SAFETY DATA SHEET

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

Product Identifier

Material Name: Mitoxantrone Injection (Hospira, Inc.)

Trade Name: Not applicable
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product used as Antineoplastic agent

Details of the Supplier of the Safety Data Sheet

Hospira, A Pfizer Company
275 North Field Drive
Lake Forest, Illinois 60045
1-800-879-3477

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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 1B
Reproductive Toxicity: Category 1B
Carcinogenicity: Category 1B

Label Elements

Signal Word: Danger

Hazard Statements:
H340 - May cause genetic defects
H350 - May cause cancer
H360D - May damage the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
P501 - Dispose of contents/container in accordance with all local and national regulations

Other Hazards An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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	GHS Classification	%
Mitoxantrone Hydrochloride	70476-82-3	274-619-1	Acute Tox. 4 (H312) Acute Tox. 4 (H302) Repr. 1B (H360D) Muta. 1B (H340) Carc. 1B (H350)	0.2
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Acetic acid	64-19-7	200-580-7	Skin Corr.1A (H314) Flam. Liq. 3 (H226)	**

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
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 CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.

Medical Conditions Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

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

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

Advice for Fire-Fighters

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

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly.

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

Precautions for Safe Handling

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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product Antineoplastic

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

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

Mitoxantrone Hydrochloride

Pfizer OEL TWA-8 Hr:	0.3µg/m^3, Skin

Sodium chloride

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

Acetic acid

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
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
Netherlands OEL - TWA	25 mg/m^3
OSHA - Final PELS - TWAs:	10 ppm 25 mg/m^3
Poland OEL - TWA	25 mg/m^3

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Portugal OEL - TWA	10 ppm 25 mg/m^3
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
Switzerland OEL -TWAs	10 ppm 25 mg/m^3
Vietnam OEL - TWAs	25 mg/m^3

Exposure Controls

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.
Personal Protective Equipment:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Hands:	Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)
Eyes:	Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)
Skin:	Wear impervious protective clothing to prevent skin contact – consider use of disposable clothing where appropriate. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)
Respiratory protection:	Under normal conditions of use, 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 (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Sterile solution	**Color:**	Dark blue
Odor:	No data available.	**Odor Threshold:**	No data available.
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

Solvent Solubility:	No data available
Water Solubility:	No data available
pH:	3.0-4.5
Melting/Freezing Point (°C):	No data available
Boiling Point (°C):	No data available.

Partition Coefficient: (Method, pH, Endpoint, Value)
Mitoxantrone Hydrochloride
No data available

9. PHYSICAL AND CHEMICAL PROPERTIES

Sodium chloride
No data available
Sodium acetate
No data available
Water for injection
No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammablity:
- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
- **Oxidizing Properties:** No data available
- **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
- **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The information included in this section describes the potential hazards of the individual ingredients.
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, effects on cardiovascular system, liver effects, and skin reaction.

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

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

11. TOXICOLOGICAL INFORMATION

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 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
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
In Vivo Cytogenetics Rat Positive
Unscheduled DNA Synthesis Rat Hepatocyte Positive
Sister Chromatid Exchange Chinese Hamster Ovary (CHO) cells Positive
In Vitro Chromosome Aberration Hamster Positive
Somatic Mutation & Recombination Test (SMART) Drosophila Positive

Carcinogen Status: See below

Mitoxantrone Hydrochloride
IARC: Group 2B (Possibly Carcinogenic to Humans)

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

Toxicity: No data available

Persistence and Degradability: No data available

Bio-accumulative Potential: No data available

Mobility in Soil: No data available

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

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Mitoxantrone Hydrochloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	carcinogen 1/23/2015 developmental toxicity 7/1/1990
Australia (AICS):	Present
EU EINECS/ELINCS List	274-619-1

Sodium chloride

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	231-598-3

Water for injection

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
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

15. REGULATORY INFORMATION

Sodium acetate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	204-823-8

Acetic acid

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-580-7

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, dermal-Cat.4; H312 - Harmful in contact with skin
Germ cell mutagenicity-Cat.1B; H340 - May cause genetic defects
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Carcinogenicity-Cat.1B; H350 - May cause cancer
Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage
Flammable liquids-Cat.3; H226 - Flammable liquid and vapor

Data Sources:	Publicly available toxicity information. Safety data sheets for individual ingredients.
Reasons for Revision:	New data sheet.
Revision date:	03-Nov-2016
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