

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 R21 R22

Harmful by inhalation Harmful in contact with skin Harmful if swallowed

R61 R68

May cause harm to the unborn child Possible risk of irreversible effects.



SECTION 4 - FIRST AID MEASURES

Eye contact : Flush with water while holding eyelids open for at least 15 minutes.

Seek medical attention immediately.

: Remove contaminated clothing. Flush area with large amounts of water. Skin Contact

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 activates, wear appropriate protective

> equipment, including self contained breathing apparatus. Formation of toxic gases is possible during heating or fire

Hazardous Combustion:

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 SIGNIFICENT QUANTIITES 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

No special measures necessary if stored and handled as prescribed. Avoid Handling

the formation and deposition of dust. Provide good ventilation of working

Store at a temperature below 25°C. Protect from light. Do not refrigerate. Storage

SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

Analytical Method Analytical method available for Doxorubicin Hydrochloride.

Contact FKOL for further information



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 Limt (OEL) is exceeded,

wear an appropriate respirator with a protection factor sufficient to

control exposures to below the OEL

SECTION 9 - PHYSICAL / CHEMICAL PROPERTIES

Physical State : Solution

Color : colorless to pale yellow

Molecular formula ; Mixture Molecular Weight : Mixture pH : 3.5-6.5



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 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 transporation unless specified below

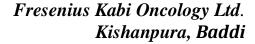
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

SECTION 15 - LABELLING / REGULATORY INFORMATION

Risk phrases:

R22 R60 R61

Harmful of swallowed May impair fertility May cause harm to the unborn child





R45 R68

May cause cancer Possible risk of irreversible effects

Safety phrases: S36/S37 Wear suitable protective clothing, gloves

S53 – Avoid exposure –obtain special instructions before use

SECTION 16 - OTHER INFORMATION

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.