SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Valproate Sodium Injection**
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:
Serious Eye Damage. Category 1.
Skin corrosion. Category 1.
Respiratory sensitisation. Category 1.
Reproductive toxicity. Category 1A.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
Causes serious eye damage.
Causes severe skin burns and eye damage.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage fertility or the unborn child.
May cause an allergic skin reaction.
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.
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 SWALLOWED: Rinse mouth. Do not induce vomiting.
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 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.
Wash contaminated clothing before reuse.
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: Side effects from therapeutic doses include hepatotoxicity, pancreatitis, hyperammonemic encephalopathy, CNS depression, somnolence, and thrombocytopenia. Serious or fatal hepatotoxicity may be preceded by nonspecific symptoms such as malaise, weakness, lethargy, facial edema, anorexia, and vomiting. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Liver conditions (especially in children), pancreatitis, allergic reaction, and liver or kidney disorders.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Valproic Acid	99-66-1	100 mg/mL	
Edetate Disodium	139-33-3	0.40 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 controlled room temperature 20 to 25°C (68 to 77°F). [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

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Clear to pale yellow
Boiling Point:	Approximately 100°C
Melting Point:	Approximately 0°C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	7.6
Molecular Formula:	Mixture
Molecular Weight:	166.2
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.
Incompatible Materials:	Avoid storage near oxidizers and water reactive materials.
Special Decomposition Products:	Decomposition products of this compound may include potentially hazardous byproducts, acrid, and toxic fumes.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	Valproate affects the digestive and central nervous systems as well as the liver and kidneys. Short-term contact may cause dermal, eye, gastrointestinal tract, and respiratory irritation. Ingestion may result in nausea, vomiting, abdominal cramps, and diarrhea. Possible allergic reaction if inhaled, ingested, or contact with the skin.

Valproic Acid :

Acute Toxicity:	Acute Toxicity: LD50 IP: Mouse 470 mg/kg LD50 SC: Mouse 860 mg/kg
Acute Effects:	Valproate affects the digestive and central nervous systems as well as the liver and kidneys. Short-term contact may cause dermal, eye, gastrointestinal tract, and respiratory irritation. Ingestion may result in nausea, vomiting, abdominal cramps, and diarrhea. Possible allergic reaction if inhaled, ingested, or contact with the skin.
Chronic Effects:	Long term exposure may result in hair loss, trembling hands and arms, mood or mental changes, tiredness and weakness, swelling of face, yellow eyes or skin, vision disturbances or uncontrolled eye movement, unusual bleeding or bruising, clumsiness or unsteadiness, dizziness, headaches, skin rash and unusual excitement, restlessness or irritability.
Teratogenicity:	Teratogenic effects such as neural tube defects (e.g. spina bifida) have been associated with therapeutic valproate therapy. Accordingly, the use of valproate products in women of childbearing potential requires that the benefits of its use be weighed against the risk of injury to the fetus.

Valproic Acid :

