sure time                    | : 2 yr                       |  |

## Aspiration toxicity

Not classified based on available information.



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### **SECTION 12: Ecological information**

| 12.1 Toxicity                                       |   |  |
|---|---|--|
| Components:   |   |  |
| Florfenicol:  |   |  |
| Toxicity to fish                                    | : | LC50 (Lepomis macrochirus (Bluegill sunfish)): > 830 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11               |
|   |   | LC50 (Oncorhynchus mykiss (rainbow trout)): > 780 mg/l<br>Exposure time: 96 h<br>Method: FDA 4.11                  |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 330 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202            |
| Toxicity to algae/aquatic plants                    | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 2.9<br>mg/l<br>Exposure time: 14 d<br>Method: FDA 4.01     |
|   |   | NOEC (Pseudokirchneriella subcapitata (green algae)): 2.9<br>mg/l<br>Exposure time: 14 d<br>Method: FDA 4.01       |
|   |   | IC50 (Skeletonema costatum (marine diatom)): 0.0336 mg/l<br>Exposure time: 72 h<br>Method: ISO 10253               |
|   |   | NOEC (Skeletonema costatum (marine diatom)): 0.00423 mg/l<br>Exposure time: 72 h<br>Method: ISO 10253              |
|   |   | EC50 (Lemna gibba (gibbous duckweed)): 0.76 mg/l<br>Exposure time: 7 d<br>Method: OECD Test Guideline 221          |
|   |   | NOEC (Lemna gibba (gibbous duckweed)): 0.39 mg/l<br>Exposure time: 7 d<br>Method: OECD Test Guideline 221          |
|   |   | EC50 (Navicula pelliculosa (Freshwater diatom)): 61 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
|   |   | NOEC (Navicula pelliculosa (Freshwater diatom)): 19 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |



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|----------------|---|-----|--|---|
|                |   |     | Exposure time: 7                                       | i flos-aquae): 0.066 mg/l<br>2 h<br><sup>-</sup> est Guideline 201      |
|                |   |     | Exposure time: 7                                       | a flos-aquae): 0.051 mg/l<br>2 h<br><sup>-</sup> est Guideline 201      |
| M-<br>icit     | Factor (Acute aquatic tox-<br>y)  | :   | 10   |   |
| To<br>icit     | xicity to fish (Chronic tox-<br>y)                                      | :   |  | 2 d<br>ales promelas (fathead minnow)<br>est Guideline 210              |
| aq             | xicity to daphnia and other<br>uatic invertebrates (Chron-<br>toxicity) |     |  | 1 d<br>a magna (Water flea)<br>est Guideline 211                        |
|                | Factor (Chronic aquatic<br>ricity)                                      | :   | 10   |   |
| Pr             | opylene glycol:   |     |  |   |
|                | xicity to fish  | :   | LC50 (Oncorhyno<br>Exposure time: 9                    | chus mykiss (rainbow trout)): 40,613 mg/l<br>6 h                        |
|                | xicity to daphnia and other uatic invertebrates                         | :   | EC50 (Ceriodaph<br>Exposure time: 4                    | nnia dubia (water flea)): 18,340 mg/l<br>8 h                            |
|                | xicity to algae/aquatic<br>ints   | :   | Exposure time: 7                                       | ema costatum (marine diatom)): 19,300 mg/l<br>2 h<br>Test Guideline 201 |
| То             | xicity to microorganisms  | :   | NOEC (Pseudom<br>Exposure time: 1                      | nonas putida): > 20,000 mg/l<br>8 h                                     |
| aq             | xicity to daphnia and other<br>uatic invertebrates (Chron-<br>toxicity) |     | NOEC: 13,020 m<br>Exposure time: 7<br>Species: Cerioda |   |
| 12.2 Pe        | ersistence and degradabil   | ity |  |   |
| <u>Cc</u>      | mponents:   |     |  |   |
|                | opylene glycol:   |     | Result: Readily b                                      | iodegradable  |

| Biodegradability | : | Result: Readily biodegradable.   |
|------------------|---|----------------------------------|
|                  |   | Biodegradation: 98.3 %           |
|                  |   | Exposure time: 28 d              |
|                  |   | Method: OECD Test Guideline 301F |

