

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Idarubicin Hydrochloride Injection**
Product Use/Restriction: Antileukemic Agent.
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: August 25, 2009
SDS Revision Date: June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER.

GHS Class: Respiratory sensitisation. Category 1.
 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.
 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.
 Specific treatment (see ... on this label).
 If skin irritation or rash occurs: Get medical advice/attention.
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
 Take off contaminated clothing and wash it before reuse.
 Store locked up.
 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: Overexposure may cause damage to the heart, liver, kidneys, bone marrow and reproductive system.
 May be harmful to the fetus.

Eye: Contact with eyes may cause irritation.

Skin: May cause skin irritation.

Inhalation: May cause irritation of respiratory tract. Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Ingestion: May cause irritation.

Signs/Symptoms: Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Effects may include stinging, watering, and redness of the eyes and redness and a burning sensation on the skin. High concentrations are irritating to tissues and may lead to local ulceration and necrosis. In case of over-exposure by injection, burning sensation, infection, hair loss, abdominal cramps, headaches, nausea, vomiting, diarrhea, blood system effects, cardiac arrest, and a variety of other health effects may occur. Death can occur in the event of a massive accidental overdose. Occupational exposure has not been fully investigated.

Target Organs: This product may produce adverse effects on the heart, liver, kidney and bone marrow. Cardiac toxicity is more common in patients who have received prior anthracyclines or who pre-existing cardiac disease. Changes in hepatic and renal function tests have been observed. Severe myelosuppression will occur in all patients given a therapeutic dose. Deaths due to infection and/or bleeding have been reported during the period of severe myelosuppression.

Aggravation of Pre-Existing Conditions: Skin, respiratory heart, liver, kidney, bone marrow and reproductive disorders. Cardiac toxicity is more common in patients who have received prior anthracyclines or who have pre-existing cardiac disease.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Idarubicin Hydrochloride	57852-57-0	1 mg/mL	
Glycerin	56-81-5	25 mg/mL	
Hydrochloric Acid (pH adjust)	7647-01-0	- Trace. -	
Water (for injection)	7732-18-5	- Quantity Sufficient. -	

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.
Unusual Fire Hazards:	No unusual fire or explosion hazard known to exist.
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.
NFPA Ratings:	
NFPA Health:	
NFPA Flammability:	
NFPA Reactivity:	
NFPA Other:	

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

Ingredient	Guideline OSHA	Guideline ACGIH	Quebec Canada	Ontario Canada	Alberta Canada
Idarubicin Hydrochloride	Not established.	Not established.	Not established.	Not established.	Not established.
Glycerin	PEL-TWA: 5 mg/m ³ Respirable fraction (R)	TLV-TWA: 10 mg/m ³	VEMP-TWA: 10 mg/m ³	OEL-TWAEV: 10 mg/m ³	OEL-TWA: 10 mg/m ³
Hydrochloric Acid (pH adjust)	Not established.	Not established.	VEMP-ceiling./Peak.: 5 ppm	OEL-CEV: 2 ppm	OEL-ceiling./Peak: 5 ppm
Water (for injection)	Not established.	Not established.	Not established.	Not established.	Not established.
Ingredient	British Columbia Canada				
Idarubicin Hydrochloride	Not established.				
Glycerin	OEL-TWA: 3 mg/m ³ Respirable fraction (R)				
Hydrochloric Acid (pH adjust)	OEL-ceiling./Peak.: 2 ppm				
Water (for injection)	Not established.				

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State: Liquid.

Color: Red orange.

Odor: Odorless.

Boiling Point: Not established.

Melting Point: Not established.

Specific Gravity: ((Ref: water = 1). = 1): ~ 1

Solubility: Soluble. in water.

Vapor Density: Not established.

Vapor Pressure: Not established.

Percent Volatile: Not established.

Evaporation Rate: (n-BuAc = 1): < 1

Evaporation Point: (n-BuAc = 1): < 1

pH: 3 - 4

Molecular Formula: Mixture

Molecular Weight: Not established.

Flash Point: Not established.

Flash Point Method: Not established.

Auto Ignition Temperature: Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.

Hazardous Polymerization: Not reported.

Incompatible Materials: This product is generally compatible with other common materials in a medical facility.

SECTION 11 : TOXICOLOGICAL INFORMATION

Idarubicin Hydrochloride :

Ingestion: Oral - Rat LD50: 5430 ug/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 13980 ug/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Carcinogenicity: Formal long-term carcinogenicity studies have not been conducted with Idarubicin Hydrochloride. Idarubicin Hydrochloride and related compounds have been shown to have carcinogenic properties when tested in experimental models (including Sprague-Dawley rats).

Mutagenicity: Idarubicin Hydrochloride has been shown to be mutagenic when tested in experimental models, including bacterial systems and mammalian cell cultures.

Reproductive Toxicity: This material is classified as a Pregnancy Category D (Positive Evidence of Risk).

Teratogenicity: Embryotoxicity/Teratogenicity/Reproductive Toxicity: Idarubicin Hydrochloride was embryotoxic and teratogenic in the rat at one tenth the human dose, which was nontoxic to dams. Idarubicin Hydrochloride was embryotoxic but not teratogenic in the rabbit, even at two tenths the human dose, which was toxic to dams. In male dogs given about one seventh the human dose for 13 weeks, or 3 times the human dose, testicular atrophy was observed with inhibition of spermatogenesis and sperm maturation with few or no mature sperm. These effects were not readily reversed after a recovery of 8 weeks. There is not conclusive information about Idarubicin Hydrochloride adversely affecting human fertility or causing teratogenesis. There has been one report of a fetal fatality after maternal exposure during the second trimester. When administered clinically by intravenous injection, Idarubicin Hydrochloride can cause myocardial toxicity leading to congestive heart failure.

Other Toxicological Information: Intravenous - Rat LD50: 3080 ug/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous - Mouse LD50: 4100 ug/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat LD50: 2930 ug/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 4690 ug/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Glycerin :

Eye: Eye - Rabbit Standard Draize test.: 500 mg/24H (RTECS)

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.: 500 mg/24H

Ingestion: Oral - Rat LD50: 12600 mg/kg [Behavioral - General anesthetic Behavioral - Muscle weakness Liver - Other changes]
Oral - Mouse LD50: 4090 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Rat LD50: 12600 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Other Toxicological Information: Intravenous - Rat LD50: 5566 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous - Mouse LD50: 4250 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal - Rat LD50: 4420 mg/kg [Behavioral - Toxic psychosis Cardiac - Other changes Kidney/Ureter/Bladder - Other changes]
Intraperitoneal - Mouse LD50: 8700 mg/kg [Behavioral - Altered sleep time (including change in righting reflex)]
Subcutaneous - Rat LD50: 100 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 91 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Hydrochloric Acid (pH adjust) :

Inhalation: Inhalation - Rat LC50: 45000 mg/m³/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Rat LC50: 8300 mg/m³/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema]
Inhalation - Mouse LC50: 8300 mg/m³/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] (RTECS)

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

Canada WHMIS: Controlled - Class: D2B Toxic

Idarubicin Hydrochloride :

TSCA Inventory Status: Exempt.

Hydrochloric Acid (pH adjust) :

Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 3

HMIS Fire Hazard: 1

HMIS Reactivity: 1

HMIS Personal Protection: X

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Disclaimer: The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

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