

SAFETY DATA SHEET



1. Identification

Product identifier	Danofloxacin mesylate injectable solution
Other means of identification	
Synonyms	ADVOCID™ * ADVOCIN™ * A180® * A180® Sterile Injectable Solution * Advocid 180 * Advocin 180 * ADVOCIN Sterile Injectable Solution * Advocin Injectable Solution
Recommended use	Veterinary product used as antibiotic agent
Recommended restrictions	Not for human use
Manufacturer/Importer/Supplier/Distributor information	
Company Name (USA)	Zoetis Inc. 10 Sylvan Way Parsippany, New Jersey 07054 (USA)
Rocky Mountain Poison and Drug Center	1-866-531-8896
Product Support/Technical Services	1-800-366-5288
Emergency telephone numbers	CHEMTREC (24 hours): 1-800-424-9300 International CHEMTREC (24 hours): +1-703-527-3887
Company Name (CA)	Zoetis Canada Inc. 16740 Trans-Canada Highway Kirkland, Quebec, H9H 4M7
Emergency telephone number	International CHEMTREC (24 hours): +1-703-527-3887
Contact E-Mail	productsupport@zoetis.com
Product Support	1-800-461-0917

All Safety Data Sheets are available via our Zoetis Canada website at <https://www.zoetis.ca/sds/sds.aspx>

Supplier Not available.

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Specific target organ toxicity following repeated exposure	Category 2 (connective tissue, Reproductive system, nervous system, heart, kidney)
Environmental hazards	Hazardous to the aquatic environment, acute hazard	Category 3
	Hazardous to the aquatic environment, long-term hazard	Category 3

Label elements



Signal word	Warning
Hazard statement	May cause damage to organs (connective tissue, Reproductive system, nervous system, heart, kidney) through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.
Precautionary statement	
Prevention	Do not breathe the mist or vapour. Avoid release to the environment.
Response	Get medical advice/attention if you feel unwell.

Storage	Store away from incompatible materials.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Other hazards	None known.
Supplemental information	Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Drugs of this class have been associated with rare, but potentially serious cardiac events. These effects have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
2-Pyrrolidone		616-45-5	20
Danofloxacin mesylate		119478-55-6	18
Phenol		108-95-2	<1

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation	Move to fresh air. If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician. For breathing difficulties, oxygen may be necessary.
Skin contact	Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. There is a risk of photosensitization within a few hours after excessive exposure to quinolones. If excessive exposure does occur, avoid direct sunlight and wash skin with soap and water.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Remove contact lenses, if present and easy to do.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Do not induce vomiting without advice from poison control center. Never give anything by mouth to a victim who is unconscious or is having convulsions.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Exposed individuals may experience eye tearing, redness, and discomfort. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Rash. (allergic skin rash); Difficulty in breathing. Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Convulsions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones. The most common adverse reactions associated with the use of quinolones include gastrointestinal distress, such as nausea or diarrhea, and central nervous system (CNS) effects, including insomnia, dizziness, and seizures. sensory/motor nerve injury (peripheral neuropathy) may occur.
Indication of immediate medical attention and special treatment needed	May cause central nervous system effects. Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure. Monitor respiratory, cardiac and central nervous system. Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Show this safety data sheet to the doctor in attendance. CAUTION! - Individuals with a history of hypersensitivity to this material or members of the quinolone class of antimicrobials and those with known seizure disorders. Individuals with cardiac conditions may be more susceptible to toxicity in cases of overexposure.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist or vapour. Avoid contact with eyes, skin, and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Ensure adequate ventilation. Prevent product from entering drains.

Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

Wear appropriate personal protective equipment. Do not handle, store or open near an open flame, sources of heat or sources of ignition. Protect material from direct sunlight. Avoid breathing mist or vapour. Avoid contact with eyes, skin, and clothing. Avoid accidental injection. Avoid prolonged exposure. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Avoid release to the environment.

Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. @ ≤ 30C/86F. Store in a tightly closed container. Protect from light. Protect from sunlight. Keep away from heat, sparks and open flame. Do not allow material to freeze. Store away from incompatible materials (see Section 10 of the SDS). Keep out of the reach of children.

8. Exposure controls/personal protection

Occupational exposure limits

Zoetis

Components

Type

Value

Danofloxacin mesylate
(CAS 119478-55-6)

TWA

200 µg/m³

US. ACGIH Threshold Limit Values

Components

Type

Value

Phenol (CAS 108-95-2)

TWA

5 ppm

Canada. Alberta OELs (Occupational Health & Safety Code, Schedule 1, Table 2)

Components

Type

Value

Phenol (CAS 108-95-2)

TWA

19 mg/m³
5 ppm

Canada. British Columbia OELs. (Occupational Exposure Limits for Chemical Substances, Occupational Health and Safety Regulation 296/97, as amended)

Components

Type

Value

Phenol (CAS 108-95-2)

