SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Ondansetron 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
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
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 INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
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.
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:
Possible adverse reactions include: diarrhea, headache, fever, constipation, dizziness, musclemen pain, drowsiness, sedation, malaise, fatigue, shivers, injection site reaction, urinary retention, pain, chest pain, anxiety, dysuria, hypotension, fever, cold sensation, pruritus, and paresthesia. Flushing, rare cases of hypersensitivity reactions including anaphylaxis, bronchospasm, cardiopulmonary arrest, hypotension, laryngeal edema, laryngospasm, shock, shortness of breath, and stridor have also been reported.

Local reactions such as pain, redness, and burning at the site of injection have been reported. Dystonic reactions including oculogyric crisis, urticaria, hiccups, transient dizziness, and transient blurred vision have also been reported. Transient blindness which resolved within a few minutes or up to 48 hrs was also reported.

Occupational exposure has not been fully investigated. Overexposure in the workplace might have the following effects: symptoms of hypersensitivity, such as skin rash, hives, itching, and/or difficulty breathing, headache, constipation, flushing, and central nervous system activity.

Aggravation of Pre-Existing Conditions:
Minor irritation might occur following direct contact with eyes. Adverse effects might occur in the central nervous system following overexposure.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.

Ondansetron Hydrochloride	103639-04-9	2 mg/mL
Methylparaben	99-76-3	1.2 mg/mL in preserved product
Citric Acid Monohydrate	5949-29-1	0.5 mg/mL
Sodium Citrate Dihydrate	6132-04-3	0.25 mg/mL
Propylparaben	94-13-3	0.15 mg/mL in preserved product
Sodium Chloride	7647-14-5	See Package Insert
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

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

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 between 2 to 25ºC (36 to 77ºF). 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:	Colorless.
Odor:	No information.
Odor Threshold:	No information.
Boiling Point:	Not established.
Melting Point:	Not established.
Density:	No information.
Specific Gravity:	No information.
Specific Volume:	No information.
Solubility:	Sparingly soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
Evaporation Point:	No information.
pH:	3.3 - 4.0
Molecular Formula:	Mixture
Molecular Weight:	365.86
Viscosity:	No information.
Coefficient of Water/Oil Distribution:	No information.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
VOC Content:	No information.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Reproductive Toxicity:	Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Ondansetron Hydrochloride :

Eye:	Serious damage to eye.
Skin:	Corrosive to skin.
Sensitization:	Hypersensitivity reactions have been reported in patients.

Methylparaben :

RTECS Number:	DH2450000
Eye:	Slight transient irritation to rabbit eyes.
Skin:	Not irritating to skin.
Ingestion:	Oral - Rat LD50: 2100 mg/kg (ECHA)
Other Toxicological Information:	Intravenous. - Mouse TDLo: 100 mg/kg [Vascular - shock Lungs, Thorax, or Respiration - respiratory depression] Intravenous. - Mouse TDLo: 2.5 mg/kg [Lungs, Thorax, or Respiration - tumors] Subcutaneous - Mouse TDLo: 165 mg/kg [Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression] Subcutaneous - Mouse LD50: 1.2 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50: >500 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse TDLo: 49.5 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight] Subcutaneous - Mouse TDLo: 165 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Related to Chronic Data - changes in uterine weight] Intraperitoneal. - Mouse LD50: 960 mg/kg [Peripheral Nerve and Sensation - flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - somnolence (general depressed activity) Behavioral - ataxia] Intraperitoneal. - Mouse LD50: 125 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 960 mg/kg [Details of toxic effects not reported other than lethal dose value]

Citric Acid Monohydrate :

RTECS Number:	GE7810000
Eye:	Severe eye damage in a man.
Skin:	Irritating to human skin.
Ingestion:	Oral - Rat LD50: 3000 mg/kg (CHEMINFO)
Other Toxicological Information:	Intraperitoneal. - Rat LD50 : 375 mg/kg [Details of toxic effects not reported other than lethal dose value]

Sodium Citrate Dihydrate :

Eye:	No or moderate irritation in rabbits.
Skin:	Dermal - Rat LD50: >2000mg/kg (OECD Guideline 402, GLP) (TS : Citric acid) (ECHA) No irritation in rabbits.
Ingestion:	Oral - Rat LD50: >8000 mg/kg (TS : Sodium Citrate) (CHEMINFO)

