This SDS packet was issued with item:

078912910

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078912899



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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE **COMPANY/UNDERTAKING**

Product Identifier

Material Name: Danofloxacin mesylate injectable solution

ADVOCIN™, ADVOCID™ **Trade Name:**

Advocin Injectable Solution, Advocin 180, Advocid 180 Synonyms:

Chemical Family:

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Veterinary product used as antibiotic agent

Restrictions on Use: Not for human use

Details of the Supplier of the Safety Data Sheet

Zoetis Inc. 100 Campus Drive, P.O. Box 651 Florham Park, New Jersey 07932 (USA)

Rocky Mountain Poison Control Center Phone: 1-866-531-8896

Product Support/Technical Services Phone: 1-800-366-5288

Zoetis Belgium S.A. Mercuriusstraat 20 1930 Zaventem

Belgium

Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300 **Contact E-Mail:**

VMIPSrecords@zoetis.com

Emergency telephone number:

International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Appearance: Sterile solution in 100 and 250 mL amber-glass, multi-dose vials

Classification of the Substance or Mixture

Acute Oral Toxicity: Category 4

Specific target organ systemic toxicity (repeated exposure): Category 2

Acute aquatic toxicity: Category 3

EU Classification:

EU Indication of danger: Harmful

EU Symbol:

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Label Elements

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Signal Word: Warning

Hazard Statements: H302 - Harmful if swallowed

H373 - May cause damage to organs through prolonged or repeated exposure (cartliage.

reproductive system, kidneys, central nervous system, heart)

H402 - Harmful to aquatic life

Material Name: Danofloxacin mesylate injectable solution

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Precautionary Statements: P280 - Wear protective gloves/protective clothing/eye protection/face protection

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P264 - Wash hands thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P273 - Avoid release to the environment

P314 - Get medical attention/advice if you feel unwell

P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel

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unwell

P330 - Rinse mouth

P501 - Dispose of contents/container in accordance with all local and national regulations



Other Hazards

Short Term:

May cause eye, skin and respiratory tract irritation . Drugs of this class have been associated with rare, but potentially serious cardiac events. These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure. There is a risk of photosensitization within a few hours after excessive exposure to quinolones. If excess exposure occurs, avoid direct sunlight and wash skin with soap and water.

Long Term:

This compound may cause cartilage deterioration in knee joints and adverse reproductive effects (based on animal data).

Known Clinical Effects:

Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. 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. Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment.

Australian Hazard Classification (NOHSC):

Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
2-Pyrrolidone	616-45-5	210-483-1	Not Listed	Aquatic Acute 3 (H402)	20
Danofloxacin mesylate	119478-55-6	Not Listed	Xn;R48/22	STOT RE 2 (H373) Aquatic Acute 3 (H402) Aquatic Chronic 3 (H412)	18

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3. COMPOSITION/INFORMATION ON INGREDIENTS					
Magnesium oxide	1309-48-4	215-171-9	Not Listed	Not Listed	2
Phenol	108-95-2	Not Listed	Not Listed	Acute Tox. 3 (H301) Acute Tox. 3 (H311) STOT RE 2 (H373) Muta. 2 (H341) Skin Corr. 1B (H314) Acute Tox. 3	<1.0
Hydrogen chloride	7647-01-0	231-595-7	T; R23 C; R35	(H331) STOT SE 3 (H335) Skin Corr. 1A (H314) Acute Tox. 3 (H331)	**
Sodium hydroxide	1310-73-2	215-185-5	C; R35	Skin Corr. 1A (H314)	**

Ingredient	CAS Number	EU EINECS/ELINCS	EU Classification	GHS Classification	%
		List			
Povidone	9003-39-8	Not Listed	Not Listed	Not Listed	*
Monothioglycerol	96-27-5	202-495-0	Not Listed	Not Listed	*

Additional Information: ** to adjust pH

* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this

mixture has been withheld as a trade secret.

For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get

medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may

not be completely removed by conventional laundering. Consult professional laundry service.

Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical

personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. Get medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Exposure: Identification and/or Section 11 - Toxicological Information.

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Medical Conditions

Aggravated by Exposure:

Individuals with a history of hypersensitivity to this material or members of the quinolone class of antimicrobials and those with known seizure disorders. 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.

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Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE-FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Emits toxic fumes of carbon mo

Products:

Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, and

other fluorine- and sulfur-containing compounds.

Fire / Explosion Hazards: Not flammable. Fine particles (such as mists) may fuel fires/explosions.

Advice for Fire-Fighters

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Dike and collect water

used to fight fire.

Additional Information: This product is a nonflammable aqueous solution.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning /

Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Prevent discharge to drains.

Collecting:

Additional Consideration for

Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

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When handling, use appropriate personal protective equipment (see Section 8). Use only in a well-ventilated area. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Avoid accidental injection. Wash thoroughly after handling. Keep away from heat, sparks, and flame. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Protect from light. Protect from freezing. Keep container tightly closed when not in use.

Storage Temperature: Store at or below 30°C (86°F).

Specific end use(s): Veterinary antibiotic agent

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Material Name: Danofloxacin mesylate injectable solution

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

Danofloxacin mesylate

Zoetis OEL TWA 8-hr 200µg/m³

Magnesium oxide

10 mg/m³ **ACGIH Threshold Limit Value (TWA)** 10 mg/m³ **Australia TWA** 5 mg/m³ **Austria OEL - MAKs** 10 mg/m³ 10 mg/m³ **Belgium OEL - TWA** 10.0 mg/m³ **Bulgaria OEL - TWA** Czech Republic OEL - TWA 5 mg/m^3 **Denmark OEL - TWA** 6 mg/m³ 10 mg/m³ France OEL - TWA Germany (DFG) - MAK 1.5 mg/m³ 4 mg/m^3

Greece OEL - TWA 10 mg/m³ 5 mg/m³

 Hungary OEL - TWA
 6 mg/m³

 Ireland OEL - TWAs
 4 mg/m³

 5 mg/m³
 10 mg/m³

Lithuania OEL - TWA 4 mg/m³
Vietnam OEL - TWAs 5 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Poland OEL - TWA 5 mg/m³