TWA

5 ppm

Canada. Manitoba OELs (Reg. 217/2006, The Workplace Safety And Health Act)

Components

Type

Value

Phenol (CAS 108-95-2)

TWA

5 ppm

Canada. Ontario OELs. (Control of Exposure to Biological or Chemical Agents)

Components

Type

Value

Phenol (CAS 108-95-2)

TWA

5 ppm

Canada. Quebec OELs. (Ministry of Labour - Regulation Respecting the Quality of the Work Environment)

Components

Type

Value

Phenol (CAS 108-95-2)

TWA

19 mg/m³
5 ppm

Biological limit values

ACGIH Biological Exposure Indices

Components	Value	Determinant	Specimen	Sampling time
Phenol (CAS 108-95-2)	250 mg/g	Phenol with hydrolysis	Creatinine in urine	*

* - For sampling details, please see the source document.

Exposure guidelines

Canada - Alberta OELs: Skin designation

Phenol (CAS 108-95-2)

Can be absorbed through the skin.

Canada - British Columbia OELs: Skin designation

Phenol (CAS 108-95-2)

Can be absorbed through the skin.

Canada - Manitoba OELs: Skin designation

Phenol (CAS 108-95-2)

Can be absorbed through the skin.

Canada - Ontario OELs: Skin designation

Phenol (CAS 108-95-2)

Can be absorbed through the skin.

Canada - Quebec OELs: Skin designation

Phenol (CAS 108-95-2)

Can be absorbed through the skin.

Canada - Saskatchewan OELs: Skin designation

Phenol (CAS 108-95-2)

Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Phenol (CAS 108-95-2)

Can be absorbed through the skin.

Control banding approach

Not available.

Appropriate engineering controls

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. General room ventilation is adequate unless the process generates dust, mist or aerosols.

Individual protection measures, such as personal protective equipment

Eye/face protection

If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection

Wear appropriate chemical resistant gloves. Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Other

Wear suitable protective clothing. Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

Respiratory protection

No personal respiratory protective equipment normally required. In case of insufficient ventilation, wear suitable respiratory equipment. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure. 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.

Thermal hazards

Not applicable.

General hygiene considerations

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Sterile solution.

Physical state

Liquid.

Form

Liquid.

Colour

Colourless.

Odour

Not available.

Odour threshold

Not available.

pH

7.5

Melting point/freezing point

Not available.

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Heat, flames and sparks. Exposure to light. Sunlight. Protect from freezing.
Incompatible materials	Peroxides. Phenols. Strong oxidising substances.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard. May cause hypersensitivity reactions in susceptible individuals.
Skin contact	Prolonged skin contact may cause temporary irritation. May cause hypersensitivity reactions in susceptible individuals. Photosensitivity may occur.
Danofloxacin mesylate	Species: Rabbit Severity: Mild
Phenol	Species: Rabbit Severity: Severe
Eye contact	Direct contact with eyes may cause temporary irritation.
Danofloxacin mesylate	Species: Rabbit Severity: No effect
Phenol	Species: Rabbit Severity: Severe
Ingestion	Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Direct contact with eyes may cause temporary irritation. Exposure may cause temporary irritation, redness, or discomfort. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Rash. (allergic skin rash); Difficulty in breathing. Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Convulsions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones. The most common adverse reactions associated with the use of quinolones include gastrointestinal distress, such as nausea or diarrhea, and central nervous system (CNS) effects, including insomnia, dizziness, and seizures. sensory/motor nerve injury (peripheral neuropathy) may occur.

Information on toxicological effects

Acute toxicity Ingestion may result in mild gastrointestinal irritation with nausea, vomiting, or diarrhea.

Product	Species	Test results
Danofloxacin mesylate injectable solution		
Acute		
Dermal		
LD50	Rat	> 5000 mg/kg (ATE)
Inhalation		
LC50	Rat	> 10 mg/l (ATE)
Oral		
LD50	Rat	> 5000 mg/kg (ATE)

Components	Species	Test results
Danofloxacin mesylate (CAS 119478-55-6)		
Acute		
Intravenous		
LD50	Mouse	50 - 100 mg/kg
	Rat	100 - 150 mg/kg
Oral		
LD50	Mouse	> 2000 mg/kg
	Rat	> 2000 mg/kg
Chronic		
Oral		
LOEL	Rat	10 mg/L/day, 2 years [Effect(s): Tumors, Female reproductive system (Female rat)] 10 mg/kg/day, 2 years [Target organ(s): Kidney, Male reproductive system]
Subchronic		
Oral		
LOEL	Rat	25 mg/kg/day, 3 months [Target organ(s): Kidney, Heart, Male reproductive system]
NOEL	Dog	2.4 mg/kg/day, 90 days [Target organ(s): Skeletal muscle]

Phenol (CAS 108-95-2)

Acute		
Dermal		
LD50	Rat	669 mg/kg
Inhalation		
LC50	Rat	316 mg/m3
Oral		
LD50	Rat	317 mg/kg

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation.

