Safety Data Sheet
European Format

Minocin Oral Suspension

Preparation Date 05-Jan-2007 **Revision Date** Not applicable **Revision Number** Not applicable

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

Product Name	Minocin Oral Suspension
Common Name	Not available
Chemical Name	Not applicable
Synonyms	Not available
Product Use	Pharmaceutical product
Classification	Anti-infective Agent
Supplier	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
Emergency Telephone Number	Chemtrec USA, Puerto Rico, Canada 1-800-424-9300 Chemtrec International 1-703-527-3887

2. COMPOSITION/INFORMATION ON INGREDIENTS

3. HAZARDS IDENTIFICATION

Emergency Overview

This contains an active pharmaceutical ingredient that can affect body functions; handle with caution.

Appearance Biopharmaceutical liquid **Physical State** Liquid **Odor** Alcohol odor

Potential Physical Hazards Not available

Potential Health Effects

Eyes	Irritating to eyes.
Skin	May cause irritation.
Inhalation	May cause mucous membrane and upper respiratory tract irritation.
Ingestion	The most common effects may include photosensitivity, central nervous system effects (lightheadedness, dizziness, vertigo), superinfection, nausea, vomiting, intracranial hypertension, and hepatotoxicity. May cause cancer. May cause harm to the unborn child. May cause harm to breastfed babies. Please see Patient Package Insert for further information.
Therapeutic Target Organ(s)	None Not listed by OSHA, NTP or IARC.

Potential Environmental Effects There is no known ecological information for this product.

4. FIRST AID MEASURES

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.

Skin Contact Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.

Inhalation Move to fresh air. Artificial respiration and/or oxygen may be necessary. If symptoms persist, call a physician.

Ingestion If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.

5. FIRE-FIGHTING MEASURES

Flammable Properties Slightly flammable

Extinguishing Media

Suitable Extinguishing Media Use alcohol-resistant foam, dry chemical or carbon dioxide..

Unsuitable Extinguishing Media Do NOT use water jet.

Fire Fighting Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. In the event of fire and/or explosion do not breathe fumes.

Hazardous Combustion Products Carbon oxides, nitrogen oxides.

Protective Equipment and Precautions for Firefighters In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Refer to protective measures listed in Sections 7 and 8.

Environmental Precautions Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained.

Methods for Containment Not available

Methods for Cleaning up Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.

7. HANDLING AND STORAGE

Handling For personal protection see Section 8. Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.

Storage No special safety precautions required. Keep container tightly closed.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name	**Exposure Guideline**
Minocycline Hydrochloride	200 mcg/m^3

Common Name	**Exposure Guideline**
Ethanol	1900 mg/m^3

Engineering Controls Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated.

Personal Protective Equipment

Eye/face Protection Provide eye protection based on risk assessment.
Skin Protection Wear nitrile or latex gloves. Wear protective garment.
Respiratory Protection No personal respiratory protective equipment normally required.

General Hygiene Considerations When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.

Other Limit access to only personnel trained in the safe handling of this material. Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Biopharmaceutical liquid	**Physical State**	Liquid
Color	Yellow	**Odor**	Alcohol odor
Odor Threshold	Not available		
pH	2 - 2.8		
Specific Gravity	Not available	**Water Solubility**	Not available
Solubility	Not applicable	**Evaporation Rate**	Not available
Partition Coefficient (n-octanol/water)	Not available	**Vapor Density**	Not available
Vapor Pressure	Not available		
Boiling Point	78.5°C / 173°F	**Autoignition Temperature**	Not applicable
Flash Point	Not applicable	**Melting Point**	217°C / 423°F
Flammability Limits in Air	**Upper** Not applicable	**Lower** Not applicable	
Explosion Limits	**Upper** Not applicable	**Lower** Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability Stable at room temperature.

Conditions to Avoid No data available

Materials to Avoid No materials to be especially mentioned.

Hazardous Decomposition Products None under normal use.

Possibility of Hazardous Reactions None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Minocycline Hydrochloride

LD50 Oral	2380 mg/kg rats 1700 mg/kg mice
Acute Dermal Irritation	Not irritating to rabbit skin.
Primary Eye Irritation	Non irritating.
Sensitization	Not a dermal sensitizer in guinea pigs.

Ethanol

LD50 Oral	3450 mg/kg mice 7060 mg/kg rats
Acute Dermal Irritation	Moderate irritation effect in rabbits.
Primary Eye Irritation	Severely irritating to rabbit eyes.
Sensitization	Not applicable

Multiple Dose Toxicity

Ethanol

No Toxicologic Effect Dose/Species/Study Length:	Repeated contact can dry the skin with cracking, peeling, and itching. Repeated high exposure may affect the liver and nervous system.

Minocycline Hydrochloride

No Toxicologic Effect Dose/Species/Study Length:	This compound was tolerated in rats in repeat-dose toxicity studies for 5 months at low dosage; higher doses caused liver toxicity. This compound was tolerated in dogs in repeat-dose toxicity studies for 5 months at low dosage; high doses caused blood effects, anorexia, body weight loss, thyroid pigmentation, thyroid hyperplasia, and skeletal discoloration.

Maximum Tolerated Dose (MTD), Oral

Ethanol

Carcinogenicity	No data available
Genetic Toxicity	May cause genetic changes.
Reproductive Toxicity	See Developmental Toxicity.
Developmental Toxicity	Repeated exposure may cause spontaneous abortions, as well as birth defects and other developmental problems (fetal alcohol syndrome).

Minocycline Hydrochloride

Carcinogenicity	In long-term carcinogenicity studies in rats, dietary administration of this compound revealed an evidence of thyroid tumor production. Thyroid hyperplasia was also found in rats and dogs treated with this compound.
Genetic Toxicity	Not tested; positive results in *in vitro* mammalian cell assays have been reported for related compounds.
Reproductive Toxicity	General reproduction and fertility studies have been conducted and revealed an evidence of impaired fertility in male rats.
Developmental Toxicity	The teratogenic potential of this compound was assessed in the mouse, rat, rabbit, dog, and monkey and revealed an evidence of adverse effects on skeletal development at maternally toxic doses. This compound crosses the placenta and may cause fetal harm.

Ethanol

Target Organ(s) of Toxicity	No data available

Minocycline Hydrochloride

Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information Not available

Ecotoxicity Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

15. REGULATORY INFORMATION

According to present data no classification and labeling is required according to Directives 67/548/EEC or 1999/45/EC.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety
Format This MSDS was prepared in accordance with Directive 2001/58/EC.
List of References See Patient Package Insert for more information.
Revision Summary Not applicable

Disclaimer:
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End of MSDS