

Minocin Intravenous

Preparation Date 09-Jan-2007

Revision Date Not applicable

Revision Number Not applicable

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

Product Name Minocin Intravenous
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 Pharmaceutical powder

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

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| 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

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| 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

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| 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

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| 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 |

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 powder | 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 | Method | None |
| 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

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| 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**

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|---|---|
| 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**

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| 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

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| Target Organ(s) of Toxicity | No data available |
|------------------------------------|-------------------|

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

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| Chemical Fate Information | Not available |
|----------------------------------|---------------|

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|--------------------|---------------|
| Ecotoxicity | Not available |
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13. DISPOSAL CONSIDERATIONS

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

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| 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 | Not applicable |

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End of MSDS