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According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



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|--------------------------------|---|------|---|--|
| 12.3 Bi                        | oaccumulative potential                                       |      |   |  |
| <u>Cc</u>                      | omponents:  |      |   |  |
| Pa                             | orfenicol:<br>artition coefficient: n-<br>tanol/water         |      | log Pow: 0.373<br>pH: 7                                     |  |
| Pa                             | opylene glycol:<br>artition coefficient: n-<br>tanol/water    |      | log Pow: -1.07<br>Method: Regulatio                         | on (EC) No. 440/2008, Annex, A.8   |
| 12.4 M                         | obility in soil   |      |   |  |
| <u>Co</u>                      | omponents:  |      |   |  |
| Di                             | orfenicol:<br>stribution among environ-<br>ental compartments |      | Koc: 52<br>Method: FDA 3.08                                 | 3  |
| 12.5 Results of PBT and vPvB a |   |      | sment   |  |
| Pr                             | oduct:  |      |   |  |
| As                             | sessment  |      | to be either persis   | ixture contains no components considered<br>stent, bioaccumulative and toxic (PBT), or<br>d very bioaccumulative (vPvB) at levels of   |
| 12.6 Ot                        | ther adverse effects  |      |   |  |
|                                | oduct:<br>ndocrine disrupting poten-<br>I                     |      | ered to have endo   | ixture does not contain components consid-<br>ocrine disrupting properties for environment<br>REACH Article 57(f).   |
| SECTI                          | ON 13: Disposal consi   | dera | tions   |  |
| 13.1 W                         | aste treatment methods  |      |   |  |
| Pr                             | oduct   |      | According to the I<br>are not product sp<br>Waste codes sho | ordance with local regulations.<br>European Waste Catalogue, Waste Codes<br>pecific, but application specific.<br>uld be assigned by the user, preferably in<br>e waste disposal authorities |

discussion with the waste disposal authorities.
 Do not dispose of waste into sewer.
 Empty containers should be taken to an approved waste handling site for recycling or disposal.
 If not otherwise specified: Dispose of as unused product.



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|---|--|
|---|--|

### **SECTION 14: Transport information**

| 14.1 UN number   |   |   |
|--|---|---|
| ADN  | : | UN 3082   |
| ADR  | : | UN 3082   |
| RID  | : | UN 3082   |
| IMDG   | : | UN 3082   |
| ΙΑΤΑ   | : | UN 3082   |
| 14.2 UN proper shipping name   |   |   |
| ADN  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(Florfenicol) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(Florfenicol) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(Florfenicol) |
| IMDG   | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(Florfenicol) |
| ΙΑΤΑ   | : | Environmentally hazardous substance, liquid, n.o.s.<br>(Florfenicol)    |
| 14.3 Transport hazard class(es)  |   |   |
|  |   | Class Subsidiary risks  |
| ADN  | : | 9   |
| ADR  | : | 9   |
| RID  | : | 9   |
| IMDG   | : | 9   |
| ΙΑΤΑ   | : | 9   |
| 14.4 Packing group   |   |   |
| ADN<br>Packing group<br>Classification Code<br>Hazard Identification Number<br>Labels<br>ADR<br>Packing group<br>Classification Code<br>Hazard Identification Number | : | III<br>M6<br>90<br>9<br>9   |

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|-------------|-----------------------------------|--|-------|-------------------------------------|---|
|             | Labels<br>Tunnel                  | restriction code                                   | :     | 9<br>(-)                            |   |
|             | Classif                           | g group<br>ication Code<br>I Identification Number | : : : | III<br>M6<br>90<br>9                |   |
|             | IMDG<br>Packin<br>Labels<br>EmS C |  | ::    | III<br>9<br>F-A, S-F                |   |
|             | Packin<br>aircraft<br>Packin      | g instruction (LQ)                                 | :     | 964<br>Y964                         |   |
|             | Labels                            | g group  | :     | III<br>Miscellaneous                |   |
|             | Packin<br>ger airo<br>Packin      | g instruction (LQ)<br>g group                      | :     | 964<br>Y964<br>III<br>Miscellaneous |   |
| 14.5        | 5 Enviro                          | onmental hazards                                   |       |                                     |   |
|             | <b>ADN</b><br>Enviroi             | nmentally hazardous                                | :     | yes                                 |   |
|             | <b>ADR</b><br>Enviror             | nmentally hazardous                                | :     | yes                                 |   |
|             | <b>RID</b><br>Enviroi             | nmentally hazardous                                | :     | yes                                 |   |
|             | <b>IMDG</b><br>Marine             | pollutant  | :     | yes                                 |   |
|             |                                   | Passenger)<br>nmentally hazardous                  | :     | yes                                 |   |
|             |                                   | <b>Cargo)</b><br>nmentally hazardous               | :     | yes                                 |   |

