

Material Safety Data Sheet ANSI Format

Minocin Solid Products

Preparation Date 26-Jan-2007 Revision Date 29-Jan-2008 Revision Number 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Minocin Solid Products

Common NameNot availableChemical NameNot applicable

Synonyms Minocin Tablets, Minocin Capsules, Minocycline Hydrochloride

Product Use Pharmaceutical product Classification Pharmaceutical product 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. HAZARDS IDENTIFICATION

Emergency Overview

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

Appearance Pharmaceutical tablet or

capsule

Physical State Solid

Odor Not available

Potential Physical Hazards Powders and solids are presumed to be combustible.

Potential Health Effects

EyesNot availableSkinNot availableInhalationNot 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.

Other Not available

Therapeutic Target Organ(s) None

Not listed by OSHA, NTP or IARC.

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

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Minocycline Hydrochloride	13614-98-7	50 - 100 mg/tablet or capsule
Inactive Ingredients	Not applicable	.? mg/tablet

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 Presumed to be a combustible particulate solid.

Extinguishing Media

Suitable Extinguishing Media

Unsuitable Extinguishing Media

Use water spray, foam, dry chemical or carbon dioxide.

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.

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7. HANDLING AND STORAGE

For personal protection see Section 8. Handle in accordance with good industrial hygiene and Handling

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/m³

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. Base respirator selection on a risk assessment. **Respiratory Protection**

When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands **General Hygiene**

Considerations 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 tablet or capsule Physical State Solid

Color Various Odor Not available

Odor Threshold Not available

Not available pН

Not applicable Not available **Specific Gravity Water Solubility** Solubility Not applicable **Evaporation Rate** Not applicable

Partition Coefficient Not available Not applicable Vapor Pressure (n-octanol/water)

Boiling Point Not applicable **Autoignition Temperature** Not applicable **Flash Point** Not applicable Method None

Melting Point Not available

Flammability Limits Upper Not applicable Lower Not applicable in Air

Explosion Limits Upper Not applicable Lower Not applicable

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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 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.

Minocycline Hydrochloride

Target Organ(s) of Toxicity No data available

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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.

U.S. Department of Transport (DOT)

Canadian Transport of Dangerous Goods (TDG)

International Civil Aviation Organization (ICAO)

Not regulated Not regulated International Air Transport Association (IATA)

Not regulated International Maritime Dangerous Goods (IMDG)/International Not regulated

Maritime Organization (IMO)

Transport of Dangerous Goods by Rail (RID)

Transport of Dangerous Goods by Road (ADR)

Not regulated

Transportation of Dangerous Goods via Inland Waterways

Not regulated

(ADN)

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status

This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health HazardNoChronic Health HazardYesFire HazardNoSudden Release of Pressure HazardNoReactive HazardNo

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This product does not contain any HAPs.

State Regulations

California Proposition 65

Listed on Proposition 65 as Developmental.

Canada

Not classified

WHMIS Hazard Class

Not determined

European Union

In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By Wyeth Department of Environment, Health & Safety

Format This MSDS was prepared in accordance with ANSI Z400.1-2004.

List of References See Patient Package Insert for more information.

Revision Summary Administrative

Disclaimer:

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End of MSDS