



MATERIAL SAFETY DATA SHEET

Revision date: 11-Aug-2005

Version: 1.1

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

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Material Name: Draxxin (Tulathromycin) Solution for Injection

Trade Name: DRAXXIN
Synonyms: Tulathromycin injectable solution
Chemical Family: Triamilide
Intended Use: Antibiotic agent

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Tulathromycin	217500-96-4	Not listed	10
Citric acid	77-92-9	201-069-1	Proprietary
Monothioglycerol	96-27-5	202-495-0	Proprietary
Sodium hydroxide	1310-73-2	215-185-5	to adjust pH
Hydrogen chloride	7647-01-0	231-595-7	to adjust pH

Ingredient	CAS Number	EU EINECS List	%
Propylene glycol	57-55-6	200-338-0	Proprietary
Water	7732-18-5	231-791-2	Proprietary

Additional Information: 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

Eye Contact: May cause irritation based on components.
Skin Contact: May cause irritation based on components. May cause allergic skin reaction (based on animal data).
Inhalation: An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).
Ingestion: 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.

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Potential Health Effects:

Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. In the event of accidental injection, an allergic reaction may occur. If an allergic reaction occurs, the worker should be removed to the nearest emergency room and the appropriate therapy instituted.
Irritant

EU Indication of danger:

EU Hazard Symbols:

Xi



R43 - May cause sensitization by skin contact.

Additional Information:
Note:

For a more detailed discussion of potential health hazards and toxicity see Section 11. 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 contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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:

Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Use caution in approaching fire.

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:

Absorb spills with non-combustible absorbent material and transfer into a labeled 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:

Collect spill with a non-combustible absorbent material. Transfer all waste to a labeled container and move it to a secure holding area.

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Additional Information: Review Sections 3, 8 and 12 before proceeding with clean up.

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: 1mg/m³, Sensitizer

Sodium hydroxide

OSHA - Final PELs - TWAs 2 mg/m³

Analytical Method: Tulathromycin: CAM-XX-00-002; STP-C 181.28 (contact Pfizer for additional details)

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 impervious gloves if skin contact is possible.
Eyes: Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing with long sleeves to avoid skin contact.
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 +/- 0.3		

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

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

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

Tulathromycin

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

Propylene glycol

Mouse Oral LD50 22 g/kg
Rat Oral LD50 20 g/kg
Rabbit Dermal LD50 20.8 g/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Hydrogen chloride

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

Citric acid

Rat Oral LD50 3000 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)

Tulathromycin

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

Propylene glycol

Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Sodium hydroxide

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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))

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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)	<i>Salmonella</i>	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> Micronucleus Chromosome Aberration	Rat	Negative
<i>In Vitro</i> Chromosome Aberration	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> 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: Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Labeling: 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

Propylene glycol

EU EINECS List 200-338-0
Inventory - United States TSCA - Sect. 8(b) Listed

Water

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

Citric acid

EU EINECS List 201-069-1
Inventory - United States TSCA - Sect. 8(b) Listed

Monothioglycerol

EU EINECS List 202-495-0
Inventory - United States TSCA - Sect. 8(b) Listed

Sodium hydroxide

CERCLA/SARA Hazardous Substances and their Reportable Quantities: 1000 lb final RQ
454 kg final RQ
EU EINECS List 215-185-5
Inventory - United States TSCA - Sect. 8(b) Listed

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

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CERCLA/SARA Hazardous Substances and their Reportable Quantities:	2270 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	500 lb TPQ
EU EINECS List	5000 lb
Inventory - United States TSCA - Sect. 8(b)	231-595-7
	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