

# SAFETY DATA SHEET



Revision date: 06-Feb-2015

Version: 3.5

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

### Product Identifier

**Material Name:** Danofloxacin mesylate injectable solution

**Trade Name:** ADVOCIN™, ADVOCID™  
**Synonyms:** Advocin Injectable Solution , Advocin 180, Advocid 180  
**Chemical Family:** Mixture

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

### Label Elements

**Signal Word:** Warning  
**Hazard Statements:** H302 - Harmful if swallowed  
H373 - May cause damage to organs through prolonged or repeated exposure ( cartilage , reproductive system , kidneys , central nervous system , heart )  
H402 - Harmful to aquatic life

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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 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)<br>Aquatic Acute 3 (H402)<br>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)<br>Acute Tox. 3 (H311)<br>STOT RE 2 (H373)<br>Muta. 2 (H341)<br>Skin Corr. 1B (H314)<br>Acute Tox. 3 (H331) | <1.0 |
| Hydrogen chloride | 7647-01-0 | 231-595-7  | T; R23<br>C; R35 | STOT SE 3 (H335)<br>Skin Corr. 1A (H314)<br>Acute Tox. 3 (H331)   | **   |
| Sodium hydroxide  | 1310-73-2 | 215-185-5  | C; R35           | Skin Corr. 1A (H314)  | **   |

| Ingredient       | CAS Number | EU EINECS/ELINCS List | EU Classification | GHS Classification | % |
|------------------|------------|-----------------------|-------------------|--------------------|---|
| 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 Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards 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.

**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 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 / Collecting:** 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.

**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**

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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### 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/m<sup>3</sup>

**Magnesium oxide**

|                                   |                        |
|-----------------------------------|------------------------|
| ACGIH Threshold Limit Value (TWA) | 10 mg/m <sup>3</sup>   |
| Australia TWA                     | 10 mg/m <sup>3</sup>   |
| Austria OEL - MAKs                | 5 mg/m <sup>3</sup>    |
| Belgium OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA                | 10.0 mg/m <sup>3</sup> |
| Czech Republic OEL - TWA          | 5 mg/m <sup>3</sup>    |
| Denmark OEL - TWA                 | 6 mg/m <sup>3</sup>    |
| France OEL - TWA                  | 10 mg/m <sup>3</sup>   |
| Germany (DFG) - MAK               | 1.5 mg/m <sup>3</sup>  |
| Greece OEL - TWA                  | 4 mg/m <sup>3</sup>    |
| Hungary OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| Ireland OEL - TWAs                | 5 mg/m <sup>3</sup>    |
| Lithuania OEL - TWA               | 4 mg/m <sup>3</sup>    |
| Vietnam OEL - TWAs                | 5 mg/m <sup>3</sup>    |
| OSHA - Final PELs - TWAs:         | 15 mg/m <sup>3</sup>   |
| Poland OEL - TWA                  | 5 mg/m <sup>3</sup>    |
| Portugal OEL - TWA                | 10 mg/m <sup>3</sup>   |
| Romania OEL - TWA                 | 10 mg/m <sup>3</sup>   |
| Slovakia OEL - TWA                | 5 mg/m <sup>3</sup>    |
| Spain OEL - TWA                   | 1.5 mg/m <sup>3</sup>  |
| Switzerland OEL - TWAs            | 4 mg/m <sup>3</sup>    |
|                                   | 10 mg/m <sup>3</sup>   |
|                                   | 3 mg/m <sup>3</sup>    |

**Phenol**

|                                       |                       |
|---------------------------------------|-----------------------|
| ACGIH Threshold Limit Value (TWA)     | 5 ppm                 |
| ACGIH - Biological Exposure Limit:    | 250 mg/g creatinine   |
| Australia TWA                         | 1 ppm                 |
| Austria OEL - MAKs                    | 4 mg/m <sup>3</sup>   |
| Belgium OEL - TWA                     | 2 ppm                 |
| Bulgaria OEL - TWA                    | 8 mg/m <sup>3</sup>   |
| Bulgaria - Biological Exposure Limit: | 2 ppm                 |
| Cyprus OEL - TWA                      | 8 mg/m <sup>3</sup>   |
| Czech Republic OEL - TWA              | 200 mg/L              |
|                                       | 8 mg/m <sup>3</sup>   |
|                                       | 2 ppm                 |
|                                       | 7.5 mg/m <sup>3</sup> |