 Spain OEL - TWA
 4 mg/m³

 Switzerland OEL -TWAs
 10 mg/m³

 3 mg/m³
 3 mg/m³

Phenol

ACGIH Threshold Limit Value (TWA) 5 ppm

ACGIH - Biological Exposure Limit: 250 mg/g creatinine

Australia TWA 1 ppm 4 mg/m³

 Austria OEL - MAKs
 2 ppm

 8 mg/m³
 8 mg/m³

 Belgium OEL - TWA
 2 ppm

8 mg/m³
Bulgaria OEL - TWA 8 mg/m³

2 ppm

Bulgaria - Biological Exposure Limit: 200 mg/L

Cyprus OEL - TWA 8 mg/m³

2 ppm

Czech Republic OEL - TWA 7.5 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION			
Denmark OEL - TWA	1 ppm 4 mg/m ³		
	4 mg/m		
Hydrogen chloride			
ACGIH Ceiling Threshold Limit:	2 ppm		
Australia PEAK	5 ppm 7.5 mg/m³		
Austria OEL - MAKs	5 ppm		
	8 mg/m ³		
Belgium OEL - TWA	5 ppm 8 mg/m ³		
Bulgaria OEL - TWA	5 ppm		
_a.gana 0	8.0 mg/m ³		
Cyprus OEL - TWA	5 ppm		
Creek Remuklic OEL TIMA	8 mg/m ³ 8 mg/m ³		
Czech Republic OEL - TWA Estonia OEL - TWA	5 ppm		
EStollia GEL - I WA	8 mg/m ³		
Germany - TRGS 900 - TWAs	2 ppm		
•	3 mg/m³		
Germany (DFG) - MAK	2 ppm		
Greece OEL - TWA	3.0 mg/m ³ 5 ppm		
510000 OLL 11111	7 mg/m ³		
Hungary OEL - TWA	8 mg/m ³		
Ireland OEL - TWAs	5 ppm		
Italy OEL - TWA	8 mg/m ³ 5 ppm		
italy OLL - TWA	8 mg/m ³		
Japan - OELs - Ceilings	5 ppm		
	7.5 mg/m ³		
Latvia OEL - TWA	5 ppm 8 mg/m ³		
Lithuania OEL - TWA	5 ppm		
	8 mg/m³		
Luxembourg OEL - TWA	5 ppm		
Malta OEL - TWA	8 mg/m ³ 5 ppm		
	8 mg/m ³		
Netherlands OEL - TWA	8 mg/m³		
Vietnam OEL - TWAs	5 mg/m ³		
Poland OEL - TWA	5 mg/m ³		
Portugal OEL - TWA	5 ppm 8 mg/m ³		
Romania OEL - TWA	5 ppm		
	8 mg/m³		
Slovakia OEL - TWA	5 ppm 8.0 mg/m ³		
Slovenia OEL - TWA	8.0 mg/m ³ 5 ppm		
CIOTOINA CEL TITA	8 mg/m ³		
Spain OEL - TWA	5 ppm		
	7.6 mg/m ³		

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Switzerland OEL -TWAs 2 ppm

 3.0 mg/m^3

Sodium hydroxide

ACGIH Ceiling Threshold Limit: 2 mg/m³ 2 mg/m³ **Australia PEAK** Austria OEL - MAKs 2 mg/m^3 **Bulgaria OEL - TWA** 2.0 mg/m³ 1 mg/m^3 Czech Republic OEL - TWA **Estonia OEL - TWA** 1 mg/m^3 France OEL - TWA 2 mg/m^3 **Greece OEL - TWA** 2 mg/m^3 **Hungary OEL - TWA** 2 mg/m³ Japan - OELs - Ceilings 2 mg/m^3 0.5 mg/m^{3} Latvia OEL - TWA **OSHA - Final PELS - TWAs:** 2 mg/m^3 0.5 mg/m³ Poland OEL - TWA 2 mg/m³ Slovakia OEL - TWA 2 mg/m³ Slovenia OEL - TWA 1 mg/m^3 Sweden OEL - TWAs **Switzerland OEL -TWAs** 2 mg/m³

Exposure Controls

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE). **Equipment:**

Hands: Wear impervious gloves as minimum protection.

Safety glasses or goggles Eves:

Wear impervious protective clothing when handling this compound. Skin:

Respiratory protection: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Sterile solution Color: Colorless

No data available. No data available. Odor: **Odor Threshold:**

Molecular Formula: Mixture **Molecular Weight:** Mixture

No data available **Solvent Solubility:** No data available Water Solubility: Soluble: Water Solubility: 7.5

pH:

Melting/Freezing Point (°C): No data available Boiling Point (°C): No data available. Partition Coefficient: (Method, pH, Endpoint, Value)

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available Vapor Pressure (kPa): No data available Vapor Density (g/ml): No data available

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Relative Density: No data available No data available Viscosity:

Flammablity:

No data available Autoignition Temperature (Solid) (°C): Flammability (Solids): No data available Flash Point (Liquid) (°C): No data available **Upper Explosive Limits (Liquid) (% by Vol.):** No data available Lower Explosive Limits (Liquid) (% by Vol.): No data available Polymerization: Will not occur

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

Possibility of Hazardous Reactions

Oxidizing Properties: No data available

Conditions to Avoid: Protect from Heat and light, freezing.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Hazardous Decomposition Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic

Products: vapors.

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects

General Information:

Toxicological properties of the formulation have not been investigated. The information in this section describes the potential hazards of the individual ingredients and the formulation.

