

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Methotrexate 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: March 10, 2025

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word:

DANGER.

GHS Class:

Reproductive toxicity. Category 1A.
 Eye Irritation. Category 2.
 Skin Irritation. Category 2.
 Skin Sensitization. category 1.
 Reproductive toxicity. Effects on or via lactation.

Hazard Statements:

May damage fertility or the unborn child.
 Causes serious eye irritation.
 Causes skin irritation.
 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.
 IF ON SKIN: Wash with plenty of water.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF exposed or concerned: Get medical advice/attention.
 Specific treatment (see ... on this label).
 If skin irritation occurs: Get medical advice/attention.
 If skin irritation or rash occurs: Get medical advice/attention.
 If eye irritation persists: Get medical advice/attention.
 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:

Potential Health Effects:

Methotrexate may cause cancer and may be mutagenic, teratogenic, and fetotoxic.

Eye:

Contact with eyes may cause irritation.

Chronic Health Effects:

Chronic exposure may cause hepatotoxicity, fibrosis, and cirrhosis.

Signs/Symptoms:

Possible adverse reactions are related to the dose and frequency of administration and may include: hepatotoxicity, methotrexate-induced lung disease, diarrhea, ulcerative stomatitis, malignant lymphomas, anemia, leukopenia, nausea, and abdominal distress.

Inhalation of methotrexate may cause GI disturbances: nausea, vomiting, loss of appetite, diarrhea, and congestion of the lungs and cough. Bone marrow suppression and liver damage may also be seen.

Severe, occasionally fatal skin reactions have been reported following single or multiple doses of methotrexate. Potentially fatal opportunistic infections, especially *Pneumocystis carinii* pneumonia, may occur with methotrexate therapy.

Other frequently reported adverse effects are malaise, fatigue, chills, fever, dizziness, and decreased resistance to infection. See the package insert for more information.

Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:

Methotrexate can affect the bone marrow, liver, lungs, and kidneys. Methotrexate elimination is reduced in patients with impaired renal function, ascites, or pleural effusion.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Methotrexate	59-05-2	25 mg/mL	
Benzyl Alcohol	100-51-6	0.9 % (in preserved product only)	
Sodium Chloride	7647-14-5	0.49 % (0.26 % in preserved product)	
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.
Note to Physicians:	Calcium Leucovorin is a potent agent for neutralizing the immediate effects of methotrexate on the blood forming system. Administer leucovorin as soon as possible after exposure. Methotrexate blood levels should be monitored to determine appropriate leucovorin doses. Complete hemograms and liver and kidney function tests are also recommended in cases of overexposure, especially where symptoms of intoxication are present.
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 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 controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. 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

Physical State:	Liquid solution.
Color:	Clear to pale yellow
Boiling Point:	Not established.
Melting Point:	185 - 204 °C
Solubility:	Practically insoluble. in water., SOLUBLE IN BASIC AQUEOUS MEDIA (I.E. ALKALIS OR CARBONATES). PRACTICALLY INSOLUBLE IN ETHANOL OR ETHER.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	8.5 - 8.7
Molecular Formula:	Mixture
Molecular Weight:	454.45
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:	Avoid storage near oxidizers and water reactive materials.

SECTION 11 : TOXICOLOGICAL INFORMATION

Methotrexate :

RTECS Number:	MA1225000
Eye:	Eye - Human Rinsed with water.: 150 mg
Skin:	LD50 Dermal Rabbit: > 2000 mg/kg
Ingestion:	Oral - Rat LD50: 135 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50: 146 mg/kg [Details of toxic effects not reported other than lethal dose value]
Carcinogenicity:	IARC: Group 3: Unclassifiable as to carcinogenicity to humans.

Teratogenicity:

Pregnancy Category X: Methotrexate has been reported to cause fetal death and/or congenital anomalies. Therefore it is not recommended for women of childbearing potential. Pregnant women with psoriasis should not receive methotrexate. Pregnancy should be avoided if either partner is receiving methotrexate, and for a minimum of three months after therapy for male patients, and at least one ovulatory cycle for female patients.

Methotrexate is contraindicated in pregnant women, nursing mothers, individuals with psoriasis or rheumatoid arthritis who have evidence of immunodeficiency syndromes or preexisting blood dyscrasias, and individuals with a known hypersensitivity to methotrexate.

Patients with psoriasis with alcoholism, alcoholic liver disease or other chronic liver disease should not receive methotrexate. Patients with psoriasis and immunodeficiency syndromes, or blood dyscrasias should not receive methotrexate.

Methotrexate given concomitantly with radiotherapy may increase the risk of soft tissue necrosis and osteonecrosis.

