SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Ifosfamide for 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:	October 02, 2024

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. category 1.
Germ cell mutagenicity. Category 2.
Reproductive toxicity. Category 2.
Skin Sensitization. category 1.
Acute Oral Toxicity. Category 4.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of causing genetic defects.
Suspected of damaging fertility or the unborn child.
May cause an allergic skin reaction.
Harmful if swallowed.
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 SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
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).
Rinse mouth.
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:

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses include: alopecia, nausea, vomiting, hematuria, CNS toxicity, infection, renal impairment, liver dysfunction, phlebitis, and fever. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: By Accidental Exposure: Individuals with severely depressed bone marrow function or hypersensitivity to ifosfamide.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.

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

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing dust. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

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 controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Protect from temperatures above 30°C (86°F).
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 dust, 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

Physical State:	Lyophilized powder.
Color:	White
Boiling Point:	Not established.
Melting Point:	49-50.5°C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not established.
Molecular Formula:	Mixture
Molecular Weight:	261.1
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.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Ifosfamide :

Acute Toxicity:	IMMEDIATE EFFECTS: Ingestion may cause nausea, vomiting, anorexia, or diarrhea. Acute adverse effects associated with systemic exposure may include: delayed bone marrow suppression, hemorrhagic cystitis, and reversible neurologic effects (somnolence, confusion, hallucinations, and in some instances, coma) and delayed temporary sterility. May cause skin irritation. Possible allergic rashes on contact. Possible eye irritant, may cause conjunctivitis. Acute Toxicity: LD50 IP Rat: 140 mg/kg LD50 IP Mouse: 397 mg/kg LD50 SC Rat: 160 mg/kg LD50 SC Mouse: 656 mg/kg LD50 IV Rat: 190 mg/kg LD50 IV Mouse: 338 mg/kg

Ifosfamide :

OSHA:	Not listed
IARC:	IARC: Group 3: Unclassifiable as to carcinogenicity to humans.
NTP:	Not listed
Teratogenicity:	Pregnancy Category D: Ifosfamide may cause fetal damage when administered to pregnant women.

Ifosfamide :

RTECS Number:	RP6050000
Acute Effects:	Ingestion may cause nausea, vomiting, anorexia, or diarrhea. Acute adverse effects associated with systemic exposure may include: delayed bone marrow suppression, hemorrhagic cystitis, and reversible neurologic effects (somnolence, confusion, hallucinations, and in some instances, coma) and delayed temporary sterility. May cause skin irritation. Possible allergic rashes on contact. Possible eye irritant, may cause conjunctivitis.
Ingestion:	Oral - Rat LD50: 143 mg/kg [Blood - Normocytic anemia Nutritional and Gross Metabolic - Weight loss or decreased weight gain] Oral - Mouse LD50: 1005 mg/kg [Sense Organs and Special Senses (Eye) - Lacrimation Behavioral - Ataxia Lungs, Thorax, or Respiration - Dyspnea]

Chronic Effects:	DELAYED EFFECTS: Effects from chronic systemic exposure include bone marrow suppression, hemorrhagic cystitis, reversible neurologic effects, skin pigmentation changes, and alopecia. Other effects include pulmonary symptoms, fever, allergic reactions, cardiotoxicity, and polyneuropathy.

Other Toxicological Information:

