SECTION 1: IDENTIFICATION

Product Name: Doxorubicin Hydrochloride Injection, USP
Manufacturer Name: Fresenius Kabi USA, LLC
Address: Three Corporate Drive
Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
Customer Service Phone Number: (888) 386-1300
Health Issues Information: (800) 551-7176
SDS Creation Date: January 08, 2009
SDS Revision Date: June 01, 2015
(M)SDS Format:

SECTION 2: HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.
GHS Class:
- Respiratory sensitisation. Category 1.
- Carcinogenicity. Category 1A.
- Germ cell mutagenicity. Category 2.
- Reproductive toxicity. Category 2.
- Skin Sensitization. Category 1.
- Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
- May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- May cause cancer.
- Suspected of causing genetic defects.
- Suspected of damaging fertility or the unborn child.
- May cause an allergic skin reaction.
- May cause harm to breast-fed children.

Precautionary Statements:
- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Do not breathe dust/fume/gas/mist/vapours/spray.
- Avoid breathing dust/fume/gas/mist/vapours/spray.
- Avoid contact during pregnancy and while nursing.
- Wash hands thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Contaminated work clothing should not be allowed out of the workplace.
- Wear protective gloves/protective clothing/eye protection/face protection.
- In case of inadequate ventilation wear respiratory protection.
- IF ON SKIN: Wash with plenty of water.
- IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- IF exposed or concerned: Get medical advice/attention.
- IF INGESTED: Call a Poison Control Center or doctor/physician.
- Take off contaminated clothing and wash it before reuse.
- Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview:
This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure:
Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye:
Contact with eyes may cause irritation.

Signs/Symptoms:
Potential adverse reactions from prescribed doses are described in the package insert and include: acute and delayed cardiotoxicity, myelosuppression, secondary leukemia, hepatic impairment, nausea, vomiting, mucositis, ulceration and necrosis of the colon, hypersensitivity, peripheral neurotoxicity, alopecia, hyperpigmentation of nail beds and dermal creases, rash, itching and photosensitivity. The symptoms and signs of overdosage include enhanced toxic effects of mucositis, leukopenia, and thrombocytopenia. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
Individuals with hypersensitivity to doxorubicin, any of its excipients, or other anthracyclines or anthracenediones. Also, individuals with cardiovascular disease, hepatic, renal, and bone marrow impairment.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name | CAS# | Ingredient Percent | EC Num.
--- | --- | --- | ---
Doxorubicin Hydrochloride Injection, USP | | | |
Doxorubicin Hydrochloride Injection, USP

SECTION 4 : FIRST AID MEASURES

Eye Contact: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Contact: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Other First Aid: For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point: Not established.
Flash Point Method: Not established.
Auto Ignition Temperature: Not established.
Lower Flammable/Explosive Limit: Not established.
Upper Flammable/Explosive Limit: Not established.

Fire Fighting Instructions: Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.

Extinguishing Media: Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

Hazardous Combustion Byproducts: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions: Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods for containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for cleanup: Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling: When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.

Storage: Store at refrigerated temperatures 2 to 8°C (36 to 46°F). Protect from light.

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

Hygiene Practices: Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls: General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

Eye/Face Protection: Chemical splash goggles. Wear a face shield also when splash hazard exist.

Skin Protection Description: Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:
Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.

Respiratory Protection:
No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician/doctor/nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.

Other Protective:
Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9: PHYSICAL and CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State</th>
<th>Liquid solution.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Red orange.</td>
</tr>
<tr>
<td>Boiling Point</td>
<td>100°C</td>
</tr>
<tr>
<td>Melting Point</td>
<td>205°C (raw material)</td>
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<tr>
<td>Solubility</td>
<td>Soluble in water.</td>
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<tr>
<td>Vapor Density</td>
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<td>Vapor Pressure</td>
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<tr>
<td>Percent Volatile</td>
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<tr>
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<td>Molecular Formula</td>
<td>Mixture</td>
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<tr>
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<tr>
<td>Flash Point Method</td>
<td>Not established.</td>
</tr>
<tr>
<td>Auto Ignition Temperature</td>
<td>Not established.</td>
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</tbody>
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SECTION 10: STABILITY and REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.
Hazardous Polymerization: Not reported.
Conditions to Avoid: Protect from light and excessive heat.

SECTION 11: TOXICOLOGICAL INFORMATION

Doxorubicin Hydrochloride:
Acute Toxicity: LD50 IV Mouse: 21.1 mg/kg

NTP:
NTP: Reasonably anticipated to be a human carcinogen.

Chronic Effects: Cardiotoxicity, myelosuppression, hypersensitivity, and skin or nail hyperpigmentation.
Teratogenicity: Pregnancy Category D: Doxorubicin can cause fetal harm when administered to a pregnant woman. Doxorubicin is teratogenic and embryotoxic in rats.

RTECS Number: QI9295900

Ingestion:
Oral - Mouse LD50: 698 mg/kg [Sense Organs and Special Senses (Eye) - Lacrimation Behavioral - Muscle weakness Gastrointestinal - Hypermotility, diarrhea] Oral - Mouse LD50: 570 mg/kg [Blood - Other changes]

Other Toxicological Information:
Intravenous - Rat LD50: 12510 ug/kg [Gastrointestinal - hypermotility, diarrhea Skin and Appendages - dermatis, allergic (after topical exposure) Nutritional and Gross Metabolite - weight loss or decreased weight gain] Intravenous - Mouse LD50: 1245 ug/kg [Details of toxic effects not reported other than lethal dose value] Intravenous - Rabbit LD50: 5980 ug/kg [Behavioral - food intake (animal) Behavioral - muscle weakness] Intravenous - Mouse LD50: 12.5 mg/kg [Blood - other changes] Intravenous - Mouse TDLo: 2 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct Nutritional and Gross Metabolite - weight loss or decreased weight gain] Intravenous - Rat TDLo: 6 mg/kg [Blood - changes in erythrocyte (RBC) count Reproductive - Paternal Effects - testes, epididymis, sperm duct Nutritional and Gross Metabolite - weight loss or decreased weight gain] Intravenous - Human TDLo: 0.5 mg/kg [Immunochemical Including Allergic - anaphylaxis] Intravenous - Rat TDLo: 7.5 mg/kg [Liver - other changes Kidney/Ureter/Bladder - other changes Biochemical - Metabolism (Intermediate) - lipids including transport] Intravenous - Rat TDLo: 7.5 mg/kg [Cardiac - cardiomyopathy including infarction Kidney/Ureter/Bladder - other changes Biochemical - Metabolism (Intermediate) - effect on
Sodium Chloride

RTECS Number: VZ4725000

Eye

Eye - Rabbit Standard Draize test: 10 mg [Moderate]

Skin

Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]

Administration onto the skin - Rabbit Standard Draize test: 50 mg/24H [mild]

Administration onto the Standard Draize Standard test: 500 mg/24H [mild]
SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.
Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.
DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

EINECS Number: 246-818-3
Sodium Chloride: TSCA Inventory Status: Listed
TSCA Inventory Number: 231-598-3
Canada DSL: Listed
Water for Injection: TSCA Inventory Status: Listed
Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:
SDS Creation Date: January 08, 2009
SDS Revision Date: June 01, 2015
SDS Format: 
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