

Material Safety Data Sheet

Florgane 300mg/ml suspension for injection

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product identification

Product name(s): Florgane 300mg/ml suspension for injection
 Product code(s): XVD 760

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Veterinary medicinal product
 Uses advised against: Not for human use. Refer to the product information leaflet
 Reasons why uses advised against: Refer to the product information leaflet

1.3 Details of the supplier of the safety data sheet

Company name: Animalcare Limited
 Address: 10 Great Northway
 York Business Park
 Nether Poppleton
 York
 YO26 6RB
 United Kingdom

1.4 Emergency telephone number

Daytime: +44 (0) 1904 487687

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) 1272/2008: This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Classification of this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

2.2 Label elements

Labelling according to Regulation (EC) 1272/2008: This is a veterinary medicinal product authorised under the provisions of Directive 2001/82/EC. Label elements for this substance/mixture is not required according to point 11 of the preamble in Regulation EC 1272/2008.

Hazard pictograms: Not applicable
 Signal word: Not applicable
 Hazard statements: Not applicable
 Precautionary statements: Not applicable
 Supplemental information: Not applicable

2.3 Other hazards

Hazard(s) not otherwise classified (HNOC): may cause eye irritation.
 may cause skin irritation.
 may cause sensitisation and allergic reactions in hypersensitive individuals
 may cause gastro-intestinal disturbances.
 possible risk of harm to the unborn child (may cause birth defects).
 possible risk to the male reproductive system (may cause impaired fertility).
 Toxic to aquatic organisms

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

<i>Substance name in the mixture</i>	<i>CAS No</i>	<i>Quantity</i>
Florfenicol	[73231-34-2]	30%
Carmellose sodium	[9004-32-4]	Proprietary
Povidone	[9003-39-8]	Proprietary
Lecithine	[8002-43-5]	Proprietary
Sodium citrate	[68-04-2]	Proprietary
Potassium dihydrogen phosphate	[7778-77-0]	Proprietary
Magnesium gluconate	[59625-89-7]	Proprietary
Potassium metabisulfite	[16731-55-8]	Proprietary
Methyl-p-hydroxybenzoate	[99-76-3]	Proprietary
Propyl-p-hydroxybenzoate	[94-13-3]	Proprietary

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eyes:	Immediately flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call an eye-doctor or physician in case irritation occurs or persists
Skin:	In case of contact, immediately remove contaminated clothing, gloves and shoes. Wash skin with soap and water. Consult a physician in case symptoms of irritation occur or persist
Ingestion:	If swallowed, wash out mouth with water. Do not induce vomiting. Seek medical advice in case of feeling unwell
Inhalation:	Move individual to fresh air. If not breathing, provide artificial respiration as soon as possible. Get medical attention

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for more information on health effects and symptoms

4.3 Indication of any immediate medical attention and special treatment needed

See patient package insert in shipping carton for complete information.

SECTION 5: FIRE- FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
Unsuitable extinguishing media:	None known

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:	Not flammable or combustible
Hazardous combustion products:	Decomposition products may include the following materials: Carbon oxides (CO _x), nitrogen oxides (NO _x)

5.3 Advice for fire-fighters

Special protective equipment for firefighters:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes
Further information:	Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Wear protective clothing (e.g. disposable coveralls that will be discarded after use), rubber boots and appropriate gloves. Keep unqualified people away from the area that has to be cleaned.

Advice for emergency responders: If specialised clothing is required to deal with the spillage, take note of any information in section 8 on suitable and unsuitable materials

6.2 Environmental precautions

Make sure spills can be contained, e.g. in sump pallets or kerbed areas. Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

Small spills: Wear recommended personal protective equipment (see section 8- Exposure controls/personal Protection). Use absorbent towels or brooms to clean up spill.

