

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: **Ketorolac Tromethamine 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: June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER.

GHS Class: Flammable Liquid, Category 2.
 Serious Eye Damage, Category 1.
 Respiratory sensitisation, Category 1.
 Skin Irritation, Category 2.
 Skin Sensitization, Category 1.
 Reproductive toxicity, Effects on or via lactation.

Hazard Statements: Highly flammable liquid and vapor.
 Causes serious eye damage.
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 Causes skin irritation.
 May cause an allergic skin reaction.
 May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
 Keep container tightly closed.
 Ground/Bond container and receiving equipment.
 Use explosion-proof electrical/ventilating/lighting equipment.
 Use only non-sparking tools.
 Take precautionary measures against static discharge.
 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 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 to do. Continue rinsing.
IF exposed or concerned: Get medical advice/attention.
 Immediately call a POISON CENTER or doctor/physician.
 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 experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
 Take off contaminated clothing and wash it before reuse.
 In case of fire: Use dry chemical, carbon dioxide to extinguish small fires. Use water for large fires.
 Store in a well-ventilated place. Keep cool.
 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: Adverse reactions from therapeutic doses include: edema, hypertension, pruritus, rash, nausea, dyspepsia, gastrointestinal pain, diarrhea, constipation, flatulence, gastrointestinal fullness, vomiting, stomatitis, purpura, headache, drowsiness, dizziness, and sweating. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with active peptic ulcer disease, gastrointestinal bleeding or perforation, history of peptic ulcer diseases, gastrointestinal bleeding, advanced renal impairment or at risk for renal failure due to volume depletion, hypersensitivity to ketorolac tromethamine, allergic manifestations to aspirin or other nonsteroidal anti-inflammatory drugs (NSAIDs), and those with medical conditions that are at high risk for bleeding.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Ketorolac Tromethamine	74103-06-3	15 mg/mL, 30 mg/mL, or 60 mg/2 mL	
Citric Acid, Anhydrous	77-92-9	0.1 %	
Sodium Chloride	7647-14-5	See package insert	
Ethyl Alcohol	64-17-5	Amount: 10% % Amount: 10% by weight Amount: 10% by Volume	
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

Flammable Properties:	Flammable.
Flash Point:	109 °F (43 °C)
Flash Point Method:	closed cup.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	3.3% as ethanol
Upper Flammable/Explosive Limit:	19% as ethanol
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

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 controlled room temperature 15 to 30°C (59 to 86°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/nppt/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

Ethyl Alcohol:

Guideline OSHA: PEL-TWA: 1000 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Pale Yellow light amber
Boiling Point:	Not established.
Melting Point:	153 - 155 °C
Solubility:	Not applicable.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	7.2 - 7.6
Molecular Formula:	Mixture
Molecular Weight:	376.41
Flash Point:	109 °F (43 °C)
Flash Point Method:	closed cup.
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

Ketorolac Tromethamine :

Acute Toxicity: LD50: IP Mouse 225 mg/kg

Ketorolac Tromethamine :

RTECS Number: UY7759800

Ingestion: Oral - Mouse LD50: 200 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Human TDLo: 0.14 mg/kg [Behavioral - analgesia]
Subcutaneous - Mouse TDLo: 0.3 mg/kg [Behavioral - analgesia]
Intraperitoneal. - Mouse LDLo: 100 mg/kg [Details of toxic effects not reported other than lethal dose value]

Citric Acid, Anhydrous :

RTECS Number: GE7350000

Eye: Eye - Rabbit Standard Draize test.: 750 ug/24H [severe]
Skin: Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Ingestion: Oral - Rat LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 5040 mg/kg [Lungs, Thorax, or Respiration - Other changes Musculoskeletal - Other changes]
Oral - Mouse LD50: 7280 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse LD50: 42 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]
Intravenous. - Rabbit LD50: 330 mg/kg [Behavioral - convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - cyanosis Gastrointestinal - changes in structure or function of salivary glands]
Subcutaneous - Rat LD50: 5500 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]
Subcutaneous - Mouse LD50: 2700 mg/kg [Lungs, Thorax, or Respiration - other changes Musculoskeletal - other changes]
Intraperitoneal. - Rat LD50: 290 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 903 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD16: 197 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD: 382 mg/kg [Details of toxic effects not reported other than lethal dose value]

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

Ethyl Alcohol :

RTECS Number: KQ6300000
Eye: Eye - Rabbit Rinsed with water.: 100 mg/4S
Skin: Administration onto the skin - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit Open irritation test: 400 mg
Administration onto the skin - Rabbit Standard Draize test.: 20 mg/24H

Inhalation: Inhalation - Rat LC50: 20000 ppm/10H [Details of toxic effects not reported other than lethal dose value]
Inhalation - Mouse LC50: 39 gm/m³/4H [Details of toxic effects not reported other than lethal dose value]