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|                                |                                |
|--------------------------------|--------------------------------|
| Denmark OEL - TWA              | 1 ppm<br>4 mg/m <sup>3</sup>   |
| <b>Hydrogen chloride</b>       |                                |
| ACGIH Ceiling Threshold Limit: | 2 ppm                          |
| Australia PEAK                 | 5 ppm<br>7.5 mg/m <sup>3</sup> |
| Austria OEL - MAKs             | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Belgium OEL - TWA              | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA             | 5 ppm<br>8.0 mg/m <sup>3</sup> |
| Cyprus OEL - TWA               | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Czech Republic OEL - TWA       | 8 mg/m <sup>3</sup>            |
| Estonia OEL - TWA              | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Germany - TRGS 900 - TWAs      | 2 ppm<br>3 mg/m <sup>3</sup>   |
| Germany (DFG) - MAK            | 2 ppm<br>3.0 mg/m <sup>3</sup> |
| Greece OEL - TWA               | 5 ppm<br>7 mg/m <sup>3</sup>   |
| Hungary OEL - TWA              | 8 mg/m <sup>3</sup>            |
| Ireland OEL - TWAs             | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Italy OEL - TWA                | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Japan - OELs - Ceilings        | 5 ppm<br>7.5 mg/m <sup>3</sup> |
| Latvia OEL - TWA               | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Lithuania OEL - TWA            | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Luxembourg OEL - TWA           | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Malta OEL - TWA                | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Netherlands OEL - TWA          | 8 mg/m <sup>3</sup>            |
| Vietnam OEL - TWAs             | 5 mg/m <sup>3</sup>            |
| Poland OEL - TWA               | 5 mg/m <sup>3</sup>            |
| Portugal OEL - TWA             | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Romania OEL - TWA              | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Slovakia OEL - TWA             | 5 ppm<br>8.0 mg/m <sup>3</sup> |
| Slovenia OEL - TWA             | 5 ppm<br>8 mg/m <sup>3</sup>   |
| Spain OEL - TWA                | 5 ppm<br>7.6 mg/m <sup>3</sup> |

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                       |                       |
|-----------------------|-----------------------|
| Switzerland OEL -TWAs | 2 ppm                 |
|                       | 3.0 mg/m <sup>3</sup> |

**Sodium hydroxide**

|                                |                       |
|--------------------------------|-----------------------|
| ACGIH Ceiling Threshold Limit: | 2 mg/m <sup>3</sup>   |
| Australia PEAK                 | 2 mg/m <sup>3</sup>   |
| Austria OEL - MAKs             | 2 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA             | 2.0 mg/m <sup>3</sup> |
| Czech Republic OEL - TWA       | 1 mg/m <sup>3</sup>   |
| Estonia OEL - TWA              | 1 mg/m <sup>3</sup>   |
| France OEL - TWA               | 2 mg/m <sup>3</sup>   |
| Greece OEL - TWA               | 2 mg/m <sup>3</sup>   |
| Hungary OEL - TWA              | 2 mg/m <sup>3</sup>   |
| Japan - OELs - Ceilings        | 2 mg/m <sup>3</sup>   |
| Latvia OEL - TWA               | 0.5 mg/m <sup>3</sup> |
| OSHA - Final PELs - TWAs:      | 2 mg/m <sup>3</sup>   |
| Poland OEL - TWA               | 0.5 mg/m <sup>3</sup> |
| Slovakia OEL - TWA             | 2 mg/m <sup>3</sup>   |
| Slovenia OEL - TWA             | 2 mg/m <sup>3</sup>   |
| Sweden OEL - TWAs              | 1 mg/m <sup>3</sup>   |
| Switzerland OEL -TWAs          | 2 mg/m <sup>3</sup>   |

**Exposure Controls**

|                                       |  |
|---------------------------------------|--|
| <b>Engineering Controls:</b>          | 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.  |
| <b>Personal Protective Equipment:</b> | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).  |
| <b>Hands:</b>                         | Wear impervious gloves as minimum protection.  |
| <b>Eyes:</b>                          | Safety glasses or goggles  |
| <b>Skin:</b>                          | Wear impervious protective clothing when handling this compound.   |
| <b>Respiratory protection:</b>        | 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