Large spills: Wipe surface area clean with soap and water
Dike spilled material or otherwise contain material to ensure runoff does not reach a waterway

6.4 Reference to other sections

See Section 1 for emergency contact information

See section 8 for personal protection

See Section 13 for additional waste treatment information

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Advice on safe handling: Avoid skin and eye contact. Wear suitable protective clothing and gloves during handling. Assure good restraint of the animal during injection to reduce the risk of accidental self-injection

Hygiene measures: Wash hands after use

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep out of reach of children. Keep in the original packaging. Keep container tightly closed

Storage temperature: Store below 25°C and protected from light

Further information on storage conditions: None

7.3 Specific end use(s)

Recommendations: Read the Product Information Leaflet before use

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

The following constituents are the only constituents of the product which have a PEL, TLV, TWA or other recommended exposure limit. At this time, the other constituents have no known exposure limits

<i>Substance name in the mixture</i>	<i>Type</i>	<i>Value</i>
florfenicol	TWA	180 µg/m ³

8.2 Exposure controls

Engineering measures:	Good general ventilation should be sufficient to control worker exposure to airborne contaminants
Individual protection measures:	
Hygiene measures:	No specific measures identified
Eye/face protection:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent)
Skin/body protection:	Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent)
Hand protection:	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent)
Respiratory protection:	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent)
Environmental exposure controls:	Consider the provision of containment around storage vessels

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Suspension
Colour:	White
Odour:	Odourless
Odour threshold:	No data available
pH:	5 - 7
Density:	No data available
Melting point:	No data available
Boiling point:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability:	No data available
Water solubility:	No data available
Partition coefficient:	No data available
Auto-ignition temperature:	No data available
Thermal decomposition:	No data available
Viscosity:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Explosive properties:	No data available
Oxidizing properties:	The substance or mixture is not classified as oxidizing

9.2 Other information

No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No dangerous reaction known under normal conditions of normal use

10.2 Chemical stability

Stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under normal conditions of normal use

10.4 Conditions to avoid

Avoid contact with incompatible materials

10.5 Incompatible materials

None Known

10.6 Hazardous decomposition products

Decomposition products may include the following materials: Carbon oxides nitrogen oxides

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Florfenicol LD ₅₀ >2000 mg/kg (Mouse, oral) single oral doses of ≥ 640 mg/kg caused emesis and soft stools in dogs
Chronic toxicity:	Florfenicol NOEL 30 mg/kg/day (Rat, oral) 13 weeks Florfenicol NOEL 3 mg/kg/day (Dogs, oral) 52 weeks
Skin irritation/sensitization:	not irritating to the rabbit skin slightly irritating to the rabbit eye no skin sensitisation in Guinea pigs
Reproductive toxicity:	Florfenicol NOEL 20 mg/kg/day (Dogs, oral) 2 years (testicular toxicity)
Carcinogenicity:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No drug related carcinogenic/tumorigenic effects based on animal data
Mutagenicity:	not genotoxic in in vitro and in vivo assays

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Average biodegradation half-life in manure amended soils: 2 weeks (relatively rapid rate of mineralization and biodegradation in soil)

Half-life for aerobic biodegradation in water: >28 days (not readily biodegradable in water)

Photolytic half-life: >150 days (no significant direct or indirect photodegradation).

Hydrolysis is not a significant degradation route for florfenicol.

Koc (different soils) = 10 – 23 → florfenicol binds slightly to soils.

Ecotoxicity data (Acute toxicity of florfenicol in aquatic organisms)

Rainbow trout	LC ₅₀ (96 h)	> 780 mg/L
Bluegill sunfish	LC ₅₀ (96 h)	> 830 mg/L
Daphnia magna	EC ₅₀ (48 h)	> 330 mg/L
Green algae (based on max. cell density)	MIC	1.5 mg/L
Green algae (based on max. growth rate)	MIC	> 2.9 mg/L

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

No data available

12.6 Other adverse effects

No data available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers

SECTION 14: TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15: REGULATORY INFORMATION

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

This product has been authorised under the provisions of Directive 2001/82/EC

15.2 Chemical safety assessment

For this product, a chemical safety assessment was not carried out

SECTION 16: OTHER INFORMATION

For animal treatment only

We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind, express or implied, and we assume no responsibility for any loss, damage or expense, direct or consequential, arising out of their use

End of document