Ingestion: Oral - Rat LD50: 7060 mg/kg [Lungs, Thorax, or Respiration - Other changes]
Oral - Mouse LD50: 3450 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Rat LD50: 7 gm/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Human TDLo: 1.6 gm/kg/6H [Biochemical - Metabolism (Intermediary) - other]
Intravenous. - Mouse TDLo: 3 gm/kg [Behavioral - sleep]
Intravenous. - Mouse TDLo: 3 gm/kg [Behavioral - sleep Behavioral - tolerance]
Intravenous. - Rat LD50: 1440 mg/kg [Lungs, Thorax, or Respiration - dyspnea]
Intravenous. - Rabbit LD50: 2374 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rat TDLo: 0.5 gm/kg [Brain and Coverings - recordings from specific areas of CNS]
Intravenous. - Human TDLo: 0.89 mL/kg [Vascular - regional or general arteriolar constriction Vascular - measurement of regional blood flow]
Intravenous. - Mouse LD50: 1973 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rat TDLo: 4 gm/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic]

structures (e.g., placenta, umbilical cord) Reproductive - Effects on Embryo or Fetus - other effects to embryo Reproductive - Specific Developmental Abnormalities - musculoskeletal system]

Intravenous. - Rat TDLo: 3 gm/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]

Intravenous. - Rat TDLo: 4 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]

Intravenous. - Rabbit TDLo: 15 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - other effects to embryo]

Subcutaneous - Mouse LD50: 8285 mg/kg [Details of toxic effects not reported other than lethal dose value]

Subcutaneous - Rabbit LDLo: 20 gm/kg [Details of toxic effects not reported other than lethal dose value]

Subcutaneous - Mouse TDLo: 5 gm/kg [Liver - hepatitis (hepatocellular necrosis), zonal]

Intraperitoneal. - Rat TDLo: 3000 mg/kg [Nutritional and Gross Metabolic - body temperature decrease]

Intraperitoneal. - Rat TDLo: 3500 mg/kg [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - dehydrogenases]

Intraperitoneal. - Rat TDLo: 1000 mg/kg [Brain and Coverings - other degenerative changes Liver - other changes Biochemical - Metabolism (Intermediary) - lipids including transport]

Intraperitoneal. - Rat TDLo: 0.25 gm/kg [Behavioral - alteration of operant conditioning]

Intraperitoneal. - Rat TDLo: 0.5 gm/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of operant conditioning]

Intraperitoneal. - Mouse TDLo: 1.5 mg/kg [Behavioral - antianxiety]

Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - alteration of operant conditioning Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Mouse TDLo: 2.5 gm/kg [Behavioral - somnolence (general depressed activity) Behavioral - alteration of operant conditioning Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Mouse TDLo: 4 gm/kg [Behavioral - somnolence (general depressed activity)]

Intraperitoneal. - Mouse TDLo: 2 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 1 gm/kg [Behavioral - antianxiety Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Mouse TDLo: 1000 mg/kg [Liver - other changes]

Intraperitoneal. - Mouse TDLo: 0.25 gm/kg [Behavioral - analgesia]

Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 1000 mg/kg [Behavioral - food intake (animal)]

Intraperitoneal. - Rat LD50: 3600 ug/kg [Details of toxic effects not reported other than lethal dose value]

Intraperitoneal. - Mouse LD50: 528 mg/kg [Details of toxic effects not reported other than lethal dose value]

Intraperitoneal. - Rabbit LD50: 963 mg/kg [Details of toxic effects not reported other than lethal dose value]

Intraperitoneal. - Guinea pig LD50: 3414 mg/kg [Details of toxic effects not reported other than lethal dose value]

Intraperitoneal. - Mouse TDLo: 4.2 gm/kg [Nutritional and Gross Metabolic - body temperature decrease]

Intraperitoneal. - Rat TDLo: 2.45 gm/kg [Behavioral - altered sleep time (including change in righting reflex)]

Intraperitoneal. - Rat TDLo: 0.5 gm/kg [Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Mouse TDLo: 1.75 gm/kg [Behavioral - ataxia]

Intraperitoneal. - Mouse TDLo: 0.5 gm/kg [Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Rat TDLo: 3000 mg/kg [Behavioral - sleep]

Intraperitoneal. - Rat TDLo: 2 gm/kg [Brain and Coverings - other degenerative changes Endocrine - differential effect of sex or castration on observed toxicity Biochemical - Metabolism (Intermediary) - other]

Intraperitoneal. - Rat TDLo: 1 gm/kg [Sense Organs and Special Senses (Taste) - change in function]

Intraperitoneal. - Mouse TDLo: 4.25 gm/kg [Behavioral - sleep]

Intraperitoneal. - Rat TDLo: 2.4 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Neurotransmitters or modulators (putative) - dopamine at other sites]

Intraperitoneal. - Mouse TDLo: 2 mg/kg [Brain and Coverings - recordings from specific areas of CNS]

Intraperitoneal. - Rat TDLo: 1.5 gm/kg [Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum]

Intraperitoneal. - Rat TDLo: 1.25 mg/kg [Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Mouse LDLo: 4000 mg/kg [Behavioral - alteration of classical conditioning Nutritional and Gross Metabolic - body temperature decrease]

Intraperitoneal. - Rat TDLo: 2700 mg/kg [Behavioral - ataxia]

