MATERIAL SAFETY DATA SHEET

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

Pfizer Inc
Pfizer Pharmaceuticals Group
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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): 1-800-424-9300

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

Material Name: Draxxin (Tulathromycin) solution for injection

Trade Name: Draxxin
Synonyms: Tulathromycin injectable solution
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Tulathromycin	217500-96-4	Not listed	10
Monothioglycerol	96-27-5	202-495-0	*
Citric acid	77-92-9	201-069-1	*
Hydrogen chloride	7647-01-0	231-595-7	**
Sodium hydroxide	1310-73-2	215-185-5	**
Propylene glycol	57-55-6	200-338-0	*

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

Additional Information:
* Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to slightly yellow solution in multiple-dose vials
Signal Word: WARNING

Statement of Hazard:
May cause eye irritation
May cause allergic skin reaction.

Additional Hazard Information:
Short Term: May cause eye and skin irritation (based on components) . May cause allergic reaction (based on animal data) . Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain.

EU Indication of danger: Irritant

EU Hazard Symbols:

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact: Remove clothing and wash affected skin with soap and water. 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. 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: May emit toxic fumes of oxides of carbon and nitrogen.

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 spill with absorbent material. 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: 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: Use appropriate ventilation. Avoid breathing dust, vapor or mist. Avoid contact with eyes, skin and clothing.

Storage Conditions: Keep container tightly closed when not in use.

Storage Temperature: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tulathromycin
Pfizer OEL TWA-8 Hr: 1 mg/m³, Sensitizer

Hydrogen chloride
ACGIH Ceiling Threshold Limit: = 2 ppm Ceiling
Australia PEAK = 5 ppm Peak
= 7.5 mg/m^3 Peak

Sodium hydroxide
OSHA - Final PELS - TWAs: 2 mg/m³
ACGIH Ceiling Threshold Limit: = 2 mg/m^3 Ceiling
Australia PEAK = 2 mg/m^3 Peak

Propylene glycol
Australia TWA = 10 mg/m^3 TWA
= 150 ppm TWA
= 474 mg/m^3 TWA

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

Analytical Method: Analytical method available for Tulathromycin. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local and general ventilation should be used as necessary, when handling this material in bulk.

Personal Protective Equipment:

Hands: Wear two layers of disposable gloves.
Eyes: Safety glasses or goggles
Skin: Protective coveralls should be worn. The sleeves should either be taped or have gloves worn over them to prevent material from contacting the 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:	Solution in multiple-dose vials	**Color:**	Colorless to slightly yellow
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

pH: 5.4

10. STABILITY AND REACTIVITY

Stability: Stable
Conditions to Avoid: None known
Incompatible Materials: No data available

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

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)

Citric acid
Rat Oral LD50 3000 mg/kg

Propylene glycol
Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Tulathromycin
Rat Oral LDmin. > 2000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Hydrogen chloride
Rat Inhalation LC50 1H 3,124 ppm
Mouse Inhalation LC50 1H 1,108 ppm
Mouse Oral LD50 900 mg/kg

Sodium hydroxide
Mouse IP LD50 40 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)

Citric acid
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Tulathromycin
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Positive
Skin Sensitization - GPMT Guinea Pig Severe

Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

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

Tulathromycin

1 Month(s)	Rat	Oral	50 mg/kg/day	NOAEL	Liver, Blood
3 Month(s)	Rat	Oral	15 mg/kg/day	NOAEL	Liver
1 Month(s)	Dog	Oral	15 mg/kg/day	NOAEL	Liver
3 Month(s)	Dog	Oral	5 mg/kg/day	NOEL	Liver
1 Year(s)	Dog	Oral	5 mg/kg/day	NOAEL	Liver, Male reproductive system

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

Tulathromycin

2 Generation Reproductive Toxicity	Rat	Oral	50 mg/kg/day	NOAEL	Paternal toxicity
2 Generation Reproductive Toxicity	Rat	Oral	100 mg/kg/day	NOAEL	Neonatal toxicity, Fertility
Embryo / Fetal Development	Rat	Oral	200 mg/kg/day	NOAEL	No effects at maximum dose
Embryo / Fetal Development	Rabbit	Oral	50 mg/kg/day	NOAEL	No effects at maximum dose

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

Tulathromycin

Bacterial Mutagenicity (Ames)	*Salmonella*	Negative
In Vitro Chromosome Aberration	Human Lymphocytes	Negative
In Vivo Micronucleus Chromosome Aberration	Rat	Negative
In Vitro Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
In Vitro Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative

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

Hydrogen chloride

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Based on the concentration of the active ingredient in the formulation, No harmful effects to aquatic organisms are expected.

Bioaccumulation and Toxicity: The active ingredient was not acutely toxic to aquatic organisms at its maximum solubility. See aquatic toxicity data, below.

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

Tulathromycin

Daphnia Magna	OECD	EC50	1 hr Hours	> 20	mg/L
Mysid Shrimp	OECD	LC50	48 Hours	> 20	mg/L
Sheepshead Minnow	OECD	LC50	48 Hours	> 20	mg/L
Red Algae	OECD	IC50	168 Hours	> 20	mg/L

Aquatic Toxicity Comments: A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Tulathromycin
Polytox IC-50 24 Hours 19 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: Xi
EU Indication of danger: Irritant

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S24/25 - Avoid contact with eyes and skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause eye irritation
May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B

Water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Monothioglycerol

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

EU EINECS List	202-495-0

Citric acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1

Hydrogen chloride

CERCLA/SARA 313 Emission reporting	= 1.0 % de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ = 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 5000 lb EPCRA RQ gas only
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS List	231-595-7

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ = 454 kg final RQ
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 List	215-185-5

Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet