



MATERIAL SAFETY DATA SHEET

Revision date: 26-Jan-2012

Version: 2.0

Page 1 of 8

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Material Name: Mitoxantrone Hydrochloride Injection

Trade Name:	Mitoxantrone Injection
Synonyms:	Mitoxantrone
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as Antineoplastic agent.

2. HAZARDS IDENTIFICATION

Appearance: Aqueous sterile solution, dark blue.
Signal Word: DANGER

Statement of Hazard: May cause cancer.
May cause genetic defects.

Additional Hazard Information:
Short Term: May cause skin irritation. May cause eye irritation (based on components) .
Long Term: Animal studies indicate that this material may cause adverse effects on the the developing fetus.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include hematological effects, kidney effects, gastrointestinal disturbances, cardiovascular effects, liver effects, and skin reaction.

EU Indication of danger: Carcinogenic: Category 2
Mutagenic: Category 2

EU Hazard Symbols:



EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Mitoxantrone Hydrochloride Injection
Revision date: 26-Jan-2012

Page 2 of 8
Version: 2.0

2. HAZARDS IDENTIFICATION

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Mitoxantrone Hydrochloride	70476-82-3	274-619-1	Xn,R21-R22; Mut. Cat.2,R46; Repr. Cat.2,R61; Canc. Cat.2,R45	0.2
Acetic acid USP - glacial	64-19-7	200-580-7	C;R35 R10	0.08

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Edetate disodium	139-33-3	205-358-3	Not Listed	*
Nitrogen, NF	7727-37-9	231-783-9	Not Listed	###
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	###
Sodium acetate	127-09-3	204-823-8	Not Listed	**

Additional Information: * Proprietary
** to adjust pH
as required
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

MATERIAL SAFETY DATA SHEET

Material Name: Mitoxantrone Hydrochloride Injection
Revision date: 26-Jan-2012

Page 3 of 8
Version: 2.0

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: Restrict access to work area. Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Mitoxantrone Hydrochloride Pfizer OEL TWA-8 Hr:	0.3µg/m ³ , Skin
Acetic acid USP - glacial	
ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm
	37 mg/m ³
Australia TWA	10 ppm
	25 mg/m ³
Austria OEL - MAKs	10 ppm
	25 mg/m ³
Belgium OEL - TWA	10 ppm
	25 mg/m ³
Bulgaria OEL - TWA	25.0 mg/m ³
Cyprus OEL - TWA	10 ppm
	25 mg/m ³
Czech Republic OEL - TWA	25 mg/m ³

MATERIAL SAFETY DATA SHEET

Material Name: Mitoxantrone Hydrochloride Injection
Revision date: 26-Jan-2012

Page 4 of 8
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Denmark OEL - TWA	10 ppm 25 mg/m ³
Estonia OEL - TWA	10 ppm 25 mg/m ³
Finland OEL - TWA	5 ppm 13 mg/m ³
Germany - TRGS 900 - TWAs	10 ppm 25 mg/m ³
Germany (DFG) - MAK	10 ppm 25 mg/m ³
Greece OEL - TWA	10 ppm 25 mg/m ³
Hungary OEL - TWA	25 mg/m ³
Ireland OEL - TWAs	10 ppm 25 mg/m ³
Latvia OEL - TWA	10 ppm 25 mg/m ³
Lithuania OEL - TWA	10 ppm 25 mg/m ³
Luxembourg OEL - TWA	10 ppm 25 mg/m ³
Malta OEL - TWA	10 ppm 25 mg/m ³
OSHA - Final PELs - TWAs:	10 ppm 25 mg/m ³
Poland OEL - TWA	15 mg/m ³
Portugal OEL - TWA	10 ppm
Romania OEL - TWA	10 ppm 25 mg/m ³
Slovakia OEL - TWA	10 ppm 25 mg/m ³
Slovenia OEL - TWA	10 ppm 25 mg/m ³
Spain OEL - TWA	10 ppm 25 mg/m ³
Sweden OEL - TWAs	5 ppm 13 mg/m ³

Sodium chloride

Latvia OEL - TWA	5 mg/m ³
Lithuania OEL - TWA	5 mg/m ³

Analytical Method:

Analytical method available for Mitoxantrone Hydrochloride. Contact Pfizer Inc for further information.