Intravenous. - Human TDLo: 2298 mg/kg/3D (intermittent) [Kidney/Ureter/Bladder - hematuria Blood - leukopenia]
Intravenous. - Human TDLo: 1915 mg/kg/2W (intermittent) [Kidney/Ureter/Bladder - hematuria Kidney/Ureter/Bladder - inflammation, necrosis, or scarring of bladder]
Intravenous. - Human TDLo: 130 mg/kg/13D (intermittent) [Gastrointestinal - nausea or vomiting Kidney/Ureter/Bladder - hematuria Kidney/Ureter/Bladder - other changes]
Intravenous. - Rat LD50: 190 mg/kg [Blood - normocytic anemia Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Intravenous. - Mouse LD50: 338 mg/kg [Sense Organs and Special Senses (Eye) - lacrimation Behavioral - ataxia Lungs, Thorax, or Respiration - dyspnea]
Intravenous. - Human TDLo: 2873 mg/kg/5D (continuous) [Behavioral - hallucinations, distorted perceptions Kidney/Ureter/Bladder - hematuria Tumorigenic - active as anti-cancer agent]
Intravenous. - Rabbit TDLo: 240 mg/kg [Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands]
Intravenous. - Rabbit TDLo: 120 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct]
Intravenous. - Rabbit TDLo: 90 mg/kg [Related to Chronic Data - changes in testicular weight]
Intravenous. - Rabbit TDLo: 60 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)]
Intravenous. - Rabbit TDLo: 300 mg/kg/10W (intermittent) [Gastrointestinal - other changes]
Intravenous. - Rat TDLo: 10 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intravenous. - Rat TDLo: 260 mg/kg [Reproductive - Specific Developmental Abnormalities - urogenital system Reproductive - Effects on Newborn - behavioral]
Intravenous. - Rat TDLo: 27500 ug/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - respiratory system Reproductive - Specific Developmental Abnormalities - urogenital system]
Intravenous. - Rat TDLo: 13750 ug/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intravenous. - Rat TDLo: 13750 ug/kg [Reproductive - Effects on Newborn - stillbirth Reproductive - Effects on Newborn - weaning or lactation index (e.g., number alive at weaning per number alive at day 4) Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain)]
Intravenous. - Rabbit TDLo: 260 mg/kg [Reproductive - Fertility - other measures of fertility Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intravenous. - Rabbit TDLo: 65 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intravenous. - Rabbit TDLo: 300 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands]
Intravenous. - Rabbit TDLo: 450 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)]
Subcutaneous - Rat LD50: 160 mg/kg [Blood - normocytic anemia Nutritional and Gross Metabolic - weight loss or decreased weight gain]
Subcutaneous - Mouse LD50: 656 mg/kg [Sense Organs and Special Senses (Eye) - lacrimation Behavioral - ataxia Lungs, Thorax, or Respiration - dyspnea]
Subcutaneous - Mouse TDLo: 540 mg/kg/9W (intermittent) [Blood - changes in leukocyte (WBC) count]
Subcutaneous - Mouse TDLo: 5220 mg/kg/87W (intermittent) [Blood - changes in leukocyte (WBC) count]
Subcutaneous - Mouse TDLo: 2600 mg/kg/65W (intermittent) [Tumorigenic - carcinogenic by RTECS criteria Tumorigenic - tumors at site of application]
Intraperitoneal. - Rat LD50: 140 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 397 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rabbit LDLo: 200 mg/kg [Sense Organs and Special Senses (Eye) - miosis (pupillary constriction) Behavioral - muscle weakness Lungs, Thorax, or Respiration - respiratory depression]
Intraperitoneal. - Guinea pig LDLo: 400 mg/kg [Sense Organs and Special Senses (Eye) - ptosis Behavioral - muscle weakness Behavioral - ataxia]
Intraperitoneal. - Mouse TDLo: 1000 mg/kg [Brain and Coverings - other degenerative changes Behavioral - convulsions or effect on seizure threshold Liver - other changes]
Intraperitoneal. - Mouse TDLo: 400 mg/kg [Vascular - structural changes in vessels Kidney/Ureter/Bladder - inflammation, necrosis, or scarring of bladder Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]
Intraperitoneal. - Rat TDLo: 480 mg/kg/10W (intermittent) [Kidney/Ureter/Bladder - other changes in urine composition Nutritional and Gross Metabolic - changes in phosphorus Related to Chronic Data - death]
Intraperitoneal. - Rat TDLo: 432 mg/kg/6W (intermittent) [Related to Chronic Data - death]
Intraperitoneal. - Rat TDLo: 300 mg/kg/30D (continuous) [Endocrine - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - phosphatases Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases]
Intraperitoneal. - Rat TDLo: 250 mg/kg/5D (intermittent) [Kidney/Ureter/Bladder - other changes in urine composition Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol) Nutritional and Gross Metabolic - changes in sodium]
Intraperitoneal. - Mouse TDLo: 360 mg/kg/6W (intermittent) [Related to Chronic Data - death]
Intraperitoneal. - Rat TDLo: 250 mg/kg/5D (intermittent) [Kidney/Ureter/Bladder - changes in blood vessels or in circulation of kidney Kidney/Ureter/Bladder - changes in tubules (including acute renal failure, acute tubular necrosis) Kidney/Ureter/Bladder - inflammation, necrosis, or scarring of bladder]
Intraperitoneal. - Rat TDLo: 240 mg/kg/3D (intermittent) [Kidney/Ureter/Bladder - urine volume increased Kidney/Ureter/Bladder - proteinuria Kidney/Ureter/Bladder - other changes in urine composition]
Intraperitoneal. - Rat TDLo: 90 mg/kg [Reproductive - Paternal Effects - prostate, seminal vesicle, Cowper's gland, accessory glands]
Intraperitoneal. - Rat TDLo: 300 mg/kg [Reproductive - Paternal Effects - testes, epididymis, sperm duct]
Intraperitoneal. - Rat TDLo: 300 mg/kg [Reproductive - Maternal Effects - ovaries, fallopian tubes]
Intraperitoneal. - Rat TDLo: 810 mg/kg [Reproductive - Maternal Effects - uterus, cervix, vagina]
Intraperitoneal. - Mouse TDLo: 20 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - urogenital system]
Intraperitoneal. - Mouse TDLo: 20 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Fertility - litter size (e.g. number fetuses per litter; measured before birth)]
Intraperitoneal. - Mouse TDLo: 10 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 940 mg/kg/1Y (intermittent) [Tumorigenic - carcinogenic by RTECS criteria Skin and Appendages - tumors Reproductive - Tumorigenic effects - uterine tumors]
Intraperitoneal. - Mouse TDLo: 450 mg/kg/8W (intermittent) [Tumorigenic - neoplastic by RTECS criteria Lungs, Thorax, or Respiration - tumors]
Intraperitoneal. - Rat TD: 1872 mg/kg/1Y (intermittent) [Tumorigenic - carcinogenic by RTECS criteria Skin and Appendages - tumors Reproductive - Tumorigenic effects - uterine tumors]
Intraperitoneal. - Mouse TD: 3120 mg/kg/1Y (intermittent) [Tumorigenic - carcinogenic by RTECS criteria Blood - lymphoma, including Hodgkin's disease]
Intraperitoneal. - Mouse Micronucleus test: 70 mg/kg/24H
Intraperitoneal. - Mouse Sperm Morphology: 500 mg/kg/5D (intermittent)