|   |                    |                          |                    |
|---|--------------------|--------------------------|--------------------|
| <b>Physical State:</b>                                      | Sterile solution   | <b>Color:</b>            | Colorless          |
| <b>Odor:</b>  | No data available. | <b>Odor Threshold:</b>   | No data available. |
| <b>Molecular Formula:</b>                                   | Mixture            | <b>Molecular Weight:</b> | Mixture            |
| <b>Solvent Solubility:</b>                                  | No data available  |                          |                    |
| <b>Water Solubility:</b>                                    | No data available  |                          |                    |
| <b>Solubility:</b>  | Soluble: Water     |                          |                    |
| <b>pH:</b>  | 7.5                |                          |                    |
| <b>Melting/Freezing Point (°C):</b>                         | No data available  |                          |                    |
| <b>Boiling Point (°C):</b>                                  | No data available. |                          |                    |
| <b>Partition Coefficient: (Method, pH, Endpoint, Value)</b> |                    |                          |                    |
| No data available   |                    |                          |                    |
| <b>Decomposition Temperature (°C):</b>                      | No data available. |                          |                    |
| <b>Evaporation Rate (Gram/s):</b>                           | No data available  |                          |                    |
| <b>Vapor Pressure (kPa):</b>                                | No data available  |                          |                    |
| <b>Vapor Density (g/ml):</b>                                | No data available  |                          |                    |

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Relative Density: No data available  
Viscosity: No data available

### Flammability:

Autoignition Temperature (Solid) (°C): No data available  
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 Products: Thermal decomposition products may include carbon monoxide, carbon dioxide and other toxic 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.  
Routes of exposure: eye contact , skin contact

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

#### Povidone

Rat Oral LD50 100 g/kg

#### Danofloxacin mesylate

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

#### Phenol

Rat Oral LD50 317 mg/kg  
Rat Dermal LD50 669mg/kg  
Rat Inhalation LC50 316mg/m<sup>3</sup>

#### 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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**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.

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

##### **Danofloxacin mesylate**

|                 |        |           |
|-----------------|--------|-----------|
| Eye Irritation  | Rabbit | No effect |
| Skin Irritation | Rabbit | Mild      |

##### **Phenol**

|                 |        |        |
|-----------------|--------|--------|
| Eye 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)  | Dog | Oral | 2.4 mg/kg/day | NOEL | Skeletal muscle                         |
| 2 Year(s)  | Rat | Oral | 10 mg/kg/day  | LOEL | Kidney, Male reproductive system,       |

##### **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 arthropathy, 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**

|                            |       |      |                |      |                  |
|----------------------------|-------|------|----------------|------|------------------|
| Reproductive & Fertility   | Rat   | Oral | 6.25 mg/kg/day | NOEL | Fertility        |
| Embryo / Fetal Development | Rat   | Oral | 50 mg/kg/day   | NOEL | Not Teratogenic  |
| Embryo / Fetal Development | Mouse | Oral | 100 mg/kg/day  | NOEL | Not Teratogenic, |

##### **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.

##### **Teratogenicity**

No evidence of teratogenicity or embryotoxicity was observed for danofloxacin in mice, rats, or rabbits.

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

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### 11. TOXICOLOGICAL INFORMATION

#### Danofloxacin mesylate

|                               |                   |          |
|-------------------------------|-------------------|----------|
| Bacterial Mutagenicity (Ames) | <i>Salmonella</i> | Negative |
| Mammalian Cell Mutagenicity   | Mouse Lymphoma    | Negative |
| Unscheduled DNA Synthesis     | Rat Hepatocyte    | Negative |
| <i>In Vitro</i> Cytogenetics  | Human Lymphocytes | Negative |
| <i>In Vivo</i> 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.

**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  
and their Reportable Quantities: 5000 lb  
2270 kg

Sodium hydroxide  
CERCLA/SARA Hazardous Substances  
and their Reportable Quantities: 1000 lb  
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**

|   |            |
|---|------------|
| 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 |

##### **Phenol**

|                                    |            |
|------------------------------------|------------|
| 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 and their Reportable Quantities:  | 5000 lb    |
|  | 2270 kg    |
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs                 | 500 lb     |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 5000 lb    |
| California Proposition 65  | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                        | Present    |
| Australia (AICS):  | Present    |
| Standard for the Uniform Scheduling for Drugs and Poisons:         | Schedule 5 |
|  | Schedule 6 |
| EU EINECS/ELINCS List  | 231-595-7  |

**Sodium hydroxide**

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

**Monothioglycerol**

|   |            |
|---|------------|
| 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                       | 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.

**Data Sources:** The data contained in this MSDS may have been gathered from confidential internal 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 Information. Updated Section 15 - Regulatory Information.

**Prepared by:** Toxicology and Hazard Communication  
Zoetis Global Risk Management

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**End of Safety Data Sheet**