

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** **Metoclopramide Hydrochloride Injection, USP Simplist™**  
**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  
**(M)SDS Format:**

### SECTION 2 : HAZARD(S) IDENTIFICATION

**GHS Pictograms:**



**Signal Word:** WARNING.

**GHS Class:** Eye Irritation. Category 2.  
Acute Oral Toxicity. Category 4.

**Hazard Statements:** Causes serious eye irritation.  
Harmful if swallowed.

**Precautionary Statements:** Wash hands thoroughly after handling.  
Do not eat, drink or smoke when using this product.  
Wear protective gloves/protective clothing/eye protection/face protection.  
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.  
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
Rinse mouth.  
If eye irritation persists: Get medical advice/attention.  
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.

**Target Organs:** In clinical use, target organs include the central nervous system and gastrointestinal tract.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Metoclopramide Hydrochloride	54143-57-6	0.5 by weight	
<b>Notes :</b>	Non-hazardous ingredients include Water for Injection and Sodium citrate. Sodium hydroxide 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

**Flash Point:** Not established.

<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.
<b>Lower Flammable/Explosive Limit:</b>	Not established.
<b>Upper Flammable/Explosive Limit:</b>	Not established.
<b>Fire Fighting Instructions:</b>	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.
<b>Extinguishing Media:</b>	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.
<b>Protective Equipment:</b>	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Hazardous Combustion Byproducts:</b>	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

<b>Personal Precautions:</b>	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.
<b>Environmental Precautions:</b>	Avoid runoff into storm sewers, ditches, and waterways.
<b>Methods for containment:</b>	Contain spills with an inert absorbent material such as soil, sand or oil dry.
<b>Methods for cleanup:</b>	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

<b>Handling:</b>	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.
<b>Storage:</b>	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Protect from light, heat, and freezing.
<b>Work Practices:</b>	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
<b>Hygiene Practices:</b>	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

<b>Engineering Controls:</b>	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.
<b>Eye/Face Protection:</b>	Chemical splash goggles. Wear a face shield also when splash hazard exist.
<b>Skin Protection Description:</b>	Protective laboratory coat, apron, or disposable garment recommended.
<b>Hand Protection Description:</b>	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
<b>Respiratory Protection:</b>	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 ( <a href="http://www.cdc.gov/niosh/nppt/topics/respirators/">http://www.cdc.gov/niosh/nppt/topics/respirators/</a> ) for a list of respirator types and approved suppliers.
<b>Other Protective:</b>	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

### EXPOSURE GUIDELINES

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid solution.
<b>Color:</b>	Colorless.
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	No information.
<b>Boiling Point:</b>	Approximately that of water, 100°C (212°F)
<b>Melting Point:</b>	Approximately that of water, 0°C (32°F)
<b>Specific Gravity:</b>	1.0045

Solubility: Soluble. in water.  
Vapor Density: Not established.  
Vapor Pressure: Not established.  
Percent Volatile: Not established.  
pH: 2.5 - 6.5  
Flash Point: Not established.  
Flash Point Method: Not established.  
Auto Ignition Temperature: Not established.

## SECTION 10 : STABILITY and REACTIVITY

Chemical Stability: Stable under normal temperatures and pressures.  
Hazardous Polymerization: Not reported.  
Conditions to Avoid: Protect from light and excessive heat. Do not autoclave. Do not freeze.

## SECTION 11 : TOXICOLOGICAL INFORMATION

### Metoclopramide Hydrochloride :

Ingestion: Oral - Rat LD50 - Lethal dose, 50 percent kill: 270 - 870 mg gm/kg  
Mutagenicity: Negative in bacterial reverse mutation assay  
Reproductive Toxicity: FDA Cat B (All trimesters.) Animal reproductive studies reveal no adverse effects. Not expected to be teratogenic in humans but cannot rule out.

## 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.

## SECTION 15 : REGULATORY INFORMATION

### Metoclopramide Hydrochloride :

TSCA Inventory Status: Listed  
EINECS Number: 230-634-5  
Canada DSL: Listed

## SECTION 16 : ADDITIONAL INFORMATION

### HMIS Ratings:

HMIS Health Hazard: 1  
HMIS Fire Hazard: 1  
HMIS Reactivity: 1  
HMIS Personal Protection: X

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