



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Lomefloxacin Hydrochloride Tablets

Trade Name: Maxequin(R)
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Lomefloxacin Hydrochloride	98079-52-8	Not listed	442 mg ***
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Opaspray M-1-7111-B	Not Assigned	Not listed	0
Lactose Monohydrate	64044-51-5	Not listed	*
Hypromellose	9004-65-3	Not listed	*
PEG-40 Stearate	9004-99-3	Not listed	*
Hydroxypropyl cellulose	9004-64-2	Not listed	*
Carboxymethylcellulose Calcium	9050-04-8	Not listed	*
Polyethylene glycol 400	25322-68-3	Not listed	*

Additional Information: * Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White Tablets
Signal Word: DANGER

Statement of Hazard: Harmful if swallowed.
May damage the unborn child.
Toxic to aquatic life with long lasting effects.

Additional Hazard Information:
Short Term: Photosensitivity may occur.
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on blood, gastrointestinal system, liver, kidneys.

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Known Clinical Effects: Clinical use of this drug has caused photosensitivity, skin rash, nausea, diarrhea, abdominal pain, tongue discoloration, headache, seizure.

EU Indication of danger: Harmful
Toxic to Reproduction: Category 2
Dangerous for the Environment

EU Hazard Symbols:



EU Risk Phrases:

R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

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: 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. If irritation occurs or persists, get medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: May burn emitting oxides of: carbon nitrogen hydrogen fluoride

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

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 spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

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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:

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

General Handling:

If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid generating airborne dust. Wash thoroughly after handling.

Storage Conditions:

Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lomefloxacin Hydrochloride

Pfizer OEL TWA-8 Hr:

0.035mg/m³

Magnesium stearate

ACGIH Threshold Limit Value (TWA)

= 10 mg/m³ TWA except stearates of toxic metals

Australia TWA

= 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Analytical Method:

Analytical method available for Lomefloxacin. Contact Pfizer Inc for further information.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands:

Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes:

Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin:

Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection:

Not required for the normal use of this product. 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:

Film-coated tablets

Color:

White

Molecular Formula:

Mixture

Molecular Weight:

Mixture

10. STABILITY AND REACTIVITY

Stability:

Stable under normal conditions of use.

Conditions to Avoid:

None known

Incompatible Materials:

As a precautionary measure, keep away from strong oxidizers.

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11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

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

Lomefloxacin Hydrochloride

Rat Oral LD50 1556 mg/kg

Lactose Monohydrate

Rat Oral LD50 29700 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg

Rat Inhalation LC50 > 2000 mg/m³

PEG-40 Stearate

Rat Oral LD50 > 20,000 mg/kg

Hypromellose

Rat Oral LD50 > 10,000 mg/kg

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)

Polyethylene glycol 400

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

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

Lomefloxacin Hydrochloride

90 Day(s) Dog Oral 25 mg/kg/day LOAEL Skeletal muscle

91 Day(s) Rat 300 mg/kg/day LOAEL Gastrointestinal system, Liver, Kidney

1 Year(s) Non-human Primate Oral 100 mg/kg/day LOAEL Blood

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

Lomefloxacin Hydrochloride

Embryo / Fetal Development Rabbit Oral 25 mg/kg LOAEL Fetotoxicity

Embryo / Fetal Development Monkey Oral 50 mg/kg LOAEL Fetotoxicity

Embryo / Fetal Development Monkey Oral Not Teratogenic

Embryo / Fetal Development Rabbit 50 mg/kg/day LOAEL Teratogenic

Embryo / Fetal Development Rat 300 mg/kg/day LOAEL Teratogenic

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

Lomefloxacin Hydrochloride

Bacterial Mutagenicity (Ames) *Salmonella*, *E. coli* Negative

Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative

Chromosome Aberration Human Lymphocytes Negative

In Vivo Micronucleus Mouse Negative

Mammalian Cell Mutagenicity HGPRT Positive

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

12. ECOLOGICAL INFORMATION

Environmental Overview: The active ingredient in this formulation : Toxic to aquatic life with long lasting effects. See Aquatic toxicity data of the active ingredient, below:

Mobility, Persistence and Degradability: The active ingredient in this formulation : Not readily biodegradable.

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

Lomefloxacin Hydrochloride

Rainbow Trout	LC-50	24 Hours	> 500 mg/L
Hyallolela azteca	LC-50	48 Hours	420 mg/L
Daphnia	LC-50	24 Hours	> 290 mg/L
Daphnia	LC-50	48 Hours	130 mg/L
Skeletonema Algae	LC-50	48 Hours	2.84 mg/L

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: T ; N
EU Indication of danger: Harmful
Toxic to Reproduction: Category 2
Dangerous for the Environment

EU Risk Phrases:
R22 - Harmful if swallowed.
R61 - May cause harm to the unborn child.
R51/53 - Toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

EU Safety Phrases:
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S61 - Avoid release to the environment. Refer to special instructions/Safety data sheets.

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OSHA Label:

DANGER

Harmful if swallowed.

May damage the unborn child.

Toxic to aquatic life with long lasting effects.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

Lactose Monohydrate

Australia (AICS):	Present
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Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

PEG-40 Stearate

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Hydroxypropyl cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Carboxymethylcellulose Calcium

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Polyethylene glycol 400

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by:

Corporate Occupational Toxicology & Hazard Assessment

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End of Safety Data Sheet