MATERIAL SAFETY DATA SHEET

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

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Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300  
Emergency telephone number: ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Mitoxantrone Hydrochloride Injection

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

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mitoxantrone Hydrochloride</td>
<td>70476-82-3</td>
<td>274-619-1</td>
<td>0.2</td>
</tr>
<tr>
<td>Acetic acid USP - glacial</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>0.08</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edetate disodium</td>
<td>139-33-3</td>
<td>205-358-3</td>
<td>*</td>
</tr>
<tr>
<td>Nitrogen, NF</td>
<td>7727-37-9</td>
<td>231-783-9</td>
<td>###</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>*</td>
</tr>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>###</td>
</tr>
<tr>
<td>Sodium acetate</td>
<td>127-09-3</td>
<td>204-823-6</td>
<td>**</td>
</tr>
</tbody>
</table>

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

3. HAZARDS IDENTIFICATION

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

Statement of Hazard: Harmful if swallowed.  
Fatal in contact with skin.  
May cause genetic defects.  
May damage the unborn child.  
May cause cancer.

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 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.

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.

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.

5. FIRE FIGHTING MEASURES

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

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: Not applicable

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: Avoid contact with eyes, skin and clothing. Use appropriate ventilation. When handling, use appropriate personal protective equipment (see Section 8).

Storage Conditions: Protect from light. Store at controlled room temperature.

Storage Temperature: < 25 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Mitoxantrone Hydrochloride
Pfizer OEL TWA-8 Hr: 0.3ug/m³, Skin

Acetic acid USP - glacial
OSHA - Final PELS - TWAs:
= 10 ppm TWA
= 25 mg/m³ TWA

ACGIH Threshold Limit Value (TWA)
= 10 ppm TWA
ACGIH Threshold Limit Value (STEL)
= 15 ppm STEL
Australia STEL
= 15 ppm STEL
Australia TWA
= 10 ppm TWA
= 25 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protective Equipment:

Hands: Wear two layers of disposable gloves.
Eyes: Safety glasses or goggles
Skin: Wear protective clothing with long sleeves to avoid skin contact. Wash hands and arms thoroughly after handling this product.
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
Molecular Formula: Mixture
Color: Dark blue
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY
Stability: Stable under normal conditions of use.
Conditions to Avoid: Exposure to light.
Incompatible Materials: None identified

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)

Sodium chloride
Rat Oral LD50 3000 mg/kg
Mouse Oral LD 50 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

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium chloride
10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

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
OSHA: Present
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

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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
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
Harmful if swallowed.
Fatal in contact with skin.
May cause genetic defects.
May damage the unborn child.
May cause cancer.

Canada - WHMIS: Classifications
Mitoxantrone Hydrochloride

California Proposition 65
Australia (AICS): Present
EU EINECS List 274-619-1

Acetic acid USP - glacial
CERCLA/SARA Hazardous Substances and their Reportable Quantities:
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons:
EU EINECS List 200-580-7

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

Nitrogen, NF
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-783-9

Sodium chloride
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-598-3

Water for injection
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-791-2

Sodium acetate
Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 204-823-8

16. OTHER INFORMATION

Reasons for Revision:
Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.
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.

End of Safety Data Sheet