## 14.6 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.

#### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.



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### **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

| UK REACH List of restrictions (Annex 17)   |                            | :   | Conditions of restriction for the fol-<br>lowing entries should be considered:<br>Number on list 3   |   |
|--|----------------------------|-----|--|---|
|  |                            |     | here according to<br>in the regulation, i<br>use/purpose or th<br>restriction. Please<br>tions in correspon<br>determine whethe<br>cable to the placin<br>not. | nixture(s) are listed<br>their appearance<br>irrespective of their<br>e conditions of the<br>e refer to the condi-<br>ading Regulation to<br>er an entry is appli-<br>ng on the market or |
| UK REACH Candidate list of<br>concern (SVHC) for Authorisa                               | , ,                        | :   | Not applicable   |   |
| The Persistent Órganic Pollut<br>Regulation (EU) 2019/1021 a<br>ain)                     | ants Regulations (retained | :   | Not applicable   |   |
| Regulation (EC) on substance layer   | es that deplete the ozone  | :   | Not applicable   |   |
| UK REACH List of substance<br>(Annex XIV)  | s subject to authorisation | :   | Not applicable   |   |
| GB Export and import of hazardous chemicals - Prior<br>Informed Consent (PIC) Regulation |                            | :   | Not applicable   |   |
| Control of Major Accident Ha   |                            | OMA | AH)  |   |
| ,  | 5                          |     | Quantity 1   | Quantity 2  |
| E2   | ENVIRONMENTAL<br>HAZARDS   |     | 200 t  | 500 t   |

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

#### The components of this product are reported in the following inventories:

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



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#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

| SECTION 16: Other info   | rmation  |
|--------------------------|--|
| Other information        | : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines. |
| Full text of H-Stateme   | nts  |
| H361fd                   | <ul> <li>Suspected of damaging fertility. Suspected of damaging the<br/>unborn child.</li> </ul>                                 |
| H372                     | <ul> <li>Causes damage to organs through prolonged or repeated<br/>exposure.</li> </ul>  |
| H400                     | : Very toxic to aquatic life.  |
| H410                     | : Very toxic to aquatic life with long lasting effects.  |
| Full text of other abbre | eviations  |
| Aquatic Acute            | : Short-term (acute) aquatic hazard  |
| Aquatic Chronic          | : Long-term (chronic) aquatic hazard   |
|                          |  |

| Aquatic Acute   | : Short-term (acute) aquatic hazard                      |
|-----------------|--|
| Aquatic Chronic | : Long-term (chronic) aquatic hazard                     |
| Repr.           | : Reproductive toxicity                                  |
| STOT RE         | : Specific target organ toxicity - repeated exposure     |
| GB EH40         | : UK. EH40 WEL - Workplace Exposure Limits               |
| GB EH40 / TWA   | : Long-term exposure limit (8-hour TWA reference period) |
|                 |  |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road: AIIC - Australian Inventory of Industrial Chemicals: ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - 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 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; UK REACH Regulations SI 2019/758



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SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

### Further information

| Sources of key data used to | : | Internal technical data, data from raw material SDSs, OECD |
|-----------------------------|---|--|
| compile the Safety Data     |   | eChem Portal search results and European Chemicals Agen-   |
| Sheet                       |   | cy, http://echa.europa.eu/                                 |

| Classification of the mixtur | Classification procedure: |                    |
|------------------------------|---------------------------|--------------------|
| STOT RE 2                    | H373                      | Calculation method |
| Aquatic Chronic 2            | H411                      | Calculation method |

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.

GB / EN