RTECS Number:	YV7875000
Ingestion:	Oral - Rat LD50: 670 mg/kg [Behavioral - Somnolence (general depressed activity) Gastrointestinal - Hypermotility, diarrhea] Oral - Mouse LD50: 1098 mg/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 675 mg/kg [Details of toxic effects not reported other than lethal dose value]
Reproductive Toxicity:	For Valproic Acid (active ingredient) RTECS Number YV7875000 Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).
Other Toxicological Information:	Subcutaneous - Mouse LD50: 860 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat TDLo: 600 mg/kg [Endocrine - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - other oxidoreductases Biochemical - Metabolism (Intermediary) - effect on cyclic nucleotides] Subcutaneous - Mouse TDLo: 2400 mg/kg [Liver - other changes Biochemical - Metabolism (Intermediary) - other] Subcutaneous - Rat TDLo: 8400 mg/kg/2W (intermittent) [Endocrine - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - other oxidoreductases Biochemical - Metabolism (Intermediary) - effect on cyclic nucleotides] Subcutaneous - Rat TDLo: 660 mg/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - other developmental abnormalities] Subcutaneous - Mouse TDLo: 2400 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 - Central Nervous System] Intraperitoneal. - Mouse LD50: 470 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rabbit LD50: 1200 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse TDLo: 450 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse TDLo: 200 mg/kg [Biochemical - Metabolism (Intermediary) - amino acids (including renal excretion)] Intraperitoneal. - Rat TDLo: 200 mg/kg [Behavioral - analgesia Behavioral - changes in psychophysiological tests] Intraperitoneal. - Rat TDLo: 600 mg/kg [Behavioral - changes in motor activity (specific assay)] Intraperitoneal. - Rat TDLo: 200 mg/kg [Behavioral - analgesia] Intraperitoneal. - Rat TDLo: 400 mg/kg [Behavioral - muscle weakness] Intraperitoneal. - Rat TDLo: 600 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - changes in motor activity (specific assay)] Intraperitoneal. - Mouse TDLo: 225 mg/kg [Behavioral - anticonvulsant Biochemical - Metabolism (Intermediary) - amino acids (including renal excretion)] Intraperitoneal. - Mouse TDLo: 394.5 mg/kg [Behavioral - anticonvulsant Behavioral - muscle weakness Biochemical - Metabolism (Intermediary) - amino acids (including renal excretion)] Intraperitoneal. - Rat TDLo: 400 mg/kg [Brain and Coverings - other degenerative changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases Biochemical - Neurotransmitters or modulators (putative) - dopamine in striatum] Intraperitoneal. - Rat TDLo: 75 mg/kg [Behavioral - anticonvulsant] Intraperitoneal. - Mouse TDLo: 253 mg/kg [Behavioral - changes in psychophysiological tests] Intraperitoneal. - Mouse TDLo: 100 mg/kg [Behavioral - anticonvulsant Behavioral - somnolence (general depressed activity) Behavioral - changes in psychophysiological tests] Intraperitoneal. - Rat LDLo: 650 mg/kg [Gastrointestinal - other changes Liver - hepatitis (hepatocellular necrosis), zonal Blood - changes in leukocyte (WBC) count] Intraperitoneal. - Rat LDLo: 650 mg/kg [Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - transaminases] Intraperitoneal. - Rat TDLo: 120 mg/kg [Blood - changes in platelet count Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Rat TDLo: 360 mg/kg [Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol) Blood - changes in leukocyte (WBC) count Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Rat TDLo: 500 mg/kg [Liver - hepatitis (hepatocellular necrosis), zonal] Intraperitoneal. - Mouse TDLo: 363 mg/kg [Behavioral - changes in motor activity (specific assay) Behavioral - ataxia] Intraperitoneal. - Mouse TDLo: 100 mg/kg [Behavioral - anticonvulsant] Intraperitoneal. - Mouse TDLo: 400 mg/kg [Behavioral - anticonvulsant Behavioral - antianxiety] Intraperitoneal. - Mouse TDLo: 432 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 - fetal death Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)] Intraperitoneal. - Mouse TDLo: 432 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intraperitoneal. - Mouse TDLo: 519 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System] Intraperitoneal. - Mouse TDLo: 600 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue)] Intraperitoneal. - Mouse TDLo: 300 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system] Intraperitoneal. - Mouse TDLo: 600 mg/kg [Reproductive - Specific Developmental Abnormalities - other developmental abnormalities] Intraperitoneal. - Mouse TDLo: 300 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants) Reproductive - Specific Developmental Abnormalities - Central Nervous System] Intraperitoneal. - Mouse TDLo: 400 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System] Intraperitoneal. - Mouse TDLo: 600 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Central Nervous System]

Edetate Disodium :

RTECS Number:	AH4375000
Eye:	Rabbit, not irritating.
Skin:	Rabbit, not irritating.
Inhalation:	Inhalation - Rat LOAEC 30 mg/m³/6 h (aerosol) (OECD Guideline 412) (ECHA)
Ingestion:	Oral - Rat LD50 2800 mg/kg (ECHA)
Other Toxicological Information:	Intravenous. - Mouse LD50 : 56 mg/kg (RTEC)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

Edetate Disodium :

Ecotoxicity:	Guppy (Poecilia reticulata) LC50 (96hr) 320 mg/L (OECD SIDS) Zebra fish (Danio rerio) NOEC (35d) >= 25.7 mg/L (OECD Guideline 210 , GLP) (TS : Ethylenediamintetraacetic acid, calcium disodium complex) Water flea (Daphnia magna) EC50 (48hr) 140 mg/L, NOEC (21d) 25 mg/L (EEC Guideline XI/681/86, GLP) (TS : Ethylenediaminetetraacetic acid, disodium salt) Green algae (Scenedesmus quadricauda) NOEC (24 d) 200 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

Valproic Acid :

EINECS Number:	202-777-3
California PROP 65:	Listed: developmental.
Canada DSL:	Listed

Edetate Disodium :

TSCA Inventory Status:	Listed
EINECS Number:	205-358-3
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

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