Other Toxicological Information:

Intravenous. - Human TDLo: 4650 ug/kg/4W (intermittent) [Liver - fatty liver degeneration Liver - liver function tests impaired]
 Intravenous. - Human TDLo: 7143 ug/kg [Gastrointestinal - nausea or vomiting Blood - changes in leukocyte (WBC) count Blood - changes in platelet count]
 Intravenous. - Rat LD50: 14 mg/kg [Details of toxic effects not reported other than lethal dose value]
 Intravenous. - Mouse LD50: 65 mg/kg [Details of toxic effects not reported other than lethal dose value]
 Intravenous. - Rat TDLo: 20 mg/kg [Gastrointestinal - malabsorption Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - multiple enzyme effects Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]
 Intravenous. - Rat TDLo: 30 mg/kg [Gastrointestinal - other changes]
 Intravenous. - Rat TDLo: 20 mg/kg/1H [Gastrointestinal - 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 - other oxidoreductases]
 Intravenous. - Human TDLo: 25 mg/kg [Lungs, Thorax, or Respiration - pulmonary emboli Kidney/Ureter/Bladder - other changes Blood - thrombocytopenia]
 Intravenous. - Mouse TDLo: 71500 ug/kg/5D (intermittent) [Liver - changes in liver weight Blood - thrombocytopenia Related to Chronic Data - death]
 Intravenous. - Mouse TDLo: 20 mg/kg/5D (intermittent) [Tumorigenic - active as anti-cancer agent]
 Intravenous. - Human TDLo: 0.86 mg/kg/4W (intermittent) [Gastrointestinal - hypermotility, diarrhea Gastrointestinal - nausea or vomiting Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases]
 Intravenous. - Rat TDLo: 300 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
 Intravenous. - Rat TDLo: 100 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)]
 Intravenous. - Rabbit TDLo: 600 ug/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
 Intravenous. - Rabbit TDLo: 600 ug/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
 Intravenous. - Rabbit TDLo: 9600 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
 Intravenous. - Rabbit TDLo: 9600 ug/kg [Reproductive - Effects on Embryo or Fetus - fetal death]
 Subcutaneous - Rat LD50: 58 mg/kg [Details of toxic effects not reported other than lethal dose value]
 Subcutaneous - Mouse LD50: 250 mg/kg [Details of toxic effects not reported other than lethal dose value]
 Subcutaneous - Rat TDLo: 1.5 mg/kg/6D (intermittent) [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - hepatic microsomal mixed oxidase (dealkylation, hydroxylation, etc.) Biochemical - Effect on specific coenzyme - NAD,NADP]
 Subcutaneous - Rat TDLo: 6 mg/kg/6D (intermittent) [Liver - other changes]
 Subcutaneous - Rat TDLo: 7 mg/kg/14D (intermittent) [Liver - other changes]
 Subcutaneous - Rat TDLo: 1.4 mg/kg/7D (intermittent) [Brain and Coverings - other degenerative changes Sense Organs and Special Senses (Eye) - retinal changes (pigmentary depositions, retinitis, other) Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - multiple enzyme effects]
 Subcutaneous - Mouse TDLo: 2500 ug/kg/32D (intermittent) [Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]
 Subcutaneous - Rat TDLo: 280 ug/kg/4D (intermittent) [Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]
 Subcutaneous - Mouse DNA inhibition: 12 mg/kg
 Subcutaneous - Mouse TDLo: 8 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death]
 Intraperitoneal. - Rat LD50: 6 mg/kg [Details of toxic effects not reported other than lethal dose value]
 Intraperitoneal. - Mouse LD50: 50 mg/kg [Details of toxic effects not reported other than lethal dose value]
 Intraperitoneal. - Mouse TDLo: 0.5 mg/kg [Immunological Including Allergic - increase in humoral immune response]
 Intraperitoneal. - Mouse TDLo: 40 mg/kg [Tumorigenic - active as anti-cancer agent]
 Intraperitoneal. - Rat TDLo: 20 mg/kg [Kidney/Ureter/Bladder - changes in both tubules and glomeruli Blood - changes in leukocyte (WBC) count Biochemical - Metabolism (Intermediary) - lipids including transport]
 Intraperitoneal. - Rat TDLo: 20 mg/kg [Liver - other changes Kidney/Ureter/Bladder - changes in both tubules and glomeruli Kidney/Ureter/Bladder - other changes]
 Intraperitoneal. - Rat TDLo: 20 mg/kg [Blood - changes in erythrocyte (RBC) count Blood - changes in leukocyte (WBC) count Blood - changes in platelet count]
 Intraperitoneal. - Rat TDLo: 20 mg/kg [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - other oxidoreductases Biochemical - Metabolism (Intermediary) - other Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]
 Intraperitoneal. - Rat TDLo: 20 mg/kg [Spinal Cord - inflammatory changes]
 Intraperitoneal. - Rat TDLo: 20 mg/kg [Liver - other changes Kidney/Ureter/Bladder - changes in both tubules and glomeruli Blood - changes in bone marrow (not otherwise specified)]
 Intraperitoneal. - Mouse TDLo: 3.5 mg/kg/7D (intermittent) [Immunological Including Allergic - decrease in humoral immune response]
 Intraperitoneal. - Rat TDLo: 7.5 mg/kg/3D (intermittent) [Blood - change in clotting factors Blood - leukopenia]
 Intraperitoneal. - Rat TDLo: 4.5 mg/kg/3W (intermittent) [Kidney/Ureter/Bladder - other changes Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol) Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - phosphatases]
 Intraperitoneal. - Rat TDLo: 12 mg/kg/2W (intermittent) [Biochemical - Metabolism (Intermediary) - effect on inflammation or mediation of inflammation]
 Intraperitoneal. - Rat Micronucleus test: 250 mg/kg
 Intraperitoneal. - Rat Cytogenetic analysis: 250 mg/kg
 Intraperitoneal. - Mouse Micronucleus test: 10 mg/kg
 Intraperitoneal. - Mouse DNA damage: 16 mg/kg/4D (continuous)
 Intraperitoneal. - Mouse DNA inhibition: 2000 mg/kg
 Intraperitoneal. - Mouse Cytogenetic analysis: 50 mg/kg
 Intraperitoneal. - Mouse Dominant lethal test: 10 mg/kg
 Intraperitoneal. - Mouse Sperm Morphology: 2 mg/kg
 Intraperitoneal. - Mouse Micronucleus test: 1.5 mg/kg/3D (intermittent)
 Intraperitoneal. - Rat TDLo: 200 ug/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
 Intraperitoneal. - Rat TDLo: 5 mg/kg [Reproductive - Fertility - abortion]
 Intraperitoneal. - Rat TDLo: 200 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g.

