

Minocin Capsules

Preparation Date 01-Nov-2006

Revision Date 09-Sep-2008

Revision Number 2

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

Product Name Minocin Capsules
Common Name Not available
Chemical Name Not applicable
Synonyms Not available
Product Use Pharmaceutical product
Classification Anti-infective Agent

Supplier Wyeth
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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

Common Name	CAS-No	EC No.	Composition	Classification
Inactive Ingredients	Not applicable	Not applicable	Remainder	Not applicable
Minocycline Hydrochloride	13614-98-7	237-099-7	50 - 100 mg/capsule	R45/61, S13/37/38/39

3. HAZARDS IDENTIFICATION

Emergency Overview

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

Appearance Pharmaceutical Capsule **Physical State** Solid **Odor** Not available

Potential Physical Hazards

Powders and solids are presumed to be combustible.

Potential Health Effects

Eyes

Not available

Skin

Not available

Inhalation

Not available

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 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 Not flammable

Extinguishing Media

Suitable Extinguishing Media Use water spray, 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

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	Base respirator selection on a risk assessment.
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	Pharmaceutical Capsule	Physical State	Solid
Color	Various	Odor	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	Water Solubility	Not available
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Density	Not applicable
Vapor Pressure	Not applicable		
Boiling Point	Not applicable	Autoignition Temperature	Not applicable
Flash Point	Not applicable	Melting Point	Not available
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.

Multiple Dose Toxicity

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

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 <i>in vitro</i> 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.

Minocycline Hydrochloride	
Target Organ(s) of Toxicity	No data available

12. ECOLOGICAL INFORMATION

Chemical Fate Information	Not available
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Ecotoxicity	Not available
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13. DISPOSAL CONSIDERATIONS

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

Transport Information	This material is not classified as hazardous for transport.
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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	Changes to Section 11 based on Supplier MSDS.

Disclaimer:

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End of MSDS