Corrosivity	
Danofloxacin mesylate	Species: Rabbit Severity: Mild

Serious eye damage/eye irritation

Direct contact with eyes may cause temporary irritation.

Eye contact

Danofloxacin mesylate

Species: Rabbit
Severity: No effect

Phenol

Species: Rabbit
Severity: Severe

Respiratory or skin sensitisation

Respiratory sensitisation

Due to partial or complete lack of data the classification is not possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Skin sensitisation

Due to partial or complete lack of data the classification is not possible. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Skin sensitization and/or photosensitization potential (allergic response after UV exposure) of other quinolones have been demonstrated in guinea pigs, mice, and humans.

Germ cell mutagenicity

No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Mutagenicity

Danofloxacin mesylate

Bacterial Mutagenicity (Ames)
Result: negative
Species: Salmonella

In Vitro Cytogenetics
Result: negative
Species: Human lymphocytes

In Vivo Cytogenetics
Result: negative
Species: Mouse Bone Marrow

Mammalian Cell Mutagenicity
Result: negative
Species: Mouse Lymphoma

Unscheduled DNA Synthesis
Result: negative
Species: Rat Hepatocyte

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

ACGIH Carcinogens

Phenol (CAS 108-95-2)

A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Phenol (CAS 108-95-2)

Not classifiable as a human carcinogen.

IARC Monographs. Overall Evaluation of Carcinogenicity

Phenol (CAS 108-95-2)

3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity

Due to partial or complete lack of data the classification is not possible. Repeat-dose studies in animals have shown a potential to cause adverse effects on testes. Possible risk of impaired fertility. Classification not possible. No evidence of teratogenicity or embryotoxicity was observed for danofloxacin in mice, rats, or rabbits.

Developmental effects

Danofloxacin mesylate

100 mg/kg/day Embryo / Fetal Development, Not Teratogenic
Result: NOEL
Species: Mouse
Organ: Oral

50 mg/kg/day Embryo / Fetal Development, Not Teratogenic
Result: NOEL
Species: Rat
Organ: Oral

Reproductivity
Danofloxacin mesylate

6.25 mg/kg/day Reproductive & Fertility, Fertility
Result: NOEL
Species: Rat
Organ: Oral

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure May cause damage to organs (connective tissue, Reproductive system, nervous system, heart, kidney) through prolonged or repeated exposure.

Aspiration hazard Not an aspiration hazard.

Further information Possible risks of irreversible effects. sensory/motor nerve injury (peripheral neuropathy) may occur. This compound may cause cartilage deterioration in knee joints. Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Drugs of this class have been associated with rare, but potentially serious cardiac events. These effects have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

12. Ecological information

Ecotoxicity Harmful to aquatic life with long lasting effects. Avoid release to the environment.

Components	Species	Test results
2-Pyrrolidone (CAS 616-45-5)		
	LC50	Daphnia magna (Water Flea) 13.21 mg/l, 48 Hours
Aquatic		
Crustacea	EC50	Water flea (Daphnia pulex) 13.21 mg/l, 48 hours
Danofloxacin mesylate (CAS 119478-55-6)		
	IC50	Champia 2.7 mg/l, 168 Hours
		Polytox 0.92 mg/l
	LC50	Cyprinodon variegatus (Sheepshead Minnow) > 100 mg/l, 48 Hours
		Daphnia magna (Water Flea) 63.5 mg/l, 48 Hours
		Mysidopsis bahia (Mysid Shrimp) > 100 mg/l, 48 Hours
Phenol (CAS 108-95-2)		
Aquatic		
Crustacea	EC50	Water flea (Daphnia obtusa) 4.7 - 6.4 mg/l, 48 hours
Fish	LC50	Asiatic knifefish (Notopterus notopterus) 8 - 8.25 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Avoid release to the environment. Do not discharge into drains, water courses or onto the ground. Do not contaminate ponds, waterways or ditches with chemical or used container. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information**TDG**

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not established.

15. Regulatory information

Canadian regulations This product has been classified in accordance with the hazard criteria of the HPR and the SDS contains all the information required by the HPR.

Controlled Drugs and Substances Act

Not regulated.

Export Control List (CEPA 1999, Schedule 3)

Not listed.

Greenhouse Gases

Not listed.

Ontario. Toxic Substances. Toxic Reduction Act, 2009. Regulation 455/09 (July 1, 2011)

Phenol (CAS 108-95-2)

Precursor Control Regulations

Not regulated.

International regulations**Stockholm Convention**

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information

Issue date	31-May-2017
Version No.	01
List of abbreviations	ATE: Acute Toxicity Estimate according to REGULATION (EC) No 1272/2008 (CLP).
Disclaimer	Zoetis Inc. believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time. The information in the sheet was written based on the best knowledge and experience currently available.
Revision information	Product and Company Identification: Synonyms Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Multiple Properties Toxicological Information: Toxicological Data GHS: Qualifiers