



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 19-Sep-2017

Version: 1.1

Page 1 of 9

## 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

Hospira UK Limited  
Horizon  
Honey Lane  
Hurley  
Maidenhead, SL6 6RJ  
United Kingdom

### Emergency telephone number:

CHEMTREC (24 hours): 1-800-424-9300

Contact E-Mail: pfizer-MSDS@pfizer.com

### 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

## SAFETY DATA SHEET

Material Name: Mitoxantrone Injection (Hospira, Inc.)  
Revision date: 19-Sep-2017

Page 2 of 9  
Version: 1.1



**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)<br>Acute Tox. 4 (H302)<br>Repr. 1B (H360D)<br>Muta. 1B (H340)<br>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)<br>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.

## SAFETY DATA SHEET

Material Name: Mitoxantrone Injection (Hospira, Inc.)  
Revision date: 19-Sep-2017

Page 3 of 9  
Version: 1.1

**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 CO<sub>2</sub>, 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 firefighting 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. Cleanup 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

## SAFETY DATA SHEET

Material Name: Mitoxantrone Injection (Hospira, Inc.)  
Revision date: 19-Sep-2017

Page 4 of 9  
Version: 1.1

### 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<sup>3</sup>, Skin

#### Sodium chloride

Latvia OEL - TWA 5 mg/m<sup>3</sup>

Lithuania OEL - TWA 5 mg/m<sup>3</sup>

#### Acetic acid

ACGIH Threshold Limit Value (TWA) 10 ppm

ACGIH Threshold Limit Value (STEL) 15 ppm

Australia STEL 15 ppm

Australia TWA 37 mg/m<sup>3</sup>

Australia TWA 10 ppm

Australia TWA 25 mg/m<sup>3</sup>

Austria OEL - MAKs 10 ppm

Austria OEL - MAKs 25 mg/m<sup>3</sup>

Belgium OEL - TWA 10 ppm

Belgium OEL - TWA 25 mg/m<sup>3</sup>

Bulgaria OEL - TWA 25.0 mg/m<sup>3</sup>

Cyprus OEL - TWA 10 ppm

Cyprus OEL - TWA 25 mg/m<sup>3</sup>

Czech Republic OEL - TWA 25 mg/m<sup>3</sup>

Denmark OEL - TWA 10 ppm

Denmark OEL - TWA 25 mg/m<sup>3</sup>

Estonia OEL - TWA 10 ppm

Estonia OEL - TWA 25 mg/m<sup>3</sup>

Finland OEL - TWA 5 ppm

Finland OEL - TWA 13 mg/m<sup>3</sup>

Germany - TRGS 900 - TWAs 10 ppm

Germany - TRGS 900 - TWAs 25 mg/m<sup>3</sup>

Germany (DFG) - MAK 10 ppm

Germany (DFG) - MAK 25 mg/m<sup>3</sup>

Greece OEL - TWA 10 ppm

Greece OEL - TWA 25 mg/m<sup>3</sup>

Hungary OEL - TWA 25 mg/m<sup>3</sup>

Ireland OEL - TWAs 10 ppm

Ireland OEL - TWAs 25 mg/m<sup>3</sup>

Latvia OEL - TWA 10 ppm

Latvia OEL - TWA 25 mg/m<sup>3</sup>

Lithuania OEL - TWA 10 ppm

Lithuania OEL - TWA 25 mg/m<sup>3</sup>

Luxembourg OEL - TWA 10 ppm

Luxembourg OEL - TWA 25 mg/m<sup>3</sup>

Malta OEL - TWA 10 ppm

Malta OEL - TWA 25 mg/m<sup>3</sup>

Netherlands OEL - TWA 25 mg/m<sup>3</sup>

OSHA - Final PELs - TWAs: 10 ppm

OSHA - Final PELs - TWAs: 25 mg/m<sup>3</sup>

Poland OEL - TWA 25 mg/m<sup>3</sup>

## SAFETY DATA SHEET

Material Name: Mitoxantrone Injection (Hospira, Inc.)  
Revision date: 19-Sep-2017

Page 5 of 9  
Version: 1.1

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                       |                                |
|-----------------------|--------------------------------|
| Portugal OEL - TWA    | 10 ppm<br>25 mg/m <sup>3</sup> |
| Romania OEL - TWA     | 10 ppm<br>25 mg/m <sup>3</sup> |
| Slovakia OEL - TWA    | 10 ppm<br>25 mg/m <sup>3</sup> |
| Slovenia OEL - TWA    | 10 ppm<br>25 mg/m <sup>3</sup> |
| Spain OEL - TWA       | 10 ppm<br>25 mg/m <sup>3</sup> |
| Sweden OEL - TWAs     | 5 ppm<br>13 mg/m <sup>3</sup>  |
| Switzerland OEL -TWAs | 10 ppm<br>25 mg/m <sup>3</sup> |
| Vietnam OEL - TWAs    | 25 mg/m <sup>3</sup>           |

#### Sodium chloride

**Pfizer Occupational Exposure Band (OEB):** OEB 1 (control exposure to the range of 1000ug/m<sup>3</sup> to 3000ug/m<sup>3</sup>)

#### 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

|                                     |                    |                          |                    |
|-------------------------------------|--------------------|--------------------------|--------------------|
| <b>Physical State:</b>              | Sterile solution   | <b>Color:</b>            | Dark blue          |
| <b>Odor:</b>                        | No data available. | <b>Odor Threshold:</b>   | No data available. |
| <b>Molecular Formula:</b>           | Mixture            | <b>Molecular Weight:</b> | Mixture            |
| <b>Solvent Solubility:</b>          | No data available  |                          |                    |
| <b>Water Solubility:</b>            | No data available  |                          |                    |
| <b>pH:</b>                          | 3.0-4.5            |                          |                    |
| <b>Melting/Freezing Point (°C):</b> | No data available  |                          |                    |
| <b>Boiling Point (°C):</b>          | No data available. |                          |                    |

## SAFETY DATA SHEET

Material Name: Mitoxantrone Injection (Hospira, Inc.)  
Revision date: 19-Sep-2017

Page 6 of 9  
Version: 1.1

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Mitoxantrone Hydrochloride**

No data available

**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

**Flammability:**

**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

## SAFETY DATA SHEET

Material Name: Mitoxantrone Injection (Hospira, Inc.)  
Revision date: 19-Sep-2017

Page 7 of 9  
Version: 1.1

### 11. TOXICOLOGICAL INFORMATION

Rabbit Dermal LD50 125mg/kg  
Rat Intravenous LD50 4.8mg/kg

#### 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 LOEL Fetotoxicity  
Reproductive & Fertility Rabbit Intravenous 0.5 mg/kg NOEL Negative  
Embryo / Fetal Development Rabbit No route specified 0.2 mg/kg/day NOEL Teratogenic  
Embryo / Fetal Development Rat No route specified 6 mg/kg/day NOEL 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

## SAFETY DATA SHEET

Material Name: Mitoxantrone Injection (Hospira, Inc.)  
Revision date: 19-Sep-2017

Page 8 of 9  
Version: 1.1

### 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<br>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    |



## SAFETY DATA SHEET

Material Name: Mitoxantrone Injection (Hospira, Inc.)  
Revision date: 19-Sep-2017

Page 9 of 9  
Version: 1.1

### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List 231-791-2

#### 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:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.  
**Revision date:** 19-Sep-2017  
Product Stewardship Hazard Communication  
**Prepared by:** 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