SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Levetiracetam 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:	May 08, 2012
SDS Revision Date:	November 10, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Specific Target Organ Toxicity -STOT Repeated exposure RE. Category 1 (Oral, Nervous system).
Reproductive toxicity. Category 2.
Skin Sensitization. Category 1.
Specific Target Organ Toxicity - STOT, Single Exposure SE. Category 3.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
Causes damage to organs through prolonged or repeated exposure.
Suspected of damaging fertility or the unborn child.
May cause an allergic skin reaction.
May cause drowsiness or dizziness.
May cause harm to breast-fed children.

Precautionary Statements:
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 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.
Call a POISON CENTER or doctor/physician if you feel unwell.
Get medical advice/attention if you feel unwell.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
Take off contaminated clothing and wash it 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:

- Eye: Contact with eyes may cause irritation.
- Skin: May cause skin irritation.
- Inhalation: May cause irritation of respiratory tract.
- Ingestion: May cause irritation.

Signs/Symptoms: The substance is used for the treatment of epilepsy and is generally well tolerated after repeated oral intake up to 3000 mg/day. The most frequently reported adverse events are drowsiness, weakness, and dizziness

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Levetiracetam, USP	102767-28-2	500 mg/ 5 mL	

Acetic Acid, USP	64-19-7	As needed to adjust pH
Sodium Chloride, USP	7647-14-5	45 mg/mL
Sodium Acetate Trihydrate, USP	6131-90-4	8.2 mg/mL
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 at 25ºC (77ºF); excursions permitted to 15 to 30ºC (59 to 86ºF). [See USP Controlled Room Temperature].
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

Acetic Acid, USP :

Guideline ACGIH:	TLV-TWA: 10 ppm
Guideline OSHA:	PEL-TWA: 10 ppm

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Clear, colorless.
Odor:	Faint odor.
Boiling Point:	Not established.
Melting Point:	Not established.
Specific Gravity:	0.6 (H20 = 1)
Solubility:	Soluble in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	5 -7
Molecular Formula:	Mixture
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:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Chronic Effects:	None known.
Levetiracetam, USP :	
RTECS Number:	UX9656166
Ingestion:	Oral - Human TDLo: 146.4 mg/kg/8D (intermittent) [Behavioral - Somnolence (general depressed activity)] Oral - Human TDLo: 71.4 mg/kg [Behavioral - somnolence (general depressed activity) Gastrointestinal - nausea or vomiting]
Other Toxicological Information:	Intravenous. - Rat LD50: 1038 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 1081 mg/kg [Details of toxic effects not reported other than lethal dose value]
Acetic Acid, USP :	
RTECS Number:	AF1225000
Eye:	Eye - Rabbit Rinsed with water.: 5 mg/30S
Skin:	Administration onto the skin - Rabbit LD50: 1060 uL/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit TDLo: 0.04 gm/kg/24H [Skin and Appendages - Primary irritation (After topical exposure)] Administration onto the skin - Rabbit Open irritation test: 525 mg Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H Administration onto the skin - Rat TDLo: 0.25 mg/kg [Gastrointestinal - Ulceration or bleeding from duodenum] Administration onto the skin - Mouse Unscheduled DNA synthesis: 79279 ug/kg

	Administration onto the skin - Mouse Mutation test systems : 1201 mg/kg
Inhalation:	Inhalation - Mouse LC50: 5620 ppm/1H [Sense Organs and Special Senses (Eye) - Conjunctive irritation Sense Organs and Special Senses (Eye) - effect, not otherwise specified Blood - Other changes]
Ingestion:	Oral - Rat LD50: 3310 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse LD50: 525 mg/kg [Behavioral - convulsions or effect on seizure threshold] Subcutaneous - Rabbit LDLo: 600 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse TDLo: 50 mg/kg [Behavioral - analgesia] Intraperitoneal. - Mouse TDLo: 93.75 mg/kg [Behavioral - convulsions or effect on seizure threshold]

Sodium Chloride, USP :

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

Sodium Acetate Trihydrate, USP :

RTECS Number:	AJ4580000
Eye:	Eye - Rabbit Standard Draize test. : 10 mg [mild]
Skin:	Acute Toxicity: LD50 Dermal Rabbit: 10 mg/kg
Inhalation:	Inhalation - Rat LC50 : >30 gm/m3/1H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Rat LD50 : 3530 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Mouse LD50 : 6891 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Mouse LDLo: 1195 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LDLo: 1300 mg/kg [Behavioral - toxic psychosis Behavioral - fluid intake Kidney/Ureter/Bladder - urine volume increased] Subcutaneous - Mouse LD50: 3200 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.

SECTION 15 : REGULATORY INFORMATION

Levetiracetam, USP :

Canada DSL:	Listed

Acetic Acid, USP :

TSCA Inventory Status:	Listed
EINECS Number:	200-580-7
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.6(51)

Sodium Chloride, USP :

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

Sodium Acetate Trihydrate, USP :

TSCA Inventory Status:	Listed
EINECS Number:	204-823-8
Canada DSL:	Listed

Water for Injection :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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

SDS Creation Date:	May 08, 2012
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