Propylparaben :

RTECS Number:	DH2800000
Eye:	rabbit, not irritating.
Skin:	rabbit, not irritating.
Ingestion:	Oral - Rat LD50: > 5000 mg/kg (OECD Guideline 401) (ECHA)
Other Toxicological Information:	Subcutaneous - Mouse LD50: 1650 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse TDLo: 51 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight] Subcutaneous - Rat TDLo: 99 mg/kg/3D (intermittent) [Related to Chronic Data - changes in uterine weight] Subcutaneous - Mouse TDLo: 195 mg/kg/3D (intermittent) [Reproductive - Maternal Effects - uterus, cervix, vagina Related to Chronic Data - changes in uterine weight] Intraperitoneal. - Mouse LD50: 200 mg/kg [Details of toxic effects not reported other than lethal dose value]

Sodium Chloride :

RTECS Number:	VZ4725000
Eye:	Rabbit, Moderate irritation.
Skin:	Dermal- Rabbit LD50: > 10000 mg/kg (ECHA) Slight irritation.
Inhalation:	Inhalation - Rat LC50:> 42 mg/L/1h (ECHA)
Ingestion:	Oral - Rat LD50: 3550 mg/kg (ECHA)
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.
Methylparaben :	
Ecotoxicity:	Japanese rice fish (Oryzias latipes) LC50 (96hr) 60 mg/L Water flea (Daphnia magna) 48hr-EC50 36 mg/L, NOEC (21d) 0.20 mg/L Green algae (Pseudokircheneriella subcapitata) 72hr- EC50 56 mg/L (JAPAN MOE)
Biodegradation:	Readily biodegradable (89% after 28 days).
Bioaccumulation:	Low potential to bioaccumulate (BCF :6.4).
Citric Acid Monohydrate :	
Ecotoxicity:	Golden orfe (Leuciscus idus) LC50 (96hr) = 440–760 mg/l .(TS : Citric Acid) (OECD SIDS) Water flea (Daphnia magna) LC50 (24hr) 1535 mg/L .(TS : Citric Acid) (ECHA) Green algae (Scenedesmus quadricauda) EC0 (7d) = 640 mg/l .(TS : Citric Acid) (OECD SIDS)
Bioaccumulation:	Readily biodegradable (90%).
Sodium Citrate Dihydrate :	
Ecotoxicity:	Golden orfe (Leuciscus idus melanotus) LC50 (48 h) 440 mg/L (TS : Citric acid) Water flea (Ceriodaphnia sp.) EC50 (48hr) 736 mg/L (TS : Sodium Citrate) Green algae (Scenedesmus quadricauda) Toxicity Threshold (8d) 640 mg/L, NOEC (8d) 425 mg/L (ECHA)
Propylparaben :	
Ecotoxicity:	Zebra fish (Danio rerio) LC50 (96hr) 6.4 mg/L (OECD Guideline 203, GLP) Water flea (Daphnia magna) EC50 (48hr) 15.4 mg/L Green algae (Pseudokirchnerella subcapitata) EC50 (72hr) 16 mg/L (OECD Guideline 201, GLP) (ECHA)
Biodegradation:	Readily biodegradable (91.5 % after 28 d)
Bioaccumulation:	Low potential to bioaccumulate due to log Pow of 2.34.
Sodium Chloride :	
Ecotoxicity:	Bluegill sunfish (Lepomis macrochirus) LC50 (96hr) 5840 mg/L, Fathead minnows (Pimephales promelas) NOEC 33 d 252 mg/L Water flea (Daphnia magna) LC50 (48hr) 874 mg/L , Water flea (Daphnia pulex) NOEC (21d) 314 mg/L Marine diatom (Nitzschia sp.) EC50 (120hr) 2430 mg/L (ECHA)

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

Methylparaben :	
TSCA Inventory Status:	Listed
EINECS Number:	202-785-7
Canada DSL:	Listed
Citric Acid Monohydrate :	
Canada DSL:	Listed
Propylparaben :	
TSCA Inventory Status:	Listed
EINECS Number:	202-307-7
Canada DSL:	Listed
Sodium Chloride :	
TSCA Inventory Status:	Listed
EINECS Number:	231-598-3

Canada DSL:	Listed

Water for Injection :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

SDS Creation Date:	January 08, 2009
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SDS Format:	
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