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Routes of exposure: eye contact, skin contact

Acute Toxicity: (Species, Route, End Point, Dose)

Povidone

Oral LD50 100 g/kg Rat

Danofloxacin mesylate

Oral > 2000 mg/kg Rat LD50 IV LD50 50-100mg/kg Mouse IV LD50 100-150mg/kg Rat Mouse Oral LD50 > 2000mg/kg

Phenol

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

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Hydrogen chloride

Rat Sub-tenon injection (eye) LC50 1H 3,124 ppm

Mouse Inhalation LC50 1H 1,108ppm

Mouse Oral LD50 900mg/kg

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11. TOXICOLOGICAL INFORMATION

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

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Irritation / Sensitization: (Study Type, Species, Severity)

Danofloxacin mesylate

Eye Irritation Rabbit No effect Skin Irritation Rabbit Mild

Phenol

Eve Irritation Rabbit Severe Skin Irritation Rabbit Severe

Sodium hydroxide

Eye Irritation Rabbit Severe Skin Irritation Rabbit Severe

Irritation / Sensitization Comments:

May cause eye irritation.

Skin Irritation / Sensitization

May cause skin irritation. May cause allergic reactions in susceptible individuals. Skin sensitization and/or photosensitization potential (allergic response after UV exposure) of other

quinolones have been demonstrated in guinea pigs, mice, and humans.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Danofloxacin mesylate

3 Month(s) Rat Oral 25 mg/kg/day LOEL Kidney, Heart, Male reproductive system

90 Day(s) Oral 2.4 mg/kg/day NOEL Skeletal muscle Dog

10 mg/kg/day LOEL Kidney, Male reproductive system, 2 Year(s) Rat Oral

Chronic Effects/Carcinogenicity

In two-year oral studies of danofloxacin in mice and rats at doses of 10, 50, or 100 mg/kg/day, testicular and kidney effects were observed in male rats and slightly increased incidence of

uterine tumors were seen in female rats.

Subchronic Effects

Oral studies of danofloxacin in rats at 25, 75, or 100 mg/kg/day for 3 months produced kidney effects of dose-related severity in females. Males exhibited myocardial fibrosis and reduced testis weight at >25 mg/kg/day. Danofloxacin caused arthopathy, a joint disease associated with this class of compounds, when administered orally to beagles at doses up to 25 mg/kg/day

for 90 days with 2.4 mg/kg/day identified as the NOEL.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Danofloxacin mesylate

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Reproductive & Fertility 6.25 mg/kg/day **NOEL** Fertility Rat Oral

Embryo / Fetal Development 50 mg/kg/day NOEL Not Teratogenic Rat Oral Embryo / Fetal Development 100 mg/kg/day Not Teratogenic, Mouse Oral NOEL

Reproductive Effects Danofloxacin was studied in two- and three-generation oral studies in rats at doses up to 150

> mg/kg/day. Effects seen predominantly at the high dose included depressed pregnancy rates, decreased libido and reductions in litter size. Reduction in birth rate was seen at all doses

above 6.25 mg/kg/day which was also the NOEL for reduced litter size.

No evidence of teratogenicity or embryotoxicity was observed for danofloxacin in mice, rats, or **Teratogenicity**

rabbits.

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

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11. TOXICOLOGICAL INFORMATION

Danofloxacin mesylate

Bacterial Mutagenicity (Ames) Salmonella Negative
Mammalian Cell Mutagenicity Mouse Lymphoma Negative
Unscheduled DNA Synthesis Rat Hepatocyte Negative
In Vitro Cytogenetics Human Lymphocytes Negative
In Vivo Cytogenetics Mouse Bone Marrow Negative

Mutagenicity Danofloxacin was negative in vitro and in vivo.

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Danofloxacin mesylate

2 Year(s) Female Rat Oral 10 mg/L/day LOEL Tumors, Female reproductive system

Carcinogen Status: See below . None of the components of this formulation are listed as a carcinogen by IARC,

NTP or OSHA.

Povidone

IARC: Group 3 (Not Classifiable)

Hydrogen chloride

IARC: Group 3 (Not Classifiable)

At increase risk from exposure: 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 preexisting

cardiovascular illnesses.