Intraperitoneal. - Rat TDLo: 500 mg/kg [Behavioral - analgesia]

Intraperitoneal. - Rat TDLo: 2000 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - other]

Intraperitoneal. - Mouse TDLo: 4 gm/kg [Behavioral - withdrawal]

Intraperitoneal. - Mouse TDLo: 2.0 gm/kg [Behavioral - ataxia Nutritional and Gross Metabolic - body temperature decrease]

Intraperitoneal. - Rat TDLo: 2 gm/kg [Brain and Coverings - other degenerative changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - phosphokinase]

Intraperitoneal. - Rat TDLo: 1000 mg/kg [Behavioral - muscle weakness]

Intraperitoneal. - Rat TDLo: 2000 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - ataxia Behavioral - alteration of operant conditioning]

Intraperitoneal. - Rat TDLo: 500 mg/kg [Behavioral - alteration of classical conditioning]

Intraperitoneal. - Rat TDLo: 3000 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Metabolism (Intermediary) - amino acids (including renal excretion)]

Intraperitoneal. - Mouse TDLo: 1.5 gm/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antianxiety]

Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - ataxia Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 2 gm/kg [Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 3.5 gm/kg [Behavioral - altered sleep time (including change in righting reflex)]

Intraperitoneal. - Mouse TDLo: 0.3 mg/kg [Behavioral - alteration of operant conditioning]

Intraperitoneal. - Mouse TDLo: 1.2 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - antianxiety Behavioral - alteration of operant conditioning]

Intraperitoneal. - Mouse TDLo: 1.8 mg/kg [Behavioral - alteration of classical conditioning Behavioral - antianxiety Behavioral - alteration of operant conditioning]

Intraperitoneal. - Mouse TDLo: 4 gm/kg/8D (intermittent) [Behavioral - alteration of classical conditioning Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 4.8 mg/kg/4D (intermittent) [Behavioral - changes in motor activity (specific assay)]

Intraperitoneal. - Mouse TDLo: 12 mg/kg/3D (intermittent) [Behavioral - alteration of classical conditioning]

Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - changes in psychophysiological tests Nutritional and Gross Metabolic - weight loss or decreased weight gain]

Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 7000 mg/kg/7D (intermittent) [Behavioral - tolerance Behavioral - changes in psychophysiological tests]

Intraperitoneal. - Rat TDLo: 3 gm/kg/3D (intermittent) [Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 37.8 mg/kg/21D (intermittent) [Behavioral - changes in motor activity (specific assay) Behavioral - tolerance Behavioral - alteration of classical conditioning]

Intraperitoneal. - Mouse TDLo: 12.6 mg/kg/21D (intermittent) [Behavioral - tolerance]

Intraperitoneal. - Rat Mutation test systems not otherwise specified: 250 gm/kg/16D (continuous)

Intraperitoneal. - Mouse Micronucleus test: 1240 mg/kg/2D

Intraperitoneal. - Rat TDLo: 15 gm/kg [Reproductive - Effects on Newborn - behavioral Reproductive - Effects on Newborn - physical]

Intraperitoneal. - Rat TDLo: 2240 mg/kg [Reproductive - Effects on Embryo or Fetus - extra-embryonic structures (e.g., placenta, umbilical cord)]
 Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
 Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) 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)]
 Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
 Intraperitoneal. - Rat TDLo: 3600 mg/kg [Reproductive - Effects on Newborn - behavioral]
 Intraperitoneal. - Mouse TDLo: 5800 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
 Intraperitoneal. - Mouse TDLo: 5800 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
 Intraperitoneal. - Mouse TDLo: 5622 ug/kg [Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
 Intraperitoneal. - Mouse TDLo: 4 mg/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
 Intraperitoneal. - Mouse TDLo: 4300 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
 Intraperitoneal. - Mouse TDLo: 2.9 gm/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
 Intraperitoneal. - Rat TDLo: 11.25 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
 Intraperitoneal. - Mouse TDLo: 15 mg/kg [Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
 Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)]
 Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - other effects to embryo Reproductive - Specific Developmental Abnormalities - eye/ear]
 Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities]
 Intraperitoneal. - Mouse TDLo: 5.8 gm/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
 Intraperitoneal. - Mouse TDLo: 22.8 gm/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - eye/ear]

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.
IATA Shipping Name: Non regulated.
IATA UN Number: Non regulated.

SECTION 15 : REGULATORY INFORMATION

Citric Acid, Anhydrous :

TSCA Inventory Status: Listed
EINECS Number: 201-069-1
Canada DSL: Listed
Canada IDL: Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.409(80)

Sodium Chloride :

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

Ethyl Alcohol :

TSCA Inventory Status: Listed
EINECS Number: 200-578-6

Canada DSL: Listed
Canada IDL: : 3300 ppm
Water for Injection :
TSCA Inventory Status: Listed
Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 2
HMIS Fire Hazard: 3
HMIS Reactivity: 1
HMIS Personal Protection: M

SDS Creation Date: January 08, 2009

SDS Revision Date: June 01, 2015

Disclaimer:

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