dead and/or resorbed implants per total number of implants) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
Intraperitoneal. - Rat TDLo: 300 ug/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death]
Intraperitoneal. - Mouse TDLo: 50 mg/kg [Reproductive - Effects on Newborn - live birth index (measured after birth) Reproductive - Effects on Newborn - viability index (e.g., number alive at day 4 per number born alive) Reproductive - Effects on Newborn - growth statistics (e.g.%, reduced weight gain)]
Intraperitoneal. - Mouse TDLo: 200 mg/kg [Reproductive - Maternal Effects - oogenesis]
Intraperitoneal. - Mouse TDLo: 10 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
Intraperitoneal. - Mouse TDLo: 25 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
Intraperitoneal. - Mouse TDLo: 260 mg/kg [Reproductive - Paternal Effects - spermatogenesis (incl. genetic material, sperm morphology, motility, and count)]
Intraperitoneal. - Mouse TDLo: 20 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
Intraperitoneal. - Mouse TDLo: 50 mg/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]

Benzyl Alcohol :

RTECS Number: DN3150000

Skin: Administration onto the skin - Rabbit LD50: 2000 mg/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit Standard Draize test.: 100 mg/24H
Administration onto the skin - Rat LD50: 100 pph/90M [Details of toxic effects not reported other than lethal dose value]

Inhalation: Inhalation - Mouse LC50: >500 mg/m3 [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]
Inhalation - Rat LC50: >500 mg/m3 [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]

Ingestion: Oral - Rat LD50: 1230 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - excitement Behavioral - coma]
Oral - Mouse LD50: 1360 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 1360 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]
Oral - Rat LD50: 1660 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]
Oral - Rat LD50: 1.5 mL/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Rat LD50: 53 mg/kg [Lungs, Thorax, or Respiration - dyspnea]
Intravenous. - Mouse LD50: 324 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat LDLo: 1700 mg/kg [Sense Organs and Special Senses (Eye) - miosis (pupillary constriction) Behavioral - coma Kidney/Ureter/Bladder - other changes]
Intraperitoneal. - Rat LD50: 400 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 650 mg/kg [Behavioral - altered sleep time (including change in righting reflex) Behavioral - somnolence (general depressed activity) Lungs, Thorax, or Respiration - dyspnea]
Intraperitoneal. - Rat LDLo: 650 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]
Intraperitoneal. - Rat TDLo: 514 mg/kg [Behavioral - ataxia]

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 skin - Rabbit Standard Draize test.: 500 mg/24H [mild]

Inhalation: Inhalation - Rat LC50: >42 gm/m3/1H [Details of toxic effects not reported other than lethal dose value]

Ingestion: Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes]
Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Intravenous. - Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability]
Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death]
Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion]
Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold]
Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral]
Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg

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: Methotrexate Injection
DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Methotrexate :

TSCA Inventory Status: Listed
EINECS Number: 200-413-8
California PROP 65: Listed: developmental.
Canada DSL: Listed

Benzyl Alcohol :

TSCA Inventory Status: Listed
EINECS Number: 202-859-9
Canada DSL: Listed
Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.169(170)

Sodium Chloride :

TSCA Inventory Status: Listed
EINECS Number: 231-598-3
Canada DSL: Listed

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: March 10, 2025

SDS Revision Notes: Overall SDS review - no changes to formulation. Added HMIS ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE) to Section 16.

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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