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 & Drug Safety	1-866-531-8896
Product Support/Technical Services	1-888-963-8471
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	CHEMTREC (24 hours): 1-800-424-9300
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 identification

Physical hazards	Not classified.	
Health hazards	Germ cell mutagenicity	Category 2
	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	Suspected of causing genetic defects. May cause damage to organs (connective tissue, Reproductive system, nervous system, heart, kidney) through prolonged or repeated exposure. Harmful to aquatic life. Harmful to aquatic life with long lasting effects.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist/vapours. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.
Response	IF exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
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.
Other hazards	None known.

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
Magnesium oxide		1309-48-4	2.03
Phenol		108-95-2	< 1
Other components below reportable levels			59.72

ATE: Acute toxicity estimate.
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. Call a physician if symptoms develop or persist.
Skin contact	Remove contaminated clothing. Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse. In the event of accidental self injection or needle stick injury, wash the injury thoroughly with clean running water. Get medical attention immediately.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.
Ingestion	Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious person.
Most important symptoms/effects, acute and delayed	Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. Prolonged exposure may cause chronic effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Symptoms may be delayed.
General information	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. IF exposed or concerned: Get medical advice/attention. For personal protection, see section 8 of the SDS.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
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. Avoid contact with eyes, skin, and clothing. Wear appropriate protective equipment and clothing during clean-up. Do not breathe mist/vapours. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. 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	Wear personal protective equipment Avoid release to the environment. Large Spills: Stop the flow of material, if this is without risk. Absorb in vermiculite, dry sand or earth and place into containers. Clean surface thoroughly to remove residual contamination. 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 discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Do not breathe mist/vapours. Avoid contact with eyes, skin, and clothing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Avoid release to the environment. Observe good industrial hygiene practices. Avoid accidental injection.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store locked up. Store as directed by product packaging. Store away from incompatible materials (see Section 10 of the SDS).

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 (TLV)

Components	Type	Value	Form
Magnesium oxide (CAS 1309-48-4)	TWA	10 mg/m3	Inhalable fraction.
Phenol (CAS 108-95-2)	TWA	5 ppm	

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

Components	Type	Value	Form
Magnesium oxide (CAS 1309-48-4)	TWA	10 mg/m3	Fume.
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	Form
Magnesium oxide (CAS 1309-48-4)	STEL	10 mg/m3	Respirable dust and/or fume.
	TWA	3 mg/m3	Respirable dust and/or fume.
		10 mg/m3	Inhalable fume.
Phenol (CAS 108-95-2)	TWA	5 ppm	

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

Components	Type	Value	Form
Magnesium oxide (CAS 1309-48-4)	TWA	10 mg/m3	Inhalable fraction.
Phenol (CAS 108-95-2)	TWA	5 ppm	

Canada. New Brunswick OELs: Threshold Limit Values (TLVs) Based on the 1991 and 1997 ACGIH TLVs and BEIs Publication (New Brunswick Regulation 91-191)

Components	Type	Value	Form
Magnesium oxide (CAS 1309-48-4)	TWA	10 mg/m3	Inhalable fraction.
Phenol (CAS 108-95-2)	TWA	5 ppm	

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

Components	Type	Value	Form
Magnesium oxide (CAS 1309-48-4)	TWA	10 mg/m3	Inhalable fraction.
Phenol (CAS 108-95-2)	TWA	5 ppm	

Canada. Quebec OELs. (Ministry of Labor - Regulation respecting occupational health and safety), as amended

Components	Type	Value	Form
Magnesium oxide (CAS 1309-48-4)	TWA	10 mg/m3	Inhalable dust.
Phenol (CAS 108-95-2)	TWA	19 mg/m3 5 ppm	

Canada. Saskatchewan OELs (Occupational Health and Safety Regulations, 1996, Table 21), as amended

Components	Type	Value	Form
Magnesium oxide (CAS 1309-48-4)	15 minute	20 mg/m3	Inhalable fraction.
	8 hour	10 mg/m3	Inhalable fraction.
Phenol (CAS 108-95-2)	15 minute	7.5 ppm	
	8 hour	5 ppm	

Biological limit values

ACGIH Biological Exposure Indices (BEI)

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) Danger of cutaneous absorption

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: Can be absorbed through the skin.

Phenol (CAS 108-95-2) Can be absorbed through the skin.

US ACGIH Threshold Limit Values: Skin designation

Phenol (CAS 108-95-2) Danger of cutaneous absorption

Control banding approach Not available.

Appropriate engineering controls	Good general ventilation 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. Provide eyewash station and safety shower.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
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. 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	Observe any medical surveillance requirements. 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

Physical state	Liquid.
Form	Liquid.
Colour	Colourless.
Odour	Not available.
Melting point/freezing point	Not available.
Boiling point or initial boiling point and boiling range	Not available.
Flammability	Not applicable.
Upper/lower flammability or explosive limits	
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Flash point	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
pH	7.5
Kinematic viscosity	Not available.
Solubility	
Solubility (water)	Soluble
Partition coefficient (n-octanol/water) (log value)	Not available.
Vapour pressure	Not available.
Density and/or relative density	Not available.
Vapour density	Not available.
Particle characteristics	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.
Incompatible materials	Strong oxidising agents.
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

Prolonged inhalation may be harmful. 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

Narcosis. Behavioural changes. Decrease in motor functions. Direct contact with eyes may cause temporary irritation. Difficulty in breathing. Exposure may cause temporary irritation, redness, or discomfort. Rash. Oedema. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. (allergic skin rash); 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 Not acutely toxic

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
2-Pyrrolidone (CAS 616-45-5)		
Acute		
Oral		
LD50	Rat	6500 mg/kg
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]
Magnesium oxide (CAS 1309-48-4)		
Acute		
Oral		
LD50	Rat	3870 mg/kg
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

Canada - Alberta OELs: Irritant

Magnesium oxide (CAS 1309-48-4)	Irritant

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 Suspected of causing genetic defects.

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

Magnesium oxide (CAS 1309-48-4)	A4 Not classifiable as a human carcinogen.
Phenol (CAS 108-95-2)	A4 Not classifiable as a human carcinogen.

Canada - Manitoba OELs: carcinogenicity

Magnesium oxide (CAS 1309-48-4)	Not classifiable as a human carcinogen.
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.

Chronic effects Prolonged inhalation may be harmful. May cause damage to organs through prolonged or repeated exposure.

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 cadiovascular illnesses may be at increased risk from exposure.

12. Ecological information

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

Components		Species	Test Results
2-Pyrrolidone (CAS 616-45-5)			
Aquatic			
Crustacea	LC50	Daphnia magna (Water Flea)	13.21 mg/l, 48 Hours
Acute			
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
Aquatic			
Crustacea	LC50	Daphnia magna (Water Flea)	63.5 mg/l, 48 Hours
		Mysidopsis bahia (Mysid Shrimp)	> 100 mg/l, 48 Hours
Fish	LC50	Cyprinodon variegatus (Sheepshead Minnow)	> 100 mg/l, 48 Hours
Phenol (CAS 108-95-2)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	4.24 - 10.7 mg/l, 48 hours
Fish	LC50	Asiatic knifefish (Notopterus notopterus)	6.85 mg/l, 96 hours

Persistence and degradability No data available for 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 allow this material to drain into sewers/water supplies. Dispose of contents/container in accordance with local/regional/national/international regulations. 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.
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.
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.

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 Industrial Chemicals (AICIS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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

Revision date 18-February-2025

Version No. 02

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 This document has undergone significant changes and should be reviewed in its entirety.