



Complying to 91/155/EC, 93/112/EC

Product Safety Data Sheet

Florgane 300mg/ml

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name	Florgane 300mg/ml suspension for injection
Product Code	XVD760, XVD765
Supplier	Animalcare Ltd, Common Road, Dunnington, York, YO19 5RU, Telephone No. +44 (0) 1904 487687 Fax No. +44 (0) 1904 487611 E-Mail: animalcare@animalcare.co.uk. Emergency Telephone +44 (0) 1904 487687 (daytime)

2. HAZARDS IDENTIFICATION

Primary physical and health hazards

- 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



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3. COMPOSITION / INFORMATION ON COMPONENTS

	Substance	CAS Number
Active ingredient	Florfenicol 300mg/ml mg per ml	73231-34-2
Excipients	Carmellose sodium	9004-32-4
	Povidone	9003-39-8
	Lecithine	8002-43-5
	Sodium citrate	68-04-2
	Potassium dihydrogen phosphate	7778-77-0
	Magnesium gluconate	59625-89-7
	Potassium metabisulfite	16731-55-8
	Methyl-p-hydroxybenzoate	99-76-3
Propyl-p-hydroxybenzoate	94-13-3	

4. FIRST AID MEASURES

- Skin contact:** 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.
- Eye contact:** 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.
- 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.

Show the physician the label and/or package insert, and/or this MSDS where possible.

Note that florfenicol may cause allergic reactions in susceptible individuals.



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5. FIRE FIGHTING MEASURES

- Flammability: flash point: not applicable (liquid)
- Extinguishing media: water spray, carbon dioxide, dry chemical powder
- Special fire fighting procedures: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
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6. ACCIDENTAL RELEASE MEASURES

- Personal precautions: 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.
- Spill clean up methods: Use proper absorbent materials to clean-up the liquid. Incidental, small scale spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate.
Large dry or liquid scale spills or spills outside a hood or enclosure (e.g. manufacturing, traffic accidents) should be handled by appropriate emergency personnel. HEPA vacuum cleaning prior to wet mopping/cleaning is required.
- Environmental precautions: Prevent further migration of the product and contaminated materials used for cleaning in the environment.
Prevent spilled material from flowing into surface and ground water, streams, lakes, drainage systems, sewage or adjacent land.
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7. HANDLING AND STORAGE

Precautions: Store below 25°C and protected from light. Do not use when the product is expired (expiry date on the label). For use in animals only.
Keep out of the reach of children.

Work/hygiene practices: 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.
Wash hands after use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Guideline for florfenicol: 180 µg/m³ TWA for 8 h

Eye protection: Wear suitable eye protection when handling product

Skin protection: Wear chemical resistant gloves when handling product

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: If shaken: milky-white liquid (suspension)
If left untouched: transparent supernatants + white precipitate

Odour: No special odour

Boiling point: No information available

Melting point: No information available

pH: 5 - 7

Vapour pressure : Non volatile



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10. STABILITY AND REACTIVITY

Stability/reactivity: Stable when stored under normal conditions.

Conditions and materials to avoid: None known.

Hazardous polymerisation: Will not occur.

11. TOXICOLOGICAL INFORMATION

Florfenicol: acute exposure

- inhalation LC₅₀ (4 hr) in rats: >0.28 mg/L → low inhalation toxicity
- oral LD₅₀ rats and mice: > 2000 mg/kg → low acute oral toxicity
single oral doses of ≥ 640 mg/kg caused emesis and soft stools in dogs.
- not irritating to the rabbit skin
- slightly irritating to the rabbit eye
- no skin sensitisation in Guinea pigs

Florfenicol: repeated-dose exposure

- 13-week oral toxicity study in rats: - decreased body weight gain at 100 mg/kg/d
(with 4-week recovery) - testicular toxicity in males at 100 mg/kg/day
- NOEL: 30 mg/kg/day.
- 13-week oral toxicity study in dogs: - hepatotoxicity at all dose levels



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(30 and 100 mg/kg/d)

- testicular toxicity in males and hematopoietic changes at 100 mg/kg/day.

- 13-week oral toxicity study in dogs: - hepatotoxicity at 12 mg/kg/d (with 4-week recovery) - NOEL: 3 mg/kg/day
- 1-year toxicity study in dogs: - hepatotoxicity at 12 mg/kg/day - NOEL: 3 mg/kg/day
- 2-year toxicity study in rats: (interim kill at 52 weeks) - testicular toxicity at 12 and 48 mg/kg/d - decreased erythroid paramet. at 48 mg/kg/d - NOEL: 3 mg/kg/day - benign interstitial cell tumors in testes - conclusion → non-carcinogenic
- 2-year toxicity study in mice: - testicular toxicity at 48 mg/kg/d - non-carcinogenic - NOEL: 20 mg/kg/day
- 2-generation reproduction study in rats: - reduced epididymal weights in male - NOEL: 1 mg/kg/day



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- teratogenicity study in rats:
 - 0, 4, 12 or 40 mg/kg/d from gestation days 6-17
 - Maternotoxicity (reduced food and water consumption) and embryotoxicity (reduced fetal weight and retarded ossification) at \geq 12 mg/kg/day
 - NOEL: 4 mg/kg/day

- not genotoxic in in vitro and in vivo assays.

Florfenicol 30% inj. susp.: No product-specific toxicological information available.



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12. ECOLOGICAL INFORMATION

The following data refer to florfenicol only

Environmental fate

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

13. DISPOSAL CONSIDERATIONS

Disposal should be in accordance with local, regional or national legislation.



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14. TRANSPORT INFORMATION

DOT: not regulated

ICAO/IATA: not regulated

IMO: not regulated

ADR: not regulated

15. REGULATORY INFORMATION

Classification: Xn (Harmful)

N (Dangerous to the environment)

R-Phrases: R36/38 (Irritating to the eyes and skin)

R51/53 (Toxic to aquatic organisms, may cause long-term adverse effects in aquatic environment)

R43 (May cause sensitisation by skin contact)

R62 (Possible risk of impaired fertility)

R63 (Possible risk of harm to the unborn child)

S-Phrases: S24/25 (Avoid contact with skin and eyes)

S26 (In case of contact with the eyes, rinse immediately with plenty of water and seek medical advice)

S36/37/39 (Wear suitable protective clothing, gloves and eye/face protection)

S46 (If swallowed, seek medical advice immediately and show container or label)

S61 (Avoid release to the environment)



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16. OTHER INFORMATION

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.