Engineering Controls:

Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls:

Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands:

Impervious, disposable gloves (double suggested) are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

MATERIAL SAFETY DATA SHEET

Material Name: Mitoxantrone Hydrochloride Injection
Revision date: 26-Jan-2012

Page 5 of 8
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Skin: Impervious disposable protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Sterile solution	Color:	Dark blue
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Edetate disodium

Rat Oral LD50 2000-2200 mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Mitoxantrone Hydrochloride

Rat Oral LD50 682 mg/kg
Mouse Oral LD50 502 mg/kg
Rat Dermal LD50 1640 mg/kg
Rabbit Dermal LD50 125 mg/kg
Rat Intravenous LD50 4.8 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Mitoxantrone Hydrochloride

Reproductive & Fertility Rat No route specified 0.25 mg/kg LOAEL Fetotoxicity
Reproductive & Fertility Rabbit Intravenous 0.5 mg/kg NOAEL Negative

MATERIAL SAFETY DATA SHEET

Material Name: Mitoxantrone Hydrochloride Injection
Revision date: 26-Jan-2012

Page 6 of 8
Version: 2.0

11. TOXICOLOGICAL INFORMATION

Embryo / Fetal Development	Rabbit	No route specified	0.2 mg/kg/day	NOAEL	Teratogenic
Embryo / Fetal Development	Rat	No route specified	6 mg/kg/day	NOAEL	No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Mitoxantrone Hydrochloride

<i>In Vivo</i> Cytogenetics	Rat	Positive
Unscheduled DNA Synthesis	Rat Hepatocyte	Positive
Sister Chromatid Exchange	Chinese Hamster Ovary (CHO) cells	Positive
<i>In Vitro</i> Chromosome Aberration	Hamster	Positive
Somatic Mutation & Recombination Test (SMART)	Drosophila	Positive

Carcinogen Status: See below

Mitoxantrone Hydrochloride

IARC: Group 2B (Possibly Carcinogenic to Humans)
OSHA: Listed

At increase risk from exposure: This material has been shown to be secreted in low concentrations in human breast milk. Women of childbearing age or nursing mothers should exercise caution regarding exposure.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Carcinogenic: Category 2
Mutagenic: Category 2

MATERIAL SAFETY DATA SHEET

Material Name: Mitoxantrone Hydrochloride Injection
Revision date: 26-Jan-2012

Page 7 of 8
Version: 2.0

15. REGULATORY INFORMATION

EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.

EU Safety Phrases:

S36/37 - Wear suitable protective clothing and gloves.
S45 - In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:

DANGER
May cause cancer.
May cause genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A



Mitoxantrone Hydrochloride

California Proposition 65	developmental toxicity initial date 7/1/90
Australia (AICS):	Present
EU EINECS/ELINCS List	274-619-1

Acetic acid USP - glacial

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb
Inventory - United States TSCA - Sect. 8(b)	2270 kg
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
	Schedule 2
	Schedule 5
	Schedule 6
EU EINECS/ELINCS List	200-580-7

Edetate disodium

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	205-358-3

Nitrogen, NF

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

MATERIAL SAFETY DATA SHEET

Material Name: Mitoxantrone Hydrochloride Injection
Revision date: 26-Jan-2012

Page 8 of 8
Version: 2.0

15. REGULATORY INFORMATION

REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-783-9
Sodium chloride	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3
Water for injection	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2
Sodium acetate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-823-8

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.
R21 - Also harmful in contact with skin.
R45 - May cause cancer.
R46 - May cause heritable genetic damage.
R61 - May cause harm to the unborn child.
R10 - Flammable.
R35 - Causes severe burns.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 7 - Handling and Storage.

Prepared by: Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet