

## MATERIAL SAFETY DATA SHEET

### SECTION 1- PRODUCT IDENTITY AND COMPANY INFORMATION

Product Name : Doxorubicin Hydrochloride Injection

Pack Size : 2mg/ml liquid in 5ml, 25ml

Company Name : Fresenius Kabi Oncology Ltd

Company Address : Vill . Kishanpura, Tehsil Nalagarh  
Distt: Solan , H.P 174101 INDIA

Telephone : +91-01795 304300

Fax : +91-01795 304330

### SECTION 2- TYPICAL COMPOSITION

Ingredient	CAS Number
Doxorubicin Hydrochloride	25316-40-9
Sodium Chloride	7647-14-5
Water for Injection	7732-18-5
Hydrochloric Acid	7647-01-0

Therapeutic Category: Antineoplastic

### SECTION 3 - HEALTH HAZARDS

Hazard Class : Not considered hazardous when handled under normal condition with good house keeping

#### R20

Harmful by inhalation

#### R21

Harmful in contact with skin

#### R22

Harmful if swallowed

#### R61

May cause harm to the unborn child

#### R68

Possible risk of irreversible effects.

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**SECTION 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

**SECTION 5 - FIRE AND EXPLOSION HAZARDS**

- Extinguishing Media : Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area
- Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.
- Hazardous Combustion: Formation of toxic gases is possible during heating or fire Products
- Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

**SECTION 6 - ACCIDENTAL RELEASE INFORMATION****STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED**

Use appropriate personal protective equipment (see section 8). Sweep up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of waste at an approved facility is recommended.

**SECTION 7 - HANDLING AND STORAGE**

- Handling : No special measures necessary if stored and handled as prescribed. Avoid the formation and deposition of dust. Provide good ventilation of working area
- Storage : Store at a temperature below 25°C. Protect from light. Do not refrigerate.

**SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION**

- Analytical Method : Analytical method available for Doxorubicin Hydrochloride. Contact FKOL for further information

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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.
Environmental Exposure Controls	:	Refer specific member state legislation for requirement under community environmental legislation.
Personal Protective Equipment	:	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE0
Personal Protection	:	Not required when handling tablets. If containers are compromised or exposure is likely wear : Goggles, Lab coat, Gloves
Respiratory Protection	:	Not required when handling tablets or containers. NIOSH/MSHA Approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to condition.
Recommended Facilities:	:	Eye wash, washing facilities
Hands	:	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operation.
Eyes	:	Wear safety glasses or goggles if eye contact is possible.
Skin	:	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations
Respiratory protection	:	If applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL

<b>SECTION 9 - PHYSICAL / CHEMICAL PROPERTIES</b>
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Physical State	:	Solution
Color	:	colorless to pale yellow
Molecular formula	:	Mixture
Molecular Weight	:	Mixture
pH	:	3.5-6.5

**MATERIAL SAFETY DATA SHEET****SECTION 10 - STABILITY AND REACTIVITY DATA**

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

**SECTION 11 - TOXICOLOGICAL INFORMATION**

General Information: The information included in this section describes the potential hazards of the active ingredient

Corrosivity /irritation (eye, skin, respiratory tract)  
This product is expected to be irritating to contaminated skin, eyes and other tissues.

Sensitisation (skin, respiratory)  
Considered to be an allergen based on platinum compounds.

**SECTION 12 - ENVIRONMENTAL INFORMATION**

No specific information is available on the effect of cisplatin on plants or animals in the environment.

**SECTION 13 - DISPOSAL INFORMATION**

Place the spillage in a plastic hazardous waste disposal bag and label it CAUTION :  
HAZARDOUS CHEMICAL WASTE.  
Dispose of material accordingly to federal, state and local disposal regulations or company operating procedure Disposal by incineration is recommended.  
At home; discard away from children's reach

**SECTION 14 - TRANSPORTATION INFORMATION**

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

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

**SECTION 15 - LABELLING / REGULATORY INFORMATION**

Risk phrases:

**R22**

Harmful of swallowed

**R60**

May impair fertility

**R61**

May cause harm to the unborn child

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**R45**

May cause cancer

**R68**

Possible risk of irreversible effects

**Safety phrases : S36/S37**    Wear suitable protective clothing, gloves  
**S53** – Avoid exposure –obtain special instructions before use

<b>SECTION 16 -        OTHER INFORMATION</b>
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No additional information.

The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the Foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Material Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.