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12. ECOLOGICAL INFORMATION

Environmental Overview:

Environmental properties of the formulation have not been investigated. In the environment, the active ingredient in this formulation is expected to bind tightly to soil or sediment and not persist. Bioaccumulation and/or long term effects are not expected. The active ingredient in this formulation may be harmful to aquatic organisms. Releases to the environment should be avoided.

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Toxicity:

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Danofloxacin mesylate

Daphnia magna (Water Flea) LC50 48 Hours 63.5 mg/L

Mysidopsis bahia (Mysid Shrimp) LC50 48 Hours > 100 mg/L

Cyprinodon variegatus (Sheepshead Minnow) LC50 48 Hours > 100 mg/L

Champia IC50 168 Hours 2.7 mg/L

2-Pyrrolidone

Daphnia magna (Water Flea) LC50/48hr 13.21mg/L

Danofloxacin mesylate Polytox IC-50 0.92 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State

specific and Community specific provisions must be considered. 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.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

U.S. DOT Reportable Quantity (RQ), 49 CFR 172.101 Appendix A:

Hydrogen chloride

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CERCLA/SARA Hazardous Substances 5000 lb and their Reportable Quantities: 2270 kg

Sodium hydroxide

CERCLA/SARA Hazardous Substances 1000 lb and their Reportable Quantities: 454 kg

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.



2-Pyrrolidone

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	210-483-1

Danofloxacin mesylate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Magnesium oxide

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	215-171-9

Povidone

40110	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

Pheno

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CERCLA/SARA 313 Emission reporting Not Listed

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15. REGULATORY INFORMATION

California Proposition 65 Not Listed EU EINECS/ELINCS List Not Listed

Hydrogen chloride

CERCLA/SARA 313 Emission reporting 1.0 %
CERCLA/SARA Hazardous Substances 5000 lb and their Reportable Quantities: 2270 kg
CERCLA/SARA - Section 302 Extremely Hazardous 500 lb

TPQs

CERCLA/SARA - Section 302 Extremely Hazardous 5000 lb

Substances EPCRA RQs

California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
Standard for the Uniform Scheduling
For Drugs and Poisons:
Schedule 6
EU EINECS/ELINCS List

Not Listed
Not Listed
Present
Schedule 5
Schedule 5
Schedule 6
231-595-7

Sodium hydroxide

Not Listed **CERCLA/SARA 313 Emission reporting CERCLA/SARA Hazardous Substances** 1000 lb and their Reportable Quantities: 454 kg **California Proposition 65** Not Listed Inventory - United States TSCA - Sect. 8(b) Present Present Australia (AICS): Standard for the Uniform Scheduling Schedule 5 for Drugs and Poisons: Schedule 6 **EU EINECS/ELINCS List** 215-185-5

Monothioglycerol

CERCLA/SARA 313 Emission reporting

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Present

EU EINECS/ELINCS List

Not Listed

Not Listed

Not Listed

Present

202-495-0

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed

Acute toxicity, dermal-Cat.3; H311 - Toxic in contact with skin

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled

Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

Germ cell mutagenicity-Cat.2; H341 - Suspected of causing genetic defects

Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

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C - Corrosive

T - Toxic

Xn - Harmful

Xi - Irritant

Mutagenic: Category 3

R34 - Causes burns.

R35 - Causes severe burns.

R23 - Toxic by inhalation.

R68 - Possible risks of irreversible effects.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

R48/20/21/22 - Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.

R23/24/25 - Toxic by inhalation, in contact with skin and if swallowed.

The data contained in this MSDS may have been gathered from confidential internal sources, Data Sources:

raw material suppliers, or from the published literature.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

Updated Section 2 - Hazard Identification. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology

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Information. Updated Section 15 - Regulatory Information.

Toxicology and Hazard Communication Prepared by:

Zoetis Global Risk Management

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.

End of Safety Data Sheet