

# SAFETY DATA SHEET

## SECTION 1: IDENTIFICATION

Methotrexate for Injection, USP Product Name:

Manufacturer Name: Fresenius Kabi USA, LLC Address: Three Corporate Drive Lake Zurich, Illinois 60047

General Phone Number: (847) 550-2300 Customer Service Phone (888) 386-1300

Number:

Health Issues Information: (800) 551-7176 SDS Creation Date: January 08, 2009 June 10, 2015 SDS Revision Date:

## SECTION 2: HAZARD(S) IDENTIFICATION

GHS Pictograms:









Signal Word: DANGER

GHS Class: Acute Oral Toxicity. Category 3.

Serious Eye Damage. Category 1. Skin corrosion. Category 1. Reproductive toxicity. Category 1A. Skin Sensitization. Category 1. Specific Target Organ Toxicity - STOT, Single Exposure SE. Category 3. Reproductive toxicity. Effects on or via lactation.

Hazard Statements:

Toxic if swallowed. Causes serious eye damage.

Causes severe skin burns and eye damage. May damage fertility or the unborn child. May cause an allergic skin reaction. May cause respiratory irritation. May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.

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.
Use only outdoors or in a well-ventilated area.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
IF SWALLOWED: Rinse mouth. Do not induce vomiting.
IF ON SKIN: Wash with plenty of water.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing.

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with

water/shower.

IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

IF IN CIES. Killse Cautiously with Mack for School School

Rinse mouth.

If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. Wash contaminated clothing before reuse.

Store in a well-ventilated place. Keep container tightly closed.

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.

Possible adverse reactions are related to the dose and frequency of administration and may include: hepatotoxicity, methotrexate-induced lung disease, diarrhea, ulcerative stomatitis, malignant Signs/Symptoms:

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.

Methotrexate for Injection, USP Revision: 06/10/2015

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 Sodium	59-05-2	1 gm/vial	
Hydrochloric Acid	7647-01-0	As needed to adjust pH	
Sodium Hydroxide	1310-73-2	As needed to adjust pH	

# 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.

Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing Skin Contact:

contaminated clothing and shoes.

Get medical attention if irritation develops or persists.

If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained Inhalation:

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 Ingestion:

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.

Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to Fire Fighting Instructions:

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

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

Page 2 of 6

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.

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. Methods for cleanup:

Methotrexate for Injection, USP Fresenius Kabi USA, LLC Revision: 06/10/2015

## 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 15 to 30°C (59 to 86°F). [See USP Controlled Room

Temperature]

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety

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

**Hydrochloric Acid:** 

Melting Point:

Guideline ACGIH: TLV-STEL: 2 ppm(ceiling)

Guideline OSHA: OSHA PEL-STEL 5 ppm Ceiling/Peak

## SECTION 9: PHYSICAL and CHEMICAL PROPERTIES

Physical State: Lyophilized powder. Yellow to Orange Color **Boiling Point:** Not established.

Solubility: Practically insoluble in water. Soluble in basic aqueous media (i.e. alkalis or carbonates). Practically

insoluble in ethanol or ether

185 - 204 °C

Vapor Density: Not established Not established. Vapor Pressure: 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. Not established Auto Ignition Temperature:

# 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 Sodium:**

RTECS Number: MA1225000

Eve - Human Rinsed with water: 150 mg

Methotrexate for Injection, USP Revision: 06/10/2015

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

Other Toxicological Information:

Methotrexate for Injection, USP

Revision: 06/10/2015

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]

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

Intravenous. - Rat TDLo: 300 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead

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 - musculockolotal exectors]

musculoskeletal system]

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 deposition), then the sense of the sense

other) Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - multiple enzyme

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) -

Subcutaneous - Rat IDLo: 280 ug/kg/4D (Intermittent) [Blochemical - 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 1

Intraperitoneal. - Mouse LD50: 50 mg/kg [Details of toxic effects not reported other than lethal dose

Intraperitoneal. - Mouse TDLo: 0.5 mg/kg [Immunological Including Allergic - increase in humoral immune responsel

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 transport1

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]

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]

Fresenius Kabi USA, LLC

Page 4 of 6

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

- 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 Development 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. Intraperitoneal. - Mouse TDLo: 25 mg/kg [Reproductive - Specific Developmental Abnormalities

musculoskeletal system Reproductive - Specific Developmental Abnormalities - craniofacial (including

nose and tongue)]

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)]

#### Hydrochloric Acid:

RTECS Number: MW4025000

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)

#### Sodium Hydroxide:

RTECS Number: WB4900000

Eye:

Eye - Rabbit Standard Draize test.: 400 ug Eye - Rabbit Standard Draize test.: 50 ug/24H (RTECS)

Skin: Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H

Ingestion: Oral - Rabbit LDLo: 500 mg/kg [Details of toxic effects not reported other than lethal dose value]

## 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. (Methotrexate for Injection)

DOT UN Number: UN3249 DOT Hazard Class: 6.1 DOT Packing Group: PG III

Limited Quantities: §173.153 Exceptions for Division 6.1 (poisonous materials). §173.153 (b)(2) For DOT Exemption:

Limited Quantities: §173.153 Exceptions for Division 6.1 (poisonous materials). §173.153 (b)(2) 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. Consumer Commodities: §173.153 Exceptions for Division 6.1 (poisonous materials). §173.153(c) Consumer commodities. Until December 31, 2020, a limited quantity package of poisonous material in Packing Group III or a drug or medicine in Packing Group II or III that is also a "consumer commodity" as defined in §171.8 of this subchapter, may be renamed "Consumer commodity" and reclassed as ORM-D or, until December 31, 2012, as ORM-D-AIR material and offered for transportation and transported in accordance with the applicable provisions of this

subchapter in effect on October 1, 2010.

IATA Shipping Name: Medicine, solid, toxic (Methotrexate for Injection).

IATA UN Number: UN3249 IATA Hazard Class: 6.1 IATA Packing Group: PG III

# SECTION 15: REGULATORY INFORMATION

## <u>Methotrexate Sodium</u>:

TSCA Inventory Status: EINECS Number: 200-413-8

California PROP 65: Listed: developmental.

Methotrexate for Injection, USP Revision: 06/10/2015

Canada DSL: Listed

<u>Hydrochloric A cid</u>:

Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.169(170)

**Sodium Hydroxide:** 

TSCA Inventory Status: Listed
Canada DSL: Listed

# SECTION 16: ADDITIONAL INFORMATION

## **HMIS Ratings**:

HMIS Health Hazard: 33
HMIS Fire Hazard: 0
HMIS Reactivity: 0
HMIS Personal Protection: X

SDS Creation Date: January 08, 2009
SDS Revision Date: June 10, 2015

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.

 $\label{local_conversion} \textbf{Copyright} \textcircled{e} \ \ \textbf{1996-2015} \ \ \textbf{Actio} \ \ \textbf{Corporation}. \ \ \textbf{All} \ \ \textbf{Rights} \ \ \textbf{Reserved}.$ 

Methotrexate for Injection, USP Revision: 06/10/2015