MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-262-8200

Emergency telephone number:
ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Alatrofloxacin mesylate intravenous solution

Trade Name: Not determined
Synonyms: TROVAN® intravenous solution
Chemical Family: Fluoronaphthyridone
Intended Use: Antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Alatrofloxacin mesylate	157605-25-9	Not listed	*

Ingredient	CAS Number	EU EINECS List	%
Water for injection	7732-18-5	231-791-2	*

Additional Information: * Proprietary

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless liquid
Signal Word: CAUTION

Statement of Hazard: Accidental ingestion of large amounts of this material may be harmful; see known clinical effects, below May cause central nervous system effects May be a liver or reproductive toxin (based on animal data)
Eye Contact: None known
Skin Contact: None known
Inhalation: None known
Ingestion: Abdominal pain, constipation, fatigue, and drowsiness have also been reported.
Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including dizziness, nausea, headache, vomiting, vaginitis, diarrhea, and rash. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. 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. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides, and other fluorine- and sulfur-containing compounds.

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning / Collecting: Contain the source of the spill or leak. Use non-combustible absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly.

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

Additional Consideration for Large Spills: Review Sections 3, 8 and 12 before proceeding with clean up. Contain the source of the spill or leak if it is safe to do so. Dike, pump, or use non-combustible material to absorb spill; then place in a suitable, labeled recovery container. Transfer all waste to a labeled container and move it to a secure holding area. Close container and move it to a secure holding area. Clean spill area thoroughly with detergent and water. Collect wash water with a non-combustible absorbant material and transfer to labeled container for treatment and disposal.

7. HANDLING AND STORAGE

General Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Use only in a well-ventilated area. Avoid contact with eyes. Avoid contact with skin and clothing. Avoid breathing vapor or mist.

Storage Conditions: Store under refrigeration in closed container. Protect from light.

Storage Temperature 0 - 5 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Alatrofloxacin mesylate

Pfizer OEL TWA-8 Hr: 0.3 mg/m³, (as free base)

Analytical Method: No method available

Engineering Controls: Good general ventilation should be sufficient to control airborne levels.

Personal Protective Equipment:

Hands: None required under normal and foreseeable conditions of use.
Eyes: Not required under normal conditions of use.
Skin: None required under normal and foreseeable conditions of use.
Respiratory protection: None required under normal conditions of use. Whenever air contamination (mist, vapor or odor) is generated, respiratory protection is recommended as a precaution to minimize exposure.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Liquid **Color:** Colorless
Molecular Formula: C26H25F3N6O5•CH3SO3H in H2O **Molecular Weight:** Mixture

Water solubility: Very soluble
pH: 3.75

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: Light
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

Hazardous Decomposition Products: No data available
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

NTP: Not classified
IARC: Not classified
OSHA: No

Alatrofloxacin mesylate

Rat Oral LD50 > 2,000 mg/kg

Ingestion Acute Toxicity The acute oral LD50 of alatrofloxacin in rats is reported to be greater than 2000 mg/kg. The intravenous minimum lethal dose are reported to be 125 mg/kg for mice and greater than 75 mg/kg for rats, with a maximum tolerated dose of 100 mg/kg in mice. Signs of toxicity observed in mice following IV dose of 125 mg/kg or greater included clonic convulsions, straub tail, twitching, tremors, gasping, and blanching prior to death. Bulging eyeball, jittery appearance, ataxia, decreased activity, decreased respiration, and flushing of the feet and ears were also reported in both mice and rats.

Subchronic Effects

Subchronic intravenous (IV) toxicity studies for alatrofloxacin were conducted in rats and dogs for 1-month. Signs of toxicity associated with IV administration were central nervous system effects at high doses of 20 or 50 mg/kg/day (dogs and rats), emesis (dogs), erythema (dogs and rats), transient recumbency and hypoactivity (rats), weight gain inhibition (rats), and a slight decrease in red blood cell parameters (rats). Rapid intravenous administration of alatrofloxacin in rodents and dogs resulted in convulsions.

Chronic Effects/Carcinogenicity

No long-term toxicity studies have been conducted to evaluate the chronic toxicity or carcinogenic potential of this material.

Reproductive Effects

See teratogenicity below.

Teratogenicity

Teratogenic potential of alatrofloxacin was evaluated in rabbits at doses of 2, 6.5 or 20 mg/kg/day and in rats at doses of 6.5, 20 or 50 mg/kg/day. At 20 mg/kg/day in rabbits, 3 does aborted, body weight and food consumption were decreased, and skeletal malformations were also noted primarly at this same level. No drug-related external or visceral malformations, and no adverse effects on numbers of corpora leutea or implantation sites, or on resorptions were reported at 2 and 6.5 mg/kg/day. Administration of 50 mg/kg/day of alatrofloxacin in rats caused decreases in maternal body weight gain and food consumption. Limited number of fetuses (26/264) presented with "kinky tails", and there were significant increases in skeletal variations, cervical ribs, shortened last ribs, asymmetry of the sternabrae, and splitting of the vertebral body. Delays in ossification and skeletal malformations were also reported. Similar effects on maternal body weight and food consumption, ossification and skeletal abnormalities were reported at 20 mg/kg/day. In these studies, the NOAEL for teratologic effects of alatrofloxacin in rabbits and rats was 6.5 mg/kg/day. Liver Central nervous system Testes

Mutagenicity

No evidence of mutagenicity was observed for this substance when it was tested in the following in vitro and in vivo assays: the Ames test, the microbial mutation assay, the mammalian cell gene mutation assay using (CHO/HGPRT), and the chromosomal aberrations assay using human lymphocytes and mouse bone marrow cells. No chromosomal aberrations or gene mutations in mammalian cells were observed for neither compound.

Carcinogen Status:

Not listed as a carcinogen by IARC, NTP or US OSHA.

At increase risk from exposure:

Individuals with a known history of hypersensitivity to this material or other materials in its chemical class may be more susceptible to toxicity in cases of overexposure.

Additional Information:

FDA PREGNANCY CATEGORY C. No adequate and well-controlled studies in pregnant women. Animal studies have shown adverse effects on the fetus. In clinical usage, it is considered that potential therapeutic benefits to the pregnant women may be acceptable despite the risk to the fetus.

12. ECOLOGICAL INFORMATION

Environmental Overview:

The use and/or disposal of this material, its metabolites and degradation products is not expected to cause adverse effects upon animals, plants, humans, other organisms, or the environment.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:

Incineration is the recommended method of disposal for this material. This material may also be disposed in landfills. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

Not regulated

Proper shipping name: Alatrofloxacin mesylate IV solution

15. REGULATORY INFORMATION

OSHA Label:
CAUTION
Accidental ingestion of large amounts of this material may be harmful; see known clinical effects, below May cause central nervous system effects May be a liver or reproductive toxin (based on animal data)

Canada - WHMIS: Classifications

WHMIS hazard class:
None required

Water for injection

EU EINECS List	231-791-2
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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.

End of Safety Data Sheet