



Novantrone

Preparation Date 26-Jan-2007

Revision Date 28-Mar-2008

Revision Number 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name Novantrone
Common Name Not available
Chemical Name Not applicable
Synonyms Mitoxantrone HCl
Product Use Pharmaceutical product
Classification Antineoplastic 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 Biopharmaceutical liquid **Physical State** Liquid **Odor** Not available

Potential Physical Hazards Not available

Potential Health Effects

Eyes Irritating to eyes.
Skin Not available
Inhalation Not available
Ingestion The most common effects may include cardiotoxicity, congestive heart failure, myelosuppression, nausea, alopecia, menstrual disorder, may cause eye irritation, upper respiratory tract infection, urinary tract infection, stomatitis, arrhythmia, diarrhea, urine abnormal, constipation, back pain, sinusitis, headache, and blue-green color to the urine.

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) Systemic.

Listed by NTP and IARC. Not listed by OSHA.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Mitoxantrone HCl	70476-82-3	2 mg/ml
Inactive Ingredients	Not applicable	Remainder

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	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

Common Name Mitoxantrone HCl	Exposure Guideline 0.2 mcg/m ³
Engineering Controls	Enclose operations to prevent aerosol generation. Use HEPA filtered, externally vented, biosafety cabinet when preparing or handling this product.
Personal Protective Equipment	
Eye/face Protection	Wear safety glasses with side-shields.
Skin Protection	Wear double gloves or "chemotherapy" gloves. Immediately change gloves when torn, punctured, or contaminated. Wear closed-front, low-permeability protective gowns with tight-fitting wrist cuffs when working with this product.
Respiratory Protection	Base respirator selection on a risk assessment.
General Hygiene Considerations	Avoid contact with skin, eyes and clothing. Conduct a task-specific risk assessment prior to authorizing work with this product. Wash hands before breaks and immediately after handling this product.
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	Clear	Odor	Not available
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not available	Water Solubility	Sparingly soluble in water
Solubility	Not applicable	Evaporation Rate	Not applicable
Partition Coefficient (n-octanol/water)	Not available	Vapor Density	Not available
Vapor Pressure	Not applicable		
Boiling Point	Not available	Autoignition Temperature Method	Not applicable
Flash Point	Not applicable		None
Melting Point	Not applicable		
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

Mitoxantrone HCl	
LD50 Oral	502 mg/kg mouse 682 mg/kg rat
Acute Dermal Irritation	Not irritating to rabbit skin.
Primary Eye Irritation	Very irritating to the rabbit eye.
Sensitization	Not a dermal sensitizer in guinea pigs.

Multiple Dose Toxicity

Mitoxantrone HCl	
No Toxicologic Effect	In a series of subchronic and chronic studies in several laboratory animals, mitoxantrone produced toxicity in bone marrow, lymphoid organs, heart, gastrointestinal tract, and kidneys.
Dose/Species/Study Length:	

Maximum Tolerated Dose (MTD), Oral

Mitoxantrone HCl	
Carcinogenicity	An increased incidence of fibroma and external auditory canal tumors were observed in mice and rats. Male mice also showed an increased incidence of liver adenomas.
Genetic Toxicity	Evidence of Genotoxicity was observed in a battery of studies.
Reproductive Toxicity	Studies in rats found an increased incidence of low fetal birth weight and retarded development of the fetal kidney. In rabbits, studies found an increased incidence of premature delivery.
Developmental Toxicity	Not found to be teratogenic in rabbits.

Mitoxantrone HCl	
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.

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated
Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

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 Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

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

Changes to Section 8

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End of MSDS