



MATERIAL SAFETY DATA SHEET

SECTION 1 - IDENTIFICATION OF PRODUCT AND COMPANY

| | | |
|-----------------------------|----------------------------|----------------|
| Pfizer Inc | Emergency telephone | 1-866-531-8896 |
| Pfizer Animal Health | Hours of operation | 24 Hours |
| 235 East 42nd Street | Telephone | 1-800-366-5288 |
| New York, NY 10017 | | |

| | |
|------------------------|--|
| Trade names | A180™ |
| Product name | Danofloxacin mesylate injectable solution |
| Chemical family | Fluoroquinolone |
| Therapeutic use | Antibiotic agent |
| Description | Sterile solution in 100 and 250 mL amber-glass, multi-dose vials |

SECTION 2 - COMPOSITION

| <u>Ingredient</u> | <u>CAS Number</u> | <u>Amount</u> |
|--------------------------|-------------------|---------------|
| Danofloxacin mesylate* | 119478-55-6 | <20% |
| 2-Pyrrolidone | 616-45-5 | Trade secret |
| Povidone | 9003-39-8 | Trade secret |
| Hydrochloric acid, NF* | 7647-01-0 | Trade secret |
| Magnesium oxide* | 1309-48-4 | Trade secret |
| Phenol* | 108-95-2 | Trade secret |
| Monothioglycerol - NF* | 96-27-5 | Trade secret |
| Sodium hydroxide NF* | 1310-73-2 | Trade secret |
| Water for injection, USP | 7732-18-5 | Trade secret |

*Hazardous

Note: Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

SECTION 3 - HAZARDS IDENTIFICATION

| | |
|-----------------------------|---|
| Signal word | CAUTION! |
| Statements of hazard | MAY CAUSE EFFECTS TO CARTILAGE AND REPRODUCTIVE SYSTEM . |
| Eye effects | Not expected to cause eye irritation. |
| Skin effects | Not expected to cause skin irritation. |
| Inhalation effects | An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8). |

SECTION 3 - HAZARDS IDENTIFICATION ... continued

| | |
|---------------------------------------|---|
| Ingestion effects | See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section. |
| 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. |
| Other potential health effects | Repeat-dose studies in animals have shown a potential to cause adverse effects on the reproductive system. 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. This compound may cause cartilage deterioration in knee joints and adverse reproductive effects (based on animal data). Quinolones may affect 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. |
| 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. |

SECTION 4 - FIRST AID MEASURES

| | |
|-------------------|--|
| Skin | Wash skin with soap and water. Remove contaminated clothing and shoes. Wash clothing and thoroughly clean shoes before reuse. If irritation occurs or persists, get medical attention. |
| Eyes | Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention. |
| Inhalation | Remove to fresh air. Get medical attention immediately. |
| Ingestion | Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. |

SECTION 5 - FIRE FIGHTING MEASURES

| | |
|--------------------------------------|---|
| Fire fighting instructions | Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance. |
| Extinguishing media | Use carbon dioxide, dry chemical, or water spray. |
| Flash point | No data available |
| Hazardous combustion products | Emits toxic fumes of carbon mono- and di- oxides, nitrogen oxides, sulfur oxides, and other fluorine- and sulfur-containing compounds |

SECTION 6 - ACCIDENTAL RELEASE MEASURES

| | |
|--------------------|--|
| General | Review Sections 3, 8 and 12 before proceeding with clean up. |
| Small spill | Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Clean spill area thoroughly. Prevent discharge to drains. |
| Large spill | Collect spill with a non-combustible absorbent material and transfer to labeled container for disposal. Close container and move it to a secure holding area. Prevent discharge to drains. |

SECTION 7 - HANDLING AND STORAGE

| | |
|--------------------------------------|--|
| General handling | Keep away from heat. Use only in a well-ventilated area. Avoid contact with skin and clothing. Wash thoroughly after handling. |
| Storage conditions | Protect from light. Protect from freezing. Keep container tightly closed when not in use. |
| Temperature range for storage | Store at or below 30°C (86°F). |

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

| | | | |
|-----------------------------|---|-------------|--|
| Exposure limits | | | |
| <u>Compound</u> | <u>Issuer</u> | <u>Type</u> | <u>OEL</u> |
| Danofloxacin mesylate | Pfizer | TWA-8 Hr | 0.2 mg/m ³ |
| Hydrochloric acid, NF | ACGIH | Ceiling | 5 ppm |
| | OSHA | Ceiling | 5 ppm |
| Magnesium oxide | ACGIH | TWA-8 Hr | 10 mg/m ³ (fume) |
| | OSHA | TWA-8 Hr | 15 mg/m ³ (total particulate) |
| Exposure information | The exposure limit(s) listed for solid components are only relevant if dust may be generated. | | |

SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ... continued

| | |
|-------------------------------|--|
| Measurement method | Danofloxacin: CAM-KSB-96-02; STP D143.13 (contact Pfizer for additional details) |
| Ventilation | Engineering controls should be used as the primary means to control exposures. Good general ventilation should be sufficient to control airborne levels. For laboratory use, handle in a lab hood. |
| 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. |
| Eye protection | Safety glasses or goggles |
| Skin protection | Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas. |
| Hand protection | Rubber gloves |

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---------------------------|-------------------|
| Physical form | Sterile solution |
| Color | Colorless |
| Molecular weight | Mixture |
| Molecular formula | Mixture |
| pH | 7.5 |
| Boiling point | No data available |
| Melting point | Not applicable |
| Density | No data available |
| Vapor pressure | No data available |
| Water solubility | Soluble |
| Solvent solubility | No data available |

SECTION 10 - STABILITY AND REACTIVITY

| | |
|---|---------------------|
| Reactivity | Stable |
| Conditions to avoid | Protect from light. |
| Incompatibilities | None known |
| Hazardous decomposition products | None known |

SECTION 10 - STABILITY AND REACTIVITY ... continued

Hazardous polymerization Will not occur

SECTION 11 - TOXICOLOGY INFORMATION

Toxicology summary There are no data for this formulation. The information included in this section describes the potential hazards of the active ingredient.

Acute toxicity

| <u>Compound</u> | <u>Type</u> | <u>Route</u> | <u>Species</u> | <u>Result</u> |
|-----------------------|------------------|--------------|----------------|----------------|
| Danofloxacin mesylate | LD ₅₀ | Oral | Rat | >2000 mg/kg |
| | LD ₅₀ | IV | Rat | 100-150 mg/kg |
| | Irritation | Ocular | Rabbit | Non-irritating |
| | Irritation | Dermal | Rabbit | Mild |

Eye See Acute toxicity table.

Skin See Acute toxicity table.

Inhalation No data available

Ingestion See Acute toxicity table

Mutagenicity Danofloxacin was negative *in vitro* and *in vivo*.

Sensitization Skin sensitization and/or photosensitization (allergic response after UV exposure) of other quinolones have been demonstrated in guinea pigs, mice, and humans.

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.

**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.

Carcinogen status None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

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.

SECTION 11 - TOXICOLOGY INFORMATION ... continued

| | |
|--|--|
| Teratogenicity | No evidence of teratogenicity or embryotoxicity was observed for danofloxacin in mice, rats, or rabbits. |
| At increased 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. |

SECTION 12 - ECOLOGICAL INFORMATION

| | |
|--|--|
| Environmental overview | In the environment, the active ingredient in this formulation is expected to bind tightly to soil or sediment and not persist. The active ingredient in this formulation may be harmful to aquatic organisms. Bioaccumulation and/or long term effects are not expected. |
| Mobility, persistence, and degradability: | Although freely soluble in water, the active ingredient in this formulation is expected to bind tightly to soil or sediment and be immobile. Unbound material is expected to degrade. |
| Bioaccumulation and toxicity: | The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to aquatic organisms are not expected. Acute toxicity to aquatic organisms may occur. See aquatic toxicity data, below. |

Aquatic toxicity

| <u>Compound</u> | <u>Type</u> | <u>Species</u> | <u>Result</u> |
|-----------------------|-------------|-------------------|---------------|
| Danofloxacin mesylate | LC50 | Daphnia magna | 63.5 mg/L |
| | LC50 | Mysid Shrimp | >100 mg/L |
| | LC50 | Sheepshead minnow | >100 mg/L |
| | IC50 | Champia | 2.7 mg/L |
| | IC50 | Polytox | 0.92 mg/L |
| | MIC | Polytox | 0.1 mg/L |

SECTION 13 - DISPOSAL INFORMATION

| | |
|---------------------------|---|
| Disposal procedure | Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material. |
|---------------------------|---|

SECTION 14 - TRANSPORTATION INFORMATION

| | |
|--------------------------------------|--|
| General shipping instructions | Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations. |
|--------------------------------------|--|

SECTION 15 - REGULATORY INFORMATION

| | |
|--------------------------|--|
| EU Classification | Harmful; Dangerous for the Environment |
|--------------------------|--|

SECTION 15 - REGULATORY INFORMATION ... continued

EU Labelling**Xn****EU Label Pictogram(s)****Risk phrases**

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
R52 - Harmful to aquatic organisms.

Safety phrases

S36 - Wear suitable protective clothing.
S57 - Use appropriate containment to avoid environmental contamination.

Canadian WHMIS

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.

SECTION 16 - OTHER

Disclaimer

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without a warranty of any kind, expressed or implied.