

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name: Ketorolac Tromethamine Injection, USP Simplist™ 30mg/mL
Manufacturer Name: Fresenius Kabi Simplist™
Address: Three Corporate Drive
 Lake Zurich, Illinois 60047
General Phone Number: (847) 550-2300
SDS Creation Date: March 18, 2016
SDS Revision Date: March 18, 2016

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/hotsurfaces. — 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.

Potential Health Effects: 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.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Ketorolac Tromethamine	74103-06-3	<=3 by weight	
Ethyl Alcohol	64-17-5	<=10 by weight	
Notes :	Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1.0% may include sodium chloride. Sodium hydroxide and hydrochloric acid may be added to adjust the 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.
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

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 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/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

Ethyl Alcohol :

Guideline OSHA: PEL-TWA: 1000 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Pale Yellow light amber
Odor:	Odorless.
Odor Threshold:	No information.
Boiling Point:	91°C (196°F) at 760 mmHg (10% ethanol water solution)
Melting Point:	-4°C (25°F) at 760 mmHg (10% ethanol water solution)
Specific Gravity:	0.991
Solubility:	Miscible in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	6.9 - 7.9
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.
Conditions to Avoid:	Extreme heat, sparks, and open flame. Incompatible materials, oxidizers and oxidizing conditions.
Incompatible Materials:	Avoid storage near oxidizers and water reactive materials.
Special Decomposition Products:	Thermal decomposition products or combustion include oxides of carbon and nitrogen

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]

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]

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

Ethyl Alcohol:

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

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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

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