Chronic Effects:	DELAYED EFFECTS: Effects from chronic systemic exposure include bone marrow suppression, hemorrhagic cystitis, reversible neurologic effects, skin pigmentation changes, and alopecia. Other effects include pulmonary symptoms, fever, allergic reactions, cardiotoxicity, and polyneuropathy.

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:	Medicine, solid, toxic, n.o.s (Ifosfamide)
DOT UN Number:	UN 3249
DOT Hazard Class:	6.1
DOT Packing Group:	PG III

Notes :	EXCEPTIONS: Limited quantities of poisonous material (Division 6.1) in Packing Groups II and III are excepted from the labeling requirements, unless the material is offered for transportation or transported by aircraft, and are excepted from the specification packaging requirements of this subchapter when packaged in combination packagings according to this paragraph. (Title 49 CFR → Subtitle B → Chapter I → Subchapter C → Part 173 → Subpart D → §173.153). For poisonous materials in Packing Group III, inner packagings not over 5.0 kg (11 pounds) each for solids, packed in a strong outer packaging.

SECTION 15 : REGULATORY INFORMATION

Ifosfamide :

EINECS Number:	223-237-3
California PROP 65:	Listed: developmental.

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	3*
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

SDS Creation Date:	January 08, 2009
SDS Revision Date:	October 02, 2024
SDS Revision Notes:	Overall SDS review - no changes to formulation. Added HMIS Ratings.

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.